

JRC SCIENCE FOR POLICY REPORT

Revision of EU Ecolabel Criteria for Cosmetic Products and Animal Care Products (previously Rinse-off Cosmetic Products)

*Final Technical Report:
Final criteria*

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Abstract

This Technical Report aims at providing a technical basis to the revision process of the EU Ecolabel criteria for Rinse-off cosmetic products. The set of criteria currently in force was adopted in 2014 (Commission Decision 2014/893/EU). The revised EU Ecolabel criteria are set to cover a much wider scope: all cosmetic products as defined in the Cosmetic Product Regulation (Regulation (EC) No 1223/2009). Moreover, a separate set of criteria was developed for animal care products. The product group has been renamed as 'cosmetic products' and 'animal care products'.

To support the revision process, a first version of this technical report was produced as a working document, which was updated and complemented as the revision developed. This document provided the rationale to the revised criteria proposal and summarized the research and the outcome of three stakeholder consultations, which were crucial to develop revised criteria that are able to select the best environmental products available on the market while taking into account the state of the art of the market.

After a revision process that lasted 30 months, this is the final version of the Technical Report which supports the final criteria for cosmetic products and animal care products.

1 INTRODUCTION

The objective of this project is to revise the existing EU Ecolabel criteria (Commission Decision 2014/893/EU¹) for rinse-off cosmetic products. The criteria were for the first time adopted in 2007² 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 report³ 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 (TR2.0⁵) was discussed in the second Ad-hoc Working Group meeting (AHWG2) (June 2020).

A third version of the report (TR3.0⁶) was published in October 2020 taking into consideration the feedback received during and after the second Ad-hoc Working Group meeting, and further research.

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/product-bureau/sites/default/files/contenttype/product_group_documents/1581684261/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/sites/default/files/contenttype/product_group_documents/1581684261/Technical_Report_EU_Ecolabel_Cosmetics.pdf

⁵ Revision of the European Ecolabel criteria for rinse-off cosmetics. Technical Report: criteria proposal for revision of EU Ecolabel for rinse-off cosmetics (May 2020). Available at:

https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2020-07/Technical_Report_EU_Ecolabel_COSMETICS_v2-0.pdf

⁶ Revision of the European Ecolabel criteria for rinse-off cosmetics. Technical Report: criteria proposal for revision of EU Ecolabel for rinse-off cosmetics (October 2020). Available on line at:

<https://susproc.jrc.ec.europa.eu/product-bureau/sites/default/files/2020-10/Technical%20Report%203.0.pdf>

This final technical report 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'.
- **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 final EU Ecolabel criteria for the newly named 'cosmetic products and animal care products' product group and subsequently a rationale is given.
- **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 during the consultation period of October 2020, together with responses and explanations on how they have been addressed in this final report has been published as a **separated document**.

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 report³, 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 PRODCOM⁷, Euromonitor International⁸, Cosmetics Europe⁹ association and Mintel GNPD¹⁰ 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 report³.

⁷ Community Production database: <https://ec.europa.eu/eurostat/web/prodcom/data/database/>

⁸ <https://www.euromonitor.com/>

⁹ <https://www.cosmeticseurope.eu/cosmetic-products/>

¹⁰ MINTEL database: <https://www.mintel.com/>

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.

Final Product group name:

Cosmetic products and animal care products

Final Product group scope and definition:

Article 1:

The product group 'cosmetic products' shall comprise any substance or mixture falling under the scope of Regulation (EC) No 1223/2009, intended to be placed in contact with the external parts of the human body, 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.

The product group 'Cosmetic products' shall include rinse-off and leave-on products for both private and professional use.

Article 2:

The product group 'animal care products' shall comprise any 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 rinse-off products for both private and professional use.

[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).]*

Final Complementary definitions:

- 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) 'children products' means products marketed to be used up to the age of 12 years and products marketed as 'family product';
- 3) 'ingoining 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 ingoining substances (e.g. formaldehyde from preservatives and arylamine from azodyes and azopigments) shall also be regarded as ingoining substances. Residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials that remain in the raw materials ≥ 1000 ppm (≥ 0.1000 w-% ≥ 1000 mg/kg) are always regarded as ingoining substances, regardless of the concentration in the final product;
- 4) 'impurities' means residuals, pollutants, contaminants, by-products, etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or in the in the final product in concentrations less than 100 ppm (0.0100 w-%, 100 mg/kg) in the rinse off product and less than 10 ppm (0.0010 w-%, 10.0 mg/kg) in the leave on product;
- 5) 'microplastics' 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;
- 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) 'nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm, in accordance with Regulation (EC) No 1223/2009();
- 8) '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.
- 9) 'substances identified to have endocrine disrupting properties' means substances which have been identified to have endocrine disrupting properties (human health and/or environment) according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (candidate list of substances of very high concern for

authorisation), or according to Regulations (EU) No 528/2012() or (EC) No 1107/2009() of the European Parliament and of the Council.

[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)

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).

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).]

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 products¹¹ (later referred to as Cosmetics Regulation), where according to article 2 a **cosmetic product** is defined as: *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.*

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.

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 during this revision.

¹¹ 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>

To enlarge the scope, the evidence from other schemes on the potential compliance of the specific requirements for the different cosmetic products was 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 ecolabel¹².

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).

Since the extension of the scope of the EU Ecolabel entails all products included under the Cosmetics Regulation, it was considered appropriate to align the scope definition to the mentioned Regulation, which is preferable as regards harmonisation of approaches, but also legal drafting. Since leave-on products are now included in the EU Ecolabel scheme, 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 Manual¹³ and other guidance documents of the Cosmetic Regulation. Therefore, **the scope definition was modified to refer to any substance or mixture falling under the scope of Regulation (EC) No 1223/2009 of the European Parliament and of the Council.**

For the second proposal (TR2.0) it was suggested to cover most cosmetic products on the market, in order to align as much as possible with Nordic Swan Ecolabel and including **wet wipes and animal care products (that are not covered under the Cosmetics Regulation)**. However, during the consultation process, many stakeholders expressed their concern over including wet wipes under the scope of the EU Ecolabel as this product category goes against the circular economy thinking, being it a single-use product. Moreover, it was challenging to establish strict requirements on the biodegradability of the substrate. Indeed, 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 was 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.

¹² 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>

¹³ 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

With respect to animal care products, in order to separate the products included in the Cosmetic Regulation from the Animal care products, two annexes have been defined:

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

The inclusion of new product categories within the scope of the EU Ecolabel implied the need for differentiating the requirements between two subgroup of products: rinse-off products and leave-on products. **The definitions of these products have been proposed to be included in the Commission Decision.** In addition, two tables are proposed to be included in the User Manual in order to clarify which products belong to each type and which criteria affect to the different products.

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

1.2.2 Key environmental aspects and relation with the criteria proposal

The EU Ecolabel and other 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.

An LCA of the products included in the criteria in force was carried out¹⁴ considering the latest version of the Simapro software and the new Ecoinvent database. In addition, three new products were analysed: toothpaste, leave-on skin care products and sun care products. Indeed, sun care products contain a completely different formulation compared to the other products suggested to be included in the scope, and are therefore worthwhile a separate assessment. A full LCA was not performed on animal care products, as the formulation of this product category was considered very similar to the shower, bath and other body cleanser preparation category already included in the last revision process. Therefore, results for shower, bath and other body cleanser preparation products have been assumed valid also for animal care products. Similarly, feminine hygiene products were expected to be represented by such results. Also, a full LCA was not performed on shaving products. The

¹⁴ 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)

inventory data and further details on the assumptions considered to model the environmental profile of cosmetic products can be found in the preliminary report³.

During the revision process, the LCA modelling was revised taking into account stakeholders' comments on the functional unit. 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 1**. The reference flow equals 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 showering¹⁵.

Table 1. Data used to calculate the reference flow for each product.

| Product category | Product volume (g) ¹⁶ | Single dosage (g) ¹⁷ | Frequency of application (times/day) ¹⁸ | Daily dosage (g) |
|------------------|----------------------------------|-----------------------------------|--|------------------|
| Liquid soap | 300ml | Washing hands: 2.3 Shower: 8.7 | Washing hands: 5 Shower: 1 | 20.2 |
| Solid soap | 100g | Washing hands: 0.35 Shower: 4 | | 5.8 |
| Shampoo | 250ml | 10,5 | 1,0 | 10,5 |
| Hair conditioner | 200ml | 14,0 | 0,3 | 3,9 |
| Skin care | 200ml | 3,4 | 2,3 | 7,8 |
| Sun care | 200ml | 9,0 | 2,0 | 18,0 |
| Toothpaste | 75ml | 1,8 | 1,5 ¹⁹ | 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 approach²⁰.

¹⁵ 5 times of hand washing and 1 shower a day.

¹⁶ Information from MINTEL database: most used packaging for each product category.

¹⁷ 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](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>

¹⁸ The SCCS'S notes of guidance for the testing of cosmetic substances and their safety evaluation (8th revision), 2012

¹⁹ 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>

²⁰ http://ec.europa.eu/environment/eussd/smgp/pdf/JRC_Normalisation_method_and_data_EF_web.pdf

The weighted results can be found in **Figure 1**. Please note 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.

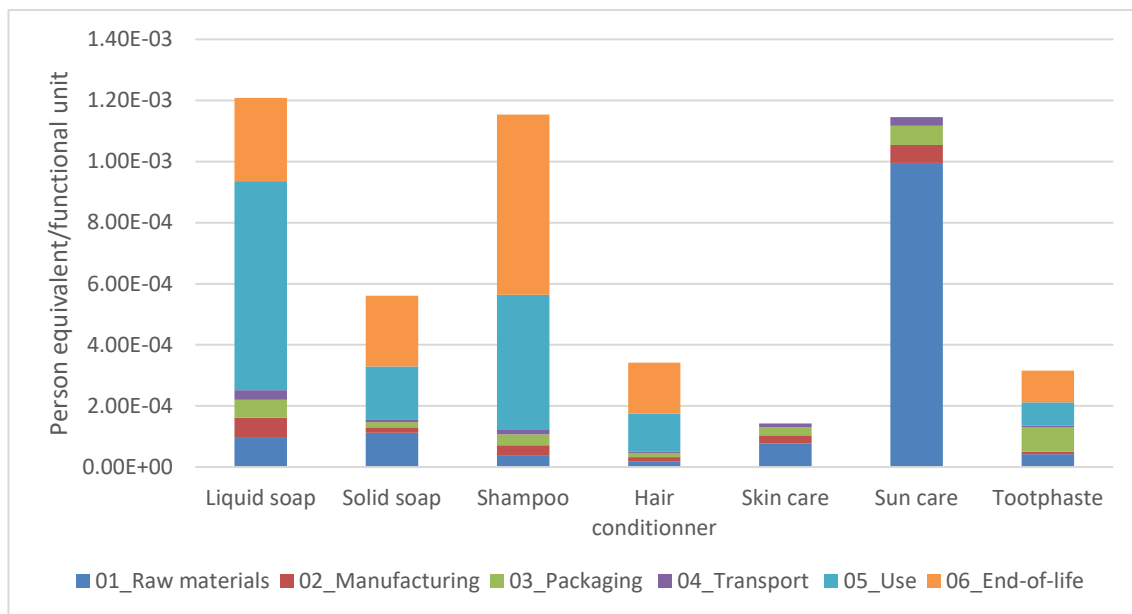


Figure 1. Environmental impact of each cosmetic product.

As can be seen in **Figure 1**, the use phase and the end-of-life are the main hotspots for liquid soap, solid soap, shampoo and hair conditioner. On the other hand, raw material extraction is the most contributing life cycle stage for skin care and sun care products. Finally, in toothpaste, packaging, use phase and end-of-life show similar contributions.

In the light of the information contained in the preliminary report, the feedback received and further evidence collected, the main environmental areas of relevance and the areas of improvement of the existing criteria that have been addressed in more detail in this technical report are summarised in Table 2:

Table 2. Link between the environmental aspects identified and the EU Ecolabel criteria

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

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

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

Existing criteria structure is suggested to be kept, however the content has been modified in the light of the research performed. 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 3. Comparison of the criteria structure

| Existing EU Ecolabel criteria | Revised proposal | |
|--|--|--|
| | Annex I – Cosmetic products | Annex II – Animal care products |
| Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) | Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse off products | Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse off products |
| Criterion 2. Biodegradability | Criterion 2. Biodegradability of rinse-off products | Criterion 2. Biodegradability of rinse-off products |
| | Criterion 3. Biodegradability and aquatic toxicity of leave on products | |
| Criterion 3. Excluded or limited substances and mixtures | Criterion 4. Excluded and restricted substances | Criterion 3. Excluded and restricted substances |
| Criterion 4. Packaging | Criterion 5. Packaging | Criterion 4. Packaging |
| Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives | Criterion 6. Sustainable sourcing of palm oil, palm kernel oil and their derivatives | Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives |
| Criterion 6. Fitness for use | Criterion 7. Fitness for use | Criterion 6. Fitness for use |
| Criterion 7. Information on EU Ecolabel | Criterion 8. Information on EU Ecolabel | Criterion 7. Information on EU Ecolabel |

2 ASSESSMENT AND VERIFICATION

Final Assessment and verification

a) Requirements

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.

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), for the assessment of the biodegradability (criterion 2) of the ingoing substances and for the assessment of the biodegradability and aquatic toxicity of leave on products (criterion 3). For substances not included in 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 or via the websites of the individual competent bodies.

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 International Nomenclature of Cosmetic Ingredients (INCI) designations, DID No (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.

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 shall be provided. Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture.

A written confirmation from the applicant that the criteria is fulfilled shall also be required for the assessment.

Note: Label, claims and/or instructions information accompanying the product shall be used to categorise 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 1.

Table 1. Threshold levels applicable to substances for cosmetic products (% weight by weight), shown by criterion. Abbreviations: CLP: Classification, Labelling and Packaging; CMR: carcinogenic, mutagenic, toxic for reproduction; N/A: not applicable

| Criterion name | | Preservatives | Colorants | Fragrances | Impurities | Other substances (e.g. surfactants, enzymes, UV filters) |
|---|---|----------------------------|----------------------------|----------------------------|------------|--|
| Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV) of rinse-off cosmetic products | | no limit (* ¹) | no limit (* ¹) | no limit (* ¹) | ≥ 0.0100 | no limit (* ¹) |
| Criterion 2. Biodegradability of rinse-off cosmetic products | | no limit (* ¹) | no limit (* ¹) | no limit (* ¹) | ≥ 0.0100 | no limit (* ¹) |
| Criterion 3. Biodegradability and aquatic toxicity of leave-on cosmetic products | | no limit (* ¹) | no limit (* ¹) | no limit (* ¹) | ≥ 0.0010 | no limit (* ¹) |
| Criterion 4. Excluded and | Criterion 4 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (rinse-off) | ≥ 0.0100 (* ²) | ≥ 0.0100 (* ²) | ≥ 0.0100 | ≥ 0.0100 | ≥ 0.0100 |

| | | | | | | |
|-----------------------|--|---------------|---------------|---------------|---------------|---------------|
| restricted substances | Criterion 4 (a) (i): Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (leave-on) | ≥ 0.0010 (*2) | ≥ 0.0010 (*2) | ≥ 0.0010 | ≥ 0.0010 | ≥ 0.0010 |
| | Criterion 4 (a) (ii) : Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 (CMR) (rinse-off and leave-on) | no limit (*1) | no limit (*1) | no limit (*1) | no limit (*1) | no limit (*1) |
| | Criterion 4 (a) (iii): product classification (rinse-off and leave on) | no limit (*1) | no limit (*1) | no limit (*1) | no limit (*1) | no limit (*1) |
| | 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 | no limit (*1) | ≥ 0.0100 | N/A |
| | Criterion 4 (d): Fragrances (leave-on) | N/A | N/A | no limit (*1) | ≥ 0.0010 | N/A |
| | Criterion 4 (e): Preservatives (rinse-off) | no limit (*1) | N/A | N/A | ≥ 0.0100 | N/A |
| | Criterion 4 (e): Preservatives (leave-on) | no limit (*1) | N/A | N/A | ≥ 0.0010 | N/A |
| | Criterion 4 (f): Colorants (rinse-off) | N/A | no limit (*1) | N/A | ≥ 0.0100 | N/A |

| | | | | | | |
|---|---|---------------|---------------|---------------|----------|--------------------|
| | Criterion 4 (f): Colorants (leave-on) | N/A | no limit (*1) | N/A | ≥ 0.0010 | N/A |
| | Criterion 4 (g): UV filters (leave-on) | N/A | N/A | N/A | ≥ 0.0010 | no limit (*1) (*3) |
| Criterion 6: Sustainable sourcing of palm oil, palm kernel oil and their derivatives | Criterion 6: Sustainable sourcing of palm oil, palm kernel oil and their derivatives (rinse-off) | no limit (*1) | no limit (*1) | no limit (*1) | ≥ 0.0100 | no limit (*1) |
| | Criterion 6 (a): Sustainable sourcing of palm oil, palm kernel oil and their derivatives (leave-on) | no limit (*1) | no limit (*1) | no limit (*1) | ≥ 0.0010 | no limit (*1) |

(*1) "no limit" means: regardless of the concentration (analytical limit of detection) for all substances, with the exception of impurities, which can be present up to a concentration of 0,0100 w-% in the final formulation in rinse off products and up to 0,0010 w-% in the final formulation in leave on products.

(*2) for preservatives and colorants classified as H317 and H334 the threshold is 'no limit'

(*3) applicable only to UV filters`

[References:

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)

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).]

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.

During the revision:

- The text 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.
- In order to increase the clarity of the EU Ecolabel criteria, a table indicating the scope of each requirement in terms of threshold limit was included in the measurement thresholds section, taking as a reference the table included in the EU Ecolabel for Detergents²¹.

²¹ Commission Decision (EU) 2017/1218 of 23 June 2017 establishing the EU Ecolabel criteria for laundry detergents (notified under document C(2017) 4243). Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.180.01.0063.01.ENG&toc=OJ:L:2017:180:TOC

3 CRITERIA PROPOSAL

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

Annex I: Final Criterion 1: Toxicity to aquatic environment of rinse-off products

The total CDV toxicity of the rinse-off product, as specified in Table 2, shall not exceed the following limits:

Table 2 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 hair styling and treatment products (hair dyes) | 12 000 |
| Rinse-off skin care products (exfoliants) | 12 000 |
| Shaving foams, shaving gels, shaving creams | 12 000 |
| Toothpaste and mouthwash | 12 000 |
| Other rinse-off products | 12 000 |

The CDV shall be calculated using the following equation:

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

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 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:

| Ingoing added substance | Acute toxicity | | | Chronic toxicity | | | Degradation | | |
|-------------------------|----------------|------------|------------|------------------|------------------|--------------|-------------|---------|-----------|
| | 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: Final Criterion 1: Toxicity to aquatic environment

The total CDV toxicity of the product shall not exceed the limits in Table 2:

Table 2 CDV limits

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

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

Rationale of the proposed criterion text

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

The CDV represents a risk-based parameter that combines the amount used, the (aerobic) biodegradability and the aquatic toxicity of all substances present in the cosmetic formulation. The CDV expresses the amount of water needed for the hypothetical dilution of a product down to a harmless concentration for the aquatic environment. The unit is expressed in litres per functional unit. It is calculated based on the chronic toxicity and chronic safety factors. If no chronic test results are available, the acute toxicity and safety factor must be used.

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

Although during the revision process the solidity of the CDV method has been questioned as an indicator to assess the toxicity of rinse-off products with respect to the aquatic environment, 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, this method has been maintained also to ensure alignment with other ecolabelling schemes, especially Nordic Swan.

During the revision process the CDV thresholds have been revised based on current licence holders and other national schemes, in order to increase the stringency of the EU Ecolabel, thus reflecting the evolvement of the market (see Table 4). Considering that the scope of the product group has been enlarged to include all cosmetic products under the Cosmetic Regulation, this criterion has been adapted to cover additional rinse off products. New thresholds have been set for these products based on other national schemes.

For animal care products, the threshold was set based on other national schemes.

Table 4. Comparison between criterion 1 in EU Ecolabel in force (2014) and the final proposal for cosmetic products.

| Product category | EU Ecolabel in force (2014) | Revised EU Ecolabel (2021) |
|---|------------------------------------|-----------------------------------|
| Shampoos, soaps, shower preparations, shaving soaps and toothpaste (solid form) | 3 300 ^a | 2 200 |
| Liquid soaps and shower preparations | 18 000 | 10 000 |
| Shampoos (liquid form) | 18 000 | 11 000 |
| Feminine hygiene cosmetic products | Not included | 12 000 |
| Hair conditioners | 25 000 | 12 000 |
| Rinse-off skin care products (exfoliants) | Not included | 12 000 |
| Rinse-off hair styling and treatment products (hair dyes) | Not included | 12 000 |
| Shaving foams, shaving gels, shaving creams | 20 000 | 12 000 |
| Toothpaste and mouthwash | Not included | 12 000 |
| Other rinse-off products | Not included | 12 000 |
| Animal care products | Not included | 12 000 |

^a only solid soaps and solid shaving soaps included in the product category

3.2 CRITERION 2: Biodegradability of rinse-off cosmetic products

Annex I: Final Criterion 2: Biodegradability of rinse-off products

a) Biodegradability of surfactants

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

The following shall be 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 3:

Table 3. aNBO and anNBO limits

| Product | aNBO (mg/g AC) | anNBO (mg/g AC) |
|--|---------------------------|----------------------------|
| Shampoos, soaps, shower preparations and toothpaste (solid form) | 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 hair styling and treatment products (hair dyes) | 15 | 15 |
| Rinse-off skin care products (exfoliants) | 15 | 15 |
| Shampoo (liquid form) | 20 | 20 |
| Toothpastes, mouthwashes | 15 | 15 |
| Shaving foams, shaving gels, shaving creams | 70 | 40 |
| Other rinse-off products | 15 | 15 |

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, together with a toxicologist declaration 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 conditions is fulfilled:

1. the substance is readily degradable and has low adsorption ($A < 25\%$);
2. the substance is readily degradable and has high desorption ($D > 75\%$);
3. the substance is readily degradable and non-bioaccumulating.

Testing for adsorption/desorption may be conducted in accordance with Guidelines 106 of the Organisation for Economic Co-operation and Development (OECD).

-----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)). 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: Final Criterion 2: Biodegradability

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"

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. Surfactants in this respect are considered relevant due to the fact that they are used in high amounts in liquid soaps, shampoos and conditioners.

An analysis of other ecolabels (Nordic Swan, Blue Angel and Bra Miljöval) was performed during the revision to study how biodegradability and bioaccumulation was addressed in other schemes.

The main relevant discussion points discussed during the revision process are detailed below.

Fragrances

Several stakeholders mentioned: *many fragrance ingredients are biodegradable 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.*

According to CB forum information on the assessment of fragrances, 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. Therefore, It was proposed to guidance with this regards in the User manual.

Thresholds

With regards thresholds and ambition level, several stakeholders asked to further restrict biodegradability thresholds. Several stakeholders suggested full alignment to Nordic Swan thresholds, which are stricter than the EU Ecolabel criteria in force. Stakeholders highlighted the need of a continuous improvement of the EU Ecolabel scheme, even if this implies that EU Ecolabel licences are lost.

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 5. 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 aNBO EU Ecolabel (mg/g AC) | Current aNBO 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 preparations
- 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 fragrances. Against this background **the thresholds were aligned with Nordic Swan values**. Values for shaving products remained unchanged due to lack of data.

However, considering that the shampoo category would be the most affected one by the alignment with Nordic Swan values, and that a high number of current licenses would be lost, **it was proposed a compromise value for this product category (20 mg/g AC)**.

Exemption of surfactants on toothpastes

During the revision process, an exemption was included from the requirement of **anaerobic biodegradability for surfactants in toothpastes**. The objective of this exemption 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 allow only surfactants that are both aerobically and anaerobically degradable in toothpastes. Labelled products are available on the market.

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

(Q)SAR (Quantitative structure-activity relationship) method

Collectively referred to as (Q)SARs, these are mathematical models that can be used to predict the physicochemical, biological and environmental fate properties of compounds from the knowledge of their chemical structure. QSAR models were introduced during the revision process if actual test data is missing as test data from actual testing is more reliable than data from QSAR modelling. However, a high number of stakeholders and CBs mentioned that QSAR models/results should be verified by independent parties or toxicologist. Moreover:

- Standard criteria are not available to verify the validity of a (Q)SAR prediction.
- The OECD (Organisation for Economic Co-operation and Development) has just started two projects on the matter: QSAR assessment framework and Good Computational Modelling Practices (GCMP). The former aims at establishing criteria for acceptance of QSAR predictions, the latter aims at defining criteria equivalent to GLP but for computational models.

Therefore, it is suggested to **explore QSAR use in the next revision**, once the OECD projects are finalised and criteria of acceptance are clearly defined.

3.3 CRITERION 3: Biodegradability and aquatic toxicity of leave on cosmetic products

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

At least 95% by weight of the total content of organic ingoing substances shall 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 (molecular weight > 700g/mol)

UV filters in leave-on products with sun protection function shall be exempt from that requirement.

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) -----

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

This is a new criterion that was added during the revision process, to take into account that the revised EU Ecolabel criteria include leave on products, for which biodegradability and aquatic toxicity requirements are different than for rinse-off products.

Considering that leave on products are new in EU Ecolabel (no historical data), and that the only data available for new leave-on categories is from Nordic Swan Ecolabel, a complete alignment with this ecolabel has been proposed.

The main discussion points addressed during the revision process are summarised below.

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, which makes impossible to have them meeting this criterion. Moreover, the nano form of TiO₂ has been reclassified as category 2 carcinogen (H351 by inhalation), with the reclassification entering into force from 1st October 2021, therefore also not passing criterion 4 (a) (ii). Thus, stakeholders considered that including sunscreen products in the scope could discredit the reputation of the EU Ecolabel.

However sunscreens need 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 compliance with the EU Ecolabel criteria. Nordic Swan has 58 certified sunscreen products (+ 10 sunscreens for children). Therefore, it has been proposed to **keep sunscreens under the scope**. In line with Nordic Swan, UV filters are exempted from the biodegradability criterion. In addition, there is a specific criterion on UV filters in criterion 4 to ensure non bioaccumulation and low toxicity for UV filters.

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 EU Ecolabel.

Considering that existing EU Ecolabel in force values (BCF < 100 and log Kow < 3) correspond to the old classification under 1999/45/EG, and the general harmonization with Nordic Swan, **it was been 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).**

3.4 CRITERION 4: Excluded and restricted substances

Annex I: Final Criterion 4: Excluded and restricted substances

4(a) Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008

(i) Unless derogated in Table 5, the product shall not contain substances at or above the concentration of 0.0100 % weight by weight for rinse-off products and 0.0010% weight by weight for leave-on cosmetics that meet the criteria for classification with the hazard classes, categories and associated hazard statement codes listed in Table 4, 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 prevail.

Table 4 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 (*1) | |
| 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 | |

(*1) The following substances are exempt: enzymes (including stabilisers and preservatives in the enzyme raw material) if they are in liquid form or as granulate capsules; α -tocopheryl acetate; Amidoamin, which can be included with a maximum concentration of 0.3% as an impurity in Cocamidopropyl Betaine

(CARB). In the case of colorants and preservatives with a H317 or H334 hazard class, the requirement applies regardless of the concentration.

Table 5. Derogations to restrictions on ingoing substances classified under Regulation (EC) No 1272/2008 and applicable conditions

| Substance type | Applicability | Derogated hazard class, category and hazard statement code | Derogation conditions |
|-----------------|---------------------------------|--|---|
| Surfactants | Rinse-off and leave-on products | H412: Harmful to aquatic life with long-lasting effects | Total concentration < 20 % in the final product |
| Sodium Fluoride | Rinse-off oral care products | H301: Toxic if swallowed | Only in oral care products (mouthwash and toothpaste) |

(ii) Unless derogated in Table 7, substances that meet the criteria for classification with the hazard statements listed in Table 6 shall not be contained in the final product nor in its ingredients, regardless of their concentration.

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

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

Table 7. Derogations to restrictions on substances classified as CMR under Regulation (EC) No 1272/2008 and applicable conditions

| Substance type | Applicability | Derogated hazard class, category and hazard statement code | Derogation conditions |
|------------------------------|--|--|--|
| Titanium dioxide (nano-form) | UV filters in leave-on products with sun protection function | H351: Suspected of causing cancer | Must comply with SCCS/1516/13, SCCS/1580/16, and SCCS/1583/17. It cannot be used in powder or spray form |

(iii) Ingoing substances classified as environmentally hazardous according to Regulation EC 1272/2008 may be included in the product to a maximum:

$$100 \cdot c [H410] + 10 \cdot c [H411] + c [H412] \leq 2,5\%$$

where c is the fraction of the product, measured in percentage by weight, made up of the classified substance.

The following exemptions apply:

- 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 classified as H412 shall be exempted from the requirement.

Criterion 4 (a) shall 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 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) Butylated Hydroxytoluene (BHT) [2] and Butylated hydroxyanisole (BHA);
- (iii) Cocamide DEA;
- (iv) Deltamethrin;
- (v) Diethylenetriaminepentaacetic acid (DTPA) and its salts;
- (vi) Ethylenediaminetetraacetic acid (EDTA) and its salts and non-readily biodegradable phosphonates [3];
- (vii) Microplastics and microbeads;
- (viii) Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products, where the recommendations [4] by Cosmetic Europe for mineral oils are not complied;
- (ix) Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council;
- (x) Nitromusks and polycyclic musks;
- (xi) Perfluorinated and polyfluorinated substances [5];
- (xii) Phthalates;
- (xiii) Resorcinol;
- (xiv) Sodium hypochlorite, chloramine and sodium chlorite;
- (xv) Sodium Lauryl Sulphate (SLS) in toothpaste products;
- (xvi) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate [6];

- (xvii) Substances identified to have endocrine disrupting properties;
- (xviii) The following fragrances: benzyl salicylate, butylphenyl methylpropional, tetramethyl acetyloctahydrophthalenes (OTNE);
- (xix) The following isoflavones: daidzein, genistein;
- (xx) The following preservatives: benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan;
- (xxi) The following UV filters: benzophenone, benzophenone-1, benzophenone-2, benzophenone-3, benzophenone-4, benzophenone-5, ethylhexyl methoxycinnamate, homosalate, octocrylene;
- (xxii) Triphenyl phosphate.

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

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 shall not be present in the product, regardless of their concentration.

4(d) Fragrances

(i) Children products shall be fragrance-free. Criterion 4 (d) (i) shall not apply to toothpaste marketed for children.

(ii) Products marketed as 'mild/sensitive' shall be fragrance-free.

(iii) Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' [7] shall not be present in EU Ecolabel products in concentrations higher than 0.0100% in rinse-off products and 0.0010% in leave-on products.

(iv) 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 manufacturer shall follow the recommendations of the IFRA Standards concerning prohibition, restricted use and specified purity criteria for materials.

4(e) Preservatives

(i) Preservatives classified as H317 or H334 are banned regardless of the concentration.

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

(iii) 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.

(iv) Preservatives used in products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail lacquers) shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

4(f) Colorants

(i) Colorants classified as H317 or H334 shall be prohibited regardless of the concentration.

(ii) Colorants in the product shall 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.

(iii) Colorants used in products in contact with the mouth (e.g. toothpaste, mouthwash, lip care products, nail lacquers) shall have been approved as food additives in accordance with Regulation (EC) No 1333/2008.

(iv) The content of barium, bismuth, cadmium, cobalt, hexavalent chromium (Chromium VI), lead and nickel occurring as impurity in decorative cosmetics and hair dyes shall be restricted to concentrations below 10 ppm. The content of mercury occurring as impurity in decorative cosmetics and hair dyes shall be 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 shall not be bioaccumulating ($BCF < 500$ / $\log K_{ow} < 4.0$) or shall have a lowest measured toxicity of $NOEC/ECx > 0.1$ mg/l or $EC/LC50 > 10.0$ mg/l.

Assessment and verification: The applicant shall provide a signed declaration of compliance with all above sub-criteria, supported by declarations from suppliers, for criteria 4 (a) (ii), 4 (e), 4 (f) and 4 (g); and the following supporting evidence:

To demonstrate compliance with sub-criterion 4 (a) the applicant shall provide the SDS of the final product.

To demonstrate compliance with sub-criteria 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 sub-criteria 4 (a), 4 (b) and 4 (c) are fulfilled.

For substances exempted from sub-criterion 4 (a) (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to demonstrate compliance.

For mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in sub-criterion 4 (b), compliance with the recommendations [4] by Cosmetic Europe for mineral oils shall be demonstrated.

For sub-criterion 4 (c), reference to the latest list of substances of very high concern shall be made on the date of application [8].

To demonstrate compliance with sub-criterion 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 sub-criterion 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 sub-criterion 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 sub-criterion 4 (g), the applicant shall provide: copies of the SDS of any UV filters 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 laid down in Annex VI to Regulation (EC) No 1223/2009 shall be provided.

The above evidence may 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] 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 0.0010%

[3] non-readily biodegradable phosphonate may still be used in solid rinse-off products up to a total concentration of 0.0600% w/w.

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

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

[6] these substances may be allowed if present as impurities, but up to a total concentration of 500 ppm in the product formulation.

[7]

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

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

[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).]

Annex II: Final Criterion 3: Excluded and restricted substances

3(a) Restrictions on ingoing substances classified under Regulation (EC) No 1272/2008

(i) Unless derogated in Table 5, the product shall not contain substances at or above the concentration of 0.0100 % weight by weight for rinse-off products that meet the criteria for classification with the hazard classes, categories and associated hazard statement codes listed in Table 4, 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 prevail.

Table 4 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 (*1) | |
| 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 | |

(*)Enzymes are exempt (including stabilisers and preservatives in the enzyme raw material) if they are in liquid form or as granulate capsules. In the case of colorants

and preservatives with a H317 or H334 hazard class, the requirement shall apply regardless of the concentration.

Table 5. Derogations to restrictions on ingoing substances classified under Regulation (EC) No 1272/2008

| Substance type | Applicability | Derogated hazard class, category and hazard statement code | Derogation conditions |
|----------------|----------------------|--|---|
| Surfactants | Animal care products | H412: Harmful to aquatic life with long-lasting effects | Total concentration < 20 % in the final product |

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

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

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

(iii) The final product shall not be classified and labelled as being acutely toxic, a specific target organ toxicant, a respiratory or skin sensitiser, carcinogenic, mutagenic or toxic for reproduction, or hazardous to the aquatic environment, as defined in Annex I to Regulation (EC) No 1272/2008 and in accordance with the list in Table 4 and 6 of this Annex.

Criterion 3 (a) does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006 (*) which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any substance and mixture in the final product.

3(b) Specified excluded substances

Substances 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) Butylated Hydroxytoluene (BHT) and Butylated hydroxyanisole (BHA);
- (iii) Cocamide DEA;
- (iv) Deltamethrin;
- (v) Diethylenetriaminepentaacetic acid (DTPA) and its salts;
- (vi) Ethylenediaminetetraacetic acid (EDTA) and its salts and non-readily biodegradable phosphonates;
- (vii) Microplastics and microbaeds;
- (viii) Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council;
- (ix) Nitromusks and polycyclic musks;
- (x) Perfluorinated and polyfluorinated substances [3];
- (xi) Phthalates;
- (xii) Resorcinol;
- (xiii) Sodium hypochlorite, chloramine and sodium chlorite;
- (xiv) Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate [4];
- (xv) Substances identified to have endocrine disrupting properties;
- (xvi) The following fragrances: benzyl salicylate, butylphenyl methylpropional, tetramethyl acetyloctahydranophthalenes (OTNE);
- (xvii) The following isoflavones: daidzein, genistein;
- (xviii) The following preservatives: benzalkonium chloride, formaldehyde releasers, isothiazolinones, kojic acid, parabens, triclocarban, triclosan;
- (xix) Triphenyl phosphate.

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

Same as Annex I.

3(d) Fragrances

(ii) Substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' [5] shall not be present in EU Ecolabel products in concentrations higher than 0.0100%.

(ii) Same as Annex I

3 (e) Preservatives

Same as Annex I (except (iv))

3(f) Colorants

Same as Annex I (Only (i) and (ii))

Assessment and verification: The applicant shall provide a signed declaration of compliance with all above sub-criteria, supported by declarations from suppliers for criteria 3 (a) (ii), 3 (e), and 3 (f); and the following supporting evidence:

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

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

- (i) SDS of any substance/mixture and their concentration in the final product.
- (ii) a written confirmation that sub-criteria 3(a), 3(b) and 3(c) are fulfilled.

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

For requirement sub-criterion 3(c), reference to the latest list of substances of very high concern [5] shall be made on the date of application.

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

To demonstrate compliance with sub-criterion 3(e), the applicant shall provide: copies of the SDS of any preservative added, and information on its BCF and/or log K_{ow} values.

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

The above evidence may 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] These substances may be allowed if present as impurities, but up to a total concentration of 500 ppm in the product formulation.

[4]

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

[5] http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Rationale of the proposed criterion text

The technical analysis included in the preliminary report³ 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). In addition, a new sub-requirement on UV filters was added in the first proposal:

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)

Rationale of proposed requirement

This criterion 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*".

During the revision process, the main discussion points were the following:

- Thresholds of classified substances, which have been set at to 0.0100% w/w in rinse-off products and 0.0010% w/w in leave-on products, in line with the Cosmetics Regulation.
- Removal of the word 'mixtures', in line with the definition of 'ingoiing substance', the agreement at the CB level, the alignment with Nordic Swan and with the EU Ecolabel for detergents (both referring to substances only)
- Derogated substances, which have been removed at the beginning of the revision process, and granted, after submission of relevant data from the industry and after discussion with stakeholders in a sub-group meeting that took place in September 2020²², to:
 - H412-classified surfactants in rinse-off and leave-on products if present in a total concentration of < 20% w/w in the final product;

²² Discussion paper and minutes of the meeting can be found at: <https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/444/documents>

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- Sodium Fluoride in rinse-off oral care products;
 - Titanium dioxide (nano-form) used as a UV filter in leave-on products with sun protection function, if complying with SCCS/1516/13, SCCS/1580/16, and SCCS/1583/17 and if not used in powder or spray form.
 - The exclusion (no limit) of colorants and preservatives classified as H317 or H334
 - Thresholds for CMR substances/mixtures, which have been set to 0% (no limit, analytical limit of detection);
 - The reference to the classification of the final product, which has been replaced by the following formula: $100 \cdot c[H410] + 10 \cdot c[H411] + c[H412] \leq 2.5\%$, where c is the concentration of the sum of the substances classified with the number inside the parenthesis (H412 surfactants which are derogated are not included in the formula);
 - It was proposed to include a reference to SCCS opinions published after the adoption of the Commission Decision, that should be taken into account in the EU Ecolabel wherever it leads to a clear, unique conclusion on the conditions under which a substance and/or mixture is considered safe. However it was finally not included in order to avoid confusion and ensure harmonisation of interpretation of the criteria.

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), 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.

During the revision process, the following changes were made, and discussion topics were addressed:

- Eliminating the following substances from the exclusions list:
 - (ii) Nitrilo-tri-acetate (NTA; already excluded according to the Cosmetic Regulation);
 - (iii) Boric acid, borates and perborates already excluded according to the Cosmetic Regulation);
 - (v) Octamethylcyclotetrasiloxane (D4; already excluded according to the Cosmetic Regulation);
 - (viii) Formaldehyde (already excluded according to the Cosmetic Regulation);

-
- (ix) Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Atranol and Chloroatranol (already excluded according to the Cosmetic Regulation);
 - (xi) nano silver (included in the general exclusion of nanomaterials).
 - Including a definition of 'microplastic', in accordance with the definition of 'microplastic'²³ laid down in EU Ecolabel criteria for detergents²⁴
 - Including the following substances to the exclusion list:
 - Butylated hydroxyanisole (BHA);
 - BHT, unless used in perfumes and its total concentration in the final product is below 0.001%.
 - The preservative benzalkonium chloride;
 - The fragrance tetramethyl acetyloctahydronaphthalenes (OTNE);
 - Sodium hypochlorite, chloramine and sodium chlorite;
 - EDTA (diethylenetriaminepentaacetic acid and its salts), however allowed up to a concentration of 0.06 mg/g AC if used in solid rinse-off products;
 - Cocamide DEA;
 - phthalates;
 - Sodium Lauryl Sulfate (SLS), in toothpaste;
 - Sodium phosphate, dihydrate; Disodium phosphate, heptahydrate; Trisodium orthophosphate; and Phosphoric acid, trisodium salt, dodecahydrate, however allowed if present as impurities, and anyway in less than a total concentration of 500 ppm in the product formulation;
 - Nanomaterials, unless used according to the conditions laid down for specific nanomaterials in Annexes III, IV and VI to the Cosmetic Regulation.;
 - Identified endocrine disruptor substances;
 - Perfluorinated and polyfluorinated substances;
 - Isothiazolinones;
 - Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH) in lip care products, unless the recommendations by Cosmetic Europe for mineral oils are complied with and compliance is demonstrated.
 - Potential endocrine disruptor compounds, as identified by the DG GROW list (A+B) and not already excluded in the EU Ecolabel (17

²³'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.

²⁴ COMMISSION DECISION (EU) 2017/1214 of 23 June 2017 establishing the EU Ecolabel criteria for hand dishwashing detergents.

substances): Ethylhexyl methoxycinnamate, Resorcinol, Benzophenone, Benzophenone-1, Benzophenone-2, Benzophenone-3, Benzophenone-4, Benzophenone-5, Homosalate, Octocrylene, Butylphenyl methylpropional, Benzyl salicylate, Triphenyl phosphate, Daidzein, Deltamethrin, Genistein, Kojic acid and Triclocarban;

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 during the revision process; however the text was aligned with the same criterion used in the most recently adopted EU Ecolabel criteria.

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 results⁴ 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).

The main topics of discussion that arose during the revision process are summarised below.

Fragrance allergens in cosmetic products

During the revision process 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 2012²⁵ 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 those 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, a new sub-requirement was included in the criteria, restricting the 82 substances listed under Table 13-1 of the SCCS opinion on 'Fragrance allergens in cosmetic products' to up to 0.01% in rinse-off products and 0.001% in leave-on products.

Products designed for children or as 'mild/sensitive'

Babies and children are categories where the risk of exposure to allergens should be minimised, in order to avoid the development of allergies (see also the rationale to sub-criterion 4 (a)). Therefore, a ban was introduced on fragrances in products marketed for children (0-12 years). However, to avoid that children are discouraged to clean their teeth because of the absence of flavours/fragrances in toothpaste, an exception to criterion 4 (d) (i) was made for toothpaste for children.

Moreover, to protect consumers, a ban was introduced on fragrances in products marketed and/or claimed to be mild/sensitive.

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.*

Moreover, criterion 4(b) additionally bans 7 preservatives/classes of preservatives.

²⁵ https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf

One important topic of discussion during the revision process was the presence of preservatives in products in contact with the mouth. Due to the risk of swallowing toothpaste products, a new sub-requirement was inserted which allows in products in contact with the mouth (toothpastes, mouthwash, lipstick, nail lacquer, etc.) only those preservatives which are approved by Regulation (EC) No 1333/2008²⁶ on food additives.

Another topic that was addressed during the revision process was the definition of bioaccumulating thresholds for preservatives.

In the existing criteria in force the BCF and log K_{ow} cut-off values come from the Dangerous Substances Directive (DSD). However, the DSD Directive was replaced by Regulation EC 1272/2008 (CLP Regulation), allowing more relaxed thresholds. Therefore, it was proposed to align with the CLP Regulation and Nordic Swan, and define the bioaccumulating thresholds as $BCF < 500$ and $\log K_{ow} < 4.0$.

Finally, a ban was introduced on preservatives classified as H317 or H334 according to the CLP regulation (see the rationale to sub-criterion 4 (a)).

Requirement 4(f) Colorants

Rationale of proposed requirement

In the EU Ecolabel criteria in force it is required that colorants in the product must not be bioaccumulating. 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 found that Nordic Swan and Bra Miljöval set that the colorant in use must be approved as a food additive. The requirement excludes about ten colorants with log K_{ow} values up to 17, which are approved under the Cosmetics Regulation.

The main topics addressed during the revision process are summarised in the next sections.

Colorants in decorative cosmetics

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

It was suggested by stakeholders to set strict thresholds on some heavy metals in decorative cosmetics, namely lead, cadmium and mercury to 1 ppm and bismuth oxychloride regardless of the concentration. However, other stakeholders were against even a limit of 10 ppm 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

²⁶ 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>

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 2008/128 specifically address presence of arsenic, lead, mercury and cadmium.

For lead, it was found by a study²⁷ 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 study²⁸ 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. However, lipstick is only one of the decorative cosmetic products. The iron oxides referred to in Commission Regulation (EU) No 231/2012²⁹ set a purity for lead <10ppm by total dissolution. These levels ensure that small amounts that may eventually be in cosmetic or personal care products do not pose a risk to human health. These safety limits for impurities in colorants are based in food legislation and cosmetic products must meet those same requirements. The most baseline problem would be that producers could not find supplies of colorants that met the 1ppm limit for each heavy metal. Ochre, for example, is not a safety concern above 1ppm as it does not pass the skin barrier. Therefore, for lead a limit of 10 ppm was set.

Studies³⁰ 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 recently³¹ 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.

Bismuth 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 compounds³².

²⁷ 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>

²⁸ Al-Saleh, Al-Enazi, Shinwari, 2009. Assessment of lead in cosmetic products. *Regulatory toxicology and pharmacology*. 10.1016/j.yrtph.2009.02.005

²⁹ <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32012R0231>

³⁰ 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.

³¹ <https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/fdas-testing-cosmetics-arsenic-cadmium-chromium-cobalt-lead-mercury-and-nickel-content#learned>

³² <https://echa.europa.eu/brief-profile/-/briefprofile/100.029.202>

Therefore, a total ban on bismouth oxychloride is not considered justified, and a limit of 10 ppm was proposed.

Colorants in products in contact with the mouth

Stakeholders had polarised views on the need of a requirement that allows the use of colorants in products which are in contact with the mouth only if approved as food additives according to Regulation 1333/2008³³, due to the 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, the food additives compliance is required for colorants to be used in products in contact with the mouth, e.g. mouthwash, lip care products, nail lacquers.

Definition of bioaccumulating thresholds

In the existing criteria in force the BCF and log K_{ow} cut-off values come from the Dangerous Substances Directive (DSD). However, the DSD Directive was replaced by Regulation EC 1272/2008 (CLP Regulation), allowing more relaxed thresholds. Therefore, it was proposed to align with the CLP Regulation and Nordic Swan, and define the bioaccumulating thresholds as $BCF < 500$ and $\log K_{ow} < 4.0$

H317/H334 colorants

As explained in the rationale to sub-criterion 4 (a), a ban was introduced on colorants classified as H317 or H334 according to the CLP regulation.

Requirement 4(g): UV filters

Rationale of proposed requirement

The expansion of the scope to include additional product categories such as sunscreens called for the need to include a requirement 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.

³³ 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>

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.

Additionally, a new requirement was included, in line with Nordic Swan specifications, targeting the bioaccumulation and the toxicity aspects of the UV filters.

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. Bioaccumulation requirements were aligned with the CLP Regulation and Nordic Swan ($BCF < 500$ and $\log K_{ow} < 4.0$). 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.

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 revision process, the wording of the assessment and verification has been slightly modified according to changes in criterion text.

3.5 CRITERION 5: Packaging

Annex I: Final Criterion 5: Packaging

The minimum volume for a rinse off product to be certified other than toothpaste shall 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, shall be allowed, with the exception of secondary packaging which groups the product and its refill and products that include several elements for their use. For the rinse-off products for domestic use sold with pump that can be opened without compromising the design, a refilling option shall be provided in the same or higher packaging capacity.

Note: Cardboard boxes used to transport the products to the retail stores shall 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) shall 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 shall be exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$\text{PIR} = (W + (W_{\text{refill}} \times F) + N + (N_{\text{refill}} \times F)) / (D + (D_{\text{refill}} \times F))$$

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:

$$F = V \times R / V_{\text{refill}}$$

Note: [1] Proportional weight of the grouping packaging (e.g. 50 % of the total grouping packaging weight, if two products are sold together).

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 R is not a whole number, it shall be rounded up to the next whole number.

In case no refill is offered PIR shall be calculated as follows:

$$\text{PIR} = (W + N)/D$$

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 shall be exempted from this requirement.

For decorative cosmetics the following shall apply:

$$\text{PIR} = \frac{\sum(W_{\text{packaging},i} + W_{\text{not-recycled},i})}{2 * W_{\text{product total}}} \leq 0.80$$

Where:

W_{packaging, i} — the weight of the packaging component i

W_{non-recycled, i} — the weight of non-recycled material in packaging component i (if it is not recycled material in the packaging is W_{non-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 demonstrate that the refills shall be available for purchase on the market. The applicant shall provide third party verification and traceability for postconsumer recycled content. Certificate of recyclers pursuant a certification scheme following standard EN15343 may be used to support verification and certificate of product production pursuant a certification scheme following a batch mass balance approach (controlled blending) as described in the ISO22095 Chain of Custody Models.

c) Information and design of primary packaging

(i) Information on primary packaging

Dosage and refills: Applicants shall indicate the correct dosage or the appropriate quantity to be used on the label of the primary packaging together with the following sentence:

"using the correct dosage of the product minimises impacts on the environment and saves money."

In cases where the correct dosage cannot be defined for a specific product because it depends on consumer aspects (e.g. length of the hair), the following sentence shall be used instead:

"dose the product with care so as not to over-consume it unnecessarily"

If the product is refillable, the applicant shall complete the information with a reference to use refills in order to minimise impacts on the environment and save money.

End of life information: Applicants shall include a sentence or a pictogram in relation to empty product disposal (e.g. *"after its use, the empty package/container should be disposed of in a dedicated container for recycling"*)

(ii) Design of primary packaging

Rinse off products: The primary packaging shall be designed:

a) to make correct dosage easy by using a pump [1] or ensuring that the opening at the top is not too wide. Refills are exempted from this requirement.

b) to ensure that at least 95% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 5%, 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 whose primary packaging can be manually opened and the residue product can be extracted with adding water shall be exempted from the requirement in b).

Leave-on products:

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

b) Cream bottles shall 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 formula set out for rinse-off products.

Notes:

[1] 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.

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 sentences indicated in sub-criterion 5 (c) (i) (if applicable). Applicant shall provide documented evidence of which case under sub-criterion 5 (c) (i) applies for their product(s). 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 shall be exempted from this requirement.

Table 8. Materials and components excluded from packaging elements

| Packaging element | Excluded material or component* |
|-------------------|---|
| Label or sleeve | <ul style="list-style-type: none"> - 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 (except LDPET (< 1 g/cm³)) 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). - PSL (pressure sensitive) label unless the adhesive is water releasable at washing conditions of the recycling process. - PET PSL label, unless the adhesive is water releasable at washing conditions of the recycling process and has no reactivation. |
| Closure | <ul style="list-style-type: none"> - PS closure in combination a with a PET, PP or HDPE packaging - PVC closure in combination with a PET, PP or HDPE packaging |

| | |
|------------------|--|
| | <ul style="list-style-type: none"> - PETG closures and/or closure material with density of above 1 g/cm³ in combination with a PET packaging - Closures (or part of) made of metal, glass, EVA - Closures (or part of) 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 | <ul style="list-style-type: none"> - Polyamide, EVOH provided with tie layers made by a polymer different than the one used for the packaging body, functional polyolefins, metallised and light blocking barriers |

(*) EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, LDPET – Low Density Polyethylene terephthalate, PET — Polyethylene terephthalate, PETC – crystalline polyethylene terephthalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PSL – pressure sensitive label, PVC — Polyvinylchloride

Assessment and verification: the applicant shall submit a signed declaration of compliance specifying the material composition, supported by manufacturer documentation, of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging.

Annex 2: Final Criterion 4: Packaging

The minimum volume for an animal care product to be certified shall 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, shall be allowed, with the exception of secondary packaging which groups the product and its refill and products that include several elements for their use. For the products for domestic use sold with pump that can be opened without compromising the design, a refilling option shall be provided in the same or higher packaging capacity.

Note: Cardboard boxes used to transport the products to the retail stores shall 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) shall 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 shall be exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

$$\text{PIR} = (W + (W_{\text{refill}} \times F) + N + (N_{\text{refill}} \times F)) / (D + (D_{\text{refill}} \times F))$$

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:

$$F = V \times R / V_{\text{refill}}$$

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 shall be rounded up to the next whole number.

In case no refill is offered PIR shall be calculated as follows:

$$\text{PIR} = (W + N) / D$$

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 shall be exempted from this requirement.

Note:

[1] Proportional weight of the grouping packaging (e.g. 50 % of the total grouping packaging weight, if two products are sold together).

Assessment and verification: the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration 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 demonstrate that the refills shall be available for purchase on the market. The applicant shall provide third party verification and traceability for postconsumer recycled content. Certificate of recyclers pursuant a certification scheme following standard EN15343 may be used to support verification and certificate of product production pursuant a certification scheme following a batch mass balance approach (controlled blending) as described in the ISO22095 Chain of Custody Models.

(c) Information and design of primary packaging

(i) Information on primary packaging

Dosage and refills: Applicants shall indicate the correct dosage or the appropriate quantity to be used on the label of the primary packaging together with the following sentence:

“using the correct dosage of the product minimises impacts on the environment and saves money.”

In cases where the correct dosage cannot be defined for a specific product because it depends on consumer aspects (e.g. length of the hair), the following sentence shall be used instead:

“dose the product with care so as not to over-consume it unnecessarily”

If the product is refillable, the applicant shall complete the information with a reference to use refills in order to minimise impacts on the environment and save money.

End of life information: Applicants shall include a sentence or a pictogram in relation to empty product disposal (e.g. “after its use, the empty package/container should be disposed of in a dedicated container for recycling”)

Note: Products whose dimensions do not allow a proper display of information due to lack of space or text legibility reasons shall be exempted from this requirement.

(ii) 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.

The primary packaging shall be designed:

a) to make correct dosage easy by using a pump [1] or ensuring that the opening at the top is not too wide. Refills are exempted from this requirement.

b) to ensure that at least 95% of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 5%, shall be calculated as follows:

$$R = ((m_2 - m_3)/(m_1 - m_3)) \times 100 (\%)$$

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 whose primary packaging can be manually opened and the residue product can be extracted with adding water shall be exempted from the requirement in b).

Notes:

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

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 the product in the packaging and a high resolution image of the product packaging that clearly shows the sentences indicated in sub-criterion 5 (c) (i) (if applicable). Applicant shall provide documented evidence of which case under sub-criterion 5 (c) (i) applies for their product(s). The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.

(d) Design for recycling of plastic packaging

Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 7.

Pumps and aerosol containers are exempted from this requirement.

Table 7. Materials and components excluded from packaging elements

| Packaging element | Excluded material or component* |
|-------------------|---|
| Label or sleeve | <ul style="list-style-type: none">- 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 (except LDPET (< 1 g/cm³)) 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 |

| | |
|--|---|
| | <ul style="list-style-type: none"> - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling). - PSL (pressure sensitive) label, unless the adhesive is water releasable at washing conditions of the recycling process. - PET PSL label, unless the adhesive is water releasable at washing conditions of the recycling process and has no reactivation. |
| Closure | <ul style="list-style-type: none"> - PS closure in combination 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 (or part of) made of metal, glass, EVA - Closures (or part of) 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 | <ul style="list-style-type: none"> - Polyamide, EVOH provided with tie layers made by a polymer different than the one used for the packaging body, functional polyolefins, metallised and light blocking barriers |
| <p>(*) EVA – Ethylene Vinyl Acetate, EVOH – Ethylene vinyl alcohol, HDPE – High-density polyethylene, LDPE – Low Density Polyethylene terephthalate, PET – Polyethylene terephthalate, PETC – crystalline polyethylene terephthalate, PETG – Polyethylene terephthalate glycol-modified, PP – Polypropylene, PS – Polystyrene, PSL – pressure sensitive label, PVC – Polyvinylchloride</p> | |
| <p>Assessment and verification: the applicant shall submit a signed declaration of compliance specifying the material composition, supported by manufacturer documentation, of the packaging including the container, label or sleeve, adhesives, closure and barrier coating, together with a sample of primary packaging.</p> | |

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*³⁴.

In 2018, the European Commission published the European strategy for plastics in a circular economy³⁵ 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 plastics³⁶. 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 change³⁷.

In order to avoid the use of small bottles, a pre-requirement has been included during this revision process 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.

³⁴

https://www.ellenmacarthurfoundation.org/assets/downloads/Completing_The_Picture_How_The_Circular_Economy-_Tackles_Climate_Change_V3_26_September.pdf

³⁵ <https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf>

³⁶ <https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf>

³⁷ According to our calculations, with Simapro software and ILCD method.

Requirement a) - Primary packaging

Rationale of the criterion text

The majority of the products certified with the EU Ecolabel 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 only to be 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.

During the revision, as a result of the stakeholder's feedback, the following modifications were made:

- An exemption has been considered for toothpastes in order to allow the use of secondary packaging for multipacks of toothpastes. However, the secondary packaging is not essential in this case as the multipack is an optional market strategy with no environmental benefits.
- Considering the practical difficulties to refill leave on products, it was specified that the requirement apply to rinse off products.
- It was specified that cardboard boxes used to transport the products to the retail stores should not be considered as secondary packaging.
- Finally, several stakeholders mentioned that refill operation can introduce contamination and can become a health issue at customers such as hospitals, food service. Therefore the refilling requirements has been limited to products for domestic use sold with pump that can be opened without compromising the design.

Requirement b) - Packaging Impact Ratio (PIR)

Rationale of the criterion text

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. The existing PIR value is 0.28g.

In the 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 during the revision in order to identify the number of products that will be out of the new approach if the value is modified. Table 6 shows how the percentage of licenced products would decrease with decreasing PIR.

Table 6. 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% |

Additionally, a CB provided new data in a later stage of the revision, stating that the value of PIR should be more restrictive and reduced. According to the CB, the average across 34 certified products is 0,15 g, suggesting a threshold of 0,18 g. Moreover, according to the information provided by CB and stakeholders, there are products certified under the EU Ecolabel with a percentage of recycled or renewable materials in their content. The range goes from the 20% to 90% of material from renewable or recycled sources.

The main changes carried out during the revision process are summarised here:

- 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.
- Reduction to PIR value from 0.28 to 0.20g. This reduction would affect 35 % of current licences (out of the 120 products assessed). New data from a 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.
- The provision of third party verification and traceability for postconsumer recycled content was added to the assessment and verification. It has been suggested that certification schemes of recyclers may be used to support verification

Requirement c) – Information and design of primary packaging

Rationale of the criterion text

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 7 shows how the percentage of licenced products would decrease with decreasing R.

Table 7. 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% |

The main relevant discussion points discussed during the revision process are detailed below.

R value

Initially it was decreased from 10% to 8%, however 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".

Finally, it was decided to further reduce the R value from 6 to 5%. More than 70% of current licences comply with this value. Rinse off products that can be opened and the residue product can be extracted with adding water were proposed to be exempted from R requirement.

Criteria for leave on products

Considering the inclusion of the scope of leave on product stakeholders suggested to modify this requirement and make a requirement similar to the Nordic Swan Ecolabel. 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 were included in line with Nordic Swan.

Opening design

Stakeholders 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. Therefore, an exemption was granted for refills. In fact, the goal of this opening is to refill the original packaging and not to provide the correct dosage to the user.

Finally, several stakeholders asked to further precise the text: "opening at the top is not too wide". Unfortunately, it was not possible to get information on the standard opening diameter of current licence products, and more guidance could not be given.

Information requirement

Several stakeholders mentioned the importance to include a requirement on provision of information of the correct dosage. Therefore a requirement on provision of information of the correct dosage was included in a separated heading (5 (c) (i) Information on primary packaging).

However, several stakeholders mentioned the difficulties to define correct dosage. For example a shampoo won't be used in the same dosage if you have short hair or long hair. A sun cream won't be used in the same dosage if you are a children or an adult. Therefore an exemption for these situations has been considered. In this case the applicant shall include a sentence in order to promote the use of minimum needed not to waste the products.

Additionally, it has been proposed that if the product is refillable, there shall be information to promote the use of refills.

A sentence on proper disposal of the empty container has been included in line with other EU Ecolabel product groups.

Given that cosmetic products are small and the regulatory requirements already take up space, requirement 5 (c) (i) is proposed to be subject to space and legibility of the information

Requirement d) - Design for recycling of plastic packaging

Rationale of the criterion text

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 Terephthalate 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 [Error! Bookmark not defined.](#)

An exemption for toothpaste tubes was included in this criterion 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.

The main relevant discussion points discussed during the revision process are detailed below.

In general, 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. In fact, it was mentioned that companies often get confused to see that for one product some design item is allowed and for another product the same design item is not allowed.

Label/sleeves

- **PET and PETG:** Considering the requirements of the packaging criterion of Blue Angel, initially it was proposed that PETG and PET label or sleeve in combination with a PET bottle should be avoided. Therefore the restriction: “any PET label or sleeve in combination with a PET packaging” was initially included.

Moreover, PETG density is similar to PET density and cannot be separated by the process. Unfortunately their thermal behaviours are quite different. Therefore PETG labels/sleeves should not be used in any case on PET bottles. Also PET labels/sleeves should not be used because of the printing. However LDPET below 1gr/cm³ is fine as it can be separated from during the recycling process. This has been further specified in the criterion text.

Finally, the criteria was further aligned to hard surface cleaners EU Ecolabel criteria, and PETG restriction was included.

- **PP/PE labels:** PP labels are the preferred choice for PP packaging, as well as PE labels are the preferred choice for HDPE packaging. No issues in sorting, negligible issues in recycling are experienced. Also the use of PP on HDPE and PE on PP packaging should be allowed. Therefore PP and PE are proposed to be permitted with PP or HDPE packaging.
- **Adhesives:** 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 bottles³⁸ and general guidelines³⁹ were provided.

Based on bilateral communication with recycling association it was 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. Therefore, **it was proposed to include a requirement on adhesives.**

- **Full sleeves:** It was commented that 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. However, recent industry practices revealed innovative

³⁸ <https://recyclclass.eu/wp-content/uploads/2020/04/PE-HD-natural-containers-guidelines-27-04-2020-3.pdf>

³⁹ <https://recyclclass.eu/recyclclass/design-for-recycling-guidelines/>

solutions with this regards, therefore a yes or not approach is not taking into account these new solutions and a requirement in full sleeves was not proposed.

- **Virgin PET and rPET from already food contact approved material:** One stakeholder commented that these should not be allowed to use to avoid a “competition” between soap manufacturers and food/drinking manufacturers. However, the following comments were received from industry and from an eco-organism who compared Cotrep, EPBP and Recyclclass standards was received: *“The criteria “Virgin PET and rPET from already food contact approved material shall not be allowed to use” must be removed. The term “food grade” is used to describe equipment and quality suitable for use in food production. In fact, it is a certification and practical safety requirement present in many industries. This certification does not induce competition with food. With this criteria the use of recycled PET would be impossible.”* and *“The restriction on virgin PET and rPET from already food contact approved material should be removed, since this restriction could apply in the long term to other materials such as PE and PS, which would make it impossible to use them in cosmetic packaging and leave few alternative materials to be used.*

Therefore, a requirement has not been proposed.

Closures:

It was clarified that metal caps aren't allowed because 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:

- **Polyamide:** 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 bilateral communication with arecycling association, PA is admitted only if provided as multilayers and will get delaminated during the prewashing phase in PET recycling. The **polyamide restriction was proposed to be kept** under the EU Ecolabel.

- **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 recycle 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. Against this, it has been proposed to restrict EVOH only in the specific case that the tie layers are made by a polymer different that the one used for the packaging body.

Requirement (e) – SVHCs (REMOVED)

Several stakeholders requested the inclusion of SVHCs 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 SVHCs 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. Several stakeholders requested the inclusion of SVHCs 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 SVHCs 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.

However, the following comments were received on the proposal:

- *We supports the new requirement on exclusion of SVHC's in packaging materials, but we are not aware of to what extent applicants have knowledge about the content in packaging. A number of license holders in the Nordic Swan Ecolabel who are implementing the use of recycled plastic in their packaging, have not been focusing on the presence of SVHCs and are therefore not able to document it currently.*
- *We welcome the restriction of SVHCs in packagingConsistency with the non-toxic environment objective of the European Green Deal. Recycled materials should only be sourced from known "clean" materials to ensure consumer trust in the circular economy. Manufacturers are obliged to know whether their packaging contains or not SVHCs (art. 33 of REACH).*

Finally, it was decided not to propose this requirement during this revision as there is not a clear picture of the feasibility of this requirement due to the lack of feedback from industry at this stage. In addition there is a risk that setting requirements on SVHCs for packaging could lead to producers moving to virgin material in order to avoid compliance with this requirement.

It is proposed to gather data with this regards during next revision in order to set SVHC restriction once a better picture of the situation is available.

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.

In summary, no relevant changes have been included during the revision process. The criterion practically remains as it was presented in TR3.0, with few minor wording clarifications.

3.6 CRITERION 6: Sustainable sourcing of palm oil, palm kernel oil and their derivatives

Annex I: Final Criterion 6: Sustainable sourcing of palm oil, palm kernel oil and their derivatives

In the specific case of 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.

Assessment and verification

To demonstrate compliance, evidence through third-party chain of custody certifying that the raw materials used in the product or in its manufacturing originate from sustainably managed plantations shall be provided. For palm oil and palm kernel oil, Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models shall be accepted:

- until 1st January 2025: identity preserved, segregated, and mass balance;
- after 1st January 2025: identity preserved and segregated.

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 shall be accepted: identity preserved, segregated, and mass balance.

For palm oil, palm kernel oil and their derivative, a balance calculation and/or invoices/delivery notes from the raw material producer shall be provided, showing that the proportion of certified raw material corresponds to the amount of certified palm oil raw materials. Alternatively, a declaration from the producer of raw materials shall be provided, showing that all purchased palm oil raw materials are certified. Competent bodies shall annually check the validity of the certificates for each certified product/ingredient [1].

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>

Annex II: Final Criterion 5: Sustainable sourcing of palm oil, palm kernel oil and their derivatives

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. Ecocert⁴⁰, COSMOS⁴¹, NATRUE⁴², RSPO⁴³. 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 an 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

⁴⁰ <https://www.ecocert.com/en/expertise/organic-farming>

⁴¹ <https://cosmos-standard.org/>

⁴² <https://www.natrue.org/our-standard/natrue-criteria-2/>

⁴³ <https://www.rspo.org/>

the sustainable sourcing of all types of renewable ingredients make it unfeasible to set a prescriptive requirement on all type of ingredients. Moreover, other ecolabelling schemes set the same criteria on palm oil, palm kernel oil and their derivatives as the EU Ecolabel.

The main topics of discussion that were addressed during the revision process are summarised below.

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 study⁴⁴ 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 study⁴⁵ 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

⁴⁴ 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

⁴⁵ 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>

criteria have been revised⁴⁶ 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 scheme⁴⁷, 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)⁴⁸.

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, the requirement was kept in the current form. However, it should be noted that according to the verification and assessment text, other certification schemes were proposed to 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.

Assessment and verification of criterion 6 (a)

During the revision process, many stakeholders questioned the acceptance of the Book and Claim (B&C) system as a verification method for this requirement, pointing to the complexity of the system and the dubious environmental integrity.

The book and claim supply chain model provides tradable certificates for RSPO certified oil palm to actors in the palm oil supply chain, which allows for the transfer of RSPO certified oil palm products volume credits from the mill and its supply base to the end user independently of the physical supply chain. However, it was claimed

⁴⁶ <https://rspo.org/news-and-events/announcements/revise-rspo-supply-chain-certification-standard-and-systems-documents-endorsed>

⁴⁷ <https://rspo.org/impact>

⁴⁸ <https://www.iscc-system.org/wp-content/uploads/2019/10/ISCC-Impact-Report-2018.pdf>

that this verification system is much weaker and can be misleading for consumers in relation to other supply chain types: identity preserved, segregated and mass balance.

Ingredients sourced 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 figures⁴⁷, 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 MassBalance – 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, B&C credits were excluded from the accepted RSPO supply chain system certifications. Moreover, given the trends presented above and on RSPO's website on the evolvment of the market, it is proposed to exclude the Mass Balance supply chain system from the accepted methods starting from 1st January 2025. This requirement has also been included in the Nordic Swan ecolabel.

Requirement (b) - Certification of plant based ingredients (REMOVED)

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 synthesized materials, and contributes to a high level of biological diversity⁴⁹.

⁴⁹ Council Regulation (EC) No 834/2007

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.

Moreover, a large number of other natural/organic certification schemes exist: Eco-cert (with two different labels: Organic Cosmetics and Natural Cosmetics); NATRUE (where 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); COSMOS-standard (establishing certified ingredients - with organic content - and approved raw materials - with no organic content, not covered by the EU Organic Regulation); the IFOAM-FAO-UNCTAD⁵⁰ set of standards.

During the revision process it has been proposed to require a minimum content of organic certified ingredients within those covered by the EU Organic Regulation, setting the minimum threshold to 20%:

"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."*

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 cosmetic products, 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. Moreover, Regulation 2018/848 (repealing regulation 834/2007) extended the scope also to certain other products closely linked to agriculture listed in the Annex I, entering into force from 1 January 2021. Finally, 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.

Stakeholders were concerned of the clarity of the requirement and of what ingredients would be affected. Indeed, a positive list of ingredients included in EU

⁵⁰ IFOAM: International Federation of Organic Agriculture Movements; FAO: the Food and Agriculture Organization; UNCTAD: United Nations Conference on Trade and Development

organic framework does not exist. Although private, voluntary standards (like NATRUE or COSMOS) may have their own databases with organic raw materials, in the context of the provisions in the EU Ecolabel these databases would not help users. Without an official definition or harmonised criteria for (natural and) organic cosmetic products, one cannot prescribe the use of any particular standard or guideline to attribute what an accepted organic raw material would be. As such the only reference for organic raw materials remains that in law i.e. the EU Organic Regulation and any regulations that are recognised equivalents by the EU.

An additional point of concern was the feasibility of the requirement. As explained in previous TR, in order to comply with this requirement, only substances to which Regulation 2018/848 applies should be taken into account, i.e. only substances eligible for 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. 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.

Many representatives of industry stated that it may not be feasible to reach a 20% threshold, especially when operators cannot count organic raw materials certified under the scope of private standards (only ingredients certified Competent Bodies duly recognised and appointed through the EU Regulation on organic production 2018/848 would be available). Other stakeholders stated that it is difficult to foresee the feasibility of this requirement, when a positive list of ingredients is not available, therefore exclusively relying on market adaptation.

Also, stakeholders claimed that such a requirement would increase the risk of greenwashing for consumers, because of the low threshold proposed, but also because the cosmetic product may in the end contain no organic ingredient. Indeed, in the case that none of the ingredients used in the formulation are within the scope of Regulation 2018/848, the organic content of a cosmetic product could be 0% and still comply with the criterion. However, it has to be stressed that compliance with criterion 6(b) would 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.

A final aspect to take into consideration is the extra burden that manufacturers of products with a high content of natural ingredients would be unintentionally but *de facto* exposed to. This criterion may in fact have the rebound effect to favour petrochemical substances, which would be subject to less certifications and declarations than plant-based ingredients. On the contrary, the aim of this criterion was 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.

Stakeholders suggested to change the criterion to a requirement of a minimum content of bio-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 16128-2:2017⁵¹ 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.

Based on all the aspects above, in this final version of the TR **it was proposed to remove criterion 6 (b) from the EU Ecolabel for cosmetic products.**

⁵¹ 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

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

According to the manual of borderline products on the scope of application of the Cosmetics Regulation⁵², wet wipes are not included in the Cosmetic Regulation (“a wipe itself is neither a substance nor a mixture”, but a “vehicle to deliver a substance or mixture to the human skin”). While the substance is covered by the Cosmetic Regulation, the vehicle is not covered. However, since other national labelling schemes set requirements for wet wipes, at the initial stage of the revision it was proposed to include wet wipes in the scope of the EU Ecolabel. A specific criterion to minimise the environmental impact of the wet wipes was therefore proposed.

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 referred 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.

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 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*

⁵² https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products_en

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- *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**.

3.8 CRITERION 7: Fitness for use

Annex I: Final Criterion 7: 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, 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 shall be used, and consumer tests shall not be considered equivalent. The tests shall lead to 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 shall be 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 may be used. For consumer tests, the consumers shall be asked about the product's efficiency/performance compared to an equivalent market-leading product. The questions to the consumers shall 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?

Consumer tests shall include a minimum of 20 consumers, and at least 80% of them shall be at least as satisfied with the product as with an equivalent market-leading product.

Notes:

[1] The dosage used should be the same as the one identified in criterion 5 (c) (i). In the case a correct dosage could not be specified in criterion 5 (c) (i), the applicant shall indicate the dosage used for carrying out the test, substantiating the choice.

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 Regulation (EC) No 1223/2009 and Commission Regulation (EU) No 655/2013 may be used to demonstrate that the product fulfils its primary function and any secondary claimed function. It is not necessary to perform new specific tests to demonstrate a function previously demonstrated.

References:

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

Annex II: Final proposal for criterion 6: Fitness for use

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 shall be 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"⁵³ (revised in May 2008) contain the general principles for all efficacy tests and the information which should appear on all test reports. The guideline provided by Cosmetics Europe advice also which information should be included in the test protocols and test reports⁵⁴, e.g. information that can assure the reliability of the study.

In addition, there is a "Technical document on cosmetic claims"⁵⁵ agreed by the Sub-Working Group on Claims and endorsed by the Working Group on Cosmetic Products⁵⁶, 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:

- User tests, which use the sensorial approach (sight, touch, olfaction) through consumers or experts,
- Laboratory tests, which favours specific criteria 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.

According to Commission Regulation (EU) No 655/2013⁵⁷ claims on cosmetic products should conform to the following common criteria: legal compliance, truthfulness, evidential support, honesty, fairness, informed decision making.

Due to the absence of harmonized tests for specific product groups, user tests are often used.

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)⁵⁸, which apply universally across the EU.

⁵³ Available online under:

https://www.cosmeticseurope.eu/files/4214/6407/6830/Guidelines_for_the_Evaluation_of_the_Efficacy_of_Cosmetic_Products_-_2008.pdf

⁵⁴ The following indications given below are not exhaustive and might not all be relevant depending the test under consideration.

⁵⁵ Available online under: <https://ec.europa.eu/docsroom/documents/24847/attachments/1/>

⁵⁶ 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).

⁵⁷ 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>

⁵⁸ 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>

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). 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.

The main discussion topics addressed during the revision process are summarised below.

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.

This aspect was taken into account in criterion 5 (c) Design of primary packaging, 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.

Therefore, a sentence was included in criterion 7, requiring that tests should be conducted on the dosage specified according to criterion 5 (c). In the case a correct dosage could not be specified in criterion 5 (c), the applicant is requested to indicate the dosage that have been used for carrying out the test.

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 was specified in the text that when recognised standardised laboratory tests are available (for example Commission Recommendation 2006/647 (*) for sunscreen products), these must be used, and consumer tests will not be considered equivalent.

Moreover, the criterion text now specifies 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.

A special requirement was added for toothpaste, requiring 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.

Animal testing in Annex II

According to the Cosmetic Regulation, animal studies are not allowed after 2013 for the purpose of cosmetic products. However, animal care products do not fall under the scope of the Cosmetic Regulation.

During the revision process, 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 tested 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.

Competent Bodies moreover expressed concern over how they could verify the product's capacity to fulfil its primary and secondary functions through studies, and without testing the product on the final user - the animals. However, the ban on animal testing for cosmetic is effective from 2013, meaning that a number of historical data exist for ingredients that were tested on animals (in vivo) before that date. Moreover, databases also exist reporting information on substances and formulations. Finally, the applicants could (and should) make use of laboratory tests, which can be (and, for cosmetic products, are) not on animals.

Rationale of proposed assessment and verification

In the EU Ecolabel criteria in force 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 order to avoid that this criterion unnecessarily duplicates existing legislation, during the revision process it was set 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. Therefore, it is not necessary to perform new specific tests to demonstrate a function previously demonstrated.

3.9 CRITERION 8: Information appearing on the EU Ecolabel

Annex I: Final Criterion 8: Information appearing on the EU Ecolabel

The optional label with box shall contain the following information:

- (a) 'Fulfilled strict requirements on harmful substances';
- (b) 'Tested performance';
- (c) 'Less 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: Final Criterion 6: Information appearing on the EU Ecolabel

The optional label with box shall contain the following information:

- (a) 'Fulfilled strict requirements on harmful substances';
- (b) 'Tested performance (not animal tested)';
- (c) 'Less 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.

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 website⁵⁹.

⁵⁹ http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

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.

According to the feedback received from the revision questionnaire (see Preliminary Report³for more details) the majority of the respondents agree with the current text appearing on the EU Ecolabel.

During the revision, the following changes were included:

- The sentences “Limited impact on aquatic ecosystems” and “Fulfil strict biodegradability requirements” were replaced by the generic sentence with a focus on hazardous substances: **‘Restricted hazardous substances’**; similar to the sentence in lubricants product group: ‘Less hazardous substances ending up in the environment’
- In addition the sentence **‘Tested performance’** was included in line with EU Ecolabel for lubricants.
- For the case of Animal care products, it was 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 criteria now include 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.

The definition of ingoing substances is now much more comprehensive and protective for consumers and the environment, compared to the existing criteria in force. It includes also additives used in the raw materials (e.g. preservatives and stabilisers) and substances that can be released from ingoing substances (e.g. formaldehyde).

Compared to the existing criteria in force, criterion 1 on Toxicity to aquatic organisms for rinse off cosmetic products and criterion 2 on Biodegradability of rinse off cosmetic products show more stringent thresholds for all product categories. Moreover, all surfactants shall be readily biodegradable under aerobic and anaerobic conditions. A new criterion has been included for leave on products: criterion 3 on Biodegradability of leave on cosmetic products.

In criterion 4 Excluded and restricted substances, the level of ambition has been increased under many aspects: the total ban on substances of very high concern (SVHCs) and carcinogenic, mutagenic and toxic to reproduction (CMRs), many more substances included to the list of excluded substances (including identified and potential endocrine disruptors, phthalates, perfluorinated and polyfluorinated substances, isothiazolinones, mineral oil saturated hydrocarbons – MOSH - and mineral oil aromatic hydrocarbons – MOAH- in lip care products, microplastics and microbeads, and nanomaterials, except those for which safe conditions for use are set out in Annexes III, IV and VI of the Cosmetic Regulation), 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 with a hazard profile is drastically reduced. Moreover, fragrances cannot be used in products addressed to children or marketed as “mild/sensitive”, and preservatives and colorants classified as sensitisers are prohibited regardless of concentration.

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, information to be included in the primary packaging and restriction on SVHC in the packaging.

Criterion 6 on the sustainable sourcing of palm oil, palm kernel oil and their derivatives have been strengthened by excluding the Book and Claim system from the accepted verification methods. Moreover, from 1st January 2025 the Mass Balance system also will not be accepted for palm oil and palm kernel oil. Such requirement ensures, among other aspects, the responsible use of energy and natural resources and the maintenance of biodiversity.

Finally criterion 7 Fitness for use has been greatly improved in clarity, and the laboratory or consumer tests must be performed at least on the efficacy/performance of the product and its ease of application. For consumer tests, that will be accepted only in case no recognised standardised laboratory test is available, the number of panellists has been increased, 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.

Moreover, after 3 years from the adoption of the revised EU Ecolabel criteria, a mid-term assessment will be performed to evaluate the appropriateness and validity of the criteria, especially taking into account the legislative development under the Sustainable Chemicals Strategy initiative (e.g. potential inclusion of hazard classes for endocrine disrupters within CLP), any new evaluations by the SCCS, and technological developments.

A number of features could not be addressed in this revision due to lack of data, unavailability of methods or unclear aspects that could not be clarified. These aspects are suggested to be explored during next revision:

- Inclusion of wet wipes.
- The appropriateness of having different thresholds for rinse off vs leave on products
- The development of a CDV method not on the basis of grams of active content of the product, but per litre of product.
- Removing the exemption for surfactants in toothpaste from biodegradability requirement.
- Inclusion of QSAR models.
- The alignment of the definition of microplastics to the most recent policy initiatives/evolutions in this regard (eg. ECHA definition under the restriction process)
- The assessment on the ban on phenoxyethanol.
- Exclusion of additional potential endocrine disrupters, notably ethylhexyl salicylate, isoamyl P-methoxycinnamate, and other substances listed on <https://edlists.org/>.

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- A further decrease of the thresholds for heavy metals in decorative cosmetics and hair dyes.
 - The assessment on the need of increasing the stringency of the criterion on UV filters.
 - Inclusion of 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.
 - The introduction of a criterion on VOC emissions for some product categories (e.g. nail lacquers and hair dyes).
 - The development of a criterion incentivising the uptake of natural ingredients farmed according to the EU Organic framework.
 - Restriction of SVHC for plastic used in the packaging.

5 TABLE OF COMMENTS

A table summarising all comments received during the three stakeholder consultations together with JRC responses is available at the following website:

<https://susproc.jrc.ec.europa.eu/product-bureau//product-groups/444/documents>

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