# Revision of European Ecolabel Criteria for Soaps, Shampoos and Hair Conditioners



## Technical report including revised draft criteria proposal for the product group of rinse-off cosmetic products

**February 2013**

JRC EUROPEAN COMMISSION

ipts Institute for Prospective Technological Studies

LEITAT Technological Center member of TECNIO
managing your technologies

# Revision of European Ecolabel Criteria for Soaps, Shampoos and Hair Conditioners



## Technical report including revised draft criteria proposal for the product group of rinse-off cosmetic products

**Prepared by**

**Carme Hildago, Natalia Fuentes (LEITAT)**
**Renata Kaps, Jiannis S. Kougoulis (JRC IPTS)**

## TABLE OF CONTENTS

## INDEX OF TABLES

**ABBREVIATIONS**

| | |
|---|---|
| aNBDO | - Aerobic Non-Biodegradable Organics |
| anNBDO | - Anaerobic Non-Biodegradable Organics |
| ANEC | - European Association for the Coordination of Consumer Representation in Standardisation |
| AC | - Active Content |
| AI | - Active Ingredients |
| BCF | - Bioconcentration factor |
| BEUC | - Bureau Européen des Unions de Consommateurs |
| CDV | - Critical Dilution Volume |
| C&L | - Classification & Labelling |
| CLP | - Regulation on classification, labelling and packaging of substances and mixtures |
| CPNP | - Cosmetic Products Notification Portal |
| DALY | - Disability-adjusted life year |
| DID-list | - Detergent Ingredient Database |
| DSD | - Dangerous substance directive 67/548/EC |
| DPD | - Dangerous preparation directive 1999/45/EC |
| ECHA | - European Chemicals Agency |
| EPD | - Environmental Product Declaration |
| ESIS | - European chemical substances information system |
| GHS | - Globally Harmonised System |
| GNPD | - Global database of new products |
| GSP | - Good sustainability practice |
| IPCC | - Intergovernmental Panel on Climate Change |
| IUPAC | - International Union of Pure and Applied Chemistry |
| LCA | - Life Cycle Assessment |
| PAF | - Potentially Affected Fraction of species |
| PBT | - Persistent bioaccumulative toxic |
| PE | - Polyethylene |
| PET | - Polyethylene terephthalate |
| PNEC | - Predicted No Effect Concentration |
| PP | - Polypropylene |

| | |
|---|---|
| PVC | - Polyvinyl chloride |
| RSP | - Retail Selling Price |
| RSPO | - Roundtable on Sustainable Palm Oil |
| SCCP | - Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers |
| SCENIHR | - Scientific Committee on Emerging and Newly Identified Health Risks |
| SCHER | - Scientific Committee on Health and Environmental Risks |
| SDS | - Safety data sheet |
| SF | - Safety factor |
| SVHC | - Substances of very high concern |
| TF | - Toxicity factor |
| vPvB | - Very persistent and very bioaccumulative |

## INTRODUCTION

A proposal of revised EU Ecolabel criteria for the product group of "soaps, shampoos and hair conditioners"[1] is presented in this document. The recommendations for revision of the current criteria has been done based on input received from stakeholders who were involved in this revision process (among others the representatives of the cosmetic industry, of relevant associations, NGOs, Members of the EU Ecolabel Board and other)[2].

Further, the proposals for criteria revision are motivated and/or justified by the results obtained in the technical analysis: the Life Cycle Assessment (LCA) conducted (which assesses the environmental impacts of products covered by the scope of the product group along their life cycle) and the analysis of substances contained in these products[3].

Life cycle assessment of liquid soaps, solid soaps, shampoos and hair conditioners show that hot spots among all life stages of these products are related to use stage (20.5% of the total products impact), disposal to water (between 20 and 14% depending on the kind of product), packaging (between 17 and 24%) and chemicals used (44% of the total environmental impact for solid soaps, 23% for hair conditioners, 9% for shampoo and 10% for liquid soaps). Other stages (manufacturing of products (11.5% on average of the total products impact), distribution (7% of the total products impact) and waste packaging treatment (2% for bottles and 0.1% for solid soap packaging)) have lower load in the overall environmental impact of these products.

Ecolabelled soaps, shampoos and hair conditioners should not contain harmful ingredients and impurities. They should not pose any potential threat to human health and environment along the product life cycle. Analysis of the most commonly used substances that perform the same function in each category has been conducted and the identification of substances of concern has been made, based on ingredients inherent properties. The consideration of more stringent requirements (in comparison with the currently existing criteria) is proposed for some criteria in order to ensure better environmental performance of this product group. Special attention should also be given to the inclusion of health criteria, as indicated in the Commission Statement of 14 December 2006, accompanying the EU Ecolabel criteria development for this product group.

The proposed criteria are as follows:

1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
2. Biodegradability
3. Excluded or limited substances and mixtures
4. Packaging requirements

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

[2] See results of questionnaires on the current EU Ecolabel criteria for the product group under study and on the proposal for the new criteria in Appendix x of the "Technical Background Report" for the 1st AHWG meeting, available online at: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html .

[3] For more information see details in "Technical analysis" report, available online at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

5. Sustainable sourcing of palm oil
6. Fitness for use
7. Information appearing on the EU Ecolabel

The criteria proposals and the discussion with rationale are described criterion by criterion in the report.

The main changes in comparison with the previous criteria version presented in November at the second EU Ecolabelling Board meeting can be summarised as follows:

- The definitions of ingoing substances, Active Content (AC), primary packaging and secondary packaging have been added,

- The proposal of including pet products have been deleted, as it was agreed not to cover them in the product group scope,

- The definition of functional unit and reference flow were removed, as thy are not referred to in the criteria,

- The formula for calculating Critical Dilution Volume was amended,

- The revised threshold values for CDV and biodegradability ( criterion 1 and 2) were introduced,

- The criterion 2 b) "biodegradability of organic substances" was restructured to harmonise with criteria for other product groups, e.g. for industrial and institutional laundry detergents.

- In the criterion 3 a) the list of excluded substances was amended. The fragrances excluded are aligned with the SCCS opinion from 2012 (established fragrance contact allergens of special concern are excluded from the ecolabelled products).

- The formulation of criterion 3 b) was amended. The requirement that "The final product must not be labelled according to the hazard statements above and moreover the final product formulation shall not contain any hazardous substances, or combinations thereof, that result in the formulation being greater than 0.85 of the limit required for classifying dangerous substances as defined within ANNEX II of Directive 1999/45/EC and as required by the Regulation (EC) No 1272/2008 (CLP Regulation)" was removed.

- The criterion 4 a) regarding the primary packaging, which is allowed, was added.

- The limit value for and Packaging Impact Ratio (PIR) was changed. Metal packaging is excluded from this requirement.

- The criterion 4 e) Design of packaging was introduced. A requirement on testing residual product is asked.

- The previously proposed criterion 4 b) Single use products was withdrawn.
- The previously proposed criterion 4 e) Aerosol propellants was withdrawn.
- Criterion 5 Sustainable sourcing of palm oil was amended based on input received.
- Criterion 6 Fitness for use was changed. The Annex II is removed from the decision text. It is required that the tests shall be conducting following the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products"[4].



[4] Available online at: https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html and the EU Ecolabel website.

## 1. PRODUCT GROUP SCOPE AND DEFINITION

The definition of the product group of "**rinse-off cosmetic products**" is based on the currently valid definition of the product group and the definition given in the new Cosmetics Regulation (EC) No 1223/2009. The preliminary definition and proposed scope of the product group has been discussed with the stakeholders using the Questionnaire 1 and at the first and second AHWG meetings, as well as the EU Ecolabelling meetings. The preliminary proposed definition and scope have been revised in the light of the feedback received along the consultation process.

In comparison with the last proposal, after the discussions conducted in the framework of the EU Ecolabelling meeting in November 2012, it has been decided to extend the scope of the product group to pre-shaving preparations but not to cover by the scope the shampoos for animals (pets).

The final proposal of the product group definition is as follows:

The product group "Rinse-off cosmetic products" shall comprise soaps, shampoos, hair conditioners and pre-shaving products, i.e. "any rinse-off substance or mixtures intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance or mixture intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners) and any rinse-off substance or mixture intended to be placed in contact with the epidermis with a view to protect it and to lubricate the hair before shaving (pre-shaving products)".

The product group shall cover products for both private and professional use.

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

Further, for the purpose of this Ecolabel Decision, the following definitions shall apply:

(1) "Ingoing substances" means preservatives and colouring agents, regardless of the concentration and other substances intentionally added, as well as by-products and impurities from raw materials, the concentration of which equals or exceeds 0.010 % by weight of final formulation.

(2) "Active Content" means the sum of organic ingoing substances in the product (expressed in grams). It must be calculated on the basis of the complete formulation of the product. Rubbing/abrasive agents in hand cleaning agents are not included in the calculation of AC.

(3) "Primary packaging" (sales packaging) means packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase[5]. It is defined as the smallest unit of distribution and it shall be in direct contact with the contents.

(4) "Secondary packaging" (grouped packaging) means packaging 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; it can be removed from the product without affecting its characteristics.

**Substantiating information and discussion regarding the scope and definition**

In accordance with the Commission Decision establishing the ecological criteria for the product group of soaps, shampoos and hair conditioners[6] the currently valid definition of this product group comprises "***any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners)***"[7].

The current criteria for soaps, shampoos and hair conditioners aim to promote the products which:

- Reduce water pollution,
- Minimise waste production,
- Reduce or prevent the potential risks for the environment related to the use of hazardous substances.

This product group covers products for both private and professional use and it does not cover products that are specifically marketed for disinfecting or anti-bacterial use.



[5] EU Directive on Packaging and Packaging Waste 94/62/EC.
[6] Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:186:0036:0045:EN:PDF.
[7] Note: disinfecting products (cleaning products with anti-microbial function) are excluded from the product group (from ordinary cleaning products).

**Consideration on the extension of scope and revision of definition**

***Scope of the product group***

In this revision process extension of the existing scope of soaps, shampoos and hair conditioners product group described above has been considered, taking into account that other cleaning products with a certain degree of similarity, for example a common function or a way of application or with similar chemical composition exist and, although they have not been so far covered by the EU Ecolabel, they could be included in the scope in the revised criteria document. This was discussed in the first AHWG meeting and several stakeholders in general welcomed a possible extension of the current scope.

With this aim, typical ingredients of each new considered product were analyzed and compared with a typical composition of soaps, shampoos and hair conditioners[8]. First, a list of products which fulfils the same or a similar function of cleaning was prepared. The composition of the following products:

- shaving products: shaving-foam, -cream, -gel and -soap,
- toothpaste,
- shampoo for animals, especially pets,
- wet wipes,
- cleansing and remover make-up products,

was analysed in order to see if the ingredients and functions are similar to the products already covered by the existing criteria. Further, also the environmental fate of the considered products was analysed.

Based on the outcomes of this preliminary analysis some products with rinse-off application were found to have a similar composition and are considered to be suitable to be included in the product group, as it is the case of **shaving foam, gel, cream and soap**. It is expected that products having similar ingredients have, from an LCA point of view, to a great extent a similar environmental profile. This would allow including these types of products even in this criteria revision.

Other products with cleaning function and rinse-off application proposed to be included are **pets' shampoos**. Products for animals are rinsed-off to water in the same way as shampoos and soaps for people and the composition is similar. There has been some interest in the ecolabelling of shampoos for pets (e.g. in Nordic Ecolabel), even though there are no labelled products on the market at the moment[9]. Some feedback regarding this extension has been received and this issue has been discussed during the second AHWG meeting.



[8] For details please see Appendix I: Scope of the product group of the Technical Background Report 2, available online at the project website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/docs/.

[9] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011. In the current version of the Nordic Swan criteria for Cosmetic Products the animal shampoos are included in the scope of the product group.

Further, some products with a similar way of application are not proposed to be included in the revised scope based on the results obtained because their composition differs too much from soaps and shampoos, as it was e.g. in the case of **toothpaste**.

Some other products with cleaning function, for example **wet wipes**, were found to have to a limited extent similar composition (except of the material used as support in wipes). Nevertheless, their way of application and the final disposal differ from those of the rinse-off products (wet wipes will be disposed with other household waste) and therefore it is not proposed to include them in the extended product group.

Concerning **cleansing and remover make-up products**, the composition differs from soaps and shampoos and the way of application is different from rinsed-off products, which causes that the final fate is different. In consequence they were excluded from the potential scope extension.

**Rationale and discussion conducted along the consultation process**

When assessing the potential environmental impacts that a cosmetic product can cause, all life cycle stages have to be taken into account: ingredients manufacturing, product manufacturing, packaging and distribution, use and disposal after use with municipal waste or through wastewater (considering the possible final release of substances into the environment and the harmful effects that they could cause).

The release of the products into the environmental compartments (water, soil, air) will be determined partly by the way of application[10]. **Rinse-off products** will be disposed and diluted to water after use via the wastewater route, while **non rinse-off products** (e.g. wet wipes, cleansing and remover make-up) are initially applied to remain on body surfaces (skin), although a fraction of these chemicals can also reach the municipal sewage plants if they are eliminated e.g. by washing, or can accidentally reach the aquatic environment. Finally, those cosmetic products containing a solid single-use support (e.g. wipes) or those which are removed with solid cottons or single-use towels (e.g. cleansing and remover make-up) will be disposed as solid waste after being used.

After use the **rinse-off products** will be released to domestic wastewater, which is expected to be treated in a sewage plant before being released to aquatic environments. In the LCA conducted for this revision process, it was found that release to water was one of the life stages with major environmental impacts. After being treated, depending on the level of sewage treatment and on the properties of the ingredients, some substances will be degraded but a certain fraction of the ingredients from cosmetic products may end up in the aquatic environment or be adsorbed into the sludge. Therefore, for these products properties such as high biodegradability, low bioaccumulation and low toxicity to the aquatic environment are

[10] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011.

important[11] to guarantee that the products' ingredients will have low impact on the environment. For that reason the current EU Ecolabel criteria for this product group are aimed to high extent at reducing the impact of rinse-off products' ingredients released into the aquatic environment.

The environmental safety is determined basically by the environmental fate and the potential impact of a chemical in the specific environmental compartment[12]. Both aspects depend on the properties of the substances. The environmental fate is determined by the physicochemical properties such as water solubility, adsorption behaviour, volatility and biodegradability, which determine the distribution of a chemical in the environmental compartments (water, soil, air). The potential impact of a chemical in the specific environmental compartment is determined by the ecotoxicological properties.

The ingredients present in rinse-off products are to a certain extent different from those in non rinse-off products mainly because they differ in their purpose: use and function are different.

For example in most cases, more than 80% of the mass of organic product ingredients in rinse-off products are readily biodegradable, while in leave-on products are only more than 60%. This is mainly due to a significant percentage of polymeric and/or poorly soluble ingredients present in leave-on cosmetic products that biodegrade slowly or not at all. As a result, the biodegradability criterion could differ for both kinds of products and setting specific thresholds would be needed.

Another issue that is expected to differ for rinse-off and non rinse-off products is the eco-toxicity. Rinse-off products will be disposed of after use via the waste water route. Consequently, a certain percentage of the ingredients from rinse-off cosmetic products may end up in the aquatic environment. Surfactants are the key components in rinse-off products and can interact with biological surfaces; therefore they are relatively toxic to aquatic organisms. Toxicity to the aquatic environment is thus of high importance for rinse-off products.

Aspects such as use of fragrances and nanomaterials could be also different for both types of products because leave-on products are initially applied to remain on body surfaces, and stricter requirements need to be taken into consideration.

Finally, some specific substances should be proposed to be restricted based on the composition on leave-on and rinse-off cosmetic products.

Consequently, it can be expected that the environmental behaviour and impacts are different for these two product groups. For these reasons a new category for "leave-on cosmetic products" (non rinse-off products) could be created in the future, but taking into account different thresholds parameters for e.g. regarding biodegradability, toxicity, specific restricted

[11] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011. In the current version of the Nordic Swan criteria for Cosmetic Products the animal shampoos are included in the scope of the product group.

[12] Pharmaceuticals and Personal Care Products in the Environment Letter to the Editor ENVIRONMENTAL SAFETY ASPECTS OF PERSONAL CARE PRODUCTS— A EUROPEAN PERSPECTIVE. Environmental Toxicology and Chemistry, Vol. 28, No. 12, pp. 2485–2489, 2009 SETAC (USA).

substances. For products with this way of application (intended to be applied and absorbed by the skin or hair and not rinsed-off) other aspects have to be considered and additional criteria, which differ from those existing ones, would need to be developed. Differences in ingredients used and different impacts in the end of life phase would need to be analyzed further in a comprehensive study in order to develop the criteria for other cosmetic products than those already covered by the current product scope or products very similar to them in composition and environmental profile.

Furthermore, some stakeholders from Member States but also industry expressed interest to cover within the scope of EU Ecolabel all cosmetic products. This proposal would, nevertheless, require extensive environmental evaluation of different product groups and appropriate determination of key environmental areas for which the criteria should be set. Such a development could be conducted in the future if it is proved that significant environmental improvement can be achieved.

Written stakeholders feedback received with regard to the first proposal for the revised Ecolabel criteria and the discussions around the first AHWG meeting supported including other rinse-off products with similar purposes like **shaving foam, shaving gel, shaving cream and shaving soap**.

Less clear was the consideration on inclusion of **shampoos for animals**, especially pets and this issue was discussed during the second AHWG meeting again.

To the question of the expansion to pet shampoos without insecticides and other biocides apart from conservation of the product, feedback has been received that these products did not really fit to the entire group, as they were not covered by the cosmetics directive. Furthermore, they are not used regularly and by high share of the population of the EU.

The stakeholder asked for information related to sales volume:

- compared to shampoos with insecticides and other biocides and
- compared to the other products groups soaps, shampoos, hair conditioners, shaving products.

According to the Mintel Database, from shampoo pets identified in the European market in 2012, only the 28% of these products claim to have insecticide, anti-bacterial and anti-parasite properties. The rest of pet grooming products, such as shampoo and cleansers products, have other claims such as pH neutral and skin-friendly, deodorizing, shine effects, conditionings, etc. Pet grooming products such as shampoo and cleansers are increasingly influenced by tendencies seen in personal care products for humans, in line with the humanisation of pets trend where pets are increasingly seen as part of the family. Accordingly, these products could be similar to human shampoos in terms of contents.

The number of pet shampoo products present in the European market identified in Mintel GNPD Database is of approximately 200 products, this is only **a 2% of shampoo products of the market** (the rest is intended for humans).

Regarding sales volume, no data is available in European Statistics (Eurostat), since there is no specific product group for pet shampoos (Prodcom categories and data). But according to the Mintel GNDP Database, data referred for the general category of pets supplies show that, while sales in many categories have declined in recent years as a result of the recession, the **pet supplies market has remained quite stable**. This is partly a function of the deep emotional bonds that many people have formed with their pets as well as strong demand for a broad range of goods that help owners care for their pets and keep them healthy.

After the presentation of the information collected, at the EU Ecolabelling Board meeting it was decided to include only the pre-shaving products and not to cover by the product group scope the similar products for animals (pets).

The results and conclusions of the scope revision can be summarised as follows:

- Shaving products are proposed to be included in the product category under study due to a certain degree of similarity: similar chemical composition and environmental fate (they are rinsed-off to water).

- Rinse-off products for animals are not covered by the cosmetics directive, but could be covered by the scope of the revised product group due to similar formulation and environmental fate; it was however decided not to include them in the revised product group scope.

- The wet wipes for "cosmetic purposes" (such as facial wipes, cleansing wipes, hand and body wipes, or moist towelettes) are not proposed to be included in this product group because the way of application differs from the application of rinse-off products and the environmental profile is expected to be very different compared to the products analysed in the LCAs conducted in the project and presented in the technical background report.

- An extension of the scope for toothpaste is not proposed because its composition differs significantly from the composition of the currently covered products. Further, an inclusion of toothpaste will need a comprehensive investigation for determining new or significantly modifying current criteria proposal as the user comes in contact with toothpaste through the mouth e.g. for substances criterion there is of relevance a different exposure path which would need to be investigated.

- Cleansing and remover make-up products were not proposed to be included because the way of application is different from rinse-off products, which also causes that the final LCA environmental profile is different.

***Definition of the product group***

The definition of cosmetic products, as given in the Cosmetics Regulation (EC) No 1223/2009, is as follows:

*'**cosmetic product**' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;*

Taking this into account and considering the existing definition of the product group of soaps, shampoos and hair conditioners, the revised name and definition of this product group were initially proposed to be as follows:

"***any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact with the hair system with a view to improve the condition of the hair (hair conditioners) and any rinse-off substance and preparation intended to be placed in contact with the epidermis with a view to protect it and to lubricate the hair before shaving (pre-shaving preparations)"***.

Moreover, as supported by many stakeholders and agreed in the first AHWG **a change of the product group name from "soaps, shampoos and hair conditioners" to "rinse-off cosmetic products"** is undertaken.

Several comments have been received regarding the change the product group name to "Rinse-off Cosmetic Products" based on the following arguments:

- "Rinse-off" and "leave on" cannot exactly be attributed to the specific categories of cosmetic products therefore the name would be much vague. In case of hair-conditioners e.g. both kinds are offered, this is also the case for other products.

- The proposed scope will only include part of rinse-off products, e.g. external intimate hygiene products, mouth wash, toothpaste, exfoliation products, hair bleaching products etc. are or might be rinse-off products but will not be covered by the Ecolabel.

Although this is true that not all rinse-off cosmetic products will be firstly included in the proposed scope, to avoid confusion the revised definition of the product group is proposed as follows:

"*any rinse-off substance and preparation intended to be placed in contact with the epidermis and the hair system with a view exclusively or mainly to cleaning them. That product group shall also comprise any rinse-off substance and preparation intended to be placed in contact*

*with the hair system with a view to improve the condition of the hair (hair conditioners)* ***and any rinse-off substance and preparation intended to be placed in contact with the epidermis with a view to protect it and to lubricate the hair before shaving (pre-shaving preparations)"****.*

Based on this revised definition of the product group, products such as mouth wash, toothpaste and hair bleaching products are excluded because they are in contact with the *teeth and the mucous membranes of the oral cavity or changing the appearance of the hair*, which is not included in the definition. In case of hair conditioners that are not rinse-off, they will not be included by definition.

Moreover, to the revised definition of the product group it can be added that: The product group "Rinse-off Cosmetic Products" shall comprise soaps, shampoos, hair conditioners and pre-shaving preparations, i.e. any rinse-off *substance and preparation intended to be placed (...)*.

Furthermore, "rinse-off" and "leave on" cannot exactly be attributed to the specific categories of cosmetic products because Cosmetics Directive 76/768/EEC (Regulation (EC) **No 1223/2009**, which will replace the Cosmetics Directive from 11 July 2013), mainly regulates health impacts and it does not take into consideration environmental issues as the EU Ecolabel does.

If the product group name will be based on the categories of cosmetic products selected from the classification in the CPNP, the name would also be vague as it would only include part of rinse-off products, e.g. make-up remover products, after-shaving products, scalp and hair roots care products are or might be: skin cleansing products, shaving and pre-/after-shaving products and hair and scalp products, but will not be covered by the Ecolabel.

The name "rinse-off cosmetic products" together with the definition of the product group is considered to describe most precisely the product covered by the scope.

## 2. ASSESSMENT AND VERIFICATION

The following assessment and verification procedure is proposed in the revised criteria:

Requirements

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

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

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

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

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

Appendix I makes reference to the detergent ingredient database (DID list) which contains the most widely used ingoing substances used in detergent 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 or via the websites of the individual competent bodies.



The following information shall be provided to the competent body:

– The full formulation of the product indicating trade name, chemical name, CAS no. and INCI designations, DID no.[13], the ingoing quantity including and excluding water, the function and the form of all ingredients regardless concentration.

– 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[14].

[13] DID no. is the number of the ingoing substance on the DID list ("Detergent Ingredient Database" list), and is used in determining compliance with Criteria 1 and 2. Part A and Part B of the DID list can be found on the EU Ecolabel website:
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.

[14] OJ L 396, 30.12.2006.

* DID no. is the number of the ingoing substance on the DID list ("Detergent Ingredient Database" list), and is used in determining compliance with Criteria 1 and 2.

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

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

a) Measurement thresholds

Unless indicated differently, the compliance with the ecological criteria is required for all ingoing substances intentionally added, as well as for by-products and impurities from raw materials, the concentration of which equals or exceeds 0.010 % by weight of final formulation.

For preservatives, colouring agents and fragrances compliance with the criteria is required regardless of their concentration, except for criterion 3(b) on excluded or limited substances and mixtures.

## 3. REVISED CRITERIA PROPOSAL

The proposal of the revised EU Ecolabel criteria for the extended product group of rinse-off cosmetic products and the respective issues which were taken into consideration in the revision process are described in more detail below in the below sections, criterion by criterion, following the current proposal if the revised criteria document. The changes made as a result of the development process following the first and second AHWG meeting and the EU Ecolabelling meeting are explained below the single criterion proposals.

The currently proposed criteria aim, in particular, at promoting products that have reduced impact on aquatic ecosystems, contain limited amount of substances of concern and contribute to the minimisation of waste production by reducing the amount of packaging. Additionally, the criteria enhance the consumers' environmental awareness.

Criteria are set for each of the following aspects:

1. Toxicity to aquatic organisms: Critical Dilution Volume (CDV)
2. Biodegradability
3. Excluded or limited substances and mixtures
4. Packaging requirements
5. Sustainable sourcing of palm oil
6. Fitness for use
7. Information appearing on the EU Ecolabel

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

**Proposed criterion and assessment and verification procedure**

The total critical dilution volume toxicity (CDV) of the product shall not exceed the following limits:

| Product | CDV (l/g AC) |
|---|---|
| Shampoo, shower products and liquid soaps | 18 000 |
| Solid soaps | 3 300 |
| Conditioners | 28 000 |
| Shaving foams, shaving gels, shaving creams | 20 000 |
| Shaving soaps | 3 300 |

The CDV is calculated using the following equation:

$$\mathbf{CDV = \Sigma\ CDV\ (ingoing\ substance\ i) = \Sigma\ weight\ (i) \times DF(i) \times 1\ 000/TFchronic\ (i)}$$

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 Detergent Ingredient Database list-part A (DID list-part A). If the ingoing substance in question is not included in the DID list-part A, the applicant shall estimate the values following the approach described in the DID list-part B and attaching the associated documentation.*

**Substantiating information, rationale and discussions conducted**

- **<u>Critical dilution volume</u>**

Critical dilution volume (CDV) is used in the EU Ecolabel to assess toxicity of products to the aquatic environment. This criterion is very important for soaps, shampoos and hair conditioners, as they are rinse-off products which are released entirely to water during use phase or after use.

The CDV represents a risk-based parameter by combining 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 ecolabelled product complies with high environmental standards.

The CDV expresses the amount of water needed for the hypothetical dilution of a product. The unit is expressed in litters 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 on the basis of 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 CDV of dangerous substances is important and the CDV can be decreased by adding substances.

For the first AHWG meeting the following issues were considered with regard to the above criterion:

- First, it has been proposed to consider modifying the method for Critical Dilution Volume (CDV) calculation,

- The stakeholders discussed also the proposal of decreasing the threshold values of critical dilution volume (CDV) for each kind of product: soaps, shampoos and hair conditioners.

Initially it was proposed to consider calculating the CDV value per 1 g of product, instead of per 1 g of AC; i.e. each ingredient's CDV would be calculated per total weight of the ingredients contained in the product[15]. Nevertheless, after discussion conducted during the stakeholders meeting it was agreed to keep the current calculation method. It has been indicated that the current CDV formula promotes concentrated products, while in the case of the proposed new one a risk exists that it could favour diluted products (i.e. with higher water content but lower efficiency). It was emphasized that from an environmental point of view, concentrated products should be supported as they require less transport and packaging material. Further, it was added that concentrated products are often less expensive, they require less water in the product chain and consequently fewer preservatives.

In some other product categories different approaches for calculating the CDV of the product are used. For example in the EU Ecolabel criteria for Laundry Detergents[16] the CDV is calculated according to the weight of each ingredient per recommended dose. Using this

[15] For details please see Technical background report for the 1st AHWG meeting, available online at: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.
[16] Commission Decision of 28 April 2011on establishing the ecological criteria for the award of the EU Ecolabel for laundry detergents; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:111:0034:0047:EN:PDF.

approach is relevant and could be appropriate in case of liquid soaps for which doses can be more easily determined e.g. in reference to hand washing. However, determining standard doses for shampoos and hair conditioners would not be straightforward e.g. the dosage is dependent to the length of the hair washed.

In the first AHWG it was highlighted that it would be good if the CDV could be linked to the performance (efficiency) of the product. Then the risk that products could be diluted to reach the CDV values (which in consequence would result in lower product efficiency), could be avoided and a new formula could be used. Stakeholders input supporting were welcome but incorporating this aspect in the CDV calculation is not easy and no alternative to the current calculation method, which could suit the product group under study, has been proposed so far.

An alternative method to calculate the CDV was proposed by a stakeholder during the AHWG based on the State of the Art Report on Mixture Toxicity[17]. Nevertheless, the proposal is considered very comprehensive and complex. Due to the complexity of this new formula it was proposed to investigate it in more detail ahead the next criteria revision.

Based on the discussions held in the first AHWG meeting and the written feedback received from many stakeholders it was agreed to keep the current calculation formula, as given below:

**CDVtox = Σ CDV (ingoing substance i) = Σ weight (i) x DF(i) x 1000/TF chronic (i)**

- **Proposed threshold values**

The following stricter limits for CDV were preliminarily proposed for discussing during the first AHWG meeting:

- Shampoos and liquid soaps: 18 000 l/g AC
- Solid soaps: 3000 l/g AC
- For hair conditioners this issue was left open for a discussion due to limited information.

An analysis of CDV threshold values contained in the new version of the Nordic Swan for cosmetic products shows that they are stricter than the current EU Ecolabel thresholds: in Nordic Swan the CDV values for liquid soap (including shower gel and bath foam), as well as for shampoo, is 13000 l/g of active ingredients (AI), while the CDV value for solid soaps is 3000 l/g AI. A comparison of the current EU Ecolabel and the current Nordic Swan CDV values is given in below table:

[17] Available online at: http://ec.europa.eu/environment/chemicals/pdf/report_Mixture%20toxicity.pdf.

**Table 1. CDV values for Nordic Ecolabel and the current EU Ecolabel**

| | Nordic Ecolabel | EU Ecolabel |
|---|---|---|
| | (l/g active ingredient) | (l/g AC) |
| Liquid soap, shampoo | 13000 | 20 000 |
| Hair conditioner | | 30 000 |
| Solid soap | 3 000 | 3 500 |

In order to propose new values for the revised EU Ecolabel criteria stakeholders (including Competent Bodies) were contacted and asked for information regarding the CDV values which are obtained by the currently existing products. 57 Ecolabelled products were analyzed based on the feedback[18]. The data from the previous report on the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[19] was also included. It was found that the current CDV limits are higher than the average values found from the sample investigated in the case of liquid soap and shampoos (see below table). This indicated that a proposal for stricter CDV limits could be substantiated. In the case of solid soaps and hair conditioners only values for one product from each of these categories were received. They amounted to 2281 l/g AC and 4904 l/g AC, respectively. Based on this fact no definite conclusion could be derived and stakeholders are asked for additional comments.

**Table 2. CDV average values and current limits**

| | CDV (average 2012) (l/g AC) | | CDV (average 2006)[19] (l/g AC) | | Current limit (l/g AC) |
|---|---|---|---|---|---|
| | Average | Range | Average | Range | |
| Liquid soap, shampoo | 14717 | 7342 - 19909 | 18622 | 3600 – 83000 | 20000 |
| Hair conditioner | | | 73735 | 2300 - 380000 | 30000 |
| Solid soap | | | 3925 | 2000 – 9300 | 3500 |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC.

Moreover, based on feedback received from Competent Bodies the following threshold values were proposed:

- For shampoos and liquid soaps it was proposed to set values at 13 000 l/AC (aligned with the Nordic Swan label requirements) or 18 000 l/g AC,

[18] For further details see appendix IV: Summary of data of the Technical Background Report, available online at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/docs.
[19] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

- For solid soaps the values of 3000 (aligned with the Nordic Swan label requirements) or 3500 l/g AC were indicated,
- For hair conditioners different values were proposed of 10 000, 13 000, 25 000 or 28 000 l/g AC.

Combining the two elements of information received from the existing products and the stakeholders' feedback, it was possible to propose the following CDV limits for the revised criteria in case of shampoos, liquid soaps and solid soaps for the second AHWG meeting. For hair conditioners this was not possible as no additional feedback was received. Therefore, keeping the current limits or limits close to the current threshold (i.e. of 25000 or 28000) was proposed for discussion:

- Shampoo and liquid soaps: 18000 l/g AC
- Solid soaps: 3000 l/g AC
- Hair conditioners: Discussion point

When including into the scope of the Ecolabel other rinse-off cosmetic products like shaving foam, shaving gel, shaving cream and shaving soap, it was important to set also CDVs limits for these products. Discussions during the second AHWG meeting referred to e.g. if the CDV limit for liquid soaps can be applied to shaving foam, shaving gel, shaving cream and shampoos for animals; and if limits for shaving soaps can be the same as solid soaps.

In this meeting and also the following EUEB meeting the proposal for the CDV threshold values was once again discussed with the stakeholders. The feedback received in the further consultation process is summarised below:

Several stakeholders pointed out that lowering significantly the CDV values would contribute to reducing the number of products which can be awarded with Ecolabel (which currently is considered low, i.e. only 55 licences granted so far). It was emphasized that the Ecolabel aims at 10-20% of the available on the market products, which is certainly not the case at present.

One of the proposal suggested to lower the existing values e.g. by 10%. This change was already perceived as challenging for the industry. In this situation the proposed values would be:

- 18 000 L/g AC for liquid soaps,
- 3 300 l/g AC for solid soaps
- and 27 000 l/g AC for hair conditioners.

The value of 18 000 f l/g AC or liquid soaps found approval, while for solid soaps – keeping the current value of 3500 l/g AC and for hair conditioners – the value of 28 000 L/g AC was considered more appropriate by some of the stakeholders.

Little information regarding the new thresholds for shaving products was available. The representatives of the Nordic Swan mentioned that there are the same value for shaving foam and gels as for soaps in their scheme and the same was proposed as option to be implemented in the revised EU Ecolabel. In further feedback received in written form the value of 20 000 l/g AC was proposed for pre-shaving preparations: shaving foams, gels and creams. As these

products are for the first time covered by the scope of this product group it is proposed to have the more conservative value of 20 000 l/g AC in this criteria version.

Based on the above discussion the final formulation of the criterion is proposed for the discussion on the EUEB forum. The threshold values, set as a best compromise between the available evidence and the feedback received, are as follows.

The total CDV of the product shall not exceed the following limits:

| **Product** | **CDV (l/g AC)** |
|---|---|
| Shampoo, shower products and liquid soaps | 18 000 |
| Solid soaps | 3 300 |
| Conditioners | 28 000 |
| Shaving foams, shaving gels, shaving creams | 20 000 |
| Shaving soaps | 3 300 |

### 3.2 CRITERION 2: Biodegradability

| **Proposed criterion and assessment and verification procedure** |
|---|

***a) Biodegradability of surfactants***

All surfactants shall be biodegradable under aerobic conditions.

All non-ionic and cationic surfactants must also be biodegradable under anaerobic conditions.

***b) Biodegradability of organic substances***

The content of all organic substances in the product that are aerobically non-biodegradable (not readily biodegradable) (aNDBO) and anaerobically non-biodegradable (anNDBO) shall not exceed the following limits:

| **Product** | **aNBDO (mg/g AC)** | **anNBDO (mg/g AC)** |
|---|---|---|
| Shampoo, shower products and liquid soaps | 25 | 25 |
| Solid soaps | 10 | 10 |
| Conditioners | 45 | 45 |
| Shaving foams, shaving gels, shaving creams | 70 | 40 |
| Shaving soaps | 10 | 10 |

Rubbing/abrasive agents in hand cleaning agents are not included in the calculation.

***Assessment and verification****: the applicant shall provide documentation for the degradability of surfactants as well as the calculation of* $aNBDO_{non\text{-}surf}$ *and anNBDO for the product. A spreadsheet for use in calculating* $aNBDO_{non\text{-}surf}$ *and anNBDO values is available on the EU Ecolabel website.*

*For both surfactants and* $aNBDO_{non\text{-}surf}$ *and anNBDO 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 Appendix I.*

*In the absence of documentation in accordance with the above requirements, a 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%) or*

2. *Readily degradable and has high desorption (D > 75%) or*

3. *Readily degradable and non-bioaccumulating.*

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

**Substantiating information, rationale and discussion conducted**

Basic elements used for classification of aquatic environmental impacts are: Acute aquatic toxicity; Potential for or 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[20]. Surfactants in this respect are considered relevant due to the fact that they are used in high amounts in liquid soaps, shampoos and conditioners[21]. Maximum and estimated amounts of surfactants used in products under study are presented in below table:

**Table 3. Surfactants used in studied products**

| | Liquid soaps | | Solid soaps | | Shampoos | | Hair conditioners | |
|---|---|---|---|---|---|---|---|---|
| | Maximum amount (Frame formulation COLIPA[22]) | Estimated amount (Technical report) | Maximum amount (Frame formulation COLIPA) | Estimated amount (Technical report) | Maximum amount (Frame formulation COLIPA) | Estimated amount (Technical report) | Maximum amount (Frame formulation COLIPA) | Estimated amount (Technical report) |
| Percentage of surface ants in product (% w/w) | 93% | 12.2% | 5% | - | 70% | 10% | 15% | 1.8% |

Notes:

- Concentration includes anionic and non-ionic surfactants, amphoretic surfactants and cationic surfactants.

[20] 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.

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

[22] COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

- Amounts estimated in the technical report are lower than maximum concentrations of frame formulations of COLIPA (now Cosmetics Europe). Estimated amounts are based in real formulations while in frame formulations maximum values are expressed, which are significantly higher than average content in products.

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. 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[23].

During the first AHWG meeting in Seville the following issues were addressed with regard to biodegradability criteria:

- First, the issue whether all surfactants must be readily aerobically and anaerobically biodegradable was discussed.

- Additionally, the proposal of decreasing the threshold values for aNBDO (Aerobic Non-Biodegradable Organics) and for anNBDO (Anaerobic Non-Biodegradable Organics) was considered.

During the meeting 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 that all surfactants are readily aerobically and anaerobically biodegradable, while other disagreed with the importance of the anaerobic biodegradability and questioned its environmental relevance[24] as well as the feasibility of fulfilling the respective criterion.

Nordic Swan[25], the Good Environmental Choice as well in Swedish Bra Miljöval[26] ecolabels for cosmetics require that all surfactants have to be readily aerobically and anaerobically biodegradable. The ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners, as well as hand dishwashing detergents state that each surfactant used in the product shall be readily biodegradable. Surfactants that are not biodegradable under anaerobic conditions may be used in the product within specified limits (provided that the surfactants are not classified with H400/R50 – very toxic to aquatic life).

Ready biodegradability of surfactants is required for products sold on the European market according to the Detergents Regulation (Regulation 648/2004/EC). However, this regulation does not define requirements to anaerobic biodegradability of ingredients.

According to the opinion of the Scientific Committee on Health and Environmental Risks (SCHER) a requirement of anaerobic degradation of surfactants is not itself regarded as an

[23] Procter & Gamble (http://www.scienceinthebox.com/en_UK/programs/natural_synthetic_en.html)
[24] http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_109.pdf
[25] Nordic Ecolabelling of Cosmetic products. Version 2.1., 2011.
[26] http://www.naturskyddsforeningen.se/bra-miljoval/in-english/about-bra-miljoval/how-does-it-work/.

effective measure of environmental protection. A general requirement on the biodegradability of the surfactants, with the aNBDO/anNBDO threshold values, combined with the CDV criterion shall ensure that the overall content of not readily biodegradable and/or toxic substances is limited, giving to the manufacturers at the same time flexibility in the product composition.

Some of the CBs stakeholders disagree however with the abovementioned opinion and asked for all surfactants to be aerobically and anaerobic ally degradable. The rationale regarding the requirement of anaerobic biodegradability of surfactants submitted is as follows:

"*There are many situations where the aerobic biodegradation of surfactants does not guarantee that they do not reach the environment, either there is no sewage treatment plant, or the passage in the sewage treatment plant is too fast, or flooding reduces the purification rate*.

*It is known that some surfactants adsorb to solid matter in the sewage sludge. This might reduce the actual degradation rates compared to laboratory values, resulting e.g. in a discharge via sewage sludge on agricultural land. Furthermore (and this is very important) this can result in a discharge to the sediment where anaerobic conditions prevail. This is a very strong argument to consider anaerobic degradability for surfactants.*

*Furthermore, some surfactants disturb the fermentation processes of the sewage sludge in the digestion towers. As the situation in anaerobic sediment is comparable to the digestion of sewage sludge, it is very likely that the biocoenosis in sediments is affected, but this has not been analyzed in scientific experiments yet. Anyway, there is no study to show that there is no negative effect on the microorganism populations.*

*Shampoos with the Ecolabel should not contain substances that might have such negative effects. Unless these presumptions were not disproved the precautionary principle should suffice to include the anaerobic biodegradability in the Ecolabel criteria*".

Opposite opinions were, nevertheless, also expressed by other stakeholders. Some of the written feedback stated that "*if surfactants are readily biodegradable, there is no need to be also anaerobically biodegradable, because the tiny amount that ends up in sludge and eventually on agricultural soil will degrade aerobically further once the sludge has been amended on soil. Sludge is usually stored in anoxic condition at Sewage Treatment Plants but spreading on soil put back the sludge into aerobic condition. Furthermore, current legislation requires a period of 180 days before any crop are planted, to allow remaining organic chemicals to degrade further. In case there is no wastewater treatment and domestic sewer are directly discharged into river, a portion of the river may become anoxic and no aquatic organisms are present anymore. The only biological organisms still present in the rivers that should be protected are microorganisms that will start digesting organic matters. Once oxygen is back, readily biodegradable surfactants will be degraded before aquatic life is back"*.

In general, industry disagreed with the proposal that all surfactants must be anaerobically biodegradable. LAS is a widely and most effective used surfactant and, at present, industry is not able to reformulate certain products without some currently used surfactants being non-anaerobically biodegradable such as LAS (linear alkyl benzene sulphonate). The "Opinion on Anaerobic Degradation of Surfactants and Biodegradation of Non Surfactant Organic Ingredients" of the Scientific Committee on Health and Environmental Risks (SCHER)[27] from 2008 was referred to by several stakeholders in the consultation process. In accordance with this document the based on the available scientific evidence:

- poor biodegradability under anaerobic conditions is not expected to produce substantial modifications in the risk for freshwater ecosystems as the surfactant removal in the WWTP seems to be regulated by its aerobic biodegradability,

- the requirement for ready and ultimate biodegradability under anaerobic conditions is not by itself regarded as an effective measure for environmental protection.

This opinion was supported by the Commission who conducted a study in 2009 to establish a knowledge base sufficient to review the anaerobic biodegradation of surfactants[28]. It was concluded that, in contrast to the adverse effects observed in the absence of aerobic degradation, the lack of anaerobic degradation does not seem to be correlated with any apparent risk for these environmental compartments, as a result anaerobic biodegradability should not be used as an additional pass/fail criterion for the environmental acceptability of surfactants.

The information requirements of the REACH registration dossiers submitted by industry to the ECHA, ensure data on the health and environmental effects of substances, including surfactants such as linear alkyl benzene sulphonate (LAS). The chemical safety report demonstrates safe use of the substances during their entire life cycle and consequently, this information should therefore be sufficient to decide whether restrictions on certain surfactants are needed from an environmental point of view.

According to REACH, LAS[29] does not pose a significant risk for the environment and human health. A chemical safety assessment was carried out for the first deadline in 2010 with an extensive database which allowed calculating Predicted No Effect Concentration (PNEC) in several compartments, as well as to demonstrate that LAS is neither a persistent bioaccumulative toxic (PBT) nor a (very persistent and very bioaccumulative) vPvB substance[30]. As a conclusion, this assessment shows that the risk characterisation ratio (RCR=PEC/PNEC) is less than one for all exposure scenarios and environmental

[27] 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.

[28] Report from the Commission to the European Parliamnet and the Council. Pursuant to Article 16 of Regulation (EC) N° 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents, concerning anaerobic biodegradation. Brussels, 2009. Report available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0230:FIN:EN:PDF.

[29] Information on chemical properties of LAS registered substance is directly accessible via ECHA web: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9fe772aa-2c02-269e-e044-00144f67d031/AGGR-ac3161f3-4caa-44c8-a5a6-c25c0371b7b9_DISS-9fe772aa-2c02-269e-e044-00144f67d031.html#L-56795e2a-31d0-4ea8-8d56-0f225a9bbbac.

[30] For more details see: http://www.heraproject.com/files/48-F-HERA_LAS_Report_(Version_4_-_June_09).pdf.

compartments, therefore the risks to the environment are unlikely. Recent risk assessment carried out also confirms this conclusion[31]. The "Screening Information Data Set" (SIDS) program operated under the auspices of the Organization for Economic Cooperation and Development (OECD) prepared a report on LAS, where it is stated that due to ready and/or rapid biodegradation and limited potential for bioaccumulation LAS is not considered of high priority with regard to the environmental protection.

For the discussion during the second AHWG the approach proposed in the recently developed Ecolabel criteria for Industrial and Institutional Automatic Dishwasher Detergents was proposed for consideration regarding the issue of non-anaerobically biodegradable surfactants, i.e. it is required that "All non-ionic and cationic surfactants must also be biodegradable under anaerobic conditions".

This proposal was not supported by several stakeholders, who requested in their feedback that all surfactants in that product group should be readily aerobically and anaerobically biodegradable. It was substantiated that according to the DID-list from 2007 there exist surfactants which are anaerobically biodegradable and can meet such a requirement. On the other hand, extensive scientific information regarding one of the anionic surfactants, LAS, has been submitted to the project team. The scientific evidence demonstrates that risk to the environment and human health (as also briefly presented above) is unlikely and it should be exempted from this requirement.

Based on this scientific evidence regarding LAS (as an example of the anionic surfactant, commonly used in the product group under study), it is proposed to keep the proposal from the previous draft stating that "All non-ionic and cationic surfactants must also be biodegradable under anaerobic conditions".

- **Threshold values for the revised criteria for aerobic and anaerobic biodegradability of organic substances**

Furthermore, discussions regarding the threshold values for biodegradability were considered in the revision process. The threshold values for aerobic and non-aerobic biodegradability included in the existing EU Ecolabel criteria for soaps, shampoos and hair conditioners have been compared with the values included in the new Nordic Swan criteria document for cosmetic products. With regard to **aerobic biodegradability of non-surfactants** much stricter limit values are applied in the Nordic Swan for ingredients that are not readily biodegradable than in the existing EU Ecolabel criteria (see below table):

[31] D. Rasmussen et al., REACH Chemical Safety Report, HERA LAS report, 2012.

**Table 4. aNBDO $_{non-surf}$ values for Nordic Ecolabel and EU Ecolabel**

| | Nordic Ecolabel | EU Ecolabel |
|---|---|---|
| | **aNBDO$_{non-surf}$ (mg/g AI)** | **aNBDO $_{non-surf}$ (mg/g AC)** |
| Liquid soap, shampoo | 15 | 30 |
| Hair conditioner | 15 | 50 |
| Solid soap | 5 | 15 |

In the framework of the stakeholders' consultation and during the first AHWG meeting stakeholders submitted their feedback regarding setting stricter threshold values for the aerobic biodegradation of non-surfactants in the EU Ecolabel. In general, most stakeholders agreed to set more stringent values. Based on the analysis of data for more than 220 products submitted by CBs (79% thereof shampoos, shower gels and liquid soaps, 16% solid soaps and 5% hair conditioners) it was proposed by to set the threshold values as follows:

- for shampoos, shower gels and liquid soaps - 19 mg/g AC,
- for solid soaps - 13 mg/g AC,
- for hair conditioners - 40 mg/g AC

Afterwards, additional 57 ecolabelled products were analyzed based on the feedback received from the stakeholders (other Competent Bodies and licence holders)[32]. The data from the report of the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[33] was also included. It was found that current limit of aNBDO is higher that the values available for average product in the case of liquid soaps and shampoos (see the table below). For solid soaps and hair conditioners, only data regarding one product from each of the categories have been obtained directly (the aNDBO values for these products were 48 mg/g AC and 8 mg/g AC, respectively), thus no conclusion could be made on this basis.

**Table 5. aNBDO $_{non-surf}$ average values and current limits**

| | aNBDO (average 2012) (mg/g AC) | | aNBDO (average 2006)[33] (mg/g AC) | | Current limit (mg/g AC) |
|---|---|---|---|---|---|
| | **Average** | Range | **Average** | Range | |
| Liquid soap, shampoo | **15** | 0-25 | 45 | 0-460 | **30** |
| Hair conditioner | | | 123 | 0-310 | **50** |
| Solid soap | | | 13 | 0-47 | **15** |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC

[32] For further details see appendix 16: Summary of data of the Technical Backgroung Report_2, available at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

[33] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

Based on these outcomes of the consultation and the feedback received the following $aNBDO_{non\text{-}surf}$ (mg/g AC) threshold values were proposed for the discussions for the second AHWG meeting in the revised version of the criteria for **aerobic biodegradability**:

- Shampoo and liquid soaps: 20 mg/g AC
- Solid soaps: 10 mg/g AC
- Hair conditioners: 45 mg/g AC.

With regard to the **anaerobic biodegradability** criterion, Nordic Swan criteria sets also tighter limits than current EU Ecolabel criteria (please see below table):

**Table 6. anNBO values for Nordic Ecolabel and EU Ecolabel**

| | Nordic Ecolabel | EU Ecolabel |
|---|---|---|
| | **$AnNBDO_{tox}$ (mg/g AI)** | **$anNBDO_{tox}$ (mg/g AC)** |
| Liquid soap, shampoo | 15 | 25 |
| Hair conditioner | 15 | 50 |
| Solid soap | 5 | 15 |

In the framework of further stakeholders' consultations and during the AHWG meeting stakeholders submitted their feedback, in general, most stakeholders agreed to set more stringent values for the anaerobic biodegradation in the EU Ecolabel. Based on the analysis of previously mentioned 220 ecolabelled products, submitted to the project team, the following threshold values were proposed:

- for shampoos, shower gels and liquid soaps - 21 mg/g AC,
- for hair conditioners - 40 mg/g AC
- for solid soaps - 13 mg/g AC,

Later, additional 57 ecolabelled products were analyzed based on the feedback received from the stakeholders[34]. The data from the report of the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[35] was also included. It was found that current limit anNBDO is higher that the values for average product in the case of liquid soap and shampoos (see the following table), which indicates that it may be appropriate to propose stricter anNBDO limits. For solid soaps only data regarding one product were received, which did not allow to make any conclusion from this feedback. The reported value is 7 mg/g AC.

[34] For further details see appendix IV: Summary of data of the Technical Background Repport_2, available at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.
[35] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

**Table 7. anNBDO average values and current limits**

| | anNBDO (average 2012) (mg/g AC) | | anNBDO (average 2006)[35](mg/g AC) | | Current limit (mg/g AC) |
|---|---|---|---|---|---|
| | **Average** | Range | **Average** | Range | |
| Liquid soap, shampoo | **15** | 3,6-29 | 62 | 0-410 | **25** |
| Hair conditioner | | | 141 | 0-530 | **50** |
| Solid soap | | | 11 | 0-39 | **15** |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC

Based on the data and information collected the proposed anNBDO (mg/g AC) limits proposed for the second AHWG meeting were as follows:

- Shampoo and liquid soaps: 20 mg/g AC

- Hair conditioners: 45 mg/g AC.

- Solid soaps: 10 mg/g AC

It has been emphasized that for some substances **anaerobic biodegradability (anNBDO) values** can be difficult to obtain and thus the compliance with the requirements is difficult to prove. It has been suggested to apply in this situation a solution worked out in the criteria development for industrial and institutional laundry detergents and industrial and institutional automatic dishwasher detergents product groups[36]:

"*In the absence of documentation in accordance with the above requirements, a 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%) or*

*2. Readily degradable and has high desorption (D > 75%) or*

*3. Readily degradable and non-bioaccumulating.*

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

This formulation is included in the criterion regarding biodegradability.

[36] For detail see the document available online at: http://ec.europa.eu/environment/ecolabel/documents/Last-draft-Criteria-automatic-dishwasher-detergents-PRO.pdf.

The threshold values proposed above for aerobic and anaerobic biodegradability have been extensively discussed with the stakeholders at the second AHWG meeting and with stakeholders who submitted their further feedback. Main concerns regarding decreasing too much the values in the criterion on biodegradability of organic substances was related to the consequences for the possibility of using perfumes in the product group under study. It was pointed out that important part of non-biodegradable substances can be assigned to fragrances; thus the concentration of perfume has direct influence on biodegradability of the product. It was emphasized that in some products, raw materials such as fat acid soaps and vegetal abrasive agents are often odorous materials. Higher amount of fragrances is needed then to mask this. Furthermore, the stakeholders indicated that very often choice and acceptance of cosmetic product is dependant on the presence of the fragrance. Therefore, reducing too much the values of biodegradability was not supported by many (although not all participants), as it was expected to reduce even more the number of licensed products.

Particularly split views have been expressed regarding the aNBDO and anNBDO for shampoos, shower products and liquid soaps, where some of the stakeholders agreed with the value of 20 mg/g AC, while others asked not to reduce the value below 25 mg/g AC. Several stakeholders submitted their proposals for the threshold values for pre-shaving preparations, with the exception of solid shaving soaps, for which the value as for other soaps is proposed. Final analysis of the values collected resulted in the following proposal:

Aerobic biodegradability of non-surfactants (aNBDOnon-surf)

| **Product** | **$aNBDO_{non\text{-}surf}$ (mg/g AC)** |
|---|---|
| Shampoo, shower products and liquid soaps | 25 |
| Solid soaps | 10 |
| Conditioners | 45 |
| Shaving foams, shaving gels, shaving creams | 70 |
| Shaving soaps | 10 |

Anaerobic biodegradability (anNBDO)

| **Product** | **anNBDO (mg/g AC)** |
|---|---|
| Shampoo, shower products and liquid soaps | 25 |
| Solid soaps | 10 |
| Conditioners | 45 |
| Shaving foams, shaving gels, shaving creams | 40 |
| Shaving soaps | 10 |

### 3.3 CRITERION 3: Excluded or limited substances and mixtures

**Proposed criterion and assessment and verification procedure**

***a) Specified limited and/or excluded ingoing substances***

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

- Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives
- NTA (nitrilo-tri-acetate)
- Boric acid, borates and perborates
- Nitromusks and polycyclic musks
- Octamethylcyclotetrasiloxane (D4)
- Butylated Hydroxi Toluene (BHT)
- Ethylenediaminetetraacetate (EDTA) and its salts and non-readily biodegradable phosphonates.
- The following preservatives: triclosan, parabens (ethyl-, methyl-, propyl- and butyl-parabens), formaldehyde and formaldehyde releasers (bronopol, 5-bromo-5-nitro-1,3-dioxane, sodium hydroxyl methyl glycinate (SHMG), DMDM hydantoin, diazolidinyl urea and imidazolidinyl urea) and nanosilver.
- The following fragrances: Cinnamal, Cinnamyl Alcohol, Citral, Coumarin, Eugenol, Farnesol, Geraniol, Hydroxycitronellal, Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC), Isoeugenol, Limonene (oxidised), Linalool (oxidised) and two natural mixtures: Oak moss (Evernia prunastri ) and Tree moss (Evernia furfuracea).

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

***b) Hazardous substances and mixtures***

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product shall not contain substances meeting criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain 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 below generally refer to substances. However, if information on substances cannot be obtained, the classification rules for mixtures apply.

**List of hazard statements and risk phrases:**

| **Hazard Statement**[1] | **Risk Phrase**[2] |
|---|---|
| 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 |

[1] *Regulation (EC) No 1272/2008 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*
[2] *Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC and Directive 1999/45/EC as amended*

Substances or mixtures which change their properties through processing e.g., become no longer bioavailable, or undergo chemical modification in a way that removes the previously identified hazard are exempted from the above requirement.

**Derogations**

The following substances are specifically exempted from this requirement:

| | | |
|---|---|---|
| Preservatives* | H411: Toxic to aquatic life with long-lasting effects<br>H412: Harmful to aquatic life with long-lasting effects<br>H413: May cause long-term adverse effects to aquatic life | R51-53<br>R52-53<br>R53 |
| Fragrances** | H412: Harmful to aquatic life with long-lasting effects<br>H413: May cause long-term adverse effects to aquatic life | R52-53<br><br>R53 |
| Antifungal, antimicrobial agent: Zinc pyrithione (ZPT) | H400 Very toxic to aquatic life | R50 |

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

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

***Assessment and verification:*** *The applicant shall demonstrate compliance with this criterion by providing a declaration on the non-classification of each ingoing substance into any of the hazard classes associated to the hazard statements referred to in the above list in accordance with Regulation (EC) 1272/2008, as far as this can be determined, as a minimum, from the information meeting the requirements listed in Annex VII of Regulation (EC) 1907/2006. This declaration shall be supported by summarized information on the relevant characteristics associated to the hazard statements referred to in the above list, to the level of detail specified in section 10, 11 and 12 of Annex II of Regulation (EC) 1907/2006 (Requirements for the Compilation of Safety Data Sheets).*

*Information on intrinsic properties of substances may be generated by means other than tests, for instance through the use of alternative methods such as in vitro methods, by quantitative structure activity models or by the use of grouping or read-across in accordance with Annex XI of Regulation (EC) 1907/2006. The sharing of relevant data is is recommended and competent bodies may ask for additional relevant information.*

*The information provided shall relate to the forms or physical states of the substance or mixtures as used in the final product.*

*For substances listed in Annexes IV and V of REACH, exempted from registration obligations under Article 2(7)(a) and (b) of Regulation 1907/2006 REACH, a declaration to this effect will suffice to comply with the requirements set out above.*

*The applicant shall also demonstrate compliance with this criterion by providing the calculations as required based on the R-phrases/H-statements that apply to the formulation and as indicated using the rules provided by the CLP Regulation.*

### *c) Substances listed in accordance with article 59(1) of Regulation (EC) No 1907/2006*

No derogation from the exclusion in Article 6(6) of the Regulation (EC) No66/2010 shall be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in the product in concentrations higher than 0.010 % (weight by weight).

***Assessment and verification:*** *The list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:*

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

*Reference to the list shall be made on the date of application. The applicant shall provide the exact formulation of the product to the competent body. The applicant shall also provide a declaration of compliance with this criterion, 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 intended for infants, babies and children under the age of three year shall be fragrance-free. Infant, baby and/or children products refers to products that are marketed as designed and intended for infants, babies and/or children or have any of these words on the label/packaging.

(ii) Any ingoing substance 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 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 declaration of compliance.*

### *e) Preservatives*

(i) The product may only include preservatives in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

(ii) Preservatives must not release substances that are classified in accordance with the requirements of Criterion 3b or/and are endocrine disrupters[37].

(iii) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

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

***Assessment and verification:*** *the applicant shall provide copies of the safety data sheets of any preservative added, together with information on their BCF and/or logPow values and information on their exact concentration in the product. The manufacturer or supplier of the preservatives shall provide information on the dosage necessary to preserve the product.*

### *f) Colorants*

Colorants allowed in the product must not be bioaccumulating. A colorant is considered not bioaccumulating if BCF < 100 or logPow < 3.0. If both – BCF and logPow – values are available, the highest measured BCF value shall be used. In the case of colouring agents approved for use in foodstuffs 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 colorants added, or documentation to ensure that the colouring agent is approved for use in food.*



[37] http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list

**Substantiating information, rationale and discussion conducted**

Limiting environmentally harmful substances from the product group of rinse-off cosmetics is important, as most ingredients of rinsed-off products normally end up in the aquatic environment through sewage treatment systems after use and sometimes they can be released directly to aquatic environment. The Cosmetics Directive does not prohibit use of substances in cosmetic products on the basis of their environmental properties. On the contrary, the EU Ecolabel regulation requires that ecolabelled products have reduced impact on the environment.

LCA studies showed that chemicals used for manufacturing in this product group have relevant load in the overall environmental impact of these products, i.e. 44% of the total environmental impact for solid soaps, the 23% for hair conditioners, 9% for shampoos and 10% for liquid soaps.

The environmental impacts associated with substances used are mainly related to the use of land and the use of non-renewable energy to synthesize them. Potential environmental impacts that these substances can cause if they are released to different environment compartments are also taken into account. The analysis of environmental impact for each product and the contribution of each life stage to different environmental impact categories are presented in the Technical Analysis Report[38].

The life stage "release to water" includes the treatment of sewage water once the product has been used. The wastewater contains the water consumed during a washing action and the rinsed-off product (soap, shampoo or hair conditioner). This stage has important share in all environmental impact categories analysed.

In accordance with the new EU Ecolabel Regulation 66/2010 the following general requirements about substances should be met in order to award the products with the EU Ecolabel:

*"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 (CMR), in accordance with 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, nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency".*

The Regulation allows for derogation of specific substances under strictly defined conditions:

[38] Available at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

*"For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6".*

Finally, there is a provision regarding exclusion from derogation for substances classified as the substances of very high concern (SVHC):

*"No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 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)".*

These requirements are reflected in the proposed criterion on "Excluded and limited substances and mixtures", as it is also done in other recently developed or revised criteria documents for other product groups. The discussions regarding single criteria and rationale for their establishing and revision are given in sub-sections below.

- ***Sub-criterion a) Specified limited and/or excluded ingoing substances***

Being proactive (i.e. taking as basis the precautionary principle) some specific substances which raise environmental or health related concern have been discussed and considered to be specifically excluded or restricted in the product group under study. They are briefly presented below:

Exclusion of several **phthalates** (Bis(2-methoxyethyl) phthalate, diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP)), was preliminarily considered in the criteria revision. In the consultation process this proposal was withdrawn, as they are already included in the list of excluded substances in the Cosmetics Regulation 1223/2009by the Commission Directive 2004/93/EC. This concerns all the cosmetic producers and importers of cosmetics to the European Union; therefore, this exclusion is not needed for ecolabelled products available at European market.

**D4 (octamethylcyclotetrasiloxane)** CAS 556-67-2 is used as an emollient or solvent although is not in the list of most commonly used substances. The Cosmetic Toiletry and Perfumery Association (CTPA) indicate that the cyclic siloxanes in cosmetics are, in general, used in the following main areas:

- As hair-conditioning agents
- As skin-conditioning agents (emollient)
- As solvents

The types of products in which they are reported to be used include: aftershave lotions, perfumery products, shampoos, conditioners and shaving products[39].

Based on its classification[40] H413: may cause long lasting harmful effects to aquatic life, H361: suspected of damaging fertility or the unborn child and H226: flammable liquid and vapour, should be restricted. It is restricted in Nordic Ecolabelled products as it is considered to be persistent in the environment. In Canada, D4 has been added to "List of Toxic Substances in Schedule 1 of CEPA 1999", which means it is considered toxic and is subject to governmental regulation.

**Butylated Hydroxy Toluene (BHT, CAS 128-37-0)** – BHT is used as an antioxidant/preservative in cosmetic products, mainly in shampoos, deodorants, body lotions and make-up, usually at a concentration of 0,1% or less. It is classified as H410 (R50/53) - very toxic to aquatic life with long lasting effects[41]. Based on the classification, it should be restricted. BHT can also induce allergic reactions in the skin[42].

**Triclosan** (5-chloro-2-(2,4-dichlorophenoxy)phenol )[43] is a preservative added to soaps, hair conditioners and shaving cream products. Triclosan is classified as an agent that may cause adverse environmental effects[44]. Based on its classification[45], triclosan should be restricted: H410: very toxic to aquatic life with long lasting effects, H315: causes skin irritation and H319: causes serious eye irritation. Use of triclosan in cosmetic products is also a matter of concern from a toxicological point of view. Due to its classification, triclosan would be excluded from ecolabelled products through the criterion on excluded or restricted substances and mixture, which restricts substance sclassified with H410; nevertheless, as derogation for H410 is under consideration for the functional group of preservatives, it is proposed to exclude for time being triclosan explicitly in the revised criteria.

**Ethyl-, methyl-, propyl- and butyl-Parabens** - In 1999, the European Union adopted a Strategy on Endocrine Disrupters and committed significant resources to develop and classify a priority list of suspected endocrine disrupting chemicals[46]. A candidate list with 553 substances with evidence of endocrine disruption was reviewed and classified in three categories: Category 1 – evidence of endocrine disrupting activity in at least one species using intact animals; Category 2 – at least some in vitro evidence of biological activity related to endocrine disruption; Category 3 – no evidence of endocrine disrupting activity or no data available. Ethyl-, methyl-, propyl- and butyl- parabens are all categorised as potential endocrine disrupters (Category 1) under the EU strategy for endocrine disrupters. Safer

[39] Brooke D N, Crookes M J, Gray D and Robertson S. Science Report – Environmental Risk Assessment Report: Octamethylcyclotetrasiloxane. For more details: http://publications.environment-agency.gov.uk/PDF/SCHO0309BPQZ-E-E.pdf

[40] http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d9d2de7-dd46-653e-e044-00144f67d249/AGGR-d50b7533-2f91-4049-9110-98ba0524a880_DISS-9d9d2de7-dd46-653e-e044-00144f67d249.html#L-03cd909b-6f8e-4aee-9d90-52aa86e337e2.

[41] http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d82f461-e7b6-3a89-e044-00144f67d249/AGGR-51b3c77a-ec07-4b3e-a1e2-870ae9e21d5e_DISS-9d82f461-e7b6-3a89-e044-00144f67d249.html#L-abb9496c-aaa4-455b-8305-187c411b237d.

[42] U.S. National Library of Medicine, in Haz-Map: Occupational Exposure to Hazardous Agents, 2010, http://hazmap.nlm.nih.gov.

[43] Scientific Committee on Consumer Products (SCCP) Opinion on Triclosan, January 2009, available online at: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf.

[44] Norwegian Scientific Committee for Food Safety, Risk assessment on the use of triclosan in cosmetics, 2005, available online at: http://vkm.no/dav/117573d6c4.pdf.

[45] http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031/AGGR-09e9b0f0-bf29-4975-8fbe-a3a2dd0ac2be_DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031.html#L-137752f6-fbea-4638-b8d8-acce5e212979.

[46] For more information, please see: http://ec.europa.eu/environment/endocrine/strategy/short_en.htm.

alternatives to parabens exist[47], and around 5,4% of products are now marketed as "paraben-free".

**Formaldehyde** - Formaldehyde is a known sensitizer and a known carcinogen, however in the Cosmetics Directive is accepted as preservative. The new Regulation on cosmetic products requires that "All finished products containing formaldehyde or substances in this Annex and which release formaldehyde must be labelled with the warning 'contains formaldehyde' where the concentration of formaldehyde in the finished product exceeds 0,05 %". Based on its classification[48]: H351: suspected of causing cancer, H301: toxic if swallowed, H311: toxic in contact with skin, H331: toxic if inhaled; H314: causes severe skin burns and eye damage and H317: may cause an allergic skin reaction should be restricted the use of formaldehyde in ecolabelled products. In accordance with the current list of R/H phrases formaldehyde would automatically be excluded by the abovementioned criterion on excluded and restricted substances and mixtures, which will be included in the revised criteria document.

**Formaldehyde releasers:** Formaldehyde releasers are used as preservatives that decompose to form formaldehyde upon degradation. The amount of formaldehyde released can be above the classification limits for formaldehyde[49]. There are some studies that demonstrate that people exposed to formaldehyde releasers may experience an allergic reaction[50]. The following formaldehyde releasers are proposed to be restricted:

- **Bronopol (2-bromo-2-nitropropane-1,3-diol)**: According to Annex VI of CLP, harmonised classification and labelling for certain hazardous substances, bronopol is classified as H312: harmful in contact with skin , H302: harmful if swallowed, H335: may cause respiratory irritation, H318: causes serious eye damage and H400: Very toxic to aquatic life. Bronopol has a moderate capacity for inducing skin allergies. It is a strong eye irritant and to be capable of causing difficulties in breathing and induce eczematous reactions in people who are already sensitized.

- **5-bromo-5-nitro-1, 3-dioxane**: is reported to be moderately allergenic on skin because it releases formaldehyde under basic conditions.

- **Sodium hydroxyl methyl glycinate (SHMG)**: Formaldehyde-releasing preservative that has been associated with allergic contact dermatitis, possibly due to the formaldehyde they release. Studies on SHMG in animals have demonstrated potential for sensitization and dermatitis, and formaldehyde –allergic patients have been reported to improve when products containing SHMG are avoided[51].

[47] For more information see details in "Preliminary results from the technical analysis" report, tables 26, 43 and 51 with different variants that fulfil equivalent function: preservatives., available online at the project's website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.
[48] For details see the information contained at ECHA website: http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d8ad2a1-0d51-13f7-e044-00144f67d249/AGGR-aa1957ab-42e8-43c6-856d-09b14245e171_DISS-9d8ad2a1-0d51-13f7-e044-00144f67d249.html#L-9cf4f64b-5725-4012-aad3-657063a4f5b6.
[49] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.
[50] http://share.eldoc.ub.rug.nl/FILES/root2/2010/Formretof/de_Groot_2010_Contact_Dermatitis.pdf.
[51] Sodium hydroxymethylglycinate, Rusell k, Jacob SE. Dermatitis. 2010 Apr 21 (2):109-10.

- **DMDM Hydantoin**: Is an antimicrobial formaldehyde releaser preservative. People exposed to such formaldehyde-releasing ingredients may develop a formaldehyde allergy. It is also a strong skin, eye, and lung irritant.

- **Diazolidinyl Urea**: Is an antimicrobial preservative that acts as a formaldehyde releaser in cosmetics and personal care products. It is effective against a broad spectrum of bacteria, fungi and yeast. It may cause allergy on skin when it is exposed to this substance.

- **Imidazolidinyl Urea**: Is an antimicrobial preservative that acts as a formaldehyde releaser in cosmetics and personal care products.

Furthermore, it was proposed to restrict the use of **Ethylenediaminetetraacetic acid (EDTA)**. EDTA is persistent in the environment and contributes to remobilization of heavy metals bioavailability in the environment, which is a big concern[52]. In the EU Ecolabel criteria for Detergents EDTA is already excluded. In the feedback received it was emphasized that better biodegradable chelants are already available, e.g. Methylglycinediacetic acid MGDA (Trilon M) or Ethylenediamine-N,N'-disuccinic acid EDDS.

During the stakeholders' consultation several additional substances which may disrupt the hormonal system (so-called EDCs) have been proposed by stakeholders for consideration to be restricted in Ecolabelled products:

- 3- benzylidene camphor,
- 4-methylbenzylidene camphor,
- 4-nitrophenol,
-4,4' –dihydroxybenzophenone,
- Benzophenone-1,
- Benzophenone-2,
- Benzophenone-3,
- Butylparaben,
- Dicyclohexyl phthalate (DCHP),
- Diethyl phthalate (DEP),
- Dihexyl phthalate (DHP),
- Ethylhexyl methoxycinnamate,
- Metam natrium,
- Propylparaben,
- Quadrosilan,
- Resorcinol,
- Tert-butylhydroxiyanisole (BHA).

Butylparaben and propylparaben were already proposed to be restricted based on their classification as potential endocrine disrupters (Category 1) under the EU strategy for endocrine disrupters.

[52] Oviedo C., Rodríguez J.: EDTA: The chelating agent under environmental scruting, Quim. Nova, Vol. 26, No. 6, 901-905, 2003, available online at: http://www.scielo.br/pdf/qn/v26n6/a20v26n6.pdf, accessed January 2013.

Regarding to dicyclohexyl phthalate (DCHP), diethyl phthalate (DEP) and dihexyl phthalate (DHP), they are not included in the candidate list of substances of very high concern for authorisation. Opinion on phthalates in cosmetic products provided by the Scientific Committee on Consumer Products (SCCP)[53], concluded that:

- Dicyclohexyl phthalate (DCHP): Despite the lack of adequate toxicological data, for low concentration of DCHP found in perfumes, it is suggested that unintentional exposure from perfume and other cosmetics would have no measurable risk for the consumer.

- Diethyl phthalate (DEP): Is found at higher concentrations in perfumes, however DEP has low toxicity. There is some epidemiological evidence for DEP of impairment of some reproductive function markers (sperm motility, concentration, morphology, DNA damage) in the human male, but the results are not consistent. The toxicity of this phthalate, where data is sparse, is low (lower than for other phthalates).

- Dihexyl phthalate (DHP): Is a plasticizer mainly used in the manufacture of polyvinyl chloride (PVC) and other plastics (including tool handles and PVC flooring) but not in cosmetic products[54]. No current harmonised classification in Annex VI of CLP is provided.

For these reasons and based on a prioritization system, they were not proposed to be restricted.

Regarding to 3- benzylidene camphor, 4-methylbenzylidene camphor, 4-nitrophenol, 4,4' – dihydroxybenzophenone, Benzophenone-1, Benzophenone-2, Benzophenone-3, Ethylhexyl methoxycinnamate, Metam natrium and Quadrosilan, they are not usually present in this product group, thus no restrictions have been proposed.

Finally, resorcinol and tert-butylhydroxyanisole (BHA) have numerous uses, including in cosmetics. Tert-butylhydroxyanisole (BHA) is an antioxidant and preservative in cosmetics but specifically is found in lipstick and eye shadow, while resorcinol is used[55] in oxidative hair colouring products which are not included in the scope in this product group.

The specific **fragrances** proposed to be explicitly excluded from cosmetic products due to their sensitizing potential are described in later section regarding fragrances.

[53] Opinion of the Scientific Committee on Consumer Products on phthalates in cosmetic products, 2007. For more details, see: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_106.pdf.

[54] Background document to the Opinion proposing harmonized classification and labelling at Community level of Di-n-hexyl phthalate (DnHP), Committee for Risk Assessment (RAC), 13 September 2011. For more details see: http://echa.europa.eu/documents/10162/0fc1bf32-1cd4-4294-a7fc-7ba778f78f13.

[55] Opinion on resorcinol, Scientific Committee on Consumer Safety, 23 March 2010. For more details see: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_015.pdf.

- ***Sub-criterion b) Hazardous substances and mixtures***

Sub-criterion 3 b) "hazardous substances and mixtures" consists of the standard text and the table of 25 R-phrases/H-statement. According to the EU Ecolabel Regulation 66/2010, the product or any component of it shall not contain substances meeting criteria for classification with specified hazard statements or risk phrases in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EC nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006.

In the previous criteria version the following statement was included in this sub-criterion: *The final product must not be labelled according to the hazard statements above and moreover the final product formulation shall not contain any hazardous substances, or combinations thereof, that result in the formulation being greater than 0.85 of the limit required for classifying dangerous substances as defined within ANNEX II of Directive 1999/45/EC and as required by the Regulation (EC) No 1272/2008 (CLP Regulation)*. After the stakeholders consultation it was agreed to remove this requirement.

Further, as mentioned before, during the consultation process the stakeholders were asked to submit justified derogation requests for specific substances. These substances would otherwise have be excluded or restricted by the new criterion on "Excluded or limited substances and mixtures", following the Article 6(6) of the EU Ecolabel Regulation 66/2010. The substitution of the substances which are subject of a derogation request (by non classified substances) is currently considered not possible or not widely applicable due to e.g. technological constraints. The derogation can be granted in specific circumstances indicated in Article 6(7) of the regulation. Industrial stakeholders submitted the following derogation request regarding the restriction set in the criterion:

| | | |
|---|---|---|
| Surfactants < 20% in the product | H412 Harmful to aquatic life with long-lasting effects<br>When readily biodegradable | <br>R52-53 |
| Preservatives* | H411: Toxic to aquatic life with long-lasting effects<br>H412: Harmful to aquatic life with long-lasting effects<br>H413: May cause long-term adverse effects to aquatic life | R51-53<br>R52-53<br>R53 |
| Fragrances** | H412: Harmful to aquatic life with long-lasting effects<br>H413: May cause long-term adverse effects to aquatic life | R52-53<br><br>R53 |
| Antifungal, antimicrobial agent: Zinc pyrithione (ZPT) | H400 Very toxic to aquatic life | R50 |

The more detailed description of the derogation requests with the rationale submitted follows separately for different function groups: surfactants, preservatives and fragrances.

- ***Derogation request for surfactants***

| | Ingredient type | CLP classification | DSD classification | Short Rationale |
|---|---|---|---|---|
| 1 | Surfactants | H412 Harmful to aquatic life with long-lasting effects When readily biodegradable | R52-53 | 2nd ATP to CLP will make a large number of important surfactants classified as H412 despite their readily biodegradability |

*"Although currently no surfactants are classified as chronically toxic to the aquatic environment, the change in the CLP rules as per the 2nd ATP (Adaptations to Technical Progress), applying as of December 2012, will result that significant number of very important surfactants for cosmetics will be classified as either H412 or even H411. Ready biodegradability will no longer exempt surfactants from the classification as chronically toxic if chronic data are available.*

*Surfactants such as some specific alkyl sulfates, alkyl ether sulfates, betaines, cocamide MEA and even APGs will likely be classified as H412. These are typical 'workhorse' surfactants in soaps and shampoos, and cannot easily be replaced".* Before December 2012 these surfactants due to their ready biodegradability have been considered not to pose a threat to the environment.

Additionally to this information from the industry, MS representatives submitted feedback regarding the 2nd ATP of CLP in reference to the EU Ecolabel criteria for detergents. This feedback regarding surfactants used in detergents applies also in the case of soaps and shampoos product group and is as follows: "*According to the 2nd ATP of CLP, the classification for chronic aquatic toxicity of surfactants has to be fully based on chronic toxicity data alone. At this moment surfactants that are readily biodegradable and have a low potential for bioaccumulation are exempted from this classification. Hence, with the 2nd ATP coming into force on the 1st of December 2012, a great number of these readily biodegradable surfactants will be classified with chronic toxicity category 2 (H411) or 3 (H412). This would mean that these surfactants cannot comply anymore with the corresponding EU Ecolabel criteria for detergents".*

Along the consultation process Cosmetics Europe shared the available information prepared by the European Committee of Organic Surfactants and their Intermediates (CESIO) and the international Association for Soaps, Detergents and Maintenance Products (AISE). Excerpt of it is given below:

"*The third edition of GHS (Globally Harmonized System of Classification and Labelling) revised the classification criteria for chronic aquatic toxicity. This revision will now be implemented in the 2nd ATP of the CLP. By end 2012, all substances placed on the market will have to be classified accordingly.*

*As a result of this 2nd ATP, the classification for chronic aquatic toxicity will be fully based chronic toxicity data, if available, and no longer exempts substances because of their rapid degradability. This implies that the majority of readily degradable surfactants used in laundry and cleaning products will become classified as Chronic category 3 and in some cases even Chronic category 2. This is demonstrated in the attached DID list in Annex II. This shows that already 24 out of 58 surfactants currently in the current DID-list will be affected if the 2nd ATP criteria are applied on the currently available ecotoxicity data in the DID-list. However, the number of surfactants classified as Chronic cat 2 and 3 in this list will certainly increase to close to 40 or even more, due to new data being generated as part of the REACH obligations.*

*The consequence of the above is that the majority of widely used 'workhorse' surfactants would not be allowed in Ecolabelled household cleaning products anymore by end 2012, based on new classification rules, despite their rapid degradation".*

The lists of surfactants which are expected to be affected by this change in CLP, as submitted to the JRC IPTS is included in this report in Annex I. Unfortunately, so far no definite list of the surfactants was obtained from the industry therefore the real scale of concerned surfactants is not confirmed. The representatives of CESIO informed that this updated list is currently being prepared by the industry and should be ready in the coming time.

The information received suggests, nevertheless, that the majority of the main surfactants used is affected. This would have significant influence on the future Ecolabel criteria for this one and also other above-mentioned product groups. It should be remembered that there are other criteria on surfactant, the CDV and biodegradability, which should ensure minimisation of the environmental impact of these ingredients. As discussed with the stakeholders who submitted the derogation, it was agreed not to propose derogation for surfactants classified as H411 or H410. Industry will make effort to use in their applications only less severely classified alternatives (H412).

In the process of the consultation the industry has been additionally asked for submitting the following information:

- The list of surfactants that were not classified before and are now classified based on real toxicological data
- Market data on these surfactants
- Evidence of the non-feasibility of their technical substitution

This derogation request will be once again considered once the industry shares the updated list with JRC IPTS and it will be presented during the EU Ecolabelling Board meeting.

- ***Derogation request for fragrances***

**Table 8. Short rationale for derogation request regarding fragrances**

| Ingredient type | CLP classification | DSD classification | Short Rationale |
|---|---|---|---|
| Perfumes | H412 Harmful to aquatic life with long-lasting effects | R52-53 | As already agreed for home care products. Fragrances must have been manufactured and/or handled in accordance with the IFRA code of practice. Fragrances are a very important part of the consumer perception. |

Source: Stakeholders' information sent to the EC

The derogation is based on the following rationale submitted by the stakeholders:

"*Limiting the use of perfumes that are classified as H412 would dramatically restrict their use in ecolabelled products, and would therefore reduce their consumer acceptance. The above requested derogation is also acknowledged for consumer home care products (laundry, machine dish wash and hand dish wash detergents as well as all purpose and sanitary cleaners), whose recently published new criteria (2011) all contain the same derogation.*

*With respect to maximum concentrations, these are already strongly limited by the CDV requirement through the very restrictive values for fragrances in the DID list. Actually if only H412 or non classified fragrances can be used, the entry in the DID list would need to be changed according to the below table*:

**Table 9. Proposal to amend the DID list**

| Nr | Name | LC50/ EC50 | SF acute | TF acute | NOEC (*) | SF chronic | TF chronic | DF | Aerobic | An-aerobic |
|---|---|---|---|---|---|---|---|---|---|---|
| **Perfumes** | | | | | | | | | | |
| 142 | Current: Perfume ** | 2 | 1000 | 0.002 | | | 0.002 | 0.5 | I | N |
| 142a | Proposed: Perfumes H412 classified or not environmentally classified** | 10 | 1000 | 0.01 | | | 0.01 | 0.5 | I | N |

Source: Stakeholders 'information sent to the EC

*Here the toxicity value is based on the lowest toxicity value (worst case), that is linked to the hazard classification of H412 (category 3) under the 2nd ATP to CLP (entry iii in table 4.0)*[56]*. The current eco-toxicity value for perfumes would not be allowed, as it would make the perfume classify as H411 (R51/53).*

*Fragrances that are not classified for the environment should still be assessed as being H412, unless toxicity data is available that can be used to derive a lower TF as is currently already specified in the DID list*".

In the revised criteria document the above given derogation is proposed. Additional proposal regarding the DID list has been provided to the entity responsible for the revision of the DID-list.

- ***Derogation request for preservatives***

In the framework of the consultation, industry submitted derogation request regarding the restriction on preservatives in the product under study. The proposed derogation request and the respective rationale are given below:

**Table 10. Short rationale for derogation request regarding biocides**

| Ingredient type | CLP classification | DSD classification | Short Rationale |
|---|---|---|---|
| Biocides used for preservation | H411 Toxic to aquatic life with long-lasting effects H412 Harmful to aquatic life with long-lasting effects | R51-53 and R52-53 | Biocides can only be added in order to preserve the product, plus they may not be bioaccumulative as specified in the CLP. |

Source: Stakeholders 'information sent to the EC

*"Preservatives are essential to deliver a safe product to consumers. Due to their nature (as they are intended to actively prevent microbial growth within cosmetic products, usually by attacking/fighting germs) the great majority of effective preservatives are classified for their environmental effects. In order to be able to produce microbiologically safe Ecolabelled products, derogation for these classified preservatives is needed. Preservatives still need to be proven to be not bioaccumulative. Note that the recently published consumer home care products (laundry, machine dish wash and hand dish wash detergents as well as all purpose and sanitary cleaners), all contain the same derogation to allow effective preservation of the products, under the restriction that the preservatives are not bioaccumulative.*

[56] Commission Regulation (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, available on line at**:** http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:FULL:EN:PDF.

*No maximum levels will need to be set as these preservatives are typically used at very low concentrations (regulated under the Cosmetic Products Regulation) and their levels are very much restricted through the CDV requirement as well."*

Finally, derogation for one anti-dandruff agent was submitted in the consultation process.

**Anti dandruff agents: Zinc pyrithione (ZPT)**

*"ZPT is an antifungal and antimicrobial agent used since the 1960s to help treat a variety of scalp and skin conditions. Dandruff is affecting >40% of the population (Schwartz, J.R. et al., 2004). Antidandruff actives in hair care products, especially those with high proven efficacy and low environmental profile are regarded as highly valuable for a large number of consumers. The Nordic Ecolabel criteria foresee derogation for zinc compounds. ZPT fulfils a very important function for a large number of consumers and cannot be easily replaced by other ingredients with both similar efficacy and better environmental profile. In addition, it has clearly been demonstrated (REACH registration dossier) that ZPT, as degradable antidandruff agent, does not pose a risk to the environment".*

No maximum levels for the derogation of ZPT need to be set in the Ecolabel criteria as maximum concentrations in ready for use preparations are already established under the Cosmetic Products Regulation (1223/2009).

Both of these derogations are proposed to be included in the revised criteria version.

- ***Sub-criterion d) Fragrances***

There are more than 5 000 different fragrance substances, which are used frequently as mixtures in various consumer products; mainly in cosmetics but also in household products (e.g. room fresheners), textiles, shoes and even toys. Approximately 80% of the total fragrances volume is used in cosmetic products and 20% in household products[57]. Population come into daily contact with cosmetic products, at least 95% of the female and 75% of the male population[58].

Some fragrances are sensitizers and known triggers of allergic reactions such as asthma and contact dermatitis[59]. Approximately 35% of all allergic reactions to cosmetics are due to perfume ingredients, therefore fragrances are one of the major causes of allergic contact

[57] Scientific Committee on Consumer Safety SCCS Opinion on Fragrance allergens in cosmetic products, December 2011, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf.

[58] Final report of the project supported by the 5th Framework Programme of the European Commission, under the Quality of Life and Management of Living Resources thematic programme, key action Environment and Health: (contract QLK4-CT-1999-01558) "Fragrance chemical allergy: a major environmental and consumer health problem in Europe", March 2003, available on line at: http://ec.europa.eu/research/quality-of-life/ka4/pdf/report_fragrance-allergy_en.pdf.

[59] Wijnhoven S.W.P., Ezendam J., Schuur A.G. , van Loveren H., van Engelen J.G.M, Allergens in consumer products, RIVM Report 320025001/2008, available online at: http://www.rivm.nl/bibliotheek/rapporten/320025001.pdf.

dermatitis remaining a significant clinical problem[60]. Fragrances with low molecular weight come in close contact with the skin and can cause contact allergy. The clinical manifestation is eczema, inflammatory skin disease. The face, neck, axillae and hands are the most affected areas in case of contact allergy.

In addition to the skin exposure, fragrances are volatile and therefore a perfume exposes also the eyes and naso-respiratory tract. Respiratory allergy occurs less frequently than contact dermatitis. Approximately 2-4% of population is affected by respiratory symptoms. In an epidemiological investigation, a significant association was found between contact allergy and respiratory complaints related to fragrances[61].

Studies based on the limited testing with eight common fragrance allergens[62] performed on different parts of population show that contact allergy to fragrances affects 1 to 3% of the general population in Europe[63]. However, if the testing was performed with the full spectrum of fragrance allergens, this percentage might be higher. Approximately 16% of eczema patients in the European population are sensitised to fragrance ingredients. Prevention of contact sensitisation to fragrances is an important objective and thus is proposed to address this issue under the EU Ecolabel criteria by reducing the amount of allergens in products and consequently preventing the exposure to known contact allergens.

In 1999, the Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers (SCCP), based on dermatological data reflecting the clinical experience[64], identified and prepared a list of 24 fragrance substances potentially resulting in contact allergy. They were divided into two lists (see also below tables):

- list A – indicating the most frequently reported and well recognized contact allergens,
- list B – indicating fragrances less documented as consumer allergens.

**Table 11. Fragrance chemicals most frequently reported as contact allergens**

| Common name | CAS No |
|---|---|
| Amyl cinnamal | 122-40-7 |
| Amylcinnamyl alcohol | 101-85-9 |
| Benzyl alcohol | 100-51-6 |
| Benzyl salicylate | 118-58-1 |
| Cinnamyl alcohol | 104-54-1 |
| Cinnamal | 104-55-2 |

[60] Final report of the project supported by the 5th Framework Programme of the European Commission, under the Quality of Life and Management of Living Resources thematic programme, key action Environment and Health: (contract QLK4-CT-1999-01558) "Fragrance chemical allergy: a major environmental and consumer health problem in Europe", March 2003, available on line at: http://ec.europa.eu/research/quality-of-life/ka4/pdf/report_fragrance-allergy_en.pdf

[61] Elberling J, Linneberg A, Mosbech H, Dirksen A, Frolund L, Madsen F, Nielsen N H, Johansen J D. A link between skin and airways regarding sensitivity to fragrance products? Br J Dermatol 2004: 151: 1197-203.

[62] Fragrance Mix included in the standard patch test tray containing the eight most common allergens in Europe: amyl cinnamal, cinnamyl alcohol, cinnamal, eugenol, geraniol, hydroxycitronellal, isoeugenol, oak moss and sorbitan sesquioleate (added as an emulsifier).

[63] Scientific Committee on Consumer Safety SCCS Opinion on Fragrance allergens in cosmetic products, December 2011, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf.

[64] The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers Opinion concerning Fragrance Allergy in Consumers – A review of the problem – Analysis of the need for appropriate consumer information and Identification of consumer allergens, December 1999, available online at: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf.

| Common name | CAS No |
|---|---|
| Citral | 5392-40-5 |
| Coumarin | 91-64-5 |
| Eugenol | 97-53-0 |
| Geraniol | 106-24-1 |
| Hydroxycitronellal | 107-75-5 |
| Hydroxymethylpentylcyclohexenecarboxaldehyde | 31906-04-4 |
| Isoeugenol | 97-54-1 |

Source: SCCPNFP, 1999

**Table 12. Fragrance chemicals less frequently reported as consumer allergens**

| Common name | CAS no |
|---|---|
| Anisyl alcohol | 105-13-5 |
| Benzyl benzoate | 120-51-4 |
| Benzyl cinnamate | 103-41-3 |
| Citronellol | 106-22-9 |
| Farnesol | 4602-84-0 |
| Hexyl cinnamaldehyde | 101-86-0 |
| Lilial | 80-54-6 |
| d-Limonene | 5989-27-5 |
| Linalool | 78-70-6 |
| Methyl heptine carbonate | 111-12-6 |
| 3-Methyl-4-(2,6,6-trimethyl-2-cyclohexe-1-yl)-3-buten-2-one (= γ-methylionone) | 127-51-5 |

Source: SCCNFP, 1999



In June 2012 the Scientific Committee on Consumer Safety (SCCS) issued an opinion on "Fragrance allergens in cosmetic products"[65]. It confirmed that contact allergy to fragrances may develop due to skin contact with a sufficient amount of such substances, among other through the use of cosmetics. The revision of the SCCNFP Opinion on fragrance allergy in consumers from 1999 confirmed that the findings of this report are still valid. It has also been stated that based on the review of the recent clinical and experimental studies more fragrance substances have been identified to have sensitising properties for humans. The analysis showed that 82 substances could be classified as established contact allergens in humans. Among them there are 54 single chemicals and 28 natural extracts (12 chemicals and 8 natural extracts thereof were found to pose a high risk of sensitisation).

Furthermore, two fragrances (natural mixtures) were added to the previously described list:

[65] Scientific Committee on Consumer Safety SCCS Opinion on fragrance allergens in cosmetic products, 2012, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf.

- Oak moss (90028-68-5)[66]
- Tree moss (90028-67-4)[67]

If one or more of these 26 fragrance ingredients are present in concentration of above 0.01% it is required that they are indicated on the product pack label in order to facilitate the consumers who may have allergic reactions to specific substances to identify and choose products which are appropriate for them.

During the first AHWG meeting the following issues were considered for the revision of the current criterion:

- Restriction of sensitizing substances classified as:
    - **H334 (R42):** may cause allergy or asthma symptoms of breathing difficulties if inhaled and/or
    - **H317 (R43):** may cause an allergic skin reaction.
- Extension of the scope of this criterion to substances other than fragrances known to act as sensitizers for allergic skin reaction and contact dermatitis.
- Proposal that all ecolabelled products intended for babies and for children under the age of three year should be fragrance-free.

In the framework of the open consultation it was proposed to ban the use of twelve fragrance substances identified as posing a high risk of sensitisation to consumers. They are listed in Table 13-5 of the SCCS opinion mentioned above and given in table below. It was emphasized that limiting the exposure to these chemicals would aid protecting sensitised consumers from developing allergic contact dermatitis. Additionally, it has been asked to restrict the use of two substances: **chloroantranol and atranol** – main allergenic constituents of Everna prunasteri (oak moss) and Everna furfuracea (tree moss), which presence in cosmetic products has been considered not safe by the SCCS.

The list of established fragrance contact allergens of special concern as given in Table 13-5 of the SCCS opinion is given in below table.

**Table 13. Established fragrance contact allergens of special concern (single chemicals only)**

| **Common name** |
|---|
| Cinnamal |
| Cinnamyl Alcohol* |
| Citral |
| Coumarin |
| Eugenol* |
| Farnesol* |

[66] Chloroantranol is the allergen constituent in tree moss (Evernia furfuracea).
[67] Atranol is the allergen constituent in oak moss (Evernia prunastri).

| |
|---|
| Geraniol* |
| Hydroxycitronellal |
| Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) |
| Isoeugenol* |
| Limonene (oxidised) |
| Linalool* (oxidised) |

*including their respective esters

Additionally, eight natural extracts are indicated as ingredients of special concern in the SCCS opinion from 2012 (given below), among them the previously mentioned, **chloroantranol and atranol** – main allergenic constituents of Everna prunasteri (oak moss) and Everna furfuracea (tree moss).

**Table 14. Established natural extract fragrance contact allergens of special concern (single chemicals only)**

| Common name | CAS No |
|---|---|
| Oak moss | 90028-68-5 |
| Tree moss | 90028-67-4 |
| CANANGA ODORATA and Ylang-ylang oil | 83863-30-3; 8006-81-3 |
| EUGENIA CARYOPHYLLUS LEAF / FLOWER OIL | 8000-34-8 |
| JASMINUM GRANDIFLORUM / OFFICINALE | 84776-64-7; 90045-94-6; 8022-96-6 |
| MYROXYLON PEREIRAE (Balsam of Peru) | 8007-00-9 |
| SANTALUM ALBUM (Sandelholz) | 84787-70-2; 8006-87-9 |
| TURPENTINE (oil) | 8006-64-2; 9005-90-7; 8052-14-0 |

Furthermore, SCCS established other lists with contact allergens in humans:

- Table 13-1 listing established contact allergens in humans
- Table 13-2 "where sufficient animal evidence was present, these substances were categorised as established contact allergens in animals"
- Table 13-3 "for other fragrance substances, combinations of limited clinical data together with structure activity relationship (SAR) considerations have been applied to indicate likely fragrance allergens in man".
- and Table 13-4 "substances with insufficient human data were also considered as possible fragrance allergens. For these further tests (experimental/clinical data) are required".

In the consultation process one stakeholder proposed to be stricter on the sensitizing substances and to consider restricting the use of the substances listed in 13-1. In the criteria proposal prepared for the second AHWG meeting the restriction of substances given in Table 13-5 of the opinion (see Table 13 above) and additionally of **chloroantranol and atranol** (main allergenic constituents of Everna prunasteri and Everna furfuracea) was proposed. Consideration of extended restriction covering all substances listed in Table 13-1 was also put for discussion during the AHWG meeting.

The potential restrictions were discussed extensively during the meeting. It was emphasized by the industry that introducing such wide ban (i.e. of the fragrances listed in Table 13-1) would reduce very significantly the choice of the manufacturers and would certainly contributed to following decrease of the licence numbers. Fragrances play particularly important role for this product group.

Further consultation during the meeting indicated also that the industrial representatives consider referring to the new SCCS opinion from June 2012 too premature. It was informed that "with regard to the fragrances contained in the opinion 2012 - discussions are still in progress within DG SANCO regarding the regulatory follow-up to the recent opinion, and with industry regarding some scientific aspects".

One of the stakeholders proposed to refer to the latest ATP to the CLP Regulation, which provides a system to differentiate between sub categories 1A/1B for the endpoints respiratory and skin sensitization. It divides the sensitizers into sub category 1A – the very potent sensitizers and subcategory B - other sensitizers. It was proposed to exclude from the EU Ecolabel only the substances which are classified as 1A (see table below).

**Table 15. Most potent sensitizers – sub category 1A**

| **Common name** | **CAS No** |
|---|---|
| p-Tolylacetaldehyde | 104-09-6 |
| Cinnamaldehyde | 104-55-2 |
| Methyl 2-octynoate (Methyl heptine carbonate) | 111-12-6 |
| 1-(2,6,6-Trimethylcyclohexa-1,3-dienyl)-2-buten-1-one (Damascenone) | 23696-85-7 |
| E-1-(2,6,6-Trimethylcyclohexa-1,3-dienyl)-2-buten-1-one (tr-Damascenone) | 23726-93-4 |
| Z-1-(2,6,6-Trimethylcyclohexa-1,3-dienyl)-2-buten-1-one (cis-Damascenone) | 59739-63-8 |
| Citronitrile Z isomer | 53243-59-7 |
| Citronitrile E isomer | 53243-60-0 |
| Citronitrile generic | 93893-89-1 |
| Isoeugenol | 97-54-1 |
| trans-Isoeugenol | 5932-68-3 |

Nevertheless, this classification is not consistent with the SCCS opinion classification and contains only a few of the established fragrance contact allergens of special concern of the SCCP list. Split views were expressed among stakeholders. Industrial stakeholders proposed to refer in the revised criteria document to the previous SCCP opinion from 1999 on the most frequent contact allergens of special concern (including two natural mixtures) and to exclude them from the Ecolabelled products. This position was not supported by a MS stakeholder who indicated that the proposed by the industry 1A list does not contain one of the most frequently reported chemical causing fragrance allergy, i.e. Hydroxyisohexyl 3-cyclohexene carboxaldehyde – HICC. In this list it is assigned to category 1B – other sensitizers. This list does also not contain the most sensitizing natural fragrances, Evernia prunastri and Evernia furfuracea.

Rationale [68]for substantiating the exclusion of HICC (Lyral), Evernia prunastri and Evernia furfuracea are given below:

"*Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) has been the most frequently reported chemical causing fragrance allergy since the 1999 opinion on fragrance allergy. In total, reports of more than 1500 cases have been published in the scientific literature (see chapter 7.1 and Annex I of the opinion), which will severely underestimate the actual prevalence in the population. HICC has been shown to be a significant cause of disease as many of those with contact allergy to HICC had also reactions to cosmetics, which contained or were likely to contain HICC. The SCCP concluded in 2003 that 200 ppm of HICC would be tolerated by the majority of sensitised individuals and this level of exposure would have a low potential to induce sensitisation. Since 2003 attempts have been made by the fragrance industry to contain the outbreak of HICC allergy, but with no convincing success so far. Recent voluntary restrictions (recommendations to lower use concentrations, at least for some product types, to the level recommended by the SCCS in 2003) are not reflected in available evidence and are considered insufficient. The SCCS considers that the number of cases of HICC allergy documented over the last decade is exceptionally high and that continued exposure to HICC by the consumer is not considered safe, even at concentrations as low as 200 ppm.*

*Chloroatranol and atranol are the main allergenic components of Evernia prunastri and Evernia furfuracea. The SCCS concluded in 2004 that these should not be present in cosmetic products, due to their exceptionally high sensitisation potential. Attempts to effectively reduce the content of these compounds in "oak moss abs." have largely failed to reduce contact allergy to Evernia prunastri and Evernia furfuracea and the data presented in this opinion show that the number of cases remains high*."

Due to very split views further experts who were involved in the works of the SCCS group were consulted. They explained that the discussion on the opinion from 2012 is conducted but

[68] Scientific Committee on Consumer Safety SCCS Opinion on fragrance allergens in cosmetic products, 2012, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf.

it refers to the definitions of thresholds for suggested preventive action but not the list of the substances, with are included in Table 13-5. The experts supported referring in the EU Ecolabel criteria to the new opinion, which analyses and summarises the current scientific state-of art of knowledge on the sensitizing fragrances used in cosmetic products.

Based on the analysis of feedback received and the further consultation conducted it was decided to propose in the revised criteria version the fragrances indicated as the established fragrance contact allergens of special concern (including their respective esters marked with "*"), i.e.:

- Cinnamal
- Cinnamyl Alcohol*
- Citral
- Coumarin
- Eugenol*
- Farnesol*
- Geraniol*
- Hydroxycitronellal
- Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC)
- Isoeugenol*
- Limonene (oxidised)
- Linalool* (oxidised)
- Oak moss
- Tree moss

**International Fragrance Association Code of Practice**

The International Fragrance Association (IFRA) issues recommendations for the safe use of fragrance ingredients in the form of Code of Practice. This document "provides recommendations for good operating practice and guidelines on fragrance ingredient safety assessment, and includes fragrance safety standards which may limit or ban the usage of certain fragrance materials"[69]. The recommendations for the safe use of fragrances ingredients are based on experimental evidence of sensitisation in healthy human volunteers but secondary prevention of clinical disease in sensitised consumers is not considered in the code of practice[70].

The IFRA Code of Practice was published for the first time in 1973 and it is amended on annual basis (if needed) with revisions of the existing use restrictions or introducing of new restrictions. The Code is binding for all IFRA members. Currently it is being revised and a new version will be available soon. Among IFRA committees there is Environmental Task

[69] The International Fragrance Association (IFRA): Code of Practice, December 2006, available online at: http://www.ifraorg.org/en-us/code_of_practice_1.

[70] The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers Opinion concerning Fragrance Allergy in Consumers – A review of the problem – Analysis of the need for appropriate consumer information and Identification of consumer allergens, December 1999, available online at: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf.

Force (ETF), which aims at advising the fragrance industry on the issues of environmental safety of fragrances. Further, it assists in the identification and management of environmental aspects of their use. In accordance with the current criteria document "any ingredient added to the product as a fragrance must have been manufactured, handled and applied in accordance with the code of practice of the International Fragrance Association".

In the revised criteria document it is proposed to keep the current requirement regarding fragrances – formulated as follows: "Any ingoing substance 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 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".

**Other aspects regarding fragrances discussed along the consultation process**

Additionally, a harmonisation between the criteria for this product group and the criteria from all purpose cleaners and other similar products was supported in order to ensure a general more horizontal harmonisation between various EU Ecolabel decisions and the equal level of strictness of criteria set for various product groups. Further, it was considered whether the scope of this restriction should apply to substances other than fragrances which are known to act as sensitizers for allergic skin reaction and contact dermatitis.

Based on the discussions conducted and the consultation process it was therefore proposed to restrict to 0.010 % by weight of the final product the **use of sensitizing substances classified with H334 (R42) and/or H317 (R43)** in rinse-off cosmetic products. One stakeholder proposed to set the threshold as 0.1% (for compliance with this restricition), due to the importance of these ingredients for this product group. Nevertheless, the harmonisation with other Ecolabel criteria for similar product groups would require keeping the threshold of 0.010. These two additional H-statements will be included in the criterion on "Excluded or limited substances and mixtures" Opinion regarding the threshold which should finally be used will be once again consulted with the EUEB members at the March 2013 meeting.

Additionally, a proposal of introducing a new restriction on the use of fragrances in **products which are intended for babies and children under the age of three year** was presented and discussed. According to Commission recommendation 98/485/EC of 1 July 1998, member states shall adopt the measures required to ensure a high level of child health protection in regard to some hazardous substances in childcare articles and toys intended to be placed in the mouth for children of age lower than three years.

Children bodies and immune systems are still in development and consequently children react more than adults to allergens. Higher respiratory rate and their thinner skin are factors contributing that the children are more susceptible to the effects of allergens.

Children are at risk of developing allergies because every day their skin is exposed at an early age to well-known allergens in fragrances. Thus, the highest possible safety standards should be applied to children to avoid the exposure to products containing allergenic substances such as perfumes.

An analysis of perfume-free products has been conducted in the framework of the study. Its main results are presented below. First, in below table, the shares of perfume-free products among all products under study are indicated for each product group.

**Table 16. Share of perfume-free products**

| Product group | Percentage of perfume-free products |
|---|---|
| Liquid soaps | 1,5% |
| Solid soaps | 1,7% |
| Shampoos | 1,3% |
| Hair conditioners | 0,8% |

*Source: Mintel Global New Product Database*

In the next table, the shares of products intended for babies in the product group under study are given, together with the percentage of perfume-free products among all baby products. Around 10% of baby products available at the market currently are marketed as fragrance-free. Only for solid soaps this share is lower. This is nevertheless, significantly more if compared with the total amount of perfume-free products available on the market.

**Table 17. Share of baby products and perfume-free baby products**

| Product group | Percentage of baby products | Percentage of perfume-free baby products in the total amount of baby products |
|---|---|---|
| Liquid soaps | 3,8% | 10% |
| Solid soaps | 5,1% | 3% |
| Shampoos | 3,0% | 11% |
| Hair conditioners | 0,3% | 12% |

*Source: Mintel Global New Product Database*

The proposal to introduce ban on fragrances use in products intended for babies and children gained stakeholders' support. It is thus required that all ecolabelled products covered by the scope of the revised criteria which are intended for use for babies and children under the age of three year shall be fragrance-free. Infant, baby and/or children products refers to products

that are marketed as designed and intended for infants, babies and/or children or have any of these words on the label/packaging.

- ***Sub-criterion 3 e) Dyes and colouring agents***

Colouring agents and dyes are added to the product in very small amounts in order to colour the cosmetic itself. This function has been considered important in order to facilitate the consumer applying appropriate dosage of the product. It also influences the appearance of the product. There exist products which are colorant agents-free (transparent), nevertheless they constitute very niche segment of the market and are intended for particularly environmentally and natural products oriented consumers.

This criterion does not refer to hair dyes, i.e. products which are used to change the colour of hair. They are not covered by the scope of this product group.

In the new Regulation 1223/2009 on cosmetic products substances addressed in the current criterion dyes and colouring agents, are grouped in one functional group called 'colorants'. The Regulation defines them as follows:

'colorants' means *substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants*.

The Regulation limits the use of colorants in cosmetic products to substances other than those which are listed in Annex IV[71]. 153 substances are listed in this annex. Colorants used in the product under study are used mainly to colour the product itself to influence its appearance and make easier dosing the product.

Contact of the human body with certain colorants, their impurities, or their decomposition products (that may occur during processing or storage of the cosmetic product) can produce allergic reactions, sensitization or photosensitization in susceptible people[72].

The concentrations of the colorants in cosmetic products are usually low, below 0.1%, and they represent a large variety of chemical structures which exhibit different ecological properties. During the initial development of the criteria[73] it has been emphasized that the environmental properties of colorants are often very poorly documented. Many of them are toxic; nevertheless they are used in very small quantities. In order to reduce the environmental and health related impacts of these ingredients it was agreed to exclude colorants that may bioaccumulate.

[71] "and colorants which are listed there but not used in accordance with the conditions laid down in that Annex, except for hair colouring products referred to in paragraph 2" – for details see the Regulation 1223/2009.
[72] Rosenthal et al., 1988; Wei et al., 1994, 1995; Mselle, 2004; Antonovich and Callen, 2005; Klontz et al., 2005
[73] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.

To ensure the manufacturers a sufficient choice of colorants, the substances which have been approved for use in food are also accepted in Ecolabelled products under study, since they are supposed to be evaluated as safe. Their list can be found at the EC website[74].

During consultation conducted it was asked what the availability of products not containing colorants was. The industry responded that such type of products do exist on the market but they constitute only several percentage of the total sales in some countries, while in other Member States it is very hard to sell such products. The colouring function is considered attractive for consumers, so in order to promote (and not decrease) the use of Ecolabel and consequently the consumption of products awarded with it, a total restriction of these agents would not be recommended.

The CLP Regulation[75] introduces restriction on bioaccumulation of substances. According to it "*Bioaccumulation of substances within aquatic organisms can give rise to toxic effects over longer time scales even when actual water concentrations are low. For organic substances the potential for bioaccumulation shall normally be determined by using the octanol/water partition coefficient, usually reported as a log Kow. The relationship between the log Kow of an organic substance and its bioconcentration as measured by the bioconcentration factor (BCF) in fish has considerable scientific literature support. Using a cut-off value of log Pow ≥ 4 is intended to identify only those substances with a real potential to bioconcentrate. While this represents a potential to bioaccumulate, an experimentally determined BCF provides a better measure and shall be used in preference, if available. A BCF in fish of ≥ 500 is indicative of the potential to bioconcentrate for classification purposes".*

During the first AHWG meeting the following issues were considered for the revision of the current criterion:

- The issue of aligning the definition regarding potential bio-accumulation of substances with the CLP Regulation,
- Maintaining the thresholds given for the bioconcentration factor and log octanol/water partition coefficient at the currently valid levels: BCF ≤ 100 or log Pow < 3 (harmonisation of the criteria for similar product groups, e.g. with all-purpose cleaners),
- Potential exclusion of dyes or colouring agents from product formulation.

The issue whether the bioconcentration factor and log octanol/water partition coefficient (logPow) shall be adjusted to the levels set in the CLP was discussed with the stakeholders during the AHWG meetings. Based on the feedback received from the Competent Bodies and in order to harmonize horizontally with the thresholds given in the currently valid criteria documents for All Purpose Cleaners[76], Dishwashing Detergents[77], Hand Dishwashing Detergents[78] and Laundry Detergents[79] the following values will be maintained, i.e.:

[74] Lists of authorized food additives: http://ec.europa.eu/food/food/fAEF/additives/lists_authorised_fA_en.htm.
[75] Regulation (EC) 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) 1907/2006. OJL 353, 31.12.2008, p. 1-1355: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF.
[76] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0383:EN:NOT.
[77] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0263:EN:NOT.
[78] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0382:EN:NOT.
[79] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011D0264:EN:NOT.

- BCF ≤ 100,
- Log Pow < 3.

Stakeholders supported keeping the criterion with stricter BCF and logPow values but did not support adding additional restrictions. Thus, based on the precautionary principle, the thresholds given in the currently valid criteria will be kept. The current criterion formulation will not change in the revised criteria draft proposal. The stricter (than given in the CLP) threshold values of BCF and logPow will be further valid in order to indicate if a substance is considered to be potentially bio-accumulating. This has been confirmed also in the consultation following the AHWG meetings with the representatives of the Member States (the same decision is valid also for preservatives). Only the change of name from 'dyes and colouring agents' to 'colorants' is proposed to be done to align with the terms used in the new Cosmetic Regulation 1223/2009.

- ***Sub-criterion 3 e) Preservatives***

The new Cosmetic Regulation 1223/2009 defines the 'preservatives' as *substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product*.

Preservatives function is to ensure that products are safe to use by the consumers over long period and to maintain the appearance of the product. Annex V of the new Cosmetic Regulation lists the preservatives (56 positions) which are allowed for use in cosmetic products.

Although preservatives are used in small amounts, due to their toxicity, requirements regarding this functional group are considered very important. The combination of high toxicity, poor degradability and bioaccumulation gives a high risk for environmental damage. In the current criteria document it is required that if a preservative fulfils the criteria for classification with H410/R50-53 or H411/R51-53 risk phrases it is only permitted to be used in the product if it is not potentially bio-accumulating. A substance is considered to be potentially bioaccumulating if the bio-concentration factor (BCF) is > 100 or, if no BCF-results are available, the log Pow (log octanol/water partition coefficient) is > 3.0.

During the first AHWG meeting the following issues were considered for the revision of the current criterion:

- Maintaining the thresholds given for the bioconcentration factor and log octanol/water partition coefficient: BCF ≤ 100 or Log Pow < 3
- Restriction of the following substances:
  - Triclosan
  - Parabens
  - Formaldehyde
  - Formaldehyde releasers: Bronopol (2-bromo-2-nitropropane-1,3-diol), 5-bromo-5-nitro-1,3-dioxane, sodium hydroxyl methyl glycinate, DMDM Hydantoin, Diazolidinyl urea and Imidazolidinyl Urea.

During the stakeholders consultation process it has been discussed and agreed to keep the current formulation of the criterion with the strict values of the BCF and log Pow and not to align them with the less strict thresholds given in CLP the Regulation. Based on the precautionary principle, the thresholds given in the currently valid criteria will be maintained.

Additionally, the proposal of restricting the use of above mentioned substances, found as problematic, was analysed. They are described in more detail in section regarding the sub-criterion 3a). In the stakeholders consultation there was support to exclude the above described substances from the EU Ecolabelled products. Several of the mentioned in this section chemicals would be excluded from ecolabelled products through the criterion 3 b) "excluded or restricted substances and mixtures". Nevertheless, as derogations for some R-phrases /H-statements are still under consideration for preservatives, it is proposed to indicate all considered substances explicitly at this stage of criteria revision process. When the criteria document is finalised a cross-check on substances, which are automatically excluded by the general criterion 3 b), should be conducted.

Beside the above mentioned preservatives, stakeholders suggested several new substances for consideration to be restricted in Ecolabelled products:

- Chloromethylisothiazolinone (CMIT) / methylisothiazolinone (MIT),
- Cetrimonium chloride,
- Silver, silver salts and silver derivates.

In the technical analysis report it was found that preservatives widely used in all liquid products with the highest value for ecotoxicity were: Methylisothiazolinone (9,75E+03 PAF m3.kg-1 emitted), triclosan (2,74E+03 PAF m3.kg-1 emitted) and finally Methylchloroisothiazolinone (1,39E+03 PAF m3.kg-1 emitted). Triclosan, mentioned before, was proposed to be restricted based on its classification as very toxic to aquatic life with long lasting effects.

**Chloromethylisothiazolinone (CMIT) and methylisothiazolinone (MIT)** are commonly used in cosmetic products; however they are associated with allergic reactions, which raise concerns in their use in ecolabelled products. According to the information received there are no alternatives available so far, which are as effective and active within such wide pH range as the isothiazolinones. In the table below, the indicated dosage is related to the specific MIC (Minimum Inhibitory Concentration) of several preservatives:

**Table 18. Biocide activity scheme**

| BIOCIDE | ACTIVITY | DOSAGE | pH EFFICIENCY RANGE |
|---|---|---|---|
| | | | 2 3 4 5 6 7 8 9 10 |
| 2-Bromo-2-Nitropropane-1,3-diol (BRONOPOL) | Batteri | 0,01-0,1% | |
| Diazolinidyl urea | Batteri Gram-e muffe | 0,03-0,3% | |
| DMDM hydantoin | Funghi | 0,15-0,4% | |
| Glutaraldehyde | Batteri, funghi | 0,02-0,2% | |
| Imidazolinidyl urea | Batteri, funghi | 0,05-0,5% | |
| CMIT + MIT | Batteri, funghi | 0,006-0,0015 | |
| Parabens | Batteri, funghi | 0,30% | |
| Zinc Pyrithione | Batteri, funghi | 0,025-0,10% | |

Source: Stakeholders 'information sent to the EC

The dosage of CMIT and MIT added to the product is very low. Analysis of availability of alternatives to be used by the manufacturers as preservatives in cosmetic products show that if triclosan, parabens, formaldehyde and formaldehyde releasers (such as bronopol) are restricted, it will be very difficult to apply for Ecolabel, as substitutes (e.g. the above mentioned isothiazolinones) are very scarce. The stakeholders' feedback received emphasized that many alternative preservatives require low pH, which is nevertheless not suitable e.g. for hand washing products. Very few alternatives stable in anionic systems at pH 6-7 exist. From the DID list, the only suitable alternative indicated in the feedback was sodium benzoate. Nevertheless, it requires pH below 5.5 so cannot be used for a hand-wash. It was furthermore emphasized that the costs can be by 30% higher and the amount used would have to be much bigger, than the amount of isothiazolinones, which are very effective, if the substitutes are to be used.

MIT is classified with the following H-statements: Acute Tox. 3 H301, Acute Tox. 3 H311, Aquatic Acute 1 H400, which would exclude its use from the ecolabelled products above certain concentration. CMI and MI, are usually used and sold as a preparation: **reaction mass of CMI/MI (3:1)** due to their wider effectiveness in combating bacteria, fungi and yeasts and also lower price. The pH of the product to be preserved is one of the main factors that limit the use of preservatives. Depending on the stabilization and other compounds present in the formulation, CMI/MI can be used almost with no pH restrictions (which is its big advantage comparing to other preservatives). If only CMI separately is used, the CMI component begins to degrade quickly. CMI degradation also occurs in systems containing small amounts of reducing agents such as sulphites, sulphides or sulphur containing amino acids. That´s one of the reason why CMI/MI is almost always used in preparation.

According to the ESIS classification[80], if the concentration of CMI/MI (3:1) is ≥ 0,0015% (15ppm), it must be classified as Skin Sens 1; H317. In the Cosmetic Regulation, in Annex V isothiazolinones are covered by entry N° 39 "mixture of 5-chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate"). The maximum concentration allowed for rinse-off cosmetic products under study is 0.0015%.

The use of various isothizolinones and their potential exclusion from the ecolabelled products was discussed extensively along the consultation process. There was no agreement among stakeholders whether their exclusion should be proposed in the revised criteria version. Feedback supporting their exclusion and asking to withdraw such a proposal was submitted by many participants of the consultation process.

Some stakeholders referred to the opinion of the Scientific Committee on Consumer Safety (SCCS) in June 2012 an opinion on Benzisothiazolinone[81]. In this document, after the analysis of available evidence, authors concluded that benzisothiazolinone is safe when used as a preservative up to a maximum authorised concentration of 0.01% in cosmetic products. Nevertheless, its sensitising potential is of concern. Further, in the opinion it is stated that "Benzisothiazolinone is a skin sensitiser in animal models with potency similar to methylisothiazolinone. Methylisothiazolinone, at 100 ppm (0.01%) in cosmetic products is causing contact allergy and allergic contact dermatitis in the consumer". Regarding the levels of exposure to benzisothiazolinone in cosmetic products which are safe from the point of view of sensitisation, the SCCS stated that there is no sufficient information available and that "until safe levels of exposure have been established, the use of benzisothiazolinone in cosmetic products as a preservative or for other functions cannot be considered safe in relation to sensitisation".

Additional feedback received from MS stakeholders (supported with scientific evidence) referred also to the sensitizing properties of the mixture methyl- and methylchloro-isothiazolinone mixture (MIC/CIT). The project team was also informed that the Danish Environmental Protection Agency investigates MIT and other isothiazolinones with regard to their sensitising potentials. Request and rationale for the exclusion of the isothiazolinones was received from several stakeholders. The feedback is presented below:

Based on the analysis of the abovementioned opinions and scientific information it seems reasonable to exclude the use of isothiazolinones from ecolabelled products. Nevertheless, the industrial feedback received was very negative towards this requirement. It was emphasized that if the proposed preservatives (i.e. triclosan, parabens (), formaldehyde and formaldehyde releasers will all be excluded, only preservatives of low efficiency will be allowed to be used. Industry emphasized that in some formulations, e.g. for industrial applications containing vegetal raw material or those which have specific pH (pH > 8) weak preservatives like benzyl alcohol, sodium or potassium benzoate cannot be used to preserve the product.

[80] For details, please see the website: http://esis.jrc.ec.europa.eu/ .
[81] Scientific Committee on Consumer Safety (SCCS) opinion on Benzisothiazolinone, adopted in June 2012, available online at: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_099.pdf, accessed January 2013.

Stakeholders proposed a compromise solution asking to include in the criteria a clause that isothiazolinone derivatives can only be used as preservatives in cases the manufacturer can prove that as no other preservative can replace them in this specific formulation; i.e. the use of isothiazolinones would in principle be banned, with the exceptions, where the manufacturer can prove that it has more impact on safety or environment to replace isothiazolinones by another preservative.

The issue of isothiazolinones will be again raised during the EU Ecolabelling meeting. In this criteria version they are not excluded explicitly so far. Additional consultations with industrial stakeholders on the specific applications where isothiazolinones cannot be substituted are still conducted. Received information will be presented in the meeting.

**Cetrimonium chloride** is a quaternary ammonium salt. In cosmetics and personal care products, this ingredient is used in the formulation of hair conditioners, other hair care products and in some skin care products. Although quaternary ammonium derivative formulations have the potential to be sensitizing, especially when combinations of the concerned compounds are used, the Scientific Committee on Consumer Safety[82] stated that the use of cetrimonium chloride does not pose a risk under the following concentrations limit - up to 2.5% in rinse-off hair care products.

The EU Cosmetics Directive allows it to be used at a maximum concentrations of 0,1% in ready for use preparations. Cetrimonium chloride is not classified as dangerous in accordance with the CLP classification. For these reasons, cetrimonium chloride was not proposed to be restricted, and its maximum content is already set by the Cosmetics Directive.

Finally, **silver, silver salts and silver derivates** were proposed by stakeholders for consideration to be restricted in Ecolabelled products. Research regarding the degree of risk associated with silver is not conclusive but regulatory action is expected with the EU Biocide Directive. Although use of silver appears to be growing in some markets, its presence in this product group, as it is shown in the technical analysis report, is very limited. Because of cost and the fact that a biocide function is not considered to be valuable in all products, they are expected to play only niche roles, such as in sportswear. For that reason, silver derivates were not proposed to be excluded in this revision process.

In the later stage of the consultation (during the second AHWG meeting), request for excluding **nano-silver** was submitted. Silver nanoparticles (AgNP) reveal high ecotoxicity even at very low effect concentrations. AgNP are classified as very toxic towards aquatic organisms (very low values of EC50, e.g. for algae of 4 µg/l and also for crustaceans – far below 1 mg/l have been reported). Another important aspect with regard to this product group is that at low concentrations inhibition of nitrifying bacteria can occur and the function of

[82] Opinion of the SCCS on Alkyl (C16, C18, C22) trimethylammonium chloride, other uses than as a preservative, 8 December 2009. For more details: http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_012.pdf.

wastewater treatment plants may be affected due to the presence of AgNP[83]. Therefore, in the revised criterion 3a) the nano-silver is proposed to be excluded from the ecolabelled products.

***Criterion proposal***

As it is proposed to group all substances relevant criteria and include them in one common criterion 3 "Excluded or limited substances and mixtures", with regard to preservatives the following requirements are set:

- **in the sub-criterion 3 a) Specified limited and/or excluded ingoing substances**:

  the following substances: triclosan, ethyl-,methyl-, propyl- and butyl-parabens, formaldehyde and formaldehyde releasers ( bronopol, 5-bromo-5-nitro-1,3-dioxane, sodium hydroxyl methyl glycinate (SHMG), DMDM hydantoin, diazolidinyl urea and imidazolidinyl urea, nanosilver, isothiazolinones are excluded.

  Additionally the following statement is proposed:

  If the applicant can prove that it has more impact on safety or environment to replace isothiazolinones by another preservative, the use of isothiazolinones could be allowed, provided the proof submitted by the manufacturer is considered sufficient by the competent body.

- **in the sub-criterion 3 e) Preservatives:**

(i) The product may only include preservatives in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

(ii) Preservatives must not release substances that are classified in accordance with the requirements of Criterion 3b or/and are endocrine disrupters[84].

(iii) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an antimicrobial or disinfecting effect.

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

Although the Regulation 1223/200932 on cosmetic products does not currently restrict substances with endocrine disrupting effects, Article 15(4) "calls upon the Commission to review this Regulation with regard to substances with endocrine-disrupting properties, when EU, or internationally, agreed criteria for identifying substances with endocrine disrupting

[83] Mikkelsen et al. : Survey on basic knowledge about exposure and potential environmental and health risks for selected nanomaterials, Danish Environmental Protection Agency, 2011.
[84] http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list

properties are available, or at the latest by 11 January 2015". In the framework of the work on the Biocidal Products Directive (BPD) 98/8/EC31, approximately 400 substances are under review for PBT (Persistent, Bioaccumulative or Toxic), or CMR (carcinogen, mutagen or toxic for reproduction) or potential endocrine disruptive properties. Identified substances will be included in the Annex I[85]. In the criteria development process it was supported to exclude from the Ecolabelled products endocrine disrupters (CAT 1 substances) placed on the priority list of endocrine disrupting substances.



[85] The priority list of endocrine disrupting substances (CAT 1) published at: http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm#priority_list.

### 3.4 CRITERION 4: Packaging

**Proposed criterion and assessment and verification procedure**

***a) 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 completed and 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. Pre-shaving products packed in metal aerosol containers are exempted from this requirement.

PIR shall be calculated as follows:

**PIR= Sum (Wi + (Wirefill x F) + Ni + (Nirefill x F)) / (D + (Drefill x F))**

Where:

*Wi* – *weight of packaging (primary + proportion of secondary, including labels)*

*Wirefill* – *weight of refill packaging (primary + proportion of secondary, including labels)*

*Ni* – *weight of Non renewable + non-recycled packaging (primary + proportion of secondary, including labels)*

*Nirefill* – *weight of non-renewable and non-recycled refill packaging (primary + proportion of secondary, including labels)*

*D* – *weight of product contained by the "parent" pack*

*Drefill* – *weight of product delivered by the refill*

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

**F = V x R / Vrefill**

*Where:*

*V* – *volume capacity of the parent pack*

*Vrefill* – *volume capacity of the refill pack*

*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*

***Assessment and verification:*** *the applicant shall provide the calculation of the PIR of the product. A spreadsheet for this calculation is available in the user manual on the EU Ecolabel website. The applicant shall provide a completed and signed declaration for the content of recycled 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 and/or retailer shall document that the refills will be/are available for purchase on the market.*

### *c) Sustainable sourcing of paper and cardboard packaging and paper bleaching process*

Chlorine gas or other chlorinated compounds shall not be used as a bleaching agent for paper and cardboard packaging.

Virgin wood fibres used for paper and cardboard packaging shall be demonstrated to be produced from forest managed according to the principles of Sustainable Forestry Management (SFM).

***Assessment and verification:*** *Manufacturers shall provide a declaration of compliance with the criterion. If virgin fibres are used, documentation to prove that forests from which virgin wood fibres used for producing the product packaging are obtained are managed according to Sustainable Forest Management principles shall also be provided. For verification, certificates of chain of custody for the wood fibres certified as FSC, PEFC or any other sustainable forest management official standard will be accepted as proof of compliance.*

### *d) Design of packaging*

The packaging must 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 a 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:

$$R = ((m2-m3) / (m1-m3))$$

Where:
**m1** **-** Primary packaging and product
**m2** **-** Primary packaging and product residue in normal conditions of use (see APPENDIX I below)
**m3** **-** Primary packaging emptied and cleaned

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

*e)* ***Disassembly of primary packaging***

All materials in the packaging shall be separable by hand (paper, cardboard, plastic, metal, glass) for sorting or shall be suitable for recycling. Packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes.

***Assessment and verification****: the applicant shall submit a completed and signed declaration of compliance*

**Substantiating information, rationale and discussions conducted**

Packaging has an important load in the overall life cycle impact of the products under study. According to life cycle assessment carried out in the framework of the current study on average 22% of products' impact can be assigned to packaging and packaging waste. Impacts of packaging come mainly from the material used (derived from resources and energy consumed for producing packaging materials). It is thus important to address the weight, materials and characteristics of packaging in the Ecolabel criteria for this product group in order to minimize its environmental impact.

Different materials are used for packaging of cosmetic products under study. For liquid soaps, shampoos and hair conditioners, packaging is usually made of different kinds of plastics. For all plastic materials impacts come mainly from energy use in its manufacturing. For solid soaps, packaging is usually made of paper or cardboard. Criteria on packaging material (i.e. on the kind of material restricted or excluded) are not proposed in this document. Restrictions are proposed regarding the weight and substances used in the packaging materials, as explained below.

Preliminarily, during the first AHWG meeting, the following issues were discussed with regard to the restriction on the packaging:

- Options of modifying the formula to calculate Weight/Content Relationship (WCR). It was agreed that the formula should take into account availability of refillable and refill packaging. The issue of using bioplastics and/or biodegradable plastics for packaging purposes should also be analysed.

- Setting stricter limit for WRC, according to current data regarding ecolabelled products.

- Whether disposable toiletries (not refillable), such as shampoo and soap toileteries, shall not be used (to align the criteria with the criteria for the EU Ecolabel Tourist accommodation services).

- Sustainable sourcing of packaging materials (e.g. of paper and cardboard).

- Packaging shall not contain substances included in the candidate list of Substances of Very High Concern (SVHC) for authorization.

- Specific packaging requirements for different kinds of material used: plastic, metal, paper and cardboard.

- It should be possible to separate all materials in the packaging (paper, cardboard, plastic, metal) for further treatment. Parts comprising mixed materials that cannot be separated should be restricted, with the exception of pump parts.

- Additional requirements regarding aerosol packaging - due to the potential extension of the scope by shaving foams and gels.

Based on the input received from these discussions and further information collected, the issues of importance were analysed further. A brief summary of them is given below criterion by criterion.

***Sub-criterion 4 a) Packaging and Sub-criterion 4 b) Packaging Impact Ratio (PIR)***

- **Calculation of Weight/Content Relationship (WCR) – revision of the calculation formula**

Discussions of the first AHWG meeting and written feedback received from stakeholders addressed the issue which materials and parameters should be included in the calculation. Different aspects have been considered: refilling systems, recycled material, renewable sourced materials and biodegradability.

**Refilling systems** (i.e. where two kinds of packaging, refillable and refill, exist for a product) allow for important packaging material reduction, so it is important to include them in the Ecolabel criteria. Some soap products have the option of refilling or reusable package, where the refill package is usually lighter that the conventional one. It is quite usual in hand-soaps where refillable package has a dispenser and refill package is a simpler bottle. There exist also some other soap products with refill packaging such as body liquid soap. Among all liquid soap products of the European market, 10% have refilling systems[86]. For shampoos, only 26

[86] Mintel GNPD Data Base. Category: liquid soaps, 2012.

products have been found with refilling system (0.02%), and for hair conditioner products – only 2 (0.04%)[87].

Refilling system can provide packaging saving of nearly 80% of weight, which can be converted to approximately 80% of saving of environmental impact of packaging stage[88], as it mainly results from raw material consumption. The assessment done shows that environmental impacts are directly proportional to the weight of packaging[89]. For instance, in accordance with the results obtained in the technical analysis, in the case of liquid soaps, by using a refilling system, the total environmental impact of the product decreases by 18% compared to the original soap with non-refill packaging.

Thus, it is considered of high importance to promote through Ecolabel criteria the refill/refilling systems in this product group.

The initial proposal of the revision process was to include refillable and refill packaging in the current formula as follows:

$$WCR = \Sigma(((Wi_{refillable}/r + Wi_{refill}) + Ni)/(Di \times r))$$

Where;

*Di* – the weight in grams of product that the packaging-component contains

*r* – the return number, i.e. the number of times the packaging-component i is used for the same purpose through a system of return or refill (by default r = 1 if no reuse occurs)

Wi*refillable* – the weight (in grams) of refillable packaging-component i

Wi*refill* – the weight (in grams) of refill packaging-component i

If there is not any refillable/refill packaging, then, Wi*refillable*= Wi, r=1 and Wi*refill*=0

Ni: the weight (in grams) of the packaging component that comes from **virgin and non-renewable material** rather than recycled or renewable sources (this applies to both primary and secondary packaging). If the packaging component does not contain **recycled material or bio based polymer, then Ni = Wi**.

Stakeholders agreed with the need of including refilling packaging in the WRC calculation. Further feedback received was aimed to improve the proposal presented at the AHWG meeting by considering that in some cases refill and refillable could have different volume capacity, and also the two kinds of packages can have different content of recycled or renewable material. A new formula was proposed where different capacities were considered.

[87] Mintel GNPD Data Base.
[88] Data obtained from direct calculation for a refilling product of liquid soap.
[89] Assuming that the average packaging composition remains. For details please see the report "Preliminary results from the technical analysis, available at project website: http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html.

The improved formula was evaluated and proposed for discussion in the second AHWG meeting.

**PIR= Sum (Wi + (Wirefill x F) + Ni + (Nirefill x F)) / (D + (Drefill x F))**

Where:

| | |
|---|---|
| Wi | – weight of packaging (Primary + proportion of secondary per SKU[90]) |
| Wirefill | – weight of refill packaging (Primary + proportion of secondary per SKU) |
| Ni | – weight of non-renewable + non-recycled packaging (Primary + proportion of secondary per SKU) |
| Nirefill | – weight of Non renewable and non recycled refill packaging (Primary + proportion of secondary per SKU) |
| D | – weight of product contained by the "parent" pack |
| Drefill | – weight of product delivered by the refill |
| F | – number of refills required to meet the total refillable quantity, calculated as follows: |

**F = V x R / Vrefill**

Where:

| | |
|---|---|
| V | – volume capacity of the parent pack |
| Vrefill | – volume capacity of the refill pack |
| 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 the current criteria R was set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number. Comparing this factor with other Ecolabels, it appears to be too high and was criticised by several stakeholders. It is proposed that manufacturer should provide the number of foreseen refillings. Indicatively (based on the consultation process) the R could be set as R=5 for plastics and R=2 for cardboard, unless the applicant can document a higher number. Nevertheless, in the revised version no default values are proposed and it is proposed as an applicant's task to submit respective information.

Moreover some rules for refilling systems were proposed to be taken into consideration:

- The refillable parent pack must be designed to accept refills without incurring waste by spillage and should perform its intended function throughout the designed refill rate.

- To qualify both parent pack and refill must be continuously available to consumers throughout the period of the eco-label award.

- If different refill packaging types / sizes are to be used with the parent pack, a separate calculation should be performed for each size or type.

[90] SKU – Stock Keeping Unit.

– When calculating weight of refill, analysis should be made of the actual amount of product delivered into the parent pack by the refill. Product retained in the refill should be excluded.

These rules will be included in the user manual accompanying the criteria.

**Considerations on recycled, renewable and degradable materials**

In the existing criteria, the use of **recycled material** is already included in the formula. It is proposed to maintain this parameter, as the use of recycled material allows to decrease the consumption of raw materials and to save resources and energy used for producing packaging.

It is further proposed to include **renewable packaging material** in weight calculation method in the revised criteria. Renewable material is derived from renewable sources (e.g. wood pulp and paper, and plant based polymers).

Bio-polymers allow using renewable resources instead of non-renewable sourced polymers, so they contribute to reduction in the use of primary raw materials and specifically the use of petroleum-based plastics. It was proposed to consider differentiating this kind of polymers from other polymers in the weight calculation method in the revised criteria.

Bio-based polymers are macromolecules derived from plants, bacteria, algae or other sources that are long chains of molecules linked together through a chemical bond. They are generally able to perform the functions of traditional petroleum-based ingredients. Bio-based plastics can be either biodegradable or non-biodegradable. They are often degradable through microbial processes such as composting, but this depends on how they are produced.

The main bio-polymers used in packaging for cosmetics are: polylactic acid (PLA) obtained mainly through fermentation of dextrose, which is extracted from a starch source material (starch comes from different vegetables sources such as rice, maize, potatoes); and polyhydroxyalkanoates (PHAs), which are polymers synthesized by bacteria from sugars fermentation[91]. PLA is the most common polymer used in this kind of packaging.

According to information obtained from one stakeholder, renewable sourced biodegradable polymers are already being used for packaging of cosmetic products. One of the examples is PLA, which is used e.g. in single use bottles for hotel toiletries and in several cosmetics ranges (e.g. Plant Love from Cargo Cosmetics in Canada). Sugar cane derived packaging is used by a Brazilian company NATURA, which has nearly 15 % of the Brazilian cosmetic market.

Nevertheless, it is also worth mentioning that bio-polymers, for which the raw materials are obtained from plants, can have social and ethical implications, as these crops farming for

[91] Envase sostenible para la industria cosmetic, available online at: http://marketingcosmeticaperfumeria.wordpress.com/2011/03/22/envase-sostenible-para-la-industria-cosmetica/.

industrial uses compete with food resources supply. Main environmental concerns are related to the amount of non-renewable energy used for their production, water pollution and land use due to the intensifying crop production to meet the demand[92]. Therefore, bio-plastics should be made from resources obtained and managed in a sustainable way to be included in the calculation. "Sustainable biomaterials" can be defined as those that are sourced from sustainably grown and harvested cropland or forests, manufactured without hazardous inputs and impacts[93].

As only bio-polymers that come from sustainable source could be included in the formula calculation, a declaration of the manufacturer/supplier indicating the origin of the bio-polymer and a declaration that sustainable crop principles are accomplished in the entire supply-chain would be required. These sustainable crop principles should follow those defined by the Common Agriculture Policy (CAP) of Europe[94] and the FAO[95].

As this proposal has not been widely supported in this criteria revision a specific requirement regarding the bio-polymers has not been proposed in the revised criteria version. However, it was explicitly asked for to take this issue of evaluation the environmental impacts of renewable sourced biodegradable polymers compared to petrochemical plastic under consideration in the future revision process. There are some LCA studies available already[96] and this area certainly needs further exploration, whether in the future criteria can this kind of plastics can be addressed specifically.

Additionally, **biodegradable and degradable plastics** were proposed in feedback received from some stakeholders to be included as a parameter in the calculation formula. About this proposal, some information has been gathered to see if it is suitable and feasible in this revision process

It should be differentiated among different kinds of "degradable" plastics:

- Biodegradable (compostable) plastic: Biodegradable polymers are often bio-based but they can also be petroleum-based (e.g. polycaprolactone). Some biodegradable plastics even contain a mixture of petroleum-based polymers and bio-polymers. They meet scientific standards for biodegradability and compostability of plastics and plastic products. According to definition of EN 13432[97] biodegradable plastics can be completely broken down by micro-organisms in the environment into non-toxic compounds (water, $CO_2$ and biomass under aerobic conditions, as well as methane under anaerobic conditions). Biodegradable plastics could be preferable than

[92] BIO Intelligence Service, AEA Technology, Institute for European Environmental Policy for DG Environment, Plastic waste in the environment, Final report, April 2011, available online at: http://ec.europa.eu/environment/waste/studies/pdf/plastics.pdf.
93 http://www.sustainablebiomaterials.org.
[94] Common Agriculture Policy (CAP) http://ec.europa.eu/agriculture/index_en.htm.
[95] Biobased Materials: Essential for the Next Generation of Products, available online at: http://www.fao.org/agriculture/crops/core-themes/theme/spi/en/.
[96] e.g. 1) Patel, M., Bastioli, C., Marini, L., Würdinger, E. :Life-cycle Assessment of Bio-based Polymers and Natural Fiber Composites. Biopolymers Online, 2005 and 2) Detzel A., Krueger M.: Life Cycle Assessment of PLA, A comparison of food packaging made from NatureWorks® PLA and alternative materials, IFEU GmbH, Heidelberg, July 2006.
[97] EN 13432 - Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging.

conventional recyclable plastic for some specific uses, but only if they can be treated as organic waste, i.e. through composting.

- Degradable plastics: for instance, degradable plastic with special additives and oxo-biodegradable plastics. They are often non-renewable plastics which are degradable due to addition of some substances that catalyse the degradation of the polymer in the environment producing smaller plastic fragments and $CO_2$. This kind of plastics does no meet biodegradability or compostability standards and there is no certification for oxo-/UV-degradability in Europe yet[98]. They do not present environmental benefits unless they are treated by a specific treatment under conditions that allow their degradability.

Biodegradable plastics could present environmental benefits only if they have the appropriate treatment (composting), as biodegradability is not predictable and dependent on appropriate degradation conditions. The behaviour of biodegradable plastic waste depends on the treatment they have as packaging waste, which can not, nevertheless, be guaranteed in the current situation. According to the information collected[99], currently around 58% of plastic waste packaging is treated by recycling and valorisation (thermal treatment) and 42% by landfilling (data for the EU in 2008). There is no collection scheme for biodegradable / degradable plastics and they can even cause difficulties to conventional plastic recycling systems. The use of biodegradable or degradable plastics may have implications for the recycled plastics industry, as it could potentially lead to the contamination of recycled plastics, affecting the quality and physical integrity of the resulting material. Investment may be needed in sorting technology to deal with this challenge.

Biodegradable and degradable plastics can present higher environmental impacts (e.g. with regard to green house gas emissions) if they are disposed of in uncontrolled landfills. The Landfill Directive 1999/31/EC[100] sets intermediate and long-term targets for the phased reduction of biodegradable waste going to landfill, which will limit the disposal of biodegradable plastics in landfills as well.

As conclusion, it is considered that at present the Ecolabel scheme shall promote recycling as the best treatment for packaging plastic, according to the hierarchy defined in the Waste Framework Directive, 2008/98/EC[101] and Packaging Waste Directive 94/62/EC[102]. The full life cycle impacts of biodegradable plastics are still an important topic of research. It seems important that for biodegradable and degradable polymers waste streams the necessary infrastructure (e.g. design of landfills, separate collection centres for recycling, recycling systems) needs to be adjusted. As the current waste treatment for packaging can not guarantee

[98] BIO Intelligence Service, AEA Technology, Institute for European Environmental Policy for DG Environment, Plastic waste in the environmenta, Final report, April 2011, available online at: http://ec.europa.eu/environment/waste/studies/pdf/plastics.pdf.

[99] PlasticsEurope, EuPC, EuPR, EPRO and Consultic (2009) *The Compelling Facts about Plastics - An analysis of European plastics production, demand and recovery for 2008*.

[100] Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999L0031:EN:NOT.

[101] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0098:EN:NOT.

[102] European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0062:EN:NOT.

the final destination of packaging, it has been decided not to promote biodegradable and degradable polymers for this criteria revision process. This issue is nevertheless proposed to be considered and investigated further in the later revision, when more evidence and information is available.

One stakeholder proposed further to set **impact factors for different materials** in the Packaging Impact Ratio formula based on the LCA outcomes. However, the LCA conducted is a generic one and should serve to give the overall picture regarding the environmental performance of an average product along its life cycle. Setting such material weighting factors needs specific and detailed investigation of each packaging material type (needs a detailed full LCA on packaging), this proposal could not be incorporated in the current calculation formula. Other stakeholders supported that the choice of materials is indeed an issue worth considering. Nevertheless, it was also stated that suggesting or restricting materials would need more thorough LCA analysis, which is likely to be too complex for eco-labels. Thus, the focus on material weight reduction was considered to be currently the best option to avoid complexity of the criteria.

Regarding the **scope of the formula**, it was proposed to maintain the current scope, where primary and secondary packaging is included. Tertiary packaging is excluded from calculation, as this will be specific to individual business customer requirements such as order quantity, stock control and shipping methods. The major part of stakeholders agreed with this proposal.

As the above mentioned terms are open to interpretation and different published definitions exist, it was proposed that Ecolabel criteria follow the definitions given in Article 3 of the EU Directive on Packaging and Packaging Waste 94/62/EC. These definitions are as follows:

(a) Sales packaging or primary packaging, i. e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of purchase;
(b) Grouped packaging or secondary packaging, i. e. packaging 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; it can be removed from the product without affecting its characteristics;
(c) Transport packaging or tertiary packaging, i. e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packaging in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers.

One CB stakeholder proposed to allow only primary packaging and add to the criteria document the following requirement (in order to avoid unnecessary packaging material): "Primary packaging, defined as the smallest unit of distribution shall be in direct contact with the contents. No additional packaging for the product as it is sold, e.g. carton over a bottle, shall be allowed". Although it is agreed that the packaging should be minimised, it should be also taken into account that sometimes two products (e.g. the normal one and the refill, or two

products in the promotion) are sold together and these need to be connected with additional grouping packaging. For this reason, it would make sense to allow in the scope also the secondary packaging. Nevertheless, it should also be ensured that the primary packaging consists only of one packaging unit (i.e. as mentioned above there is e.g. no carton over a bottle or other packaging kind) and that the primary packaging is only the one which is in direct contact with the product. Therefore, the abovementioned requirement will be included in the revised criteria version as ***sub-criterion a)***.

Finally, as the new formula has been extended and other parameters apart of the weight are taken into account (Packaging weight / content ratio, renewable, recycled and refillable packaging), it is proposed to rename the formula (called so far "Weight/Content Ratio") as **"Packaging Impact Ratio" PIR**.

One additional issue was raised by one industrial stakeholder who manufactures product classified as "liquid soap", which is however in powder form and has much lower density than conventional products (in general lower by 50%). It was pointed out that in this situation the lower density product would be disadvantaged. In this case either the dose delivered should be considered and included in the formula or a correction factor relating the mass to the volume of the product could be used (e.g. *if the density of the product is below 1 g/cm$^3$, the calculated PIR value should be multiplied additionally by the product density [expressed in g/cm$^3$] and this value should be not exceed 0.28*).

Introducing reference to the dose delivered is not easy due to the fact that for some products the standard dose cannot be easily set (e.g. for shampoos or hair conditioners). This would be possible for soaps. Further consultation was conducted with the stakeholder who submitted this request and it was finally agreed that if the PIR value is kept as 0.28, the currently proposed formula may be kept.

- **Setting more strict limit for PIR**

Impact of packaging is directly related to its weight**,** as the main environmental impacts result from the material used. Initiatives that reduce the amount of raw material used, such as refilling systems and recycling processes, allow minimizing the environmental impact of packaging, and as a result, the environmental impact of the entire product.

The current weight/content ratio limit is 0.3 g of packaging for 1 g of product. According to Ecoembes[103], weight packaging for packaged products in Spain has decreased by 6% from 2006 to 2010. It is thus assumed that packaging for product group of soaps, shampoos and hair conditioners at European level also follows this trend and the current average weight is lower than the weight from 2006. Ecolabelled products should not have unnecessary packaging, so packaging should be as light as possible, but of course fulfilling the intended function (which is the priority). They should be different (i.e. better performing from the

[103] www.ecoembes.com.

environmental point of view) from average marketed product in terms of formulations, but also in packaging.

Stakeholders were consulted regarding the information on the average weight/content ratio. Preliminarily, 57 ecolabelled products were analyzed based on the feedback received[104]. The data from the report of the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners[105] was also included. Additionally, industry provided data of some products which indicated that non-refilling packaging average weight/content ratio for these products were 0,25; whereas for refilling products the average ratio was 0,17. It was concluded that in general the current limit on WCR is higher that the values for average product (see next table), which indicates that it may be appropriate to propose stricter WCR limits. Moreover, the use of recycled or renewable materials and refilling systems will allow obtaining lower values.

**Table 19. WCR average values and current limits**

| **PRODUCT** | **WCR (average 2012) (g packaging/ g product)** | | **WCR (average 2006)[106] (g packaging/ g product)** | | **Current limit (g packaging/ g product)** |
|---|---|---|---|---|---|
| | **Average** | Range | **Average** | Range | |
| **Rinse-off cosmetic products under study** | 0,19 | 0,1-0,29 | 0,15 | 0,1-0,2 | 0,3 |

Sources: own work based on information from reports indicated in footnote and stakeholders 'information sent to the EC

Based on these results, the following PIR limits were proposed for discussion for the revised criteria in the second AHWG meeting.

- for all packaging except of metal aerosol packaging: < 0,2 (g packaging/g product)
- for metal aerosol packaging: < x (g packaging/g product) – For discussion if it is necessary at to set it?

The discussions conducted in the meeting and subsequent feedback received indicated that the value of 0.2 g packaging/g product is considered too strict by all stakeholders. Analysis of the feedback gave the value of 0.28 g packaging/g product as the most appropriate. Lower value could work for systems with refill packaging but it was emphasized that this option is often problematic for the manufacturers. Although, they have in their offer the refills, retailers often do not want to accept it for sale and customers often do not choose this option. The value of

[104] For further details see annex IV: Summary of data.
[105] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.
[106] Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

0.28 was validated also in the calculations conducted by the industry with the application of the new formula and is finally proposed for the revised criteria version.

After discussions it has been decided to exempt the metal aerosol packaging from this requirement. Metal packaging is only allowed for this kind of packaging in the rinse-off cosmetic products group. As the value of metal is much higher, the manufacturers make attempts to reduce its amount as far as possible. Even more important is that there is the European Union Aerosol Dispensers Directive (ADD)[107], which sets special requirements on this kind of packaging. Additionally, metallic waste can be easily separated from other waste materials and due to the much higher value and, in comparison with e.g. plastics, the recovery quote for metals is high. Therefore, it has been decided not to add additional requirements regarding metallic aerosol dispensers.

- **Sub-criterion c) Sustainable sourcing of paper and cardboard packaging and paper bleaching process**

**Sustainable sourcing of packaging materials**

Secondary packaging and primary packaging for some products such as solid soaps is usually made of cardboard material.

For virgin paper and cardboard packaging made of wood fibres it is important to guarantee sustainable origin along the supply chain. Natural forests throughout the world are threatened by global demand for forest products. Much of the world's remaining natural forests still suffer from illegal exploitation, poor management and conversion to other land uses, commonly resulting in severe degradation or complete destruction. In some countries as much as 80% of the timber is harvested illegally, often involving the violation of human rights and destruction of protected forests[108].

The main forest products certification is FSC (Forest Stewardship Council) and PEFC (The Programme for Endorsement of Forest Certification Schemes). FSC[108] is an independent, non-governmental, not-for-profit organization established to promote the responsible management of the world's forests. FSC *certification* provides a credible link between responsible production and consumption of forest products. Currently there are 147 102 231 ha of certified exploitation in 80 countries and a total amount of 1114 licences[108]. FSC in cosmetic packaging is increasing and there are lots of examples available in the market. PEFC[109] is a non-governmental organization established in order to support sustainable forest management. It functions as a global umbrella organisation for the assessment and mutual recognition of national forest certification schemes. Currently there are 243 million ha of certified forests.

[107] Council Directive of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, OJ L 147, 9.6.1975, p. 40.
[108] Fores Stewardship Council website: http://www.fsc.org.
[109] Programme for the Endorsement of Forest Certification website: http://www.pefc.org/.

It is proposed to set a criterion for cardboard packaging to guarantee that the **virgin material** comes from forestry which is managed in a sustainable way. Materials made of wood fibres used for packaging should be demonstrated to be produced from forest managed according to the principles of Sustainable Forestry Management (SFM). A definition of SFM was developed by the Ministerial Conference on the Protection of Forests in Europe (MCPFE)[110], and has since been adopted by the Food and Agriculture Organization (FAO). It defines sustainable forest management as:

*"The stewardship and use of forests and forest lands in a way, and at a rate, that maintains their biodiversity, productivity, regeneration capacity, vitality and their potential to fulfil, now and in the future, relevant ecological, economic and social functions, at local, national, and global levels, and that does not cause damage to other ecosystems".*

Outside Europe they shall at least correspond to the United Nations Conference on Environment and Development (UNCED) Forest Principles (Rio de Janeiro, June 1992)[111] and, where applicable, to the criteria or guidelines for sustainable forest management as adopted under the respective international and regional initiatives (ITTO, Montreal Process, Tarapoto Process, UNEP/FAO Dry-Zone Africa Initiative).

Verification should follow the same scheme than other product category groups of Ecolabel, for instance the Furniture[112]. Manufacturers should provide documentation to prove that forests are managed according to Sustainable Forest Management principles. For verification, certificates of chain of custody for the wood fibers certified as FSC, PEFC or any other sustainable forest management official standard will be accepted as proof of compliance.

Regarding the bleaching processes used for paper packaging the requirement set in the currently valid criteria document is proposed to be kept, i.e.: "Paper/cardboard packaging: Chlorine gas or other chlorinated compounds shall not be used as a bleaching agent".

Chlorine gas is classified as H400 (very toxic to aquatic life), H315 (causes skin irritation), H319 (causes serious eye irritation), H331 (toxic if inhaled) and H335 (may cause respiratory irritation). Chlorine bleaching process produces highly toxic and persistent organochlorines such as dioxins. Dioxins are recognized as persistent environmental pollutants, regulated internationally by the Stockholm Convention on Persistent Organic Pollutants. In the EU Ecolabel criteria for tissue paper and for copying and graphic paper it is required that chlorine gas shall not be used as a bleaching agent and the same requirement is proposed for the product group under study. The same is required for this product group under study.

Limited feedback was received regarding this requirement. In general, there was agreement on exclusion of chlorine gas or other chlorinated compounds used as a bleaching agent. It was indicated that beside the use of wood fibres produced from sustainable managed forestry, use

[110] European Operational Level Guidelines for Sustainable Forest Management, as endorsed by the Lisbon Ministerial Conference on the Protection of Forests in Europe (2 to 4 June 1998).
[111] Report of the United Nations Conference on Environment and Development, available online at: http://www.un.org/documents/ga/conf151/aconf15126-3annex3.htm/.
[112] Commission Decision of 30 November 2009 on establishing the ecological criteria for the award of the Community eco-label for wooden furniture, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:320:0023:0032:EN:PDF.

of recycled fibres shall be preferred. It was decided to keep both of these requirements and to allow the packaging manufacturer, either to use the recycled fibres of fibres from sustainably managed forests.

- ***Sub-criterion d) Design of packaging***

Besides the above described criteria, the stakeholders proposed to keep one old requirement on the design of the product's packaging, i.e. "The packaging must be designed to make correct dosage easy (e.g. by ensuring that the opening at the top is not too wide)", which was primarily proposed to be moved to the consumer test part.

And additionally, it was asked to introduce one additional, related to it, requirement. In order to minimise the environmental impact of the product the amount (share) of the product which can be used should maximised (i.e. the packaging should be designed in a way that the amount of product left in the packaging is minimized).

According to additional information submitted by the stakeholders the study of the Institute for European Environmental Policy ("Packaging in the context of the product, supply chain and consumer needs", 2004) revealed that among the properties which contribute to minimisation of the unintentional product waste are: large opening, transparency of the packaging, ability to place the product upside-down to allow most product to rinse down the container and be used by the consumer, and easiness to re-close. Also product's characteristics have influence, easiness to pour, press or scrape out, have long shelf life, etc. Nevertheless, these characteristics cannot be used universally and need to be tailored to the product (e.g. transparent packaging is not suitable for products susceptible to photo-degradation). Additionally, the feedback received informs that there is no agreed methodology on how such parameters on product design and minimisation of the product retained in the packaging could be determined and the thresholds set (various product types would require different characteristics).

Later in the consultation process, a protocol for evaluating the residual product after the complete use has been shared with JRC IPTS by one CB stakeholder. The procedure of testing is as follows:

**Protocol for measuring the residual quantity of a rinse-off cosmetic product in the packaging**

This protocol was developed by the French National Institute for Consumer Affairs (INC) in cooperation with the French Environment and Energy Management Agency (ADEME).

**1) Definition of the indicator**

One function of the packing is to facilitate the use of the product. The **restitution rate** shows the percentage of product actually consumable.

**Residual amount (R)**: amount of product remaining in the container after the consumer has emptied the container. The rate is expressed as a weight percentage and defined as follows:

| **R =** mass of the product residue divided by mass of product in the container |
|---|

**2) Measurements**

Measurements aim at determining precisely the mass of product and packaging.
Measurements are adapted to each product based on the characteristics of the packaging and are defined in dedicated specifications.

The following masses are measured:

- Primary packaging and product: **m1**
- Primary packaging and product residue in normal conditions of use (see APPENDIX I below): **m2**
- Primary packaging emptied and cleaned: **m3**;

**3) Results**

From previous measurements, we have:

- The mass of product in the container

| $\mathbf{m_{product} = m1\text{-}m3}$ |
|---|

- The mass of product residue in normal conditions of use

| $\mathbf{m_{residues} = m2\text{-}m3}$ |
|---|

We deduce:

| **R = ((m2-m3) / (m1-m3))** |
|---|

**APPENDIX I: normal conditions of use**

**Cosmetics:**

- Tube: Applying for three minutes successive pressures on the body of the primary packaging in direct contact, with the cap in downward position. The test is considered complete when no amount of liquid will flow after five successive pressures on the body of the primary packaging in direct contact. Neither the cap is dismantled, nor water is introduced inside the packaging.

- Spray: Applying successive pressures on the tip of the spray by pressing the spring down entirely. Wait until the spring has returned to its initial position prior to applying a new pressure. Repeat until no amount of product flows from the spray after five successive pressures. Neither the cap is dismantled, nor water is introduced inside the packaging

- Pot: The product is removed using the index and middle fingers by rubbing the edges and the bottom of the pot carefully but relentlessly. Neither the cap is dismantled, nor water is introduced inside the packaging

- Vial/flask: Returns the vial upside down, with the cap in downward position. After the trickle is not continuous, the bottle is left in the same position for another two minutes. Neither the cap is dismantled, nor water is introduced inside the packaging

This requirement was considered for the current criteria version and a brief consultation regarding the minimum share (% w/w) of the product which can easily be used by the consumer has been conducted. The received proposal regarding the threshold value was 90%, i.e. at least a 90% of the product can be removed easily by the user from the container. This threshold was consulted further with industry association and it was supported. Thus, proposal regarding testing in accordance with the above protocol is proposed. The protocol will be included in the user manual, available at the EU Ecolabel website.

The formulation of this criterion is proposed as follows:

The packaging must 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 a 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:

$$R = ((m2-m3) / (m1-m3))$$

Where:
**m1** - Primary packaging and product
**m2** - Primary packaging and product residue in normal conditions of use
**m3** - Primary packaging emptied and cleaned

- ***Sub-criterion e) Disassembly of primary packaging***

Recyclability of waste packaging is of high importance. From 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 rate is higher for paper and cardboard packaging waste than for plastic packaging waste. Among packaging plastics, PET is the polymer with higher recycling rate, whereas PVC is the polymer less recyclable (nevertheless, used in low amounts for this product group).

EU Ecolabel criteria should try to ensure the **recyclability** of various components of packaging. The best case is mono-material packaging. For packaging made of different materials, all materials in the packaging should be separable by hand (paper, cardboard, plastic, metal, glass) for sorting or should be suitable for recycling. Packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes.

Several stakeholders argued that in some cases it may be better to stay with multiple materials in case this allows for material reduction, especially in countries with low waste recycling rates and lack of recycling facilities. Nevertheless, it is agreed that Ecolabel should promote recycling as the best waste treatment and it is considered appropriate to set a requirement to guarantee recyclability of packaging. And even if multiple materials are used, it should be ensured that this design will not be impeding recyclability of the packaging (e.g. not compatible for recycling materials, difficult to separate).

The proposed formulation is presented below:

*All materials in the packaging shall be separable by hand (paper, cardboard, plastic, metal, glass) for sorting or shall be suitable for recycling. Packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes*.

**Sub-criteria withdrawn from the revised proposal**

- ***Sub-criterion "Requirements on substances used in packaging" – Sub-criterion withdrawn***

In the current EU Ecolabel criteria for this product group a number of requirements addressing restriction on substances is already set. Beside the exclusion of some specific substances it was also required that "*no constituent substance must be classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Rep) including rules for self-classification class III*". Additionally, "*the packaging must contain neither additives based on Cadmium or Mercury or compounds with these elements*".

In the light of the article 6.6 and 6.7 of the new EU Ecolabel Regulation 66/2010 discussion on potential new requirements on substances in packaging was also conducted. One option considered in the criteria revision process was to apply the same requirements on substances for the product and the packaging material. The formulation of the criterion would be then: "*The packaging must not contain substances which do not fulfil criterion 3b and 3c*". This would ensure that the user is in general prevented from being exposed to substances classified as hazardous (as they will not be used) and would simplify and reduce the number of criteria. However, manufacturers may face difficulties as the packaging material is not

produced by them but it is only purchased. Therefore they have limited control and information on which substances are used in the different packaging materials. As, in general, the stakeholder asked to reduce the administrative burden, and as the new Ecolabel Regulation asks to focus the criteria on the most important environmental impacts, this proposal was not supported much in the consultation process. Another option was then proposed for consultation, as it was considered more practical. This option was to set more specific requirements on substances used in packaging using as main reference the currently valid criteria.

During the discussions conducted at the AHWG meeting the proposal to set a restriction on the substances placed at the candidate list of Substances of Very High Concern (SVHC) was supported. Some common substances of concern used in plastic materials are indicated in Table 31.

**Table 20. Substances at the Candidate List contained in plastic materials**

| Name of substance | Plastics involved | EC number | CAS number | Reason for inclusion in Candidate List |
|---|---|---|---|---|
| 2,4-Dinitrotoluene | Monomer | 204-450-0 | 121-14-2 | Carcinogenic (article 57a) |
| 4,4'- Diaminodiphenylmethane (MDA) | Monomer | 202-974-4 | 101-77-9 | Carcinogenic (article 57a) |
| Acrylamide | PA Monomer | 201-173-7 | 79-06-1 | Carcinogenic and mutagenic (articles 57 a and 57 b) |
| Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) | PVC | 287-476-5 | 85535-84-8 | PBT and vPvB (articles 57 d and 57 e) |
| Benzyl butyl phthalate (BBP) | PVC PP catalysts | 201-622-7 | 85-68-7 | Toxic for reproduction (article 57c) |
| Bis (2-ethylhexyl)phthalate (DEHP) | PVC PP catalysts | 204-211-0 | 117-81-7 | Toxic for reproduction (article 57c) |
| Chromium trioxide | HDPE catalysts | 215-607-8 | 1333-82-0 | CMR |
| Dibutyl phthalate (DBP) | PVC PP catalysts | 201-557-4 | 84-74-2 | Toxic for reproduction (article 57c) |
| Diisobutyl phthalate | PVC PP catalysts | 201-553-2 | 84-69-5 | Toxic for reproduction (article 57c) |
| Hexabromocyclododecane (HBCDD) and all major diastereoisomers | Flame Retardant EPS, XPS | 247-148-4 221-695-9 | 25637-99-4 | PBT (article 57d) |
| Lead chromate | Pigment | 231-846-0 | 7758-97-6 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Lead chromate molybdate sulphate red (C.I. Pigment Red 104) | Pigment | 235-759-9 | 12656-85-8 | Carcinogenic and toxic for reproduction (articles 57 a and 57 c) |
| Lead sulfochromate yellow (C.I. Pigment Yellow 34) | Pigment | 215-693-7 | 1344-37-2 | Carcinogenic and toxic for reproduction (art. 57 a and 57 c) |
| Tris(2-chloroethyl)phosphate | Flame Retardant, plasticiser | 204-118-5 | 115-96-8 | Toxic for reproduction (article 57c) |

Source: Website of PlasticsEurope: http://www.plasticseurope.org/plastics-sustainability/consumer-protection/reach.aspx

In the revised criteria preliminarily the exclusion of the currently covered substances (i.e. cadmium and mercury and the CMR substances) and the proposed addition of SVHC was proposed. The criterion would be formulated as follows:

*The packaging material shall not contain substances or preparations exceeding 0,010 % by weight of the final product packaging that are classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Rep) and included in Annex VI to the Regulation (EC) No 1272/2008 nor any substances that are identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, present in the product in concentrations higher than 0.010 % (weight by weight). Additionally, the packaging shall contain neither additives based on Cadmium or Mercury or compounds with these elements.*

In the framework of the stakeholders' consultation it was mentioned that CMR classified substances which concentration exceeds 100 ppm are forbidden in packaging. The use of self-classification rule (as in the current criterion) was found inappropriate, as the substance classification would depend then on the supplier's declaration. The harmonized classification through ECHA should be supported (as proposed above).

Some stakeholders supported this requirement; nevertheless, they emphasized that for the packaging materials requiring the manufacturers' self-declaration should be sufficient, instead of asking for copies of Safety Data Sheets (SDS). Other stakeholders found this criterion unnecessary. It was emphasized that the available evidence does not allow evaluating how relevant the hazardous substances are in this product group. Packaging is of importance; nevertheless, most of hazardous substances (e.g. SVHC) are used mainly in PVC which is not of significance for this product group. Additionally, the current approach asks for simplifying the criteria. Due to lacking evidence about the use of hazardous substances in the packaging of the cosmetic products, and in order to harmonise with the EU Ecolabel criteria for similar product groups, it is proposed to withdraw this criterion from the revised criteria version.

- ***Sub-criterion " Labelling of packaging" – Sub-criterion withdrawn***

During the AHWG meetings the requirement on marking of plastic parts in order to facilitate the identification of the various plastic material types was discussed. The proposed formulation (used horizontally in various EU Ecolabels for similar product groups) is as follows: "*To allow for identification of different parts of the packaging for recycling, plastic*

*parts in the primary packaging must be marked in accordance DIN 6120, Parts 2 or the equivalent. Caps and pumps are exempted from this requirement*".[113]

During stakeholders consultation the representative of PlasticsEurope emphasized that marking of packaging does not really support recycling, as sorting is not made manually. One participant asked if marking might be used by consumers who perform the first sorting. Though, this can be the case, it was also indicated that the share of plastics sorted out by consumers is very small in comparison with the total amount of sorted waste. There were split views whether to keep this criterion or not. Finally, it is proposed to remove this criterion but to keep the criterion on "Disassembly of primary packaging"which requires that "all materials in the packaging shall be separable by hand (paper, cardboard, plastic, metal, glass) for sorting or shall be suitable for recycling. Packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes".

- ***Sub-criterion "Aerosol propellants" – Sub-criterion withdrawn***

**Aerosols containing hydrocarbon propellants**

As it is proposed to extend the scope to shaving products, e.g. foams and/or gels, it was considered whether to set additional requirements concerning their packaging, since today high percentage of those products is still sold in aerosols containers. This packaging is also to certain extent different than the packaging of products currently covered by the scope of the product group under study.

The materials and types of packaging used for each kind of shaving preparation were analysed. The results of this analysis are given in below table:

**Table 21. Kind of packaging and materials used in shaving preparations**

| TOTAL | | Plated Steel | Plated aluminium | Plastic (PE, multilaminated, PP, PET) | Glass |
|---|---|---|---|---|---|
| | **TOTAL** | **36,0%** | **36,0%** | **27,0%** | **1,0%** |
| **Aerosol** | **65%** | 35,2% | 30,0% | 0,0% | 0,0% |
| **Tube** | **24%** | 0,4% | 4,4% | 19,1% | 0,0% |
| **Bottle** | **8%** | 0,0% | 0,9% | 6,2% | 0,9% |
| **Can** | **1%** | 0,4% | 0,6% | 0,0% | 0,0% |
| **Jar** | **1%** | 0,0% | 0,0% | 0,7% | 0,1% |
| **Others** | **1%** | 0,0% | 0,2% | 1,0% | 0,0% |

Source: Based on GNPD (Global Database of New Products) results from 2011

[113] Reference to the ISO 11469 in the criterion on marking was asked for and is integrated in the revised assessment and verification part.

In general, it has been found that:

- 72% of shaving preparations are sold in metal packaging, where:
  - ✓ 65,2% are sold using aerosol containers,
  - ✓ 6,9% are sold in different kind of packaging other than aerosol container (tube, bottle, can and others),
- 27% of shaving preparations are sold in plastic packaging,
- 1% of shaving preparations are sold in glass packaging.

The majority of shaving foams and gels are sold in aerosol containers, while shaving soaps and creams are sold in various kinds of plastic packaging. The most common packaging materials used for foams and gels is metal packaging – plated steel and aluminium. For shaving gels also plastics are used, although to a lower extent than metals. Shaving creams are in addition sold (but less commonly) in aluminium tubes. While for shaving soaps different kinds of packaging are used.

In general, if kinds of packaging and materials used for all shaving preparations are analysed together, it can be seen that plated steel, plated aluminium (see table above) and various plastics are the main materials used, while aerosol container, followed by a tube and, to a much lower extent, bottle are the most common types of packaging.

Stakeholders submitted their comments on this issue. Shaving foams and gels usually contain **aerosol propellants** to support the fitness for use of the product design. Chloroflurocarbons (CFCs) are not longer used in aerosols as they are prohibited since 1987 by the Montreal Protocol on Substances that Deplete the Ozone Layer[114], but hydrocarbon propellant are applied instead. They indicated that hydrocarbon propellants contribute to formation of low level ozone, although it should be added that aerosol packaging is not the most important source for the formation of low level ozone. Nevertheless, these emissions should be prevented as they contribute to acid rains and to the greenhouse effect. Moreover, ozone can contribute to lung tissue damage and create high incidences of asthma and allergenic reactions in humans.

The most commonly used hydrocarbon propellants are propane, n-butane and isobutene, furthermore, dimethyl ether (DME) and methyl ethyl ether. One of their disadvantages is flammability. Nitrous oxide and carbon dioxide are also used as propellants, e.g. in food.

In the **Aerosol Dispensers Directive (ADD)[115]** aerosol dispensers are defined as "non-reusable containers made of metal, glass or plastic and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid particles in suspension in a gas, as a foam, paste or powder or in a liquid state".

[114] The Montreal Protocol on Substances that Deplete the Ozone Layer, available online at: http://ozone.unep.org/pdfs/Montreal-Protocol2000.pdf.

[115] Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers, available online at: http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/add/index_en.htm.

According to the current criterion regarding packaging set in the Commission decision for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners[116]: "***sprays containing propellants must not be used***". It was proposed for consideration and discussion whether to extend the current criterion formulation by the following requirement: **"aerosols containing hydrocarbon propellants shall not be used".**

There are alternatives available in the market for foams and sprays, which substitute these hydrocarbon propellants[117], using other propellant such as compressed air. Nevertheless, the discussions with the industry revealed that this is still a very niche share of the market.

Some feedback on the proposed potential restrictions of hydrocarbon propellants has been received already from industrial stakeholders along the consultation process. The main points are as follows: "*Hydrocarbon propellants are VOCs[118]. Different types of VOCs make differing contributions to tropospheric ozone formation. The VOCs used in aerosols have a low potential to create ground-level ozone. VOCs contribute only indirectly to climate change and do not contribute to acid rains. Hydrocarbon propellants in shaving products only present a very minor environmental impact: the potential to create ground-level ozone is low and the total quantity is negligible because the propellant is only present at 5 % w/w of the product*".

After the second AHWG and EU Ecolabelling Board meeting further feedback was asked from the stakeholders regarding this requirement; nevertheless, no additional information was received regarding this requirement. Additional screen of available information was conducted but not sufficient information substantiating this restriction was found. Additionally, other environmental labelling analysed, e.g. the Nordic Swan, have no requirement regarding the hydrocarbon propellants used in cosmetic products. In consequence, it is proposed to withdraw the criterion regarding the hydrocarbon propellants from the revised criteria version.



- ***Sub-criterion "Disposable toiletries (not refillable)" – Sub-criterion withdrawn***

After the AHWG meeting some stakeholders proposed aligning the revised criteria with criterion number 19 about **Disposable Products** of the Commission decision establishing the ecological criteria for tourist accommodation services[119]: "***unless required by law, disposable toiletries (not refillable) such as shampoo and soap, and other products (not reusable), such as shower caps, brushes, nail files, etc. shall not be used. Where such disposable products are requested by law the applicant shall offer to guests both solutions and encourage them with appropriate communication to use the non-disposable products***".

[116] Commission Decision 2011/383/EU of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:169:0052:0064:EN:PDF.

[117] See e.g. article "AirOpack, a green alternative to aerosol dispensers", available online at: http://www.premiumbeautynews.com/en/AirOpack-a-green-alternative-to,2123?checklang=1.

[118] Volatile Organic Compounds

[119] Commission decision 2009/578/EC of 09 July 2009 establishing the ecological criteria for the award of the Community eco-label for tourism accommodation service, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:198:0057:0079:EN:PDF.

It was proposed to set restriction on the use of disposable toiletries (not refillable) for products such as shampoos, soaps and hair conditioners.

The term "single use products" was consequently proposed instead of "disposable toiletries" as the later covers also other products, e.g. shower caps, brushes, nail files. Further, it was suggested to refer to the number of washing actions as used and defined in the life cycle assessment part. A practical way to apply such a type of restriction is to set a minimum net weight content for the products that are sold without the option of refilling. Products of low weight correspond to a low number of washing actions and expresses better what is understood as "disposable toiletries" in the EU Ecolabel criteria for tourist accommodation (as described above). The following proposal was made for the second AHWG meeting:

"Products that are intended for very limited number of washing actions, approximately 4 or less and sold without the option of refilling shall not be awarded the EU Ecolabel. Therefore, a minimum product net weight of 50 ml for liquid soaps, hair conditioners and shampoos and a minimum product net weight of 10 g for solid soaps are required."

Further discussions and feedback received from the meeting indicated that such a criterion should finally not be finally included in the criteria set. It was emphasized that majority of currently ecolabelled products are the cosmetics offered by hotel chains, and that their use brings positive impact for the environment.

Furthermore, the minimum weight of 50 ml for single use liquid soaps was not found appropriate, as COLIPA guidelines indicate that dosage of 10 to 14 ml is enough for a single use. Majority of the toiletries offered in hotels have volume between 10 and 35 ml. Asking for at least 50 ml big bottles for single use products could in the end result in waste of product and packaging material. Multiple use packaging should be promoted, but in a different manner than setting a restriction on the minimum product volume.

As a consequence of the above discussions, it was agreed to withdraw this requirement from the revised criteria proposal.

### 3.5 CRITERION 5: Sustainable sourcing of palm oil

**Proposed criterion and assessment and verification procedure**

Palm oil and palm kernel oil used as an ingredient must be sourced from sustainably managed plantations.

***Assessment and verification:*** *the applicant shall provide supply-chain evidence that the palm oil originates from a certified source. Such evidence may be RSPO certification (identity preserved, segregated or mass balance) or their equivalent. Where the applicant is using chemical derivatives of palm oil, defined by the RSPO in the "RSPO Rules for Home and Personal Care Derivatives"[120], it is acceptable to demonstrate sustainability for these through book and claim systems such as GreenPalm or equivalent. The conversion factors listed in the RSPO Rules should be used to calculate the number of certificates required.*

**Substantiating information, rationale and discussion conducted**

- **Use of renewable ingredients**

A potential criterion regarding use of renewable ingredients in order to limit the use of fossil fuel based ingredients and to promote vegetable based ingredients was in a first stage proposed for consideration. This proposal was discussed with stakeholders during the 1st AHWG meeting.

During last years environmental concerns related to the use of fossil based ingredients versus vegetable based ingredients 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.

Nevertheless, as discussions and different studies about possibilities of substitution of non-renewable ingredients indicate, some issues on economic and ecological impacts of vegetable ingredients' production have to be taken into consideration in this respect.

In accordance with a study conducted by Procter & Gamble for the case of surfactants, comparisons between synthetic and petrochemical surfactants have been done, and it has been found that a total substitution of petrochemical by oleochemical may be not recommended for several reasons given below[121]:

- The wide range in consumer needs (wash conditions) would be more difficult to be met with oleochemical surfactants alone.

[120] Available at: http://www.greenpalm.org/upload/files/45/RSPO_Guiding_Rules_for_HPC_derivativesV9.pdf.
[121] Procter & Gamble, Natural and Synthetic Surfactants - Which one is better?, available online at: http://www.scienceinthebox.com/en_UK/programs/natural_synthetic_en.html.

- Data from biodegradation, removal by sewage treatment, toxicity and LCA studies show that petrochemical and oleochemical surfactants are of comparable environmental quality.

- Replacement of petrochemical by oleochemical surfactants would not lead to any significant reductions in water or air emissions, nor would it reduce energy consumption across the life cycle of the surfactants.

In the revision of the Nordic Ecolabel for cosmetic products of 2011[122], the possibility of limiting the amount of non-renewable materials was discussed. But finally it was decided not to set general requirements regarding renewable raw materials, only a voluntary requirement was set. It was concluded that many aspects need to be considered, e.g. energy consumption during production of the raw materials, comparison between the extraction and transportation of renewable and non-renewable materials. Moreover, the difficulty of ingredients traceability was emphasized by manufacturers. Consumers and licensees indicated a wish for Nordic Ecolabelling to expand this area and consider the issue of renewable raw materials in the future, but it was concluded that it was necessary to investigate the matter further ahead of future revisions**.**

There is currently not much experience with promoting renewable raw materials within the EU ecolabelling of chemical products. In the EU Ecolabel criteria for Lubricants[123] there is a requirement regarding the amount of renewable oil. As verification the applicant shall provide the competent body with a declaration of compliance with this criterion.

In other EU Ecolabel product groups' revisions it was decided not to set this kind of criteria. It was stated that for renewable raw materials, sustainability requirements are expected to be difficult for many manufacturers to be fulfilled due to challenges of procurement of relevant documentation, especially since raw materials are often mixtures of substances originating from different sources. One of the challenges businesses are facing in terms of actual using sustainable palm oil in products is the complexity and lack of transparency in the supply chain. This difficulty could lead to increase in use of non-renewable raw materials compared to the situation today, which is not desirable from an environmental point of view[124].

In some stakeholders' written feedback received after the first AHWG meeting it was emphasized that promoting vegetable based ingredients and limiting the use of fossil fuel based ingredients might not be feasible at present. It was stated that such proposal should be deeply driven by scientific based arguments like e.g. Life Cycle approach.

[122] Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011.
[123] Commission Decision 2011/381/EU of 24 June 2011on establishing the ecological criteria for the award of the EU Ecolabel to lubricants, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:169:0028:0039:EN:PDF.
[124] Revision of Ecolabel Criteria for Laundry Detergents 2008-2010, Background report, available online at: http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/pdf/laundry/final_draft.pdf .

There are some projects, such as ERASM LCA, which will lead to updating some previous exercises carried out in 1995[125] that showed no differences between oleo-based surfactants and petrochemical surfactants; nevertheless more research is still needed.

In consequence, it was not proposed to be set a criterion promoting vegetable-based ingredients against the use of fossil-based ingredients in this revision process, as environmental advantages of these ingredients along their Life Cycle are not proved in many cases and it needs further scientific-based investigation. Moreover the compliance of this criterion will be difficult to prove and to verify. In the future revision the advances in LCA related studies on this matter should be taken into consideration.

- **Sustainable sourcing of vegetable oil/palm oil**

Although no specific criteria promoting vegetable-based ingredients are proposed, in the product group studied, high percentage of products uses already ingredients derived from vegetable oils.

During the first AHWG meeting some stakeholders expressed their concern on the issue of sustainable management in this area, especially for palm oil plant based ingredients. Palm oil is the most commonly used oil in this product group. Discussions were held about the feasibility of setting a criterion on sustainable sourcing of materials to guarantee that vegetable oil ingredients used in the product come from sustainable managed plantations. Some stakeholders supported the proposal of having a criterion on sustainable sourcing of palm oil and mentioned the voluntary move in the industry towards sustainable sourcing of palm oil, as this subject gains more and more customer interest and concern. Other stakeholders added that there are many issues which should be taken into account in this respect and it could be a good impulse for the Ecolabel to start addressing ethical issues in the scheme. Nevertheless, it was also said that setting requirements for renewable raw materials, which are difficult to meet and to document, could result in unintended promotion of synthetically produced ingredients. As conclusion, further information was requested in the view of the new proposal and this issue was discussed further in the second AHWG meeting.

Some European regulations and schemes have started to set criteria in this area. For example the Nordic Ecolabel considered the "Possibility to set obligatory requirements in respect of sustainability and sourcing of raw materials from renewable sources – certified raw materials and certified organic raw materials". No obligatory requirement is set though, as it was considered that more research is needed.

In the European Union, under the Renewable Energy Directive (RED)[126], only those vegetable oils that have been verifiably certified as sustainable can receive state support for energy use and may be counted towards national renewable energy targets.

[125] Stallmans M. et al, European Life Cycle Inventory for Detergent Surfactants Production, Tenside Surf. Det. 32 (1995) 2, available online at: http://www.lasinfo.org/reports/eu_life_cycle_inv_deterg_surfact_prod.pdf.

Vegetable oil is an expressed oil of vegetable origin consisting primarily of triglycerides of fatty acids. In cosmetics and personal care products, Vegetable oil and hydrogenated Vegetable Oil are used in the formulation of bath products, cleansing products, eye makeup, fragrances, foot powders, facial makeup, personal cleanliness products, suntan products and other skin products. Driven by the increasing global demand for edible oils, in the past few decades rapid expansion in the production of two major edible oils: soy oil in South America and palm oil throughout the tropics and stretching into the sub-tropics has been observed.

Compared with other major oil crops – rapeseed, soy and sunflowers – the palm oil is the highest-yielding provider of vegetable oil worldwide[127]. Elaeis Guineensis (Palm) Oil, Elaies Guineensis (Palm) Kernel Oil, Hydrogenated Palm Oil and Hydrogenated Palm Kernel Oil are oils obtained from the palm tree, *Elaeis guineensis*. In cosmetics and personal care products, these palm oil ingredients are used in the formulation of skin care products, makeup and suntan products. Elaeis Guineensis (Palm) Oil, Elaies Guineensis (Palm) Oil, Hydrogenated Palm Oil and Hydrogenated Palm Kernel Oil are primarily used as skin conditioning agents - occlusive. The Hydrogenated Palm Oil ingredients may also be used as viscosity increasing agents[128]. Several ingredients used for soaps, shampoos and conditioners such as elaeis guineensis, sodium lauryl sulphate, cetyl alcohol, stearic acid, isopropyl and other palmitates, steareth-2, steareth-20 and fatty alcohol sulphates, may be derived from palm oil.

According to the information of the Roundtable on Sustainable Palm Oil (RSPO)[129], the area under palm-oil cultivation increases very rapidly, mainly in regions of Malaysia and Indonesia. This fact caused the conversion of large areas of forests with high ecological value threatening the rich biodiversity of these ecosystems. Palm oil cultivation can generate positive effects on the income and livelihood of farming families and hence on development in rural areas. Despite these favourable characteristics, it can contribute to negative impacts such as destruction of rainforests, extinction of endangered species, displacement of small farmers and giant monoculture plantations. So palm oil has environmental benefits provided it is produced sustainably.

RSPO is the one of the initiatives that aim to promote the growth and use of sustainable vegetable oils. Similar initiatives regarding other renewable products, e.g. soya beans (Round Table on Responsible Soy (RTRS)) and sugar cane, are currently being developed. Some producer countries are developing their own certificates for palm oil such as Malaysia Sustainable Palm Oil (MSPO) certification and the mandatory Indonesian Sustainable Palm Oil (ISPO) certification. All accepted certifications should prove compliance with the ISO Guide 65/66.

---

[126] Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC.

[127] Palm Oil – sustainability is possible! Promotion and certification of smallholders helps sustainable palm oil production. Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, available online at: http://www.giz.de/Themen/de/SID-77EE5142-FCBBA49E/dokumente/2011giz-en-sustainable-palm-oil-production.pdf, accessed August 2012.

[128] Information available at the website of Cosmetics Info: http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=293, accessed August 2012.

[129] Towards the next step – Highlights from the 10th Annual Roundtable Meeting on Sustainable Palm Oil, available online at: http://www.rspo.org/file/RSPO_THENEXTSTEP_FINAL_V2_061212.pdf, accessed January 2013.

Sustainable palm oil production is comprised of legal, economically viable, environmentally appropriate and socially beneficial management and operations. The set of principles and criteria for the RSPO certification are available in the document *RSPO Principles and Criteria for Sustainable Palm Oil Production*[130].

RSPO certification is based on economic, social and ecological criteria:

- Economic criterion: continuous efficiency improvements; documentation on the improvement of production conditions and continuous increases in yield which lead to work and employment

- Ecological criterion: rainforest or other areas of high conservation value may not be destroyed to make way for new plantations

- Social criterion: working conditions must be consistent with industry standards and minimum wages must be paid. The RSPO also addresses health and safety at work.

The RSPO certification scheme has both production and chain of custody certificates being issued. There are four main routes by which the RSPO's supply chain requirements can be met[131]:

- Identity Preserved (IP): This methodology assures 100% of the physical product originates from a specific estate or plantation. However, the costs associated with such strict control mean that it is expensive and so it is not expected to be used except in exceptional or extremely high volume circumstances where the economics of scale could offset the costs.

- Fully Segregated: A fully segregated supply chain will ensure that various different CSPO sources are mixed together, but kept separate from non-certified palm oil. Thus, a new commodity grade will be created.

- Mass Balance (MB): The controlled mixing of certified & non-certified palm oil is the hallmark of a mass balance system.

- Book and Claim: In a comparable manner to carbon trading, book and claim operates through a system of parallel certificate trading between buyers and sellers.

The RSPO is considered the most important international initiative on sustainably certified palm oil. It is a not-for-profit association that unites stakeholders from seven sectors of the palm oil industry - oil palm producers, palm oil processors or traders, consumer goods manufacturers, retailers, banks and investors, environmental or nature conservation NGOs

[130] *RSPO Principles and Criteria for Sustainable Palm Oil Production* , available online at: http://www.rspo.org/file/RSPO%20Criteria%20Final%20Guidance%20with%20NI%20Document.pdf

[131] Defra, Review of policy options relating to sustainable palm oil procurement, 2011, available online at: http://www.proforest.net/proforest-news/defra-palm-oil-report/defra-report-on-uk-palm-oil-consumption-and-sustainable-policy-options-published.

and social or developmental NGOs - to develop and implement global standards for sustainable palm oil. The members of the RSPO account for roughly 50% of global palm oil production and also include the most important buyers and the processing industry. In July 2010 there were already two million tonnes of RSPO-certified palm oil available on the world market, with an upward trend. These data indicate that the availability of certified palm oil is sufficient and it is expected to be increased in the following years thanks to the commitment of industry and the consumers' demand. In fact, concerns exist that the market demand for certified palm oil is not as high as expected. Without a market demand, producers are unlikely to undertake certification. RSPO figures for 2010 show that the situation has improved, showing that 56% of available certified palm oil was purchased[132].

In a recent study "Review of policy options relating to sustainable palm oil procurement"[132] elaborated by Defra in 2011 in UK, it was stated that sourcing RSPO certified palm oil and its related products is currently possible, and available in volumes sufficient to cover the UK's consumption.

The main limitation could be the availability of certified palm derivatives such as surfactants, glycerine and emulsifiers from sustainable sources. Significant changes towards sustainable palm oil supply now depend on the manufacturers developing the availability of certified oleochemical derivatives.

- **Proposal of criterion formulation**

As explained above, promoting vegetable-based ingredients against fossil-based ingredients is not proposed, as advantages of these ingredients are not proved in many cases. Nevertheless, due to the importance of derived palm oil ingredients used in this category group and the environmental and social impacts that this can cause, it was seen desirable to set a new criterion to guarantee that palm oil derived ingredient come from sustainable plantations. This option found support of several stakeholders, who also aid the criterion formulation and the proposal for assessment and verification. Nevertheless, the feedback was not unanimous. Some stakeholders indicated the doubts regarding the controllability of the RSPO certification systems and proposed to take up this criterion area in the next criteria revision; while other proposed to set this first step already in this criteria set. Some support and proposal of amended formulation was also received from the side of industrial stakeholders.

A revised criterion proposal, based on the received feedback, is given below:

Palm oil and palm kernel oil used as an ingredient must be sourced from sustainably managed plantations.

[132] Defra, Review of policy options relating to sustainable palm oil procurement, 2011, available online at: http://www.proforest.net/proforest-news/defra-palm-oil-report/defra-report-on-uk-palm-oil-consumption-and-sustainable-policy-options-published.

***Assessment and verification:*** *the applicant shall provide supply-chain evidence that the palm oil originates from a certified source. Such evidence may be RSPO certification (identity preserved, segregated or mass balance) or their equivalent. Where the applicant is using chemical derivatives of palm oil, it is acceptable to demonstrate sustainability for these through book and claim certification or equivalent.*

### 3.6 CRITERION 6: Fitness for use

**Proposed criterion and assessment and verification procedure**

A product's fitness for use is the capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection, etc.) The product's fitness for use shall be demonstrated either through laboratory test(s) or a consumer test. The test shall be conducting following the "Practical guidance on methodology for cosmetic claim substantiation"[133].

***Assessment and verification****: the applicant shall document the test protocol that has been followed in order to test the products efficacy. Applicants shall present results from this protocol that demonstrate that the product fulfils its primary function and which substantiate the claims placed on the product label and/or packaging (i.e. secondary functions).*

**Substantiating information, rationale and discussion**

Environmental assessment conducted in this study has showed that high percentage of total environmental impact of products is due to the use phase (on average 20.5% of contribution to the overall environmental impact for all investigated products), coming from the consumption of water during the washing action. 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 energy needed to heat the water is included in the studied system, the use stage is responsible for 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 ecolabelled products are environmentally friendlier but poor in performance/inefficient. For that reason performance tests should address all important characteristics and functions of the product.

During the first AHWG meeting the proposal to consider a more stringent consumer testing was discussed. The criterion on fitness for use addresses currently the aspects of performance, dosage and application. It was discussed whether a more stringent consumer test addressing additionally the below indicated aspects should be required for this product group in the revised criteria set:

- How easy is it to rinse-off the product in comparison with the market-leading product?
- If the product does not cause to consumers any sensitising effects in use and/or after use.

[133] Available online at: https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html and the EU Ecolabel website.

Further issues for consideration were as follows:

- Should a consumer test be different for professional use soaps and household soaps?
- Should the number of people tested be increased (currently 10 people)?
- When a laboratory performance test is provided, manufacturer shall also prove the ease of dosage and application.
- Should, apart from the main function of the product, the performance test make reference to the characteristics with which each product is sold/marketed, i.e. claims (hydrating, moisturizing, softening, etc.)?

In the framework of the consultation process it was discussed that industry does already a lot of tests of their products in order to manufacture competitive and good quality goods. There exist industry guidelines and also common criteria for tests claims including best practices available, which could be used as a support for the EU Ecolabel criteria. Also consumer organisations conduct consumer tests. Nevertheless, there lack EU harmonised testing procedures or methods.

The existing "Practical guidance on methodology for cosmetic claim substantiation"[134] developed and published by Cosmetics Europe (former COLIPA) aims to help "*the cosmetics industry to comply with the applicable European regulations for the efficacy evaluation of cosmetic products*". The document provides an overview of established testing methodologies in the area of cosmetic claims. Various guidelines published are also useful in this area, e.g. EEMCO[135] guidelines relative to instrumental clinical techniques, international guidelines (e.g. ISO, CNE, ICH, etc.).

According to the practical guidance by Cosmetics Europe, different types of experimental studies 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, 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.

[134] Practical guidance on methodology for cosmetic claim substantiation, Cosmetics Europe, May 2008.
[135] EEMCO Group – European Group for Efficacy Measurements on Cosmetics and Other Topical Products.

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[136]:

- 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.

However, experimental studies are not restrictive and do not exclude other experimental approaches which must, nevertheless, 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,
    - 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.

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

The guideline provided by Cosmetics Europe advice also which information should be included in the test protocols and test reports[137], 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
        - Product tested,
        - Volunteers: Inclusion and exclusion criteria, number of subjects, training and trained panellists for sensorial evaluation tests by experts,
        - Methodology.
    - Ex vivo/ in vitro tests
        - Substrate,
        - Methodology: 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.

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

- 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,
    - 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.

The Cosmetics Europe´s guidelines state also that verification of cosmetic claims should be a component of product development and tests shall address the properties based on which the product is marketed. It is also the background of the Nordic Ecolabelling´s requirements in this respect. The applicant must be able to document that the performance of the product has been evaluated and documented in a relevant manner. Tests should also include the functions for which the product is marketed. This will avoid misguiding information. In accordance with the requirement to include claim substantiation in the cosmetic product information package, a short summary of the technical data supporting the effect claimed should be accessible to the control authorities.

The new Regulation 1223/2009 on cosmetic products[138] introduces a number of important changes to the way cosmetic products are regulated in the EU. The Regulation may restrict the ability of cosmetics companies to use certain claims of their products. The following guidelines apply:

[138] Regulation EC 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, available online at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:EN:PDF.

- The labelling and advertising of cosmetic products “shall not be used to imply that products have characteristics or functions which they do not have”.

- The Regulation requires the European Commission, in cooperation with the EU Member States, to set up an action plan related to claims, to adopt a list of common criteria for claims. The content of that list may provide restrictions on product claims.

- By July 11, 2016, the Commission shall report to the European Parliament on the use of claims on the basis of the common criteria and shall report to the European Parliament on the use of claims on the basis of common criteria and shall take appropriate measures to ensure compliance with those criteria[139].

There was an agreement in the consultation process that if there were claims on the products they should be tested. However, the companies and the Competent Bodies should be given flexibility how to prove and control the compliance with the criterion on fitness for use. The criterion is considered very important for the customers, nevertheless, it must be remembered that of highest importance is that an Ecolabelled product should be distinguished from other products available on the market due to their very good performance from the environmental point of view. The product's quality should be ensured, but is not of primary importance.

The stakeholders discussed also the issue of the link between the performance requirements and the CDV value. The lack of synergy between these concepts was mentioned. It was emphasized that it would be good to have a criterion integrating these issues; nevertheless such a formula has not been developed yet. This issue could be considered further in the next revision of the criteria.

In the revised criteria version a definition of fitness for use, as provided by the industrial association stakeholder, is included. “A product's fitness for use is the capacity to fulfil its primary function (e.g. cleaning, conditioning) and any secondary functions claimed (e.g. anti-dandruff, colour protection, etc.)”. Fitness for use should enable a fair comparison of product applications per product category and should especially be related to the definition of use dosages.

Other stakeholder submitted also their comments regarding this criterion. There was an agreement that the initially proposed number of participants (30) of the test it too high. The supported value was between 15 and 20 participants.

One stakeholder provided to the JRC IPTS a proposal of protocol for the 'Ease of application' and for the 'Cleansing efficacy'. Nevertheless, this test is designed for soaps and heavy duty cleaning products and the procedure is not directly suitable for the product group under study.

The stakeholders emphasized also the difficulties in defining “a market-leading product” or a reference product for the comparison in the consumer testing. It was asked to specify if the consumer test can be done in anonymous conditions. Testing of new products against a well

[139] The progress of these developments should be observed and taken into account in the next criteria revision process.

know market-leader which consumers can recognize could influence the results of the consumer test. It was also indicated that a market-leading product can be chosen for characteristics which are not related at all with its environmental performance; e.g. it is chosen for its fragrance, or because it has gentle effect on releasing grease from the skin (but because it contains stronger surfactants). Therefore, the comparison was not found useful for the purpose of the Ecolabel.

It was emphasized that the functionality that should be required to rinse-off products that aim to Ecolabel it shall be related to the environmental properties of the package and the product during use, rather than its cosmetic benefits compared to other products not ecolabelled. Additionally, questions formulated in the proposed revised test guidelines were fund too subjective. It must be however kept in mind that this criterion is to ensure satisfactory performance of the product for the customers. Consumer tests will always be to certain extent subjective, as the results are dependant on the consumer's perception. Nevertheless, in order to compensate this subjectivity statistically significant number of participants representatively chosen shall take part in the test (15-20 people).

One of the improvements of the performance test, which was mentioned by the stakeholders, referred to testing of the minimum share of the product which can be removed easily from the bottle, tube or other packaging. The protocol proposed for checking this aspect was described already in the rationale for criterion 4 e) Design of packaging. This issue is of particular importance e.g. for hotel toiletries, where often significant portion of the product remains in the bottle, if the packaging is e.g. a rigid bottle which cannot be deformed to get the remaining liquid product out of it. This criterion will be included in the criterion 4 on Packaging.

Another aspect which was proposed in the stakeholders' feedback received is the issue of ensuring that at the time of dosing the product its high fluidity will not cause excessive losses. Nevertheless, feedback received to this proposal indicated that "*a more highly viscous product is more likely to "stick" in the container so this requirement could increase the amount of product which cannot be removed from the package. In any case this type of waste is a function of product viscosity, package design (e.g. size of opening), "squeezeability" of the container and container size*".

Finally, it was indicated in the feedback that due to the wide variety of products, claims and efficacy tests, it is not possible to define one method that fits all products and claims. Industry developed the set of guidelines which shall be followed by testing cosmetic products efficacy and claims. This guidance, described before, is used by the cosmetic manufacturers testing their products. In this criteria revision it is proposed remove the Appendix II (guidelines for testing) from the criteria decision and to ask the applicants to conduct consumer or laboratory testing following the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products"[140].

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

A test protocol (as described above) shall be submitted to the Competent Body. Additional information regarding the testing will be provided also in the user manual.

### 3.7 CRITERION 7: Information appearing on the EU Ecolabel

**Proposed criterion and assessment and verification procedure**

***Information appearing on the EU Ecolabel***

The logo should be visible and legible. The use of the EU Ecolabel logo is protected in primary EU law. The EU Ecolabel registration/licence number must appear on the product, it must be legible and clearly visible.

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 (a-b):*** *the applicant shall provide a sample of the product label, together with a declaration of compliance with this criterion.*

**Substantiating information, rationale and discussion conducted**

According to Article 8 (3b) of the EU Ecolabel Regulation 66/2010, for each product group, three key environmental characteristics of the ecolabelled 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:

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

In the AHWG meetings the following statements were presented to be placed on the optional label with text box:

- Fulfils strict environmental requirements on the use of substances, or
- Minimized use of substances harmful to the environment

but they have not found clear support of the stakeholders.

Further, the indication on exclusion of hazardous substances was discussed, but some stakeholders emphasized that such information could suggest that not ecolabelled products do

contain hazardous substances, which would be against the Cosmetics Regulation. Therefore such statements should be avoided.

In the limited feedback received keeping the following three statements was finally supported and they are proposed in the current revised criteria version:

- Reduced impact on aquatic ecosystems,
- Fulfils strict biodegradability requirements,
- Limits packaging waste.

Moreover, some stakeholders supported including additional optional text, which manufacturers may place (it is however voluntary) on the product label or packaging with the objective to increase the customer awareness and point out the main aspects of the product use which contribute to the environmental impacts (e.g. the consumption of hot water). A possible formulation could be:

- "To minimize the environmental impacts of this product apply proper dosage of the product and rationally consume water, in particular hot water"

Nevertheless, the EU Ecolabel regulation does nor allow to set recommendation only and the proposal cannot be taken over in the legal criteria text.

## 4. ANNEXES

**Annex I A: CLP chronic aquatic toxicity classification and labelling exemption for laundry and cleaning products**
**Document prepared by the international Association for Soaps, Detergents and Maintenance Products (AISE) and submitted by the Cosmetics Europe.**

Example: Implications of the new classification rules on surfactants in the DID-list

Reclassification of surfactants in the DID list based on available toxicity data currently in the list, based on criteria as in the proposed 2nd ATP to the CLP regulation. (grey marked lines are those surfactants that would become classified) Note that with new data coming in, especially NOEC's, under REACh obligations, many more surfactants will be classified, even those where NOEC's currently in the DID list lead to a 'Not-Classified'

| Number | Name | LC50/ EC50 | SF acute | TF acute | NOEC (*) | SF chronic | TF chronic | DF | Aerobic | Anaerobic | | Chronic Aquatic toxicity Category |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Anionic surfactants** | | | | | | | | | | | | |
| 1 | Linear alkyl benzene sulphonates 11,5 - 11,8 (LAS) | 4.1 | 1000 | 0.0041 | 0.69 | 10 | 0.069 | 0.05 | R | N | | **3** |
| 2 | LAS (C10-13 alkyl) triethanolamine salt | 4.2 | 1000 | 0.0042 | 3.4 | 100 | 0.034 | 0.05 | R | O | | **NC** |
| 3 | C 14/17 Alkyl sulphonate | 6.7 | 5000 | 0.0013 | 0.44 | 10 | 0.044 | 0.05 | R | N | | **3** |
| 4 | C 8/10 Alkyl sulphate | 132 | 5000 | 0.0264 | | | 0.0264 | 0.05 | R | Y | | **NC** |
| 5 | C 12/14 Alkyl sulphate (AS) | 2.8 | 1000 | 0.0028 | 2 | 100 | 0.02 | 0.05 | R | Y | | **NC** |
| 6 | C 12/18 Alkyl sulphate (AS) (#) | | | 0.0149 | | | 0.027 | 0.05 | R | Y | | **NC** |
| 7 | C 16/18 Fatty alcohol sulphate (FAS) | 27 | 1000 | 0.027 | 1.7 | 50 | 0.034 | 0.05 | R | Y | | **NC** |
| 8 | C 12/15 A 1-3 EO sulphate | 4.6 | 1000 | 0.0046 | 0.1 | 10 | 0.01 | 0.05 | R | Y | | **2** |
| 9 | C 16/18 A 3-4 EO sulphate | 0.57 | 10000 | 6E-05 | | | 0.000057 | 0.05 | R | Y | | **NC** |
| 10 | Dialkyl sulpho succinate (**) | 15.7 | 1000 | 0.0157 | | | 0.0157 | 0.5 | I | N | | **3** |
| 11 | C 12/14 Sulpho- fatty acid methylester | 9 | 10000 | 0.0009 | 0.23 | 50 | 0.0046 | 0.05 | R | N | | **3** |
| 12 | C 16/18 Sulpho- fatty acid methylester | 0.51 | 5000 | 0.0001 | 0.2 | 50 | 0.004 | 0.05 | R | N | | **3** |
| 13 | C 14/16 alfa Olefin sulphonate | 3.3 | 10000 | 0.0003 | | | 0.00033 | 0.05 | R | N | | **NC** |
| 14 | C 14/18 alfa Olefin sulphonate | 0.5 | 5000 | 0.0001 | | | 0.0001 | 0.05 | R | N | | **NC** |
| 15 | Soap C>12-22 | 22 | 1000 | 0.022 | 10 | 100 | 0.1 | 0.05 | R | Y | | **NC** |
| 16 | Lauroyl Sarcosinate | 56 | 10000 | 0.0056 | | | 0.0056 | 0.05 | R | Y | | **NC** |
| 17 | C9/11 2-10 EO Carboxymethylated, sodium salt or | 100 | 10000 | 0.01 | | | 0.01 | 0.05 | R | O | | **NC** |
| 18 | C12/18 2-10 EO Carboxymethylated, sodium salt o | 8.8 | 1000 | 0.0088 | 5 | 100 | 0.05 | 0.05 | R | O | | **NC** |
| 19 | C 12/18 Alkyl phosphate esters | 38 | 1000 | 0.038 | | | 0.038 | 0.05 | R | N | | **NC** |
| **Non-ionic surfactants** | | | | | | | | | | | | |

| Number | Name | LC50/ EC50 | SF acute | TF acute | NOEC (*) | SF chronic | TF chronic | DF | Aerobic | Anaerobic | | Chronic Aquatic toxicity Category |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 20 | C8 A 1-5 EO | 7.8 | 1000 | 0.0078 | | | 0.0078 | 0.05 | R | Y | | **NC** |
| 21 | C 9/11 A, >3-6 EO predominantly linear | 5.6 | 1000 | 0.0056 | | | 0.0056 | 0.05 | R | Y | | **NC** |
| 22 | C 9/11 A, >6-10 EO predominantly linear | 5 | 1000 | 0.005 | | | 0.005 | 0.05 | R | Y | | **NC** |
| 23 | C 9/11 A, 5-11 EO multibranched | 1 | 1000 | 0.001 | | | 0.001 | 0.05 | R | O | | **NC** |
| 24 | C10 A, 5-11EO multibr.(Trimer-propen-oxo-alcohol) | 10 | 1000 | 0.01 | | | 0.01 | 0.05 | R | Y | | **NC** |
| 25 | C 12/15 A, 2-6 EO predominantly linear | 0.43 | 1000 | 0.0004 | 0.18 | 50 | 0.0036 | 0.05 | R | Y | | **3** |
| 26 | C12/14 5-8 EO 1 t-BuO (endcapped) | 0.23 | 1000 | 0.0002 | 0.18 | 100 | 0.0018 | 0.05 | R | O | | **3** |
| 27 | C 12/15 A, 3-12 EO multibranched 1 | 1 | 1000 | 0.001 | 3.2 | 100 | 0.032 | 0.05 | R | O | | **NC** |
| 28 | C 12/15 (mean value C<14) A, >6-9 EO | 0.63 | 1000 | 0.0006 | 0.24 | 10 | 0.024 | 0.05 | R | Y | | **3** |
| 29 | C 12/15 (mean value C>14) A, >6-9 EO | 0.4 | 1000 | 0.0004 | 0.17 | 10 | 0.017 | 0.05 | R | Y | | **3** |
| 30 | C 12/15 A, >9-12 EO | 1.1 | 1000 | 0.0011 | | | 0.017 | 0.05 | R | Y | | **NC** |
| 31 | C 12/15 A >12-20 EO | 0.7 | 1000 | 0.0007 | | | 0.0007 | 0.05 | R | O | | **NC** |
| 32 | C 12/15 A >20-30 EO | 13 | 1000 | 0.013 | 10 | 100 | 0.1 | 0.05 | R | O | | **NC** |
| 33 | C 12/15 A, >30 EO | 130 | 1000 | 0.13 | | | 0.13 | 0.5 | I | O | | **NC** |
| 34 | C 12/18 A, 0-3 EO | 0.3 | 1000 | 0.0003 | | | 0.0003 | 0.05 | R | Y | | **NC** |
| 35 | C 12/18 A, 5-10 EO | 1 | 1000 | 0.001 | 0.35 | 100 | 0.0035 | 0.05 | R | O | | **3** |
| 36 | C 12/18 A, >10-20 EO | 1 | 1000 | 0.001 | | | 0.0035 | 0.05 | R | O | | **NC** |
| 37 | C 16/18 A, 2-8 EO | 3.2 | 1000 | 0.0032 | 0.4 | 100 | 0.004 | 0.05 | R | Y | | **3** |
| 38 | C 16/18 A, >9-18 EO | 0.72 | 1000 | 0.0007 | 0.32 | 10 | 0.032 | 0.05 | R | Y | | **3** |
| 39 | C 16/18 A, 20-30 EO | 4.1 | 1000 | 0.0041 | | | 0.0041 | 0.05 | R | Y | | **NC** |
| 40 | C 16/18 A, >30 EO (**) | 30 | 1000 | 0.03 | | | 0.03 | 0.5 | I | Y | | **3** |
| 41 | C12-15 A 2-6 EO 2-6 PO | 0.78 | 1000 | 0.0008 | 0.36 | 100 | 0.0036 | 0.05 | R | O | | **3** |
| 42 | C10-16 A 0-3 PO 6-7 EO | 3.2 | 5000 | 0.0006 | 1 | 100 | 0.01 | 0.05 | R | O | | **3** |
| 43 | Glycerin (1-5 EO) cocoate | 16 | 1000 | 0.016 | 6.3 | 100 | 0.063 | 0.05 | R | Y | | **NC** |
| 44 | Glycerin (6-17 EO) cocoate | 100 | 1000 | 0.1 | | | 0.1 | 0.05 | R | Y | | **NC** |
| 45 | C 12/14 Glucose amide | 13 | 1000 | 0.013 | 4.3 | 50 | 0.086 | 0.05 | R | Y | | **NC** |
| 46 | C 16/18 Glucose amide | 1 | 1000 | 0.001 | 0.33 | 50 | 0.0066 | 0.05 | R | Y | | **3** |
| 47 | C 8/10 Alkyl polyglycoside | 28 | 1000 | 0.028 | 5.7 | 100 | 0.057 | 0.05 | R | Y | | **NC** |
| 48 | C8/12 Alkyl polyglycoside, branched | 480 | 1000 | 0.48 | 100 | 100 | 1 | 0.05 | R | N | | **NC** |
| 49 | C 8/16 or C12-14 Alkyl polyglycoside | 5.3 | 1000 | 0.0053 | 1 | 10 | 0.1 | 0.05 | R | Y | | **3** |
| 50 | Coconut fatty acid monoethanolamide | 9.5 | 1000 | 0.0095 | 1 | 100 | 0.01 | 0.05 | R | Y | | **3** |
| 51 | Coconut fatty acid monoethanolamide 4-5 EO | 17 | 10000 | 0.0017 | | | 0.0017 | 0.05 | R | Y | | **NC** |
| 52 | Coconut fatty acid diethanolamide | 2 | 1000 | 0.002 | 0.3 | 100 | 0.003 | 0.05 | R | O | | **3** |
| 53 | PEG-4 Rapeseed amide | 7 | 1000 | 0.007 | | | 0.007 | 0.05 | R | Y | | **NC** |

| Number | Name | LC50/ EC50 | SF acute | TF acute | NOEC (*) | SF chronic | TF chronic | DF | Aerobic | Anaerobic | | Chronic Aquatic toxicity Category |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Amphoteric surfactants** | | | | | | | | | | | | |
| 60 | C12/15 Alkyl dimethylbetaine | 1.7 | 1000 | 0.0017 | 0.1 | 100 | 0.001 | 0.05 | R | O | | **2** |
| 61 | Alkyl C12/18 amidopropylbetaine | 1.8 | 1000 | 0.0018 | 0.09 | 100 | 0.0009 | 0.05 | R | Y | | **2** |
| 62 | C12/18 Alkyl amine oxide | 0.3 | 1000 | 0.0003 | | | 0.0003 | 0.05 | R | Y | | **NC** |
| **Cationic surfactants** | | | | | | | | | | | | |
| 70 | Alkyl trimethyl ammonium salts | 0.1 | 1000 | 0.0001 | 0.046 | 100 | 0.00046 | 0.5 | I | O | | **2** |
| 71 | Alkyl ester ammonium salts | 2.9 | 1000 | 0.0029 | 1 | 10 | 0.1 | 0.05 | R | Y | | **3** |

(*) These NOEC's, if present, were used to derive chronic classification. (**) Classified due to slower aerobic biodegradation in combination with ecotox data.
R = Readily biodegradable, I = Inherently biodegradable, Y = Biodegradable under anaerobic conditions, N = Not biodegradable under anaerobic conditions,
O = The ingredient has not been tested, NC = Not Classified.

**Annex I B: REACH phase-1 surfactants: classification for chronic aquatic toxicity under the 2nd ATP to CLP Regulation Document prepared by the European Committee of Organic Surfactants and their Intermediates (CESIO) and submitted by the Cosmetics Europe.**

| Surfactant type | Family | Lead company | CAS-No. | Substance Name | NOEC (as 100 % AS) | 2nd ATP (as 100 % AS) | AS commercial product |
|---|---|---|---|---|---|---|---|
| anionic | FAS | BASF/Cognis | 151-21-3 | Sulfuric acid, (C12-alkyl) esters, sodium salts | 0.684 mg/l (QSAR) | Chronic Cat.3 | 100% |
| anionic | FAS | BASF/Cognis | 85586-07-8 | Sulfuric acid, (C12-14-alkyl) esters, sodium salts | 0.51 mg/l (QSAR) | Chronic Cat.3 | 100% |
| anionic | FAS | BASF/Cognis | 73296-89-6 | Sulfuric acid, C12-16-alkyl esters, sodium salts | 0.48 mg/l (QSAR) | Chronic Cat.3 | 100% |
| anionic | FAS | BASF/Cognis | 68955-19-1 | Sulfuric acid, C12-18-alkyl esters, sodium salts | 0.42 mg/l (QSAR) | Chronic Cat.3 | 100% |
| anionic | FAES | BASF/Cognis | 68891-38-3 | Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-hydroxy-, C12-14-alkyl ethers, sodium salts (< 2.5EO) | 1.2 mg/l (QSAR) | - | 70%<br>28% |
| anionic | FAES | BASF/Cognis | 68081-91-4 | Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-hydroxy-, C12-18-alkyl ethers, sodium salts (2EO) | 0.96 mg/l (QSAR) | Chronic Cat.3 | |
| nonionic | APG | BASF/Cognis | 68515-73-1 | D-Glucopyranose, oligomeric, decyl octyl glycosides | 1.0 mg/l (Daphnia) | Chronic Cat.3 | 50% |
| nonionic | APG | BASF/Cognis | 110615-47-9 | D-Glucopyranose, oligomeric, C10-16-alkyl glycosides | 1.0 mg/l (Daphnia) | Chronic Cat.3 | 50% |
| nonionic | FAEO | BASF/Cognis | 68213-23-0 | Alcohols, C12-18, ethoxylated (< 2.5EO) | 0.048 mg/l (HC5-value) | Chronic Cat. 2 | 100% |
| nonionic | FAEO | BASF/Cognis | 68920-66-1 | Alcohols, C16-18 and C18:1-unsatd., ethoxylated (< 2.5EO) | 0.002 mg/l (HC5-value) | Chronic Cat.1 | 100% |

| Surfactant type | Family | Lead company | CAS-No. | Substance Name | NOEC (as 100 % AS) | 2nd ATP (as 100 % AS) | AS commercial product |
|---|---|---|---|---|---|---|---|
| anionic | sec Alkane sulphonate | Clariant | 97489-15-1 | Sulfonic acids, C14-17 (even and odd numbered) sec-alkane, sodium salts | 0,85 mg/l (28d; fish toxicity) | Chronic cat 3 | |
| anionic | Alpha olefin Sulphonate | Huntsman | | | | Not classified (Acute Cat 2) (Chronic Daphnia test proposed) | |
| anionic | Na Xylene Sulphonate | Sasol | 1300-72-7 | | | Not classified | |
| anionic | Na Toluene Sulphonate | Stepan | 657-84-1 | | | Not classified | |
| anionic | Alkyl Sulphate | Huntsman | | Ammonium Lauryl Sulphate | | Chronic Cat 3 (Acute Cat 2) | |
| anionic | Na C12-13 ether sulphate: | Huntsman | | | | Chronic Cat 3 (Acute Cat 2) | |
| anionic | | | | | | | |
| nonionic | Alkanolamide | Stepan | | C8-18 MEA (1) | | Chronic Cat 2 | |
| nonionic | Alkanolamide | Stepan | | C8-18 DEA (1) | | Chronic Cat 2 | |
| nonionic | Alkyl amido (propyl) Amine Oxides | KAO | 866889-72-7 | Amides, C12-14 (even numbered), N-[3-(dimethylamino) propyl], N'-Alkyl dimethyl amine oxides | | No data on chronic aquatic toxicity for it =➔ Not affected by the 2nd ATP to the CLP | |
| nonionic | Alkyl dimethyl amine oxides | Huntsman | | C12-18 amine oxide (OD) | | Chronic Cat 2, (Acute Cat 1, M =1) | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Amphoteric | Alkyl Betaine | Huntsman | | | | Chronic Cat 3 (Acute Cat 2) (chronic Daphnia test proposed, but algae are the most sensitive) | |
| Amphoteric | Alkyl Betaine | Huntsman | | Coco amido propyl betaine (C12 - 18) | | Chronic Cat 3 (Acute Cat 2) | |
| Amphoteric | alkylamidopropylbetaines | Stepan | | Cocamidopropyl betaine | > 0.1 & < 1 mg /l | Aquatic Chronic 3<br><br>chronic fish and daphnia data (2) | |

(1) Hazard statement: H411: Toxic to aquatic life with long lasting effects

(2) Pictogram: No pictogram / Signal word: No signal word / Hazard statement: H412 Harmful to aquatic life with long lasting effects

Rem: Acute Cat 2 is between parentheses as this is not used under CLP, but is used under UN GHS.