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Revision of the European Ecolabel criteria for rinse-off cosmetics

Technical Report: Criteria proposal for revision of EU Ecolabel for rinse-off cosmetics

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1 INTRODUCTION

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

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

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

This technical report is supported and complemented by the preliminary report published in parallel with this technical report. The preliminary report includes scope and definition, market analysis, and technical analysis. Content of these reports will be discussed in the first Ad-hoc Working Group meeting (AHWG1) which is planned to take place in November 2019.

This 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 first revised EU Ecolabel criteria for the 'cosmetic products' product group. The proposal is written in a blue box and subsequently a rationale is given. A rationale summarises the research conducted during the first part of the revision process. The existing EU Ecolabel text (grey box) is included for each criterion in order to allow the reader to compare the proposals with the text in force.
- **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.

[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

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.

A brief description of these above-mentioned elements 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 a questionnaire on the current scope and definition. 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 has been done considering different relevant aspects.

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

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

Moreover, the database Mintel has been used for the qualitative analysis of the formulations of products available on the market. The latest developments, technical innovations and novelties regarding formulations and products functionalities have been also identified in the report, to cover the high innovation and research of this sector.

Using the formulations identified, an analysis of the health related impacts of cosmetic products has been done, taking REACH and CLP regulations as a basis.

A Life Cycle Assessment has been performed to identify the environmental contribution of each product and the most important (from the environmental point of view) life cycle stage of 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 has been updated by using the latest version of Simapro and ecoinvent. A new LCA modelling was performed for the product categories: skin care leave-on, sun care products (being this a special category of skin care products) and toothpaste. 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 awarded products was asked to the Competent Bodies in order to collect the data necessary to revise the existing EU Ecolabel criteria on hazardous substances and their current amendments, derogations or further modifications.

Based on all the aspects of this technical analysis, improvement potential actions have been identified.

Two questionnaires have been sent out to all registered stakeholders in the initial stage of the revision process. The answers of the stakeholders have been presented in the preliminary report. The information obtained during this preliminary phase of the revision process has been included in the preliminary report published along with this technical report.
Both documents (preliminary report and technical report) will serve as a basis for discussions with stakeholders in the 1st AHWG meeting foreseen to be held in November 2019.

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

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

The product group shall not cover products that are specifically marketed for disinfecting or anti-bacterial use. Anti-dandruff shampoos are allowed.

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

Skin care products includes creams, oils and lotions intended to be in contact with the epidermis, including aftersuns and self-tanning creams, make-up cleansers, exfoliants and sunscreens.

Animal care products include rinse-off products intended to be in contact with animal hair to clean them or to improve the condition of it, such as shampoos and conditioners for animals.

Existing complementary definitions

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

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

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

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

First complementary definitions proposal:

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

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

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

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

Rationale of the proposed name, scope and definitions

The existing product group definition is based on the definition contained in the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on

cosmetic products[3] (later referred to as Cosmetics Regulation), where according the article 2 a **cosmetic product** is defined as: a*ny substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.*

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

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

In addition, another questionnaire was launched during the revision process to obtain information regarding the following aspects:

- Proposal of the scope extension
- Existing EU Ecolabel criteria

This later questionnaire was answered by 50 respondents.

A general agreement on scope extension to additional products was expressed in stakeholders' responses to both questionnaires. For this reason, it is considered reasonable to extend the scope to other cosmetic products not currently covered.

The cosmetic group is a broad and heterogeneous product group. In order to analyse in a systematic way all products covered by the Cosmetics Regulation, the different products have been classified into categories considering both MINTEL[4] and PRODCOM databases.

Moreover, other products out of the scope of the Cosmetics Regulation, namely wet wipes, animal care products and intimate products, are also analysed in the preliminary report in order to identify the relevance of adding into the scope of the EU Ecolabel these product categories.

The categorisation proposed to be used in the revision of the scope is presented in Table 1. Products covered by the existing EU Ecolabel are marked in orange.

Table 1: Proposed categorization to be used during the revision of the scope. Products covered by the existing EU Ecolabel are marked in greenorange.

PROPOSED CATEGORIES		
SHOWER, BATH and OTHER BODY CLEANSER PREPARATIONS	**Bar soaps**	Products intended to be placed in contact with the epidermis and/or the hair system with a view exclusively or mainly to cleaning them.
	Liquid soaps	
	Shampoos	
	Feminine hygiene cosmetic products	
HAIR STYLING AND TREATMENT (Including rinse-off and not rinse-off)	**Conditioners**	Products to improve the condition of the hair
	Hair colorants	Hair preparation with colorants and dyes
	Hair treatment	Preparations for permanent waving or straightening of hair
	Hair styling	Hair modelling waxes, sprays, mousses and lacquers
SKIN CARE	Rinse-off	Exfoliants
	Leave-on	Creams, oils and lotions for the skin care, including aftersun and self-tanning creams, make-up cleansers, sun screens
SHAVING PREPARATIONS		Shaving foams and gels
MOUTHWASH		Mouth washes and oral perfumes

[3] 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

[4] MINTEL is a market intelligence agency

TOOTHPASTE		Dentifrices
DEPILATORY PRODUCTS	Rinse-off	Depilatory creams and foams
	Leave-on	Depilatory waxes and not rinse-off depilatory creams and foams
DEODORANTS AND ANTIPERSPIRANTS		Personal deodorants and anti-perspirants
PERFUMES		Perfumes, toilet waters & eau de cologne
PERFUMED BATH SALTS AND OTHER BATH PREPARATIONS	Bath salts	Perfumed bath salts
	Other bath preparations without cleaning function	Bath oils and other bath preparations without cleaning function
DECORATIVE COSMaETICS		All beauty and make-up cosmetics: body colour cosmetics, eye colour cosmetics, face colour cosmetics, lip colour cosmetics, multiuse colour cosmetics, nail colour cosmetics
NAIL ENAMEL REMOVER		Products intended to remove nail colour cosmetics
HAND SANITIZERS		Products intended to reduce the infectious agents on the hands
ANIMAL CARE PRODUCTS	Shampoos and conditioners	Rinse-off products for animal care products
	Other preparations	Perfumes and dry shampoos
INTIMATE GELS/LUBRICANTS PRODUCTS		Intimate products with formulations similar to products covered by the Cosmetics Regulation such as lubricants, anal creams and orgasm gels.

The selection of product categories to be included in the revised scope definition has been done considering the following relevant aspects:

- The potential risk of the product to be released to the environment. If the product doesn't end up in water, the environmental impact is minimised. When the EU Ecolabel criteria are developed, the focus should be on the stages where the product has the highest environmental impact. According to the results of the LCA report of the last revision, the release to water could reach the 14-20% of total product environmental impact
- The consumption of the different products, where if a product is widely used, the amount of this product that ends up in water could be higher.
- On the other hand, the EU Ecolabel aims to ensure that the most environmental friendly 10% to 20% of the products currently on the market can meet the criteria of the specific product group. Market data have been analysed in order to cover the products with higher market share.
- Moreover, the success of the EU Ecolabel depends on the interest of the stakeholders to award their products. The results of the preliminary questionnaire and the scope questionnaire have been considered in the methodology to assess the potential of inclusion of products.
- Article 11 of the EU Ecolabel Regulation[5] establishes that the EU Ecolabel criteria shall take into account existing criteria developed in officially recognised ecolabelling schemes in the Member States (EN ISO 14024 type I). The existing type I ecolabelling schemes have been identified and considered to expand the scope to the products covered by other environmental schemes.
- Finally, it is expected that products having similar ingredients to those currently included in the existing scope, would have a similar environmental profile. This would ease the inclusion of these type of products in this criteria revision.

[5] Regulation (EC) No 66/2010 of the European parliament and of the council of 25 November 2009 on the EU Ecolabel.

The potential to include other cosmetic products in the revised EU Ecolabel scope has been determined through a simple scoring system that establishes a classification of the proposed products as low, medium or high potential of inclusion.

A pre-selection of the products has been done considering the environmental hotspot of this product group: the potential risk of release into water. Products classified as "low risk of release into water" are proposed to be excluded from the scope extension without further assessment. The cosmetic products that are classified with low risk of release into water and, as a result, are not included in the scoring system presented in this section, are:

- Deodorants and antiperspirants
- Perfumes
- Decorative cosmetics
- Nail enamel remover
- Hand sanitizers
- Animal care products, other preparations.
- Intimate gels or lubricants

Based on the assessment included in the preliminary report the potential of inclusion in the scope for the different cosmetic categories has been determined.

The products resulting with a **high potential of inclusion** (skin care products, toothpaste and feminine hygiene cosmetic products) are suggested to be considered and they will be studied in the next tasks to evaluate the feasibility of their inclusion.

The products ranked with **low potential of inclusion** (depilatory products) are not proposed to be included in the revised scope, together with the products with **low risk of release into water** (deodorants and antiperspirants, perfumes, decorative cosmetics, nail enamel remover, hand sanitizers and intimate gels and lubricants).

Regarding the products with **medium potential of inclusion**, the following is proposed:

- **Hair styling and treatment products**: This category is proposed not to be included in the scope extension. The formulation (ingredients) largely differs from the formulation of the products included in the existing scope. Moreover, there are specific ingredients included in this product group (propellants, plasticisers, reducing agents, oxidising agent, alkaline agents and straightening agents) that probably won't be able to comply with EU Ecolabel toxicity requirements.
- **Mouthwashes**: this subcategory is proposed not to be included. This category differs from the category toothpaste, as the formulation of oral rinses and toothpastes is different. In this revision the most relevant product has been prioritized: toothpastes have higher market rates, and they are considered more as a priority by the participants to the questionnaires.
- **Perfumed bath salts and other bath preparations**: This category is proposed not to be included. Despite the fact that these products are considered rinse-off products, the market share of perfumed bath salts and other bath preparations is approximately of 2% (according to PRODCOM data). Moreover, the product does not seem to awake interest among the participants to the revision process.
- **Animal care products (shampoos and conditioners)**: This category is proposed to be included in the expansion of the scope. The formulation of these products is very similar to that of shampoos and conditioners for human use. Products with biocidal or antimicrobial activity are not eligible for EU Ecolabel and are therefore excluded.

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

Table 2: Summary of product groups proposed to be included in the revision of the EU Ecolabel criteria for rinse-off cosmetic products. Products in bold are already considered in existing criteria.

PROPOSED PRODUCT GROUPS		
SHOWER, BATH and OTHER BODY CLEANSER PREPARATIONS	Rinse-off	**Shampoo, shower preparations, liquid soaps** **Solid soaps** **Hair conditioners** **Shaving foams, shaving gels and shaving creams** Feminine hygiene cosmetic products
SKIN CARE PRODUCTS	Rinse-off	Exfoliants
	Leave-on	Lotions, creams and oils (including aftersun and self-tanning creams) Sun screen products Make-up cleanser
TOOTHPASTE	Rinse-off	Dentifrice Dental cleanser
ANIMAL CARE PRODUCTS[6]	Rinse-off	Shampoos Conditioners Other preparations

1.2.2 Key environmental aspects and relation with the criteria proposal

The environmental performance of the product should be considered throughout its life cycle. The EU Ecolabel and other national ecolabels of type I include the assessment of the environmental performance of different life cycle stages of the product, in order to cover all life cycle of cosmetics products and avoid problem shifting. Specific requirements exist for the raw material consumption (limitation on hazardous substances and renewable raw material criterion), packaging, use (including messages for consumers in order to reduce the product consumption), and end-of-life (criteria to reduce the environmental impact of rinse-off products).

The cosmetic sector is moving toward more sustainable products because of the actual consumer behaviours. Consumers value the efficacy and quality of the product firstly and furthermore they consider the environmental awareness, increasing the trend for natural and sustainable products[7].

Raw materials

The restriction of the most harmful substances and ingredients is important to reduce the environmental impact of the products. One example of conflictive ingredient is the microplastics.

[6] Products with biocidal or antimicrobial activity are not eligible for EU Ecolabel and are therefore excluded.
[7] Activity Reports: CE Consumer Insights 2017 (June, 2017), Cosmetics Europe. Available on line at: https://www.cosmeticseurope.eu/files/6114/9738/2777/CE_Consumer_Insights_2017.pdf

The Cosmetics Europe association recommended in 2015 to reduce the use of plastic microbeads for cleansing and exfoliating purposes in cosmetics products. The result was a reduction of 97% of use of plastic microbeads in cosmetics between 2011 and 2017.

In addition to the excluded or limited substances in the formulation, there are other examples to improve the environmental performance of a cosmetic product, such as ensuring the sustainable source of ingredients. The use of vegetable raw materials has been increased over the years; the sustainability of these raw materials should be certified.

The Roundtable on Sustainable Palm Oil (RSPO) certification was created to ensure the credibility of palm oil sustainability claims[8]. Current EU Ecolabel decisions for cosmetic products include a specific criterion to certify the origin of the raw material.

Production or manufacturing

According to the Technical Analysis Report[9] of the previous revision, the manufacturing stage causes the 13% of the total environmental impact of a cosmetic product. The environmental performance of the manufacturing stage is affected by different sources: energy consumption, water consumption and waste water treatment, and waste generated during the production.

Packaging

Packaging innovation is playing a key role in influencing purchasing decisions. Consumers are willing to pay more for products with environmentally friendly packaging (49% of Spanish consumer answered that they would pay more for products sold in environmentally friendly packaging[10]).

Existing EU Ecolabel criteria for rinse-off cosmetic products include specifications to reduce the environmental impact due to packaging: reducing the weight of the packaging or using recyclable materials and components.

Transport or distribution

Despite the distribution of cosmetics is the life cycle stage with lower environmental contribution to the total impact, the cosmetic sector is developing practices to reduce the emissions associated with the transport of cosmetics. The packaging of the product is related to this life cycle stage: improving the capacities of the product, a large number of units can be transported simultaneously.

Use

The use phase of rinse-off products has an important environmental impact. However, it is difficult to reduce the environmental impact of this life cycle stage because it depends on the consumer behaviour and decision. The impact is related with the water and energy consumed during the use: around 90% of the total CO_2 emissions across the product life cycle of shampoo stems from the heating and use of tap water[11].

End-of-life

The product that ends-up in water generates an environmental impact due to the harmful substances included in the formulation. Restriction on the toxicity to aquatic organisms and on the minimum biodegradability of the product ingredients is included in existing EU Ecolabel criteria in order to reduce the environmental impact of this life cycle stage.

Previous revision relevant aspects

The previous revision of the product group rinse-off cosmetic (previously named Soaps, Shampoos and Hair Conditioners) took place during 2012. For the previous revision different

[8] https://rspo.org/certification

[9] Revision of European Ecolabel Criteria for Soaps, Shampoos and Hair Conditioners, Technical Report. August 2012. Available online at: http://susproc.jrc.ec.europa.eu/Rinse-off_cosmetic_products/docs/Technical%20analysis%20report_2.pdf

[10] Plastic Free, MINTEL. Benjamin Punchard, December 2018.

[11] Environmental Sustainability. The European Cosmetics Industry's contribution 2017-2018. Cosmetics Europe, the personal care association. Available online at: https://www.cosmeticseurope.eu/files/9615/2872/3399/CE_Environmental_Sustainability_Report_2018.pdf

products were analysed to identify the environmental performance of each one and the life cycle stages with higher impact. The most relevant results obtained during the previous technical analysis are presented in this section.

A Life Cycle Assessment approach was taken into account to evaluate the different products selected and to obtain an overall environmental profile of the products. To assess the environmental impact, different sources of information were consulted:

- Existing studies about similar products.
- Information from products database (Database Mintel)

The Technical Analysis Report[9] included the study of four products: liquid soap, solid soap, shampoo and hair conditioners. The main results of the LCA are presented below:

- Raw material extraction and transformation of chemicals have a relevant impact due to the energy and resource consumed to synthesize the different ingredients. The results obtained indicated that the chemicals contribute to 44% of the total environmental impact in case of solid soaps, to 23% for hair conditioners, to 9% for shampoo and to 10% for liquid soaps).Liquid soaps have the highest environmental impact in this stage because the amount of water in the formulation is quite low. On the other hand, hair conditioners include the silicones or waxes that can increase the environmental performance of this stage.
- The manufacturing stage has relevant contribution (from 10 to 13%) in the overall environmental impact of the product, because of the energy consumed during the production phase.
- The packaging stage contribution is between 17 to 24%, depending on the product category evaluated.
- Distribution has a contribution lower than 10% of the global environmental impact of products.
- For the use phase, only water consumption was considered as an input. The environmental contribution of this stage depends on the amount of water needed in the use stage (solid soap was considered as hand soap and has the lowest environmental contribution in this stage).
- The generation of wastewater after use and the treatments of this wastewater were considered in one life cycle stage: release of products to water. The load of this stage in the overall environmental impact of the products was between 14 and 20%.
- Finally, the environmental impact generated for the packaging waste was lower than 2%.

In order to allow fair comparison between the products included in the current criteria and the new products proposed for inclusion in the scope, the LCA of the products included in the current criteria has been actualized considering the new version of the Simapro software and the Ecoinvent database. On the other hand, three new products have been 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 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.

Liquid soap

The results are presented for a liquid soap sold in a 300ml bottle. The percentage of contribution of the different life cycle stages depends on the impact category considered. The end-of-life is the life cycle stage with higher contribution for most of the impact categories analysed

(contributing to between 30% to 96% of the total impacts), except for Freshwater ecotoxicy, Land use and Water resource depletion impact categories. The raw materials extraction has the highest contribution in terms of Land use (57%) and Ozone depletion (29%) impact categories, but its contribution is minor in all other impact categories. The use stage contributes generally more than the extraction of raw materials, especially in terms of Water resource depletion and Mineral, fossil and renewable resource depletion (52% and 38% of impacts, respectively). The packaging, the manufacturing and the transport phases contribute to a minor extent to the environmental impacts of liquid soap.

Solid soap

The end-of-life is the life cycle stage with higher contribution for most of the impact categories analysed (contributing between 20% and 90% of total impacts), except for Land use, where it contributes to 5% of total impacts only. The raw materials extraction has also an important contribution (between 20% and 50% of total impacts), except for impacts to Land use, where it represents almost 90% of total impacts, and Human toxicity (cancer and non-cancer) and Eutrophication (freshwater and marine), where its contribution stays below 10% of total impacts. The use stage contributes generally less than the extraction of raw materials, except for the categories Ionising radiation, Freshwater ecotoxicity, Water depletion and Mineral, fossil and renewable resource depletion, where it contributes to more than 20% of the impacts. The packaging, the manufacturing and the transport phases contribute to a minor extent to the environmental impacts of solid soap.

According MINTEL database, the 23% of the solid soaps are sold with secondary packaging. For this reason, one scenario including a secondary packaging grouping three products has been assessed and compared with the base case.

The use of secondary packaging implies a greater environmental impact in most of the impact categories. Nevertheless, there are some impact categories showing lower environmental impact when the secondary packaging is included: Ionizing radiation, Freshwater eutrophication, and Mineral, fossil and renewable resource depletion. The environmental benefits are generated due to the recycling of the cardboard packaging.

Shampoo

The contribution of each life cycle stage is similar to the distribution of the liquid soaps: the end-of-life is the life phase contributing the most across all impact categories, representing more than 50% of the contribution in Human toxicity (cancer effects and non-cancer effects), Acidification, Terrestrial eutrophication, Freshwater eutrophication, Marine eutrophication and Freshwater ecotoxicity. The use stage is also an important life cycle phase, representing between 13% and 50% in most impact categories apart from Human toxicity, non-cancer and Marine eutrophication were it contributes to the impacts with less than 5%. Differently than for liquid and solid soap products, raw material extraction represents in general a minor share of the total impacts (generally less than 10%), except for the 20%-contribution to Ozone depletion and 40%-contribution to Land use impact categories. The packaging, the manufacturing and the transport phases contribute to a minor extent to the environmental impacts of shampoo.

Hair conditioner

The end-of-life is the life phase contributing the most across all impact categories, representing more than 50% of the contribution in Human toxicity, Terrestrial eutrophication, Freshwater eutrophication and Marine eutrophication. The use stage is also an important life cycle phase, representing between 15% and 52% in most impact categories apart from Human toxicity, non cancer and Marine eutrophication were it contributes to the impacts with less than 5%. Differently than for liquid and solid soap products, raw material extraction represents in general a minor share of the total impacts (generally less than 10%), except for the 20%-contribution to Resource depletion, 40%-contribution to Ozone depletion and 55%-contribution to Land use impact categories. The packaging, the manufacturing and the transport phases play a moderate

role in terms of Climate change, Photochemical ozone formation, Acidification and Terrestrial eutrophication impact categories, otherwise contributing to a minor extent to the environmental impacts of hair conditioners.

Toothpaste

Packaging is the life cycle stage with the highest contribution to the environmental performance of toothpaste, with a share of total impacts between 20% and 50% in nearly all impact categories, except for Marine eutrophication and Land use impact categories (less than 5% of impacts). This life cycle stage is associated with impacts that were held by the use phase in the previous product groups. End-of-life also represents an important life stage (between 5 and 35% of total impacts in most impact categories and more than 50% of total impacts in terms of Human toxicity non-cancer, Freshwater eutrophication and Marine eutrophication. The contribution of the use phase is overall reduced with repsect to the previously analysed products, and accounts for between 1% and 28% of total impacts. The raw material extraction scores generally less than 20% of total impacts, except for Land use impact category where it represents more than 80% of impacts. The transport and the manufacturing stage have overall the lowest contribution to the environmental impacts of toothpaste.

Skin care product

The environmental impact associated with the use stage and the end-of-life of the product is 0 because it is considered that the product does not end-up in the environment. The impact generated for a skin care product is caused by the raw materials extraction, the manufacturing stage, the packaging of the product (including the waste treatment of the packaging) and the transport stage.

The life cycle stage with the higher contribution to the environmental performance of the skin care product is the raw material extraction, which represents between 40% and 75% of impacts in nearly all impact categories except for Human toxicity non-cancer (18% of impacts) and Land use (95% of impacts). The remaining share of the impacts is distributed to a similar degree between the manufacturing, the packaging and the transport stages, with the exception of Human toxicity non-cancer (where more than 50% of impacts are caused by the manufacturing stage) and Freshwater ecotoxicity (where 50% of impacts are caused by the packaging phase).

Sun care product

The use stage of this product group does not have an environmental impact, however, part of the product can end-up in sensitive environments such as the sea or ocean. The environmental impact related with the contamination of the ocean has been presented from a LCA perspective.

The environmental impact of raw materials is very high due to the use of titanium dioxide as UV-filter, generating between 70% of climate change and 96% of total impacts The other life cycle stages have a much lower contribution and overall similar between each other, although the manufacturing stage represents 25% of the Human toxicity (non-cancer) impacts and the packaging stage represents 20% of the Freshwater ecotoxicity impacts.

Comparison of products

The products associated with the highest environmental impact across all impact categories are solid soap, sun care products and liquid soap, all of them in the same order of magnitude. Exceptions are the impact of solid soap on Land use and the impact of sun care products on Mineral, fossil and renewable resource depletion, both of them scoring much higher than the other product groups. The product shampoo performs slightly better than the previous product groups, but still results in a significant burden on the environment in all impact categories. Finally, the product groups hair conditioner, skin care (non rinse-off) and toothpaste are the categories providing the smallest environmental burdens. This analysis may suggest that the daily use of liquid soap, solid soap, shampoo and sun care products provides a higher environmental burden. This could be taken into account in the further stages of the revision of the criteria of cosmetic products.

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 the following table:

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

Existing EU Ecolabel criteria	Criteria proposal	Environmental aspects	
Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)	Criterion 1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)	Hazardous substances Emission to soil/ water	It limits the hazardous substances that can be included in the product, limiting environmental and health risks for users.
Criterion 2. Biodegradability	Criterion 2. Biodegradability		It ensures that the overall aquatic toxicity is limited.
Criterion 3. Excluded or limited substances and mixtures	Criterion 3. Excluded or limited substances and mixtures		It ensures that the ingredients are biodegradable and will not persist in water.
Criterion 4. Packaging	Criterion 4. Packaging	Raw materials extraction and processing Spillage during use phase	It ensures prevention of spillage during use and promotes the minimisation of use of plastics and its recyclability.
Criterion 5. Sustainable sourcing of palm oil, palm kernel oil and their derivatives	Criterion 5. Renewable ingredients		It promotes that renewable ingredients used for the lubricant manufacturing comes from sustainable origin.
Criterion 6. Fitness for use	Criterion 6. Fitness for use	Efficiency during use Waste generation and disposal	It guarantees that the product meets certain quality (technical performance) requirements foreseen for the different applications. It reminds consumers to dispose of the packaging in a responsible manner.
Criterion 7. Information on EU Ecolabel	Criterion 7. 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 to cover the different life stages and addressing the environmental hot spots and key parameters identified in the preliminary report.

For the first AHWG meeting existing criteria are suggested to be kept, however the content have been modified in the light of the research conducted in the preliminary report. Where relevant, the names of criteria have been revised accordingly to the modifications. The following table shows the changes in the criteria structure proposed along the revision:

Table 4: Comparison of the criteria structure

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

2 ASSESSMENT AND VERIFICATION

Existing assessment and verification

a) Requirements

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

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

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

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

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

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

The following information shall be provided to the competent body:

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

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

b) Measurement thresholds

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

[References:

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

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

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

First proposal for assessment and verification

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

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

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

Competent bodies shall preferentially recognise attestations which are issued by bodies

accredited in accordance with the relevant harmonised standard for testing and calibration laboratories (General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)) or with the principles of Good Laboratory Practice (GLP); and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services. Accreditation shall be carried out in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council(1).

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

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

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

A list of all intentionally added substances in the final product shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS No, No and INCI designations, DID No (3), the ingoing quantity including and excluding water, the function and the form of all ingredients 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 (4) 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.

[References:

(1) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218/30, 13.8.2008)

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

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

(4) 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).]

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. A new statement, in line with recently voted products, has been included in the text making reference to the Regulation (EC) 765/2008 of the European Parliament and of the Council.
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 has been 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 has been added as this is a legal pre-requisite and applies horizontally for all EU Ecolabel products.
Section "*(b) Measurement thresholds"* has been removed from this general assessment and verification section as the applicability of each criterion is proposed to be indicated in the text of each single criteria to ensure more clarity.

3 CRITERIA PROPOSAL

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

Existing criterion 1: Toxicity to aquatic environment

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

Table 1

CDV limits

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

The CDV is calculated using the following equation:

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

Where:

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

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

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

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

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

Detergents Ingredients Database (DID) list

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

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

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

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

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

Worst case approach:

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

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

First proposal for criterion 1: Toxicity to aquatic environment

This criterion applies to final product

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

Table 1

CDV limits

Product	CDV (l/g AC)
Shampoo, shower preparations and liquid soaps	11 000
Solid soaps	2000
Hair conditioners	12 000
Shaving foams, shaving gels, shaving creams	20 000
Shaving solid soaps	2000
Feminine hygiene cosmetic products	12000
Toothpastes	12000
Skin care products	12000
Animal care products	12000

The CDV is 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 intentionally added 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 intentionally added substance

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

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

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

Detergents Ingredients Database (DID) list

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

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

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

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

Worst case approach:

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

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

Rationale of the proposed criterion text

Critical dilution volume (CDV) is used in the EU Ecolabel to assess the toxicity of products with respect to the aquatic environment. This criterion is especially relevant for rinse-off products which are released entirely 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 the substances. It is considered a very important single parameter to ensure that an EU ecolabelled product complies with high environmental standards.

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 liters 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 complete formulation of a product. Rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC. So,

the CDV of each substance is linked to the share (%) of other substances. As a consequence, the more substances are added, the less the CDV of dangerous substances is important and the CDV can be decreased by adding substances.

During the previous revision, it was considered to modify the method for CDV calculation; however finally it was decided to keep the calculation as it was in criteria from 2007[2]. Details of the discussions carried out during last revision process are available in previous revision technical report[12].

Out of the EU Ecolabel questionnaire sent out to stakeholders at the beginning of this revision, 56% of the respondents consider that the current limits for CDV are adequate, while, 16% do not agree with the current criterion and thresholds. Out of them 6% of the respondents consider they are too restrictive (industry representatives) other 10% of them think that they should be more restrictive.

The product category "shampoo, shower preparations and liquid soaps" is the most controversial category. Different Competent Bodies have provided the CDV value of the products which currently have EU Ecolabel licences (Table 5): all products have a CDV value below 10,500 l/g AC. Nevertheless, the compliance with the current threshold value could be challenging when a shampoo is designed with specific effects and claims.

Based on the information provided by Competent Bodies, it was found that the maximum CDV value for the product category "shampoo, shower preparations and liquid soaps" certified with the EU Ecolabel is 11000 l/g AC.

Table 5: CDV descriptive statistics of analysed ecolabelled products and current limits of the Criterion 1.

Product	Current CDV threshold (l/g AC)	Survey opinion			
		Range	Average	50th percentile	75th percentile
Shampoo, shower preparations and liquid soaps (41 products)	18 000	215–10 912	7 063	7 186	10409
Solid soaps	3 300				
Hair conditioners (2 products)	25 000	2957-3742	3350	-	-
Shaving foams, shaving gels and shaving creams	20 000	-	-	-	-
Shaving solid soaps	3 300	-	-	-	-

Table 6 shows the values of CDV included in other labelling schemes. The threshold values for the CDV of the Nordic Swan scheme have a maximum CDV of 12000 l/g AC. All rinse-off products have the same CDV, except solid and foam soaps, which have lower CDV: 2000 l/g AC and 1000 l/dose respectively.

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

Table 6: Summary of CDV limit requirements in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.

<table>
<tr><th>Nordic Swan</th><th>Blue Angel</th><th>Bra Miljöval</th></tr>
<tr>
<td>MORE RESTRICTIVE THAN EU ECOLABEL
The product's CDV must not exceed the following threshold values:
<table>
<tr><th>Type of product</th><th>CDV chronic (l/g AC)</th></tr>
<tr><td>Solid soap</td><td>2000</td></tr>
<tr><td>Other rinse-off products</td><td>12000</td></tr>
<tr><th>Type of product</th><th>CDV chronic (l/dose)</th></tr>
<tr><td>Foam soap</td><td>1000</td></tr>
</table>
</td>
<td>SAME CRITERION AS EU ECOLABEL</td>
<td>The ingredient must have an acute aquatic toxicity where LC50, EC50 and IC50 is > 1 mg/l.
The ingredient must have a chronic aquatic toxicity where NOEC/ECx is > 0.1 mg/l.</td>
</tr>
</table>

In order to align the EU Ecolabel with other regional ecolabels, for this first proposal, it is suggested that current CDV thresholds are lowered in this revision. Moreover, based on the outcome of the consultation, the threshold values for "shampoo, shower preparation and liquid soaps" could be stricter because the maximum value available for the products certified is lower than 11000 l/g AC.

With regards to the other product categories, values have been aligned to Nordic Swan. For "Hair conditioners" and "shaving foams, shaving gels, shaving creams" which present high values due to the lack of data in previous revision, it is suggested to at least align to Nordic Swan. For hair conditioners there is evidence that existing EU Ecolabel licences (for at least 2 products) are able to achieve this. No data is available for shaving foams; therefore the current CDV threshold of 20000 l/g AC remains valid.

In relation to the product categories proposed to be inserted in the scope, 12000 l/g AC has been proposed as CDV threshold value, in the absence of data at this stage and aiming to align with Nordic Swan.

Minor wording adjustments have been introduced in line with recently voted EU Ecolabel products and ingoing substances has been replaced by intentionally added substances.

Question to stakeholders
Stakeholders are requested to provide data on CDV values of existing and new proposed categories.

Rationale of proposed "assessment and verification"

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

For the verification of the criterion, 66% of the stakeholders used the spreadsheet available on the EU Ecolabel website and 33% of them find out that it is not easy to use. Difficulties to use the spreadsheet have been found by stakeholders.

No changes have been introduced in the verification text.

3.2 CRITERION 2: Biodegradability

Existing criterion 2: Biodegradability

a) Biodegradability of surfactants

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

(b)Biodegradability of organic ingoing substances

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

Table 2
aNBO and anNBO limits

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

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

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

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

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

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

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

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

(1)Until 1 December 2015:

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

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

or

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

(2) After 1 December 2015:

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

Documentation of anaerobic biodegradability

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

Extrapolation for substances not listed in the DID-list

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

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

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

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

First proposal for criterion 2: Biodegradability

This criterion shall be fulfilled by each intentionally added substance at or above the concentration of 0,010 % weight by weight in the final product.

a) Biodegradability of surfactants

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

(b)Biodegradability of organic intentionally added substances

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

Table 2
aNBO and anNBO limits

Product	aNBO (mg/g AC)	anNBO (mg/g AC)
Shampoo, shower preparations and liquid soaps	25	25
Solid soaps	10	10
Hair conditioners	15	15
Shaving foams, shaving gels, shaving creams	70	40
Shaving solid soaps	10	10
Feminine hygiene cosmetic products	15	15
Toothpastes	15	15
Rinse-off skin care products	15	15
Animal care products	15	15

For leave-on skin care products:
At least 95% by weight of the total content of organic ingoing substances must be:
-readily biodegradable (OECD 301 A-F), and/or
-lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioaccumulable, and/or
-lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
-lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol)
Exempt are: UV filters in sun products

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

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

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

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

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

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

Documentation of ready biodegradability

The following test methods for ready biodegradability shall be used:

(1)Until 1 December 2015:

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

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

or

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

(2) After 1 December 2015:

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

Documentation of anaerobic biodegradability

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

Extrapolation for substances not listed in the DID-list

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

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

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

(3)Perform low-dosage degradability test. If new testing is necessary, and in the case of

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

Rationale of the proposed criterion text

Criterion 2 is divided in two parts:

- Biodegradability of surfactants: all surfactants shall be readily biodegradable under aerobic conditions and biodegradable under anaerobic conditions.
- Biodegradability of organic ingoing substances: the content of organic substances aerobically non-biodegradable and anaerobically non-biodegradable is limited in this criterion.

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[13]. Surfactants in this respect are considered relevant due to the fact that they are used in high amounts in liquid soaps, shampoos and conditioners[14].

Most surfactants affect to a greater or lower extent the product toxicity to aquatic organisms due to their surface activity which allows reaction with the biological membranes of the organisms. The biological degradability varies according to the nature of the carbohydrate chain of the surfactant. In general, the linear chains are more readily degradable than branched chains. Also the toxic effects vary with the chain structure. Usually an increase of the chain length in the range of 10 to 16, leads to an increase in toxicity to aquatic organisms[15].

During the last revision main discussions arose on the issue if, from the environmental point of view, all surfactants should be readily aerobically and anaerobically biodegradable. Some participants strongly supported the requirement for all surfactants to be readily aerobically and anaerobically biodegradable; other stakeholders disagreed with the importance of the anaerobic biodegradability and questioned its environmental relevance[16] as well as the feasibility of fulfilling the respective criterion. Finally, based on the scientific evidence detailed in previous technical report[12], it was proposed to keep the proposal from the previous draft stating that all surfactants should be readily aerobically and anaerobically biodegradable.

The threshold values for aerobic and anaerobic biodegradability were extensively discussed with the stakeholders during last revision. Main concerns regarding decreasing too much the values in the criterion on biodegradability of organic substances was related to the consequences for the possibility of using perfumes in the product group under study. It was pointed out that

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

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

[15] Procter & Gamble (http://www.scienceinthebox.com/en_UK/programs/natural_synthetic_en.html)

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

important part of non-biodegradable substances can be assigned to fragrances; thus the concentration of perfume has direct influence on the biodegradability of the product.

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

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

According to the information provided by Competent Bodies (Table 7), all provided products include surfactants in their formulation. Regarding the aerobic non-biodegradability of the products currently certified as EU Ecolabel, the maximum threshold is 25,0 mg/g AC. The 75th percentile is 24,6 mg/g AC, this means that the 75% of the products considered are at or below that value.

Table 7: products and current limits of the Criterion 2.

Product	Current aNBO (mg/g AC)	Information provided			
		Range	Average	50th percentile	75th percentile
Shampoo, shower preparations and liquid soaps (41 products)	25	0,0 – 25,0	14,1	12,7	24,6
Solid soaps	10				
Hair conditioners (2 products)	45	9,3 – 13,6	11,5	-	-
Shaving foams, shaving gels and shaving creams	70	-	-	-	-
Shaving solid soaps	10	-	-	-	-

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

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

Product	Current anNBO (mg/g AC)	Information provided			
		Range	Average	50th percentile	75th percentile

Shampoo, shower preparations and liquid soaps (41 products)	25	0,0 – 25,0	17,2	23,2	24,6
Solid soaps	10				
Hair conditioners (2 products)	45	9,3 – 13,6	11,5	-	-
Shaving foams, shaving gels and shaving creams	40	-	-	-	-
Shaving solid soaps	10	-	-	-	-

An analysis of other ecolabels has been performed in order to study how biodegradability and bioaccumulation is addressed in other schemes (see Table 9).

Table 9: Summary of biodegradability limit requirements in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.

<table>
<tr><th>Nordic Swan</th><th>Blue Angel</th><th>Bra Miljöval</th></tr>
<tr><td colspan="3">(a) Biodegradability of surfactants</td></tr>
<tr><td>SAME CRITERION, WITH EXEMPTIONS:
The following are exempt from the requirement on anaerobic degradability:
• Emulsifiers
• Surfactants in toothpaste
In addition requirement on toothpaste:
Toothpaste must not contain sodium lauryl sulphate (SLS).</td><td>SAME CRITERION AS EU ECOLABEL</td><td>The surfactant must be readily biodegradable according to OECD 301, OECD 310 or an equivalent test.
The surfactant must be anaerobically biodegradable to 60 % according to ECETOC No 28, ISO 11734, OECD 311 or an equivalent test.</td></tr>
<tr><td colspan="3">(b) Biodegradability of organic ingoing substances</td></tr>
<tr><td>Organic substances that are not readily biodegradable must not exceed the limits:
<table>
<tr><th rowspan="2">Type of product</th><th>aNBO</th><th>anNBO</th></tr>
<tr><th colspan="2">mg/g AC</th></tr>
<tr><td>Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant</td><td>15</td><td>15</td></tr>
<tr><td>Solid soap</td><td>5</td><td>5</td></tr>
<tr><td></td><td colspan="2">mg/ dose</td></tr>
<tr><td>Foam soap</td><td>2,5</td><td>2,5</td></tr>
</table></td><td>SAME CRITERION AS EU ECOLABEL</td><td>The ingredient must have a BCF < 500 or a log Kow < 4. Exceptions:
a) LC50, EC50 and IC50 is > 100 mg/l or NOEC/ECx is > 10 mg/l.
b) it can be shown that the preservative is broken down very quickly into substances whose BCF or log Kow satisfies the requirements.
c) it is not bioavailable (molar mass > 700 g/mol).</td></tr>
<tr><td>Nordic Swan includes restrictions for those products leave-on:
At least 95% by weight of the total content of organic ingoing substances must be:
-readily biodegradable (OECD 301 A-F), and/or
-lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioaccumulable, and/or
-lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
-lowest aquatic toxicity NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol)
Exempt are: UV filters in sun products</td><td></td><td></td></tr>
</table>

Considering this background, for the first proposal, the following changes are proposed at this stage:

Sub-criterion (b) Biodegradability of organic ingoing substances:

- Nordic Swan includes stricter restrictions than EU Ecolabel for the different products. Nevertheless, according to the information provided by CBs of current licences only the threshold value for hair conditioners could be lowered. Hair conditioners have a maximum biodegradability (for both of them) of 13,6 mg/g AC, while existing threshold is 45 mg/g AC. Hair conditioners value is suggested to be lowered to 15 mg/g AC.
- In line with Nordic Swan, a threshold of 15 mg/g AC has been proposed for the product categories suggested to be included in the scope, as better data could not be found.
- Taking into account that a higher risk to end up into the environment is related with a higher potential environmental impact, it could be considered to assign a different (higher) threshold value for the biodegradability values for the leave-on products (skin care). As Nordic Swan includes restrictions for leave-on product, this restriction is suggested to be included for the EU Ecolabel of the skin care product category.

Question to stakeholders
-Suggestions on how to clarify the text if needed are welcome, -Nordic Swan includes the following exemptions on criterion on biodegradability of surfactants: *"The following are exempt from the requirement on anaerobic degradability:* *Emulsifiers* *Surfactants in toothpaste"* Are these exemptions considered relevant to be included?

Rationale of proposed assessment and verification

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

At this stage of the process, no changes have been introduced in the verification text.

Question to stakeholders
-Stakeholders are requested to provide suggestion on how verification could be improved.

3.3 CRITERION 3: Excluded or limited substances and mixtures

Existing criterion 3: Excluded or limited substances and mixtures

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

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

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

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

(b) Hazardous substances and mixtures

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

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

Table 3
Hazard statements and Risk Phrases

Hazard Statement	Risk Phrase
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R23/26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45

H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60/61/60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60/63
H360Df May damage the unborn child. Suspected of damaging fertility	R61/62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23/24/25/26/27/28
H371 May cause damage to organs	R68/20/21/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25/24/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20/21/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41
Sensitising substances	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43

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

Table 4

Derogated substances

Substances	Hazard statements	Risk phrases
Surfactants (in total concentrations < 20 % in the final product)	H412: Harmful to aquatic life with long-lasting effects H413: May cause long-term adverse effects to aquatic life	R52-53 R53
Fragrances (6)	H412: Harmful to aquatic life with long-lasting effects H413: May cause long-term adverse effects to aquatic life	R52-53 R53
Preservatives (7)	H411: Toxic to aquatic life with long-lasting effects H412: Harmful to aquatic life with long-lasting effects H413: May cause long-term adverse effects to aquatic life	R51-53 R52-53 R53

Zinc pyrithione (ZPT) used in anti-dandruff shampoos	H400 Very toxic to aquatic life	R50

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

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

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

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

(ii) For substances that have been registered under Regulation (EC) No 1907/2006 and which do not meet the requirements for CLP classification: Information based on the REACH registration dossier confirming the non-classified status of the substance;

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

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

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

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

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

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

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

(d) Fragrances

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

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

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

(e) Preservatives

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

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

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

(f) Colorants

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

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

[References:

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

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

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

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

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

First proposal for criterion 3: Excluded or limited substances and mixtures

For the purpose of criterion 3 impurities stated in the SDS, whose presence in the final product equals or exceeds 0.010%, shall comply with the same requirements as the intentionally added substances.

3(a) Hazardous substances

This criterion shall be fulfilled by each intentionally added substance present at or above the concentration of 0,010 % weight by weight in the final product.

3(a)(i) Final product

The final product shall not be classified in accordance with any of the hazard statements included in Table 3.

3(a)(ii) Substances

Substances that meet the criteria for classification with the hazard statements listed in Table 3 shall not be intentionally added in the final product.

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

Table 3 Restricted hazard statements

Acute toxicity	
Categories 1 and 2	**Category 3**
H300 Fatal if swallowed	H301 Toxic if swallowed
H310 Fatal in contact with skin	H311 Toxic in contact with skin
H330 Fatal if inhaled	H331 Toxic if inhaled
H304 May be fatal if swallowed and enters airways	EUH070 Toxic by eye contact
Specific target on organ toxicity	

Category 1	**Category 2**
H370 Causes damage to organs	H371 May cause damage to organs
H372 Causes damage to organs through prolonged or repeated exposure	H373 May cause damage to organs through prolonged or repeated exposure
Respiratory and skin sensitisation	
Category 1A	**Category 1B**
H317 May cause allergic skin reaction	H317 May cause allergic skin reaction
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled
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	
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	

This criterion does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006(*) which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any intentionally added/formed substance at or above the concentration of 0.010% weight by weight in the final product.

[the content of the below table will be filled in as a result of the evaluation of justified derogation requests substantiated with technical rationale for the need of derogation, provided by the stakeholders to the project team]

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

Table 4 Derogated substances

Substances	Hazard statements

3(b) Specified excluded substances

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

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

(ii)——Nitromusks and polycyclic musks;

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

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

(v)The following preservatives: triclosan, parabens, formaldehyde releasers, benzalkonium chloride;

(vi)Microplastics (*);

(vii)Nanosilver;

(viii)The fragrance tetramethyl acetyloctahydranophthalenes (OTNE);

(ix)Sodium hypochlorite, chloramine and sodium chlorite;

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

(xi)Cocamide DEA;

(xii)The phthalates Di-n-Octyl-Phthalate (DNOP) and Diethyl phthalate (DEP);

(xiii)Sodium Lauryl Sulfate (SLS)

(xiv)Substances classified as endocrine disruptors.

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

The final product shall not contain any intentionally added substances that have been identified in accordance with the procedure described in Article 59(1) of Regulation (EU) No 1907/2006 which establishes the candidate list for substances of very high concern at or above the concentration of 0.010% weight by weight in the final product.

3(d) Fragrances

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

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

3(e) Preservatives

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

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

3(f) Colorants

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

3(g) UV filters

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

All organic UV filters contained in the product:

- must not be bioaccumulating (BCF<100/logKow<3) or must have a lowest measured toxicity of NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l

-if including nano TiO_2, must fulfil the conditions expressed in SCCS/1516/13 (*)

-if including nano TiO_2 coated with either silica and cetyl phosphate (up to 16% and 6% respectively); alumina and manganese dioxide (up to 7% and 0.7% respectively); or alumina and triethoxycaprylylsilane (up to 3% and 9% respectively), the product must not be in the form of powders or sprayable products

Assessment and verification:

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

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

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

- SDS of intentionally added mixtures and their concentration in the final product.
- SDS of intentionally added substances and their concentration in the final product.

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

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

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

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

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

To demonstrate compliance with 3(g) the applicant shall provide: copies of the SDS of any UV filter added together with information on its BCF and/or log K_{ow} value, or lowest available NOEC/ECx/EC/LC50 value. In addition, a declaration that, if used, nano TiO2 fulfils the conditions expressed in SCCS/1516/13 (*) and SCCS/1580/16 (*) must be provided.

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

*'*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.*

[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).

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

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

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

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

Rationale of the proposed criterion text

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

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

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

In addition a new sub-requirement on UV filters have been added to take into account in this criterion also newly proposed to be added to the scope product category of sunscreens. Therefore, the following has been added:

7. Sub-criterion (g): UV Filters

Wording of the existing criteria have been slightly modified to align it with the wording of the most recently adopted EU Ecolabel criteria. Several additional changes have also been introduced.

The rationale and relevant changes to the single criteria are presented separately for each sub-criterion, following the order of the criteria as they appear in the revised proposal:

- ***Requirement 3(a) Hazardous substances***

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

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

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

An analysis of other ecolabels has been performed in order to study how the exclusion of certain hazardous substances and mixtures according to their hazard classification is addressed in other schemes (see Table 10). The other labelling schemes include criteria equal to or less stringent than the EU Ecolabel.

Table 10: Summary of restrictions on hazardous substances and mixtures content in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel

Nordic Swan	Blue Angel	Bra Miljöval
3(a) Hazardous substances		
Substances classified as environmentally hazardous according to Regulation 1272/2008/EEC may be included in the product to a maximum: *100·c H410+10·cH411+cH412 ≤ 2.5%* *where c is the fraction of the product, measured in percentage by weight, made up of the classified substance.* *Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.* *Surfactants, regardless of their function, classified with H411 or H412 are exempted from the requirement, on condition that they are readily degradable and anaerobically degradable.*	**SAME CRITERION AS EU ECOLABEL**	*Requirements only for specific ingredients:* •*surfactants* •*Preservatives* •*oils, fats and waxes (these ingredients that are exempt from registration according to Annex V of the REACH Regulation No 1907/2006)* •*emulsifier/emollient* •*additives* *The perfume or aroma (as such and not the individual substances) must not be hazardous to the aquatic environment according to the following classifications: H400, H410, H411, H413.*

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

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

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

-when it is not technically feasible to substitute these substances as such, or via the use of alternative materials or designs,

-or in the case of products which have a significantly higher overall environmental performance compared with other goods of the same category

In this first revised proposal, removing the derogation for ZPT used in anti-dandruff shampoos is suggested based on the following justification:

Zinc pyrithione (CAS 13463-41-7) is included in Annex III[17] of Cosmetics Regulation (entry 101) and is allowed in a concentration up to 0.1% in leave-on hair products. Furthermore, ZPT

[17] Annex III of Cosmetics Regulation (EC No 1223/2009): List of substances which cosmetic products must not contain except subject to the restrictions laid down.

is also regulated as a preservative in rinse-off products (excluding oral hygiene products) in concentration of up to 0.5% in general and up to 1.0% in hair products (Annex V18, entry 8).
ZPT has been subject to different safety evaluations by the Scientific Committee on Consumer Safety (SCCS). The last evaluation[19], published in February 2018, was carried out considering new studies available for a re-assessment of the safety of ZPT as an anti-dandruff agent in rinse-off hair care products at a maximum concentration of 2.0%. In the light of the new evidence available, the SCCS still considers that ZPT, when used in a concentration of up to 2.0% as an anti-dandruff agent in rinse-off hair care products, is safe for the consumer as concluded in the previous evaluation (SCCS/1512/13). However, the SCCS express further concerns regarding the use of ZPT in cosmetic products and recommends a risk assessment taking into consideration all possible sources of exposure (and not only the hair care products), particularly considering that its classification as Repr 1B (H360D) under CLP Regulation is currently under consideration.
ZPT is a biocidal active substance in the meaning of Biocidal Products Regulation (BPR)[20]. It is registered under REACH. It has no current entry in Annex VI of the CLP Regulation, i.e. it has no harmonised classification. However, a classification and labelling (C&L) dossier[21] was submitted to ECHA in October 2016 by the Swedish Chemicals Agency ("KEMI") to support the harmonised C&L of ZPT as Repr 1B (H360D: may damage the unborn child) and STOT RE1 (H372: Causes damage to organs through prolonged or repeated exposure), among other hazard statements[22]. On 14 September 2018 ECHA's Committee for Risk Assessment (RAC) adopted its scientific opinion[23] to include ZPT in Annex VI of CLP, if agreed by COM, and classify it according to the dossier submitters' proposal.
For the remaining substances/substance groups currently derogated in the existing criterion 3(b), it is suggested that such derogations are removed unless **industry can provide new/up-to-date evidence for substances or substance groups, which, according to their knowledge, would require keeping the existing derogations or should additionally be derogated from the provision of the sub-criterion 3(a)**. Information submitted by the stakeholders will undergo a thorough analysis and will be presented as possible derogation proposal for the 2nd AHWG meeting.

Question to stakeholders
Stakeholders are asked to provide justified requests for derogations for specific substances or substance groups (e.g. surfactants) using the derogation template form included in Annex 1 to this report.

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

This criterion lists substances that shall not be included in the product (as part of the formulation or as a part of a mixture included in the formulation) as defined in the existing criteria in force (3 (a) Specified excluded ingoing substances and mixtures).
The results from the survey revealed that 62% of the stakeholders agree with the current formulation of the criterion on substances and mixtures not allowed in the product formulation.

[18] Annex V of Cosmetics Regulation (EC No 1223/2009): List of preservatives allowed in cosmetic products.
[19] Scientific Committee on Consumer Safety (SCCS), Scientific opinion on Zinc pyrithione, SCCS/1593/2018. https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_216.pdf
[20] 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 167/1.
[21] https://echa.europa.eu/es/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e181221490
[22] Proposed future entry in Annex VI of CLP Regulation for ZPT by the dossier submitter: Repr. 1B H360D, STOT RE 1 H372, Acute Tox. 3 H301, Acute Tox. 2 H330, Eye Dam. 1 H318, Aquatic Acute 1 H400 (M-factor=1000), Aquatic Chronic 1 H410 (M-factor=10).
[23] https://echa.europa.eu/documents/10162/6405ddd0-2429-9e13-31bd-4e0752fe7430

Moreover, 18% of stakeholders indicated it is necessary to add other substances or mixtures in the revised criterion.

Regarding specific substances, respondents stated the following opinions:

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

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

-Substances that meet the criteria for PBT or vPvB substances in accordance with Annex XIII of the REACH Regulation (EC) No. 1907/2006, or substances included in the Candidate list
- Per- and polyfluoroalkyl substances (PFAS) and other organic halogen compounds
- Endocrine disrupting chemicals
- Cyclic siloxanes
- Isothiazolinones
- Evernia furfuracea extract and Evernia prunastri extract
- The fragrance Tetramethyl acetyloctahydranophthalenes (OTNE)

Finally, one respondent considered it important to ban all nanoparticles if the manufacturer cannot prove that they are not harmful. They suggested that since there is considerable uncertainty about the effects of nanomaterials on health and environment, and in accordance with the precautionary principle, nanomaterials should not be permitted.

An analysis of other ecolabels has been performed in order to list restricted substances/mixtures in other schemes (see Table 11). Although it may seem that other ecolabelling schemes cover more substances than the current EU Ecolabel criterion 3 (a) (and revised criterion 3 (b)), these substances are already implicitly covered by other EU Ecolabel criteria or sub-criteria and/or other EC regulations as detailed in the following paragraphs.

Table 11: Summary of requirements on restricted substances and mixtures in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel

Nordic Swan	Blue Angel	Bra Miljöval
3(b) Specified excluded substances		
The following substances must not be present in the product or raw material: *-D5 (decamethylcyclopentasiloxane, CAS no 541-02-6)* *-D6 (dodecamethylcyclohexasiloxane CAS no 540-97-6)* *-BHA (butylated hydroxyanisole, CAS no 25013-16-5)* *-Perfluorinated and polyfluorinated substances* *-Hypochlorite, chloramine and sodium chlorite* *-Benzalkonium chloride* *-Phthalates* *-Substances considered to be (potential) endocrine disruptors in accordance with the European Union's reports concerning endocrine disruptors.*	*The following substances are not permitted in the end product, either as part of the formulation or as part of any preparation included in the formulation:* *-Phosphates* *-Phosphonates, which are aerobically not readily biodegradable* *-ETPA (diethylenetriaminepentaacetic acid and its salts)* *-5-bromo-5-nitro-1,3-dioxane*	*The product must not contain lead, cadmium, cobalt, chromium, mercury, nickel, cocamide DEA, nylon, polyethylene, organic halogen compounds, phthalates, cyclic siloxanes or specific endocrine disrupting chemicals.* *The product must not contain nanomaterials.* *The product must not contain substances that meet the criteria for PBT or vPvB substances in accordance with Annex XIII of REACH or substances included on the Candidate list.* *The product must not contain any of the sensitising substances:* *- Evernia furfuracea Extract* *- Evernia prunastri Extract*

-Halogenated and/or aromatic solvents. *-Nanomaterials/particles as defined in the Cosmetics Regulation.* *-Substances that have been judged in the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated but which meet these criteria.* *An exception is made to this requirement for:* *a) hydrated silica, which is used as an abrasive in toothpaste.* *b) TiO2 approved in SCCS opinion SCCS/1516/13. I.e. TiO2 must not be photocatalytic, coating must be stable and TiO2 may not be included in spray products.*		

The proposals made by respondents above and the list of substances included in other schemes have been further investigated. Information on the following substances and substance groups (including evaluation whether they are already excluded through the existing requirements) is given below:

-5-bromo-5-nitro-1,3-dioxane

-Benzalkonium chloride

-Butylated hydroxyanisole (BHA)

-Cocamide DEA

-Cyclic siloxane compounds (D5 and D6)

-Endocrine disruptors

-ETPA (diethylenetriaminepentaacetic acid and its salts)

-Evernia furfuracea extract and Evernia prunastri Extract

-Halogenated and/or aromatic solvents.

-Hypochlorite, chloramine and sodium chlorite

-Isothiazolinones

-Nanomaterials

-PBT or vPvB substances

-PFAS and other perfluorinated compounds

-Phosphates

-Phosphonates which are aerobically not readily biodegradable

-Phthalates

-Sodium Lauryl Sulfate (SLS)

-Tetramethyl acetyloctahydranophthalenes (OTNE)

5-bromo-5-nitro-1,3-dioxane

5-bromo-5-nitro-1,3-dioxane is used in bath, hair and personal care products. It functions as a preservative, preventing or retarding bacterial growth, and thus protecting cosmetic and personal care products from spoilage. This substance does not have a harmonised classification, nor is considered a SVHC. However, according to the information provided by companies to ECHA, this substance causes severe skin burns and eye damage, is very toxic to aquatic life with long lasting effects, is harmful if swallowed, causes serious eye damage, may cause an allergic skin reaction and causes skin irritation. Being a formaldehyde releaser, this substance is already restricted by the revised criterion 3 (b).

Benzalkonium chloride

Benzalkonium chloride (also known as BZK, BKC, BAC, alkyldimethylbenzylammonium chloride; CAS No. 8001-54-5) can be used in cosmetics to perform several different functions, e.g. as a preservative, surfactant and deodorant. It is used in the formulation of shampoos, personal cleanliness products, skin cleansers, and skin care and eye makeup preparations. Benzalkonium chloride does not have a harmonised classification, nor is considered a SVHC. However, according to the information provided by companies to ECHA, this substance causes severe skin burns and eye damage, is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects, is harmful if swallowed, is harmful in contact with skin, is harmful if inhaled and causes serious eye damage. This substance is already restricted in Nordic Swan scheme. Therefore it is proposed that this substance **is included in the revised criterion 3 (b)** as excluded substances in EU Ecolabel products.

Butylated hydroxyanisole (BHA)

Due to its antioxidant properties, BHA (tert-butyl-4-methoxyphenol) is used in cosmetic and personal care products. BHA does not have a harmonised classification, nor is it considered a SVHC. However, according to the information provided by companies to ECHA in the REACH registration process, this substance is toxic to aquatic life with long lasting effects, causes serious eye irritation, is suspected of causing cancer, is suspected of damaging fertility or the unborn child, is harmful if swallowed and causes skin irritation. This substance is restricted already in Nordic Swan. Moreover, the evaluation of this substance being an endocrine disruptor is ongoing. Therefore it is proposed that this substance **is included in the revised criterion 3 (b)** as an excluded substance in EU Ecolabel products.

Cocamide DEA

Cocamide DEA is a type of fatty acids derivatives of diethanolamine (DEA). In cosmetics and personal care products, this ingredient is used in the formulation of shampoos, hair dyes, bath products, and lotions. This substance does not have a harmonised classification, nor is considered a SVHC. However, according to the information provided by companies to ECHA, this substance causes serious eye damage, is harmful to aquatic life with long lasting effects and causes skin irritation. Therefore it is proposed that this substance **is included in the revised criterion 3 (b)** as excluded substances in EU Ecolabel products.

Cyclic siloxane compounds (D5 and D6)

Cyclic siloxane compounds are used in cosmetic products with different purposes, e.g. as softeners, solvents, anti-static agents, moisturisers, anti-foaming agents and to control viscosity in hair care products and anti-perspirants, in creams/liquids, liquid soaps and gels and decorative cosmetics. The coumpounds Cyclopentasiloxane/ Decamethylcyclopentasiloxane (D5, CAS 541-02-6), Cyclohexasiloxane/ Dodecamethylcyclohexasiloxane (D6, CAS 540-97-6) as well as Cyclomethicone (a mixture of low molecular weight volatile cyclic siloxanes, the principal ingredients of which are D4, D5 and D6, in varying proportions), do not have a harmonised classification under CLP, but are included in REACH SVHC Candidate List, being classified as vPvB substances. Their use has been restricted for rinse-off products where their concentration is greater than or equal to 0.1 % by weight of either substance[24]. Therefore, the

[24] https://echa.europa.eu/documents/10162/50e79685-efaf-ac9a-4acb-d8be3f0e9ddc

presence of these compounds is excluded from EU Ecolabel products according to the revised criterion 3 (c) on SHVCs. Furthermore, ECHA is currently working on a further proposal[25] to restrict D4, D5 and D6 in leave on personal care products and other consumer/professional products (such as dry cleaning products, waxes and polishes, and other washing and cleaning products) in a concentration equal to or greater than 0.1 %.

Endocrine disruptors

Endocrine disruptors are defined as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations"[26]

The Cosmetics Regulation does not contain specific provisions for endocrine disruptors. However, substances with endocrine disrupting properties are subject to case-by-case regulatory action on the basis of the general requirements of the legislation[27]. Under the legislation on cosmetics, specific restrictions or bans have been set on a number of preservatives with endocrine disrupting properties, in particular to protect infants and young children[28] and on substances used in sunscreens as a filter for ultraviolet radiation has also been banned[29] taking into account in particular its potential endocrine disrupting properties.

In REACH substances with endocrine disrupting effects are considered under Article 57, as substances which should be included in Annex XIV (i.e. List of substances subject to authorisation). Article 57 states the following: substances — such as those having endocrine disrupting properties (…) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) *[of the article 57 of REACH[30]]* and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59. Thus, the substances categorised as endocrine disruptors under REACH, are already excluded from EU Ecolabel products through sub-criterion 3(c) on SVHCs.

ETPA (diethylenetriaminepentaacetic acid and its salts)

Pentetic acid and its salt Pentasodium Pentetate are chelating agents (compounds that bind metals) and are found mostly in hair dyes and colors, noncoloring hair products, and bath products. These substances do not have a harmonised classification, nor are considered SVHCs. However, according to the information provided by companies to ECHA, these substances cause serious eye irritation, cause skin irritation, may cause respiratory irritation, are harmful if swallowed, are harmful in contact with skin, are harmful if inhaled and are suspected of damaging fertility or the unborn child. Therefore it is proposed that these substances **are included in the revised criterion 3 (b)** as excluded substances in EU Ecolabel products.

Evernia furfuracea extract and Evernia prunastri extract

Evernia furfuracea (Tree moss) and Evernia prunastri (Oak moss) are two natural fragrances used in cosmetics. These fragrances contain two allergenic constituents: chloroantranol and

[25] https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/22920/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=208-762-8&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

[26] Definition provided in 2002 by the International Programme on Chemical Safety, a joint programme of various United Nations Agencies, including the World Health Organisation.

[27] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Towards a comprehensive European Union framework on endocrine disruptors; COM(2018) 734

[28] Certain so-called "parabens", via Commission Regulation (EU) No 358/2014 (OJ L 107, 10.4.2014, p. 5) and Commission Regulation (EU) No 1004/2014 (OJ L 282, 26.9.2014, p. 5).

[29] 3-Benzylidene Camphor -Commission Regulation (EU) 2015/1298 (OJ L 199, 29.7.2015, p. 22), following the opinion of the Scientific Committee on Consumer Safety SCCS/1513/13

[30] This covers: (a) substances meeting the criteria for classification as carcinogenic category 1 or 2; (b) substances meeting the criteria for classification as mutagenic category 1 or 2; substances meeting the criteria for classification as toxic for reproduction category 1 or 2; (d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation; (e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation.

atranol (of Evernia furfuracea and Evernia prunastri, respectively). These allergenic constituents are currently excluded in the existing criterion 3 (a) *Specified excluded ingoing substances and mixtures*. It is proposed, that they are not specified as restricted substances in the revised criterion 3 (b) because they are already excluded from cosmetics products through the amendment to the Cosmetics Regulation[31].

Halogenated and/or aromatic solvents

Most halogenated and aromatic solvents (e.g. aniline, its salts and its halogenated and sulphonated derivatives; Toluidines, their isomers, salts and halogenated and sulphonated derivatives; Xylidines, their isomers, salts and halogenated and sulphonated derivatives) are prohibited in cosmetics according to Cosmetics Regulation (EC) 1223/2209 or have a harmonised classification under CLP Regulation (EC) 1272/2009. These substances thus cannot be found in EU Ecolabel products or are excluded according to criterion on SVHCs.

Hypochlorite, chloramine and sodium chlorite

Calcium and sodium hypochlorites, chloramine and sodium chlorite can be used in cosmetics as oxidising and antimicrobial substances.

Calcium hypochlorite has a harmonised classification with H302 (harmful if swallowed), H314 (causes severe skin burns and eye damage) and H400 (very toxic to aquatic life) under the CLP Regulation (EC) No 1272/2008 and is therefore excluded from EU Ecolabel products through criterion 3 (a).

Sodium hypochlorite, solution ... % Cl active (CAS: 7681-52-9) also has a harmonised classification with H314 (causes severe skin burns and eye damage), H318 (causes serious eye damage), H400 (very toxic to aquatic life) and H410 (very toxic to aquatic life with long-lasting effects) under Regulation (EC) No 1272/2008, and it is therefore excluded from EU Ecolabel products through criterion 3 (a).

Sodium hypochlorite (other CAS numbers), chloramine and sodium chlorite do not have a harmonised classification, nor are considered SVHCs. However, according to the information provided by companies to ECHA, these substances cause severe skin burns and eye damage, are very toxic to aquatic life, very toxic to aquatic life with long lasting effects, causes serious eye damage, may intensify fire (oxidiser), and are harmful if swallowed. Therefore it is proposed that these substances **are included in the revised criterion 3 (b)** as excluded substances in EU Ecolabel products.

Isothiazolinones

Isothiazolinones are a group of preservatives widely used in cosmetics because of their effectiveness even at low concentrations. Restriction on the use of isothiazolinones is discussed in the rationale to criterion 3 (d), which addresses presence of preservatives in EU Ecolabel products.

Nanomaterials

With the term 'nanomaterial' is meant 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[32]. The substances listed in Annexes III to VI of the Regulation (EC) 1223/2009 do not cover nanomaterials, unless specifically mentioned. In EU Ecolabel, use of nanomaterials is evaluated on a case-by-case basis.

Silver and TiO2 are the two materials in nano form that have been identified as of relevance for use in cosmetics. While nanosilver used as preservative is already excluded from EU Ecolabel products due to its aquatic toxicity (current criterion 3 (a)), nano TiO2 is used as UV filter, and

[31] Commission Regulation (EU) 2017/1410 of 2 August 2017 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, OJ L 202/1.
[32] Regulation (EC) 1223/2009

it is discussed in the section related to criterion 3 (g) on UV filters, where a set of requirements on its use is proposed.

PBT or vPvB substances

Substances classified as PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative) in accordance with Annex XIII of the REACH Regulation (EC) No. 1907/2006 are included in the list of SHVCs and therefore excluded from EU Ecolabel products according to revised criterion 3 (c)

PFAS and other perfluorinated compounds

Perfluorinated compounds are used in cosmetics in applications such as hair and skin conditioners and as solvents. These can also be used as surfactants, also known as Perfluorinated Alkylated Substances (PFAS), in certain cosmetics, particularly eye shadow, foundation, facial powder, bronzer, and blush, which are products that are not included in the current nor the revised scope of the criteria. Nevertheless, the most common PFAS (such as Perfluorooctane sulfonic acid – PFOS, Perfluorooctanoic acid – PFOA, Perfluorononanoic acid – PFNA, and Perfluorooctane sulfonaminde – PFOSA) have a harmonised classification under the CLP Regulation (EC) 1272/2008, and are therefore excluded from EU Ecolabel products according to revised criterion 3 (a).

Phosphates

Phosphates are used in cosmetic products mainly as Sodium Phosphate, Disodium Phosphate and Trisodium Phosphate. They occur in the form of white crystalline solids and are used in the formulation of bath products, colognes, dentifrices, mouthwashes, hair conditioners, hair dyes and colors, permanent waves, shampoos, makeup and skin care products. Sodium phosphate (CAS No. 10049-21-5), Disodium Phosphate (CAS No. 10028-24-7, 7782-85-6 and 10039-32-4) and Trisodium Phosphate (CAS No. 7601-54-9 and 10101-89-0) do not have a harmonised classification, nor are considered SVHCs. However, according to the information provided by companies to ECHA, these substances cause severe skin burns and eye damage, cause serious eye damage, cause serious eye irritation, cause skin irritation and may cause respiratory irritation. Therefore it is proposed that these substances **are included in the revised criterion 3 (b)** as excluded substances in EU Ecolabel products.

Phosphonates which are aerobically not readily biodegradable

Phosphonates are used because of their detergent properties, and that is why they are mainly used in detergents. Substances that are not aerobically readily biodegradable cannot be used in EU Ecolabel products according to current criteria 2.

Phthalates

Phthalates are used in cosmetics in different functions, such as film formation, masking and solvents. Phthalates of concern that have a harmonised classification are:

-DEHP (Bis(2-ethylhexyl)phthalate), classified as H360FD, not directly used in cosmetics,

-BBP (Benzyl butyl phthalate), classified as H400, H410 and H360DF, used in hair spray,

-DBP (Dibutyl phthalate), classified as H400 and H360DF, used in perfumes, deodorants, hair sprays, nail polish,

-DIBP (Diisobutyl phthalate), classified as H360DF, used in nail polish, and

-DCHP (Dicyclohexyl phthalate), classified as H317 and H360D, used in perfumes and cosmetics.

The use of these substances in EU Ecolabel is therefore restricted by criterion 3 (a). Other phthalates with CLP hazards reported in individual entries are:

-DNOP (Di-n-Octyl-Phthalate), suspected H361, H317, and H413, used in cosmetics,

-DINP (Di-Isononyl Phthalate), suspected H400 and H361, not directly used in cosmetics,

-DIDP (Di-Isodecyl-Phthalate), suspected H400, H410 and H411, not directly used in cosmetics, and

-DEP (Diethyl phthalate), suspected H319, H331 and H373, used in perfumes).

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

Sodium Lauryl Sulfate (SLS)

SLS is used in cosmetics as surfactant and emulsifier. Moreover, it is used in toothpaste to contribute to foaming. This substance does not have a harmonised classification, nor is considered a SVHC. However, according to the information provided by companies to ECHA in REACH registrations, this substance is harmful if swallowed, causes serious eye damage, is harmful to aquatic life with long lasting effects, is a flammable solid, is harmful if inhaled, causes skin irritation and may cause respiratory irritation. Nordic Swan ecolabelling bans the use of SLS in toothpaste, promoting the use of alternative surfactants such as sodium-C14-C16 oleofin sulphonate, sodium lauryl sarcosinate, cocamidopropyl betaine or Stearath 30, all of which are less irritating to the skin. Therefore it is proposed that this substance **is included in the revised criterion 3 (b)** as excluded substances in EU Ecolabel products.

Tetramethyl acetyloctahydranophthalenes (OTNE)

Tetramethyl acetyloctahydronaphthalenes is a synthetic ketone used as a fragrance ingredient in perfumes, laundry products and cosmetics. OTNE does not have a harmonised classification, nor is it considered a SVHCs. However, according to the information provided by companies to ECHA in the REACH registration process, this substance causes skin irritation, may cause an allergic skin reaction and is very toxic to aquatic life with long lasting effects. Therefore it is proposed that this substance **is included in the revised criterion 3 (b)** as an excluded substance in EU Ecolabel products.

In summary, in this initial stage of the revision process, for the first proposal, the following changes to the current criterion 3 (a) *Specified excluded ingoing substances and mixtures*, are proposed:

- Eliminating the following substances from the exclusions list in 3 (a):
  - *(ix) Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Atranol and Chloroatranol.*

  These three substances are included in Annex II of Cosmetics Regulation (entries 1380, 1381, 1382, as mentioned above) and are prohibited in cosmetic products from the following dates[33]: from 23 August 2019 for products placed on the market and from 23 August 2021 for products made available on the market. Current EU Ecolabel criteria[34] are valid until 31 December 2021[35]; then, their prohibition of use in cosmetic products will have fully entered into force when the revised criteria are published.

  - *(ii) Nitrilo-tri-acetate (NTA);*
  - *(iii) Boric acid, borates and perborates;*
  - *(v) Octamethylcyclotetrasiloxane (D4);*

[33] COMMISSION REGULATION (EU) 2017/1410 of 2 August 2017 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (HICC, atranol, chloroatranol). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1410&from=EN

[34] COMMISSION DECISION of 9 December 2014 establishing the ecological criteria for the award of the EU Ecolabel for rinse-off cosmetic products.

[35] COMMISSION DECISION (EU) 2018/1590 of 19 October 2018 amending Decisions 2012/481/EU, 2014/391/EU, 2014/763/EU and 2014/893/EU as regards the period of validity of the ecological criteria for the award of the EU Ecolabel for certain products, and of the related assessment and verification requirements. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018D1590&from=EN

- *Formaldehyde*.

These substances were added to Annex II[36] of Cosmetics Regulation by the 'Omnibus Act'[37], published on 22 May 2019, that amends Annexes II, III and V of the Cosmetics Regulation. It applies without any transition period, just 20 days after its publication. Their prohibition of use in cosmetic products is therefore already in force.

- Including a definition of 'microplastic', in accordance with the definition of 'microplastic'[38] laid down in EU Ecolabel criteria for detergents[39]. This definition is also in line with the definition proposed in the scope of the proposal for restricting the use of intentionally added microplastic particles in consumer or professional use products of any kind, under REACH Regulation (process ongoing)[40]
- Including the following substances to the exclusion list:
  - Butylated hydroxyanisole (BHA);
  - The preservative benzalkonium chloride;
  - The fragrance tetramethyl acetyloctahydranophthalenes (OTNE);
  - Sodium hypochlorite, chloramine and sodium chlorite;
  - ETPA (diethylenetriaminepentaacetic acid and its salts);
  - Cocamide DEA;
  - The phthalates Di-n-Octyl-Phthalate (DNOP) and Diethyl phthalate (DEP);
  - Sodium Lauryl Sulfate (SLS)
  - Substances classified as endocrine disruptors (to discuss).

These substances show several notifications of hazard/danger provided by companies to ECHA (both individual and joint entries) and are therefore proposed to be included in the exclusion list.

Question to stakeholders
Are there any other substances with potential endocrine disrupting properties that should be covered by criterion 3 (b)? Stakeholders are asked to provide their opinion on additional substances proposed to be included for exclusion in EU Ecolabel products

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

Sub-criterion (c) is also 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*

[36] Annex II of Cosmetics Regulation (EC No 1223/2009): List of substances prohibited in cosmetic products.

[37] COMMISSION REGULATION (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (Omnibus). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0831&from=EN

[38] '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.

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

[40] https://echa.europa.eu/es/restrictions-under-consideration/-/substance-rev/22921/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=-&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

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 have been introduced in this criterion, however the text has been aligned with the same criterion used in most recently adopted EU Ecolabel criteria.

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

According to the current criteron, fragrances should be manufactured and handled following the code of practice of the International Fragrance Association (IFRA). Moreover, products designed and intended for children shall be fragrance-free.
The results of the survey to stakeholders revealed that 44% of respondents of the revision questionnaire agree with the requirements set in the current criterion, while 28% of them would like to modify the criterion. From the latter group half of the respondents considers that the restriction for fragrances should be stricter. There are also some stakeholders who consider it necessary to use fragrances in baby products accepting the inclusion of specific restrictions for this product type.
An analysis of other ecolabels has been performed in order to study how the presence of fragrances is addressed in other schemes (see Table 12). Both Blue Angel and Nordic Swan ecolabels establish that these substances must not be contained in rinse-off products in concentrations ≥ 0.010 % per substance. The working group of Nordic Swan reported that the demand for fragrance-free cosmetics is limited and the range of fragrances that do not contain allergens is also very limited. Most of the fragrances identified are classified as sensitizers (H317) under CLP Regulation and are therefore excluded for use in EU Ecolabel products according to criterion 3 (a).

Table 12: Summary of fragrance related restrictions in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.

Nordic Swan	Blue Angel	Bra Miljöval
3(d) Fragrances		
SAME CRITERION AS EU ECOLABEL *Exceptions: Flavourings are allowed in children's toothpaste.*	**MORE RESTRICTIVE THAN EU ECOLABEL**	**MORE RESTRICTIVE THAN EU ECOLABEL**
A fragrance which is judged to be sensitising with the hazard statement H317 and/or H334, or covered by the fragrance substances subject to declaration may be included at a maximum of 0.001% in leave-on products and a maximum of 0.01% in rinse-off products. *The fragrance substances: Cananga Odorata and Ylang-ylang oil, Eugenia Caryophyllus Leaf, and Jasminum Grandiflorum may be included in products with a maximum of 0.010% for rinse-off products and a maximum of 0.0010% for leave-on products.*	*Fragrances, which must be specified according to Annex III of the cosmetics regulation (Regulation (EC) No. 1223/2009), may not be contained in the product in concentrations ≥0.010% per substance.*	*No more than 0.50 % by weight perfume and aroma combined is permitted in the product.* *Individual fragrances or flavours classified with H317 must not exceed a concentration of 0.01% by weight in rinse-off products and 0.001% by weight in leave-on products.* *Substances listed in the table below, and the ones listed in Annex III to the Cosmetics Regulation (EC) No 1223/2009 must not exceed a concentration of 0.01% by weight in rinse-off products and 0.001% by weight in leave-on products. This requirement applies irrespective of the function of the substance in the product.* ***Name*** *Cananga Odorata and Ylang-ylang oil* *Eugenia Carophyllus Leaf/Flower oil* *Jasminum grandiflorum/ officinale* *Myroxylon Pereirae*

		Santalum Album
		Turpentine oil
		Cinnamomum cassia leaf oil/ Cinnamomum zeylanicum extract

At this stage, no changes have been introduced in this sub-requirement.
Nevertheless, it is proposed to discuss at the 1st AHWG meeting the possibility to limit the amount of fragrances, which must be specified according to Annex III of the Cosmetics Regulation, i.e. allergenic substances. Low thresholds for leave-on products could also be considered.

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

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

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

-The product may contain preservatives provided that they are not bioaccumulating.

A preservative is not considered bioaccumulating if BCF < 100 or log Kow < 3,0. If both BCF and log Kow values are available, the highest measured BCF value shall be used.
The results of the survey to stakeholders revealed that around 60% if the respondents of the revision questionnaire supported the current criterion formulation, with only 8% of the respondents being against it.
An analysis of other ecolabels has been performed in order to study how the presence of preservatives is addressed in other schemes (see Table 13). Nordic Swan and Bra Miljöval apply less stringent thresholds for BCF and log Kow than the EU Ecolabel.

Table 13: Summary of preservatives-related restrictions in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.

Nordic Swan	Blue Angel	Bra Miljöval
3(e) Preservatives		
The use of preservatives for purposes other than preservation of the product itself is prohibited.	*The end product may only include preservatives in order to preserve the product and in the appropriate dosage for this purpose. This does not refer to surfactants, which may also have preserving properties.* *It is prohibited to state or suggest on the packaging or by any other means that the product has an antimicrobial action.*	*Biocides must only be used to preserve the product, including its ingredients, during storage and use.*
Preservatives must not be bioaccumulating: BCF<500 or log Kow<4. *These requirements also apply to antibacterial disinfecting and microbial substances.*		*The ingredient must have a BCF < 500 or a log Kow < 4.*

One more consideration regarding preservatives, which should be taken into account and was mentioned by some stakeholders with respect to additional substances to be excluded in EU Ecolabel products, refers to the restriction on the use of isothiazolinones. Isothiazolinones are widely used in cosmetics because of their high efficacy and the broad spectrum of pH at which they are effective even at low concentrations. This makes them very difficult to be replaced by authorised alternatives. The most used isothiazolinones are Chloromethylisothiazolinone (CMIT) and methylisothiazolinone (MIT), which is a powerful biocidal reported as a sensitizing agent by SCCS[41] with suspected toxicity to the aquatic environment. The Regulation (EC) 1223/2009 prohibits MIT, the formulation CMIT/MIT in a 3:1 ratio in leave-on products (as no safe concentration is possible), and limits their presence at 15 ppm (0.0015 %) in rinse-off products. Further restrictions appear difficult to achieve by the EU Ecolabel cosmetic industry.

[41] https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_178.pdf

In 2013, during the process of drafting the criteria which are in force now, such restrictions were discussed extensively with the stakeholders[42]. Split views were expressed, with the industry firmly rejecting the possibility of excluding isothiazolinones for the sake of the stability of cosmetic products and the safety of consumers, which can show higher sensitizing reactions to one preservatives than if more substances are used simultaneously. As research may have developed new solutions for preservatives without toxic and/or sensitizing properties, further analysis is required to understand the feasibility of a possible restriction of exclusion. Examples include organic acids, sodium benzoate, potassium sorbate, essential oils, anti-oxidants and phenoxyethanol. However, these alternatives ensure a lowest protection, are only effective against yiests, bacteria OR fungi, and/or may form carcinogenic by-products with other ingredients in the formulation.

For the first proposal of the revised criteria, it is suggested the criterion to be kept in the current form.

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

It is currently required that colorants in the product must not be bioaccumulating. The definition of what is considered as not bioaccumulating is the same as in the case of preservatives. In the case of colouring agents approved for use in food, it is not necessary to submit documentation of their bioaccumulation potential.

The results of the survey to stakeholders revealed that more than 50% of the revision questionnaire respondents agree with the current criterion, while 5% indicate that the criterion should also establish a maximum content of colorants in the final product.

An analysis of other ecolabels has been performed in order to study how the presence of colorants is addressed in other schemes (see Table 14). Both Nordic Swan and Bra Miljöval set that the colorant must be approved as a food additive. The requirement excludes about ten colorants with logKow values up to 17, which are approved under the Cosmetics Regulation.

Table 14: Summary of colorant-related restrictions in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.

Nordic Swan	Blue Angel	Bra Miljöval
3(f) Colorants		
Organic colorants must not be bioaccumulating: BCF<500 or logKow<4. Alternatively, the colour must be approved for use in food. *None of barium, lead, mercury, cadmium, six inhalant chromium, nickel or bismuth may be found in colourants for decorative cosmetics and hair dye in concentrations above 0.0010%.*	**SAME CRITERION AS EU ECOLABEL**	**MORE RESTRICTIVE THAN EU ECOLABEL** *The colouring agent must be approved as a food additive (colour) according to Regulation (EC) No 1333/2008 on food additives.*

At this stage no changes have been introduced. However, it is proposed to discuss at the 1st AHWG meeting whether to include the requirement that colouring agents must be approved as a food additive according to Regulation (EC) No. 1333/2008 on food additives, in line with the requirement in Nordic Swan and Bra Miljoval.

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

Question to stakeholders
Stakeholders are requested to give their opinion on whether to limit a maximum content of colorants in the final product. Alternatively, stakeholders are asked to provide their opinion whether the approach should be harmonised with Nordic Swan and accept only colorants approved as food additives

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

A study of other labelling schemes revealed that some schemes include requirements on the use of UV filters.

Table 15: Summary of UV filters-related restrictions in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.Table

Nordic Swan	Blue Angel	Bra Miljöval
3(g) UV filters		
UV filters may only be added to leave-on products and only to protect the user – not the product *Nano UV filters are banned (exemptions: nano TiO2 filters)* *Must not be bioaccumulating (BCF<500/logKow<4) OR must have a lowest measured toxicity of NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l* *If including nano TiO2, must fulfil the conditions expressed in SCCS/1516/13*	**NO CRITERIA (SUNSCREEN PRODUCTS NOT INCLUDED IN THE SCOPE)**	**NO CRITERIA (SUNSCREEN PRODUCTS NOT INCLUDED IN THE SCOPE)** *No chemical UV absorbers can be added to the product*

Nordic Swan sets a number of requirements for the use of UV filters added to the formulation as a sun protection for the user. Sun care products are a special class of leave-on skin care products, as these are expected to be released directly in the sea, without previous treatment in a wastewater treatment plant, causing potential environmental and health problems. However, UV filters provide protection against the sun and thus reduce the risk of skin cancer, so there are also advantages to using sun protection products with UV filters.

It is proposed to include a new requirement in EU Ecolabel in line with Nordic Swan specifications.

The requirement of UV filters targeting exclusively the protection of the user ensures that such filters are covered by the Annex VI of the Cosmetics Regulation. Therefore, the number of available UV filters allowed in cosmetic products is limited by the Cosmetics Regulation

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

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

With respect to the nano-form of TiO2, the SCCS (the Scientific Committee on Consumer Safety) published in recent years three opinions on the safe use of nano-TiO_2 in cosmetics. The

first SCCS opinion[43] (from 2013) considers as safe for humans the use in UV-filters of up to 25% nano TiO_2 with the following characteristics:

-With a purity greater than or equal to 99%,

-In the rutile form, or rutile with up to 5% anatase, with crystalline structure and physical appearance as clusters of spherical, needle, or lanceolate shapes,

-With a median particle size based on number size distribution of 30 to 100 nm,

-With an aspect ratio from 1.0 and up to 4.5, and volume specific surface area up to 460 m^2/cm^3,

-Coated with one of the coating materials described in Table 1 of the SCCS/1516/13 opinion, the coatings being stable in the final formulation and during use,

-Being photostable in the final formulation,

-Having up to 10% photocatalytic activity compared to corresponding non-coated or non-doped reference.

The second SCCS opinion[44] relates to three nano-forms of TiO_2 materials coated with either silica and cetyl phosphate (up to 16% and 6% respectively); alumina and manganese dioxide (up to 7% and 0.7% respectively); or alumina and triethoxycaprylylsilane (up to 3% and 9% respectively). These materials can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin. This, however, does not apply to applications that might lead to exposure of the consumer's lungs to the TiO_2 nanoparticles through the inhalation route (such as powders or sprayable products). A third study[45] concluded that the safety of the use of nano-TiO_2 in spray applications with respect to exposure of the consumer's lungs could not be assessed because of insufficient information provided.

Finally, TiO_2 in inhalable powder form has been included as a Carc 2 (see note below) in the 14th ATP (adaptation to technical progress) to CLP, which adds a number of substances to Annex VI of CLP. The 14th ATP was adopted by the Commission on 4th of October 2019. The delegated Act has now been put forward to the European Parliament and the Council of Ministers, who will have two months to raise any objections. If there are no objections, the Act is expected to be published early 2020, with the changes becoming a legal requirement 18 months later. TiO_2 (defined as explained in the note) would then be excluded in EU Ecolabel products according to criterion 3 (c). Current EU Ecolabel criteria are valid until 31 December 2021; then, the prohibition of use in cosmetic products will have fully entered into force when the revised criteria are published.

Note: only TiO_2 placed on the market in powder form and consisting of 1% or more of particles with an aerodynamic diameter <= 10µm need to be classified as Carc.2.

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

In several studies there is clear evidence that nano- TiO_2 is considerably more toxic than micro-sized TiO_2[46], with the anatase form expected to be more toxic than the rutile form[47]. However,

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

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

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

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

although nano-TiO_2 is one of the most well investigated nano substances, several data gaps still exist in relation to its toxicological evaluation. As for consumers the highest direct exposure to nano-scale TiO_2 is expected to be through the use of sunscreens, at this stage of the revision process it is proposed that the presence of nano- TiO_2 is restricted in EU Ecolabel products through new requirements set in the proposed criterion 3 (g) UV filter, according to the latest findings of SCCS.

Question to stakeholders
Stakeholders are requested to provide their opinion on whether the bioaccumulation limit is too stringent for the formulation of UV filters Stakeholders are asked to provide information of the form (powder, liquid, etc.) in which TiO2 is added to the cosmetic formulation Stakeholders are asked if alternative means of proof other than the self-declaration can be provided for the verification of nano TiO2 use in criterion 3(g)

Rationale of proposed assessment and verification

Regarding the verification procedure, the majority of respondents to the revision questionnaire considers the current verification system as appropriate (nearly 60% of the respondents), whereas 14% of the respondents request to improve the procedure. In particular, respondents asked for a verification procedure specific for each sub-chapter of criterion 3 and a harmonization of the verification methods. Respective improvements have been proposed in the criteria text. In addition, the text formulation has been aligned to the recently adopted EU Ecolabel criteria for other product groups.

[47] Warheit et al., 2007

3.4 CRITERION 4: Packaging

Existing criterion 4: Packaging
a) Primary packaging Primary packaging shall be in direct contact with the contents. No additional packaging for the product as it is sold, e.g. carton over a bottle, is allowed, with the exception of secondary packaging which groups two or more products together (e.g. the product and refill). *Assessment and verification:* the applicant shall provide a signed declaration of compliance. (b) Packaging Impact Ratio (PIR) The Packaging Impact Ratio (PIR) must be less than 0,28 g of packaging per gram of product for each of the packaging in which the product is sold. Pre-shaving products packed in metal aerosol containers are exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows: $$PIR = (W + (Wrefill \times F) + N + (Nrefill \times F))/(D + (Drefill \times F))$$ Where: W —weight of packaging (primary + proportion of secondary (1), including labels)(g) Wrefill —weight of refill packaging (primary + proportion of secondary (1), including labels) (g) N —weight of non-renewable + non-recycled packaging (primary + proportion of secondary (1), including labels) (g) Nrefill —weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary (1), including labels) (g) D —weight of product contained in the 'parent' pack (g) Drefill —weight of product delivered by the refill (g) F —number of refills required to meet the total refillable quantity, calculated as follows: $$F = V \times R/Vrefill$$ Where; V —volume capacity of the parent pack (ml) Vrefill —volume capacity of the refill pack (ml) R —the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number it should be rounded up to the next whole number. In case no refill is offered PIR shall be calculated as follows: $$PIR = (W + N)/D$$ The manufacturer shall provide the number of foreseen refillings, or use the default values of R = 5 for plastics and R = 2 for cardboard. Assessment and verification: the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration for the content of post-consumer recycled material or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant or retailer shall document that the refills shall be available for purchase on the market. c) Design of primary packaging The primary packaging shall be designed to make correct dosage easy (e.g. by ensuring that the opening at the top is not too wide) and to ensure that at least 90 % of the product can be removed easily from the container. The residual amount of the product in the container (R), which must be below 10 %, shall be calculated as follows: $$R = ((m2 - m3)/(m1 - m3)) \times 100 \ (\%)$$ Where: m1 —Primary packaging and product (g) m2 —Primary packaging and product residue in normal conditions of use (g)

m3 —Primary packaging emptied and cleaned (g)

Assessment and verification: the applicant shall submit a description of the dosage device and test report with results of measuring the residual quantity of a rinse-off cosmetic product in the packaging. The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.

(d) Design for recycling of plastic packaging

Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 5.

Table 5

Materials and components excluded from packaging elements

Packaging element	Excluded material or component*
Label or sleeve	- PS label or sleeve in combination with a PET, PP or HDPE bottle - PVC label or sleeve in combination with a PET, PP or HDPE bottle - PETG label or sleeve in combination with a PET bottle - Sleeves made of different polymer than the bottle - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling)
Closure	- PS closure in combination a with a PET, PP or HDPE bottle PVC closure in combination with a PET, PP or HDPE bottle PETG closures and/or closure material with density of above 1 g/cm3 in combination with a PET bottle - Closures made of metal, glass, EVA - Closures made of silicone. Exempted are silicone closures with a density < 1 g/cm3 in combination with a PET bottle and silicone closures with a density > 1g/cm3 in combination with PP or HDPE bottle - Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened
Barrier coatings	- Polyamide, EVOH, functional polyolefins, metallised and light blocking barriers

(*) EVA — Ethylene Vinyl Acetate, EVOH — Ethylene vinyl alcohol, HDPE — High-density polyethylene, PET — Polyethylene terephtalate, PETG — Polyethylene terephthalate glycol-modified, PP — Polypropylene, PS — Polystyrene, PVC — Polyvinylchloride,

Pumps and aerosol containers are exempted from this requirement.

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

First proposal for criterion 4: Packaging

a) Primary packaging

Primary packaging shall be in direct contact with the contents.

No additional packaging for the product as it is sold, e.g. cardboard over a bottle, is allowed, with the exception of secondary packaging which groups two or more products together (e.g. the product and refill).

Assessment and verification: the applicant shall provide a signed declaration and relevant evidence (e.g. pictures of the product as marketed).

(b) Packaging Impact Ratio (PIR)

The Packaging Impact Ratio (PIR) must be less than 0,28 g of packaging per gram of product for each of the packaging in which the product is sold. Products packed in metal aerosol containers are exempted from this requirement. PIR shall be calculated (separately for each of the packaging) as follows:

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

Where:

W —weight of packaging (primary + proportion of secondary (1), including labels)(g)

W_{refill} —weight of refill packaging (primary + proportion of secondary (1), including labels) (g)

N —weight of non-renewable + non-recycled packaging (primary + proportion of secondary (1), including labels) (g)

N_{refill} —weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary (1), including labels) (g)

D —weight of product contained in the 'parent' pack (g) D_{refill} —weight of product delivered by the refill (g)

F —number of refills required to meet the total refillable quantity, calculated as follows:

$$F = V \times R/Vrefill$$

Where;

V —volume capacity of the parent pack (ml)

V_{refill} —volume capacity of the refill pack (ml)

R —the refillable quantity. This is the number of times that the parent pack can be refilled. Where F is not a whole number it should be rounded up to the next whole number.

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

$$PIR = (W + N)/D$$

The manufacturer shall provide the number of foreseen refillings, or use the default values of R = 5 for plastics and R = 2 for cardboard.

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

Assessment and verification: the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available on the EU Ecolabel website. If the product is sold in different packaging (i.e. with different volumes), the calculation shall be submitted for each packaging size for which the EU Ecolabel shall be awarded. The applicant shall provide a signed declaration for the content of post-consumer recycled material or material from renewable origin in the packaging and a description of the refill system offered, if applicable (kinds of refills, volume). For approval of refill packaging, the applicant or retailer shall document that the refills shall be available for purchase on the market.

c) Design of primary packaging

The primary packaging shall be designed to make correct dosage easy* (e.g. by ensuring that the opening at the top is not too wide) and to ensure that at least 90 % of the product can be easily removed from the container. The residual amount of the product in the container (R), which must be below 10%, shall be calculated as follows:

$$R = ((m2 - m3)/(m1 - m3)) \times 100 \ (\%)$$

Where:

m1 —Primary packaging and product (g)
m2 —Primary packaging and product residue in normal conditions of use (g)
m3 —Primary packaging emptied and cleaned (g)
*For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press.
Assessment and verification: the applicant shall submit a description of the dosage device (e.g. schematic illustration, pictures…) and test report with results of measuring the residual quantity of a rinse-off cosmetic product in the packaging. The test procedure for measuring the residual quantity is described in the user manual available on the EU Ecolabel website.
(d) Design for recycling of plastic packaging
Plastic packaging shall be designed to facilitate effective recycling by avoiding potential contaminants and incompatible materials that are known to impede separation or reprocessing or to reduce the quality of recyclate. The label or sleeve, closure and, where applicable, barrier coatings shall not comprise, either singularly or in combination the materials and components listed in Table 5.

Table 5

Materials and components excluded from packaging elements

Packaging element	Excluded material or component*
Label or sleeve	- PS label or sleeve in combination with a PET, PP or HDPE bottle - PVC label or sleeve in combination with a PET, PP or HDPE bottle - PETG or PETC label or sleeve in combination with a PET bottle - Sleeves made of different polymer than the bottle - Labels or sleeves that are metallised or are welded to a packaging body (in mould labelling)
Closure	- PS closure in combination a with a PET, PP or HDPE bottle PVC closure in combination with a PET, PP or HDPE bottle PETG closures and/or closure material with density of above 1 g/cm3 in combination with a PET bottle - Closures made of metal, glass, EVA - Closures made of silicone. Exempted are silicone closures with a density < 1 g/cm3 in combination with a PET bottle and silicone closures with a density > 1g/cm3 in combination with PP or HDPE bottle - Metallic foils or seals which remain fixed to the bottle or its closure after the product has been opened
Barrier coatings	- Polyamide, EVOH, functional polyolefins, metallised and light blocking barriers

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

Pumps and aerosol containers are exempted from this requirement.

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

(e) Take-back system

Applicant shall offer a take back service to their retailers in order to collect empty products from consumers

Assessment and verification: the applicant shall submit a description of the service conditions and a declaration of compliance.

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. For some products like toothpaste it can even reach 30% of the overall environmental impact. 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*[48].

In 2018, the European Commission published the European strategy for plastics in a circular economy[49] 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 is drafted in line with the objectives of the European strategy for plastics in order to facilitate the transition to a more circular economy by: (a) encouraging recycling-oriented design and (b) incentivising the demand for recycled materials. Introducing the requirement of recycled content in the packaging of cosmetics is also beneficial for the image and CSR of the companies that are producing the EU Ecolabel cosmetics due to the constantly increasing public awareness to this topic.

The introduction of recycled plastics in the manufacturing process reduce dependence on the extraction of fossil fuels. Nevertheless, the demand for recycled plastics is still very limited. According to the European strategy for plastics in circular economy, only 6% of the overall plastic demand is met by recycled plastics[50]. The introduction of the requirement for 20% of recycled material in the packaging design may result in a 30% reduction of environmental impacts in terms of climate change[51].

In the existing EU Ecolabel in force, this criterion is divided into 4 sub-criteria in order to cover different aspects of the packaging:

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

[49] https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf

[50] https://ec.europa.eu/environment/circular-economy/pdf/plastics-strategy-brochure.pdf

[51] According to our calculations, with Simapro software and ILCD method.

- **Primary packaging**: secondary packaging is not permitted, with the exception of packaging intended to group two or more products together.
- **Packaging Impact Ratio (PIR)**: the weight limit of the PIR must be less than 0,28g of packaging per gram of product. Existing criterion considers in the calculation the proportion of renewable and recycled content in the packaging, and if the product is refillable.
- **Design of primary packaging**: this requirement aims to ensure the correct dosage of the product and reduce the residual amount of the product in the container.
- **Design for recycling of plastic packaging**: plastic packaging shall be designed avoiding potential contaminants and incompatible materials to ensure separation and recycling of the container.

Other labelling schemes were investigated in terms of their requirements on packaging for cosmetic products (see Table 16):

Table 16: Summary of packaging requirements in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.

Criterion 4 — Packaging		
Nordic Swan	**Blue Angel**	**Bra Miljöval**
(a) Primary packaging		
MORE RESTRICTIVE THAN EU ECOLABEL *The secondary packaging must be from recycled material. Recycled materials mean ≥80 % recycled materials in packaging.*	**SAME CRITERION AS EU ECOLABEL**	**SAME CRITERION AS EU ECOLABEL**
(b) Packaging Impact Ratio (PIR)		
The primary packaging must meet the following calculation. The requirement applies to primary packaging. *mfi = material factor for type of material divided into the following 4 groups of materials:* *mfglass = 0.1* *mfpaper/cardboard = 0.5* *mflaminate = 1.1* *mfother materials = 1.0* *Weight material i = weight of the packaging component (including label + information sheet) in grams* *rfi = the fraction of the amount of recycled material i after the consumer stage.* *Weightpump = weight of pump (if applicable) in grams.* *t = reuse factor, t=1 for packaging which is not reused for the same purpose.* *ln = natural logarithm* *Vol product = volume of the product in ml* *a, b and c are constants that vary for different packaging types*	**SAME CRITERION AS EU ECOLABEL**	**NO CRITERION**
(c) Design of primary packaging		
For liquid hand soap no pump or dispenser sold with the product may provide more than 2 g soap per full press	**SAME CRITERION AS EU ECOLABEL**	**NO CRITERION**
(d)Design for recycling of plastic packaging		
SAME CRITERION AS EU ECOLABEL		

<table>
<tr><th colspan="3">Materials and components excluded from packaging elements</th></tr>
<tr>
<td>Metal packaging may only be used in spray bottles/propellant bottles for hairstyling products and shaving foam.</td>
<td>MORE RESTRICTIVE THAN EU ECOLABEL
The use of halogenated polymers and aluminium is not permitted.
<table>
<tr><th>Packaging component</th><th>Excluded materials and components</th></tr>
<tr><td>All components</td><td>— Components in the EuPIA list (exclusion list for printing inks and related products)</td></tr>
<tr><td>Label or sleeve</td><td>— A PETG or PETC label or a PETG sleeve or PETC sleeve in combination with a PET bottle</td></tr>
<tr><td>Closures (exempted are pumps and pressurised gas containers)</td><td>— Silicon components with PE and PP bottles
— Components made out of foamed elastomers with a PE and PP bottle
— Elastomer components with a density > 1 g/cm3 with a PET bottle</td></tr>
</table>
</td>
<td>Plastic packaging and labels must be made from polyethylene (PE), polypropylene (PP) or polyethylene terephthalate (PET). Packaging for toothpaste, deodorants and antiperspirants are exempt from this requirement.
Glass must not be used in the packaging.
Metal must not be used in the packaging. Exempt from this requirement is pressure containers of steel or aluminium and springs in spray nozzles and pump nozzles.</td>
</tr>
</table>

a)Primary packaging

The majority of the questionnaire respondents found this criterion adequate. Only 6% of respondents consider this requirement inappropriate because it is not strict enough. Proposals to improve the criterion have been collected, as for example:

–request that refills should always be provided by the license holders,

–prohibition of small bottles.

Such type of restrictions has not been found in other schemes. No changes are proposed at this stage of the revision.

b)Packaging Impact Ratio (PIR)

The PIR calculation as in the existing criterion considers the quantity of renewable and recycled materials in the packaging, as well as whether the product is refillable.

In the current scope of the formula, primary and secondary packaging is included. Tertiary packaging is excluded from calculation, as this will be specific to individual business customer requirements such as order quantity, stock control and shipping methods.

With regards to this requirement, 24% of questionnaire respondents consider the PIR difficult to calculate and/or the requirement of PIR=0.28 g of packaging per gram of product difficult to achieve (62% of them from industry). Different problems have been indicated, as follows:

–In some cases, data to calculate the PIR are difficult to obtain, since the suppliers are not able to provide the information,

–There are products which require packaging with heavy closing systems (foam pumps) which are not able to comply with the current requirement,

–Small packaging for sample use has more difficulties to comply with the criterion, and an exemption should be included for this type of product.

46% of the stakeholders have used the spreadsheet available on the EU Ecolabel website to calculate the PIR of the packaging and 87% of them find it easy to use. However, stakeholders identified some errors in the spreadsheet.

Competent Bodies provided information concerning current EU Ecolabel licences:

-Regarding the PIR values, the values range from 0,019g to the maximum allowed in the existing criterion: 0,280g.

-33% of the packaging for which data have been received contain recycled or renewable materials. The percentage of recycled or renewable materials range from the 18,4% to 98,9%.

-10,9% of the products can be refilled.

Considering data available for current ecolabelled products, the reduction of the PIR is not considered appropriate at this stage of the revision (no changes were made).

c)Design of primary packaging

20% of respondents consider the current requirement difficult to achieve.

According to the opinion of one respondent, the residual quantity of a rinse-off cosmetic product in the packaging depends not only on the dosage system, but also on the material and the viscosity of the product. Also products sold in bottles of lower capacity may have problems to achieve the requirement of 10%.

CBs could not provide information on the residual amount of product in the primary packaging for all the licenced products. The maximum reported residual amount of product remaining in the container is 7,8%.

No major changes are proposed to be made at this stage of the process. Nevertheless, it is proposed that the sentence *"packaging shall be designed to make correct dosage easy (e.g. by ensuring that the opening at the top is not too wide)"* is further specified for the specific case of whether liquid soap is sold with pump or dispenser, in line with Nordic Swan requirement, requesting for a maximum amount of product dispensed.

d)Design for recycling of plastic packaging

Recyclability of waste packaging is of high importance. From a life cycle perspective, it would generally be favourable to increase the amount of recycled material entering new life cycles in order to minimize the impact coming from new materials. The production impacts of virgin materials (and the related intermediates) 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 recyclable (nevertheless, used in low amounts for this product group).

For cosmetic products, plastics constitute the main packaging material. Labels (and to a significantly lower extent, especially for this product group, sleeves) are essential elements of packaging. Labels can be made e.g. of aluminized paper or plastic. Some labels are fixed to the packaging using different kinds of adhesives, while sleeves are made of plastic (shrink or stretch options) and do not require fixing by glue. Currently, the main plastics used in labels and sleeves are: oriented polypropylene (OPP), polypropylene (PP), polystyrene (PS), polyvinylchloride (PVC) and Polyethylene Terephtalate Glycol-modified (PETG).

The French Comité Technique pour le Recyclage des Emballages Plastiques (COTREP) conducted studies which were aimed to analyse different design options (i.e. combinations of packaging and label materials and designs) with the goal of setting recommendations on the design for recycling of plastic packaging[52]. General guidelines were prepared, explaining the behaviour of different types of labels and sleeves with various packaging materials in sorting and recycling processes.

WRAP is a not-for-profit company financed by government funding from Defra (Department for the Environment, Food and Rural Affairs), Scottish Government, the Welsh Government, the Northern Ireland Executive, and the European Union to help businesses, local authorities, communities and individuals with reducing waste, developing sustainable products and using resources in an efficient way. In the framework of its work, tools supporting sustainable practices in waste management are being developed. Among them there are HDPE and PET categorisation matrixes, which can be defined as tools supporting design for recycling.

[52] These guidelines are available on the website COTREP: www.cotrep.fr.

The above mentioned studies were used for the existing proposal of materials and components excluded from packaging elements. Detailed information can be found in the previous revision report[12].

44% of the respondents consider existing criterion clear enough. Nevertheless, some of them requested to update and make clearer the list of materials concerned.
Considering the requirements of the packaging criterion of Blue Angel, the inclusion of the crystalline polyethylene terephthalate (PETC) could be studied in this revision: PETG and PETC label or sleeve in combination with a PET bottle should be avoided.

Take-back system (New proposal)

Some cosmetics companies have offered to their shoppers the option of returning their empties:

- The French cosmetics producer L'Oreal has undertaken measures in several countries: Australian consumers can return their bodycare empties to designated stores free of charge without having to purchase new products. In Austria every returned packaging unit from the pharmacy line Vichy is marked with a stamp in a recycling passport – every six stamps the passport holder receives a free Vichy-Spa shower gel. And subsidiary Garnier not only takes back all packaging units from its own range but also from other brands. The empties are mechanically and/or manually sorted by ingredient – glass and metal are molten and plastics are shredded and processed into pellets. These are then made into either new L'Oreal packaging or plastic products for community projects.
- Consumer goods producer Henkel initiated the "Aerocycle" campaign with its "Right Guard" deodorants line in the UK; here the aluminium recycled at the end of the day is used for children's gyms, to name just one project.
- In Germany deodorant spray cans were also collected. The recycling programme R'cycle! by Unilever and drugstore chain "dm" also benefited children here: almost 800 bicycles could be made from the recycled aluminium for charitable institutions.
- Estée Lauder's make-up line MAC Cosmetics gives shoppers the option with its 'Back-to-MAC Programm' to return empty primary packaging to participating stores. In exchange for six returned cosmetics empties shoppers get a free eye shadow. The packaging is passed on to sub-contractors who in turn take care of recycling.
- At organic cosmetics and fragrance producer Farfalla shoppers can also return tubes and bottles taking part in the "Bring it back" campaign – which is especially helpful since in Switzerland plastics cannot be disposed of via collection bins in solid household waste. The plastic containers are processed into pellets by recycling partners. By company accounts, this saves about 1l of crude oil as well as two kilograms of carbon dioxide per kilogram of plastics produced.
- Austrian company Ringana has addressed the take-back of its packaging in a slightly different way: a total of ten completely emptied, pre-cleaned cosmetics glass bottles without pump mechanism and closure must be sent by surface mail and postage paid to the company. Then senders receive a free cosmetic product of their choice. The bottles are reclaimed and re-filled in an eco-friendly manner.

For the first proposal it is suggested to explore the possibility to include a take back system requirement.

Question to stakeholders
• Stakeholders are requested to provide their views on proposal. • Information concerning the feasibility of the take back implementation is welcome. • Additional data of PIR values of current licences is welcome in order to further evaluate the potential setting of stricter value. • Stakeholders are asked for their opinion regarding the possible inclusion of a requirement on mandatory provision of refill bottles for some cosmetics (e.g. shampoos, shower gels, etc.).

Rationale of proposed "assessment and verification"

Few comments against the current verification procedure for the packaging criterion have also been received: problems with the verification procedure of the maximum residual amount of product exist. One stakeholder commented the absence of a method that harmonises the proofs for the different criteria.

Some minor wording clarifications have been included at this stage.

Question to stakeholders
Stakeholders are requested to provide suggestions on how/where to clarify the assessment and verification text.

3.5 CRITERION 5: Renewable ingredients

Existing criterion 5: Sustainable sourcing of palm oil, palm kernel oil and their derivatives
Palm oil and palm kernel oil and their derivatives used in the product must be sourced from plantations that meet criteria for sustainable management that have been developed by multi-stakeholder organisations that have a broad- based membership including NGOs, industry and government. *Assessment and verification:* the applicant shall provide third-party certifications that the palm oil and palm kernel oil used in the manufacturing of the product originates from sustainably managed plantations. Certifications accepted shall include RSPO (by identity preserved, segregated or mass balance) or any equivalent scheme based on multi-stakeholder sustainable management criteria. For chemical derivatives of palm oil and palm kernel oil ([53]), it is acceptable to demonstrate sustainability through book and claim systems such as GreenPalm or equivalent.
First proposal for criterion 5: Renewable ingredients
(a) Sustainable sourcing of palm oil, palm kernel oil and their derivatives In the specific case of renewable ingredients from palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, 100% w/w of the renewable ingredients used shall meet the requirements for sustainable production of a certification scheme that is a multi-stakeholder organisation with a broad membership, including NGOs, industry and government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources. **(b) Certification of plant based ingredients** In the specific case of ingredients covered by the scope of the EU organic Regulation (EC 834/2007), X% w/w of the ingredients used shall be produced according to organic production and certified by a third-party. *Assessment and verification* To demonstrate compliance with sub-criterion (a) evidence through third-party chain of custody certificating that the input materials used in the manufacturing originate from sustainably managed plantations shall be provided. Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models: identity preserved, segregated, mass balance shall be accepted. For palm oil and palm kernel oil derivatives, the amounts of RSPO credits purchased and claimed in the RSPO PalmTrace system model during the most recent annual trading period shall be provided to demonstrate compliance to the Book and Claim supply chain model. To demonstrate compliance with sub-criterion (b), the applicant shall provide third-party certifications for the ingredients covered by the scope of the EU Organic Regulation. Certifications accepted shall include those awarded by Competent Bodies appointed through the EU Regulation on organic production 834/2007, as well as IFOAM family of standards, COSMOS, or any equivalent scheme.

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

[53] As defined by the RSPO in the 'RSPO Rules for Home and Personal Care Derivatives', available at: http://www.greenpalm.org/upload/files/45/RSPO_Guiding_Rules_for_HPC_derivativesV9.pdf.

that do not harm the natural environment. Because the manufacture of products generally involves more than one stakeholder and tracing the ingredients is difficult, certification schemes have arisen, verifying the brand's claims on sustainable production throughout the production chain. The concept of organic farming of renewable ingredients is now well established and many certification schemes exist (e.g. Ecocert[54], COSMOS[55], NaTrue[56]). On the contrary, sustainable cultivation of palm forests has only recently started to be monitored and verified through the creation of certification schemes, the main one being RSPO[57]. Finally, for some ingredients certification schemes assessing their sustainability are not available yet (for example coconut oil).

Criterion 5 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

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. Palm oil is seen as one of the most controversial, because of the issue of deforestation and land use change (direct and indirect) involving loss of natural habitats, associated with their plantations in Southeast Asia and Amazon rainforest.

To address the socio-economic issues and minimise the environmental impacts related to the cultivation of these oil-producing plants, some voluntary sustainability certification schemes have been developed. These include: ISCC (International Sustainability and Carbon Certification), RSPO (Round Table on Sustainable Palm Oil), RSB (Roundtable on Sustainable Biomaterials) bioproduct standard, as well as several others.

In the existing EU Ecolabel criteria for rinse-off products, after many discussions, only a requirement for the ingredients from palm cultivation was decided to be included, as this was one of the renewable raw materials of high visibility and linked to important environmental concerns[9].

According to the information provided by the Competent Bodies, 11% of the products contain palm or palm kernel oils and 93,5% of the products contain derivatives from palm oil and palm kernel oil. All EU Ecolabel awarded products including palm or palm kernel oil are RSPO certified.

22% of the respondents to the revision questionnaire consider that the criterion should be extended to other sustainable sources of raw materials indicating that there are other certifications to proof the sustainable origin of the ingredients. Such an extension of the criterion would promote the use of other sustainable ingredients based on coco, rape oil or soya oil.

Following a deep analysis of certification schemes for sustainable sourcing of ingredients, it was concluded that the lack of data and the absence of mature schemes to verify the sustainable sourcing of all types of renewable ingredients were the main reasons behind the unfeasibility to set a prescriptive requirement on all type of ingredients. Moreover, other ecolabelling schemes set the same criteria on palm oil, palm kernel oil and their derivatives as the EU Ecolabel (see Table 17).

Table 17: Summary of criteria related to sustainable sourcing of ingredients as found in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes compared with EU Ecolabel.

Nordic Swan	Blue Angel	Bra Miljöval
For each organic ingredient: proportion of this raw materials on an annual basis, raw material origin, and sustainability certification (if it is certified)	**SAME CRITERION AS EU ECOLABEL**	**SAME CRITERION AS EU ECOLABEL**

[54] https://www.ecocert.com/en/expertise/organic-farming
[55] https://cosmos-standard.org/
[56] https://www.natrue.org/our-standard/natrue-criteria-2/
[57] https://www.rspo.org/

Nordic Swan includes an informative requirement. However this option is not feasible for EU Ecolabel scheme where only prescriptive requirements should be set.

Therefore, at this stage of the proposal mainly wording adjustments have been made in line with EU Ecolabel for Lubricants. In addition, reference is made to the fact that the certification scheme must take into account environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources.

Requirement (b) - Certification of plant based ingredients

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 OGMs and limiting the input of chemically synthetized materials, and contributes to a high level of biological diversity[58].

According to EU Regulations EC 1223/2009 and EU 655/203, claims present in a cosmetic product label shall be justified. Moreover, the EU organic legal framework (Regulation 2018/848 repealing regulation 834/2007) includes also raw materials used for non-food products intended to be produced, prepared, labelled, distributed, placed on the market and imported into or exported from the Union, such as: yeasts used as food or feed; maté, sweetcorn, vine leaves, palm hearts, hop shoots, and other similar edible parts of plants and products produced therefrom; sea salt and other salts for food and feed; silkworm cocoon suitable for reeling; natural gums and resins; beeswax; essential oils; cork stoppers of natural cork, not agglomerated, and without any binding substances; cotton, not carded or combed; wool, not carded or combed; raw hides and untreated skins; plant-based traditional herbal preparations.
The analysis of other schemes suggested the possibility of a requirement focusing on the certification of organic ingredients (see Table 18). Moreover, as market trends indicate that the cosmetic sector is going toward conscious sourcing of ingredients, the proposed method would support such increasing trend.

Table 18: Summary of criteria related to the certification of organic ingredients as found in Nordic Swan, Blue Angel and Bra Miljöval labelling.

Nordic Swan	Blue Angel	Bra Miljöval
If it is stated on the product that the product is/contains organic ingredients, at least one of the following must be complied with for these raw materials: *• The EU Regulation on organic production 834/2007.* *• Organically certified under NOP* *• Organically certified under NPOP* *• Organically certified under a system approved by IFOAM* *This is stated, for example, with an asterisk following the substance on the INCI list and with the following text: "Organic under EU 889/2008/NOP/NPOP/xx"*	**NO CRITERION**	**NO CRITERION**

With regards other available certification schemes, Eco-cert certification includes two different labels: Organic Cosmetics (a minimum of 20% of organic ingredients in leave-on products, or for rinse-off products, non-emulsified aqueous products, and products with at least 80% minerals or ingredients of mineral origin, at least 10% of the total product by weight must come from organic farming) and Natural Cosmetics (a minimum of 5% of all ingredients by weight must come from organic farming).
In relation to Natrue, 95% of the natural substances of plant and animal origin and of derived natural substances contained in the product must come from controlled organic farming and/or wild collection, certified by a duly recognized certification body or authority to an organic standard or regulation approved in the IFOAM Family of Standards[59].

[58] Council Regulation (EC) No 834/2007
[59] https://www.ifoam.bio/pt/ifoam-family-standards-0

In the framework of a multi-year collaboration IFOAM - Organics International developed together with his UN partners, the Food and Agriculture Organization (FAO) and the United Nations Conference on Trade and Development (UNCTAD), a set of standard requirements that functions as an international reference to assess the quality and equivalency of organic standards and regulations.

The COSMOS-standard is a new cosmetic certification developed to harmonise various certifications and labels in order to create one standard that is internationally recognised for natural and organic cosmetics. The "COSMetic Organic Standard" was officially launched in February 2011, and as a result of Europe's leading natural cosmetic certifiers coming together and forming a non-profit association, COSMOS-standard AISBL. The COSMOS-standard association consists of five founding members who now authorise and oversee the certification, including the Soil Association (UK), Ecocert (France), Cosmebio (France), BDIH (Germany) and AIAB/ICEA (Italy). The COSMOS certification includes two type of ingredients: the certified ingredients (with organic content) and the approved raw materials (with no organic content which are not covered by the EU Organic Regulation). The approved raw materials have no organic content but are acceptable for use in the COSMOS-standard because they use only the chemical processes and reagents that the standard allows.
Nordic Swan request that a certification of the organic production of ingredients is provided in all cases where organic production is claimed on the label/package. However considering that EU Ecolabel should go beyond legislation it is suggested for the first revised proposal to discuss the possibility to request a **minimum content of organic certified ingredients when plant based ingredients (covered by the EU organic regulation) are used.**

Rationale of proposed assessment and verification

The assessment and verification of existing criterion 5 has the support of 60% of the revision questionnaire´s respondents, while 24% of them consider it difficult to check the proofs to guarantee the sustainable origin of the raw material, as not all ingredients are RSPO-certified.
Several stakeholders indicated that the Book and Claims[60] should be removed as a verification method. Moreover, it is considered necessary to improve the explanation and better define the evidence required for the verification.
For the sub-criterion 5 a), the formulation of the text has been aligned with the recently voted criteria for lubricants in order to ensure harmonisation across different EU Ecolabels.

With regards sub-criterion 5 b), it is suggested that a proof of organic certification for the relevant ingredients is provided, awarded by Competent Bodies designated according to the EU Regulation No 834/2007 on organic production, IFOAM family of standards, COSMOS scheme or equivalent schemes

Question to stakeholders
Stakeholders are asked to provide their views on the newly proposed requirement on certified organic ingredients.

3.6 CRITERION 6: Fitness for use

Existing criterion 6: Fitness for use

[60] RSPO Supply Chains: https://rspo.org/certification/supply-chains

The product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection) shall be demonstrated either through laboratory test(s) or a consumer test. The tests shall be conducted following the 'Guidelines for the Evaluation of the Efficacy of Cosmetic Products'(12) and the instructions given in the user manual available on the EU Ecolabel website. Assessment and verification: the applicant shall document the test protocol that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging. [References: (12) Available at: https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=23 and the EU Ecolabel website.]
First proposal for criterion 6: Fitness for use
The product's capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection) shall be demonstrated either through laboratory test(s) or a consumer test. The tests shall be conducted following the 'Guidelines for the Evaluation of the Efficacy of Cosmetic Products'(*) and the instructions given in the user manual available on the EU Ecolabel website. Assessment and verification: The applicant shall document the test protocol that has been followed in order to test the product's efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging. [References: (*) Available at: https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=23 and the EU Ecolabel website.]

Rationale of the proposed criterion text

Environmental assessment conducted in this study has showed that high percentage of total environmental impact of certain rinse-off cosmetic products is due to the use phase (up to 50% of total impacts, depending on the product and on the impact category). Some characteristics of the product, such as the ease for being rinsed-off or long-lasting results, would contribute to saving the amount of water consumed during the use phase, minimizing the overall environmental impact of the products. If the energy needed to heat the water is included in the studied system, the use stage could be responsible for up to 82% of the total environmental impact of the product (for the case of liquid soap, and in similar extent for other products).

The quality of products awarded with the EU Ecolabel is one of important aspects of the scheme, which must be considered in order to prevent creating the image that EU Ecolabel products are environmentally friendlier but poor in performance/inefficient. For that reason performance tests should address all important characteristics and functions of the product.

The criterion on fitness for use addresses currently the aspects of performance, dosage and application. In the 1st AHWG meeting it should be discussed whether the current formulation is stringent and precise enough, giving at the same time enough flexibility to cover all the different products, which will be finally covered under the scope of the revised criteria.

Cosmetic Europe's "Guidelines for the evaluation of the efficacy of Cosmetics Products"[61] (revised in May 2008) contain the general principles for all efficacy tests and the information which should appear on all test reports. Human and non-human testing methods for efficacy assessment are also explained in this document. In addition, there is a "Technical document on cosmetic claims"[62] agreed by the Sub-Working Group on Claims and endorsed by the Working Group on Cosmetic Products[63], published in July 2017.

[61] Available online under: https://www.cosmeticseurope.eu/files/4214/6407/6830/Guidelines_for_the_Evaluation_of_the_Efficacy_of_Cosmetic_Products_-_2008.pdf

[62] Available online under: https://ec.europa.eu/docsroom/documents/24847/attachments/1/

[63] 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

There are different types of studies, which can be used to provide data on the performance of cosmetic products:

-The sensorial approach (sight, touch, olfaction) by consumers or experts,

-The instrumental approach which favours specific criteria measured using in vivo, ex-vivo or in vitro approaches, which do not reproduce normal conditions of the use of products but allow objective analysis of specific activities.

Due to the absence of harmonized tests for specific product groups, user tests are often used. In a consumer test required by the current Ecolabel the minimum number of participants is 10. The product is compared with a referenced market-leading product. At least 80% of the consumers must be satisfied with the product as with the market-leading product.

In general, the use tests by consumers evaluate the consumers' perception of product efficacy and cosmetic properties based on parameters they can observe or feel. There are two main types of use tests[64]:

-Blind use test: Tests without providing any information such as brand, decor, communication which could influence the consumers´ judgement and alter their perception of the effect of the product alone.

-Concept use tests: Product tests combined with elements of communication that help to check whether the concept, the communication and the effect of the product as perceived by the consumers match; information from concept use tests are used to complement that contained in the product efficacy dossier.

There are specific guidelines for certain product categories, but for some of them only. For instance the European Commission adopted recommendations on the efficacy of sunscreen products and related claims[65], which apply universally across the EU.

Nevertheless, any experimental studies must satisfy the general principles applicable to all scientific procedures described below:

-Methods must be reliable and reproducible.

-The studies should follow a well-designed and scientifically valid methodology according to good practices.

-The criteria used for evaluation of product performances should be defined with accuracy and chosen in compliance with the aim of the test. For example, shampoo test must include at least cleaning performance and usability (dosage and how easy is it to apply the product).

-Studies conducted on volunteers should respect ethical rules and products tested should have previously undergone a safety investigation.

-Human studies should be conducted on the target population when necessary, defined by strict inclusion/exclusion criteria.

-Ex vivo/in vitro tests must be conducted under standardized conditions and their protocols must refer to published and/or “in house” validated methods. Clear descriptions of the methodology should be documented, as well as the statistical analysis of the data. These tests should be conducted in a controlled environment.

-A study protocol must be drawn up, monitored and validated in order to ensure that the operating procedures are correctly followed.

-The test laboratories must have standardized operating procedures. The person conducting the study must:

-Have the appropriate qualifications,

-Have the training and experience in the proposed study,

(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).

[64] Practical guidance on methodology for cosmetic claim substantiation, Cosmetics Europe, May 2008.

[65] 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

-Respect for ethical quality and professional integrity.

-Data processing and the interpretation of results must be fair and should not overstep the limits of the test´s significance.

The guideline provided by Cosmetics Europe advice also which information should be included in the test protocols and test reports[66], e.g. information that can assure the reliability of the study.

Testing requirements (test protocols)

-General information:

-Study objective,

-Product tested and reference product (if used): type of product, quantity of product applied, product to be tested and reference product (s) (if used),

-Test procedure: timetable and study location,

-Data management – Data processing – Analysis of results: Calculations carried out and statistical analysis used must be specified. Statistical methods (statistical tests chosen, alpha risk and software used) should be indicated,

-Equipments and reagents: Description, specification and identification of equipment, usage conditions and relevance of the measurement.

-Specific Information:

-Evaluation on human volunteers

- oProduct tested,
- oVolunteers: Inclusion and exclusion criteria, number of subjects, training and trained panellists for sensorial evaluation tests by experts,
- oMethodology.

-Ex vivo/ in vitro tests

- oSubstrate,
- oMethodology: the number of subjects and tests must be specified. The test planning should be explained with timetable defined.

Documentation requirements (test reports)

- General Information:

-Identification: the sponsor of the study, organisation in charge and address of the laboratories where the tests take place, person responsible for testing (if appropriate other investigators involved), product tested (type of product, formula number, batch number or code etc.) and issue date of the report.

-Objective of the test,

-Test schedule: Starting and finishing date,

-Methodology,

-Statistics: Definition of method employed, outcome of statistical analysis and if not stated in the report, justification,

-Results,

-Discussion,

-Conclusion,

-Signatures of the persons responsible for testing: technician, investigator, quality assurance and person responsible for the statistical analysis,

-Summary of the report.

- Specific information:

-Evaluation on human volunteers: justification of panel choice with regard to specific effects' assessment and demographic criteria,

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

-Use tests by consumers: socio-demographic criteria (panel) and presentation of results,

-Sensorial evaluation tests by trained expert panels: Presentation of results (choice of presentation of results), analysis of the inter-variability of the panel and list of criteria assessed,

-Evaluation by a professional expert and Instrumental tests: Presentation of results: quantitative data (number of subjects, median, standard deviation, percentages), qualitative data (absolute or relative frequency), method used to assess the observed effect and interpretation of results,

-Ex Vivo/ In Vitro tests: Presentation of results.

According to Commission Regulation (EU) No 655/2013[67] claims on cosmetic products should conform to the following common criteria:

- **Legal compliance**: Presumed for all products circulating in the EU.
- **Truthfulness**: Concerning the presence of certain ingredients or properties in the finished product.
- **Evidential support**: All manufacturers should provide a proof of effect claimed for their products, taking into account the state of the art at the moment when the product is marketed.
- **Honesty:** The effect claimed should not go further than the evidence available.
- **Fairness:** Different products shall not be compared to prove the benefits of one of them.
- **Informed decision making**: Claims and advertising shall be clear and understandable for the target audience.

These criteria should be taken into account when it comes to best-practice verification for personal care and cosmetic products. Ensuring adequate testing for products should then be a key concern for the industry, regardless of the mere regulatory requirements.

In the current EU Ecolabel for cosmetic products it is required that the product shall be tested to demonstrate its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e. g. anti-dandruff, colour protection).

55% of respondents of the revision questionnaire consider the current criterion adequate. However, some point out that the criterion is subjective and the current limit of the consumer test (80% of testers considering at least as good as a market-leading product[68]) is difficult to achieve.

Regarding the verification procedure, 10% of the respondents disagree with the currently set method. They argue that for confidentiality reasons it is not appropriate to provide the contact details of the consumers. Moreover, a generic formulation like IKW (Industrieverband Körperpflege- und Waschmittel e.V) tests should be considered.

Even though the majority of stakeholders agree with current criteria (52%), they point out improvement potential in the verification process. The use of a generic formulation as reference could be considered, as it is used for example in laundry detergents or automatic dishwashing products to be awarded with EU Ecolabel. Moreover, a standard procedure could be studied to allow a more objective test.

An analysis of other ecolabels has been performed in order to study how fitness for use is addressed in other schemes. These ecolabelling schemes suggest that EU Ecolabel applicants could perform a consumer or laboratory test to demonstrate the functionality of the product, like the Nordic Swan and Blue Angel Ecolabels do. Nevertheless, Nordic Ecolabel allows for existing products that have been on the market for at least 3 years, the use of sales as documentation of the primary functions. Sales must be increasing or stable to demonstrate their fitness for use. This point could be kept under consideration when revising this requirement in the EU Ecolabel scheme.

In this phase of the revision, the project team is trying to gather as much information as possible on the specific product testing, to aid defining of the most possibly practical approach to performance testing of cosmetics products.

Table 19: Summary of criteria related to fitness for use of cosmetic products as found in Nordic Swan, Blue Angel and Bra Miljöval labelling schemes.

Nordic Swan	Blue Angel	Bra Miljöval

[67] 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

[68] COSMETICS EUROPE: Guidelines for the evaluation of the efficacy of cosmetics products https://www.cosmeticseurope.eu/files/4214/6407/6830/Guidelines_for_the_Evaluation_of_the_Efficacy_of_Cosmetic_Products_-_2008.pdf

SAME CRITERION AS EU ECOLABEL *For existing products that have been on the market for at least 3 years, sales figures can be used as documentation of the primary function. Sales must be increasing or stable to be used as documentation for the primary performance/quality*	**SAME CRITERION AS EU ECOLABEL**	**NO CRITERION**
Sunscreen *The labelling of sunscreen products with information text and SPF factor are to follow Commission Recommendation 2006/647/EC on the efficacy of sunscreen products and the claims made relating thereto*		

Rationale of proposed assessment and verification

At present it is required that the applicant shall provide results from testing, which demonstrate that the product fulfils the primary and secondary functions claimed on the product label or packaging. They need to document the test protocol that has been followed in order to test the product's efficacy. Depending on the final shape of this criterion the proposed assessment and verification may change in the later stage of the revision process. At this stage of the process no changes were made to the text.

Question to stakeholders
Stakeholders are requested to provide information on testing protocols, methodologies for general and specific cosmetic products, as well as additional proposals of improvement for the currently valid criterion.

3.7 CRITERION 7: Information appearing on the EU Ecolabel

Existing criterion 7: Information appearing on the EU Ecolabel
The optional label with text box shall contain the following text: — Reduced impact on aquatic ecosystems, — Fulfils strict biodegradability requirements, — Limits packaging waste. The guidelines for the use of the optional label with text box can be found in the 'Guidelines for use of the Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: the applicant shall provide a sample of the product label or an artwork of the packaging where the EU Ecolabel is placed, together with a signed declaration of compliance.
First proposal for criterion 7: Information appearing on the EU Ecolabel
The optional label with box shall contain the following information: - Limited impact on aquatic environment - Fulfills strict biodegradability requirements - Limits packaging waste The guidelines for the use of the optional label with text box can be found in the 'Guidelines for use of the Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: the applicant shall provide a sample of the product

Existing criterion 7: Information appearing on the EU Ecolabel
The optional label with text box shall contain the following text: — Reduced impact on aquatic ecosystems, — Fulfils strict biodegradability requirements, — Limits packaging waste. The guidelines for the use of the optional label with text box can be found in the 'Guidelines for use of the Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf Assessment and verification: the applicant shall provide a sample of the product label or an artwork of the packaging where the EU Ecolabel is placed, together with a signed declaration of compliance.
First proposal for criterion 7: Information appearing on the EU Ecolabel
label or an artwork of the packaging where the EU Ecolabel is placed, together with a signed declaration of compliance.

Rationale of proposed criterion text

According to Article 8 (3b) of the EU Ecolabel Regulation 66/2010, for each product group, three key environmental characteristics of the EU Ecolabel product may be displayed in the optional label with text box. The guidelines for the use of the optional label with text box can be found in the "Guidelines for the use of the EU Ecolabel logo" on the website[69].

Information about the EU Ecolabel on the product helps to inform the consumer on the environmental preference of this product and make easy the environmentally friendly decision. For this reason this criterion is included in all EU Ecolabels.

The choice of phrases to be displayed on the EU Ecolabel will depend on the final shape of the criteria therefore for the moment only minor changes are being proposed and more important modification may be made, when the final criteria is better known.

According to the feedback received from the revision questionnaire (see Preliminary Report[12] for more details) the majority of the respondents agree with the current text appearing on the EU Ecolabel.

No relevant changes introduced at this stage.

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

4 IMPACT OF CHANGES TO CRITERIA

This section consists of a summary of the main general changes proposed for the revised criteria and potential implications for current license holders and possible applicants.

At this early stage of the process the main fundamental changes consist of the extension of the scope and of the increased strictness of the requirements.

This chapter will be further developed in the following versions of this technical report once the proposals are further discussed.

5 ANNEX I. SUBSTITUTION INFORMATION AND DEROGATION REQUEST FORM

Stakeholders should fulfil to communicate the derogation from of substances that cannot be replaced and are not able to comply with article 6 (6) of the EU Ecolabel Regulation.

1. Common information requirements

To be treated as confidential?	☐Yes ☐No

Contact name	
Organisation	
Email	
Telephone No.	
Supplementary documents attached	

1a. Chemical substance name(s)	
1b. CAS, EC or Annex VI numbers	
1c. Current EU regulatory status	
1d. CLP Classifications from the EU Ecolabel hazard listing	
1e. Proportional contribution to final product classification (for mixture ingredients)	
1f. Existing scientific evidence and risk assessments relating to the substance	
1g. Functional need and significance to the final product	
1h. Typical concentration in the final product and specific components or articles	

2. Additional information required for <u>derogation requests</u>

2a. The relevance of the hazard classification(s) along the life cycle of the product (e.g. manufacturing, use, disposal)	
2b. Market availability of alternatives and the potential for substitution	

3. Additional information required about substitutes

3a. Comparative evaluation of environmental performance	
3b. The relevance of the hazard substitution along the life cycle of the product (e.g. manufacturing, use, disposal)	
3c. Compliance with product performance and functional requirements	
3d. Market diffusion and technical maturity	

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