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Revision of the EU Ecolabel criteria for rinse-off cosmetics

Technical Report (TR3.0): Revision proposal for the EU Ecolabel criteria for rinse-off cosmetics

Vidal-Abarca Garrido Candela, Faraca Giorgia, Kaps Renata, Fernández Asunción and Wolf Oliver (JRC Dir. B – Growth and Innovation)

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Joint Research Centre

Contact information [optional element]
Name:
Address:
E-mail:
Tel.:

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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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•Give, in up to five sentences, the most important conclusions, key facts and figures.
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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] published in October 2019. The preliminary report includes analyses on the scope and definition, market analysis, and technical analysis. A first draft of the technical report (TR1.0)[4], 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.

A second technical report (TR2.0) was be discussed in the second Ad-hoc Working Group meeting (AHWG2) (June 2020).

This technical report (TR3.0) 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 was 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/product-bureau//product-groups/444/documents

- **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 and second draft of the criterion, presented during the AHWG1 and AHWG2 respectively.
  - Summary of the main outcomes received during the AHWG2 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 AHWG2 and during the consultation period, together with responses and explanations on how they have been addressed in this TR3.0 report has been published as a **separated document** under: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/444/documents

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).]*
Third product group scope and definition proposal:
Article 1: The product group 'Cosmetic products' shall comprise any substance or mixture falling under the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council. The product group 'Cosmetic products' shall include products for both private and professional use. 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

The next table shows which criteria apply to the different type of products. (to be included in the User Manual):

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) of rinse off cosmetic products	**x**	
Criterion 2. Biodegradability of rinse off cosmetic products	**x**	
Criterion 3. Biodegradability and aquatic toxicity of leave on products		**x**
Criterion 4. Excluded or limited substances and mixtures	**x**	**x**
Criterion 5. Packaging	**x**	**x**
Criterion 6. Renewable ingredients	**x**	**x**
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.

Third complementary definitions proposal:

1) *'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. Inorganic rubbing/abrasive agents are not included in the calculation of the active content;
2) 'cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes 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.
3) *'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. For the purpose of this EU Ecolabel a product marketed as 'family product' should be considered as an 'Infant, baby and/or children's products'.
4) '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) 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.
5) '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.
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) '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;

9)

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.

A general agreement on extending the scope was expressed by the stakeholders' in their responses to questionnaires carried out at the beginning of this revision process. 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.

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]).

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

[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

stakeholders was in favour of their inclusion, some comments received agreed to include animal care products but in a different Commission Decision.

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 was proposed in TR2.0. 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[6].

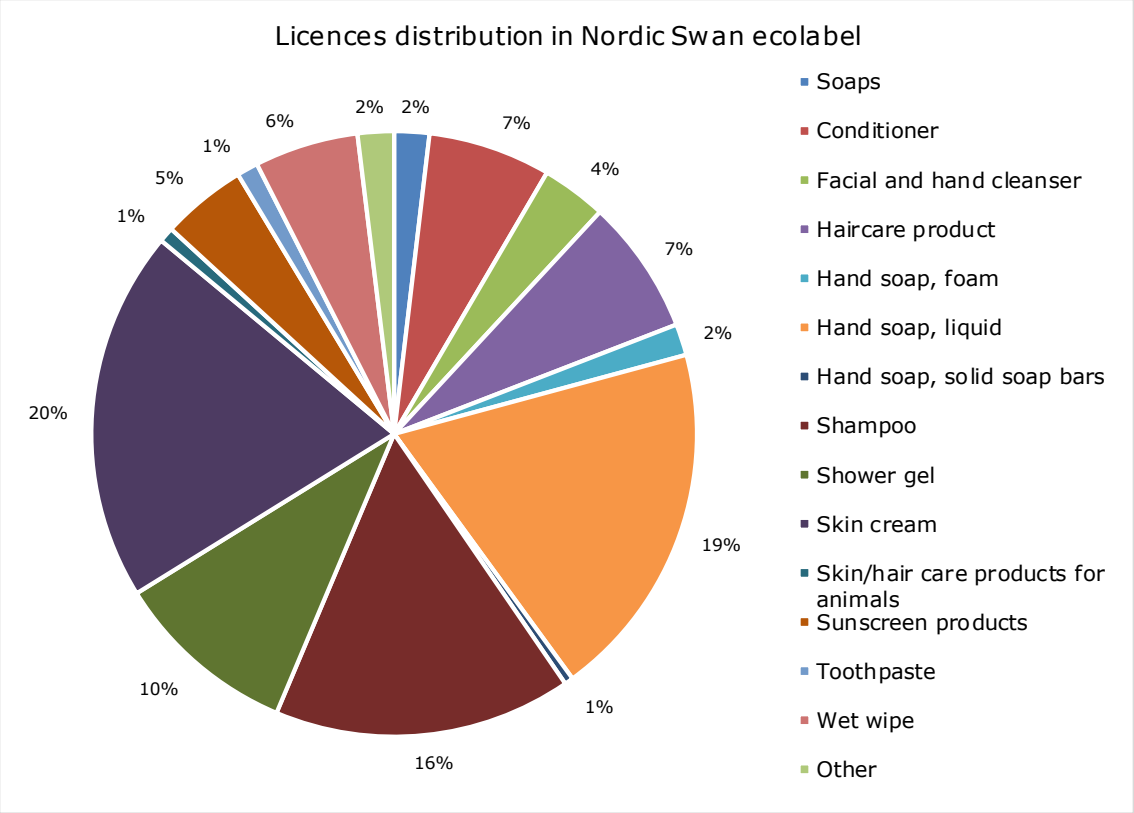
The most important group of products certified is skin care (leave on), representing 20% of the total amount of Nordic Swan-certified products (19% of such skin care products are specific for children). Hand soaps (liquid) represent the 19% of the Nordic Swan-certified products, followed by shampoos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

[6] 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.

For the second proposal it was 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, were: hair styling and treatment products, mouthwashes, deodorants and antiperspirants, decorative cosmetics, nail enamel removers and wet wipes.**

The following table summarises the products proposed to be included in the scope in TR2.0 of the revised EU Ecolabel criteria.

Table 1. 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[7]	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 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).

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

Animal care products is another product that generated controversy among the stakeholders. In the second proposal this products was 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, in order to separate the products included in the Cosmetic Regulation from the Animal care products, two annexes were defined in TR2.0:

- **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.

Complementary definitions were revised in TR2.0 to clarify 'ingoing substances' which has been aligned to Nordic Swan, and 'active content' definition. In addition, the definitions for 'impurities' and 'children products' were included, aligning with Nordic Swan.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Although there is a general agreement on the extension of the scope, several stakeholders are against the inclusion of animal care products, and sun screens. In addition a lot comments have been received against the inclusion of wet wipes.

Animal care products

Several stakeholders are against the inclusion of animal care products, mentioning that these products are not covered by the Cosmetics Regulation. Moreover, stakeholders commented that these products are tested on animals, and this could be confusing for the users.

There are at least 12 products certified under Nordic Swan scheme for this category. It is considered important to give consumers the opportunity to choose a better option of animal care products for their pets. Although these products are not covered by the Cosmetics Regulation, this EU Ecolabel sets strict requirements for these products aligned to cosmetic products. In addition, considering the expressed concern on the animal testing, fitness for use criterion has been modified to ensure the absence of animal testing. **It is proposed to keep animal care products under the scope of this EU Ecolabel under a separated annex to cosmetic products**.

Sunscreens

Several stakeholders are against the inclusion of sunscreens under the scope mainly because UV filters toxicity and low biodegradability. However, sunscreens needs to be used during summer to avoid solar radiation, it is an essential product. It is important to recognise better alternatives through EU Ecolabel. Nordic Swan has 58 certified sunscreen products (+ 10 sunscreens for children). It is therefore proposed to keep sunscreens under the scope.

Wet wipes

In relation to **wet wipes** most stakeholders disagree with it inclusion under the scope. Main reasons:

- Single-use products
- Low biodegradability
- The specific requirement based on AHP and graphic tissue paper seems to be not strict enough and there is a lack of solid biodegradability standard to refer to.

Against this, **it has been decided to remove wet wipes from the scope for this revision**. Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers.

Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products.

In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explored in next revision.

Scope definition

Considering the extension to all cosmetics included under the Cosmetics Regulation it makes sense to align the scope definition to the mentioned Regulation, which is preferable as regards harmonisation of approaches, but also legal drafting. In particular now when leave-on products are included in the EU Ecolabel scheme, so the EU Ecolabel covers all cosmetic products, there is no reason to deviate from the definition of the cosmetic products from the Regulation. Moreover, once the definition is aligned, it will be easier to apply Borderline Products Manual[8] and other guidance documents of the Cosmetic Regulation. Therefore, **the scope definition has been simplified to refer to any substance or mixture falling under the scope of**

[8] Borderline products manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)) available at: https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

Regulation (EC) No 1223/2009 of the European Parliament and of the Council.

Definition of rinse off and leave on products remain unchanged.

Complementary definitions

The section of complementary definitions was changed in relation to the following aspects.

The **definition of cosmetic products** as defined in the cosmetic Regulation has been included.

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

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

For the purpose of this EU Ecolabel a product marketed as "family product" should be considered as 'Infant, baby and/or children's products'.

In summary, the changes introduced in TR3.0 are:

- Wet wipes have been removed. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be further explored in next revision.
- Alignment of the scope definition to Cosmetics Regulation.
- Minor modifications introduced in relation to complementary definitions.

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[9] considering the latest version of the Simapro software and the new

[9] 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)

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 2. 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[10].

Table 2. Data used to calculate the reference flow for each product.

Product category	Product volume (g)[11]	Single dosage (g)[12]	Frequency of application (times/day)[13]	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

[10] 5 times of hand washing and 1 shower a day.

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

[12] 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

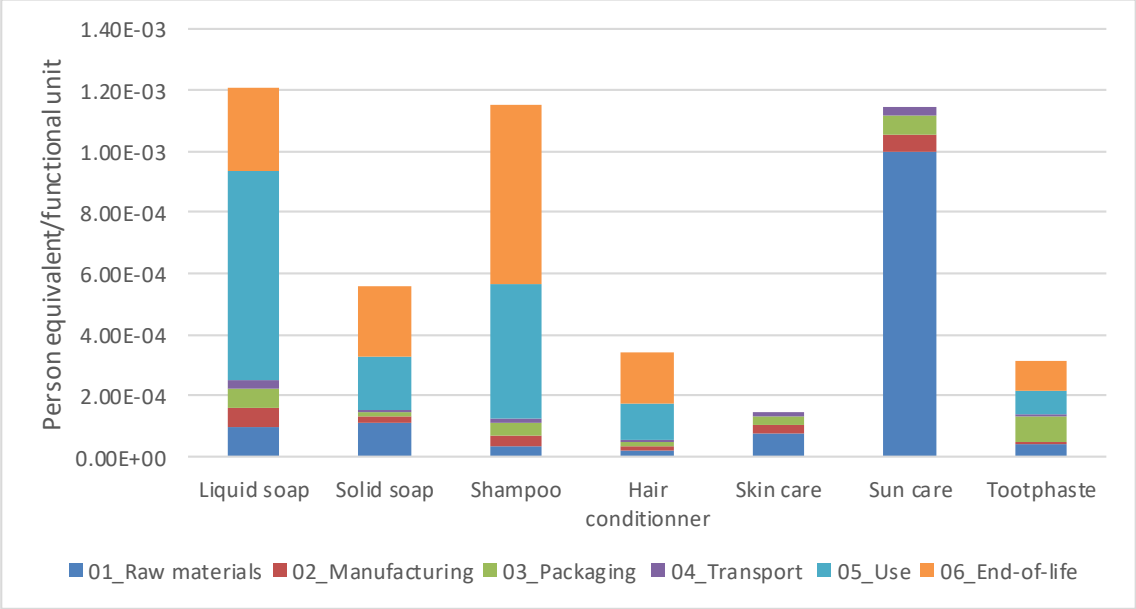
[13] The SCCS'S notes of guidance for the testing of cosmetic substances and their safety evaluation (8th revision), 2012

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[14]	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[15].

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.

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

[14] 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

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

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 3:

Table 3. Link between the environmental aspects identified and the EU Ecolabel criteria

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

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 and AHWG2. 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 4. 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) of rinse off cosmetic products
Criterion 2. Biodegradability	Criterion 2. Biodegradability of rinse-off cosmetic products
	Criterion 3. Biodegradability and aquatic toxicity of leave on cosmetic products
Criterion 3. Excluded or limited substances and mixtures	Criterion 4. Restricted substances
Criterion 4. Packaging	Criterion 5. Packaging
Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives	Criterion 6. Renewable ingredients
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).]

Third 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[16] (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.

[16] *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[17] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32018D1702&from=EN - ntr3-L_2018285EN.01008501-E0003shall 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[18] or via the websites of the individual competent bodies.

A written confirmation from the applicant that the criteria is fulfilled is also needed for the assessment.

Note: Label and/or instructions information accompanying the product shall be used to categorize the cosmetic product. Where a cosmetic product is marketed for different cosmetic uses, the cosmetic product category for which stricter criteria applies shall be assigned to the product.

b) Measurement thresholds

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

[17] *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)*

[18] *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

Table 2. Threshold levels applicable to substances for cosmetic products (% weight by weight), shown by criterion. Abbreviations: CLP: Classification, Labelling and Packaging; N/A: not applicable; r.c.: regardless of the concentration

Criterion name		Preservatives	Colorants	Fragrances	Impurities	Ingoing substances (e.g. surfactants, enzymes, UV filters)
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse off cosmetic products		≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
Criterion 2. Biodegradability of rinse off cosmetic products		≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
Criterion 3. Biodegradability and aquatic toxicity of leave on cosmetic products		≥ 0.001	≥ 0.001	≥ 0.001	≥ 0.010	≥ 0.001
Criterion 4. Restricted substances	Criterion 4 (a) (i): Restrictions on ingoing substances/mixtures classified under the CLP Regulation (rinse-off)	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
	Criterion 4 (a) (i): Restrictions on ingoing substances/mixtures classified under the CLP Regulation (leave-on)	≥ 0.001	≥ 0.001	≥ 0.001	≥ 0.001	≥ 0.001
	Criterion 4 (a) (ii) : Restrictions on ingoing substances/mixtures classified under the	r.c. (*1)	r.c. (*1)	r.c. (*1)	r.c. (*1)	r.c. (*1)

	CLP Regulation (CMR) (rinse-off and leave-on)					
	Criterion 4 (a) (iii): product classification (rinse-off)	≥ 0.010 (*2)	≥ 0.010 (*2)	≥ 0.010 (*2)	≥ 0.010 (*2)	≥ 0.010 (*2)
	Criterion 4 (a) (iii): product classification (leave-on)	≥ 0.001 (*2)	≥ 0.001 (*2)	≥ 0.001 (*2)	≥ 0.001	≥ 0.001 (*2)
	Criterion 4 (b): Specified excluded substances (rinse-off and leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 4 (c): Restrictions on Substances of Very High Concern (rinse-off and leave-on)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)	no limit (*1)
	Criterion 4 (d): Fragrances (rinse-off)	N/A	N/A	≥ 0.010	N/A	N/A
	Criterion 4 (d): Fragrances (leave-on)	N/A	N/A	≥ 0.001	N/A	N/A
	Criterion 4 (e): Preservatives (rinse-off)	≥ 0.010	N/A	N/A	N/A	N/A
	Criterion 4 (e): Preservatives (leave-on)	≥ 0.001	N/A	N/A	N/A	N/A
	Criterion 4 (f): Colorants (rinse-off)	N/A	≥ 0.010	N/A	N/A	N/A
	Criterion 4 (f): Colorants (leave-on)	N/A	≥ 0.001	N/A	N/A	N/A

	Criterion 4 (g): UV filters (leave-on)	N/A	N/A	N/A	N/A	≥ 0.001 (*3)
Criterion 6. Renewable ingredients	Criterion 6 (a): Sustainable sourcing of palm oil, palm kernel oil and their derivatives (rinse-off)	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
	Criterion 6 (a): Sustainable sourcing of palm oil, palm kernel oil and their derivatives (leave-on)	≥ 0.001	≥ 0.001	≥ 0.001	≥ 0.001	≥ 0.001
	Criterion 6 (b): Certification of plant based ingredients (rinse-off)	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010	≥ 0.010
	Criterion 6 (b): Certification of plant based ingredients (leave-on)	≥ 0.001	≥ 0.001	≥ 0.001	≥ 0.001	≥ 0.001

(*1) r.c. means regardless of the concentration: all substances, by-products and impurities from raw materials (analytical limit of detection).

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

(*3) only UV filters

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.

No major comments were received during the 1st AHWG meeting.

Minor wording changes were introduced in the second proposal (TR2.0) in line with other product groups. In addition, in order to increase the clarity of the EU Ecolabel criteria, the 'measurement thresholds' section was reintroduced, and the table indicating the scope of each requirement in terms of threshold limit was included in the assessment and verification, taking the table included in Detergents product group as a reference.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

In relation to the **table of thresholds,** the threshold have been updated to reflect the changes in the individual criteria. Please refer to the next sections of the TR3.0.

In addition, the wording in the table of thresholds has been changed: 'no limit' was substituted by the wording 'regardless of the concentration' (r.c.). Indeed, the

wording 'no limit' has been often misinterpreted by applicants and competent bodies, which requested clearer guidance. Further guidance will be given in the user manual.

Finally, other comments have been received suggesting **minor wording modifications** that have been accepted. Main change corresponds to the inclusion of : "A written confirmation from the applicant that the criteria is fulfilled is also needed for the assessment."

3 CRITERIA PROPOSAL

3.1 CRITERION 1: Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse off products

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: Third proposal for criterion 1: Toxicity to aquatic environment of rinse off cosmetic products

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)
Shampoos, soaps, shower preparations, shaving soaps and toothpaste (solid form)	2 200
Liquid soaps and shower preparations	10 000
Shampoos (liquid form)	11 000
Feminine hygiene cosmetic products	12 000
Hair conditioners	12 000
Rinse-off skin care products (exfoliants)	12 000
Rinse-off hair styling and treatment products (hair dyes)	12 000
Shaving foams, shaving gels, shaving creams	12 000
Toothpaste and mouthwash	12 000

The CDV is calculated using the following equation:

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

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:

https://ec.europa.eu/environment/ecolabel/documents/DID%20List%20PART%20A%202016%20FINAL.pdf

https://ec.europa.eu/environment/ecolabel/documents/DID_List_PART_B_2016_FINAL.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: Third proposal for criterion 1: Toxicity to aquatic environment for animal care products

The total CDV toxicity of the product shall not exceed the limits in Table 3:

Table 3 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.

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[19].

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

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

currently present relaxed thresholds due to the lack of data in previous revision, were also aligned to Nordic Swan. The newly included product categories were assigned a CDV threshold of 12000 l/g AC, in line with Nordic Swan.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

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

- The CDV threshold values for solid cosmetic products have been relaxed to 2200 l/g AC, as the threshold in TR1.0 was considered unattainable by stakeholders.
- 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, in line with Nordic Swan ecolabel.
- New products on the scope have been included and aligned to Nordic Swan threshold.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Thresholds

Overall, there was a general agreement on the decrease of the Critical Dilution Volume (CDV) threshold values for the different product categories, as well as on the alignment with Nordic Swan. Some stakeholders suggested that CDV thresholds could be decreased even further, in line with available average values from current licences and knowing that the limits set by the Nordic Swan Ecolabelling will be decreased further as a result of the ongoing revision process. In order to make the decrease of the CDV limits feasible and customised to the product, it was suggested to set individual CDV thresholds for each of the products.

Additionally, three sets of average CDV values were provided by one CBs (France) for the category of liquid soaps, shampoos and shower preparations (see Table 5). The outcomes of the analysis performed for the previous revision document (see Table 6 of TR2.0[4]) was also taken into account. However, it is very difficult according to the Cosmetic Regulation and from a practical point of view to distinguish liquid soaps from shower gel uses. Therefore, in order not to introduce any ambiguous differentiation that it would be difficult for CBs to deal with, **it was decided to split the product category in "liquid soaps and shower gel preparations", and "shampoos"**. **The CDV values are proposed to be 10 000 l/g AC for liquid soaps and shower preparations and 11 000 l/g AC for shampoos.**

Table 5. Comparison of average CDV values of liquid soaps, shampoos and shower preparation. *Source: information provided by CBs*

Product type	CDV (l/g AC)					
	TR2.0 thresholds	Average CB 1	Average CB 2	Average CB 3	Average Table 6 (TR2.0)	TR3.0 proposed thresholds
Liquid soaps	11 000	5 558	7 785	7 364	6 375	**8 000**
Shampoos	11 000	10 409	10 410	6 353	8 392	**11 000**
Shower preparations	11 000	9 234	9 230	6 033	8 812	**10 000**

Stakeholders welcomed the slight increase of the CDV threshold for solid soaps proposed in TR2 (2 200 l/g AC), and argued that it should be relaxed even further, since industries consider the current threshold (3 000 l/g AC) already unattainable. However, Nordic Swan holds 15 licences with a CDV value below 2 000 l/g AC, demonstrating that the limit is possible to meet. As the JRC does not have direct access to the exact formulation of products and no substantiating data was provided to back up the claim of unattainability of the limit, **the CDV value for solid soap is proposed to be maintained at 2 200 l/g AC**. **This threshold is proposed be extend also to other solid products: solid shampoos, shower preparations, shaving soaps and toothpaste.**

No additional CDV data were received for any of the remaining product categories. Therefore, **CDV values were maintained at the limit set in TR2.0 (12 000 l/g AC)**. Also, no CDV data were received for leave-on products, which makes it impossible for the JRC to set thresholds. Therefore, **criterion 1 is maintained such as to be addressed to rinse-off products only**.

CDV calculation methodology

Many stakeholders criticised the current CDV calculation methodology based on active content (AC), stating that it is complicated and it encourages to add substances in order to decrease the CDV of the final product and meet the limits, which goes against the EU Ecolabel principle. While the introduction of USEtox as an alternative aquatic toxicity methods did not have the support of stakeholders because of the few data available and the high uncertainty associated with the method, stakeholders suggested to calculate CDV based on reference dosage. One suggestion was to define the reference dosage as one litre of product, in line with the criterion set in the EU Ecolabel for detergents[20]. However, it is very challenging to set one single reference dosage for the very diverse product types included in the revised scope (e.g. solid eye powder vs shaving foam). To overcome this problem, it was suggested to make

[20] Revision of six EU Ecolabel Criteria for detergents and cleaning products - Final Technical Report. Available at: https://ec.europa.eu/environment/ecolabel/documents/JRC104463_detergents_without%20watermark.pdf

use of the SCCS standards[21] used in toxicology, which provide reference dosage for most of the product categories in the revised scope. However, on top of the fact that product-dependent reference dosages would complicate the criterion, the actual reference dosage may change even within product types, depending on e.g. the length of the hair, the area to treat, or other consumer-specific factors. In addition, stakeholders and competent bodies generally agreed on aligning as much as possible with Nordic Swan, which makes use of the CDV calculation based on AC, and is expected to do so also in the next revision. While setting CDV limits based on reference dosages would lead away from Nordic Swan, it would also mean that no data would be available to set the limits. Indeed, the JRC does not have access to the formulations of EU Ecolabel products (nor of other products in the market), and one competent body only provided data on CDV of existing licences by litre of product. Finally, while it is true that the CDV of a product depends on the interaction with other substances, the environmental performance of the product is still guaranteed by all other criteria, especially criteria 2 on biodegradability, 3 on excluded or limited substances, 4 on packaging and 6 on fitness for use. According to Nordic Swan[22], there is no clear correlation between water content and CDV value, and it is judged difficult to conclude that the CDV value of a product can be decreased by diluting with water. Therefore, **it is proposed to maintain the method to calculate the CDV of the product based on AC of the product.**

Summary of changes in TR3.0

In summary, the main changes introduced to criterion 1 in TR3.0 are:

- The category "shampoo, shower preparation and liquid soap" has been split into two categories: "liquid soaps and shower preparations", and "shampoos";
- CDV values have been proposed to be decreased for liquid soaps and shower preparations (10 000 l/g AC);
- CDV values for solid soaps have been extended also to other solid products: solid shampoos, shower preparations, shaving soaps and toothpaste.

Question to stakeholders
- Stakeholders are requested to provide data on CDV values of proposed categories, especially for toothpastes, mouthwashes, shaving products and hair dyes. - There is a lack of data on dry shampoos. It is proposed to treat it as a leave-on (in the hair styling product category), because it is not rinsed off and it does not contain surfactants. What is the stakeholders' view?

[21] SCCS's notes of guidance for the testing of cosmetic substances and their safety evaluation. Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf

[22] About Nordic Swan Ecolabelled - Cosmetic products. Version 3.8. Available at: file:///C:/Users/faracgi/Downloads/Background%20document%20-%20Cosmetic%20products%20-%20version%203.8%20(1).pdf

Rationale of proposed "assessment and verification"

No changes have been introduced in the verification text in the first nor in the second revision (TR1.0 and TR2).

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0.

The main comments regarded the use of the DID-list which according to stakeholders lacks data for natural extracts and toothpaste/mouthwash ingredients and gives the same weight to all fragrances, regardless of their hazard classification. The JRC is not in charge of the development/update of the DID-list. Nevertheless, if the manufacturer of the cosmetic product is not satisfied with the DID-list values of a substance or mixture, toxicity tests can be performed for that specific sybstance/mixture, and the data obtained can be submitted and used to calculate toxicity factors (TF).

The link to the DID list in the criterion text was updated to the 2016 version of the list. Differences from the 2014 version were relatively minor and the use of the new list from 2016 is not expected to cause major changes to the CDV values of cosmetic products. The same threshold values therefore apply for the 2014 and 2016 lists.

Summary of changes in TR3.0

In summary, the main changes introduced to assessment and verification text in criterion 1 in TR3.0 are:

- For fragrances, toxicity tests can be performed by the manufacturer of the cosmetic product and the data obtained can be submitted and used to calculate toxicity factors (TF);
- The link to the DID-list was updated to the 2016 version.

3.2 CRITERION 2 (and 3): Biodegradability

This criterion has been split in two different criteria:

- Criterion 2: Biodegradability of rinse off cosmetic products
- Criterion 3: Biodegradability and aquatic toxicity of leave on cosmetic products

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: Third proposal for criterion 2: Biodegradability of rinse off cosmetic products

a) Biodegradability of surfactants

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

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:

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)
Solid soaps/shampoos	5	5
Shaving solid soaps	10	10
Feminine hygiene cosmetic products	15	15
Hair conditioners	15	15
Liquid soaps and shower preparations	15	15
Rinse-off skin care products (exfoliants)	15	15
Rinse-off hair styling and treatment products (hair dyes)	15	15
Shampoo (liquid form)	15	15
Toothpastes, mouthwashes	15	15
Shaving foams, shaving gels, shaving creams	70	40

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 for organic ingoing substances, 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

Regulation (EC) No 1907/2006 foresees in Annex XI that the standard testing regime can be adapted by the use of non-tested methods such as qualitative or quantitative structure-activity relationship (Q(SAR) models). Q(SAR) models should only be accepted if actual test data is missing.

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 not 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.

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

a) Biodegradability of surfactants

Same as text included in annex I.

b) Biodegradability of organic ingoing added 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 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"

Annex I: Criterion 3: Aquatic toxicity and biodegradability of leave on cosmetic 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

Assessment and verification: the applicant shall provide documentation for the degradability and aquatic toxicity values.

For ingoing substances which are not included in the DID list, the relevant information from literature or other sources, or appropriate test results, showing biodegradability/toxicity/potential for bioaccumulation/bioavailability specifications shall be provided as described in the Appendix.

--------Appendix (excerpt) ------- (appendix will be completed with the following additional information)

Documentation on aquatic toxicity:

The lowest available NOEC/ECx/EC/LC50 value must be used. If chronic values are available, they must be used instead of acute ones.

For acute aquatic toxicity test methods nos. 201, 202 and 203* in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used.

For chronic aquatic toxicity test methods nos. 210*, 211, 215*and 229* in the OECD Guideline for the Testing of Chemicals or equivalent test methods shall be used. OECD 201 can be used as chronic test if chronic endpoints are chosen.

*The Commission prohibited animal testing of ingredients for cosmetic products from March 2009 onwards. To determine aquatic toxicity, however, the prohibition only concerns testing with fish (does not include invertebrates). As such, OECD test guideline no. 203 (acute toxicity – fish), 210, 215 and 229 (chronic toxicity – fish) cannot be used to document acute/chronic toxicity in the future. The results of acute/chronic toxicity testing using fish produced before March 2009 may still be used, however.

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 < 500 or log Kow is < 4.0.

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 < 500 or log Kow is < 4.0.

Rationale of the proposed criterion text

Existing 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].

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.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

Summary of changes in TR2.0

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

- 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. Therefore, a more gentle reduction of thresholds was proposed in TR2.0.

Table 6. proposed thresholds in TR2.0

	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%)

- The aNBO and anNBO thresholds of shower preparations and hair conditioners were lowered to 20 mg/g AC.
- The category "shampoo, shower preparations and liquid soaps" was divided in "shampoo and liquid soaps" and "shower preparations".
- New rinse-off product categories (mouthwash, solid shampoos and hair dyes) were included in line with the scope enlargement.
- Regarding the new rinse-off proposed categories, as the only data available is from Nordic Swan Ecolabel, a complete alignment with this Ecolabel was 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 for leave on products on biodegradability (and aquatic toxicity) was proposed in TR1.0.
- It was 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.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Fragrances

It was expressed: "If fragrances are not sufficiently biodegradable, they should not be included in ecolabelled products" and several stakeholders mentioned the availability of fragrance free products on the market.

While other stakeholders mentioned: "If fragrances are not accepted anymore, you won't sell any rinse off cosmetics nor cosmetics as bold milk in southern Europe" and "Fragrance free products are not common at all in France and Southern Europe"

It was pointed out by several stakeholders that there are fragrances with low anNBO so it is no banning perfume, but using the better ones meaning that stricter values does not equal excluding fragrances.

In addition, several stakeholders mentioned: *many fragrance ingredients are biodegradable and perfumes typically contain relatively high % w/w of biodegradable ingredients. However, the default values for a perfume in the DID list in relation to biodegradation do not reflect this: the "perfume" as an ingoing organic substance is considered as 100% non-biodegradable (both aNBO and anNBO). They request the flexibility of assessing the perfume based on individual fragrance ingredient data. Thus, for the aNBO criteria, the perfume could be split into the %w/w of readily biodegradable fragrance ingredients and % w/w of not readily biodegradable; the latter then being the fraction that would contribute to the aNBO limits.*

According to CB forum information on the assessment of fragrances:

The CBs are in favour of separating a fragrance mixture that for single fragrance substances a dossier for toxicity and degradability can be submitted and that these values can be used for CDV calculation and aNBO/anNBO calculation of the whole formulation of the final product:

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

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

Thresholds

With regards thresholds and ambition level, several stakeholders asked to further restrict biodegradability thresholds. The existing values of Nordic Swan are from 2016. At least EU Ecolabel should align to these values even if EU Ecolabel licences are lost. Stakeholders highlighted the need of a continuous improvement of the EU Ecolabel scheme.

In addition, a CB communicated their values and suggested to divide "Shampoo and liquid soaps" category in order to reduce threshold of the liquid soap:

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

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

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

Several stakeholders suggested full alignment to Nordic Swan thresholds.

The following table compares existing EU Ecolabel and Nordic Sawn values and the potential level of compliance based on data from 120 products provided by competent bodies.

Table 7. Effects of the EU Ecolabel biodegradability values alignment with Nordic Swan thresholds.

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

Latest data provided by Nordic Swan revealed more than 3,100 licensed products:

- 361 Shampoos
- 239 Shower preparatiions
- 586 Liquid soaps
- 15 Solid soaps
- 167 Hair conditioners

It was mentioned that many of the Swan certified product do also contain fragrance (and colour) but that recipes are adjusted in regards to the amount of fragrance. Hence the products in the Nordics are not all "fragrance free", but in general just contains less.

Against this background it is suggested to further **align the thresholds in line to Nordic Swan values.** Values for shaving products remain unchanged due to lack of data.

Exemption for non-classified surfactants

In relation to the included exemption in TR2.0 of aerobic biodegradability for surfactants not classified for the environment in line with detergents product group, it was mentioned by the majority of stakeholders that it is better to keep current formulation and not to include such exemption.

They mention that harmonization with other product groups is important but should not supersede the possibility to set stricter but feasible requirements. They do not see the need to set less stricter requirements to biodegradability of surfactants than today.

In addition, the current EU Ecolabel criteria, as well as Bra Miljöval and the Nordic Swan, have absolute requirements on anaerobic degradability for surfactants, regardless of CLP classification.

Considering the general request for stakeholders, **this exemption has been removed** and the text has been reverted to the original text in force.

Exemption on UV filters

Few stakeholders are against the inclusion of sunscreens under the scope. Therefore they are not in favour of the UV filter exemption to this criterion. They mention that UV filters represent a large part of their formula, and they are not biodegradable. More especially, sunscreen products contain TiO2, a molecule having a strong negative impact on aquatic environment. Thus, sunscreen products cannot meet this criterion and we consider that including them in the scope could discredit the reputation of the EU Ecolabel.

However sunscreen needs to be used during summer to avoid solar radiation, it is not an optional product. It is therefore considered important to recognise better alternatives through EU Ecolabel. Nordic Swan has 58 certified sunscreen products (+ 10 sunscreens for children). Therefore, it is proposed to **keep sunscreens under the scope**. In line with Nordic Swan, UV filters are exempted from the biodegradability criterion. However, there is a specific criterion on UV filters in criterion 3 to ensure non bioaccumulation and low toxicity for UV filters.

Exemption of surfactants on toothpastes

With regards the exemption of the requirement of **anaerobic biodegradability for surfactants in toothpastes.** The objective of this exemption included in TR2.0, was 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 was 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.

Several stakeholders mentioned that they do not support to exempt all surfactants used in toothpaste from the requirement on anaerobic degradability. They mentioned that such an exemption is simply not necessary since there are suitable surfactants being both aerobically and anaerobically degradable which are used in toothpaste.

While Nordic Swan includes this exemption, other schemes like Bra Miljöval criteria, allows only surfactants that are both aerobically and anaerobically degradable in toothpastes and there are labelled products available on the market.

Considering that there has been a decrease in the thresholds to further align with Nordic Swan, **it is proposed to keep the exemption** to not create additional burden. In addition it is unknown if the number of licences of Bra Mijoval for toothpastes it is representative enough. It is suggested to explore the possibility to remove this exemption for the next revision.

Rationale of proposed assessment and verification

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

During the AHWG1 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.

The main changes introduced to assessment and verification of criterion 2 in TR2.0 were:

- **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.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

BCF and Log Kow values

With regards BCF and Log Kow values, stakeholders asked to clarify why these values are different from the cut off values used in REACH.

In addition a stakeholder mentioned that the DID list presents lack of data and that to test log Kow is challenging.

Several stakeholders suggested to align to the existing legislation. They mentioned that the higher cut-offs in CLP (and implemented in the Nordic Ecolabel) are based on scientific reasons. Hence, for example a substance with a BCF of let's say 150 would not be classified for environmental hazards (if not toxic to aquatic environment) but excluded from EUEL.

Considering that existing EU Ecolabel values (BCF < 100 and log Kow < 3) correspond to the old classification under 1999/45/EG, and the general harmonization with Nordic Swan, **it is proposed to harmonise the log Kow and BCF limits to Nordic Swan's and Regulation (EC) No 1272/2008 (BCF < 500 and log Kow< 4)**. The values have been amended and harmonized across the entire document.

QSAR method

It has been mentioned that it should be clarified that QSAR should only be accepted if actual test data is missing as test data from actual testing is more reliable than data from QSAR modelling.

The **text has been modified accordingly.**

It was mentioned that QSAR method should be verified by independent parties or toxicologist.

QSAR method is included in other EU Ecolabel group (EU Ecolabel for Lubricants) and no reference to third party toxicologist is made for this product group.

However, a question box has been included in relation to this comment to further explore if CBs will consider necessary the need of third party assessment.

Extrapolation for substances not listed in the DID-list

A stakeholder mentioned that a third party assessment should be required in the case of extrapolation for substances not listed in the DID-list. They said it is not reasonable to require that the application handling officer has the deep competence that is needed for such an assessment.

A question box has been included in relation to this comment to further explore if CBs will consider necessary the need of third party assessment.

Question to stakeholders
Third party assessment: 1. QSAR method is included in other EU Ecolabel group (EU Ecolabel for Lubricants) and no reference to third party toxicologist is made for this product group. However stakeholders are requested to provide their views on the need to provide third party certification in the case QSAR method is used for this specific product group. **2.** Do CBs consider necessary to include third party certification for the Extrapolation for substances not listed in the DID-list. Not mentioned in the existing text in force. How this worked till present?

In summary, the changes introduced in TR3.0 are:

- Considering that the requirement for leave on products include also aquatic toxicity requirements, the criterion 2 has been split into two different criteria:
    - Criterion 2: Biodegradability for rinse off cosmetic products

- Criterion 3 Biodegradability and aquatic toxicity for leave on cosmetic products

- Documentation for aquatic toxicity assessment has been specified in the Appendix in line with Nordic Swan.
- It is suggested to further **align the thresholds to Nordic Swan values.** Values for shaving products remain unchanged due to lack of data.
- Considering the general request from stakeholders, **the exemption on non-classified surfactants has been removed** and the text has been reverted to the original text in force.
- Considering that existing EU Ecolabel values (BCF < 100 and log Kow< 3) correspond to the old classification under 1999/45/EG, and the general harmonization with Nordic Swan, the log Kow values and BCF have been harmonized to Nordic Swan values and Regulation (EC) No 1272/2008 the (BCF < 500 and log Kow< 4).

3.3 CRITERION 4: Restricted substances

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: Third proposal for criterion 4: Restricted substances

Opinions published by the Scientific Committee on Consumer Safety (SCCS) during the validity period of this Commission Decision must be complied with by the substance and or mixture in all the cases where the SCCS opinion leads to a unique and clear conclusion on the conditions under which the substance and/or mixture is considered safe. All aspects of the SCCS opinion have to be taken into account.

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)

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

(i) Unless derogated in Table 6, the product shall not contain substances or mixtures at or above the concentration of 0.010 % weight by weight for rinse-off products and 0.001% weight by weight for leave-on cosmetics, that are assigned any of the hazard classes, categories and associated hazard statement codes listed in Table 5, 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 1A	**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	

(*) in the case of Respiratory and skin sensitization hazard class, the requirement applies at the substance level only.

Table 6. Derogations to restrictions on ingoing substances/mixtures classified under the CLP Regulation and applicable conditions

Substance /mixture type	Applicability	Derogated hazard class, category and hazard statement code	Derogation conditions
Surfactants	Rinse-off products	H412: Harmful to aquatic life with long-lasting effects	total concentrations < 20 % in the final product
Sodium Fluoride	Rinse-off oral care products	H301: Toxic if swallowed	Only in oral care products (mouthwash and toothpaste)
Titanium dioxide (nano-form)	UV filters in leave-on products with sun protection function	H351: Suspected of causing cancer	It needs to comply with SCCS/1516/13, SCCS/1580/16, and SCCS/1583/17. It cannot be used in powder or spray form

(ii) Unless derogated in Table 6, substances or mixtures that meet the criteria for classification with the hazard statements listed in Table 7 shall not be contained in the final product or its ingredients, regardless of their concentration.

Table 7 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.

Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.
Surfactants regardless of their function classified with H412 are exempted from the requirement.

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.

4(b) Specified excluded substances

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

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

(ii) Perfluorinated and polyfluorinated substances [2];

(iii) Nitromusks and polycyclic musks;

(iv) Butylated Hydroxytoluene (BHT) [3] 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 and microbaeds [4];

(viii) Nanomaterials [5], unless an EU regulatory authority has evaluated and authorised the use of the nanomaterial [6];

(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) in 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 [7];

(xvi) Phthalates;

(xvii) Isothiazolines;

(xviii) Ethylhexyl methoxycinnamate; Recorsinol; Benzophenones; Homosalate; Octocrylene; Butylphenyl metylpropional; Benzyl salicylate; Triphenyl phosphate;

(xix) Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products, where the recommendations [8] by Cosmetic Europe for mineral oils are not complied.

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

Substances and mixtures meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006[25] 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 present in the product, regardless of their concentration.

4(d) Fragrances

(i) Products marketed as designed and intended for children shall be fragrance-free. Criterion 4 (d) (i) does not apply to toothpaste marketed for children.

(ii) Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' [9] and listed in the Annex cannot be present in EU Ecolabel products in concentrations higher than 0.01% in rinse-off products and 0.001% in leave-on products.

(iii) 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.

4(e) Preservatives

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

(i) Preservatives in the product shall not release or degrade to substances that are classified in accordance with the requirements of criterion 4(a).

(ii) The product may contain preservatives provided that they are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 500 or log K_{ow} < 4.0. If both BCF and log K_{ow} values are available, the highest measured BCF value shall be used.

(iii) Preservatives used in products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail lacquers) must be approved as food additives, according to Regulation (EC) No 1333/2008 on food additives.

4(f) Colorants

(i) Colorants in the product must not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 500 or log K_{ow} < 4.0. 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 products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail lacquers) must be approved as food additives according to Regulation (EC) No 1333/2008 on food additives.

(iii) The content of barium, cadmium, hexavalent chromium (Chromium VI), nickel and bismuth in decorative cosmetics and hair dyes is restricted to concentrations below 10 ppm. The content of lead and mercury in decorative cosmetics and hair dyes is restricted to concentrations below 1 ppm.

4(g) UV filters

UV filters may only be added to leave-on products that target the solar protection of the user, e.g. sunscreens and multi-purpose products with a sunscreen function. UV filters shall only protect the user – not the product.

All UV filters contained in the product:

- must not be bioaccumulating (BCF<500 / log K_{ow}<4.0) 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 combinations of either silica and cetyl phosphate (up to 16% and 6% respectively); alumina and manganese dioxide (up to 7% and 0.7% respectively); or alumina and 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 4 (a) the applicant shall provide the SDS of the final product.

To demonstrate compliance with 4 (a), 4 (b) and 4 (c) the applicant shall provide:

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

(ii) A written confirmation that 4 (a), 4 (b) and 4 (c) is fulfilled.

For substances exempted from requirement 4 (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 mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in requirement 4 (b) compliance with the recommendations [8] by Cosmetic Europe for mineral oils shall be demonstrated.

For requirement 4 (c) reference to the latest list of substances of very high concern shall be made on the date of application.

To demonstrate compliance with 4 (d) the applicant shall provide a signed declaration of compliance, supported by a declaration of the fragrance manufacturer, as appropriate.

To demonstrate compliance with 4 (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 4 (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 4 (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] also named per- and polyfluoroalkyl substances (PFASs)

[3] BHT may still be used in perfumes provided that total BHT content in the perfume is below 100 ppm and total BHT concentration in the final product is 0.001%

[4] The definition of 'microplastic' and 'microbaeds' 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 The derogations set in paragraphs 3 and 5 of this document also apply

[5] as defined in article 2 of the Cosmetic Regulation

[6] Opinions will be accepted if coming from SCCS (for the assessment of the human health of the nanomaterial) or from RAC or SCHEER (for the assessment of the environmental impacts of the nanomaterial). The list of cosmetic products containing nanomaterials can be found at the online Cosmetic Products Notification Portal: https://ec.europa.eu/growth/sectors/cosmetics/cpnp/ The list of nanomaterials placed on the EU market can be found at the EU Observatory for Nanomaterials database: https://euon.echa.europa.eu/search-for-nanomaterials

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

[8] https://www.cosmeticseurope.eu/files/3715/3907/8160/Recommendation_14_Mineral_Hydro_Carbons.pdf

[9] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

[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: Third proposal for criterion 3: Restricted substances for animal care products

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

Same as Annex I.

4(b) Specified excluded substances

Substances and mixtures listed under Annex II to Regulation 1223/2008 shall not be present in the product, regardless of the concentration, neither as part of the formulation nor as part of any mixture included in the formulation. The following substances and mixtures shall also 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 [1];

(ii) Perfluorinated and polyfluorinated substances [2];

(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 and microbaeds [3];

(viii) Nanomaterials [4], unless an EU regulatory authority has evaluated the use of the nanomaterial and found that it is safe from an environmental perspective [5];

(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 [6].

(xv) Phthalates;

(xvi) Isothiazolines;

(xvii) Ethylhexyl methoxycinnamate; Recorsinol; Benzophenones; Homosalate; Octocrylene; Butylphenyl metylpropional; Benzyl salicylate; Triphenyl phosphate.

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

Same as Annex I.

4 (d) Fragrances

Same as Annex I (except (i))

4 (e) Preservatives

Same as Annex I (except (iii))

4 (f) Colorants

Same as Annex I (Only (i))

Assessment and verification:

Same as Annex I

Notes:

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

[2] also named per- and polyfluoroalkyl substances (PFASs)

[3] The definition of 'microplastic' and 'microbaeds' 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 The derogations set in paragraphs 3 and 5 also apply.

[4] as defined in article 2 of the Cosmetic Regulation

[5] Opinions on the assessment of the environmental impacts of the nanomaterial will be accepted if coming from RAC or SCHEER. The list of nanomaterials placed on the EU market can be found at the EU Observatory for Nanomaterials database: https://euon.echa.europa.eu/search-for-nanomaterials

[6] "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) according to article 57(f) of REACH Regulation (Candidate List of SVHCs), in Regulation 528/2012 or in Regulation 1107/2009

[7] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

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

Requirement 4(a) Hazardous substances (Restrictions on substances/mixtures classified under the Classification, Labelling and Packaging (CLP) Regulation)

<u>Rationale of proposed requirement</u>

This criterion corresponds to the existing criterion 4 (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 changes proposed in the first revision document (TR1.0) were the following:

- Aligning the wording of the requirement to the latest voted EU Ecolabel products.
- Removing the derogations granted according to table 4 of existing criterion 4b.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

<u>In summary, the main changes introduced to criterion 4 in TR2.0 were:</u>

- 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 set to 0.01% w/w in rinse-off products and 0.001% w/w in leave-on products, in line with the Cosmetics Regulation.
- The criterion 4(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 banned in both rinse-off and leave-on products, regardless of their concentration.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

SCCS's opinions

Stakeholders asked to better define the requirement of complying with published SCCS's opinions, especially with respect to explain the unambiguous nature of SCCS's opinions.

The European Commission frequently requests the Scientific Committee for Consumers Safety (SCCS) to publish a scientific opinion on the safety of a substance and/or mixture. Lots of scientific opinions on substances used in cosmetic products have been published by the SCCS so far. The SCCS carries out a thorough examination of available scientific information before concluding on the safety of a substance or mixtures. JRC considers 'unambiguous' those SCCS's opinions that lead to a clear, unique conclusion on the conditions under which a substance and/or mixture is considered safe. This would not be the case if data lacks prevent from a clear recommendation.

The sentence in criterion text relating to compliance with SCCS's opinion has been changed to clarify this latter part. Additionally, it is expected to better define this aspect in the user manual.

<u>Concentration thresholds of substances/mixtures</u>

Some stakeholder stated that sub-criterion 4(a) should refer to substances only, and not mixtures, since dangerous properties of the substances are likely to be 'diluted' in mixtures; therefore, it would be sufficient to look at individual substances. However, other stakeholders argued that the inclusion of mixtures in the requirement is necessary in order to consider the cumulative effect of substances added to the cosmetic product in the form of mixtures. In order to ensure a high level of protection, **the criterion text has not been changed**. Additionally, a question to stakeholders has been included in the question box below.

Additionally, one stakeholder stated that "there should be a derogation to not consider the classification of mixture for H314 and H317 classifications because having an allergic reaction with substance A does not necessarily cause an allergic reaction with substance B: there is not a cumulative effect for these specific classifications". Therefore, the text has been changed as **to remove the word "mixtures" from the requirement 4 (a) (i) for the H-classes H314 and H317**.

Substances for derogation

Stakeholders submitted the derogation requests for a number of substances and mixtures, namely: Surfactants classified as H412 and H400, Sodium Laureth Sulfate, Cocamidopropyl betaine, Ethyl N2-dodecanoyl-l-argininate hydrochloride (LAE), Sodium fluoride, Titanium dioxide and Zinc Pyrithione (ZPT).

A sub-group meeting was held in September 2020 with members of industries, NGOs and other ecolabelling schemes. The aim of the meeting was to gather as much information as possible from the various parts, in order to enable the JRC to take a final decision. The discussion paper and the minutes of the meeting can be found on the product's website[26].

- *Surfactants classified as H412 and H400*

This derogation was asked by three stakeholders.

A derogation exists in the existing EU Ecolabel criteria for surfactants classified as H412 and/or H413, on the condition that such surfactants are present in total concentrations < 20 % in the final product.

Surfactants are essential compounds in personal care products for their cleaning properties. Surfactants act by lowering the surface tension between two liquids, between a gas and a liquid, or between a liquid and a solid. Surfactants have important properties such as cleaning, wetting, dispersing, emulsifying, foaming and anti-foaming agents.

Prolonged exposure to surfactants can irritate and damage the skin because surfactants disrupt the lipid membrane that protects skin and other cells. Skin irritancy generally increases in the series non-ionic, amphoteric, anionic, cationic surfactants.

Typical concentration of surfactants is between Typical concentration of surfactants H 412 is between 1% and 20 %, till 25% (as active content), depending of the product.

According to the industry, substances classified H 400 - H 412 are readily biodegradable. After the introduction of the 2nd ATP to CLP Regulation, usually a tighter labelling was assigned to the same surfactants without any changes of

[26] https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/444/documents

surfactants properties. According to the industry, most of alternative surfactants are dangerous for environment. A few non-classified surfactants exists but with a lower associated efficiency. It is envisaged that if a derogation is not granted, products will be not so effective to satisfy Criterion 7. Moreover, the price of non-classified surfactants is reported to be at least three times higher, which is not a negligible aspect considering that their presence can be in a concentration up to 25% of the product formulation. Moreover, the market availability of non-classified surfactants is said to be poor.

Given the information above, **it is proposed to grant a derogation for surfactants classified as H412 for use in rinse-off products**, provided that the total concentration of H412 surfactants in the product does not exceed 20%. This derogation is in line with the one in the existing criteria. Derogated surfactants still have to comply with the biodegradability requirements in criterion 2.

However, **it is proposed not to grant any derogation for surfactants classified as H400.** Indeed, there exist alternative surfactants that are not H400 classified. Moreover, H400 classified surfactants are not allowed in the current criteria for EU Ecolabel. Their derogation would create a criterion less stringent than the existing criterion – contrary to the aim of the revision process. Finally, H400 surfactants are not allowed in other schemes (e.g. the Good Environmental Choice).

- *Sodium Laureth Sulfate (SLES)*

The derogation of SLES was requested by one stakeholder.

SLES is an anionic surfactant used in many personal care products. Its properties include cleaning, foaming and emulsifying. It is derived from palm kernel oil or coconut oil, and is very inexpensive.

According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye damage (H318), is harmful to aquatic life with long lasting effects (H412) and causes skin irritation (H315). According to the Safer Choice of the U.S. Environmental Protection Agency (EPA), the chemical has been verified to be of low concern (determined to be safer than traditional chemical ingredients).

SLES can be present in the shampoo/soap formulation in concentrations up to 11%. This substance is manufactured and/or imported in the European Economic Area in 100 000 – 1 000 000 tonnes per year.

Industries reported that no alternatives to SLES have been proposed by suppliers yet.

Being a surfactant, the derogation for its H412 property is already effective, due to the derogation granted to surfactants classified as H412 for use in rinse-off products. **It is proposed that no specific derogation is granted to SLES**.

- *Cocamidopropyl betaine (CAPB)*

The derogation of CAPB was requested by one stakeholder.

CAPB is a mixture of closely related organic compounds derived from coconut oil and dimethylaminopropylamine, and is used as a zwitterionic surfactant (containing both positive and negative charges on its head group) in personal care products. Its properties include cleaning, foaming, thickening, conditioning and viscosity controlling.

According to the classification provided by companies to ECHA in CLP notifications this substance is very toxic to aquatic life (H412), causes serious eye damage (H319) and causes skin irritation (H315). According to the Safer Choice of the U.S. Environmental Protection Agency (EPA), the chemical has been verified to be of low concern (determined to be safer than traditional chemical ingredients).

CAPB has to a significant degree replaced cocamide DEA, which has a notified classification and labelling as H315 and H318 and is banned in EU Ecolabel cosmetics according to criterion 3 (b). CAPB is also used to reduce irritation that purely ionic surfactants would cause. However, some studies indicate it is an allergen.

CAPB can be present in the shampoo/soap formulation in concentrations up to 3%. This substance is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year.

Industries reported that no alternatives to CAPB have been proposed by suppliers yet.

Being a surfactant, the derogation for its H412 property is already effective, due to the derogation granted to surfactants classified as H412 for use in rinse-off products. **It is proposed that no specific derogation is granted to CAPB**.

- *Ethyl N2-dodecanoyl-l-argininate hydrochloride (LAE)*

The derogation of LAE was requested by one stakeholder.

LAE) is a substance used in personal care products for its properties as a preservative and conditioner.

According to the harmonised classification and labelling (ATP01) approved by the European Union, this substance is very toxic to aquatic life (H400) and causes serious eye damage (H318). Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is harmful to aquatic life with long lasting effects (H412) . LAE is approved as a food additive (E 243). According to the Safer Choice of the U.S. Environmental Protection Agency (EPA), the chemical has been verified to be of low concern (determined to be safer than traditional chemical ingredients).

LAE can be present in concentrations up to 0.4% as a preservative in ready to use preparations (Not to be used in lip products, oral products and spray products). Alternatively, it can be present in concentrations up to 0.8% as a hair/skin Conditioner in soaps, anti- dandruff shampoos and deodorants (not in

form of spray). This substance is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year.

Alternatives to LAE are: Zinc Pyritione in anti-dandruff shampoos; Phenoxyethanol as a preservative; Triclosan as a preservative in mouthwash; Polyquaterniums as a conditioner.

ZnP is allowed in a concentration up to 0.1% in leave-on hair products according to the Cosmetic Regulation, and is prohibited in EU Ecolabel products because of its classification as H360D. Phenoxyethanol is allowed up to 0.01% in rinse off and up to 0.001% in leave on EU Ecolabel products (see next sections). Triclosan is prohibited I EU Ecolabel products according to criterion 4 (b). Polyquaterniums is allowed in concentration up to 0.01% in rinse off and up to 0.001% in leave on EU Ecolabel products, on the condition that it fulfils the biodegradability criteria.

However, product investigations in Denmark and Sweden showed that the substance appears to be very rarely used: only 3 cosmetics out of the more than 13000 products registered in the Danish Consumer Council database contained this substance. While this is probably due to the novelty of the substance and the difficulty for a preservative to enter the cosmetic market, a derogation for a H400-classified substance should require no alternatives on the market. Given also the low concentration in which LAE is typically used, **it is proposed not to grant a derogation for LAE**. This means that the substance can be used in concentrations up to 0.01% in rinse off and up to 0.001% in leave on EU Ecolabel products.

- *Sodium Fluoride (NaF)*

The derogation for NaF in toothpaste was requested by one company.

Sodium fluoride (NaF) is an inorganic compound often used as a source of fluoride in the production of pharmaceuticals and in toothpaste to prevent dental cavities.

According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is toxic if swallowed (H301), causes serious eye irritation (H319) and causes skin irritation (H315). Due to its classification as H301, NaF was proposed to be banned in EU Ecolabel toothpaste according to criterion 3 (b).

According to the Annex III of the Cosmetic Product Regulation, NaF is permitted up to "0.15 % calculated as F. When mixed with other fluorine compounds permitted under this Annex, total F concentration must not exceed 0.15 %. The product must be accompanied by the labelling Contains Sodium Fluoride. For any toothpaste with compounds containing fluorine in a concentration of 0.1 to 0.15 % calculated as F unless it is already labelled as contra-indicated for children (e.g. 'for adult use only') the following labelling is obligatory: 'Children of 6 years and younger: use a pea-sized amount for supervised brushing to minimise swallowing. In case of intake of fluoride from other sources consult a dentist or doctor.'"

However, a SCCS Opinion from 2005 has been published on the safety of fluorine compounds in oral hygiene products for children under the age of 6 years. Moreover, the World Health Organisation stress the need for sufficient fluoride intake for oral health and to minimize tooth decay.

Typical concentration of NaF in toothpaste is 1450 ppm. This substance is manufactured and/or imported in the European Economic Area in 1 000 – 10 000 tonnes per year.

Although alternative forms of fluoride exist, it might not always be possible to replace Sodium Fluoride or consider all sources of fluoride as interchangeable. The choice of a specific Fluoride source is in fact often dictated by the incompatibility with other ingredients in the formulation that could make the fluoride itself no longer active. If that is the case the substitution with an alternative is not possible.

The anticaries benefit of Fluoride sources other than Sodium Fluoride is well known and accepted. The key parameter to be ensured for the anti-caries and enamel protection of fluoride is the delivery and bioavailablity of the Fluoride ion on to tooth enamel, hence absence of reaction has to be ensured inside the formulation. Sodium Monofluorophosphate, Tin Fluoride and Olafluor have different chemistry and interactions that must be assessed on a formulation by formulation base. Alternative sources of fluoride might have impact on other product performances. For example, Tin Fluoride can stain teeth, making it not an easy replacement to be formulated or asking consumer to compromise on other benefit requested by a toothpaste like clean teeth.

Based on the information above, and given the fact that this substance is derogated also in other ecolabelling schemes, **it is proposed to grant a derogation for Sodium Fluoride for its H301 hazard class in oral care rinse-off products**.

During the subgroup meeting, another stakeholder proposed to derogate not only NaF, but also any of the other fluoride sources that are allowed as per the CPL Annex III. The suggestion was to apply the derogation not only in toothpaste, but in oral care products in general (e.g. also including mouth-rinse products). This suggestion would imply the derogation of Sodium Monofluorophosphate, Tin Fluoride and Olafluor. The following hazard classes are associated to these substances:

- Sodium Monofluorophosphate: H302, H312, H315, H319
- Tin Fluoride: H302, H314, H412
- Olafluor: H302, H315, H318, H400, H410.

Sodium monofluorophosphate appears to fulfil all EU Ecolabel criteria: therefore, it does not need any derogation. Tin fluoride and Olafluor are more rarely used, and associated with H400 and H412 hazards. Given also the trace amounts these mixtures are used in, **it is proposed not to derogate Tin fluoride and Olafluor in EU Ecolabel oral care products**. The substance can still be used in concentrations up to 0.01% in oral care rinse off EU Ecolabel products.

- *Titanium dioxide (TiO_2, nano-form)*

The derogation for titanium dioxide was requested by one stakeholder.

TiO_2 is commonly used in cosmetic products as a UV filter that provides broad spectrum UVA/UVB protection up to 340 nm.

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 (see later section on UV filters).

TiO_2 in inhalable powder form has been included as a Carc. 2 (H351, only TiO_2 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 was published early 2020, with the changes becoming a legal requirement 18 months later. 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).

TiO_2 is used in sunscreen products in a concentration of less than 25%, with a typical concentration between 0.4 - 16.7%. This substance is manufactured and/or imported in the European Economic Area in more than 1 000 000 tonnes per year.

Zinc Oxide is the only inorganic or "physical" UV filter that is an alternative to Titanium Dioxide. However, according to the harmonised classification and labelling (CLP00) approved by the European Union, Zinc Oxide is very toxic to aquatic life (H400) and is very toxic to aquatic life with long lasting effects (H410). Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance may damage fertility or the unborn child, is harmful if swallowed, is harmful if inhaled and may cause damage to organs through prolonged or repeated exposure.

Other alternatives to TiO_2 filter exist but may be potential endocrine disruptors. Of the substitutes identified by industry, only two are not potential endocrine disruptors.

Based on the above, and given the fact that the H351 classification only refers to the risk of inhalation when in powder form, **it is proposed to grant a derogation to TiO2 in nano-form for its property as H351 only for use as UV-filter in leave-on products with sunscreens, provided that the product is not in powder or inhalable form.**

- *Zinc Pyrithione (ZPT)*

One stakeholder stated that the alternative anti-dandruff agents available on the market cannot be considered as efficient as ZPT, and asked for a derogation. However, no formal derogation request was received.

ZPT is a preservative which is widely used as an anti-dandruff agent in rinse-off hair products. ZPT are allowed in concentrations up to 0.5% in rinse-off products (1.0% in rinse-off hair products) and up to 0.1% in leave-on hair products. ZPT has been subject to different safety evaluations[27] and, according to the latest one, is considered safe when used as an anti-dandruff in rinse-off hair products up to a maximum concentration of 1%[28]. However, on 14 September 2018 ECHA's Risk Assessment Committee (RAC) adopted an opinion proposing a harmonised classification and labelling as a CMR 1B substance. Moreover, joint and individual entries have been submitted to ECHA proposing a harmonised classification and labelling as H301, H318, H331, H400 and H410.

Given the existence of alternative substances that are available on the market and would be allowed in EU Ecolabel products such as selenium sulphide, piroctone olamine and other natural ingredients (e.g. Dandrilys), and the fact that relevant data was not submitted to JRC to substantiate a derogation request, **the derogation of ZPT cannot be accepted**.

4 (a) (iii) requirement: product classification

Stakeholders pointed out to a mistake in TR2.0, stating that the maximum content of compounds classified as H410, H411 and H412 in a cosmetic product should be 25%, and not 2.5%.

This formula allows for a theoretical classification of the cosmetic products, and is present in other two ecolabelling schemes. In Nordic Swan, the limit is set to 2.5%; however, surfactants classified as H412 and H413 are exempted from the requirement (they should not be considered in the calculation). On the other hand, in Blue Angel, the limit is set to 25% (the formula has a different formulation, although the resulting limit is the same); classified surfactants have no exemptions.

It is considered that the wording as in Nordic Swan is stricter than the one in Blue Angel, as it does not open up to potentially use substantially higher cumulative levels of substances with the more severe classifications H410 and H411. Therefore**, it is proposed to keep the threshold at 2.5%, and to add the exemption for surfactants classified as H412** (H413 classified surfactants are not derogated in the EU Ecolabel).

[27] by the SCCS in 1984 (XI/389/84), SCCNFP in 2002 (SCCNFP/0671/03), the SCCS in 2014 (SCCS/1512/13), 2018 (SCCS/1593/2018) and 2020 (SCCS/1614/19

[28] https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_236.pdf

Moreover, some stakeholders expressed reservations on the setting of this requirement, stating that the formula opens up to a wider acceptance of hazardous substances, and is in contrast with requirements 4 (a) (i) and (ii).

The presence of requirement 4 (a) (iii) is due to the fact that the CLP regulation cannot be applied to the cosmetic product in its finished state. Hence, the need to set a limit on the cumulative presence of H-classified substances and mixtures. This empirical formula is used in other ecolabels such as Blue Angel and Nordic Swan and puts a cap on the presence of substances that are toxic or harmful to aquatic life. The requirement set in 4 (a) (i) on individual substances/mixtures is still valid; in addition to it, the product shall comply with this formula.

In order to clarify the objective of this requirement, **the formula has been rewritten**, highlighting that it is the sum of H-classified compounds that should be compliant. In addition, **an exemption for zinc cream formulations has been added**, in line with Nordic Swan. The exemption on H412/H413 surfactants has not been included.

Summary of changes in TR3.0

In summary, the main changes introduced to criterion 4 in TR3.0 are:

- The sentence in criterion text relating to compliance with SCCS's opinion has been changed in order to clarify it;
- The word "mixtures" has been removed from the requirement 4 (a) (i) for the H-classes H314 and H317;
- Derogations were granted to H412 classified surfactants in rinse-off products, NaF in oral care products and TiO2 in UV filters for use in non-sprayable products
- Two exemptions were added to requirement 4 (a) (iii): surfactants classified as H412, and H400 zinc compounds in zinc cream formulations.

Question to stakeholders
• Is criterion 4 (a) (i) to be applied to mixtures also, or only substances?

- ***Requirement 4(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).

During the survey consultation (March 2019, before the TR1), stakeholders gave feedbacks on the substances/mixtures that should have been removed or added to the list. Moreover, an analysis of other ecolabels was performed and EU Ecolabel sub-criterion 4(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 underlying research and decision process can be found in the TR1.0[4].

In summary, for the first proposal, the following changes to the current criterion 4 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'[29] laid down in EU Ecolabel criteria for detergents[30]. 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)[31]
- 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;
  - ETPA (diethylenetriaminepentaacetic acid and its salts);
  - Cocamide DEA;
  - The phthalates Di-n-Octyl-Phthalate (DNOP) and Diethyl phthalate (DEP);

[29] '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.
[30] COMMISSION DECISION (EU) 2017/1214 of 23 June 2017 establishing the EU Ecolabel criteria for hand dishwashing detergents.
[31] https://echa.europa.eu/es/restrictions-under-consideration/-/substance-rev/22921/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=-&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

- Sodium Lauryl Sulfate (SLS);
- Sodium phosphate, Disodium phosphate and Trisodium phosphate.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

Summary of main implemented changes in TR2

Based on the analysis of stakeholder comments and the further research conducted, the following changes have been implemented in the TR2.0 proposal:

- The following substances have been proposed to be included to sub-criterion 4(b):
  - phenoxyethanol (only in leave-on products targeting children), due to its classification as H302;
  - nanomaterials, unless a EU Regulatory Authority proves it is safe to use;
  - "sodium phosphate, dihydrate", "disodium phosphate, heptahydrate", "trisodium orthophosphate" and "phosphoric acid, trisodium salt, dodecahydrate", due to thei classification as H315, H319 and H335;
  - identified endocrine disruptor substances,
  - perfluorinated and polyfluorinated substances, due to their persistence in the environment; aluminium and aluminium salts (restricted if in concentration higher than 0.6% w/w in leave-on products), in line with the SCCS opinion (Submission I, in 2014) and Nordic Swan;
  - phthalates, in line with Nordic Swan and Bra Miljoval;
  - isothiazolines, since these substances are added to the products in very low concentrations.
- The restriction of SLS has been limited to its use in toothpaste only, due to the risk of swallowing;
- The following substances have been proposed to be deleted to sub-criterion 4(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 order to be aligned with any future amendments to the definition.
- In Annex II, the following sentence was added to criterion 4(b): "substances and mixtures listed under Annex II to Regulation 1223/2008 shall not be added to the product", in order to prohibit all the substances banned according to the Cosmetic Regulation, which does not apply to animal care products.

Substances and mixtures listed in criterion 4(b) for cosmetic products that are not relevant for animals were removed from criterion 4(b) for animal care products.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Thresholds

Stakeholders commented that the heading of the sub-criterion 4(b) should be better clarified to ensure that it applies not only substances and mixtures added to the final product, but also to those substances and mixtures added to fragrances or other mixtures. Therefore, in this TR3.0 **it is proposed to go back to the criterion text of the existing Decision in force**:

"*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:*"

In addition, it was specified that these substances should not be present not even as impurities. In any case, Table 1 of the legal text gives guidance on the allowed thresholds for each criterion and sub-criterion.

Substances suggested to be included by stakeholders

Polyethylene glycol

Polyethylene glycols (PEGs) are petroleum-based compounds composed of polyether compounds repeating ethylene glycol units. PEGs, together with their derivatives, do not have definite chemical entities, rather, they are compound mixtures having different chain lengths. PEGs are used in cosmetics "as is" or in combination with their derivatives. PEGs and their derivatives are widely used in cosmetics as surfactants, cleansing agents, emulsifiers, skin conditioners, and humectants. Since many PEG types are hydrophilic, they are favourably used as penetration enhancers, especially as cream bases. PEGs are also used in toothpastes as a dispersant, to keep xanthan gum uniformly distributed throughout the toothpaste.

According to the notifications provided by companies to ECHA in REACH registrations no hazards have been assigned to PEGs. In previous studies[32], PEGs and various PEG compounds have been reviewed and assessed as relatively safe for use in cosmetics, under the present conditions of intended use.

PEGs and PEG derivatives are generally regulated as safe for use in cosmetics, with the conditions that impurities and by-products, such as ethylene oxides and 1,4-dioxane, should be removed before they are mixed in cosmetic formulations. Indeed, depending on the manufacturing process, PEGs may be contaminated with measurable amounts of ethylene oxide and 1,4-dioxane. The International Agency for Research on Cancer classifies ethylene oxide as a known human carcinogen and 1,4-dioxane as a possible human carcinogen. 1,4-dioxane is also persistent in the environment. 1,4-dioxane can be removed from cosmetics during the manufacturing process by vacuum stripping, but there is no easy way for consumers to know whether products containing PEGs have undergone this process. Indeed, a 2008 study found 1,4-dioxane as a contaminant in 46 of 100 products analysed[33].

PEGs are not restricted in other labelling schemes.

1,4-Dioxane is an impurity that may be present in trace amounts in some cosmetic products. 1,4-Dioxane itself is not used as a cosmetic ingredient but can form as a byproduct during the manufacturing process of certain ethoxylated cosmetic ingredients. 1,4-Dioxane is a CMR substance classified in EU as carc. 2 (H351). Ethylene oxide is added to cosmetics to make them less irritating to the skin, by creating a chemical reaction called ethoxylation. However, the finished products may contain traces of unreacted ethylene oxide. According to the harmonised classification and labelling (ATP14) approved by the European Union, ethylene oxide is, among other hazard classes, a CMR (H350 and H340). Therefore, both substances are already banned in EU Ecolabel products regardless of their concentration according to sub-criterion 3(c).

According to the information above **it is proposed not to set any exclusion on PEGs compounds**.

Silicones

[32] Fruijtier-Pölloth C. Safety assessment on polyethylene glycols (PEGs) and their derivatives as used in cosmetic products. Toxicology. (2005);214:1–38. doi: 10.1016/j.tox.2005.06.001;

Cosmetic Ingredient Review Expert Panel. Lanigan R.S., Yamarik T.A. Final report on the safety assessment of PEG-6, -8, and -20 sorbitan beeswax. Int. J. Toxicol. (2001)20 Suppl 4:27–38;

CIR Expert Panel. Final report of the amended safety assessment of PEG-5, -10, -16, -25, -30, and -40 soy sterol. Int. J. Toxicol. (2004);23 Suppl 2:23–47;

Jang HJ, Shin CY, Kim KB. Safety Evaluation of Polyethylene Glycol (PEG) Compounds for Cosmetic Use. Toxicol Res. 2015;31(2):105-136. doi:10.5487/TR.2015.31.2.105

[33] OCA (Organic Consumer Association). 2008. Consumer alert. Cancer-causing 1,4-dioxane found in personal care products misleadingly branded as natural and organic. Available: http://www.organicconsumers.org/bodycare/DioxaneRelease08.cfm

The term silicone represents a large family of polymers that range from low viscosity fluids, to viscous gums, to cross-linked elastomers and hard resins. Their unique chemical and physical properties have made silicones important ingredients to improve the performance of many cosmetics, sunscreens and skin treatment products. They help deliver pigments and other particles to the skin, enhance protection by sunscreens and improve the stability of antiaging ingredients.

In cosmetics there are more than 300 possible ingredients that are made from or contain silicones, and can be in a purely synthetic form, or as a combination of a synthetic polymer connected to a natural substance or substances. The most common silicones are dimethicone (also Polydimethylsiloxane (PDMS) or dimethylpolysiloxane) and cyclic siloxane compounds (D5 and D6)

These compounds do not have a harmonised classification under CLP, however PDMS and D5 are included in the EC list for the call for data on substances potentially being endocrine disruptors. Some silicones are readily biodegradable, but others can persist in the environment, accumulate and be toxic. For example, PDMS is non-biodegradable; it is however absorbed in waste water treatment facilities. D5 and D6 are included in REACH SVHC Candidate List, being classified as vPvB substances.

Due to the essential role that silicones play in cosmetics (also in terms of the marketability of the product), **it is proposed that silicones are not added to the restriction list in sub-criterion 4(b)**, also in line with other labelling schemes. However, most of the silicones will not pass other requirements, e.g. biodegradability, potential EDs or SVHC substances.

Potential endocrine disrupting compounds

The topic of inclusion/exclusion potential endocrine disruptors (EDs) in sub-criterion 4(b) was highly discussed at the 2nd AHWG meeting, and many comments were received on this matter. Many stakeholders insisted on the need to prohibit the presence of potential EDs. They referred to the existence of many lists, the most official one being an EC list (composed of two parts, A and B) published in 2019 by DG GROW identifying those substances which may potentially have endocrine disrupting properties[34]. These substances will assessed by the SCCS, and the purpose of the list is to call for relevant data with respect to the listed substances. Another important list is the one developed by the Danish, Belgian, Dutch, French and Swedish National Authorities[35]. The list is composed of three parts: substances identified as endocrine disruptors at EU level, substances under evaluation for endocrine disruption under an EU legislation, and substances considered, by the evaluating National Authority, to have endocrine disrupting properties. However,

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

[35] https://edlists.org/the-ed-lists

potential EDs are identified also in a number of other lists: ECHA's endocrine disruptor (ED) assessment list[36], which includes the substances undergoing an ED assessment under REACH or the Biocidal Products Regulation that have been brought for discussion to ECHA's ED Expert Group; the UN list of previously identified as EDCs or potential EDCs[37]; the SIN List[38], which includes substances that had indications of endocrine disruption as well as solely due to their endocrine disrupting properties. The presence of so many lists makes it difficult to set a clear and concrete requirement, as well as raises some doubts on the criteria for a substance to fall into the 'potential' category. As some stakeholders argued, no current list of potential EDs is designed to be used for regulatory risk management. Moreover, an issue arises with compounds that change their "status" on the list, e.g. from "to be assessed" to "assessed as safe".

Consumers are highly concerned on the inclusion of identified and potential EDs in cosmetic products, and it would be important to restrict them for the credibility of the label. Moreover, other labelling schemes such as Nordic Swan set requirements on potential EDs. In order to make the requirement simple, the EC list was taken as a starting point and screened for those compounds that are commonly found in cosmetic products and are not restricted by other EU Ecolabel criteria. This led to a list of eight compounds with potential endocrine disrupting properties. It is important to stress that no scientific assessment was made by JRC on the substances on the EC 2019 list. The compounds are:

- Ethylhexyl methoxycinnamate
- Recorsinol
- Benzopehenones
- Homosalate
- Octocrylene
- Butylphenyl metylpropional
- Benzyl salicylate
- Triphenyl phosphate

These compounds are proposed to be included in sub-criterion 4 (b).

Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products

[36] https://www.echa.europa.eu/ed-assessment

[37] https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/scientific-knowledge-endocrine-disrupting

[38] https://chemsec.org/policy-and-positions/endocrine-disruptors-edcs/edcs-on-the-sin-list/

Stakeholders submitted relevant data supporting the request to ban MOAH and MOSH in lip care products. The studies cited by stakeholders[39] demonstrate that the guidelines set by Cosmetic Europe on mineral oils in lip care products are very often not complied with. Therefore, **it is proposed to prohibit the presence of MOAH and MOSH, unless the recommendations by Cosmetic Europe for mineral oils are complied with and compliance is demonstrated**.

Nanomaterials

Many stakeholders asked for more clarity on the requirement banning nanomaterials, especially with respect to the type of EU regulatory authorities that can be accepted. In order to define the requirement as clearly as possible, **it is proposed to specify in a note to the criterion text** that "Opinions will be accepted if coming from SCCS (for the assessment of the human health of the nanomaterial) or from RAC or SCHEER (for the assessment of the environmental impacts of the nanomaterial)."

Moreover, even more clarity has been added, by stating that **the definition of nanomaterial** followed by the EU Ecolabel for cosmetic products is as defined in the Cosmetic Regulation. Finally, in order to help Competent Bodies with the verification of the requirement, specific mention was made to the Cosmetic Products Notification Portal, to check whether a product contains nanomaterials, and to the EU Observatory for Nanomaterials database, to check nanomaterials that are currently on the EU market.

An additional amendment has been made. Indeed, to our knowledge, no EU Regulatory Authority can formally 'recognise a nanomaterial as safe' from an environmental perspective. Indeed, EU bodies such as the RAC or the SCHEER or other EU bodies do not issue opinions that state/conclude that a (nano-)substance would be 'safe', but rather determine that a substance induces (or not) a specific adverse effect (which may lead, to the classification of the substance for a specific hazard class (through the RAC).

To date, there is little specific experience of the nanomaterials hazard in committees such as RAC. Under REACH particularly, in the absence of sufficient information, it is more likely to be stated that the hazard profile is incomplete/inconclusive, not that

[39] https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/lippenbalsem

https://www.test-aankoop.be/gezond/dagelijkse-verzorging/geteste-producten/nieuws/merendeel-lippenbalsems-mogelijk-schadelijk

https://kemi.taenk.dk/bliv-groennere/test-lipsticks-may-contain-perfume-mineral-oils-and-suspected-endocrine-disrupting

https://mobil.bfr.bund.de/cm/349/highly-refined-mineral-oils-in-cosmetics-health-risks-are-not-to-be-expected-according-to-current-knowledge.pdf

https://www.beuc.eu/publications/beuc-x-2017-128_problematic_mineral_oils_in_lip_care_products.pdf

the nanoform is safe. A different approach applies under the BPR where e.g. authorisation for use is sought.

As the notion of safety should be backed up by relevant and reliable hazard and exposure/risk assessments which are not available at the moment (under REACH) for any of the substances known to be marketed in nanoform, it is proposed to ban nanomaterials unless an EU Regulatory Authority has evaluated **and authorised the use of the substance**. **The mention to the demonstration of the safety of the substances has been removed**.

Microplastics

One stakeholder suggested to include in the definition of 'microplastics' also the derogations no. 3 and 5 to this definition that is proposed by the joint opinion[40] from RAC (Committee for Risk Assessment) and SAEC (Committee for Socio-economic Analysis).

The derogation 3 states that the definition of microplastic "shall not apply to:

a. Natural polymers (as defined in REACH Guidance on monomers and polymers) that have not been chemically modified (as defined in REACH Article 3(40)).

b. Polymers that are (bio)degradable, according to the criteria in Appendix X.

c. Polymers with a solubility > 2 g/L, according to the criteria in Appendix Y."

The derogation 5 states that the maximum permitted concentration limit "shall not apply to the placing on the market of:

a. Substances or mixtures containing microplastic where the microplastic is contained by technical means to prevent releases to the environment during end use.

b. Substances or mixtures containing microplastic where the physical properties of the microplastic are permanently modified during end use, such that the polymers no longer fulfil the meaning of a microplastic given in paragraph 2(a).

c. Substances or mixtures containing microplastics where microplastics are permanently incorporated into a solid matrix during end use."

It is proposed to **include the opinion of RAC and SAEC**. The derogations to this definition are automatically also included, without the need to specify them.

Moreover, the opinion of RAC and SAEC also gives a **definition of microbaeds, which is proposed to be included to the list in criterion 4(b)**.

[40] Opinion on an Annex XV dossier proposing restrictions on intentionally-added microplastics. Available at: https://echa.europa.eu/documents/10162/b4d383cd-24fc-82e9-cccf-6d9f66ee9089

Phenoxyethanol

Stakeholders submitted their opinions against the ban on phenoxyethanol in products marketed for children.

Indeed, a SCCS opinion exist[41] from 2016 which states that the allowed limit of 0.1% (according to the Cosmetic Regulation) is considered safe also for children. After the publication of the SCCS opinion, Nordic Swan withdrew the requirement.

Therefore, **it is proposed not to ban the preservative phenoxyethanol in sub-criterion 4(b)**. The presence and concentration of the substance will still be limited by other requirements.

BHT

It was suggested to make an exception for the exclusion of 2,6-di-tert-Butyl-4-methylphenol (BHT) in criterion 3(b) to allow its use to perfumes within safe concentration levels. Indeed, BHT is an antioxidant needed in perfumes in order to reduce the content of allergenic fragrance metabolites.

BHT does not have an harmonised classification, although according to the classification provided by companies to ECHA in REACH registrations this substance is H400 and H412. Moreover, BHT is considered to be a potential ED[34]. However, Nordic Swan also applies an exception in perfumes for the ban on BHT.

Therefore, **it is proposed to keep the ban on BHT, but not on its use in perfumes provided that total BHT content in perfume is below 100 ppm and total concentration in the final product is below 0.001%**.

Aluminium and its salts

Stakeholders were in favour of allowing aluminium and its salts in anti-perspirants products if present in a concentration lower than 0.6%.

Indeed, a SCCS opinion from 2020[42] (called Submission II, as it adds new information to the previous SCCS Submission I from 2014) considers that "the use of aluminium compounds is safe at the following equivalent aluminium concentrations up to:

- 6.25% in non-spray deodorants or non-spray antiperspirants
- 10.60% in spray deodorants or spray antiperspirants
- 2.65% in toothpaste and
- 0.77 % in lipstick"

[41] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_195.pdf

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

These concentrations are significantly higher than the ones indicated in the TR2.0. Moreover, the SCCS opinion states that dietary intakes may also contribute as a source of aluminium and its salts.

Based on the above, **it is proposed to remove the requirement for the exclusion of aluminium salts in EU Ecolabel products**. Compliance with the safety thresholds specified in the SCCS opinion from 2020 have to be taken into account. This will be guaranteed by the requirement that SCCS opinions must be taken into account.

Summary of changes in TR3.0

In summary, the main changes introduced to criterion 4 (b) in TR3.0 are:

- The opening sentence of criterion 4(b) was rewritten (same wording of the existing Decision in force): "The following ingoing substances and mixtures shall not be included in the product, neither as part of the formulation, as part of any mixture included in the formulation, nor as impurities";
- The compounds Ethylhexyl methoxycinnamate, Recorsinol, Benzopehenones, Homosalate, Octocrylene, Butylphenyl metylpropional, Benzyl salicylate, and Triphenyl phosphate, were included in sub-criterion 4 (b);
- MOAH and MOSH were included in sub-criterion 4(b), where the recommendations by Cosmetic Europe for mineral oils are not complied with (compliance must be demonstrated);
- Nanomaterials were defined in a note to the criterion text. Moreover, it was specified that opinions of their authorisation (and not their safety) will be accepted if coming from SCCS, RAC and SCHEER;
- The exclusion on microplastic was further defined, including microbaeds and setting some derogations in line with the opinion from RAC and SAEC;
- The ban on the preservative phenoxyethanol in products marketed for children was removed;
- An exception was set on the ban on BHT, when used in perfumes with a total BHT content in perfume below 100 ppm and a total concentration in the final product below 0.001%;
- The ban on aluminium and its salts was removed.

- Requirement 4(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.

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.

Taking Article 6(6) of EU Ecolabel Regulation as a reference, in the TR2.0 it was proposed to **modify the wording of sub-criterion 4(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.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0.

No major comment was received on sub-criterion 4(c). Therefore, no changes were made.

- ***Requirement 4(d) Fragrances***

Rationale of proposed requirement

According to the existing 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.

An analysis of other ecolabels was performed and its results presented in the first technical report[4] showed that Blue Angel and Nordic Swan ecolabels establish that classified fragrances or 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 4 (a).

No changes were introduced in this sub-requirement in the TR1.

During the 1st AHWG meeting, stakeholders demanded low thresholds for leave-on products as well as the exclusion of substances with allergenic properties.

No changes were introduced in this sub-requirement in the TR2.0.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Further restriction of substances

Many stakeholders asked firmly for tighter restrictions for fragrances. In particular, stakeholders asked to restrict the 82 substances listed under the SCCS opinion from 2012.

The SCCS opinion from 2012[43] lists under table 13-1 54 individual chemicals and 28 natural extracts (mixtures of chemicals) for which available studies indicate that a general level of exposure of up to 0.8 µg/cm² (0.01% in cosmetic products) may be tolerated by most consumers, including these with contact allergy to fragrance allergens. The SCCS is of the opinion that this level of exposure (up to 0.01%) would suffice to prevent elicitation for the majority of allergic individuals, unless there is experimental or clinical substance-specific data allowing the derivation of individual thresholds.

Therefore, it is proposed that **the 82 substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' are restricted in EU Ecolabel products up to 0.01% in rinse-off products and 0.001% in leave-on products**.

Products designed for children

Stakeholders expressed the need to ban fragrances in products designed and marketed for children. Indeed, it is important to limit the cumulative exposure of children to fragrances and thus reducing the risk that allergies develop. Therefore, it **is proposed that the current ban on fragrances in products for children was kept**. However, it was commented that the absence of flavours/fragrances in toothpaste for children would discourage children to clean their teeth because of the taste. Therefore, **an exception to criterion 4 (d) (i) was made for toothpaste for children**.

Summary of changes in TR3.0

In summary, the main changes introduced to criterion 4 (d) in TR3.0 are:

[43] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

- The 82 substances listed under Table 13-1 of the 2012 SCCS opinion on 'Fragrance allergens in cosmetic products' were restricted in EU Ecolabel products to a maximum concentration of 0.01% in rinse-off products and 0.001% in leave-on products;
- An exception to criterion 4 (d) (i) was made for toothpaste for children.

- ***Requirement 4(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 4(b).*
- *The product may contain preservatives provided that they are not bioaccumulating.*

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 TR1.0 for further details).

One more consideration regarding preservatives refers to the restriction on the use of isothiazolinones, whose use was permitted in TR1.0.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

In summary, the following changes were made to criterion 4(e) in TR2.0:

- Isothiazolinones were proposed to be prohibited regardless of their concentration according to criterion 4(b);
- Due to the risk of swallowing toothpaste products, a new clause was inserted which allows in toothpastes only those preservatives which are approved by Regulation (EC) No 1333/2008[44] on food additives.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a

[44] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1333

summary of the main relevant comments and the main changes introduced in the text.

Criterion 4 (e) (iii)

Stakeholders requested that criterion 4 (e) (iii) on preservatives approved as food additives was extended to cover also other products that contain a high risk to be swallowed.

Commission Directive 2008/128/EC[45] lays down specifications for food additives listed in Annex II and III to Regulation (EC) No 1333/2008. These criteria can also be used in cosmetics because the additives used in food have been safety evaluated on the basis of an exposure scenario in which they are "closer" to the body than cosmetic products. This directive lists all the additives approved for use in food and sets purity threshold values.

This was considered reasonable and therefore **the scope of the requirement is proposed to be extended to products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail lacquers)**.

Definition of bioaccumulating thresholds

In the previous revision (TR2.0) it was explained that the BCF and log K_{ow} cut-off values come from the Dangerous Substances Directive (DSD). The DSD Directive was replaced by Regulation EC 1272/2008 (CLP Regulation), allowing more relaxed thresholds. In the TR2.0, it was proposed not to change the requirement, and keep the strictest cut-off values. However, in this TR3 **it is proposed to align with the CLP Regulation and Nordic Swan, and set BCF < 500 and log K_{ow} < 4.0**

- ***Requirement 4(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. However, in the case of colouring agents approved for use in food, it is not necessary to submit documentation of their bioaccumulation potential.

An analysis of other ecolabels was performed prior to TR1.0 and found that 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

[45] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32012R0231

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.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

Colorants in decorative cosmetics

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

In summary, the following changes were made in TR2.0:

- Criterion 4(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, due to the risk of swallowing.
- 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, aligning with Nordic Swan.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Colorants in toothpaste

Stakeholders asked to remove the requirement that allows the use of food colorants only if approved as food additives according to Regulation 1333/2008[46], as it was stated that approved food additives are authorized in specific food categories with particular conditions of use which may totally differ from exposure from toothpastes.

However, Regulation 1333/2008 set provisions that concern the use of food additives:

(a) in specific foods;

(b) for purposes other than those covered by this Regulation.

[46] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1333

Therefore, use in cosmetics product is also covered. Moreover, colorants in toothpaste are not essential in the formulation. Finally, Nordic Swan and Blue Angel have licences for toothpaste despite the existence of this requirement.

Other stakeholders suggested to extend the scope of requirement 4 (f) (ii) to other products which are in contact with the mouth (high risk to be swallowed).

Commission Directive 2008/128/EC lays down specifications for food additives (including colours) listed in Annex II and III to Regulation (EC) No 1333/2008. These criteria can also be used in cosmetics because the colorants used in food have been safety evaluated on the basis of an exposure scenario in which they are "closer" to the body than cosmetic products. This directive lists all the colours approved for use in food and sets purity threshold values.

Based on the above, **it is proposed to keep the requirement on colorants to be used in toothpaste, and extend it to other products in contact with the mouth, e.g. mouthwash, lip care products, nail lacquers**.

Heavy metals in decorative cosmetics

It was suggested by stakeholders to set stricter thresholds on some heavy metals in decorative cosmetics, namely lead, cadmium and mercury to 1 ppm and bismouth oxychloride regardless of the concentration. However, other stakeholders were against the limit of 10 ppm proposed in TR2 for lead, stating that this would exclude a big part of the organic products in the market that use ochre, a natural colourant that may contain more than 10ppm of lead but that have a safety evaluation validating the safe use of these products.

Heavy metals occur in decorative cosmetics mainly as impurities to colourants. These heavy metals are already regulated in EU Ecolabel products according to requirement 4 (f) (ii): indeed, the purity thresholds set in Regulation 200/128 specifically address presence of arsenic, lead, mercury and cadmium.

For lead, it was found by a study[47] that Pb was detected in 75% of tested products, with an average concentration of 0.36 ± 0.39 ppm, including one product with 1.32 ppm. Another study[48] found that the median of lead content in 72 lipsticks was 0.73 ppm, whereas the median was 1.38 ppm in pressed powder eye shadow. Therefore, it seems feasible to set a tighter threshold on lead in decorative cosmetics.

[47] Sa Liu, S. Katharine Hammond, and Ann Rojas-Cheatham, 2013. Concentrations and Potential Health Risks of Metals in Lip Products. Environmental Health Perspectives. https://doi.org/10.1289/ehp.1205518

[48] Al-Saleh, Al-Enazi, Shinwari, 2009. Assessment of lead in cosmetic products. Regulatory toxicology and pharmacology. 10.1016/j.yrtph.2009.02.005

However, studies[49] for cadmium in lipsticks found that the 20 products analysed have a Cd content between 1.83 and 412.23 ppm, suggesting that the limit of 1ppm may be difficult to achieve.

The US Food and Drug Administration (FDA) conducted several tests on cosmetics recently[50] for presence of arsenic, cadmium, chromium, cobalt, lead, mercury, and nickel. The amounts found were for the most part very small, suggesting not to pose a health risk.

The hazards of mercury are known, and a limit of 1 ppm is justified.

Bismouth oxychloride is used as a colorant used for, among other applications, drugs, cosmetics, and food colorants. According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified to this compounds[51]. Therefore, the ban on bismouth oxychloride is not considered justified.

In this third version of the TR **it is proposed that criterion 4 (f) (iii) is modified as to set a stricter threshold of 1 ppm for lead and mercury**.

Definition of bioaccumulating thresholds

In the previous revision (TR2) it was explained that the BCF and log K_{ow} cut-off values come from the Dangerous Substances Directive (DSD). The DSD Directive was replaced by Regulation EC 1272/2008 (CLP Regulation), allowing more relaxed thresholds. In the TR2, it was proposed not to change the requirement, and keep the strictest cut-off values. However, in this TR3 **it is proposed to align with the CLP Regulation and Nordic Swan, and set BCF < 500 and log K_{ow} < 4.0**

- ***Requirement 4(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. For example, 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.

[49] Nkansah, Owusu Afriyie, & Opoku. (2018). Determination of lead and cadmium contents in lipstick and their potential health risks to consumers. Journal of Consumer Protection and Food Safety. 10.1007/s00003-018-1180-y.

[50] https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/fdas-testing-cosmetics-arsenic-cadmium-chromium-cobalt-lead-mercury-and-nickel-content#learned

[51] https://echa.europa.eu/brief-profile/-/briefprofile/100.029.202

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.

However, in TR1.0 it was proposed to include a new requirement for sunscreen in EU Ecolabel, in line with Nordic Swan specifications.

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 with 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[52] (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.

[52] 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

The second SCCS opinion[53] 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[54] 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 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[55], with the anatase form expected to be more toxic than the rutile form[56]. 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.

[53] 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

[54] 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

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

[56] Warheit et al., 2007

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

The following changes were proposed in TR2.0 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.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Marine biodegradability

One stakeholder suggested to include a new requirement on marine biodegradability for sunscreens, since sun care products have partially an end of life in the marine environment. The use of existing ISO tests was suggested: the Luminescence inhibition test (ISO 11348-3:2007) and the Algal growth inhibition test (ISO 10253:2006).

The JRC conducted further research on this topic, and relevant studies were found[57], using especially the test ISO 10253 to carry out an ecotoxicological evaluation of UV filters. However, the existing evidence does not provide enough data to set robust requirements, e.g. setting toxicity thresholds. Therefore, such methods, although potentially relevant, **could not be introduced in the EU Ecolabel requirement on UV filters**.

Protection of the user only

Several stakeholders asked to modify the wording of requirement 4 (g), to allow presence of UV filters not in leave-on products (as it was defined in TR2) but in sunscreens.

It is important that the UV filters are added to the cosmetic product in order to protect the user's health only, and not the product, since UV filters have very low

[57] Slijkerman and Keur, 2018. Sunscreen ecoproducts - Product claims, potential effects and environmental risks of applied UV filters. https://edepot.wur.nl/457209

Giraldo, A., Montes, R., Rodil, R. et al. Ecotoxicological Evaluation of the UV Filters Ethylhexyl Dimethyl p-Aminobenzoic Acid and Octocrylene Using Marine Organisms Isochrysis galbana, Mytilus galloprovincialis and Paracentrotus lividus. Arch Environ Contam Toxicol 72, 606–611 (2017). https://doi.org/10.1007/s00244-017-0399-4

Minguez, L., Pedelucq, J., Farcy, E. et al. Toxicities of 48 pharmaceuticals and their freshwater and marine environmental assessment in northwestern France. Environ Sci Pollut Res 23, 4992–5001 (2016). https://doi.org/10.1007/s11356-014-3662-5

biodegradation. However, there may be cases of products with multi functions: e.g. a leave on product which works as hydrating cream and as a sunscreen, or a foundation with UV filters included. The presence of UV filters should be allowed in these products, as long as the filter is included to protect the user. Indeed, such products may contribute to an overall waste prevention as allow for two (or more) products in one container. Therefore, **the wording of the requirement has been modified to reflect this need.**

Definition of bioaccumulation thresholds

In the previous revision (TR2.0) it was explained that the BCF and log K_{ow} cut-off values come from the Dangerous Substances Directive (DSD). The DSD Directive was replaced by Regulation EC 1272/2008 (CLP Regulation), allowing more relaxed thresholds. In the TR2, it was proposed not to change the requirement, and keep the strictest cut-off values. However, in this TR3 **it is proposed to align with the CLP Regulation and Nordic Swan, and set BCF < 500 and log K_{ow} < 4.0**

In summary, the changes proposed for criterion 4 (g) in this TR3 are the following:

- The wording of the requirement has been modified to reflect that UV filters are allowed in the product if protecting the user;

BCF and log K_{ow} cut-off values were aligned to the CLP Regulation and Nordic Swan, and set at BCF < 500 and log K_{ow} < 4.0;

- ***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.

During the 1st AHWG meeting, it was pointed out that 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.

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

Outcomes from and after AHWG2 and rationale for third proposal

Comments received mainly concerned clarification issues and wording modifications.

No changes were made to the criterion text.

3.4 CRITERION 5: 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: Third proposal for criterion 5: Packaging for cosmetic products

The minimum volume for a rinse off product to be certified should be 150ml.

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 rinse-off products sold with pump, a refilling option should be provided in the same or higher packaging capacity.

Toothpastes sold in multipacks are allowed to use additional packaging in order to hold the products.

Note: Cardboard boxes used to transport the products to the retail stores should not be considered as secondary packaging.

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 0.20 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).

For decorative cosmetics the following apply:
$PIR = \Sigma(W_{packaging,i} + W_{not\text{-}recycled,i}) / 2 * W_{product\ total} \leq 0.80$

$W_{packaging,\ i}$ — the weight of the packaging component i
$W_{non\text{-}recycled,\ i}$ — the weight of non-recycled material in packaging component i (if it is not recycled material in the packaging is $W_{non\text{-}recycled} = W_{packaging}$)

$W_{product,\ total}$ — the weight of the end product (packaging plus content)

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 from the packaging manufacturer 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.

*The declaration must fulfil the conditions of the future (January 2022) implementing act of Directive 2019/904 laying down the rules for the calculation and verification of the targets on recycled content.

c) Design of primary packaging

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

Rinse off products: The primary packaging shall be designed:

i) to make correct dosage easy by using a pump* or ensuring that the opening at the top is not too wide (diameter opening at the top below XX mm). Refills are exempted from this requirement.

* For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g (or 3 ml) soap per full press.

ii) to ensure that at least 94% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 6%, 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)

Rinse off products which primary packaging can be manually opened and the residue product can be extracted with adding water are exempted.

Leave-on products:

i) Leave-on conditioner bottles must have an emptying level of 90 % or have a lid that can be removed without tools.

ii) Cream bottles must have an emptying level of 90 % or have a lid that can be removed without tools.

The residual amount for the specified leave on products in the container (R), which must be below 10%, shall be calculated according to the above indicated formula.

Assessment and verification: the applicant shall submit a description of the dosage device (e.g. schematic illustration, pictures…), the test report with results of measuring the residual quantity of a rinse-off cosmetic product in the packaging and a high resolution image of the product packaging that clearly shows the

indicated dosage. 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 8.

Toothpaste tubes, pumps and aerosol containers are exempted from this requirement.

Table 8. **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 - PETG label or sleeve in combination with a PET packaging. - PET label or sleeve in combination with a PET packaging. - - Any other plastic materials for sleeves/labels with a density > 1 g/cm3 used with a PET packaging - - Any other plastic materials for sleeves/labels with a density < 1 g/cm3 used with a PP or HDPE packaging - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling). - Virgin PET and rPET from already food contact approved material shall not be allowed to use. - SAL (self adhesive) or PSL (pressure sensitive) label shall demonstrate the adhesive is water releasable at washing conditions of the recycling process. And in case of PET they also have to demonstrate no reactivation.
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 5% 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

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) SVHCs in cosmetic packaging

The packaging shall not contain any substances meeting the criteria referred to in Article 57 of Regulation (EC) No 1907/2006 that have been identified according to the procedure described in Article 59 of the mentioned Regulation and included in the candidate list of substances of very high concern for authorisation, at or above the concentration of 0.10% weight by weight.

Assessment and verification: the applicant shall submit a signed declaration of compliance together with a description of how they control this through the supply chain. Declarations from the suppliers could also be provided.

Annex 2: Third proposal for criterion 4: Packaging for animal care products

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*[58].

In 2018, the European Commission published the European strategy for plastics in a circular economy[59] 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[60]. 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[61].

a) Primary packaging

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 was modified in TR2.0. Secondary packaging will be only allowed to group the product and its refill.

In addition, in order to reduce the number of pumps produced and used in the cosmetic industry, **the refilling option for products sold with pump was proposed to be mandatory**.

Outcomes from and after AHWG2 and rationale for third proposal

[58] https://www.ellenmacarthurfoundation.org/assets/downloads/Completing_The_Picture_How_The_Circular_Economy-_Tackles_Climate_Change_V3_26_September.pdf
[59] https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf
[60] https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf
[61] According to our calculations, with Simapro software and ILCD method.

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Several stakeholders welcome the inclusion of mandatory refilling for products using pump. While other stakeholder asked to remove such requirement: "In some European countries, the mass market is not open to sell so much refills. Even if we propose refills, the product cannot be accepted in stores". They mention that if criterion is kept it should be limited to rinse-off products.

In addition, a stakeholder suggested to extend this requirement to leave-on products: "the refill can be the same packaging with cap and without pump in order to reuse several times this pump."

Several stakeholders requested to include an exemption of using secondary packaging to multipacks of products. Toothpastes usually sold together need to have something to hold them together.

A stakeholder asked to clarify if cardboard boxes used for transport several items is considered as secondary packaging.

Several stakeholders mentioned that small packaging are not an ecological option, so they should not be certified.

Against this background, the changes introduced in TR3.0 for primary packaging are:

- An exemption has been included for toothpastes in order to allow the use of secondary packaging for multipacks of toothpastes.
- Refills are not common practice for leave on products. Considering the practical difficulties to refill leave on products, it has been specified that the requirement apply to rinse off products.
- Cardboard boxes used to transport the products to the retail stores should not be considered as secondary packaging. This has been specified in the revised text.
- In order to avoid the use of small bottles it has been included a new requirement to limit the minimum volume for a product to be certified to 150ml. This requirement will not apply to leave on products and toothpastes usually marketed in small volumes.

b) <u>Packaging Impact Ratio (PIR)</u>

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.

The reduction of the PIR was analysed in TR2.0 in order to identify the number of products that will be out of the new approach if the value is modified. Table 8 shows how the percentage of licenced products would decrease with decreasing PIR.

Table 8. 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%**

In TR2.0 **it was 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 was proposed to be introduced for this product group as well.**

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Several stakeholders supported a further restriction of PIR values. A stakeholder mentioned: "The value of PIR shall be more restrictive and reduced. We have only 3 products by 34 certified products with this huge value and the average is 0,15. We propose a threshold of 0,18g."

With regards PIR calculation and values, a stakeholder suggested to align with Nordic Swan as the existing formula may not be suitable for new products under the scope.

Against this background, the changes introduced in TR3.0 for PIR requirement are:

- Reduction to PIR value to 0.20g. This reduction would affect 35 % of current licences (out of the 120 products assessed). However new data form French CB revealed a lower average values (0.15g) for their 34 licences. A compromise value has been proposed.

- Considering the extension of the scope, a PIR calculation formula for decorative cosmetics has been included in line with Nordic Swan scheme.
- The assessment and verification has been further clarified. For recycled content, the declaration from packaging manufacturer must fulfil the conditions of the future (January 2022) implementing act of Directive 2019/904 laying down the rules for the calculation and verification of the targets on recycled content.

c) Design of primary packaging

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.

In the TR2, Information about the residual amount of the product in the container was 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 9 shows how the percentage of licenced products would decrease with decreasing R.

Table 9. 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 (TR2.0) **the residual amount of the product in the container was suggested to be set to 8%.**

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

In relation to the residual amount, several stakeholders considered that decreasing R from 10 to 8% is not enough. They said that the requirement should go down to 5-6%.

On the contrary, some manufacturers mentioned that 8% was a very restrictive threshold and specially challenging for toothpaste: "the shoulder section of toothpaste tubes means it's very difficult to get down to this level, we propose a higher level for toothpaste". It was remarked that the data amount of residual product come from rinse-off products and these threshold would be very difficult for viscous leave-on product and it was suggested that the restriction must be limited to the rinse-off product.

A stakeholder suggested to change this requirement and make a requirement similar to the Nordic Swan Ecolabel. A hair conditioner will not often comply since the fluid will not leave the bottle just by turning the bottle upside down (as defined in the criteria) – you need to squeeze it to get the fluid out. In regards to leave-on products only jars will comply with the requirement.

In relation to the requirement: "*For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press." a* stakeholder considers this threshold as too strict and informed that packaging technical documents provide information in millilitre (ml) instead of gram (g). This stakeholder thus recommends changing the 2g threshold to 3ml.

Moreover, other stakeholders have expressed concerns about the possibility to certify containers sold as refills for dispensers, as their high opening diameter could contradict the requirement on correct dosage.

In addition a stakeholder questioned if the R criterion applies to packaging can be opened and the residue product can be extracted with adding water.

A stakeholder asked for further precision on the wording: "opening at the top is not too wide"

Finally, a stakeholder mentioned the importance to include a requirement on provision of information of the correct dosage.

Against this background, the changes introduced in TR3.0 for design of primary packaging requirement are:

- Refills have been exempted from the requirement on "opening design". The goal of this opening is to refill the original packaging and not to provide the correct dosage to the user.
- Residual amount has been decreased to 6%. According to existing data, more than 80% of existing licences will be able to reach this value.
- Considering that existing data is representative only for rinse off cosmetics, the existing requirement has been limited to rinse off cosmetics while for leave on products new requirements have been included in line with Nordic Swan.
- Requirement: "*For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press."* Considering that in many cases the information is provided in millilitres it has been included the possibility to measure this quantity also in volume (3 ml limit) in order to give flexibility to this requirement.

- Rinse off products that can be opened and the residue product can be extracted with adding water are proposed to be exempted form R requirement.
- A requirement on provision of information of the correct dosage has been included.

Question to stakeholders
- Stakeholders are requested to provide information on the standard diameter of the opening dispenser for rinse off cosmetics in order to further define "opening at the top is not too wide" on correct dosage requirement.

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).

Several 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[19].

Considering the requirements of the packaging criterion of Blue Angel, in the first revision (TR1.0) it was proposed that PETG and PETC label or sleeve in combination with a PET bottle should be avoided.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

The following changes were proposed in TR2 for this criterion:

- 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. Against this,

the the following text was included: "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.

- 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 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. EVOH material in barrier coatings was permitted in small quantities (with a maximum of 3% by weight).
- An exemption for toothpaste tubes was 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 were done to clarify that all type of plastic packaging is included in the criterion.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Label or sleeves:

A stakeholder mentioned that the adhesive used in the label can give problems for recycling of HDPE: *While water soluble glues are fully compatible with the recycling process, self-adhesive labels are very difficult to separate from the body and will contaminate the final recyclate*. Links to recycling guidelines for HDPE packaging bottles[62] and general guidelines[63] were provided.

Based on bilateral comunication with RecyclersEurope it has been found that: SAL (self adhesive) or PSL (pressure sensitive) needs to be provided with a releasable adhesive without reactivation. Water/alkali soluble and water/alkali releasable adhesives without reactivation are fully compatible with PET recycling. Against this **it is proposed to include a requirement on adhesives.**

[62] https://recyclass.eu/wp-content/uploads/2020/04/PE-HD-natural-containers-guidelines-27-04-2020-3.pdf

[63] https://recyclass.eu/recyclass/design-for-recycling-guidelines/

Another stakeholder said: *If the label and packaging are the same material, even if in mold labelling is done they can be recycled: need clarity on why they are being excluded.*

No modifications have been included with regards this comment. The label/sleeve is printed and the inks will affect reciclate quality. In the case of washable inks, at least the washing water will be contaminated.

A stakeholder highlighted that PETG density is similar to PET density and cannot be separated by the process. Unfortunately their thermal behaviors are quite different. Therefore they said that PETG labels/sleeves cannot be used in any case on PET bottles. Also PET labels/sleeves cannot be used because of the printing.

It was remarked that the preferred choice for PET bottles is always PE or PP label/sleeve with small covering (<50%).

In addition, it was recommended to further look at hard surface cleaners EU Ecolabel criterion on design for recycling, in order to further align as far as possible. It was mentioned that companies will get confused to see that for one product some design item is allowed and for another product the same design item is not allowed.

Against these comments, the criteria has been **further aligned to hard surface cleaners EU Ecolabel criteria. PETG restriction has been included.**

A stakeholder suggested that virgin PET and rPET from already food contact approved material shall not be allowed to use. Especially food contact approved rPET should not be part of a "competion" between soap manufacturers and food/drinking manufacturers, but should be reserved to the latter as food contact materials shall live up to high standards.

A requirement based on this **proposal has been included to avoid competition with food contact approved recyclates.**

Closures:

A stakeholder asked for clarification on why metal caps aren't allowed.

Closures containing metal or glass are not suitable with recycling. We cannot expect all the consumers will remove the cap/closure from the bottle before to waste it. It will create loss of material in the sorting process, contaminate the recycled plastics and also create some concerns to the recycling equipment.

Barrier coatings:

It was mentioned that a 3-layer of PET/Polyamide/PET coatings is the best possible barrier at the disposal of industrials to make a recyclable PET packaging barrier. Keeping the prohibition of polyamide for barriers would contradict European recommendations. They recommend removing this exclusion.

According to bilaterial communication with RecycleresEuroe PA is admitted only if provided as multilayers and will get delaminated during the prewashing phase in PET recycling. The **polyamide restiction is proposed to be kept** under the EU Ecolabel.

In addition a stakeholder mentioned that similarly, EVOH (Etilen-Vinil-Alcohol) is the best possible barrier for industrials to make a recyclable PE or PP barrier packaging, and European standards agree on this point. Moreover, it was remarked EVOH is not a specific plastic but a family of different plastics, some of which are not compatible with PP or PE recycling. They recommend allowing EVOH regardless of their content and adding a requirement on their recycling compatibility.

In relation to EVOH it was mentioned that EU recycling bodies such as Recyclass will allow up to 5% EVOH so they would like to understand why this has been excluded.

According to bilaterial communication with RecycleresEurope, EVOH is one polymer and not a family of polymer, even if many grades are commercially available. EVOH can be used at certain conditions. They made tests for LDPE films and HDPE containers. If the EVOH is provided up to 5 % in a LDPE film the film recyclability is compatible. If EVOH is provided up to 6% in a HDPE containers by providing PE tie layers in a proportion 1:2 respect to EVOH and if the tie layers are grafted with maleic anydryde at 0.1 at least, there is a full compatibility with HDPE recycling. Against this **it is proposed to allow a maximum content of EVOH of 5%.**

In summary, the changes introduced in TR3.0 for design for recycling of plastic packaging requirement are:

- It is proposed to **include a requirement on adhesives.**
- The criteria have been **further aligned to hard surface cleaners criteria. PETG restriction has been included.**
- A requirement **has been included to avoid competition with food contact approved recyclates.**
- it is proposed to allow a maximum content of **EVOH of 5%.**

e) <u>Take-back system</u>

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 (TR1) it was suggested to explore the possibility to include a take back system requirement.

The new proposal generated controversy over the benefits of the implementation of the take back system. Most of the stakeholders did not see it feasible to include a requirement on a take back system.

In the second proposal (TR2.0) a new requirement was proposed, considering the most conflictive packaging: the amenities.

It was proposed a take back system only for accommodation services: **if the product is sold in packaging lower than 75ml, a take back system should be implemented** to collect the empty packaging.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

With regards take-back system, stakeholders considered the new proposal much more workable now. However, they still see problematic because of it does not consider the product chain. They mention that producers are not directly dealing with hotels.

In addition a stakeholder mentioned that for the professional market for personal hygiene products, reuse is difficult to ensure. For instance hospital or hotel, refills can be source of contamination and bacterial growth.

Other stakeholder mentioned that it will be preferable to prohibit small bottles < 300ml in general.

Against this background, the changes introduced in TR3.0 for take back system requirement are:

- Considering the difficulties related to the implementation in case the producer is not directly dealing with the accommodation **it has been finally decided to not include this requirement.**
- In order to avoid the use of small bottles it has been included a new requirement to limit the minimum volume for a product to be certified to 150ml. This requirement will not apply to leave on products (e.g. decorative cosmetics) and toothpastes usually marketed in small volumes.

(e) -New- SVHCs:

Several stakeholders requested the inclusion of SHVCs restriction on packaging. They mentioned that manufacturers shall know whether the cosmetic packaging contains or not SVHCs above 0.1%. It is a legal obligation to inform consumers when the presence of SHVCs is above 0.1%. They can be questioned about this by consumers (REACH Art 33). It is important to ensure that Ecolabelled products will not be linked to SVHC. In addition, according to Chemical Task Force the packaging shall always be considered within the bill of materials if it is considered an intrinsic part of the product i.e. the packaging is an article which is required during the functional life of the product e.g. shampoo bottle.

Against this it has been **proposed to include a requirement on SVHCs on packaging.**

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.

No comments were received from and after AHWG2.

3.5 CRITERION 6: 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 ([64]), it is acceptable to demonstrate sustainability through book and claim systems such as GreenPalm or equivalent.

Annex II: Third proposal for criterion 6: 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, financial institutions 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 case raw materials/ingredients to which Regulation 2018/848 (*) applies are used, a minimum threshold of 20% w/w of these ingredients shall be produced according to organic production and certified organic. Raw materials outside the scope of certification to Regulation 2018/848 do not contribute to the minimum threshold. Water is also excluded from the calculation.

Assessment and verification

To demonstrate compliance with sub-criterion (a) evidence through third-party chain of custody certificating that the raw materials used in the product or in its manufacturing originate from sustainably managed plantations shall be provided. Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to

[64] 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.

any of the following models: identity preserved, segregated, mass balance, and independent smallholders credits shall be accepted. 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, and mass balance. Competent Bodies should annually check the validity of the certificates for each certified product/ingredient [1].

To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certificates for each raw materials/ingredients certified to the EU Organic Regulation. Raw materials outside the scope of certification to the EU Organic Regulation (Regulation 2018/848), or other Regulations recognised as equivalent by the EU, are not considered organic for the purposes of the EU Ecolabel. Certificates accepted shall include those awarded by Competent Bodies duly recognised and appointed through the EU Regulation on organic production 2018/848 or equivalent.

In the case of palm oil and palm kernel oil, certifications of compliance with RSPO supply chain systems (identity preserved, segregated, mass balance, and independent smallholders credits) and with the EU Organic Regulation can be used interchangeably (i.e. holding one of the two certifications will be sufficient to comply with criterion 6).

Notes:

[1] The verification can be done via RSPO website, where the status of the Certificate is showed in real time: https://www.rspo.org/certification/search-for-supply-chain-certificate-holders

(*) Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

Annex II: Third proposal for criterion 6: 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, e.g. Ecocert[65], COSMOS[66], NATRUE[67], RSPO[68]. However, for some ingredients certification schemes assessing their sustainability are not available yet (for example coconut oil).

Criterion 6 is divided in two parts:

(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.

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 contain RSPO certified material.

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 make it unfeasable to set a prescriptive requirement on all type of ingredients. Moreover,

[65] https://www.ecocert.com/en/expertise/organic-farming
[66] https://cosmos-standard.org/
[67] https://www.natrue.org/our-standard/natrue-criteria-2/
[68] https://www.rspo.org/

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.

At the 1st AHWG meeting, discussions were held on whether the RSPO criteria covered a no-deforestation requirement, and one possible alternative certification scheme was mentioned: the Roundtable for Sustainable Biomass.

No changes were made in the TR2.0.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Removal of requirement 6 (a)

Some stakeholders suggested to remove this requirement because of a number of reasons: it is difficult and lengthy to verify by Competent Bodies, it is responsible for a price increase of 20%, and the improved environmental performance of certified palm oil, palm kernel oil and their derivatives has not been scientifically proven. Stakeholders suggested some alternatives to the criterion formulation:

- Find another scheme to deal with palm oil, palm kernel oil and their derivatives
- Limit the use of these derivatives and fix different threshold according to products types (data were received by one competent body).

Palm oil, palm kernel oil and their derivatives can be certified sustainable according to different schemes: Roundtable on Sustainable Palm Oil (RSPO), Malaysian Sustainable Palm Oil (MSPO), Indonesian Sustainable Palm Oil (ISPO), International Sustainability & Carbon Certification (ISCC), Roundtable on Sustainable Biomaterials (RSB), Sustainable Agriculture Network (SAN), High Carbon Stocks Approach (HCS). Some of these schemes are voluntary (e.g. RSPO, ISCC), while some others are mandatory (ISPO, MSPO).

A study[69] conducted by the Forest People Programme compared these different schemes according to a point methodology taking into account the completeness, the relevance and the clarity of the schemes' requirements, and concluded that RSPO has the most robust scheme for certification whilst the ISPO has the weakest certification process and carries the least requirements on social issues. Another study[70] analysed the environmental impacts of palm oil consumption and compared the main sustainability standards for palm oil (RSPO, ISCC, ISPO, MSPO), concluding that the RSPO scheme provides some of the most restrictive requirements on social issues, such as land use rights, forced labour, child labour, the terms and condition of employment, and treatment of smallholders. It has to be noted that the RSPO criteria have been revised[71] and made more stringent since the publication of the study to ensure the effective contribution of RSPO to halting deforestation.

Currently, 19% of global palm oil is certified under RSPO scheme[72], and Europe is the leading region for sustainable palm oil use. Some EU member states pledged to achieve 100% of certified sustainable palm oil usage by 2020, therefore quantities of supply and sales are expected to increase. The Indonesian Association of Palm Oil Producers (GAPKI) projected a 50% increase in output between 2014 and 2025. ISCC also covers a large share of certified sustainable palm oil; however, the use of such palm oil is mainly for biofuel purposes. Moreover, ISCC covers also other types of crops: rapeseed/canola is the largest one in terms of cultivated area, followed by palm oil (1,630,084 certified hectares in 2018) [73].

Limiting the use of palm oil, palm kernel oil and their derivatives may be an option. However, substances substituting palm oil may have a worse environmental profile. Indeed, yields of palm oil per hectare per annum are much greater than for other oil crops, with the added attraction that it is harvested year round. This means that palm oil requires less area than competing oil crops and makes it a very attractive source of income for smallholder farmers. Moreover, alternatives to palm oil may not be available on the market as certified sustainable to the same extent as RSPO. A full environmental assessment should be conducted, comparing the performance of palm oil against that of other ingredients that may be used as alternatives, which is out of the capacity of this revision process. Moreover, data on typical content of palm oil, palm kernel oil and their derivatives were made available by one Competent Body only, and other environmental schemes do not set a similar requirement.

Based on the above, **it is proposed to keep the current requirement in the current form**. However, it should be noted that according to the verification and

[69] 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

[70] Study on the environmental impact of palm oil consumption and on existing sustainability standards. https://op.europa.eu/en/publication-detail/-/publication/89c7f3d8-2bf3-11e8-b5fe-01aa75ed71a1

[71] https://rspo.org/news-and-events/announcements/revised-rspo-supply-chain-certification-standard-and-systems-documents-endorsed

[72] https://rspo.org/impact

[73] https://www.iscc-system.org/wp-content/uploads/2019/10/ISCC-Impact-Report-2018.pdf

assessment text, other certification schemes can be accepted to comply with requirement 6a, provided that a third-party auditor confirms the equivalence between schemes. The complexity of verification for the CBs has been addressed in the next paragraph on assessment and verification.

Only minor (wording) changes have been made to this criterion.

Rationale of proposed assessment and verification

For the first proposal the sub-criterion 6 (a) formulation was aligned with the recently voted criteria for lubricants in order to ensure harmonisation across different EU Ecolabels.

During and after the 1st AHWG, the acceptance of the Book and Claim system as a verification was questioned by different stakeholders.

The only change made in the TR2.0 was to include the Independent Smallholders Credits as an accepted proof of compliance.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Acceptance of RSPO Book and Claim credits

Stakeholders firmly stated that Book and Claim (B&C) credits should not be accepted. It was argued that the JRC analysis should be done on existing licenses, because current data on the type of certifications available on the market justifies the feasibility of excluding the Book and Claim method.

Ingredients source with a B&C certification can easily be retrieved from other suppliers – from a technical point of view. However, it needs to be checked that market availabilities are ensured. According to the latest figures[72], the share of RSPO-certified ingredients available on the market with a level stricter than Mass Balance (i.e. Identity Preserved – IP, Segregated – SG, and Massa Balance – MB) has increased considerably in the last years, whereas B&C credits have decreased significantly. This trend holds true not only in terms of supply volumes but also in terms of sales. Sales of IP palm kernel oil in 2019 increased by 650% compared to 2015, whereas 2019 sales of IP palm oil were almost 10 times higher than in 2015. At the same time, 2019 sales of B&C credits decreased by around 200% compared to 2015 volumes for both palm oil and palm kernel oil. For 2020, the sales volumes of palm oil and palm kernel oil with a certification level stricter than MB represent

79% and 86% of total sales, respectively. This trend suggests that the supply market will evolve rapidly with even more increase in the supply of ingredients with a certification level stricter than MB.

Several other ecolabelling schemes, such as Bra Miljöval for Cosmetics, the Nordic Swan for Cleaning products and the Blue Angel for Laundry detergents, accepts only RSPO Mass Balance or higher.

Finally the exclusion of the B&C system from the accepted certifications will facilitate the verification of CBs. Indeed, with this modification CBs do not have to check different proofs to verify compliance.

Therefore, **it is proposed to exclude B&C credits from the accepted RSPO supply chain system certifications**. As the Independent Smallholder (IS) credits is an option inside B&C, **the acceptance of IS credits is excluded from this requirement**.

Clarity of the assessment and verification

Stakeholders commented that the actual wording of the assessment and verification is unclear, and it is not understandable what proofs are requested.

First of all, the exclusion of Book and Claim credits certifications simplified the verification *per sé*. Moreover, the wording has been modified to express that:

- The third-party chain of custody should be hold for each ingredient/raw material. This documentation can be provided by the supplier of the raw material.
- The word 'raw material' has now been used, to replace 'input material'.
- Documents shall be checked annually by CBs for each certified product/ingredient.
- The word 'audit' has been deleted, as it implies a site visit which would be impossible to perform by CBs.
- It has been specified in a note that the annual check can be performed online on the RSPO website.

These modifications have been introduced in the text for the assessment and verification.

Equivalence of certifications

Criterion 6 is divided in two parts:

- Criterion 6(a), which applies to palm oil, palm kernel oil and the derivatives from palm and palm kernel oil;
- Criterion 6(b), which applies only to the ingredients that are within the scope of the EU Organic Regulation.

As the EU Organic Regulation mainly covers unprocessed ingredients used for food products, palm and palm kernel oil are covered under this Regulation. Therefore,

palm and palm kernel oil would in principle be required to comply with criteria 6(a) and 6(b), i.e. hold two certifications. In the interest of not overloading applicants with bureaucracy and the likely price increase for the double certification needs, given the similarity of the two certification schemes, **it is proposed that certifications of compliance with RSPO supply chain systems and with the EU Organic Regulation are considered interchangeable (i.e. equivalent)**. This means that organic certifications will be accepted as equivalent to RSPO certifications, i.e. only one certification is needed.

Summary of changes in TR3.0

In summary, the main changes introduced to the assessment and verification of criterion 6(a) in TR3.0 are:

- Book and Claim credits and Independent Smallholder credits are not allowed for as proof of compliance;
- Wording modifications in the criterion text;
- Certifications of compliance with RSPO supply chain systems and with the EU Organic Regulation can be used interchangeably.

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[74].

The analysis of other ecolabelling schemes suggested the possibility of a requirement focusing on the certification of organic ingredients. 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. 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 to 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

[74] Council Regulation (EC) No 834/2007

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).

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[75].

In the framework of a multi-year collaboration IFOAM - Organics Europe 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.

Given the above, 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.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

In TR2.0 it was suggested to set the minimum threshold of the criterion to 20%.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Scope of criterion 6(b)

[75] https://www.ifoam.bio/pt/ifoam-family-standards-0

Many comments were received from stakeholders as to the clarity of the ingredients to which this criterion applies.

Current wording of criterion 6(b) states that 20% of the "ingredients covered by the scope of the EU Organic Regulation (EC 834/2007)" shall be organic.

The EU Organic Regulation (EC 834/2007) applies to (a) live or unprocessed agricultural products; (b) processed agricultural products for use as food; (c) feed; (d) vegetative propagating material and seeds for cultivation; and (e) yeasts used as food or feed. For what concerns criterion 6 (b), only point (a) on live or unprocessed agricultural products is relevant. This means that processed agricultural products for non-food use (as the cosmetic ingredients would be) are not covered by the EU Organic Regulation. Therefore, natural extracts and derivatives obtained from organic raw materials used in cosmetic formulation are also not covered by the EU Organic Regulation, although these substances are considered organic according to some private standards, e.g. COSMOS and NATRUE.

Regulation 2018/848 (repealing regulation 834/2007) extended the scope also to certain other products closely linked to agriculture listed in the Annex I, which are: 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. Please note that this Regulation will entry into force from 1 January 2021, which is earlier than the entry into force of these revised EU Ecolabel criteria for cosmetic products.

Unfortunately, a positive list of ingredients included in EU organic framework does not exist. However, a secondary legislation is under preparation by the EU, which should entry into force from January 2022 and which will include a greater range of products that can be marketed as organic. Indeed, organic farming is a fast growing area in EU agriculture, which is a direct result of increased consumer interest in organic products.

In order to comply with criterion 6(b), only substances to which Regulation 2018/848 applies should be taken into account, i.e. only substances to which Regulation 2018/848 will contribute to the achieving of the 20% threshold.

This means that, given all the ingredients in the formulation of a cosmetic product, those ingredients to which Regulation 2018/848 applies should be singled out and listed separately. The sum of the weights of the ingredients on this list represent the 100% to which the 20% should be calculated, i.e. criterion 6(b) requires that at least 20% w/w of the ingredients on this "organic" list should be certified organic according to the EU Organic Regulation. Other ingredients not covered by Regulation 2018/848 do not count neither towards the 100% nor towards the 20% threshold, i.e. are excluded from the calculation. Similarly, water is excluded from the calculation.

According to this calculation methodology, if only one ingredient of a cosmetic product is eligible to be certified organic according to Regulation 2018/848, then the applicant will have to source such ingredient from organic cultivation. This will make

the applicant comply with the requirement with a percentage of 100%. The weight of such ingredient could be 1% or 99% of the final formulation; this is not counted in the criterion.

Similarly, the organic content of a cosmetic product could be 0% and still comply with criterion 6(b), in the case that none of the ingredients used in the formulation are within the scope of Regulation 2018/848.

The aim of this criterion is to foster the uptake and use of ingredients that can officially be cultivated organically, i.e. according to Regulation 2018/848, without forcing the applicant to change the formulation of its products. Compliance with criterion 6(b) does not make a cosmetic product "organic" (also because such a definition does not exist at present in the EU legislation), nor can the product be marketed as organic.

To clarify the criterion as much as possible, **the wording of the criterion text has been modified**. Further guidance will be given in the user manual, where the calculation will be explained with a spreadsheet.

Minimum content of bio-based ingredient

Some stakeholders suggested to remove criterion 6(b) and replace it by setting a requirement on the minimum content of bio-based ingredient. Indeed, stakeholders feared that requirement 6(b) would have the rebound effect to favour petrochemical substances, which under the current set of criteria would be subject to less certifications and declarations than plant-based ingredients.

A requirements on the minimum content of bio-based ingredients cannot be set on cosmetic products for a number of reason, the main and strongest one being that the EU Ecolabel is technology neutral: it does not prefer one type of ingredient over another. All ingredients are allowed, provided that these are the less impacting throughout their life-cycle (e.g. in terms of their toxicity, biodegradability, etc.).

Moreover, an official definition of "bio-based" or "natural" ingredient or product does not exist, and the ones given by voluntary standards such as ISO 16128-1:2016 and 16128-2:2017[76] are disputable. On the contrary, what is considered as organic is well defined in the EU legislation and ensures, among other aspects, the responsible use of energy and natural resources, the maintenance of biodiversity, preservation of regional ecological balances, enhancement of soil fertility, maintenance of water quality.

[76] ISO 16128-1:2016 Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products — Part 1: Definitions for ingredients

ISO 16128-2:2017 Cosmetics — Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients — Part 2: Criteria for ingredients and products

Based on the above, **it is proposed not to replace criterion 6(b) with a requirement on the content of bio-based ingredients**.

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 TR2.0.

Outcomes from and after AHWG2 and rationale for third proposal

It was mentioned by stakeholders that certification bodies mentioned in the assessment and verification text are in contrast with the fact that the criterion requires ingredients/raw materials to be certified according to Regulation 2018/848.

Indeed, COSMOS is a private standard owner, while the IFOAM Family of Standards is a private reference point for schemes that meet equivalency for IFOAM. Only Competent Bodies duly recognised and appointed through the EU Regulation on organic production 2018/848 should be allowed to emit certificates.

In the criterion text, **reference has been deleted to COSMOS and IFOAM family of standards**, and **only certificates awarded by Competent Bodies duly recognised and appointed through the EU Regulation on organic production 2018/848 or equivalent shall be accepted**.

3.6 CRITERION on wet wipes (removed): Specific requirements for wet wipes (criterion 6 on TR2.0)

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 a cosmetic product if the substrate of the substance or mixture intended to be placed in contact with the external parts of the human body[77]. Wet wipes were proposed to be included in this revision in TR1.0 and a specific criterion to minimise the environmental impact of the wet wipes was proposed in TR.2.0.

Two different requirements were proposed. The first one 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 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.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Although few stakeholder were interested on the inclusion of wet wipes under the scope of this EU Ecolabel, the majority of stakeholder expressed their concern with its inclusion:

- *Paper substrate can hardly be used for wet wipes. The material made of pure cellulose fiber is too frail/fragile and must be further processed by a wipe manufacturer. It is often blended with viscose or PET/PP fibers.*
- *We do not support the inclusion of wet wipes in the scope as they represent a large amount of waste that can be avoided by using alternatives.*
- *We're not in favour of including wet wipes on the scope. Wet wipes are a ecologic disaster (unique usage as alternatives exists), the SUP regulation is including new requirements like not flush wet wipes and not let it in*

[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).

environment because of many "biodegradable" claims on wet wipes packaging that create confusion on consumers. I don't think ECOLABEL has interest to promote this controversial category.

- *We're not a fan from including wet wipes in the scope.*
- *When you give the ecolabel you sort of give a green light to these single use product*
- *Wet wipes generate waste. It doesn't matter whether they are biodegradable, because they have to be disposed of with household waste and then have to be incinerated.*
- *The best is that they are not included. But if they are, clear difference has to be made with conventional products.*
- *We are not in favour of the inclusion of wet wipes because we are seriously concerned about the environmental impact the existence of them (waste increase).*
- *This kind of products is not environmentally friendly and we consider this inclusion risks to promote wet wipes. That's why we strongly disagree with this inclusion because we consider that this kind of products is not in the spirit of the EU Ecolabel.*

Against this background, it has been decided to **remove wet wipes from the scope for this revision**. Pure paper substrate can hardly be used due to its fragility. Therefore cellulose is normally blended with viscose or PET/PP fibers.

Alternatives claiming being 100% biodegradable are niche on the market and no references to biodegradability standards are made on these products.

In the absence of solid biodegradability standards for this products and due to the general disagreement for its inclusion it is suggested to not include wet wipes in this revision. The inclusion of wet wipes within the EU Ecolabel scope is proposed to be **further explored in next revision.**

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: Third 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, mild/sensitive) shall be demonstrated either through laboratory test(s) or a consumer test. The tests shall follow 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.

The tests shall be conducted on the dosage indicated by the applicant [1]. The tests shall be performed at least on the efficacy/performance of the product and its ease of application. If a recognised standardised laboratory test is available (for example Commission Recommendation 2006/647 (*) for sunscreen products), this must be used, and consumer tests will not be considered equivalent. The tests need to have a conclusion which clearly states how the results of the test demonstrate each individual parameter/property tested.

If national guidelines on fluorine content in toothpaste are available, these shall be followed. Fluorine-free toothpastes which have been evaluated as protective as fluorine-containing toothpastes by an independent party are exempted.

Laboratory tests shall include at least the following parameters:

- How/why the test method was chosen and how it can be used to document the product's performance/quality
- The parameters and/or properties that were tested and why they were chosen

In case laboratory tests are not available, consumer tests can be used. For consumer tests, the consumers must be asked about the product's efficiency/performance compared to an equivalent 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 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 an equivalent 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 tests performed in compliance with Cosmetics Regulation and Regulation 655/2013 can be suitable to demonstrate that the product fulfils its primary function and any secondary claimed function. It is not necessary to perform new specific tests to demonstrate a function previously demonstrated.

[Notes:

[1] The dosage used should be the same as the one identified in criterion 5 (c).

References:

(*) Available at: https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=23 and the EU Ecolabel website.]

Annex II: Third 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.

Carrying out of animal testing of final formulations, ingredients or combinations of ingredients is strictly prohibited.

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 existing criterion in force 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.

[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).

There are specific guidelines for certain product categories, but for some of them only. For instance the European Commission adopted recommendations on the efficacy of sunscreen products and related claims (Commission Recommendation 2006/647/EC)[81], 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[82], e.g. information that can assure the reliability of the study.

According to Commission Regulation (EU) No 655/2013[83] claims on cosmetic products should conform to the following common criteria: legal compliance, truthfulness, evidential support, honesty, fairness, informed decision making.

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).

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.

Feedback received on TR1.0 and further research conducted by JRC can be found in the previous version of the report (TR2.0[4]).

The following changes were made in TR2:

- The questions included in current user manual were introduced in Criterion 7, in order to consider the "ease of application";
- 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

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Ease of application

Stakeholders were of the opinion that the test on the ease of application should be connected to a specific dosage of usage of the product that should be identified by the manufacturer and specifically indicated in the packaging of the cosmetic product.

[81] 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

[82] The following indications given below are not exhaustive and might not all be relevant depending the test under consideration.

[83] 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

This aspect was taken into account in the revised criterion 5 (d), which requires the manufacturer to identify a specific dosage of usage of the product and indicate it in the packaging of the cosmetic product, together with a sentence expressing the importance of using such a dosage.

It is proposed that a sentence is included in criterion 7 that requires that tests should be conducted on the dosage specified according to criterion 5 (d). Additionally, t**he second question in the description of consumer tests was deleted**, as it is more relevant to revised criterion 5.

Laboratory vs consumer tests

It was requested by stakeholders that, when available, laboratory tests should take precedence over consumer tests.

To avoid subjectivity in the results, **it is proposed that if recognised standardised laboratory tests are available (for example Commission Recommendation 2006/647 (*) for sunscreen products), then these must be used, and consumer tests will not be considered equivalent.**

A non-exhaustive list of available laboratory tests will be made available in the User Manual.

Moreover, **the clarity of the criterion text has been increased**. For example, the fact that laboratory tests should report how/why the test method was chosen and how it can be used to document the product's performance/quality, and the parameters and/or properties that were tested and why they were chosen. Finally, all tests are required to have a conclusion which clearly states how the results of the test demonstrate each individual parameter/property tested.

Further guidance will be given in the User Manual.

Specific tests for toothpaste

Stakeholders suggested that EU Ecolabel should require that if national guidelines on fluorine content in toothpaste are available, these shall be followed. Fluorine-free toothpastes should be exempted only if they have been evaluated as protective as fluorine-containing toothpastes by an independent party.

This requirement was added to criterion 7.

Animal testing in Annex II

The Cosmetic Regulation since 2009 lays down the provisions prohibiting animal testing of finished cosmetic products. However, animal care products do not fall under the scope of the Cosmetic Regulation.

Some stakeholders were against the inclusion of animal care products in the scope of the EU Ecolabel because it would be controversial to explain consumers that animal care products can be teste on animals.

Therefore, **a sentence has been included in the criterion on fitness for use prohibiting the performance of animal tests on final formulations, ingredients or combination of ingredients**.

In summary, the changes to criterion 6 in TR3.0 are as follows:

- Introduction of the sentence that tests shall be performed on the dosage indicated by the manufacturer (the same a in criterion 5 (d));
- Introduction of the requirement that if recognised standardised laboratory tests are available (for example Commission Recommendation 2006/647 (*) for sunscreen products), then these must be used, and consumer tests will not be considered equivalent;
- Increased clarity of the criterion text. Laboratory tests should report how/why the test method was chosen and how it can be used to document the product's performance/quality, and the parameters and/or properties that were tested and why they were chosen. Moreover, all tests are required to have a conclusion which clearly states how the results of the test demonstrate each individual parameter/property tested;
- Introduction of a special requirement for toothpaste;
- Deletion of one of the questions to be asked in consumer tests;
- In Annex II, it was specified that animal testing is strictly prohibited.

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.

In the TR2.0, it was clarified that 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.

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

Some stakeholders asked that tighter requirements should be laid down for claims on secondary functions, especially in the case of the mild/gentle claim.

However, claims in cosmetic products are regulated via the Cosmetic Regulation, Regulation 655/2013 on the justification of claims in cosmetic products, Directive 2005/29/EC on the Unfair Commercial Practices and the technical guidelines for allegations.

It is therefore **proposed that no changes are made to the criterion text**.

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: Third proposal for criterion 8: Information appearing on the EU Ecolabel for cosmetic products
The optional label with box shall contain the following information: (a) 'Restricted hazardous substances'; (b) 'Tested performance'; (c) Limited 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: Third proposal for criterion 7: 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[84].

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[19] 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 and second revision (TR1.0 and TR2.0).

Outcomes from and after AHWG2 and rationale for third proposal

All comments received during the consultation period and the responses can be found in the table of comments published in the last chapter of this TR3.0. Below there is a summary of the main relevant comments and the main changes introduced in the text.

A stakeholder proposed to focus the sentences on criterion 3 and other stakeholder mentioned that the sentence on **restriction of hazardous substances** is used in other product groups.

A stakeholder suggested "Promoting care for the environmental"

Other stakeholder commented: "It's important to modify information appearing on the EU Ecolabel to add a sentence concerning **conducted tests** in order to highlight also the performance of EU Ecolabel certified products."

Additionally a stakeholder mentioned: "we would prefer the criteria for claiming biodegradable/lower impact on environment are not required"

French CB mentioned that this criterion might be in contradiction with the French law on waste reduction and circular economy voted in February 2020. This law prohibits the use of terms "biodegradable", "respect the environment" or any equivalent wording in packaging.

Against this background, **for TR3.0 the following changes have been included**:

- The sentences "Limited impact on aquatic ecosystems" and "Fulfils strict biodegradability requirements" have been replaced by the generic sentence with a focus on hazardous substances: **'Restricted hazardous**

[84] http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

substances'; similar to the sentence in lubricants product group: 'Less hazardous substances ending up in the environment'

- In addition the sentence **'Tested performance'** has been included in line with EU Ecolabel for lubricants.

For the case of Animal care products, it has been specified that tested performance is not animal tested.

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.

The **scope** of this product has been enlarged considerably. The revised EU Ecolabel now covers all cosmetics covered by the Cosmetic Regulation and animal care products. The two product categories are dealt with in two separated annexes.

There is a **general increase in the level of ambition proposed**, based mainly on the available evidence and information from existing licences and other labelling schemes.

In relation to criterion 1 on toxicity to aquatic organisms for rinse off cosmetic products, criterion 2 on Biodegradability of rinse off cosmetic products the thresholds have made more stringent for all categories and a new requirement has been included for leave on products: criterion 3 on Biodegradability of leave on cosmetic products.

With regards criterion 4 on restricted substances, the level of ambition has been increased under many aspects: the total ban on SVHCs, many more substances included to the list of excluded substances (including endocrine disruptors, phthalates and nanomaterials), the restriction on 82 allergens, the food grade quality required for preservatives and colorants in products in contact with the mouth. Moreover, special requirements were set for UV filters. The changes applied in this criterion ensure that the inclusion of substances and mixtures with a hazard profile is drastically reduced.

In relation to criterion 5 on Packaging, the thresholds have been made more stringent based on existing licences data. The criterion has been revised to include new requirements in line with Nordic Swan to address the packaging of leave on products and new restrictions have been included: maximum volume of product to be awarded and restriction on SVHC in the packaging.

A new requirement has been included in existing criterion on criterion 6 Renewable ingredients, which targets product ingredients covered by the EU Organic Regulation, of which a minimum of 20% should be sourced from organic plantation. Such requirement ensures, among other aspects, the responsible use of energy and natural resources, the maintenance of biodiversity, preservation of regional ecological balances, enhancement of soil fertility, maintenance of water quality.

Finally criterion 7 Fitness for use has been greatly improved in clarity, and the laboratory or consumer tests have to follow specific guidelines. For consumer tests, that will be accepted only in case no recognised standardised laboratory test is available, the number of panellists has been increase, as well as the minimum level of satisfaction.

In conclusion, the revised criteria set a higher ambition level, reflecting front runners' performance, and allow a broader spectrum of products to be awarded the EU Ecolabel as a result of the changes in the scope.

5 TABLE OF COMMENTS

The table of comments received during and after the AHWG2 can be found at: https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/444/documents

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