



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

## Background report including draft criteria revision proposal

### Working Document for the 1<sup>st</sup> AHWG Meeting

February 2012

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

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proposal**

**for the 1<sup>st</sup> AHWG Meeting**

**TIME: Monday 20 February 2012 9:30-17:30**  
**PLACE: Institute for Prospective Technological Studies**  
**Sustainable Production and Consumption Unit**  
**Edificio EXPO, C/Inca Garcilaso 3, Seville**

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DRAFT WORK IN PROGRESS

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## ABBREVIATIONS

|          |  |
|----------|--|
| AC       | - Active Content   |
| CDV      | - Critical Dilution Volume   |
| C&L      | - Classification & Labelling   |
| CLP      | - Regulation on classification, labelling and packaging of substances and mixtures       |
| 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  |
| IPCC     | - Intergovernmental Panel on Climate Change  |
| LCA      | - Life Cycle Assessment  |
| PAF      | - Potentially Affected Fraction of species   |
| PE       | - Polyethylene   |
| PET      | - Polyethylene terephthalate   |
| PP       | - Polypropylene  |
| PVC      | - Polyvinyl chloride   |
| RSP      | - Retail Selling Price   |
| SCCP     | - Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers |
| SDS      | - Safety data sheet  |
| SVHC     | - Substances of very high concern  |
| vPvB     | - Very persistent and very bioaccumulative   |

## 1. SUMMARY

A preliminary proposal for revision of the EU Ecolabel criteria for the product group of "soaps, shampoos and hair conditioners"<sup>1</sup> is presented in this document. The initial recommendations for revision of the current criteria has been done based on inputs received from stakeholders who registered for this revision process (among others the representatives of the cosmetic industry, of relevant associations, NGOs, Members of the EU Ecolabel Board and other)<sup>2</sup>.

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

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 study tries to identify also potential substitutes of ingredients raising concerns regarding health and environmental risks (e.g. classified with H- and R- phrases and CLP regulation). The consideration of more stringent requirements (in comparison with the currently existing criteria) is proposed for some criteria in order to ensure a better environmental performance of this product group. Special attention should also be paid to the inclusion of health criteria, as is established in the Commission Statement of 14 December 2006.

The following issues were initially proposed to the stakeholders involved in the revision process for consideration:

- Threshold values to be applied to the critical dilution volume toxicity (CDV) for each kind of products: soaps, shampoos and hair conditioners.
- Methodology to calculate CDV from the latest version of DID list.
- Surfactants biodegradability (i.e. must all surfactants be readily aerobically and anaerobically biodegradable?).
- New criteria about chemicals and substances used in formulations intended for infants, babies and children.
- Revision of packaging requirements in function of the material used: plastic, metal, paper, etc.
- Introduction of new requirements concerning energy consumption in industries.
- Proposal of a more stringent consumer testing.
- Discussion if consumer test should be different for professional use and household products.
- Strict requirements for sensitising substances.

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<sup>1</sup> 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>.

<sup>2</sup> 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 I.

<sup>3</sup> For more information see details in "Preliminary results from the technical analysis" report, available online at the project's website: [http://susproc.jrc.ec.europa.eu/soaps\\_and\\_shampoos/stakeholders.html](http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html).

- Requirementst regarding nanomaterials (Discussion if nanomaterials/particles insoluble or biopersistent should be restricted. Approval for specific uses of nanomaterials if they do not raise concerns regarding health).

The preliminary proposal with recommendations on the revision of scope and criteria was divided into the following sections:

- o Existing definition of soaps, shampoos and hair conditioners
- o Issues with existing criteria
- o New/additionally proposed criteria

Each of them is discussed separately in chapters 5, 6 and 7.

## **2. MARKET ANALYSIS**

A market analysis has been conducted in order to characterize the relevant European cosmetic market and important tendencies at a quantitative and qualitative level for the product group under study. These following sections provide quantitative data for soaps, shampoos and hair conditioners: values of production, imports and exports. Further they present main characteristics of the cosmetic industry in Europe and the key players in this sector.

### **2.1 MARKET DATA**

The European cosmetics industry represents one-third of the total cosmetics market and it has sale revenues close to these of US and Japanese markets together<sup>4</sup>.

Cosmetic market for the EU 27 is worth nearly €67.000 million/year (Retail Selling Price, RSP). Among the EU countries, Germany has the largest cosmetics market, valued annually around €12.000 million, followed by France (€11.000 million), the UK (€10.000 million), Italy (€9.500 million), and Spain (€8.000 million). The US market, the second in importance, reaches about €40.000 million/year. The third position is occupied by the Japanese market, with nearly €30.000 million/year consumption. Arab markets as well as markets like India, China, Brazil or Russia are in continuous expansion, motivated by the gradual access of their population to fragrances and personal care products<sup>4</sup>.

In 2010 there were 4000 companies operating in the EU cosmetics industry, two thirds being SMEs, and with direct and indirect employment estimated to be 1.7 million people<sup>4</sup>.

European cosmetic products are demanded all over the world and export represents a key activity for European companies of all sizes, especially SMEs. In 2010, trade with countries outside the EU 27 showed growth of over 16%, and it reached €12.5 billion (from €10.4 billion in 2009)<sup>5</sup>.

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<sup>4</sup> COLIPA Activity Report 2010 – the work of Colipa in 2010, available online at: [www.colipa.eu/downloads/3313.html](http://www.colipa.eu/downloads/3313.html).

<sup>5</sup> Source: Eurostat

## 2.2 STRUCTURE OF INDUSTRY AND PRODUCTION

The total market for soaps is dominated by a small number of multinational companies which account for half of the market. These companies compete among each other with strong brand identity and big advertising budgets. There is fierce competition among these corporations, but soap products represent only a small part of their products range (in most cases, soap and detergents account for 20% of group turnover).

The top stakeholders include Unilever, Procter and Gamble, Colgate Palmolive and Johnson & Johnson. Despite this, there are also several hundreds of small and medium sized companies (SMEs) active at the market in most EU27 countries. In Table 1 it the top global companies can be seen.

**Table 1. Top 10 global companies, based on new product introductions (2007-2010)**

| Top 10 companies (excluding private label) |                   |
|--|-------------------|
| 1  | L'Oréal           |
| 2  | Estée Lauder      |
| 3  | Procter & Gamble  |
| 4  | Unilever          |
| 5  | Beiersdorf        |
| 6  | Coty              |
| 7  | Kao               |
| 8  | Revlon            |
| 9  | Henkel            |
| 10   | Johnson & Johnson |

*Source: Mintel Global New Product Database*

The studied product category comprises soaps, shampoos and hair conditioners. The highest growth during the last years was achieved for the category of soaps. The market is characterized by growing maturity and vast competition among major brands. Market expansion has been attributed mainly to new products development, such as liquid soaps for hand-washing and showers, supported by heavy media advertising and promotional activity carried out by the major branded manufacturers.

### Environmental issues as competitive strategy

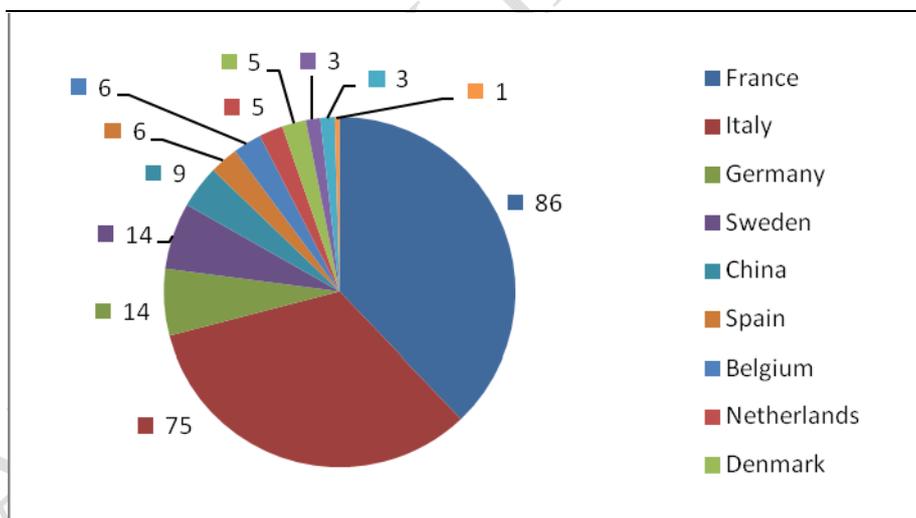
Several competitive strategies used in this sector have been characterized below. Among them there are some strategies that can be connected with the potential of the market for Ecolabelled products:

- **Environmental approach.** The growing environmental concerns of the societies have led to the development of eco-friendly products using e.g. natural, biodegradable ingredients, having biodegradable packaging and refill packages.

- **Ecolabel as a source of differentiation.** Companies tend to perceive the Ecolabel as a tool to improve its position against other competitors:
  - Products may carry the Ecolabelling trademark for marketing purposes. The Ecolabel is a well-known and well-reputed trademark in some regions.
  - Ecolabelling is a simple and cost-effective way to communicate environmental aspects and commitment to purchasers and consumers.
  - Ecolabel not only covers environmental issues but also quality requirements, since environmental and quality concerns often go together. It means that an Ecolabel licence is sometimes also seen as a mark of quality.

Currently there are 227 products of the category “soaps, shampoos and hair conditioners” which have the EU Ecolabel<sup>6</sup> (55 licences were given to manufacturers). If these data are analysed by country, it can be seen in *Figure 18* that the country with a major number of ecolabelled products is France (86 products), followed by Italy (75), Germany (14), Sweden (14). Other countries are China, Spain, Belgium, Netherlands and Denmark, with less than 10 Ecolabelled products. If we look at the number of licences Germany leads with 12, followed by Italy with 11 and France with 7. Further, the Netherlands have 5 licences, UK – 4, Spain, Poland and Australia – 3, while Austria, Belgium, Denmark, China and Slovenia have 1 licence<sup>7</sup>.

**Figure 1. Products with EU Ecolabelled products by country (2011)**



Source: Elaboration from data given in Ecolabel website: [www.eco-label.com](http://www.eco-label.com)

#### Market segmentation and claims:

Most of markets contain several segments, which are perceived as distinct customer groups possessing a common set of special needs or characteristics. In soaps industry, for example, buyer groups can be segmented by factors such as income levels, frequency of purchase, understanding of the product, and other aspects. Soap, bath and shower market is segmented according to gender,

<sup>6</sup> [www.eco-label.com](http://www.eco-label.com)

<sup>7</sup> In accordance with the information obtained per e-mail from DG Environment, dated

but little has been done with regard to segmentation into age groups, apart from having products intended for babies, children and teenagers. Market trends have been gathered based on different market reports<sup>8</sup>. Elderly women and men have been largely not considered in this respect due to the assumption that they remain wedded to old-style bath additives and bar soaps. Given these trends in segmentation, the current main claims attributed to the products gives a guidance about which concepts and attributes companies want to communicate and relate to their products to. Among the top 10 claims and 10 growing claims, there are some related to sustainability of products, such as “Ethical – Environmentally Friendly Package” or “Paraben free”. The top 10 claims are given in Table 2.

**Table 2. Top claims and 10 growing claims (2009-2010)**

| <b>Top 10 claims</b>        | <b>10 Selected claims showing a significant growth, 2009-2010</b> |
|-----------------------------|---|
| Botanical / Herbal          | Ethical – Environmentally Friendly Package                        |
| Moisturising / Hydrating    | Ethical – Animal  |
| Long - Lasting              | Seasonal  |
| Vitamin / Mineral Fortified | Mattifying  |
| Dermatological tested       | Time / Speed  |
| Brightening / Illuminating  | Paraben Free  |
| Ethical – Animal            | UV Protection   |
| Time / Speed                | Male  |
| Seasonal                    | Long – Lasting  |
| UV Protection               | Limited Edition   |

*Source: Mintel Global New Product Database*

### **Product categories overview**

This final section presents the information about the market for each product category (differentiating between bar and liquid soap and shampoo and hair conditioner). All this information is based on monitoring the launch of new products in different markets in the above categories (See Table 3 and 4) based on the research of the information and data contained in the Mintel GNPD database (the Global New Products Database)<sup>9</sup>.

<sup>8</sup> Emerging worldwide markets. Personal care. ACNielsen. 2004

A Study of the European Cosmetics Industry. Global Insight. European Commission, Directorate General for Enterprise and Industry. November 2007.

Trends on mass market beauty & personal care. Mintel (Mintel GNPD).

<sup>9</sup> For details see the database website: <http://www.gnpd.com/>.

**Table 3. Market characteristics for the category of bar and liquid soap<sup>10</sup>**

|                              |  |
|------------------------------|--|
| Products launches            | <p>New product activity was split between Bar Soap with 53% of launches and Liquid Soap with 47%.</p> <p>The UK led the way accounting for one fifth of European launches in this review period, followed by France with 12%, and Russia with 11%.</p>   |
| Natural ingredients          | <p>Naturalness is largely focused on the incorporation of plant ingredients and extracts in product formulations.</p>  |
| Protection & convenience     | <p>The possibility of using liquid soap as portable hand sanitisers which can be carried by consumers is an advantage of liquid soaps over bar soaps.</p>  |
| Sensitive skin               | <p>Launches suitable for sensitive skin accounted for a 6% share of the market.</p>  |
| Ethical concerns             | <p>Refills offer consumers a greener and more economical option and maintained at consistent 4% share of the market this period.</p>   |
| Added benefits               | <p>Exfoliation can help make skin smoother and allows moisture to be better absorbed, therefore working in conjunction with other beneficial properties.</p>   |
| Targeted & seasonal launches | <p>Penetration of bar soaps is slightly higher amongst men compared to women, who are more likely than men to use liquid soap hand wash products.</p>  |
| Fortified soaps              | <p>Some vitamins offer antioxidant benefits. They can be incorporated into products through the use of popular ingredients such as super-fruits.</p>   |
| Fragrances                   | <p>Fragrances are extremely important in this market, since less than a third (29%) of launches during this period were un-fragranced.</p>   |
| Claims                       | <p>Botanical/herbal and moisturising/hydrating were the top claims in nearly all regions; and ethical-animal products performed strongly in North America. Anti-bacterial was also a strong claim across the regions, highlighting on-going concerns relating to illness and hygiene.</p>  |
| Issues affecting the market  | <ul style="list-style-type: none"> <li>• <b>Saturation.</b> Products are failing to induce consumer engagement with brands. Most consumers do not care about what soap they buy.</li> <li>• <b>Internal competition.</b> Bar soaps have an old fashioned image and their sales have fallen.</li> <li>• <b>Economic Factors.</b> Over a half of consumers prefer to buy soap, bath and shower products that are on special offer. Almost four in ten consumers are willing to go to a further stock to buy products in promotion.</li> </ul>  |
| Trends forecast              | <ul style="list-style-type: none"> <li>• With consumers are increasingly concerned about the use of synthetic chemicals such as parabens, phthalates and colourants in cosmetics and toiletries, product innovation is likely to continue focusing on natural products formulated with botanical and herbal ingredients, such as argan oil.</li> <li>• The aromatherapy proposition remains a strong feature of the category, but formulators could take products beyond the simplistic energising/relaxing axes.</li> <li>• Products featuring skin care properties, mainly moisturisation, exfoliation and pH-balanced composition, remain another key area for new product development, appealing to consumers who are concerned about skin allergies or potential irritation.</li> </ul> |

<sup>10</sup> Source: Mintel GNPD. Category Insight Bar & Liquid Soap (period under review: Q1 and Q2 2011)

|  |  |
|--|--|
|  | <ul style="list-style-type: none"> <li>Although bar soaps appear to be in terminal decline, tapping into the nostalgia trend could be one way to rejuvenate the sector. With an elderly core consumer base that shows great loyalty to the traditional bar soap format, suppliers could take better advantage of nostalgia in product design and marketing, for example through packaging and fragrances that bring back memories and appeal to the consumer at an emotional level.</li> </ul> |
|--|--|

**Table 4. Market characteristics for the category of shampoos and hair conditioners<sup>11</sup>**

|                                    |   |
|------------------------------------|---|
| Products launches                  | Overall, new product launches decreased by 2% in the analysed period. Shampoo dominated accounting for 64% of launches with the remaining 36% falling within Conditioner. Europe retained the top spot as the most active region, accounting for 40% of total launches. The UK and Germany were the most active countries, accounting for 18% and 14% of launches respectively, followed by Italy and Spain, with 9% and 8%, respectively.                |
| A more natural image               | In the six months under review, botanical/herbal remained the top claim, accounting for over half of total launches (55%).  |
| Moisturising and nourishing        | Moisturising/hydrating remained the second most active claim, featuring in 40% of total launches.   |
| Fast acting and long-lasting       | Busy consumers welcome products which are not only quick to use, but which also provide lasting results, to minimise the need for frequent hair washing and styling.  |
| Caring for animals and environment | A steady 13% of launches featured the ethical-animal claim while products free from any animal ingredients accounted for a more limited 5% share.<br>The environmentally friendly package claim maintained at 10% share of total launches this review period, with the focus on recyclability.  |
| Fragrances and fortification       | Just over a fifth (21%) of total launches featured the vitamin/mineral fortified claim.<br>According to the Mintel's consumer research, roughly a third of American men and half of American women are influenced by a pleasant fragrance when it comes to decide which brand of shampoo, conditioner, or styling product to purchase.  |
| Claims                             | Shampoo was the dominant sub-category across regions and especially in the Middle East & Africa. Botanical/herbal and moisturising/ hydrating were top claims across all regions. Skin-friendly claims such as dermatological tested and pH neutral were especially important in Europe; vitamin/mineral fortified formulations showed heightened activity in Asia Pacific; and not testing products on animals was especially important in North America |
| Issues affecting the market        | <ul style="list-style-type: none"> <li><b>Limited competition.</b> Shampoo and Conditioner products have such a specific purpose that they face limited competition. 2-in-1 shower gel/shampoo products pose some negligible competition for Shampoo.</li> <li><b>More specialization.</b> Shampoos and conditioners become increasingly</li> </ul>   |

<sup>11</sup> Source: Mintel GNPD (period under review: Q4 2010 & Q1 2011)

|                 |  |
|-----------------|--|
|                 | <p>specialised, catering for particular hair types (e.g. greasy, dry) or styles (curly, straight) or coloured hair etc, and compete better with premium and salon-only products. Moreover, as consumers have cut back on salon visits amid ongoing economic difficulties, they turn arguably to more premium and specialised products.</p> <ul style="list-style-type: none"> <li>• <b>External influence.</b> An ageing population is likely to influence new products, since older people tend to have finer and more brittle hair and consequently they need products that focus on moisturisation and adding strength. The growth of popularity of styling appliances such as hair straightness will increase demand of products that offer moisturisation.</li> </ul>   |
| Trends forecast | <ul style="list-style-type: none"> <li>• The limited offers for men have held back usage of male-specific shampoos and conditioners. Manufacturers could examine segmentation along the lines of hair type, condition and ethnicity.</li> <li>• For natural products continues increase of the use of plant ingredients for more all natural/organic formulations and products which claim natural benefits is expected.</li> <li>• Gentle formulations are expected to remain important given that consumer awareness of allergies/sensitive skin is rising. Milder products will especially appeal to people who need or want to wash their hair on a daily basis but are concerned about over-drying or damaging hair because of excess chemicals in product formulations.</li> <li>• Brands could earn distinction by being transparent about not wasting resources or water. They could help consumers with portion control and weekly usage by introducing a subscription-based mailing service that offers concentrated sachets for refillable bottles, similar to intensive detergent sachets available in the laundry sector. This would not only pitch brands as green by saving water, but would also require less packaging and lower shipping costs for manufacturers - savings that could be passed on to the consumer.</li> <li>• Manufacturers could better highlight ease of use and/or convenient packaging attributes such as if it is easy to open and to pour with one hand.</li> </ul> |

### 2.3 CONCLUSIONS

- The European market of perfumery and cosmetics is the largest in the world. Germany has the largest market in the EU, followed by France, UK, Italy and Spain. These countries are leaders in number of new product launches and in volume of production, exports and imports.
- The biggest problem in the sector is saturation of the market with slow growth expected for the coming years to 2014 and where the sales values are unlikely to grow. In addition, the market is dominated by a small number of multinational companies which account for half of its value. In this context, the competitive strategies must offer higher added-value products. Among potential solutions there is offering of environmentally friendly products. As consumers require that these products are verified, this can be seen as great potential for the EU Ecolabel. It is nevertheless worth mentioning that packaging plays also a crucial role in consumers' choices, being one of the most important factors in decision of purchase.

- In a saturated market it is still possible to find a niche. Segmentation trends point to proliferation of products related to user's experiences (such as products designed to relax), while at the same time natural product concepts also become more and more important (in terms of composition and ingredients). New product launches try to capture the attention of consumers who look for simple, natural and environmentally friendly products. However, this simplicity does not mean that consumers do not demand products with specific properties (moisturizing, ph-balanced, etc.). Finally, it is believed that there are still niches available to be exploited, such as certain profiles of products e.g. for men, children and teenagers.
- In general there is interest in obtaining the EU Ecolabel for some products, especially products aimed at children and babies. However, few manufacturers will take the initiative to get the Ecolabel. They will apply for it if the market demands it. Hence, it is very important to stimulate market demand, e.g. by informing customers on the importance to take the environmental issues into consideration when buying products. Moreover, it has to be noticed that there exists confusion in some standards and certifications, for example, on natural and organic certifications. Therefore, this provides a good opportunity for the Ecolabel, as it could properly inform the consumer and prevent this kind of confusion.
- In summary, it can be said that the current market context is favourable to host Ecolabel products. Companies gradually understand that consumers want to buy products that cause less harmful impacts to the environment. However, in order to achieve significant impact consumers must be well informed about what the Ecolabel stands for. Only then Ecolabel can be an added value for the product, differentiating it from other ones on the saturated market of cosmetics.

### 3. LEGISLATION

Cosmetic products and their ingredients are regulated by several directives and legal regulations in order to prevent the potential harmful impacts for human health and environment. These legislative acts are described briefly in the following section.

#### MAIN REGULATORY FRAMEWORK

- **Cosmetics Directive 76/768/EEC<sup>12</sup>** is the main regulatory framework for a finished cosmetic product and was adopted in 1976 in order to ensure the free circulation of cosmetic products in the internal market and their safety. The Cosmetics Directive imposes requirements regarding substances that must not be present in cosmetic products and those that may be used in limited quantities. However, the Directive mainly regulates health impacts and it does not take into consideration environmental issues.

The Cosmetics Directive was reviewed on 30 November 2009 and the new Cosmetic Products Regulation, **Regulation (EC) No 1223/2009** of the European parliament and of the council on cosmetic products was adopted<sup>13</sup> replacing the Cosmetics Directive. The new European Cosmetics Regulation takes into account the latest technological developments, including the possible use of nanomaterials. Nanomaterials are defined and regulated by this new regulation, however, nano-sized UV-filters, pigments and preservatives are exempted.

#### Other applicable EU legislation:

- **REACH<sup>14</sup>: Regulation (EC) No 1907/2006** concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. The environmental concerns that cosmetic products may raise are considered through the application of REACH. REACH does not allow marketing of a chemical substance if it does not have appropriate registration, which has to be carried out by every legal entity that manufacture or import from outside of the European Union substances on their own, in preparations or in articles in quantities of 1 tonne or above per year. REACH places responsibility on industry to manage the risks that chemicals may pose to human health and environment, as well as to provide safety information that would be passed down the supply chain. The companies that do not undertake this procedure, will not be able to produce, sell or use their products and would consequently be forced to stop their activity.

In addition to registration, REACH regulates other procedures such as the management of the risk and hazardous properties of the substance, authorisation of substances of very high concern (carcinogenic, mutagenic and/or toxic for reproduction, persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, among others) and the restriction on

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<sup>12</sup> Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetics products (76/768/EEC) (OJL 262, 27.9.1976,P.169): <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0768:20100301:en:PDF>.

<sup>13</sup> Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products: <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>.

<sup>14</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Official Journal of the European Union L 396 of 30 December 2006; available online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF>.

the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles when an unacceptable risk to human health or the environment exists.

- **Directive 67/548/EEC**<sup>15</sup> relating to the classification, packaging and labelling of dangerous substances. This Directive sets out the criteria and the procedure to harmonise the classification and labelling of substances.
- **Directive 1999/45/EEC**<sup>16</sup> relating to the classification, packaging and labelling of dangerous preparations. This directive sets out rules on how to classify and label preparations for human health and environmental hazards. This Directive apply to the placing on the market of raw materials and starting materials but it shall not apply to cosmetic products in the finished state, intended for the final user which are already covered by Directive 76/768/EEC.
- **CLP: Regulation 1272/2008**<sup>17</sup> on classification, labelling and packaging of substances and mixtures. On 20 January 2009 this regulation entered into force. It aligns existing EU legislation to the United Nations Globally Harmonised System (GHS)<sup>18</sup>. The date from which substance classification and labelling must be consistent with the new rules was 1 December 2010 and for mixtures will be 1 June 2015. On 1 June 2015 the CLP Regulation will replace fully the: Dangerous Substance Directive (67/548/EC) and the Dangerous Preparations Directive (1999/45/EC).
- **Directive 76/769/EEC**<sup>19</sup> of 27 July 1976 on the approximation of the laws, regulation and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. This Directive compiles marketing and use restrictions for a wide variety of substances, preparations and products.
- **Directive 95/17/EC**<sup>20</sup> of 19 June 1995 laying down detailed rules for the application of Council Directive 76/764/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products.

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<sup>15</sup> Commission Directive 2009/2/EC of 15 January 2009 amending, for the purpose of its adaptation to technical progress, for the 31st time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:011:0006:0082:EN:PDF>.

<sup>16</sup> Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. OJ L 200, 30.7.1999, p. 1–68, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:200:0001:0068:EN:PDF>.

<sup>17</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, Official Journal of the European Union L353 of 31 December 2008, pp. 1–1355, available online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>.

<sup>18</sup> <http://ec.europa.eu/enterprise/sectors/chemicals/documents/classification/>

<sup>19</sup> Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC) (OJ L 262, 27.9.1976, p. 201).

<sup>20</sup> Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products. OJL 140, 23/06/1995 P. 0026-0029: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0017:en:HTML>

- **Directive 80/232/EEC**<sup>21</sup> of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products.
- **Directive 94/62/EC**<sup>22</sup> of 20 December 1994 on packaging and packaging waste. This Directive aims to prevent or reduce the impact of packaging and packaging waste on the environment. It contains provisions on the prevention of packaging waste, on the re-use of packaging and on the recovery and recycling of packaging waste.

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21 Council Directive 80/232/EEC of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products. OJL 51, 25.2.1980, p. 1-7. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31980L0232:en:HTML>.

22 European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. OJL 365, 31.12.1994, p. 10-23. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0062:en:HTML>.

#### 4. COMPARISON OF ECOLOGICAL CRITERIA ESTABLISHED IN DIFFERENT LABELS

Several countries have their own environmental labels on personal care products<sup>23</sup>. However, there are differences in the focus and the scope of the different labels. In relation to the focus, there are three main areas these ecolabels address:

- **Sustainability/safety of a product:** These two concepts are incorporated to various degrees through the life cycles. It involves a comprehensive set of criteria for sustainably designing and manufacturing products that incorporate environmental and human health effects in their evaluation.
- **Organic content** (Standards for evaluating the organic content of the products are developed).
- **Natural** (i.e. refer to products from renewable or plentiful resources).

In this section we only examine the most known ecolabels from around the world for this product category (see Table).<sup>24</sup>

**Table 5. Summary of other ecolabels applicable to soaps, shampoos and hair conditioners**

| ECOLABEL NAME                     | REGION      | PRODUCT CATEGORY          | DATE OF ADOPTION |
|-----------------------------------|-------------|---------------------------|------------------|
| ABNT Ecolabel                     | Brazil      | Personal Care products    | 2009             |
| BDIH                              | Germany     | Personal Care products    | 1996             |
| China Environmental Labelling     | China       | Cosmetics products        | 1993             |
| Cradle to Cradle                  | U.S.A       | Cosmetics / Personal care | -                |
| Degree of Green                   | U.S.A       | Cosmetics products        | 2008             |
| Earthsure                         | U.S.A       | Cosmetics / Personal care | -                |
| Ecologo                           | Canada      | Cosmetics / Personal care | 1988             |
| Ecomark                           | India       | Cosmetics / Personal care | 1991             |
| Environmental Choice New Zealand  | New Zealand | Cosmetics / Personal care | 1992             |
| Environmental Product Declaration | -           | Cosmetics / Personal care | -                |
| Green Good Housekeeping Seal      | U.S.A       | Cosmetics / Personal care | 2009             |
| Green Seal                        | U.S.A       | Cosmetics / Personal care | 1989             |

<sup>23</sup> An overview of Ecolabels and Sustainability Certifications in the Global Marketplace, Interim report document #2010-10-1, Nicholas Institute for Environmental Policy Solutions Duke University, Jay S. Golden, PhD, October 2010.

<sup>24</sup> Information on ecolabels on cosmetic/personal care available at the following website:  
[http://www.ecolabelindex.com/ecolabels/?st=category,cosmetics\\_personal\\_care](http://www.ecolabelindex.com/ecolabels/?st=category,cosmetics_personal_care).

|   |   |                           |      |
|---|---|---------------------------|------|
|   |   | care                      |      |
| <b>Hungarian Ecolabel</b>               | Hungary                                   | Cosmetics / Personal care | 1994 |
| <b>Korean Ecolabel</b>                  | Korea                                     | Cosmetics / Personal care | -    |
| <b>Nordic Ecolabel or Swan</b>          | Denmark, Finland, Iceland, Norway, Sweden | Cosmetics / Personal care | 1989 |
| <b>Thai Green Label</b>                 | Thailand                                  | Cosmetics / Personal care | 1994 |
| <b>Vitality Leaf</b>                    | Russia                                    | Cosmetics / Personal care | 2001 |
| <b>Good Environmental Choice ( GEC)</b> | Sweden                                    | Cosmetics / Personal care | 1998 |
| <b>GREEN MARK</b>                       | Taiwan                                    | Personal care             | 2007 |

A brief description of them is given below:

- **ABNT Ecolabel:** Is a life cycle based ecolabel that is a voluntary method of environmental performance certification and labelling for Personal Care products in Brazil. The scope of the product category includes: shampoos, soaps (both solid and liquid), corporal cleansers, shampoos and both liquid and solid soaps for animals. It addresses the following issues: preservation of the environment, reduction of waste (recycling) and increased revenue (sale of scrap for recycling). The ABNT Ecolabel is a guarantee that the product/service of the company causes less environmental impact than other similar products available at the market.
- **BDIH<sup>25</sup> “Certified Natural Cosmetics”:** is a recognized German eco-certification available in the personal care sector. Products marked with the BDIH seal use natural raw material such as plant oils, fats and waxes, herbals extracts and essential oils and aromatic materials from controlled biological cultivation or controlled biological wild collection. In addition to the careful selection of raw materials, the ecological impact of each product plays an important role.
- **China Environmental Labelling:** Was initiated by SEPA in 1993. It provides environmental standards for cosmetics.
- **Cradle to Cradle:** This certification is a third-party sustainability label that requires achievement in multiple areas: use materials that are safe for human health and the environment across their life cycles, product and system design for material reutilization, such as recycling or composting, use of renewable energy, efficient use of water and maximum water quality associated with production and company strategies for social

<sup>25</sup> German Association of Industries and Trading Firms for pharmaceuticals, health care products, food supplements and personal hygiene product

responsibility. This certification program applies to materials, sub-assemblies and finished products.

- **Degree of Green:** At the core of Degree of Green are data sheets that detail the environmental, health and sustainability attributes of cosmetic products. A top rating of 4 goes to product that have the least adverse effects on human health, the highest level of environmental sustainability and the least adverse effects on the environment.
- **Earthsure:** The objective of the Earth sure program is to provide comprehensive environmental data to purchasers so that the power of the market can move the economy towards overall environmental improvement. The Earth sure ecolabel discloses the environmental impact indicator results of the creation of each product.
- **Ecologo:** is North America's largest environmental standard and certification mark. The products meet stringent standards of environmental leadership. The program compares product/services with others in the same category, develops rigorous and scientifically relevant criteria that reflect the entire lifecycle of the product and awards the Ecologo to those that are verified by an independent third party as complying with the criteria. The Ecologo Program is one of two such programs in North America that has been successfully audited by the Global Ecolabelling Network (GEN) as meeting ISO 14024<sup>26</sup> standards for eco-labelling.
- **Ecomark:** To increase consumer awareness, the Government of India launched this eco-labelling scheme in 1991 for easy identification of environmentally friendly products. The criteria follow a cradle-to-grave approach (from raw materials extraction, through manufacturing and use to disposal).
- **Environmental Choice New Zealand:** A voluntary, multiple specifications based environmental labelling programme that operates to international standards and principles.
- **Environmental Product Declaration:** The International EPD System has the objective to help and support organizations to communicate the environmental performance of their products (goods and services) in an understandable way.
- **Green Good Housekeeping Seal:** The product is evaluated based on a wide range of environmental criteria, including ingredient and product safety, reduction of water use in manufacturing, energy efficiency in manufacturing and product use, packaging reduction, greenhouse gas emissions, and the brand's corporate social responsibility.
- **Green Seal:** An independent non-profit founded in 1989, Green Seal certifies thousands of products and services that meet science-base environmental standards. Green Seal utilizes a life-cycle approach to ensure tangible reductions in the whole environmental footprint.

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<sup>26</sup> ISO 14024:1999 Environmental labels and declarations - Type I environmental labelling - Principles and procedures.

- **Hungarian Ecolabel:** was developed by the Hungarian Ministry of Environment in 1994. Goals and procedures meet the requirements of ISO 14024 standard.
- **Korean Ecolabel:** Improvement in ecoproducts and product environmental friendliness by setting up the eco-product standards.
- **Nordic Ecolabel or “Nordic Swan”:** is a voluntary ecolabelling scheme that evaluates a product’s impact on the environment throughout the whole life cycle. The label guarantees among other that climate requirements are taken into account and CO<sub>2</sub> emissions (and other harmful gasses) are limited – where it is most relevant<sup>27</sup>. The Nordic Ecolabel is available for 65 product groups. The label ensures that products fulfill certain criteria using methods such as samples from independent laboratories, certificates and control visits.
- **Thai Green Label:** was initiated by the Thailand Business Council for Sustainable Development (TBCSD) and formally launched in 1994 by the Thailand Environment Institute (TEI) in association with the Ministry of Industry. The Green Label is an environmental certification awarded to specific products that are shown to have minimum detrimental impact on the environment, in comparison with other products serving the same function. The Thai Green Label Scheme applies to products and services, not including foods, drinks and pharmaceuticals.
- **Vitality Leaf:** was developed by NGO: St. Petersburg Ecological Union in 2001. Criteria for certification are developed using life cycle approach according to ISO 14024 standard. The main objectives of this ecolabel is to encourage the demand for and supply of environmentally preferable products and services, contribute to reduce environmental impacts of producers and improve the quality of the environment and to encourage the sustainable management of resources.
- **Good Environmental Choice (GEC):** Good Environmental Choice, or in Swedish Bra Miljöval<sup>28</sup>, is the ecolabelling system established by the Swedish Society for Nature Conservation (SSNC), the largest environmental NGO in Sweden.
- **Green Mark:** The Green Mark is a certification awarded to products that have gone through strict verification tests, belonging to the first 20-30% that has the lowest environmental impact. The mission of the Green Mark is to “promote the concept of recycling, pollution reduction, and resource conservation”. The objectives of the Green Mark are to guide consumers in purchasing green products and to encourage manufacturers to design and produce them.

An overview of the requirements of the criteria documents for the most recognized European ecolabels will be given in a later stage.

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<sup>27</sup> <http://www.nordic-ecolabel.org/>.

<sup>28</sup> <http://www.naturskyddsforeningen.se/bra-miljoval/in-english/about-bra-miljoval/how-does-it-work/>.

## 5. PRODUCT GROUP DEFINITION

In accordance with the Commission Decision establishing the ecological criteria for the product group of soaps, shampoos and hair conditioners<sup>29</sup> the current 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)".

The criteria for Ecolabel 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.

In order to be awarded the Community eco-label for soaps, shampoos and hair-conditioners, a product must fall within the product group "soaps, shampoos and hair-conditioners" and must comply with the ecological criteria.

### Proposal

In this revision process extension of the existing definition of soaps, shampoos and hair conditioners product group described above has been considered, taking into account that other cleaning products which fulfil the product definition may exist and could be included in the scope.

Products with a certain degree of similarity, for example a common function or way of application or with similar chemical composition could be taken into account.

With this aim, typical ingredients of each new considered product were analyzed and compared with soaps, shampoos and hair conditioners composition. Based on the outcomes of the analysis of ingredients and their function, it is proposed to consider in the 1<sup>st</sup> AHWG meeting including in the scope and product group definition of other rinse-off cosmetic products with similar purposes like shaving foam, shaving gel, shaving cream and shaving soap. Further, products for animals, especially pets, could be included.

### Motivation

First, a list of products which fulfil the same or similar function of cleaning was prepared, and products were analysed at ingredients level. Typical ingredients of each new proposed product have been analyzed and compared with soaps, shampoos and hair conditioners. The compositions of the

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<sup>29</sup> 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>.

following products were analysed in order to see if the ingredients and functions are similar to the products already covered by the existing criteria:

- Shaving-foam, -cream, -gel, -soap,
- Shampoo for animals,
- wet wipes,
- toothpaste

Based on the outcomes of this preliminary analysis<sup>30</sup> some products with hygiene purposes and rinse-off application were found to have a similar composition and were considered to be suitable to be included in the product group, as it is the case of shaving foam, gel, cream and soap.

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. 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<sup>31</sup>.

Further, some products were excluded based on the results obtained because their composition differed too much from soaps and shampoos, as it was e.g. in the case of toothpastes.

Other cleaning products, as e.g. wet wipes, were also excluded because the way of application is different from rinsed-off products.

## Conclusion

Based on the analysis of ingredients, the product group definition might include other rinse-off cosmetic products with similar purposes like shaving-foam, -gel, -cream and -soap. Very similar compositions have the products intended for animals, especially pets. These could also be considered to be included. Based on this, and taking into account the definition of cosmetic products by the Regulation (EC) No 1223/2009:

*'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;*

The current definition of this product group could 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 **or protecting 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)".

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<sup>30</sup> For details please see Appendix II: Scope of the product group.

<sup>31</sup> 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.

Following this definition a change of the product group from "soaps, shampoos and hair conditioners" to "rinse-off cosmetics" is also proposed.

*The stakeholders are asked for their feedback on the scope extension by the abovementioned products and on the proposal for changing the product group name.*

DRAFT WORK IN PROGRESS

## 6. INTRODUCTION TO REVISED ECOLABEL CRITERIA

This following table summarises the preliminary proposals with recommendations on the revision of the scope and criteria for soaps, shampoos and hair conditioners. This proposal has been reviewed based on the results of the main environmental impacts in a life cycle perspective and the identification and analysis of potential alternatives for hazardous substances. In any case, the most important life cycle environmental impacts of this product group shall be addressed in the criteria document.

An overview on the current Ecolabel criteria versus the criteria proposed for consideration during the 1<sup>st</sup> AHWG meeting (and consulted already with some stakeholders through the questionnaire responses) is given below.

As mentioned in the previous chapter it has been proposed to consider to enlarge the scope of the product group to include other rinse-off products with similar purposes like shaving -foam, -gel, -cream and –soap. The consideration of shampoos for pets could be also a discussion point in the AHWG meeting.

The proposals for revised criteria are explained in detail in chapter 7.

Table 6. Overview of current Ecolabel criteria versus the revised criteria for soaps, shampoos and hair conditioners

| CRITERIA                                 | EXISTING EU ECOLABEL CRITERIA   | Potential changes, modifications or amendments  |
|--|---|---|
| <b>1. Toxicity to aquatic organisms</b>  | <p><b>Critical Dilution Volume (CDV)</b><br/> <math>CDV (\text{ingredient } i) = \text{weight } (i) \times DF (i) \times 1000/TF \text{ chronic } (i)</math><br/> <math>CDV = \sum CDV (\text{ingredient } i)</math></p> <p><b>Critical Dilution Volume (CDV):</b><br/>                     -Liquid soaps, shampoos, shower products and other liquid cleaning products <math>\leq 20\,000</math> L/g AC<br/>                     - Solid soaps <math>\leq 3\,500</math> L/g AC<br/>                     - Hair conditioners <math>\leq 30\,000</math> L/g AC</p> | <ul style="list-style-type: none"> <li>- Methodology to calculate CDV from latest version of DID list.</li> <li>- Decrease limits to apply to critical dilution volume toxicity (CDV) per grams of product for each kind of products: soaps, shampoos and hair conditioners.</li> <li>- DID-list should be updated and enlarged to most commonly used surfactants and other ingredients.</li> </ul> |
| <b>2. Environmental harmful products</b> | <p>N, R50/53: <math>W_{R50/53}/25\% \leq 1</math><br/>                     N, R51/53: <math>(W_{R50/53}/2,5\%) + (W_{R51/53}/25\%) \leq 1</math><br/>                     R52/53: <math>(W_{R50/53}/0,25\%) + (W_{R51/53}/2,5\%) + (W_{R52/53}/25\%) \leq 1</math><br/>                     Rubbing/abrasive agents in hand cleaning agents are not included.</p>   | <ul style="list-style-type: none"> <li>- Consider including this in criterion 8</li> <li>- hazardous content and updating it to be based on CLP classification criteria.</li> </ul>   |

|   |  |  |
|---|--|--|
| <p><b>3. Aerobic biodegradability</b></p>                         | <p><b>3a) Aerobic biodegradability of surfactants:</b> Each surfactant used in the product will be readily biodegradable.</p> <p><b>3b) Aerobic biodegradability of non-surfactants (aNBDO<sub>non-surf</sub>):</b><br/> <b>aNBDO</b>= milligrams of not aerobically degradable non-surfactants per gram active content</p> <ul style="list-style-type: none"> <li>- Liquid soaps, shampoos, shower products ≤ 30 mg/g AC</li> <li>- Solid soaps ≤ 15 mg/g AC</li> <li>- Hair conditioners ≤ 50 mg/g AC</li> </ul> <p>Rubbing/abrasive agents in hand cleaning agents are not included. All ingredients (substances or preparations) exceeding 0,010% by weight of the final product will be considered.</p> | <ul style="list-style-type: none"> <li>- Surfactants biodegradability will be discussed if all surfactants must be readily aerobically and anaerobically biodegradable.</li> <li>- Decrease limits to apply to aNBDO.</li> </ul>   |
| <p><b>4. Anaerobic biodegradability (annbo<sub>tox</sub>)</b></p> | <p><b>anNBDO</b>= milligrams of not anaerobically degradable toxic ingredients per gram active content. Toxic ingredient: Lowest acute toxicity is &lt; 100 mg/l.</p> <ul style="list-style-type: none"> <li>- Liquid soaps, shampoos, shower products ≤ 25 mg/g AC</li> <li>- Solid soaps ≤ 15 mg/g AC</li> <li>- Hair conditioners ≤ 50 mg/g AC</li> </ul> <p>Rubbing/abrasive agents in hand cleaning agents are not included.</p>  | <ul style="list-style-type: none"> <li>- Decrease limits to apply to anNBDO.</li> </ul>  |
| <p><b>5. Fragrances</b></p>                                       | <p>Fragrance must have been manufactured, handled and applied in accordance with the code of practice of international Fragrance Association.</p>  | <ul style="list-style-type: none"> <li>- Discuss if sensitizing substances should be restricted to 0,01%.</li> <li>- Discuss why a total ban is not possible.</li> <li>- Consider possible extension of the scope to substances other than fragrances which are known to act as sensitizers for allergic skin reaction and contact dermatitis.</li> </ul>                                      |
| <p><b>6. Dyes or colouring agents</b></p>                         | <p>Organic dyes or colouring agents must not be potentially bio-accumulating.</p> <ul style="list-style-type: none"> <li>- BCF ≤ 100</li> <li>- log Pow ≤ 3</li> </ul>   | <ul style="list-style-type: none"> <li>- According to CLP, a colouring agent or dye will be considered to be potentially bioaccumulating if the experimentally determined BCF is ≥ 500 or log kow ≥ 4.</li> </ul> <p>Discussion point whether the scope of this criterion should be extended also to other substance groups founding the final product other than dyes or colouring agents</p> |

|  |   |  |
|--|---|--|
| <p><b>7. Biocides</b></p>                            | <p>a) Biocides 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.</p> <p>b) Biocides with classification R50-53 are only permitted if they are not potentially bio-accumulating (BCF &lt; 100 or log Pow &lt;3,0).</p> <p>c) Preservatives must not release substances that are classified with the criterion 8a.</p>  | <ul style="list-style-type: none"> <li>- According to CLP, biocides must not be potentially bioaccumulating (BCF is &lt; 500 or log Pow &lt;4).</li> <li>- Discuss which substances should be restricted: triclosan, parabens, formaldehyde and formaldehyde releasers.</li> <li>- Take into account potential implications from the revised Biocides Directive</li> </ul>   |
| <p><b>8. Environmental hazardous ingredients</b></p> | <p>The requirements concern all ingredients (substances or preparations) exceeding 0,010 % by weight of the final product.</p> <p><b>a) Classified ingredients</b><br/>No constituent substance must be classified as CMR, toxic and hazardous to the environment in accordance with CLP or substances referred to in Article 57 of REACH. Maximum 0,1% (w/w) for substances that meet the criteria of Article 57 present in mixtures or in an article.</p> <p><b>b) Specified excluded ingredients</b><br/>-Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives<br/>-NTA (nitrilo-tri-acetate)<br/>-Boric acid, borates and perborates<br/>-Nitromusks and polycyclic musks</p> <p><b>c) Specified limited ingredients</b><br/><b>EDTA</b> and its salts and non-readily biodegradable phosphonates may only be added to solid soaps and only to a maximum content of 0,6 mg/g AC.</p> | <ul style="list-style-type: none"> <li>- Apply implications of Ecolabel Regulation 66/2010 Article 6(6) and expand R- and H- phrases list similarly to recently developed EU Ecolabel criteria for other product groups<sup>32</sup></li> <li>- Restriction on substances considered PBT, vPvB and/or those having endocrine disrupting properties</li> <li>- Include some specified excluded ingredients</li> <li>- Apply article 6.7 of Ecolabel Regulation 66/2010 in which no substance classified as substance of very high concern (SVHC) based on REACH shall be present in the Ecolabelled product.</li> </ul> |
| <p><b>9. Packaging</b></p>                           | <p>a) The weight/content relationship (WCR) is less than 0,30 g packaging per gram of product.</p> <p><b>WCR = <math>\Sigma ((Wi + Ni) / (Di \times r))</math></b><br/>If the packaging is reused r is set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number.</p> <p><b>b) Labelling of packaging</b><br/>Plastic parts of the primary packaging has been marked in accordance with DIN 6120, Part 2 or the equivalent (caps and pumps are exempted from this requirement).</p> <p><b>c) Dosage</b><br/>The packaging must be designed to make correct</p>   | <ul style="list-style-type: none"> <li>- The WCR should be calculated taking into account refillable and refill packaging</li> <li>- More restricting weight limit (&lt; 0,3 g packaging/g product)</li> <li>- Packaging materials should not contain substances included in the candidate list of SVHC for authorization.</li> <li>- Packaging requirements in function of the material used.</li> <li>- It should be possible to separate all materials in the packaging (paper,</li> </ul>  |

<sup>32</sup> For details see Appendix II.

|   |   |   |
|---|---|---|
|   | dosage easy, e.g. by ensuring that the opening at the top is not too wide<br>d) The packaging does not contain additives based on Cadmium, Mercury, Lead or compounds with these elements. The packaging does not contain additives that do not fulfil criterion 8. | cardboard, plastic, metal) for sorting.<br>Parts comprising mixed materials that cannot be separated should be restricted, with the exception of pump parts.  |
| <b>10. Fitness for use</b>  | The product's fitness for use is demonstrated by:<br><br>-Laboratory test performed by test-institute or<br>-Consumer test according to Appendix I  | Proposal to consider a more stringent consumer test.  |
| <b>11. Information appearing on the eco-label</b>   | Box 2 of the eco-label shall contain the following text:<br>• Minimal impact on aquatic ecosystems<br>• Fulfils strict biodegradability requirements<br>• Limits packaging waste  | Add, depending on the final formulation of the criteria, e.g.:<br>• Limited use of hazardous substances   |
| <b>12. Energy consumption</b>   |   | Introduction of new requirements concerning energy consumption in industries.   |
| <b>13. Substances used in products intended for infants, babies and children (of less three years of age)</b> |   | New criteria about chemicals and substances used in formulations intended for infants, babies and children (of less three years of age).<br>-Discussion point: any substance raising concerns regarding allergic reactions such as asthma and contact dermatitis should be totally restricted if this is practical and technical feasible |
| <b>Discussion Point 1</b>   | <b>-Nanomaterials</b>   | Discuss if nanomaterials/particles insoluble or biopersistent should be restricted. Approved specific uses of nanomaterials/particles if it does not give rise to concerns in respect of health.  |
| <b>Discussion Point 2</b>   | <b>-Renewable sources ingredients</b>   | -Renewable sources of ingredients may have environmental benefits however this can be case specific<br><br>-consumers and license holders of MS Ecolabels have considered this relevant and raised it as a discussion point.  |

## 7. REVISED ECOLABEL CRITERIA

### 7.1 GENERAL REMARKS

The revision of the current Ecolabel criteria of the group product “soaps, shampoos and hair conditioners” is based on the outcomes of the technical analysis developed, in which the Life Cycle Approach has been used. The technical analysis<sup>33</sup> consists of two parts:

- Life Cycle Assessment of products,
- Identification and analysis of potential alternatives of hazardous substances.

The life cycle assessment has been conducted following the standards ISO 14040 and ISO 14044, and it allows identifying the potential environmental impacts of the products under study in their different life stages. These environmental products profiles help to assess where regulations and criteria should focus and to foresee the environmental improvement that can be potentially achieved if appropriate steps are taken.

Complementary to this, outcomes of the specific analysis of hazardous substances, especially for substances raising concerns related to human and environmental risks (article 6.6 of Ecolabel Regulation) should be considered. The identification and analysis of potential alternatives of hazardous substances has specifically addressed the following issues: first, the substances most commonly used that perform the same function, secondly, the identification of chemicals of high concern; finally, it should help manufacturers to find environmentally better performing substances with a lower hazard level for a specific function.

The identification of hazardous substances is based on ingredients inherent properties. The study is focused on the effects of the ingredients on health and environment measured by the classification status according to CLP regulation. Further, attention is given to substances of very high concern (Annex XIV of REACH Regulation<sup>34</sup>) and the candidate list for authorisation as referred to in REACH Regulation.

### 7.2 FUNCTIONAL UNIT AND REFERENCE DOSE

In accordance with the existing EU Ecolabel criteria document the functional unit is defined as 1 gram of ‘Active Content (AC)’. AC is defined as the weight of organic ingredients in the product. 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.

This functional unit was found as the most suitable to avoid that more diluted products have advantages against those more concentrated, as it would happen if standard dosages were established as the functional unit, as different products would have different dosages depending on

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<sup>33</sup> 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](http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html)

<sup>34</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; Official Journal of the European Union L 396 of 30 December 2006; available online at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF>.

the efficiency of each product. This issue was discussed in detail in the final report of the EU Ecolabel criteria development for this product group<sup>35</sup>, as well as for other labels such as Nordic Swan<sup>36</sup>.

It is proposed to maintain the current functional unit (1 g of Active Content/one gram of organic ingredients) for most of criteria related to limiting substances.

For some criteria, such as the calculation of the Critical Dilution Volume (CDV), the functional unit of “one gram of organic ingredients” may be not the most appropriate, as it does not assess the impact of the whole product. In this case it is proposed to consider using the weight of ingredients present in the whole product (see criterion 1). In order to relate the results of CDV with a “functional unit”, **standard dosages** have been included in the method calculation. The standard dosages of COLIPA (as given in Table 7) have been taken as a reference. In the case of solid soap the standard dosage has not been found and dosage from an LCA study on bar soaps<sup>37</sup> has been used.

**Table 7. Standard dosages according to COLIPA**

|                       |             |
|-----------------------|-------------|
| Hair conditioner:     | Dosage 14 g |
| Shampoo:              | Dosage 8 g  |
| Liquid soap (shower): | Dosage 5 g  |
| Solid soap:           | Dosage 4 g  |

Source: Quoted in the “Final report. EU Eco-label for shampoo and soaps”. Ecolabelling Norway, Eskeland,, M.B, Svanes, E., 2006

For criterion 9 (packaging), requirements are set for the whole product, as it is a ratio of weight of packaging to the weight of the whole product.

In order to clarify and distinguish the functional unit and reference flow terms used in the Ecolabel criterion 1 (CDV) with the terms used in LCA we would like to highlight the following:

In the LCA the modelled LCA functional unit and LCA reference flow were defined as:

*Functional unit: A washing action of a part of the body with the main objective of provide hygienic results and/or aesthetic improvements*

**Reference flow for the 4 kinds of products studied**

| Product     | Reference flow   |
|-------------|--|
| Liquid soap | A bottle of 250 ml of liquid soap (containing 255 g of product), with the main function of personal washing and personal care for 51 washing actions |

<sup>35</sup> Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.

<sup>36</sup> Nordic Ecolabelling of cosmetic products Nordic Ecolabelling of cosmetic products, Background document regarding ecolabelling, February 2011..

<sup>37</sup> Ugaya, Cassia M. L. ; Brones, F. ; Corrêa, S.: S-LCA: Preliminary results of Natura's cocoa soap bar. A presentation at the Life Cycle Management Conference LCM 2011 in Berlin.; available online at: <http://www.lcm2011.org/papers.html>, accessed January 2012.

|                  |   |
|------------------|---|
| Shampoo          | A bottle of 250 ml of shampoo (containing 255 g of product), with the main function of personal washing and personal care for 32 washing actions          |
| Hair conditioner | A bottle of 250 ml of hair conditioner (containing 255 g of product), with the main function of personal washing and personal care for 28 washing actions |
| Solid soap       | A solid bar soap of 100 g with the function of washing the body or a part of the body for 25 washing actions  |

Please see also more details in the report of "Preliminary results from the technical analysis"<sup>38</sup>.

### 7.3 ISSUES REGARDING REVISION OF EXISTING CRITERIA

Issues which may come under consideration for revision of the existing criteria are described in more detail below in the relevant sections

#### Proposal regarding Criterion 1: Toxicity to aquatic organisms

The following issues are considered for discussion during the 1<sup>st</sup> AHWG meeting:

**Point 1 – Modifying the method for Critical Dilution Volume (CDV) calculation** from the latest version of DID list.

The actual calculation method refers to 1g of "active content". 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.

#### Recommendation

Based on the stakeholders' consultation it is proposed to consider calculating **the CDV value per grams of product** (instead of per 1 g of AC) – i.e. each ingredient's CDV will be calculated per total weight of the ingredient contained in the product (not as weight/1g AC). The CDV of the product will be related to the dose; taking into account the recommended dosage of the product and the average dosage of use as presented in Table 7 for this product application (see the equation and explanation below). The dosage of use (specific for each product, in case it can be proved) is taken into account for concentrated products that may be adversely affected if this parameter was not included in the calculation method. If the dosage of use is not available for the product, the average dosage of use from COLIPA would be used.

$$NEW\ Calculation = (CDV_{tox}(g\ product)) \times \frac{(dosage\ of\ use\ of\ the\ product)}{(average\ dosage\ of\ use\ from\ Colipa\ for\ this\ product\ application)}$$

<sup>38</sup> [http://susproc.jrc.ec.europa.eu/soaps\\_and\\_shampoos/stakeholders.html](http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html)

Where:

$$\text{CDV}_{\text{tox}}(\text{product}) = \sum \text{CDV}(\text{ingredient } i)$$

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

**PROPOSAL: weight (i) is the weight of the ingredient (in grams) per product.** DF (i) is the degradation factor and TF chronic (i) is the toxicity factor of the ingredient (in milligrams/litre)

*EXISTING CRITERIA: weight (i) is the weight of the ingredient (in grams) per functional unit. DF (i) is the degradation factor and TF chronic (i) is the toxicity factor of the ingredient (in milligrams/litre)*

In order to avoid that more concentrated products have disadvantages, results are related to the dosage of products (see Table 8).

**Table 8. Standard dosages and frequency according to COLIPA**

|                       |             |
|-----------------------|-------------|
| Shampoo:              | Dosage 8 g  |
| Liquid soap (shower): | Dosage 5 g  |
| Hair conditioner:     | Dosage 14 g |
| Solid soap:           | Dosage 4 g  |

**Point 2** – With new data due to the first REACH registration deadline<sup>39</sup>, **DID-list should be updated** (and add CAS and/or EINECS number) and enlarged to most commonly used surfactants and other relevant ingredients.

**Point 3** – **Decreasing limits of critical dilution volume toxicity (CDV)** per grams of product for each kind of product: soaps, shampoos and hair conditioners.

Proposed CDV (*minimum*)

- Shampoo and liquid soaps: 18000 L/g AC
- Solid soaps: 3000 L/g AC
- Hair conditioners: To be discussed

*Note: with proposal Criterion 1.1. CVD limits should be established by g of product*

<sup>39</sup> December 2010

## Motivation

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.

### Point 1 – Limit values based on dosage

With the current calculation method, CDVTox value is related to 1 gram of active content. Value of CDV for each ingredient is calculated for the weight of this ingredient in 1 gram of AC (g ingredient (i)/g AC), not for the total amount of each ingredient in the whole product. Examples provided by stakeholders and some calculations done for theoretical examples showed that with the current method the calculation results do not depend of the quantity of active ingredients, as it is a relative value (to return to 1 g of active content). In some cases, if some ingredients are added or the amount of active contents is increased, CDVTox could decrease or stay unchanged.

Other product categories use another method to allow better calculation of the real environmental performance of the product in this respect. In the EU Ecolabel criteria for Laundry Detergents<sup>40</sup> the CDV is calculated according to the weight of each ingredient per recommended dose.

### Point 2 – Enlarge and update DID-list

Many substances which are widely used in soaps, shampoos and hair conditioners are not included in the current DID-list. In the 2007 DID-list version, data for: 19 anionic surfactants, 23 non-ionic surfactants, 3 amphoteric surfactants, 2 cationic surfactants, 19 preservatives and 103 of other substances is available.

Stakeholders' comments show that it is necessary to include more substances in the DID-list, as if ingredients are not in the DID-list; it is difficult for manufacturers to validate data received from their suppliers.

### Point 3 – Stricter limits for CDV values

Due to lack of data the current CDV values of ecolabelled products have not been analysed so far. Stakeholders are asked for their support in this respect.

Nevertheless, in the report of the development of EU Ecolabel criteria for soaps, shampoos and hair conditioners<sup>41</sup> it was found that CDVs of the investigated products lie mainly in the range of 1500 to 30000. Currently limit CDV is higher than the values for average product in the case of shampoos and liquid soaps (see table 8), which indicates that it may be appropriate to propose stricter CDV limits.

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<sup>40</sup> Commission Decision of 28 April 2011 on 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>.

<sup>41</sup> Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., May 2006.

**Table 9. CDV average values and current limits**

| Product                 | CDV (average) (2006) | Range         | Current limit (l/g AC) |
|-------------------------|----------------------|---------------|------------------------|
| Shampoo and liquid soap | 18622                | 3600 – 83000  | 20000                  |
| Solid soap              | 3925                 | 2000 – 9300   | 3500                   |
| Hair conditioner        | 73735                | 2300 - 380000 | 30000                  |

*Note: with the new criterion proposal new limit would be expressed as L/product.*

Also the values found in the new version of the Nordic Ecolabel are stricter than the current EU Ecolabel thresholds: CDV for liquid soap, hand soap for industry, shampoo, shower gel, bath foam, cleanser and exfoliant is 13000 l/g of active ingredients, while CDV for solid soaps is 3000 l/g of active ingredients.

41% of the consulted stakeholders agreed with the proposed requirements on Critical Dilution Volume. Note that the same percentage disagreed. Further feedback is expected in a written form and during the discussions in the AHWG meeting.

#### **Proposal regarding Criterion 2: Environmental harmful products**

- Considering including limitations of the current criterion 2 in criterion 8: “Environmental hazardous ingredients” and updating them based on the CLP.

#### **Motivation**

Criterion 8 regulates the environmental hazardous ingredients, so that it is proposed to unify all requirements regarding substances in one single criterion.

65% of the stakeholders consulted agreed with including these limitations in criterion 8.

#### **Proposal regarding Criterion 3: Aerobic biodegradability**

- Surfactants biodegradability: it is proposed to discuss if all surfactants must be readily aerobically and anaerobically biodegradable.
- Decrease limits to apply to aNBDO (Aerobic Non-Biodegradable Organics).

#### **Motivation**

The 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<sup>42</sup>.

Surfactants are ingredients which are widely used in liquid soaps, shampoos and conditioners in big amounts<sup>43</sup>. Most surfactants are more or less toxic 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. Generally, the linear chains are more readily degradable than branched chains. Also the toxic effects vary with the chain structure. Generally an increase of the chain length in the range of 10 to 16, leads to an increase in toxicity to aquatic organisms<sup>44</sup>:

From an environmental point of view, all surfactants should be readily aerobically and anaerobically biodegradable.

For non-surfactants, stricter limits are proposed for ingredients that are not readily biodegradable.

Other Ecolabel systems have more stringent criteria for these substances than the existing currently EU Ecolabel criteria. According to the new version of the Nordic Swan Ecolabel criteria, all surfactants must be readily aerobically and anaerobically biodegradable<sup>45</sup>. Limits for non biodegradable substances are also tighter than the current EU Ecolabel criteria (see Table 10):

**Table 10. aNBO values for Nordic Ecolabel and EU Ecolabel**

|                       | Nordic Ecolabel | EU Ecolabel    |
|-----------------------|-----------------|----------------|
|                       | aNBO (mg/g AI)  | aNBO (mg/g AC) |
| Liquid soap, shampoo, | 15              | 30             |
| Hair conditioner      | 15              | 50             |
| Solid soap            | 5               | 15             |

47% of consulted stakeholders agreed with limiting the use of non biodegradable surfactants and decreasing limits to apply to ANBDO. Some discussions and doubts have arisen regarding anaerobic biodegradability (about environmental relevance and feasibility of fulfilling criteria), therefore this issue is proposed for a discussion during the AHWG meeting.

Maximum and estimated amounts of surfactants used in products under study are presented in Table 11 below:

<sup>42</sup> REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>.

<sup>43</sup> Nordic Ecolabelling of cosmetic products Version 2.1 Background document regarding ecolabelling 16 February 2011

<sup>44</sup> Procter & Gamble ([http://www.scienceinthebox.com/en\\_UK/programs/natural\\_synthetic\\_en.html](http://www.scienceinthebox.com/en_UK/programs/natural_synthetic_en.html))

<sup>45</sup> Nordic Ecolabelling of Cosmetic products. Version 2.1., 2011.

**Table 11. Surfactants used in studied products**

|  | Liquid soaps  |                                     | Solid soaps                                |                                     | Shampoos                                   |                                     | Hair conditioners                          |                                     |
|--|---|-------------------------------------|--|-------------------------------------|--|-------------------------------------|--|-------------------------------------|
|  | Maximum amount (Frame formulations COLIPA <sup>46</sup> ) | Estimated amount (Technical report) | Maximum amount (Frame formulations COLIPA) | Estimated amount (Technical report) | Maximum amount (Frame formulations COLIPA) | Estimated amount (Technical report) | Maximum amount (Frame formulations COLIPA) | Estimated amount (Technical report) |
| Percentage of surfactants in product (% w/w) | 93%   | 12.2%                               | 5%   | -                                   | 70%  | 10%                                 | 15%  | 1.8%                                |

Note: Concentration includes anionic and no-ionic surfactants, amphoteric surfactants and cationic surfactants.

#### Proposal regarding Criterion 4: Anaerobic biodegradability (annbotox)

- Decrease limits to apply to anNBDO (Anaerobic Non-Biodegradable Organics).

#### Motivation

As mentioned above the basic elements used for classification for 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 water has the potential to exert toxicity over a wide temporal and spatial scale<sup>47</sup>.

Other Ecolabel systems have stricter criteria for these substances. For Nordic Ecolabel criteria, limits for not anaerobically degradable substances are also tighter than current EU Ecolabel criteria:

<sup>46</sup> COLIPA GUIDELINES. Cosmetic Frame Formulations. Guidelines realized in collaboration with the European Association of Poison Centres and Clinical Toxicologists (EAPCCT). January 2000.

<sup>47</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

**Table 12. anNBO values for Nordic Ecolabel and EU Ecolabel**

|                       | Nordic Ecolabel | EU Ecolabel     |
|-----------------------|-----------------|-----------------|
|                       | anNBO (mg/g AI) | anNBO (mg/g AC) |
| Liquid soap, shampoo, | 15              | 25              |
| Hair conditioner      | 15              | 50              |
| Solid soap            | 5               | 15              |

65% of stakeholders consulted agree with decreasing the limits to anNBDO. Some comments referred to the fact that anNBDO values for some substances can be difficult to obtain and prove, if they are not in DID list.

#### Proposal regarding Criterion 5: Fragrances

- Discuss if sensitizing substances should be further restricted (see criterion 8) or limited to 0.01%. Discuss why a total ban is not possible. Consider possible extension of the scope of criterion 5 to substances other than fragrances which are known to act as sensitizers for allergic skin reaction and contact dermatitis.

#### Motivation

Fragrances are sensitizers and known triggers of allergic reactions such as asthma and contact dermatitis<sup>48</sup>. In 1999, the Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers (SCCP), based on dermatological data reflecting the clinical experience<sup>49</sup>, identified and prepared a list with the 13 most frequently reported contact allergens.

Sensitizing substances are 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. It is proposed to consider and discuss during the AHWG meeting if these classified substances<sup>50</sup> or is one of the 13 fragrances mentioned in the below table, should be restricted to 0.01% (100 ppm) in rinse-off products.

<sup>48</sup> <http://www.rivm.nl/bibliotheek/rapporten/320025001.pdf>

<sup>49</sup> [http://ec.europa.eu/health/archive/ph\\_risk/committees/sccp/documents/out93\\_en.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out93_en.pdf)

<sup>50</sup> As it is also done in the Commission Decision for the award of the EU Ecolabel for laundry detergents.

**Table 13. Fragrances chemicals most frequently reported as contact allergens**

| SUBSTANCES                                   | 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   |
| 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    |

Some other ecolabels as e.g. Nordic Swan<sup>51</sup> restrict the use of multiple fragrances in their criteria for shampoo, conditioners, body shampoo, liquid and solid soap.

65% of the stakeholders consulted agreed to limit sensitizing substances to 0.01%.

In any case stakeholders are asked to provide further feedback and discuss if a total ban is possible. Further, consider possible extension of the scope of criterion 5 to substances other than fragrances which are known to act as sensitizers for allergic skin reaction and contact dermatitis.

#### **Proposal regarding Criterion 6: Dyes or colouring agents**

- According to CLP, a colouring agent or dye will be considered to be potentially bio-accumulating if the experimentally determined BCF is  $\geq 500$  or  $\log Kow \geq 4$ .
- Discussion point whether the scope of this criterion should be extended also to other substance groups other than dyes or colouring agents

<sup>51</sup> Nordic Ecolabelling of cosmetic products Version 2.1 • 12 October 2010 – 31 December 2014

## Motivation

The thresholds given in criterion 6 should be changed so that they are in line with CLP Regulation<sup>52</sup>. According to CLP criteria:

*"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 Kow  $\geq 4$  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  $\geq 500$  is indicative of the potential to bioconcentrate for classification purposes. "*

Therefore the following parameter in the new criteria documents should be as follows:

- BCF  $\geq 500$  (instead of  $> 100$ )
- Log Kow  $\geq 4$  (instead of 3)

59% of the consulted stakeholders agreed that the thresholds should be changed to be in line with CLP Regulation.

Another option put for discussion is to change the determination of a "substance which is potentially bio-accumulating" as presented above but to keep the stricter –and currently in force– thresholds based on the precautionary principle. Stakeholders are requested for comments regarding this option

- Discussion point whether the scope of this criterion should be extended also to other substance groups founding the final product other than dyes or colouring agents

## Proposal regarding Criterion 7: Biocides

- **Point 1** - According to CLP, biocides must not be potentially bioaccumulating (i.e. BCF is  $< 500$  or log Kow  $< 4$ ).
- **Point 2** - Discuss which substances should be additionally restricted:
  - o Triclosan
  - o Parabens
  - o Formaldehyde
  - o 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.

<sup>52</sup> 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 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>

## Motivation

- **Point 1** - Thresholds should be in line with CLP Regulation<sup>53</sup>.

As mentioned in the previous criterion, according to CLP criteria:

*"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 Kow  $\geq 4$  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  $\geq 500$  is indicative of the potential to bioconcentrate for classification purposes. "*

The values two parameters Log Kow and BCF :

- BCF  $\geq 500$  (instead of  $> 100$ )
  - Log Kow  $\geq 4$  (instead of 3)
- **Point 2** - Restricted substances:  
**Triclosan** (5-chloro-2-(2,4-dichlorophenoxy)phenol ) - Triclosan<sup>54</sup> is a preservative added to soaps, hair conditioners and shaving cream products. Triclosan is classified as an agent that may cause adverse environmental effects<sup>55</sup>. Based on its classification<sup>56</sup>, triclosan should be restricted: H410: very toxic to aquatic life with long lasting effects, H315: causes skin irritation and H319: causes serious eye irritation. Some other studies<sup>57</sup> have shown that the use of triclosan in cosmetic products is also a matter of concern from a toxicological point of view.
  - **Ethyl-, methyl-, propyl- and butyl-Parabens** - Parabens are used as preservatives. In 1999, the European Union adopted a Strategy on Endocrine Disruptors and committed significant resources to develop and classify a priority list of suspected endocrine disrupting chemicals<sup>58</sup>. 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

<sup>53</sup> 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>

<sup>54</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_166.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf).

<sup>55</sup> <http://vkm.no/dav/117573d6c4.pdf>.

<sup>56</sup> [http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031/AGGR-09e9b0f0-bf29-4975-8fba3a2dd0ac2be\\_DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031.html#L-137752f6-fbea-4638-b8d8-acce5e212979](http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031/AGGR-09e9b0f0-bf29-4975-8fba3a2dd0ac2be_DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031.html#L-137752f6-fbea-4638-b8d8-acce5e212979).

<sup>57</sup> <http://vkm.no/dav/117573d6c4.pdf>.

<sup>58</sup> [http://ec.europa.eu/environment/endocrine/strategy/short\\_en.htm](http://ec.europa.eu/environment/endocrine/strategy/short_en.htm).

disrupters (Category 1) under the EU strategy for endocrine disrupters. Safer alternatives to parabens exist<sup>59</sup>, and around 5,4% of products are now marketed as “paraben-free”:

It is proposed to discuss with the stakeholders whether ethyl-, methyl-, propyl- and butyl-Parabens should be restricted based on precautionary principle.

- **Formaldehyde** - Formaldehyde is used as a preservative. Formaldehyde is a known sensitizer and a known carcinogen. Based on its classification<sup>60</sup>: 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 it should be restricted.

Formaldehyde is already regulated and specifically excluded in Ecolabelling criteria e.g. for Thai Green Label.

- **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** – 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<sup>61</sup>. There are some studies that demonstrate that people exposed to formaldehyde releasers may experience an allergic reaction<sup>62</sup>.

53% of the stakeholders consulted agreed that the thresholds (see Point 1 above) should be in line with CLP Regulation and to restrict these specific preservatives (Point 2).

## Proposal regarding Criterion 8: Environmental hazardous ingredients

- **Point 1** - The product or any part of it shall not contain substances or mixtures meeting the criteria for classification with certain hazard classes or categories in accordance with CLP. All the implications of Ecolabel Regulation 66/2010 Article 6(6) have to be respected. Therefore it is proposed to expand H- phrases list similarly to recently developed EU Ecolabel criteria in other product groups and to formulate this criterion like done in recent Ecolabel decisions e.g. on detergents (see below).
- **Point 2** - Substances considered PBT (Persistent, Bioaccumulable and toxic), vPvB (very persistent and very bioaccumulable) and/or those having endocrine disrupting properties should be restricted.
- **Point 3** - Include some specified excluded ingredients:

<sup>59</sup> 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](http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html).

<sup>60</sup> [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](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).

<sup>61</sup> Final report. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E., 2006.

<sup>62</sup> [http://share.eldoc.ub.rug.nl/FILES/root2/2010/Formretof/de\\_Groot\\_2010\\_Contact\\_Dermatitis.pdf](http://share.eldoc.ub.rug.nl/FILES/root2/2010/Formretof/de_Groot_2010_Contact_Dermatitis.pdf).

- Substances included in the candidate list of Substances of Very High Concern (SVHC) for authorization should be restricted.
- Phthalates: Bis(2-methoxyethyl) phthalate, diisobutyl phthalate, dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP).
- D4 (octamethylcyclotetrasiloxane)
- Butylated Hydroxy Toluene (BHT)
- See criterion 7 for biocides which specified substances should be excluded: triclosan, parabens, formaldehyde and formaldehyde releasers.

**It is proposed to use the following criterion formulation for discussion:**

**Criterion: Excluded or limited substances and mixtures**

**Sub-criterion 1: Hazardous substances and mixtures**

According to the Article 6(6) of Regulation (EC) No 66/2010 on EU Ecolabel, the product or any part of it shall not contain substances or mixtures meeting the criteria for classification with the hazard classes in accordance with Regulation (EC) No 1272/2008 specified below nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006.

List of hazard statements:

| Hazard statement <sup>63</sup>                    | Risk Phrase <sup>64</sup> |
|---|---------------------------|
| 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                       |

<sup>63</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

<sup>64</sup> Council Directive 67/548/EEC with adjustment to REACH according to Directive 2006/121/EC of the European Parliament and of the Council and Directive 1999/45/EC of the European Parliament and of the Council as amended. .

|   |                       |
|---|-----------------------|
| 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 May damage fertility. May damage 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  | R48/25/24/23          |
| H373 May cause damage to organs                                     | R48/20/21/22          |
| H400 Very toxic to aquatic life                                     | R50/50-53             |
| 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 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                |

This criterion applies to all ingredients present in concentrations  $\geq 0.010\%$ , including preservatives, colouring agents and fragrances.

The use of substances or mixtures which upon processing change their properties (e.g. become no longer bioavailable, undergo chemical modification) in a way that the identified hazard no longer applies are exempted from the above requirement.

Concentration limits for substances or mixtures meeting the criterion for classification in the hazard classes or categories listed in the table above, and for substances meeting the criterion of Article 57 (a), (b) or (c) of Regulation (EC) No 1907/2006, shall not exceed the generic or specific concentration limits determined in accordance with the Article 10 of Regulation (EC) No1272/2008. Where specific concentration limits are determined, they shall prevail against the generic ones.

Concentration limits for substances meeting criteria of Article 57 (d), (e) or (f) of Regulation (EC) No 1907/2006 shall not exceed 0.1 % weight by weight.

*Assessment and verification:* 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.

#### **Sub-criterion '2: 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) No 66/2010 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 mixtures in concentrations higher than 0.010 %.

*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](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.

#### **Sub-criterion 3: Specified limited or excluded ingredients -**

Point for discussion during the AHWG meeting.

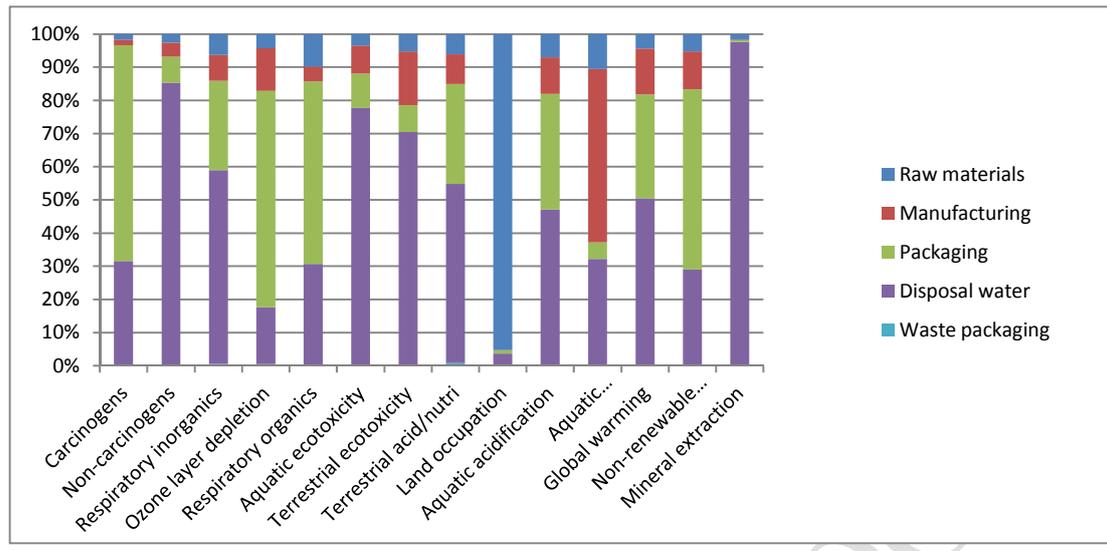
### **Motivation**

Limiting hazardous environmental impact from the product group of soaps, shampoos and hair conditioners 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 of this product group have relevant load in the general environmental impact of these products, i.e. 24% of the total environmental impact for solid soaps, the 19% for hair conditioners, 7% for shampoos and 5% 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. In Figures 2, 3, 4 and 5 the distribution of environmental impact for each product and the contribution of each life stage to different environmental impact categories is presented.

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

**Figure 2. Distribution of environmental impact for midpoints impact categories (liquid soap)**



**Figure 3. Distribution of environmental impact for midpoints impact categories (solid soap)**

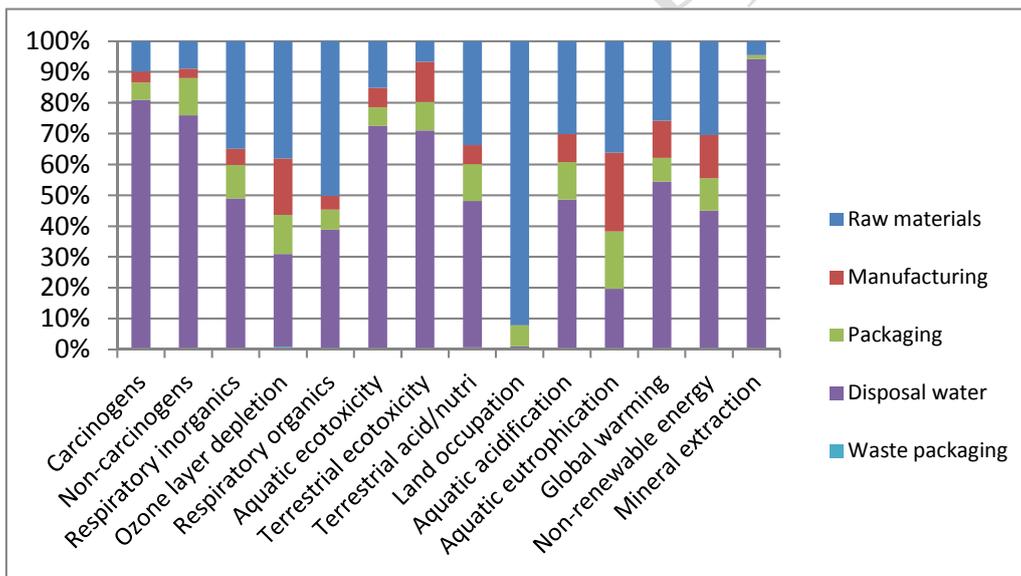


Figure 4. Distribution of environmental impact for midpoints impact categories (hair conditioners)

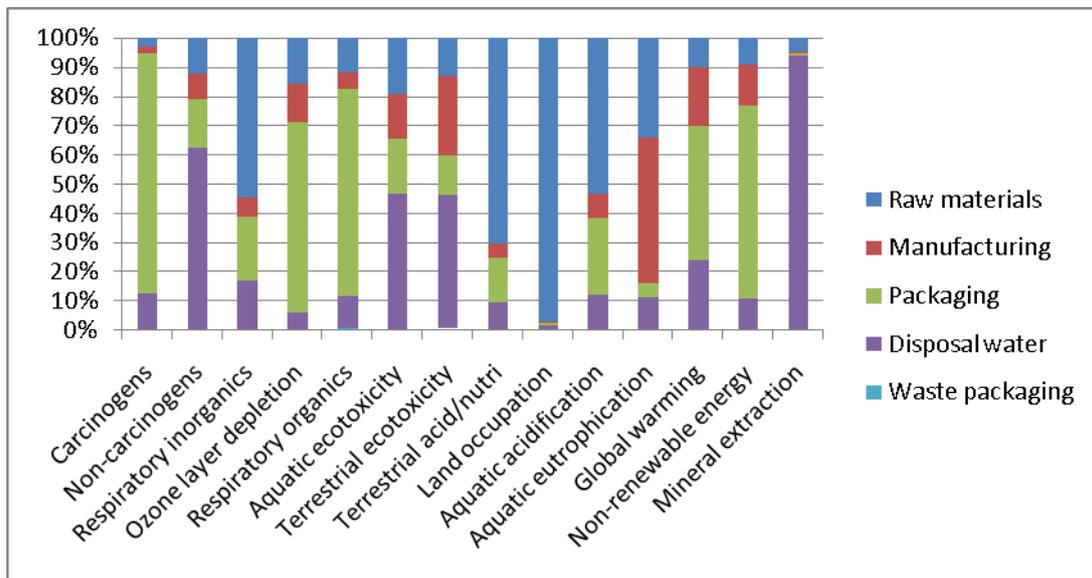
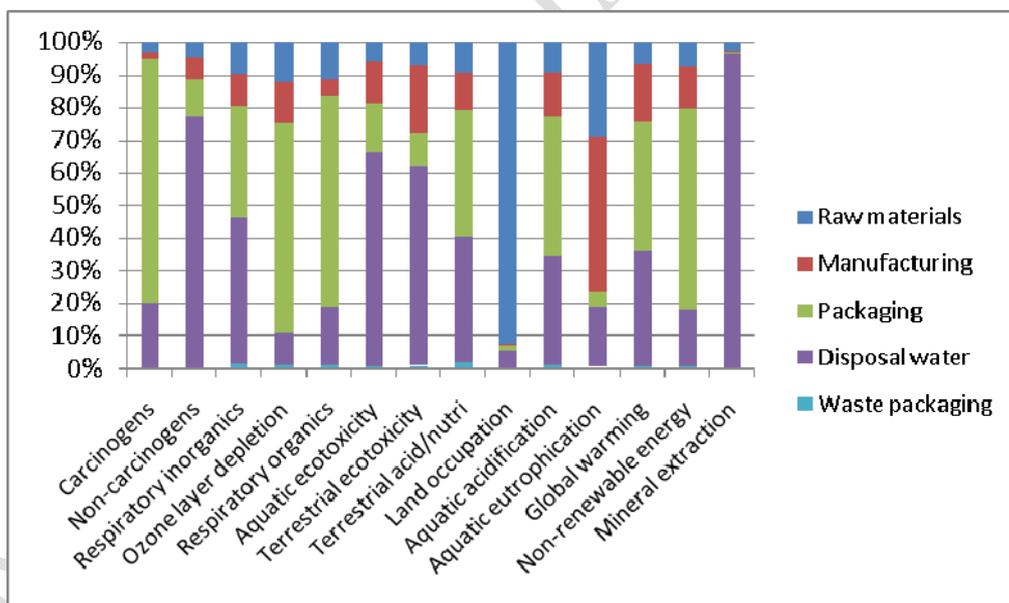


Figure 5. Distribution of environmental impact for midpoints impact categories (shampoo)



The following requirements about environmental hazardous ingredients have been proposed in the recent Commission decisions about awarding the products with the EU Ecolabel:

- **Hazardous substances:** According to the Article 6(6) of EU Ecolabel legislation EC/66/201065, the product or any part of it shall not contain substances or mixtures meeting the criteria for

<sup>65</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:027:0001:0019:EN:PDF>.

classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with CLP Regulation (EC) No 1272/2008, nor to goods containing substances referred to in Article 57 of REACH Regulation.

Hazardous substances can be classified through the hazard statements provided in Appendix III.

- Some specific substances that should be restricted based on article 6.7 of Ecolabel Regulation 66/2010
- Following the previous point and being proactive (precautionary principle) some specific substances are also considered to be restricted :
  - Substances included in the candidate list<sup>66</sup> of **Substances of Very High Concern (SVHC) for authorization**<sup>67</sup> according to REACH regulation. Currently there are 73 substances in the candidate list.
  - **Phthalates** - Some phthalates can be found in rinse-off cosmetic formulations. It is assumed that they are added in the perfume mix. Phthalates such as Bis(2-methoxyethyl) phthalate, diisobutyl phthalate, dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP), should be restricted because they are classified as toxic for reproduction and present in the candidate list of Substances of Very High Concern for authorisation according to REACH regulation.

On February 17, 2011 the European Commission named 6 chemicals as the first entrants on the Authorization list<sup>68</sup>, known as Annex XIV, which means that the next substances: dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP) were moved from the candidate list to the authorisation list under the EU REACH regulation (see Table 14).

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<sup>66</sup> 73 substances in the Candidate List [http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp#download](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp#download).

<sup>67</sup> 73 substances in the Candidate List [http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp#download](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp#download).

<sup>68</sup> COMMISSION REGULATION (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH') <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2011R0143:20110221:EN:PDF>.

Table 14. Substances subjected to authorization, Annex XIV of REACH regulation

| Substance name                                   | EC Number | CAS Number | Classification                        |
|--|-----------|------------|---------------------------------------|
| Bis(2-methoxyethyl) phthalate <sup>69</sup>      | 204-212-6 | 117-82-8   | Toxic for reproduction (article 57 c) |
| Diisobutyl phthalate <sup>70</sup>               | 201-553-2 | 84-69-5    | Toxic for reproduction (article 57c)  |
| Dibutyl phthalate (DBP) <sup>71</sup>            | 201-557-4 | 84-74-2    | Toxic for reproduction (article 57c)  |
| Benzyl butyl phthalate (BBP) <sup>72</sup>       | 201-622-7 | 85-68-7    | Toxic for reproduction (article 57c)  |
| Bis (2-ethylhexyl)phthalate (DEHP) <sup>73</sup> | 204-211-0 | 117-81-7   | Toxic for reproduction (article 57c)  |

- **D4 (octamethylcyclotetrasiloxane)** CAS 556-67-2 is used as an emollient or solvent although is not in the list of most commonly used substances. Based on its classification<sup>74</sup> 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 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 in cosmetic products. It is classified as H410 (R50/53) - very toxic to aquatic life with long lasting effects<sup>75</sup>. Based on the classification, it should be restricted.

59% of consulted stakeholders agreed with this proposed amendment in the criterion regarding substances.

### Proposal regarding Criterion 9: Packaging

The following issues are proposed for discussion during the AHWG meeting:

- **Point 1** - The Weight/Content Relationship (WCR) should be calculated taking into account **refillable and refill packaging**:

<sup>69</sup> Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/d60da5c8-85de-4cb2-b95a-fada9451373b>.

<sup>70</sup> Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/d418f8b0-ba93-402a-97fd-1e340d22c541>.

<sup>71</sup> Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/5196d655-7b11-41b2-acba-c8709064fac8>.

<sup>72</sup> Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/19fd114d-eb69-4012-a107-8ceb97787733>.

<sup>73</sup> Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/b8395d41-b6d5-427c-8294-d46997e8835d>.

<sup>74</sup> [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](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).

<sup>75</sup> [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](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).

$$WCR = \sum(((Wirefillable/r + Wirefill)+ Ni)/(Di \times r))$$

Where;

$D_i$  = 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).

$Wirefillable$  = the weight (in grams) of refillable packaging-component  $i$

$Wirefill$  = the weight (in grams) of refill packaging-component  $i$

If there is not any refillable/refill packaging, then,  $Wirefillable = W_i$ ,  $r=1$  and  $Wirefill=0$

$N_i$ : 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  $N_i = W_i$ .

- **Point 2** - More restringing **weight limit** (< 0,3 g packaging/g product) ). Proposal of limit  $WCR < 0.2$
- **Point 3** - Packaging shall not contain **substances included in the candidate list of Substances of Very High Concern (SVHC)** for authorization.
- **Point 4** – Specific Packaging requirements for each kind of material used: plastic, metal, paper and cardboard.
- **Point 5** - It should be possible to **separate all materials in the packaging** (paper, cardboard, plastic, metal) for sorting. Parts comprising mixed materials that cannot be separated should be restricted, with the exception of pump parts.

## Motivation

**Packaging has an important load** in the overall life cycle impact of product. On average 25% of products' impact comes from packaging and waste packaging (according to life cycle assessment carried out in the framework of the current study). Impacts of packaging come mainly from the material used (derived from resources and energy used for producing packaging materials). It is thus very important to address the weight, materials and characteristics of packaging in the Ecolabel criteria in order to minimize its environmental impact.

- **Point 1 - Refilling systems** (where two kinds of packaging, refillable and refill, exist for a product) allow an important packaging material reduction, so it is important to include them in Ecolabel criteria. Some soap products have the option of refilling or reusable package, where the refill package is usually lighter than the conventional package. It is quite usual in hand-soaps where refilling package have a dispenser and refill package is a more simple bottle, but there exist some other soap products with refill packaging such as body liquid

soap. Among all liquid soaps products of European market, 10% have refilling systems<sup>76</sup>. For shampoos, only 26 products have been found with refilling system (0.02%), and 2 conditioners products (0.04%)<sup>77</sup>.

Refilling system can provide a packaging saving of the 79% of weight, which can be converted to a 79% of saving of environmental impact of packaging stage<sup>78</sup>, as it is mainly produced from raw material and in material manufacturing. The assessment done shows that environmental impacts are directly proportional to the weight<sup>79</sup>. For instance, in accordance with the results obtained in the technical analysis, in the case of liquid soaps, by using a refilling system, the packaging impact contribution can decrease from 25% to 10%, and the total environmental impact of the product decrease by 27% with respect the original soap with non-refill packaging.

**Recycled material** allows to decrease the use of raw materials and to save resources and energy used for producing packaging. **Degradable polymers** allow using a renewable resource for manufacturing packaging and also guarantee increased degradability of packaging waste. It is proposed to consider differentiating these two kinds of polymers from other polymers in weight calculation method in the revised criteria.

- **Point 2** - Impact of packaging is directly related to its **amount**, as the main environmental impacts are coming from material used. Initiatives that reduce the amount of raw material used, such as refilling systems and recycling process, allow minimizing the environmental impact of packaging, and as a result, the environmental impact of the entire product.
- The current weight/content relation limit is 0.3 g of packaging for g of product. In 2006 it was determined that the average ratio amounted 0.05 – 0.1 g packaging/g product<sup>80</sup>. Current data for weight packaging for studied products has not been available, therefore stakeholders feedback is asked to complement the analysis conducted. Nevertheless, according to Ecoembes<sup>81</sup>, weight packaging for packaged products in Spain has decreased by 6% from 2006 to 2010. It is 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. Ecolabelled products should be different (i.e. better performing from the environmental point of view) from average marketed product in terms of formulations, but also in packaging.

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<sup>76</sup> Mintel GNPD Data Base. Category: liquid soaps. 2012.

<sup>77</sup> Source Mintel GNPD Data Base.

<sup>78</sup> Data obtained from direct calculation for a refilling product of liquid soap

<sup>79</sup> 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](http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html).

<sup>80</sup> Final report. For the development of ecolabelling criteria. EU Eco-label for shampoo and soaps. Ecolabelling Norway. Eskeland,, M.B, Svanes, E. May 2006.

<sup>81</sup> [www.ecoembes.com](http://www.ecoembes.com).

- **Point 3:** Packaging shall not contain **substances** included in the candidate list of Substances of Very High Concern (SVHC) for authorization. Some common substances of concern used in plastic materials are indicated in Table 15:

**Table 15. 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<br>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>

**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 for restricting packaging material are not proposed in this document. Restrictions are proposed regarding the weight and substances used in the packaging materials.

- **Point 4 – Specific packaging requirements for each kind of material used:** plastic, metal, paper and cardboard. The following requirements regarding packaging materials are proposed for discussion at the AHWG meeting:

- **Plastic:** shall not contain the substances included in the candidate list of Substances of Very High Concern (SVHC) for authorization. Stakeholders' feedback is asked to verify if some substances listed in Table 15 above are used in the packaging of the products under study.
- **Paper/cardboard packaging:** Chlorine shall not be used to bleach. Chlorine gas is classified as<sup>82</sup> 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<sup>83</sup>. In accordance with the EU Ecolabel for tissue paper<sup>84</sup> and for copying and graphic paper<sup>85</sup>, chlorine gas shall not be used as a bleaching agent.
- **Metal:** Metal packaging is used for some products proposed in the scope extensions. It has higher environmental impact than packaging made of plastic, among other due to higher energy demand. Moreover, metal aerosols can only be made of virgin materials for safety reasons. Metal packaging should only be used in EU ecolabelled products when it is necessary, that is, only in the case of aerosols for shaving products (in case they are finally included in the scope of this product group). It is considered that metal packaging for other products should be not allowed, as there are several alternative materials which are more environmentally friendly for this kind of product (short life time products).

- **Point 5 - Recyclability** of waste packaging is of high importance. From a product related 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 since 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). Biopolymer present advantages with regard to waste degradation.<sup>86</sup>

<sup>82</sup> [http://apps.echa.europa.eu/registered/data/dossiers/DISS-a6516d11-7da2-57f1-e044-00144f67d249/AGGR-585ca394-3912-4434-bd0f-a9a1fddbe4e8\\_DISS-a6516d11-7da2-57f1-e044-00144f67d249.html#section\\_1.1](http://apps.echa.europa.eu/registered/data/dossiers/DISS-a6516d11-7da2-57f1-e044-00144f67d249/AGGR-585ca394-3912-4434-bd0f-a9a1fddbe4e8_DISS-a6516d11-7da2-57f1-e044-00144f67d249.html#section_1.1).

<sup>83</sup> <http://chm.pops.int/Convention/ThePOPs/ListingofPOPs/tabid/2509/Default.aspx>.

<sup>84</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:197:0087:0095:EN:PDF>.

<sup>85</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:149:0012:0024:EN:PDF>.

<sup>86</sup> 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](http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html).

EU Ecolabel criteria should work and try to ensure the **recyclability** of all components of packaging. All materials in the packaging should be separable (paper, cardboard, plastic, metal, glass) for sorting. Packaging elements such as caps or labels have to also be considered to ensure that these elements do not pose difficulties in recycling processes.

41% of stakeholders consulted agreed on proposed amendment of the criteria on packaging.

#### Proposal regarding Criterion 10: Fitness for use

- Proposal to consider a more stringent consumer testing.

#### Motivation

The criterion on fitness for use addresses currently the aspects of performance, dosage and application.

Environmental assessment conducted in this study has showed that high percentage of total environmental impact of products is due to the use stage (28% of contribution on average for all products), coming from the consumption of water during washing action. Some characteristics of the product, such as the ease for being rinsed-off or long-lasting results, would contribute to saving water during use, minimizing the overall environmental impact of products.

Quality of products awarded with the EU Ecolabel is one of important aspects of the scheme in order to prevent creating the image that ecolabelled products are “environmentally friendlier but poor in performance/inefficient”. For that reason performance test should address all important characteristics and functions of the product.

It is proposed to discuss whether a more stringent consumer test should be required for this product group. It could address the following aspects:

- 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.

Further issues for consideration are 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 of the main function of the product, the performance test make reference to the characteristics with which each product is sold/marketed (hydrating, moisturizing, softening, etc.)?

35% of stakeholders consulted disagreed on introducing a more stringent consumer test.

#### **Proposal regarding Criterion 11: Information appearing on the eco-label**

Depending on the final formulation of the revised criteria, the optional label with text box could contain the following text:

- Limited use of hazardous substances

#### **Motivation**

According to Article 8 (3b) of Regulation (EC) No 66/2010, for each product group, three key environmental characteristics of the ecolabelled product may be displayed in the optional label with text box. This issue is left for discussion after the revised criteria are agreed.

### **7.4 NEW/ADDITIONAL PROPOSED CRITERIA**

#### **a) Introduction of new requirements concerning energy consumption in industries.**

Another issue which is proposed for consideration refers to limit values to be applied for energy consumption in product's manufacturing.

#### **MOTIVATION**

Manufacturing of cosmetic products is also an important part of their life cycle. According to LCA carried out in the technical analysis, it accounts for an average 8% of total environmental impact of the products under study.

According to sustainability reports from individual companies, many initiatives have been already developed to reduce environmental impact of manufacturing, mainly in terms of water and energy consumption. In the document "Good sustainability practice (GSP) for the cosmetics industry" some good practices has been identified to improve energy efficiency of manufacturing processes<sup>87</sup>:

Among them there are the following practices:

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<sup>87</sup> Good sustainability practice (GSP) for the cosmetics Industry. COLIPA ([colipa.eu/downloads/3704.html](http://colipa.eu/downloads/3704.html))

- Reducing temperature during manufacturing or filling by application of new technologies such as cold emulsification technology,
- Exploring options for optimisation of cleaning procedures with the aim of using less washing water and/or reducing its temperature,
- Considering insulation measures for buildings (walls, windows) to reduce energy consumption for heating and air conditioning; same for hot water piping,
- Exploring options for optimisation of production planning (sequence of batches produced using same equipment), ideal sequence may save some washing steps,
- Considering replacement of old equipment by new, energy efficient electrical devices (e.g. pumps, extruders),
- Considering 'energy recycling' from hot waste water or air.

In order to propose limits, real values of energy used in manufacturing processes of each kind of products would be necessary and manufacturer stakeholders are asked for their feedback in this respect.

Only 35% of the stakeholders consulted agreed on this proposed requirement on energy consumption. Based on the results of some questionnaires, this new proposed criterion has not been well received. General comments are that such requirement is very difficult to set up (especially for small companies) and will increase complexity for little added value, because the energy consumption in production is very limited compared to the use phase.

Further stakeholders feedback is welcome for the discussion to be conducted during the AHWG meeting

**b) New criteria about chemicals and substances used in formulations specific for infants, babies and children products.**

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.

It is proposed to consider restriction on perfumes/fragrances used in formulations intended for infants, babies and child products. Any substance raising concerns regarding allergic reactions such as asthma and contact dermatitis should be totally restricted if this is practical and technical feasible

## MOTIVATION

It is proposed that use of perfume in products for infant, baby and/or children of age below 3 years, should be restricted. 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**.

In Table 15 below, the shares of perfume-free products are indicated for each product group. In Table 16, the shares of baby products in the entire product group are given, together with the percentage of perfume-free products among all baby products.

**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*

**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*

47% of consulted stakeholders agreed on introducing restrictions on perfumes in infants, babies and children products.

Following this, it is proposed also to consider a restriction on any substance raising concerns regarding allergic reactions such as asthma and contact dermatitis. A complete ban if this is practical and technical feasible should be investigated and discussed with the stakeholders.

Stakeholders are requested to provide feedback on this

## 8. FURTHER DISCUSSION POINTS

### a) Addressing nanomaterials in EU Ecolabel.

One of the issues for discussion may refer to the question if nanomaterials and/or nanoparticles insoluble or biopersistent should be restricted. A horizontal task force within the frame of EUEB about how nanomaterials shall be addressed and/or regulated for all the different product groups within the EU Ecolabel is going to work and provide feedback.

In the meanwhile it is proposed for the current product group to discuss with stakeholders if a potential inclusion of requirements regarding nanomaterials is relevant.

If nanomaterials shall be regulated due to concerns related to their potential health and environmental risks then an inclusion of a respective text in Criterion 8 (with respect to article 6.6 of Ecolabel Regulation 66/2010) could be considered.

### MOTIVATION

Nanomaterials used in cosmetics (in sunscreens, skin care and toothpaste) are, in essence, nanoemulsions and nanopigments. Nanomaterials safety has been assessed by MS Ecolabel of COLIPA in order to guarantee that nanomaterials used in cosmetic are safe<sup>88</sup>.

Nanoemulsions are macroscopic preparations containing oil and water droplets reduced to nanometric size to increase the content of nutritious oils while preserving the transparency and the lightness of the formulas. Nanoemulsions do not cross the skin barrier. In general public health agencies worldwide have not restricted or regulated nanomaterials due to the current lack of information regarding their potential health and environmental risks.<sup>89</sup>

Nanopigments such as titanium dioxide (TiO<sub>2</sub>) and zinc oxide (ZnO) are minerals used in sunscreens for their capacity to reflect and scatter UV light thus protecting human skin against adverse effects of UV radiation, including skin cancer<sup>90</sup>. In sunscreen lotions, nano TiO<sub>2</sub> is present in large clusters which size is much greater than 100 nm to ensure optimal protection of the skin. Studies, including

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<sup>88</sup> <http://www.colipa.eu/safety-a-science-colipa-the-european-cosmetic-cosmetics-association/products-and-ingredients/nanotechnology.html>

<sup>89</sup> For details see the following publications:

Imbert D and Wickett R: Topical delivery with liposomes. *Cosmetics and Toiletries magazine*. 1995; 111:32-45.

Honeywell-Nguyen P et al.: Quantitative assessment of the transport of elastic and rigid vesicle components and a model drug from these vesicle formulations into human skin in vivo. *J. Invest. Derm.* 2004; 123(5):902-10.

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US FDA, Nanotechnology Report 200 [www.fda.gov/nanotechnology/taskforce](http://www.fda.gov/nanotechnology/taskforce); British Standards Institute, PAS 130:2007, Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles.

<sup>90</sup> IARC Handbooks of Cancer Prevention: Sunscreens. World Health Organization, Lyon 2001.

Lademann J, et al.: Penetration of TiO<sub>2</sub> microparticles in a sun screen formulation into the horny layer and the follicular orifice. *Skin Pharmacol. Appl. Skin Physiol.* 1999, 12: 247-256.

Dussert A, et al.: Characterization of the mineral content of a physical sunscreen and its distribution onto human stratum corneum. *Int. J. Cosm. Sci.* 1997, 19: 119-129.

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Mavon A, et al.: In vitro Percutaneous Absorption and in vivo Stratum Corneum Distribution of an Organic and a Mineral Sunscreen. *Skin Pharmacol. Physiol.* 2007, 20:10-20.

those undertaken within the framework of the European Union research programme NANODERM, concluded that nanopigments do not cross the skin barrier, even in cases where the skin is damaged, such as with psoriasis<sup>91</sup>.

According to information gathered, there is no established specific risk confirmed for nanotechnology<sup>92</sup>. Recent studies concluded that titanium dioxide and zinc oxide nanopigments do not show –ecotoxic properties and therefore a harm to the environment cannot be identified yet<sup>93</sup>.

Stakeholders' feedback related to the potential use of nanomaterials/particles in the cosmetic products covered by the scope of the product group is welcome, as well as comments regarding the criteria related to nanomaterials in the revised EU Ecolabel for soaps, shampoos and hair conditioners.

### **b) Renewable sources ingredients**

Finally, future criteria could also be considered regarding use of renewable ingredients in order to limit the use of fossil fuel based ingredients and to promote vegetable based ingredients. Discussions and different studies exist about possibilities of substitution of non-renewable ingredients, although some issues as economic or ecological impacts of vegetable ingredients' production have to be assessed and further considered.

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<sup>94</sup>:

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

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<sup>91</sup> Butz T, et al.: No evidence for nanoparticle penetration into living skin. Preliminary data presented at ECETOC, Barcelona, 2005.

Pinheiro T, et al.: The influence of corneocyte structure on the interpretation of permeation profiles of nanoparticles across skin. Nucl. Instru. and Meth. in Phy. Res. B 2007, 260:119–123.

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Filipe P, et al: Nanotoxicity of TiO<sub>2</sub> and ZnO containing sunscreens versus the stratum corneum barrier dogma. Expt.Tox. 2008 in press.

Sugibayashi K, et al.: Safety evaluation of TiO<sub>2</sub> nanoparticles by their absorption and elimination profiles. J. Tox. Sci. 2008 in press.

<sup>92</sup> Stern S, et al: Nanotechnology safety concerns revisited. Tox. Sci. 2008, 101:4-21.

<sup>93</sup> Margit Heinlaan M, et al.: Toxicity of nanosized and bulk ZnO, CuO and TiO<sub>2</sub> to bacteria *Vibrio fischeri* and crustaceans — *Daphnia magna* and *Thamnocephalus platyurus*. Chemosphere, 2008, doi: 10.1016/j. chemosphere.2007.11.047.

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<sup>94</sup> Procter & Gamble ([http://www.scienceinthebox.com/en\\_UK/programs/natural\\_synthetic\\_en.html](http://www.scienceinthebox.com/en_UK/programs/natural_synthetic_en.html))

In the revision of the Nordic Ecolabel for cosmetic products of 2011<sup>95</sup>, the possibility of limit the amount of non-renewable materials was discussed. But it was decided not to set general requirements regarding renewable raw materials (though a voluntary requirement was set). Many aspects need to be considered, e.g. energy consumption during production of the raw material, comparison between the extraction and transportation of renewable and non-renewable materials. The sustainability and traceability of renewable raw materials constitute a challenge, and it is expected to be difficult for manufacturers to get proper documentation to prove sustainability of ingredients, especially since the raw materials used in cosmetic industry are often mixtures originating from different sources. Such a requirement could significantly limit the quantity of raw materials available to the manufacturers.

Nordic Ecolabelling decided not to set a general requirement for renewable raw materials yet, although both consumers and licensees indicated a wish for Nordic Ecolabelling to expand this area and consider the issue of renewable raw materials in the future. It was concluded that it was necessary to investigate the matter further ahead of future revisions.

Stakeholders' feedback on this issue is very welcome. Further investigation will be conducted in the further part of the project, if considered as appropriate at the AHWG meeting.

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<sup>95</sup> Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011

## 9. BIBLIOGRAPHY AND REFERENCES

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Commission Decision of 28 April 2011 on 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>

Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetics products (76/768/EEC) (OJL 262, 27.9.1976,P.169): <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0768:20100301:en:PDF>.

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for the labelling of cosmetic products. OJL 140, 23/06/1995 P. 0026-0029: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0017:en:HTML>

Council Directive 80/232/EEC of 15 January 1980 on the approximation of the laws of the Member States relating to the ranges of nominal quantities and nominal capacities permitted for certain prepackaged products. OJL 51, 25.2.1980, p. 1-7. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31980L0232:en:HTML>.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. OJL 365, 31.12.1994, p. 10-23. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994L0062:en:HTML>

ISO 14024:1999 Environmental labels and declarations - Type I environmental labelling - Principles and procedures.

#### **Other sources**

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COLIPA: Good sustainability practice (GSP) for the cosmetics Industry. (available online at: [colipa.eu/downloads/3704.html](http://colipa.eu/downloads/3704.html))

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

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

Nordic Ecolabelling Cosmetic products 090 Background document – 16 February 2011

Nordic Ecolabelling of Cosmetic products. Version 2.1. 12 October 2010 – 31 December 2014.

## 10.APPENDIX I: RESULTS OF QUESTIONNAIRES

### 10.1 APPENDIX I.I: SUMMARISED OUTCOMES OF THE QUESTIONNAIRES ON CURRENT ECOLABEL CRITERIA

The results of questionnaires which were sent to relevant stakeholders with the aim to collect their opinions and comments about applicability of the current Ecolabel criteria are summarized in the following tables. 17 filled responses to the questionnaire were received from the stakeholders registered for the revision process. The questionnaire is available at the project's website: [http://susproc.jrc.ec.europa.eu/soaps\\_and\\_shampoos/stakeholders.html](http://susproc.jrc.ec.europa.eu/soaps_and_shampoos/stakeholders.html).

Table 4.1 Results of questionnaires on current Ecolabel criteria

| CURRENT ECOLABEL   | CRITERION 1 |    |    |      | CRITERION 2 |    |    |      | CRITERION 3 |    |    |      | CRITERION 4 |    |    |      | CRITERION 5 |    |    |      | CRITERION 6 |    |    |      |     |    |    |
|--|-------------|----|----|------|-------------|----|----|------|-------------|----|----|------|-------------|----|----|------|-------------|----|----|------|-------------|----|----|------|-----|----|----|
|  | AVERAGE %   |    |    |      | AVERAGE %   |    |    |      | AVERAGE %   |    |    |      | AVERAGE %   |    |    |      | AVERAGE %   |    |    |      | AVERAGE %   |    |    |      |     |    |    |
|  | YES         | NO | NA | MARK | YES | NO | NA |
| 1) Is the formulation matching with the goal of Ecolabel criteria? | 82          | 6  | 12 | 1,4  | 71          | 18 | 12 | 1,6  | 82          | 6  | 12 | 1,6  | 65          | 24 | 12 | 2,0  | 65          | 18 | 18 | 1,9  | 82          | 6  | 12 | 1,9  |     |    |    |
| 2) Is the current verification procedure/test sufficient?          | 76          | 6  | 18 | 1,8  | 71          | 12 | 18 | 1,6  | 82          | 0  | 18 | 1,6  | 76          | 6  | 18 | 2,1  | 76          | 12 | 12 | 1,5  | 71          | 12 | 18 | 1,7  |     |    |    |
| 3) Is administrative work too high for the Competent Bodies?       | 47          | 35 | 18 | 1,4  | 53          | 29 | 18 | 1,3  | 47          | 35 | 18 | 1,7  | 47          | 35 | 18 | 1,6  | 53          | 29 | 18 | 1,3  | 47          | 35 | 18 | 1,4  |     |    |    |
| 4) Is administrative work too high for the applicants?             | 35          | 53 | 12 | 1,9  | 27          | 67 | 7  | 2,4  | 24          | 71 | 6  | 1,9  | 47          | 41 | 12 | 2,3  | 24          | 65 | 12 | 1,8  | 29          | 59 | 12 | 1,9  |     |    |    |

NA: No Answer

Mark 1 (best) to 5 (worse)

Table 4.1 Results of questionnaires on current Ecolabel criteria

| CURRENT ECOLABEL   | CRITERION 7 |    |    |      | CRITERION 8 |    |    |      | CRITERION 9 |    |    |      | CRITERION 10 |    |    |      | CRITERION 11 |    |    |      |
|--|-------------|----|----|------|-------------|----|----|------|-------------|----|----|------|--------------|----|----|------|--------------|----|----|------|
|  | AVERAGE %   |    |    |      | AVERAGE %   |    |    |      | AVERAGE %   |    |    |      | AVERAGE %    |    |    |      | AVERAGE %    |    |    |      |
|  | YES         | NO | NA | MARK | YES         | NO | NA | MARK | YES         | NO | NA | MARK | YES          | NO | NA | MARK | YES          | NO | NA | MARK |
| 1) Is the formulation matching with the goal of Ecolabel criteria? | 82          | 6  | 12 | 1,8  | 71          | 18 | 12 | 1,6  | 71          | 12 | 18 | 2,2  | 71           | 12 | 18 | 1,8  | 76           | 12 | 12 | 1,4  |
| 2) Is the current verification procedure/test sufficient?          | 82          | 0  | 18 | 1,7  | 76          | 6  | 18 | 1,8  | 82          | 0  | 18 | 1,6  | 59           | 24 | 18 | 2,1  |              |    |    |      |
| 3) Is administrative work too high for the Competent Bodies?       | 47          | 35 | 18 | 1,6  | 47          | 35 | 18 | 1,3  | 47          | 35 | 18 | 1,4  | 47           | 35 | 18 | 1,2  |              |    |    |      |
| 4) Is administrative work too high for the applicants?             | 24          | 65 | 12 | 1,7  | 24          | 65 | 12 | 1,7  | 18          | 59 | 24 | 2,3  | 29           | 53 | 18 | 1,5  |              |    |    |      |

NA: No Answer

Mark 1 (best) to 5 (worse)

## 10.2 APPENDIX I.2: OUTCOMES OF THE QUESTIONNAIRES ON THE PROPOSALS FOR THE NEW ECOLABEL CRITERIA

The results of questionnaires are summarized in this table which was sent to relevant stakeholders with the aim to know their opinion and criteria that need to be changed, withdrawn or prolonged.

Table 4.2 Results of questionnaires on proposal for amendments and new Ecolabel criteria

| CRITERIA                                | EXISTING EU ECOLABEL CRITERIA   | POTENTIAL CHANGES, MODIFICATIONS OR AMENDMENTS   | AGREE     |    |    |
|---|---|--|-----------|----|----|
|   |   |  | AVERAGE % |    |    |
|   |   |  | YES       | NO | NA |
| <b>1. Toxicity to aquatic organisms</b> | <p><b>Critical Dilution Volume (CDV)</b><br/> <math>CDV (\text{ingredient } i) = \text{weight } (i) \times DF (i) \times 1000/TF \text{ chronic } (i)</math><br/> <math>CDV = \sum CDV (\text{ingredient } i)</math></p> <p><b>Critical Dilution Volume (CDV):</b><br/>                     -Liquid soaps, shampoos, shower products and other liquid cleaning products <math>\leq 20\,000</math> L/g AC<br/>                     - Solid soaps <math>\leq 3\,500</math> L/g AC<br/>                     - Hair conditioners <math>\leq 30\,000</math> L/g AC</p>   | <ul style="list-style-type: none"> <li>Limits to apply of critical dilution volume toxicity (CDV) for each kind of products: soaps, shampoos and hair conditioners.</li> <li>Methodology to calculate CDV from latest version of DID list.</li> </ul>      | 41        | 41 | 18 |
| <b>2.Environmental harmful products</b> | <p>N, R50/53: <math>WR50/53/25 \% \leq 1</math><br/>                     N, R51/53: <math>(WR50/53/2,5 \% ) + (WR51/53/25 \% ) \leq 1</math><br/>                     R52/53: <math>(WR50/53/0, 25 \% ) + (WR51/53/2,5 \% ) + (WR52/53/25 \% ) \leq 1</math><br/>                     Rubbing/abrasive agents in hand cleaning agents are not included.</p>   | <ul style="list-style-type: none"> <li>Consider to include this in criterion 8 hazardous content.</li> </ul>   | 65        | 18 | 18 |
| <b>3. Aerobic biodegradability</b>      | <p><b>3a) Aerobic biodegradability of surfactants:</b> Each surfactant used in the product will be readily biodegradable.</p> <p><b>3b) Aerobic biodegradability of non-surfactants (a NBDO<sub>non-surf</sub>):</b><br/>                     aNBDO= milligrams of not aerobically degradable non-surfactants per gram active content<br/>                     - Liquid soaps, shampoos, shower products <math>\leq 30</math> mg/g AC<br/>                     - Solid soaps <math>\leq 15</math> mg/g AC<br/>                     - Hair conditioners <math>\leq 50</math> mg/g AC<br/>                     Rubbing/abrasive agents in hand cleaning agents are not included. All ingredients (substances or preparations) exceeding 0,010% by weight of the final product will be considered.</p> | <ul style="list-style-type: none"> <li>Biodegradability of organics.</li> <li>Surfactants biodegradability will be discussed if all surfactants must be readily aerobically and anaerobically biodegradable.</li> <li>Limits to apply to aNBDO.</li> </ul> | 47        | 24 | 29 |

|  |  |   |    |    |    |
|--|--|---|----|----|----|
| <b>4. Anaerobic biodegradability (annbo<sub>tox</sub>)</b> | <p>anNBDO= milligrams of not anaerobically degradable toxic ingredients per gram active content. Toxic ingredient: Lowest acute toxicity is &lt; 100 mg/l.</p> <ul style="list-style-type: none"> <li>-Liquid soaps, shampoos, shower products ≤ 25 mg/g AC</li> <li>- Solid soaps ≤ 15 mg/g AC</li> <li>- Hair conditioners ≤ 50 mg/g AC</li> </ul> <p>Rubbing/abrasive agents in hand cleaning agents are not included.</p>  | <p>Limits to apply to anNBDO.</p>   | 65 | 18 | 18 |
| <b>5. Fragrances</b>                                       | <p>Fragrance must have been manufactured, handled and applied in accordance with the code of practice of international Fragrance Association.</p>  |   | 65 | 12 | 24 |
| <b>6. Dyes or colouring agents</b>                         | <p>Organic dyes or colouring agents must not be potentially bio-accumulating.</p> <ul style="list-style-type: none"> <li>-BCF ≤ 100</li> <li>-log Pow ≤ 3</li> </ul>   | <p>Hair dye substances permitted for use in hair colouring products according Annex III of EU Cosmetics Directive.</p>  | 59 | 6  | 35 |
| <b>7. Biocides</b>   | <p>a)Biocides 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.</p> <p>b) Biocides with classification R50-53 are only permitted if they are not potentially bio-accumulating (BCF &lt; 100 or log Pow &lt;3,0).</p> <p>c) Preservatives must not release substances that are classified with the criterion 8a.</p>  | <p>Discuss which substances should be restricted: Triclosan, Parabens (4-Hydroxybenzoic acid and its salts and esters)...</p>   | 53 | 18 | 29 |
| <b>8. Environmental hazardous ingredients</b>              | <p>The requirements concern all ingredients (substances or preparations) exceeding 0,010 % by weight of the final product.</p> <p><b>a)Classified ingredients</b><br/>No constituent substance must be classified as CMR, toxic and hazardous to the environment in accordance with CLP or substances referred to in Article 57 of REACH. Maximum 0,1% (w/w) for substances that meet the criteria of Article 57 present in mixtures or in an article.</p> <p><b>b)Specified excluded ingredients</b><br/>-Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives<br/>-NTA (nitrilo-tri-acetate)<br/>-Boric acid, borates and perborates<br/>-Nitromusks and polycyclic musks</p> <p><b>c)Specified limited ingredients</b><br/><b>EDTA</b> and its salts and non-readily biodegradable phosphonates may only be added to solid soaps and only to a maximum content of 0,6 mg/g AC.</p> | <ul style="list-style-type: none"> <li>- Consider if the requirements should concern all ingredients (substances or preparations) exceeding 0,010% on net weight of the product without packaging weight</li> <li>- Consider to expand R- and H- phrases list similar to recently developed EU Ecolabel criteria in other product groups</li> </ul> | 59 | 12 | 29 |

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|   |   |   |    |    |    |
|---|---|---|----|----|----|
| <b>9. Packaging</b>                               | <p>a) The weight/content relationship (WCR) is less than 0,30 g packaging per gram of product.</p> <p><b>WCR = <math>\sum ((W_i + N_i) / (D_i \times r))</math></b></p> <p>If the packaging is reused r is set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number.</p> <p><b>b) Labelling of packaging</b></p> <p>Plastic parts of the primary packaging has been marked in accordance with DIN 6120, Part 2 or the equivalent (caps and pumps are exempted from this requirement).</p> <p><b>c) Dosage</b></p> <p>The packaging must be designed to make correct dosage easy, e.g. by ensuring that the opening at the top is not too wide</p> <p><b>d) The packaging does not contain additives based on Cadmium, Mercury, Lead or compounds with these elements. The packaging does not contain additives that do not fulfill criterion 8.</b></p> | <p>-Propose that the requirements should concern all ingredients (substances or preparations) exceeding 0,010% on the packaging weight.</p> <p>-Packaging requirements in function of the material used: plastic, metal, paper, etc and related to the environmental performance of the material.</p> | 41 | 18 | 41 |
| <b>10. Fitness for use</b>                        | <p>The product's fitness for use is demonstrated by:</p> <p>-Laboratory test performed by test-institute or</p> <p>-Consumer test according to Appendix I</p>   | <p>Proposal of a more stringent consumer test. Discuss if consumer test should be different for professional use soaps and household soaps.</p>   | 24 | 35 | 41 |
| <b>11. Information appearing on the eco-label</b> | <p>Box 2 of the eco-label shall contain the following text:</p> <ul style="list-style-type: none"> <li>•Minimal impact on aquatic ecosystems</li> <li>•Fulfils strict biodegradability requirements</li> <li>•Limits packaging waste</li> </ul>   |   | 29 | 18 | 53 |
|   |   | <p>New criteria about nanomaterials. Discuss if nanomaterials/particles insoluble or biopersistent should be restricted. Approved specific uses of nanomaterials/particles if it does not give rise to concerns in respect of health.</p>   | 35 | 18 | 47 |
|   |   | <p>Introduction of new requirements concerning energy consumption in industries.</p>  | 35 | 35 | 29 |
|   |   | <p>New criteria about chemicals and substances used in formulations specific for infants, babies and child products.</p>  | 47 | 18 | 35 |

NA: No Answer

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General comments received from the stakeholders have been collected and are presented in the following table.

Table 4.3 General comments on proposal for the new Ecolabel criteria

| CURRENT ECOLABEL   | GENERAL COMMENTS   |
|--------------------|--|
| <b>CRITERION 1</b> | <ul style="list-style-type: none"> <li>- The degradation factors used for calculating CDVs are misleading as degradation tests do not reflect the special situation of biocidal substances.</li> <li>- Lower limits! General issue: DID-List should be revised - CAS-Nr. Of chemicals added, more chemicals included, new data (REACH) included.</li> <li>- The admin work seems about right if the requirement is judge to be necessary. The challenge is the associated cost.</li> <li>- If ingredients are not included in DID list, difficult to get validated data from suppliers</li> <li>- It is very difficult to have data from a big part of our raw materials suppliers. Concerning natural raw materials, there are no ecotoxicological tests available (CL50, CE50, etc). We had the problem with abrasive particles from olive, for example.</li> <li>- Clarification concerning the abrasive agents is needed. Excluded from the active content or not.</li> <li>- Make sure that a differentiation between standard products and Ecolabel products is achieved and not a standard formulation that is useable.</li> <li>- For products listed in DID it is straight forward – products without DID Nr more difficult and time-consuming – DID List should be enlarged to most commonly used surfactants and other ingredients to make it more easy to work with.</li> <li>- We suggest that an alternative, more science-based approach for evaluating the environmental impact of ingredients, should be discussed. The scope of the DID list needs to be expanded to cover exposure. Not if only summary reports are required.</li> <li>- The current limits are strict but achievable in accordance with the philosophy of the ecolabel.</li> <li>- The strict adherence to the DID list prevents the use of new valid data on toxicity (data from chronic tests instead of data from acute tests) and degradability (see below: criterion 3).</li> <li>- The actual calculation method refers to 1g of “active content”. So, the CDV of each substance is linked to the % of other substances. As a consequence, the more you add substances, the less the CDV of dangerous substances is important. In a word, you can decrease the total CDV of the formulation by adding low CDV substances (even if they are not useful in the product...). &gt;&gt;Use a recommended</li> </ul> |

dosage, and maybe another criterion like “Total Chemicals” to limit the quantity of substances used?

- But use of Excel sheet for calculation/application necessary
- CDV may be seen as being too simple, but it is a good compromise to assess the potential eco-toxicity of a product. The concept is toxicologically relevant: less CDV, less potential impact. It is easy to use and easy to understand.
- Unless you formulate directly from the DID list, the collection of the information is much too complex. Either the DID list contains information per ingredient (per CAS number as in REACH) and for as many ingredients as possible, or the applicant should be authorised to use QSAR, weight of evidence, read across to fill data gaps (as in the REACH regulation). The use of safety factors, depending on the type of data used, can discriminate products based on the quality of the data. Nowadays, ingredients produced by nature or by human bodies (fully biodegradable and not toxic) are disqualifying a formula for the EU flowers because of lack of data. Furthermore, requiring up to annex VIII data (REACH registration dossier) constitutes a huge burden (time and cost) for the applicants that decide to embrace eco-conception principles. EU flowers should be an incentive to better product for the environment, not a sanction. Harmonization between EU Ecolabel and REACH will be very welcome.
- The formula of calculation for Cdvtox is wrong

## CRITERION 2

- Some useful raw materials are classified with R 52/53.
- It is no challenge – no products in Austria are labelled in “environmental dangerous” up to now, with CLP the situation might be different (please check it!). Set lower limits or delete it.
- Biocidal substances are usually toxic at concentrations used for ready biodegradability tests. This is not reflected in this criterion.
- This criterion should be updated to include REACH/CLP regulations.
- Methodology to calculate classification R50-53, R51-53, R52-53 of substances
- Data should be available about the products
- The criterion should be kept, but restrictions should be considered instead of exclusions, following a risk-based approach.
- This criterion could be merged with criterion 8. It should be updated to be based on CLP classification criteria.
- Should be rewritten with CLP criteria: Directive 67/548 must be replaced by CLP regulation 1272/2008 R50 = H400, R50/53 = H400 and H410, R51/53 = H411 and R52/53 = H412. This criterion appears not to apply for biocides.
- Something is not very clear in the current version. It says that for substances with ecotoxicity < 10mg/L, it's needed to prove the non-

bioaccumulation. The problem is that it doesn't clearly explain what we're supposed to do if the substance is bioaccumulable...

- Please put in criterion 8! (Hopefully then more simple). In one case applicant had problems with organic abrasive agents to get data for aquatic toxicity and biodegradation. The instruction at the application pack is not sufficient. The criteria should be explained more clearly
- The level of the criterion could be discussed but the relevance cannot.
- Should be in accordance with Ecolabel Regulation regarding excluded substances – and if necessary – derogations
- Compliance with CLP/GHS is indeed a must and it is reasonable to request that an EU flower product does not carry a classification.
- Applicants should be used to calculate their ingredient / product classification. However, a good & unique database, publically accessible, should be made available to facilitate the evaluation of the formula (or be included in the DID list). As in REACH, if applicants have more information that could lead to a different classification, they should be allowed to present this information. Up to competent authorities to accept this new information.
- Perfumes are a mixture of many molecules. The environmental requirements of the ecolabel criteria should be applied also to fragrances

### CRITERION 3

- Those surfactants that are not aerobic biodegradable and cannot be replaced due to specific functionality and there are not other alternatives should be considered as acceptable (or restricted).
- All surfactants have to be readily aerobically biodegradable, and at least limits for anaerobic degradation!
- The relevance is questionable as the anaerobic degradability is not reflected in the CDV calculations.
- We strongly think that the surfactants used in Ecolabel formulation should be aerobically and anaerobically biodegradable.
- Homogeneous approach with recently developed Ecolabel criteria: no scientific evidence concerning the non anNBO surfactants. As a consequence, should be included as useable surfactants.
- The meaning of "organics" in cosmetic products needs to be clarified (organic chemicals vs. controlled growing of biological ingredients). Anaerobic biodegradability of surfactants & other organic substances is not a factor of environmental relevance (see SCHER opinion, 17.11.2008) and should not be a requirement. The restriction on biodegradability of organic chemicals is not in line with REACH.
- Ingredients should be aerobically biodegradable but there is often less data available to determine anaerobic biodegradation. This

can be an obstacle for applicants and therefore it should be reviewed to consider whether ingredients must be demonstrated to be both aerobically and anaerobically degradable.

- 0,010% is 100 ppm (very few); apart preservatives which are regulated with little percentage, the figure should be 0.1%. (SVHC threshold). Ready biodegradability is tested at concentrations usually causing toxic effects with the activated sludge. This can be prevented by switching to different test methods using lower test item concentrations, for instance simulation tests according to OECD 303, OECD 308 and OECD 309. Anaerobic biodegradability of surfactants is still under discussion and evaluation.
- The level of the requirement could be discussed...
- Criteria 3 a: aerobic biodegradability of surfactants:  
Current criteria could be modified to allow surfactants not passing the 10 days window in a ready biodegradability test, but still reaching 60% biodegradation at 28 days AND highly removed during waste water treatment (i.e > 90-95%) to be accepted. Removal could be based on monitoring or on laboratory measurements (CAS, SCAS or porous pot)  
Criteria 3b: aerobic biodegradability of non surfactants:  
This too stringent to request a readily biodegradability test for these compounds. Biodegradability for non-surfactants should be demonstrated via inherent biodegradability test (SCAS) or removal in wastewater treatment plants.  
For those having a high toxicity (R50) the total quantity accepted in a formula could indeed be restricted as it is today (i.e 30 mg/g)

#### CRITERION 4

- Anaerobic degradation should be limited, I am not aware if the limits are a challenge.
- It does not make sense because the products go directly into water and for some raw materials it is very difficult to get this information.
- Increase the level for aNBDO.
- There is often no data available to demonstrate whether or not an ingredient is anaerobically biodegradable. Although Appendix II of the ecolabel criteria outlines approaches to use where no data are available (e.g. read across to other substances on the DID list) this criterion can still be a data gap. If testing is required then the cost of this can be prohibitive for an applicant.
- If ingredients are not included in DID list, difficult to get validated data from suppliers.
- Exclusion of the surfactants in this calculation.
- It is difficult to have the information from our raw materials suppliers. Biodegradation in anaerobic conditions is not systematically tested.

|                    |  |
|--------------------|--|
|                    | <ul style="list-style-type: none"> <li>- Anaerobic data is not always available.</li> <li>- Anaerobic biodegradability should not be such an important hurdle for biodegradable ingredients.</li> <li>- The anaerobic biodegradability of readily biodegradable surfactants and other organic ingredients is not a factor of environmental relevance (see SCHER opinion of 17.11.2008) and should therefore not be a requirement.</li> <li>- The criteria for anaerobic biodegradation are quite confusing. The criterion refers to all ingredients being anaerobically biodegradable (or lowest acute toxicity &gt;100 mg/L) but Appendix II refers specifically to surfactants. For non-surfactants with no data to determine anaerobic biodegradation there appears to be little guidance except testing.</li> <li>- The relevance is questionable as the anaerobic degradability is not reflected in the CDV calculations. Anaerobic biodegradability of surfactants is still under discussion and evaluation.</li> <li>- It should be considered to require all surfactants to be anaerobic degradable. The level of the criterion could be discussed.</li> <li>- General discussion of degradability of surfactants</li> <li>- As for criteria 3b, the limits are too stringent. Either the total quantity allowed is increased or the criteria for inclusion should be R50 or 51. Ingredients that are readily biodegradable should be excluded from this criterion, as they will disappear during WWTP before eventually entering an anaerobic compartment.</li> <li>- Provided the information is readily available, which is not the case for most of the ingredient.</li> </ul> |
| <b>CRITERION 5</b> | <ul style="list-style-type: none"> <li>- Why don't restrict the use of R42, R43 substances? Is technically possible?</li> <li>- Sensitizers (R43) or the sum of sensitizers should to be limited to 0,01%</li> <li>- More restriction e.g. Allergen-free.</li> <li>- Practical approach to fragrances. But the default factor in CDV calculations is unnecessarily limiting.</li> <li>- This requirement is (almost) not limiting. If we want to set requirements to the use of fragrances, this is not sufficient. Fragrance in products for babies/infants/kids should be excluded</li> <li>- Fragrance should not be allowed In products for babies/infant or kids</li> <li>- Instead of considering that all perfumes are equivalent, in terms of environmental impact, it is important to define rules for differentiating perfumes.</li> </ul>   |

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## CRITERION 6

- BCF definition not in line with CLP Regulation.
- This point should only be valid for dyes for the product. Exclude any hair dye substances because they are highly discussed [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/sccp\\_opinions\\_en.htm#2](http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm#2). Hair dyes should not be in the scope.
- Usually the concentrations of dyes present in each formulation are under the limit of 0,01%. Is it really necessary to have a criterion for dyes?
- The proposed modification needs clarification. Thresholds should not be in contradiction with the new CLP Regulation.
- According to CLP criteria, the two parameters are now :
  - Log Pow  $\leq 4$  (instead of 3),
  - BCF  $\leq 500$  (instead of  $\geq 100$ )
- Hair dyes often has some unwanted health concerns and should not be allowed. The Cosmetics Regulation has a list of approved dyes and this should be sufficient for soaps and shampoos (I am not sure whether the proposal is possible according to the Cosmetics Regulation at all)

## CRITERION 7

- Could be much stricter and targeted on specific product groups.
- Should be restricted to special product groups to differentiate from standard – products.
- The proposed modification needs clarification. Thresholds should not be in contradiction with the new CLP Regulation.
- The term “biocides” should be replaced by “preservatives”. The current criterion is acceptable. Substances should only be restricted on the basis of a scientific rationale. BCF  $< 500$  and log Pow  $< 4$  are more relevant (in line with CLP).
- b) Must be rewritten with H410-H400 and BCF  $< 500$  and logPow  $< 4$   
In our opinion biocides approved under the cosmetic directive should be also allowed to be used under the Ecolabel if in addition the criteria lined out here are fulfilled. An additional negative list raises the question why all those criteria for toxicity, eco-toxicity and environment are reflected in such detail if at the end, a negative list is established. If only certain active substances are on that list the question is why are others not listed? If the principal of negative / positive lists is followed, the detailed criteria are not longer needed and should be replaced by two lists, which should be as comprehensive as possible. But then again, those criteria are not longer necessary.
- This criteria makes sense, but collecting the information is very difficult. At least weight of evidence, QSAR and read across should be authorized.

## CRITERION 8

- We think that it would be useful to group the substances that release formaldehyde.
- This has been calculated up to now for the net weight, I never interpreted it including the packaging weight. Harmonisation of the list of restricted R- and H-phrases with other Ecolabels should be done.
- The criterion just concerns with the substances or preparations that exceed 0,01% on net weight without considering the packaging weight. Why did you propose this change? We agree to expand R- and H phrases list similar to other product groups.
- REACH alignment. The thresholds imposed in the Ecolabel criteria for potential derogation requirement if used below certain thresholds i.e 0,01% is not in line with REACH (where it is 0,1%); this should be adjusted to 0,1% for consistency.
- Update according to article 6.6 of Ecolabel Regulation.
- Could be stricter also concerning by-products and products like EDTA can be forbidden there are greener alternatives available
- The R- and H- phrases should be specified; derogations will be needed for key ingredients (proposal to be discussed with industry).
- Possibility to expand to allergenic and corrosive risk phrases? I think the conclusion of last CB discussions about this issue was that this requirements **concerns to substances** and were included in the categories of “All purpose cleaners” and “Hand dishwashing detergents” : *The risk phrases below generally refer to substances. However, for mixtures of enzymes and fragrances, where information on substances cannot be obtained, the rules for mixtures shall be applied”*
- The CMR classification for substances must be the one harmo-nised; otherwise it’s unfeasible. Same remark with 0.01%; should be 0.1% R and H phrases might result in limitations of concentrations of bio-cidal active ingred-ients. These might impair their efficacy and thus cause concerns in terms of durability of the products to be protected. The packaging weight should be excluded...
- This should be updated so I corresponds the Ecolabel Regulation as to excluded substances and – if necessary – derogations.
- This requirement should be updated to match the Ecolabel Regulation with regards to excluded R-phrases and – if necessary – make derogations

## CRITERION 9

- Choice of packaging material should be included and also their biodegradability or possibility to recycle.
- Do you mean “all active ingredients?” besides water? Or do you refer to the concentration limits we get? How it is now formulated is much better – you know and can control the weight of the final product much easier! But: The criterion is up to now not really a challenge, even very small bottles in hotel rooms pass it. We would like to have the issue discussed – do we want them to be labelled? Packaging is an important issue for this product group!
- Companies must follow the requirements of the Packaging &Packaging Waste Directive; products must be safe during transportation as well. The proposed approach lacks a holistic packaging perspective. Low weight primary packaging usually requires more transport

packaging. Need to evaluate the entire packaging proposal.

- It's very different the environmental impact of different materials. Recycling should be stimulated by the criteria. If using recycled materials and biodegradable materials was taken into account, this packaging should be reinforced by the criteria and should be considered more environmentally friendly than a 100 % new plastic packaging, even if the relation of weights between package and product respects the present limit of the criteria.
- The packaging weight should be excluded.
- Seems that this could complicate the calculation, perhaps with help of excel calculation sheet possible
- I am not sure what the intended change is about. The WCR is regulating the amount of packing compared to the amount of product. It has nothing to do with substances in the packaging. If the intended change is regarding 9 d) I would mean that it is already the case. If a definition of "ingoing substances" is not found in the criteria it is essential that it is added in the revised version
- These criteria should be completed with requirement regarding the type of material used. Using recyclable or recycled materials should rewarded.

#### **CRITERION 10**

- The current performance and consumer test criteria are quite vague. It is good that applicants are able to submit existing performance test data and do not have to repeat testing, but increased guidance could be provided to help those applicants who are conducting a new test.
- I personally feel that it would be more important that no negative effects occur. Each surfactant is removing fat - I would prefer the skin tolerance/compatibility to be tested.
- No requirements for laboratory test.
- The professional market is different of the household market in terms of applications, performance requirement...the consumer test should not be the same.
- Questions on consumers test don't seems most appropriate; only 10 people for test.
- Define performance testing like foam performance, mildness, conditioning etc.... – more guidelines.
- Depending on what test you do external is not much work internal will lead to a work load.
- Test methods should be specified – foam, condition performance, mildness etc.
- Definition of "fitness for use" is needed. Claim substantiation is a legal requirement for all cosmetic products.
- For normal products it doesn't make scene (hand soap), only for special products.
- The current consumer test guidelines are quite vague. More specific guidelines could be provided. No need to differentiate between

|  |  |
|--|--|
|  | <p>professional and consumer use. Need to minimise any chance of confusion.</p> <ul style="list-style-type: none"> <li>- The most important claims of the product are already taken into account with the existent test. The consumer test that is applied today is stringent enough owing to the satisfaction percentage that is already high (80%).</li> <li>- With the restrictions applied a more stringent consumer test should be a problem.</li> <li>- An evolution is needed. Maybe a performance test method should be developed?</li> <li>- The problem is that no standard test is found for these products and to agree on a frame test formulation may be difficult...</li> </ul>   |
| <b>CRITERION 11</b>  | <ul style="list-style-type: none"> <li>- Reformulate that the customer really feels he does something good for the environment.</li> <li>- As these texts are optional (see logo guidelines), no problem</li> <li>- Reformulate to a key message that customers connect to ecolabel.</li> <li>- Similar approach as the recent developed criteria with optional text. Otherwise issue of lack of space when several languages have to be present on the label.</li> <li>- Too restrictive claims set.</li> <li>- This is a narrow vision of environmentally preferred products. LCA provides a holistic approach.</li> <li>- Include text about the guidelines for the use of EU Ecolabel logo.</li> <li>- Must of course be adjusted to fit revised criteria</li> </ul> |
| <p><b>New criteria about nanomaterials. Discuss if nanomaterials/particles insoluble or biopersistent should be restricted. Approved specific uses of nanomaterials/particles if it does not give rise to concerns in respect of health.</b></p> | <ul style="list-style-type: none"> <li>- Nanomaterials/particles should not be automatically restricted if safety is proven and clear benefits are recognized.</li> <li>- They should be restricted.</li> <li>- OK but there's no clear definition and regulation...Difficult to apply (and to verify for CB's)</li> </ul>   |

|   |   |
|---|---|
| <p><b>Introduction of new requirements concerning energy consumption in industries.</b></p>                                     | <ul style="list-style-type: none"> <li>- The proposal is LCA-based, but the energy consumption in production is very limited compared to the use phase. This would result in losing focus on end-of-life impacts when enlarging to the whole life cycle impacts.</li> <li>- Lets introduce the calculation of the carbon footprint related to the energy consumptions.</li> <li>- Nowadays is very difficult to harmonise a methodology in industries in order to determine energy consumptions.</li> <li>- Could lead to too tough selection with a preference for biggest companies which have money to fulfill the criteria.</li> <li>- Too complicated application procedure!</li> <li>- Preparing a dossier is already a complicated task, adding such requirement (very difficult) to set up will increase complexity for little added value.</li> </ul>                                    |
| <p><b>New criteria about chemicals and substances used in formulations specific for infants, babies and child products.</b></p> | <ul style="list-style-type: none"> <li>- Specific safety of children under the age of 3 is a requirement of the cosmetics legislation. Special criteria regarding children are not relevant to Ecolabel. There is no specific environmental impact for ingredients of a product whether it is for children or adults.</li> <li>- E.g. no Sensitizers (R43, R42) added at all.</li> <li>- For babies &lt; 3 years yes, but not for child products.</li> <li>- Very valuable point</li> <li>- Very important issue in Denmark</li> </ul>  |
| <p><b>Other comments</b></p>  | <ul style="list-style-type: none"> <li>- All criteria and hazard sentences have to be in the CLP classification (regulation n°1272/2008) and not in DSD (Directive 67/548). The CLP classification is compulsory for substances since December 1st, 2010</li> <li>- Extend the product group to cosmetic products that aren't rinsed off, i.e. body lotions. Nordic Ecolabel just defined specific criteria for cosmetic products that aren't rinsed off. Therefore we can take the Nordic regulation as guideline. Since hair conditioners has been included in this EU Ecolabel product group, and we know that these ones aren't rinsed off completely, we suggest to extend the application of EU Ecolabel. Actually the biggest problem of Ecolabel applicants on cosmetic field is to supply the customers with a complete range of product, ie from a shampoo to a body lotion.</li> </ul> |

DR

## 11. APPENDIX II: SCOPE OF THE PRODUCT GROUP

The existing definition of soaps, shampoos and hair conditioners product group has been analysed to determine if it shall be amended, e.g. if other cleaning products, which could be covered by the Ecolabel criteria for this group, exist and should be included in the current definition and scope .

Products with a certain degree of similarity, for example a common function or way of application or with similar chemical composition should be taken into account.

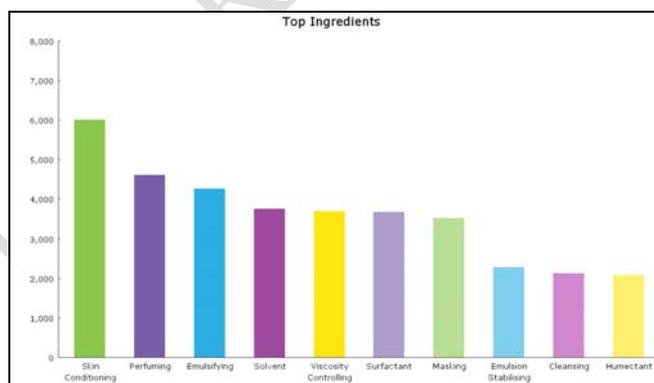
Other rinse-off cosmetic products for similar purposes should be discussed for their inclusion, e.g. shaving products. The possible inclusion of products with similar purposes for animals, especially pets, as well as products like wet wipes and toothpaste could also be discussed.

With this aim, the typical ingredients of each new considered product have been analyzed and compared with soaps, shampoos and hair conditioners. The analysis included products like:

- shaving foam,
- shaving cream,
- shaving gel,
- shaving soap,
- hand cleansing gel,
- facial wash,
- animal shampoo,

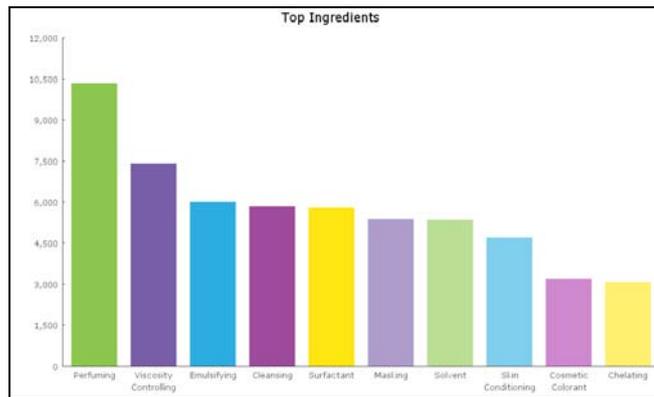
Its results are shown below.

### INGREDIENTS ANALYSIS FOR SHAVING PREPARATIONS



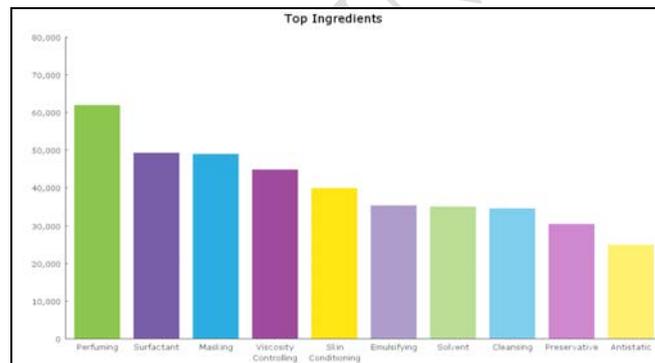
|                       |                      |
|-----------------------|----------------------|
| Skin conditioning     | Surfactant           |
| Perfuming             | Masking              |
| Emulsifying           | Emulsion Stabilising |
| Solvent               | Cleansing            |
| Viscosity controlling | Humectant            |

## INGREDIENTS ANALYSIS SOLID SOAPS



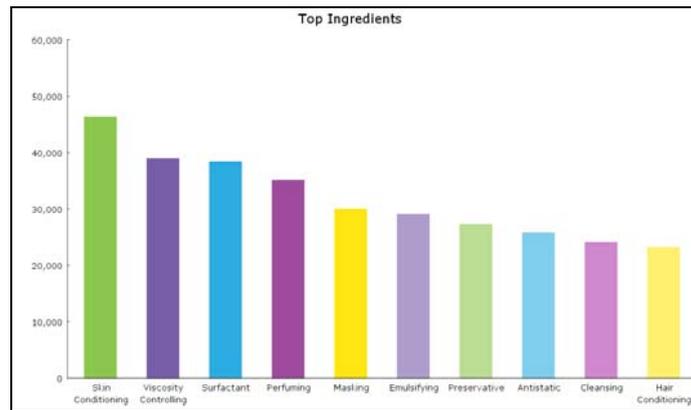
|                       |                   |
|-----------------------|-------------------|
| Perfuming             | Masking           |
| Viscosity controlling | Solvent           |
| Emulsifying           | Skin conditioning |
| Cleansing             | Cosmetic colorant |
| Surfactant            | Chelating         |

## INGREDIENTS ANALYSIS LIQUID SOAPS



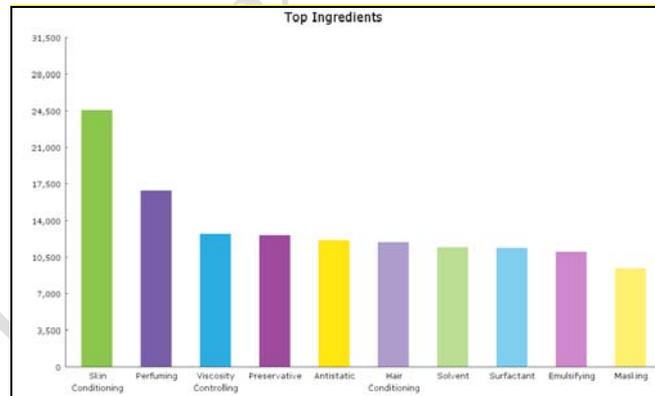
|                       |              |
|-----------------------|--------------|
| Perfuming             | Emulsifying  |
| Surfactant            | Solvent      |
| Masking               | Cleansing    |
| Viscosity controlling | Preservative |
| Skin conditioning     | Antistatic   |

## INGREDIENTS ANALYSIS SHAMPOOS



|                       |                   |
|-----------------------|-------------------|
| Skin conditioning     | Emulsifying       |
| Viscosity controlling | Preservative      |
| Surfactant            | Antistatic        |
| Perfuming             | Cleansing         |
| Masking               | Hair conditioning |

## INGREDIENTS ANALYSIS HAIR CONDITIONERS



|                       |                   |
|-----------------------|-------------------|
| Skin Conditioning     | Hair Conditioning |
| Perfuming             | Solvent           |
| Viscosity Controlling | Surfactant        |
| Preservative          | Emulsifying       |
| Antistatic            | Masking           |

## INGREDIENTS ANALYSIS PETS SHAMPOOS

|                       |                   |
|-----------------------|-------------------|
| Skin conditioning     | Hair conditioning |
| Preservative          | Solvent           |
| Masking               | Emulsifying       |
| Viscosity controlling | Bulking           |
| Perfuming             | Cleansing         |
| Antistatic            | Humectant         |
| Surfactant            |                   |

Based on COLIPA frame formulations:

| HAIR PRODUCTS  |                        |
|--|------------------------|
| SHAMPOO - LIQUID AND CREAM   |                        |
| Ingredients  | Maximum levels (% w/w) |
| Anionic surfactants (e.g. sodium/ammonium/TEA lauryl sulfates, sodium/ammonium/TEA laureth sulfates)                 | 30                     |
| Amphoteric surfactants (e.g. betaine derivatives)  | 20                     |
| Non-ionic surfactants (e.g. fatty alkanolamides)   | 15                     |
| Viscosity controlling agents (e.g. <i>propylene glycol</i> , PEG)  | 10                     |
| Cationic surfactants C12 (e.g. <i>stearamidopropyl dimethylamine</i> , <i>distearyldimonium chloride</i> )           | 5                      |
| Hair conditioning agents (e.g. silicone derivatives, cysteine derivatives, cellulose derivatives, fatty acid esters) | each up to 5           |
| Additional ingredients (e.g. UV filters, pearlescent agents, opacifying agents)                                      | each up to 5           |
| Preservatives, antimicrobials  | 1                      |
| Chelating agents (e.g. <i>disodium EDTA</i> )  | 0.5                    |
| <i>Aqua</i>  | to 100                 |

| SOAP  |                        |
|---|------------------------|
| SOAP - TOILET   |                        |
| Ingredients   | Maximum levels (% w/w) |
| Soap (based on tallow, palm oil and coconut oil fatty acids)          | 99                     |
| <i>Glycerin</i>   | 20                     |
| Emollients, humectants (e.g. <i>lanolin</i> )                         | 10                     |
| Amphoteric /anionic surfactants (e.g. <i>cocamidopropyl betaine</i> ) | 5                      |
| Mineral and/or vegetable oils (e.g. palm oil)                         | 5                      |
| <i>Perfume</i>  | 5                      |
| Cosmetic colorants  | 2.5                    |
| <i>Titanium dioxide</i>   | 2                      |
| Skin conditioning agents (e.g. <i>polyquaternium-7</i> )              | 2                      |
| Additional ingredients (e.g. plant extracts, optical brighteners)     | 2                      |
| Preservatives, antimicrobials, antioxidants, chelating agents         | 1                      |
| Aqua  | to 100                 |

| SOAP  |                        |
|---|------------------------|
| LIQUID SOAP   |                        |
| Ingredients   | Maximum levels (% w/w) |
| Anionic / amphoteric surfactants (e.g. laureth sulfates, betaines)                | 40                     |
| Non-ionic surfactants (e.g. glucose derivatives)                                  | 40                     |
| Soaps (sodium, potassium or triethanolamine)                                      | 20                     |
| Emollients (e.g. PEG-7, glyceryl cocoate)   | 20                     |
| Humectants (e.g. glycerin, propylene glycol, sorbitol)                            | 10                     |
| Viscosity controlling agents (e.g. sodium chloride, hydroxycellulose derivatives) | 5                      |
| Additional ingredients (e.g. plant extracts)                                      | 5                      |
| Pearlescent agents (e.g. glycol distearate, glycol stearate)                      | 5                      |
| Skin conditioning agents (e.g. cationic cellulose)                                | 5                      |
| Perfume   | 2                      |
| Preservatives, antimicrobials   | 2                      |
| Cosmetic colorants  | 1                      |
| Aqua  | to 100                 |

| HAIR PRODUCTS   |                        |
|---|------------------------|
| HAIR CONDITIONER  |                        |
| Ingredients   | Maximum levels (% w/w) |
| Oils, waxes (mineral and vegetable), silicones and fatty alcohols (e.g. petrolatum, triticum vulgare, amodimethicone, cetearyl alcohol) | 20                     |
| Ethanol (alcohol, alcohol denat.)   | 15                     |
| Emulsifying agents (e.g. ceteth-30, cetyl alcohol)  | 10                     |
| Amphoteric surfactants (e.g. betaines derivatives)  | 10                     |
| Additional ingredients (e.g. proteins, chelating agents, pearlescent agents)  | 10                     |
| Cationic surfactants C12 (e.g. cetrimonium chloride)  | 5                      |
| Emollients, humectants (e.g. glycerin, propylene glycol)  | 5                      |
| Viscosity controlling agents (e.g. carbomer, hydroxyethylcellulose)   | 5                      |
| Polymers, resins (e.g. polyquaternium-10, polyquaternium-11, butyl ester of PVM/MA copolymer)   | 5                      |
| Perfume   | 3                      |
| UV filters  | 1                      |
| Preservatives, antimicrobials   | 1                      |
| Cosmetic colorants  | 1                      |
| Aqua  | to 100                 |

| HAIR PRODUCTS  |                        |
|--|------------------------|
| HAIR CONDITIONER (SILICONE BASED)                              |                        |
| Ingredients  | Maximum levels (% w/w) |
| Silicones and volatile silicones (e.g. <i>cyclomethicone</i> ) | 99                     |
| Additional ingredients (e.g. UV filters, polymers)             | 10                     |
| Emulsifying agents (e.g. ethoxylated fatty alcohols)           | 6                      |
| Ethanol ( <i>alcohol, alcohol denat.</i> )                     | 5                      |

| SHAVING PRODUCTS   |                        |
|--|------------------------|
| SHAVING CREAM AND BRUSHLESS SHAVING CREAM /soaps based   |                        |
| Ingredients  | Maximum levels (% w/w) |
| Soaps (e.g. mixed sodium and potassium stearates, laurates and cocoates)                         | 60                     |
| Humectants (e.g. <i>glycerin, propylene glycol</i> )   | 30                     |
| Viscosity controlling agents, emulsifying agents (e.g. fatty acid glycol esters, fatty alcohols) | 15                     |
| Emollients (e.g. lanolin derivatives, oils, fatty acid esters)                                   | 15                     |
| Silicones (e.g. <i>dimethicone</i> )   | 10                     |
| Synthetic surfactants (e.g. anionic such as <i>sodium laureth sulfate</i> )                      | 5                      |
| <i>Perfume</i>   | 2                      |
| Additional ingredients (e.g. viscosity controlling agents, vitamins)                             | 2                      |
| Opacifying agents (e.g. <i>titanium dioxide</i> )  | 1                      |
| <i>Menthol</i>   | 1                      |
| Anticorrosives (e.g. <i>sodium metasilicate</i> )  | 0.5                    |
| <i>Sodium borate</i>   | 0.5                    |
| Chelating agents   | 0.5                    |
| Antioxidants   | 0.1                    |
| <i>Aqua</i>  | to 100                 |

| SHAVING PRODUCTS   |                        |
|--|------------------------|
| SHAVING CREAM AND BRUSHLESS SHAVING CREAM / BRUSHLESS    |                        |
| Ingredients  | Maximum levels (% w/w) |
| Fatty acids  | 40                     |
| Oils (e.g. mineral oil, lanolin oil)                     | 20                     |
| Soaps (e.g. <i>Tea-stearate</i> and <i>TEA-laurate</i> ) | 10                     |
| Silicones (e.g. <i>dimethicone</i> )                     | 10                     |
| Additional ingredients (e.g. vitamins, plant extracts)   | 2                      |
| <i>Perfume</i>   | 2                      |
| Antioxidants, chelating agents                           | 0.5                    |
| <i>Aqua</i>  | to 100                 |

| SHAVING PRODUCTS  |                        |
|---|------------------------|
| SHAVING CREAM AND BRUSHLESS SHAVING CREAM / SHAVE GEL                 |                        |
| Ingredients   | Maximum levels (% w/w) |
| Film forming agents (e.g. <i>glyceryl polymethacrylate</i> )          | 10                     |
| Silicones (e.g. <i>dimethicone</i> )                                  | 5                      |
| Viscosity controlling agents (e.g. <i>hydroxyethylcellulose</i> )     | 3                      |
| Emulsifying agents, surfactants (e.g. <i>sodium laureth sulfate</i> ) | 3                      |
| Additional ingredients (e.g. vitamins, plant extracts)                | 2                      |
| <i>Perfume</i>  | 1                      |
| Cosmetic colorants  | 1                      |
| Preservatives, antimicrobials   | 1                      |
| <i>Aqua</i>   | to 100                 |

| SHAVING PRODUCTS   |                        |
|--|------------------------|
| SHAVING CREAM AND BRUSHLESS SHAVING CREAM / SHAVING FOAM AEROSOL |                        |
| Ingredients  | Maximum levels (% w/w) |
| Mixed alkanolamine / sodium / potassium soaps                    | 30                     |
| Humectants (e.g. <i>glycerin</i> )                               | 15                     |
| Propellants (e.g. hydrocarbons)                                  | 15                     |
| Emollients (e.g. waxes, <i>lanolin</i> , silicone derivatives)   | 10                     |
| Anionic surfactants (e.g. <i>sodium laureth sulfate</i> )        | 10                     |
| Non-ionic surfactants (e.g. <i>lauramide DEA</i> )               | 10                     |
| Emulsifying agents (e.g. PEG derivatives)                        | 5                      |
| Additional ingredients (e.g. proteins, vitamins)                 | 2                      |
| <i>Perfume</i>   | 1                      |
| Preservatives, antimicrobials                                    | 1                      |
| Viscosity controlling agents (e.g. cellulose derivatives)        | 1                      |
| <i>Menthol</i>   | 0.5                    |
| <i>Aqua</i>  | to 100                 |

| SHAVING PRODUCTS   |                        |
|--|------------------------|
| SHAVING CREAM AND BRUSHLESS SHAVING CREAM / SHAVING SOAP /STICK          |                        |
| Ingredients  | Maximum levels (% w/w) |
| Mixed sodium and potassium stearates and laurates                        | 90                     |
| Humectants (e.g. <i>glycerin</i> )                                       | 15                     |
| Non-ionic surfactants (e.g. polysorbates)                                | 5                      |
| Silicones (e.g. <i>dimethicone</i> )                                     | 5                      |
| Additional ingredients (e.g. vitamins, plant extracts, chelating agents) | 2                      |
| <i>Perfume</i>   | 2                      |
| <i>Titanium dioxide</i>  | 1                      |
| Preservatives, antimicrobials  | 1                      |
| Antioxidants   | 0.1                    |
| <i>Menthol</i>   | 0.1                    |

| SHAVING PRODUCTS   |                        |
|--|------------------------|
| SHAVING CREAM AND BRUSHLESS SHAVING CREAM / SOAP TOILET                |                        |
| Ingredients  | Maximum levels (% w/w) |
| Soap (based on tallow, palm oil and coconut oil fatty acids)           | 99                     |
| <i>Glycerin</i>  | 20                     |
| Emollients, humectants (e.g. <i>lanolin</i> )                          | 10                     |
| Amphoteric / anionic surfactants (e.g. <i>cocamidopropyl betaine</i> ) | 5                      |
| Mineral and/or vegetable oils (e.g. palm oil)                          | 5                      |
| <i>Perfume</i>   | 5                      |
| Cosmetic colorants   | 2.5                    |
| <i>Titanium dioxide</i>  | 2                      |
| Skin conditioning agents (e.g. <i>polyquaternium-7</i> )               | 2                      |
| Additional ingredients (e.g. plant extracts, optical brighteners)      | 2                      |
| Preservatives, antimicrobials, antioxidants, chelating agents          | 1                      |
| <i>Aqua</i>  | to 100                 |

| SHAVING PRODUCTS  |                        |
|---|------------------------|
| SHAVING CREAM AND BRUSHLESS SHAVING CREAM / LIQUID SOAP                                   |                        |
| Ingredients   | Maximum levels (% w/w) |
| Anionic / amphoteric surfactants (e.g. laureth sulfates, betaines)                        | 40                     |
| Non-ionic surfactants (e.g. glucose derivatives)  | 40                     |
| Soaps (sodium, potassium or triethanolamine)  | 20                     |
| Emollients (e.g. <i>PEG-7, glyceryl cocoate</i> )   | 20                     |
| Humectants (e.g. <i>glycerin, propylene glycol, sorbitol</i> )                            | 10                     |
| Viscosity controlling agents (e.g. <i>sodium chloride, hydroxycellulose derivatives</i> ) | 5                      |
| Additional ingredients (e.g. plant extracts)  | 5                      |
| Pearlescent agents (e.g. <i>glycol distearate, glycol stearate</i> )                      | 5                      |
| Skin conditioning agents (e.g. cationic cellulose)  | 5                      |
| <i>Perfume</i>  | 2                      |
| Preservatives, antimicrobials   | 2                      |
| Cosmetic colorants  | 1                      |
| <i>Aqua</i>   | to 100                 |

| SKIN CARE  |                        |
|--|------------------------|
| HAND CLEANSING GEL   |                        |
| Ingredients  | Maximum levels (% w/w) |
| Anionic surfactants (e.g. <i>sodium laureth sulfate</i> )                  | 40                     |
| Oils (e.g. isoparaffins)   | 30                     |
| Amphoteric / non-ionic surfactants (e.g. ethoxylated sorbitan esters)      | 20                     |
| Emollients, humectants (e.g. <i>glycerin, propylene glycol, sorbitol</i> ) | 10                     |
| Viscosity controlling agents (e.g. <i>steareth-50</i> )                    | 5                      |
| Additional ingredients (e.g. plant extracts, vitamins)                     | 5                      |
| <i>Perfume</i>   | 2                      |
| Preservatives, antimicrobials  | 1                      |
| <i>Aqua</i>  | to 100                 |

| SKIN CARE  |                        |
|--|------------------------|
| FACIAL WASH  |                        |
| Ingredients  | Maximum levels (% w/w) |
| Anionic surfactants (e.g. <i>sodium laureth sulfate, disodium laureth sulfosuccinate</i> )             | 55                     |
| Emollients (e.g. <i>glycerin</i> )   | 20                     |
| Non-ionic / amphoteric surfactants (e.g. <i>cocamide MIPA, ceteth-20</i> , ethoxylated fatty alcohols) | 20                     |
| Viscosity controlling agents (e.g. <i>carbomer</i> )   | 6                      |
| Additional ingredients (e.g. pearlescent agents such as <i>glycol distearate</i> )                     | 5                      |
| Emulsifying agents (e.g. <i>cetyl alcohol</i> )  | 5                      |
| Preservatives, antimicrobials  | 2                      |
| <i>Perfume</i>   | 1                      |
| Cosmetic colorants   | 1                      |
| Chelating agents   | 0.5                    |
| <i>Aqua</i>  | to 100                 |

Note: disinfecting products (cleaning products with anti-microbial) are excluded from the product group (from ordinary cleaning products).

Based on the analysis of ingredients of the before mentioned (and presented in above tables) products and their comparison with the composition of products which are already covered by the product group of "soaps, shampoos and hair conditioners" it can be concluded that the product group definition might include other rinse-off cosmetic products with similar purposes like shaving foam, shaving gel, shaving cream and shaving soap. Products for animals, especially pets, can also be included.

## 12. APPENDIX III: HAZARD STATEMENTS ACCORDING TO CLP 1272/2008 FOR HAZARDOUS SUBSTANCES

Hazard statements according to CLP 1272/2008 for hazardous substances

| <i>Hazard statement according to CLP 1272/2008/EEC</i>                         | <i>Associated risk phrases according to Directive 67/548/EEC</i> |
|--|--|
| 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  | R65  |
| H311 Toxic in contact with skin  | R65  |
| H330 Fatal if inhaled  | R23; R26   |
| H331 Toxic if inhaled  | R23  |
| H340 May cause genetic defects   | R23  |
| 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   |
| 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; R39/24;<br>R39/25; R39/26;<br>R39/27; R39/28             |
| H371 May cause damage to organs  | R68/20; R68/21;<br>R68/22  |
| H372 Causes damage to organs through prolonged or repeated exposure            | R48/25; R48/24;<br>R48/23  |
| H373 May cause damage to organs through prolonged or repeated exposure         | R48/20; R48/21;<br>R48/22  |
| 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   |
| H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled | R42  |
| H317 May cause allergic skin reaction  | R43  |

### 13. APPENDIX III: CONCLUSION ON MAIN ENVIRONMENTAL IMPACTS OF SOAPS, SHAMPOOS AND HAIR CONDITIONERS BASED ON LYFE CYCLE ASSESSMENT

#### Goal of the LCA studies

Life cycle assessment allows to gain the **overall environmental profiles** of different kinds of products included in the product group of “soaps, shampoos and hair conditioners” of Ecolabel, and to identify which life stages have the greatest environmental impacts.

Further, a **sensitivity analysis on key parameters** was undertaken in order to obtain additional information on relevant life cycle stages as well as on the impact of specific substances and materials used in the product and in its packaging. Analysing how the variation of these parameters affects the environmental impacts is an important output of this investigation. However, the particular environmental impact improvement potential, as calculated, can be used mainly as a qualitative parameter as in most cases data gaps are found.

#### Limitations of the LCA study

**Limitations** on life cycle assessment studies have to be considered. Namely limitations can be identified in the collection and source of data, in its representativeness in the availability of specific substances as found in LCA databases. It may also be considered that the commonly used environmental impact assessment methods entail some limitations regarding ecotoxicity impact categories.

#### Functional unit for LCA

The functional unit describes qualitatively and quantitatively the function(s) or the service(s) provided by the product analysed. The functional unit for soaps, shampoos and hair conditioners has been defined as: **A washing action of a part of the body with the main objective of providing hygienic results and aesthetic improvements.**

In order to obtain more comprehensive results from the LCA study, the reference flow for LCA analysis has been based on mass criteria of the whole product, taking as reference the average product unit sold and standard dosages. Reference flow for each kind of product studied is presented in Table 18 below:

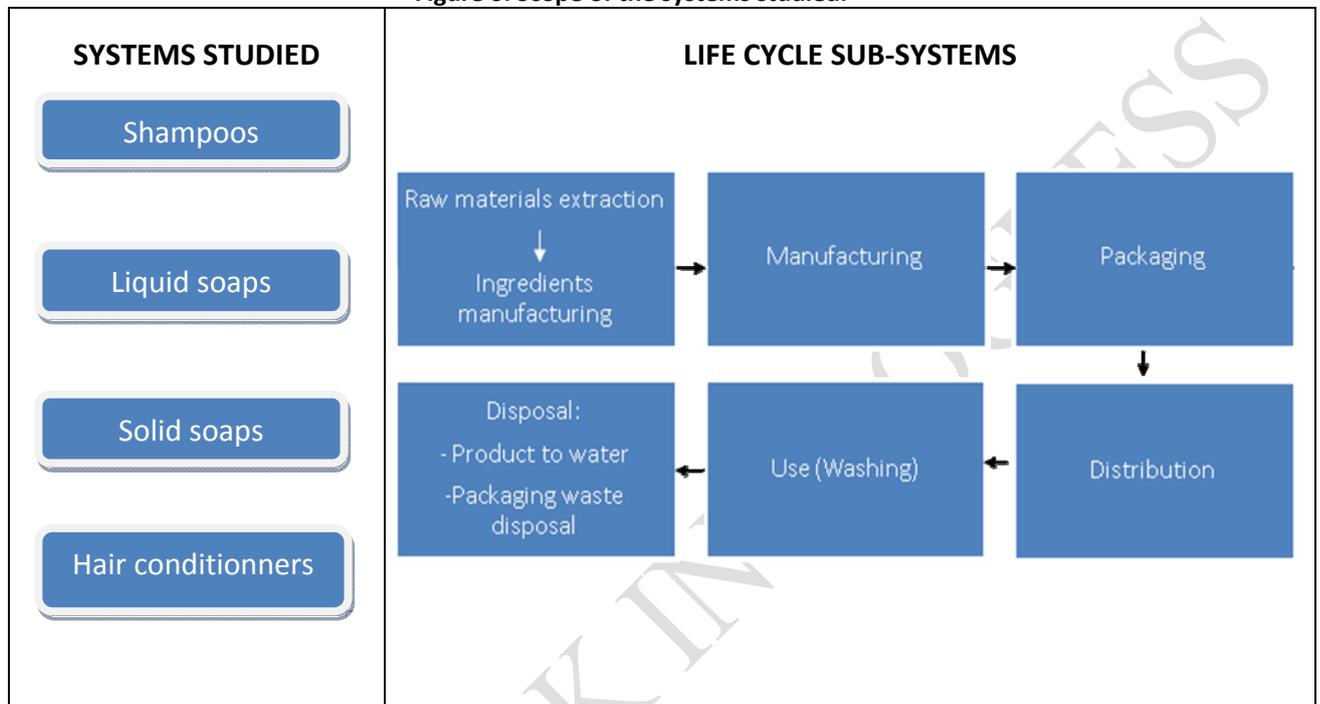
**Table 18.** Reference flow for four kinds of products studied

| <b>Product</b>   | <b>Reference flow</b>   |
|------------------|---|
| Liquid soap      | A bottle of 250 ml of liquid soap (containing 255 g of product), with the main function of personal washing and personal care for 51 washing actions      |
| Shampoo          | A bottle of 250 ml of shampoo (containing 255 g of product), with the main function of personal washing and personal care for 32 washing actions          |
| Hair conditioner | A bottle of 250 ml of hair conditioner (containing 255 g of product), with the main function of personal washing and personal care for 28 washing actions |
| Solid soap       | A solid bar soap of 100 g with the function of washing the body or a part of the body for 25 washing actions  |

## Systems products definition

LCA from cradle to grave have been done, including all life stages of products: raw materials extraction and ingredients preparation, product manufacturing, packaging, distribution, use and disposal.

**Figure 6: Scope of the systems studied.**



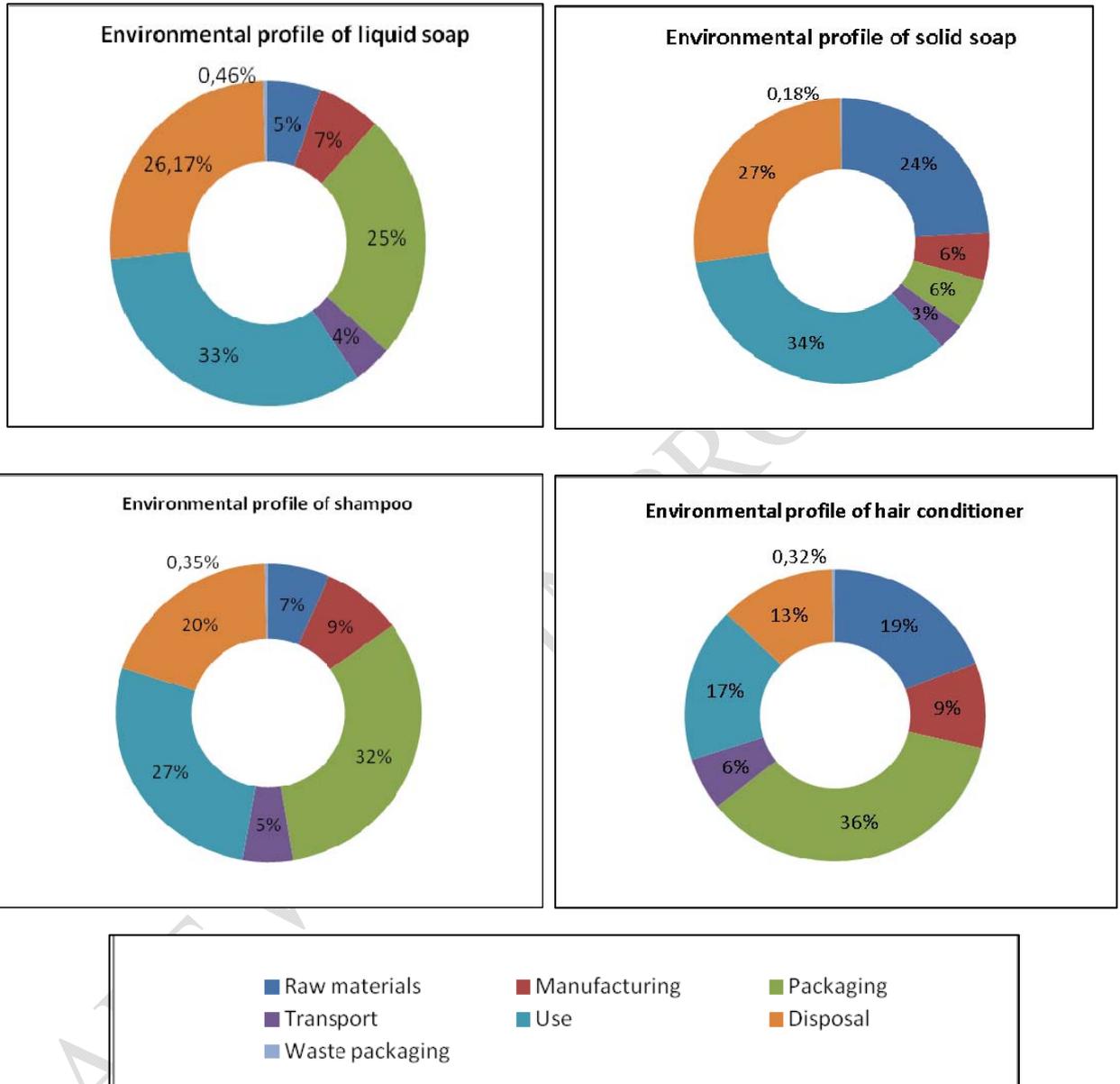
## Life Cycle Impact Assessment results

The impact assessment method used is the IMPACT 2002+<sup>96</sup>. The IMPACT 2002+ life cycle impact assessment methodology proposes a feasible implementation of a combined midpoint categories and endpoints (damage approach). For some results, the different impact categories have been aggregated in a single score obtained through weighting processes.

In Figure 7 it can be seen the general environmental impact of the four kinds of products studied: liquid soaps, solid soaps, shampoos and hair conditioners. Midpoints are used for a more specific and detailed analysis, whereas damage endpoints are useful to communicate the results obtained to broader audience. The pre-defined (mathematical) weighting of the different midpoint score within the Impact 2002+ assessment method allow us to come to a single score. However, this should be used more for communication than for analysis, as weighting is not standardised and it is generally considered more relevant for the experts groups to hold discussions in greater detail – on midpoints level. In any case it is useful to have a general picture of the contribution of each life stage related to the overall environmental impact of the whole product lifecycle and to identify the environmental hot spots.

<sup>96</sup> <http://www.sph.umich.edu/riskcenter/jolliet/impact2002+.htm>

Figure 7. Environmental impact distribution by life stage (IMPACT 2002+)



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, disposal to water, packaging and chemicals used. Other stages (manufacturing, distribution and waste packaging treatment) have a lower load in the overall environmental impact of these products.

Impact results from **life cycle assessment** show that an important load of the overall environmental impact of these products comes from the **use phase** (28% of the total products impact). Ecolabel criteria cannot easily address action in this stage; contrary to criteria of other product groups (i.e. detergents for which water and energy use depends to a certain extent on the characteristics of the

product) apart from the minimum requirements of the products' performance regarding the intended function. In any case it is very important to highlight that user's behaviour has an important role and respective communication to consumers is essential.

**Release to water** stage represents a high percentage in the total environmental impact of a product. (between 27 and 13% depending on each product). In this stage the treatment of wastewater generated after use stage has been included. Wastewater is considered to contain water used and the overall product used (as it is totally rinsed-off). It is considered that wastewater goes to a household wastewater treatment plant.

Apart from the use phase and release to water stages, **packaging** shows high environmental impact load. This high contribution indicates the importance to focus and investigate whether a further limitation of the packaging environmental impact is possible. Initiatives that reduce the amount of raw material used, such as refilling systems and recycling processes, allow minimizing the environmental impact of packaging, hence the environmental impact of the entire product.

It is important to investigate ways which could ensure a high recyclability rate of the used packaging as well as facilitate the use of recycled material, i.e. packaging elements such as caps or labels should not pose difficulties in recycling processes.

Comparisons among plastics show that in general terms, HDPE seems to have a lower environmental impact score. PET has the highest score in resource depletion whereas PVC is not commonly used in packaging and the additives found in it are considered problematic and are often restricted in Ecolabelled products. Biopolymers can present advantages in waste degradation and the use of renewable resources, although the production of this type of materials is associated with a bit higher economic and energy costs.

Comparison between paper and plastic packaging indicates lower environmental impacts for paper packaging.

Recycling rate is higher for paper and cardboard packaging waste than for plastic packaging waste. Among packaging plastics, PET is the polymer with a higher recycling rate, whereas PVC is the polymer less recyclable. Biopolymer present advantages with regard to waste degradation. It is important to guarantee recyclability of packaging and the use of recycled material, so packaging elements such as caps or labels also have to be considered to ensure that these elements do not pose difficulties in recycling processes. In order to facilitate the recyclability of packaging the materials in the packaging should be separable (paper, cardboard, plastic, metal, glass) for sorting.

It is environmentally favourable to increase the amount of recycled material entering other product life cycles in order to minimize the impact coming from materials, since the production impacts of virgin material (and the related intermediates) can be lowered by substituting some of the virgin material with recycled one.

**The preparation and production of chemicals processed and used in the final products** are also associated with significant environmental load along the product life cycle. This stage represents 24% of the total environmental impact for solid soaps, 19% of environmental impact of hair conditioners,

7% of the environmental impact of shampoo and 5% of the environment impact of liquid soaps. The impacts with higher values are related to non-renewable energy and land occupation needed to produce these ingredients, whereas toxicity categories related to the release of these substances into environmental compartments like water have lower values, mainly due to limited characterization factor for eco-toxicity.

Regarding **chemicals**, limitations have been found due to the lack of quantification of their impacts in the available LCA impact assessment databases, and some generic or similar substances have been used when needed. LCA impact assessment methods have limitations to assess human toxicity and ecotoxicity of substances. It is considered that complementary investigations regarding the use of substances and their ecotoxicity impacts are necessary because in the current lifecycle impact assessment (LCIA) methods numerous substances found in soaps, shampoos and hair conditioners are not covered. For these substances there is no characterization factor for the calculation of their environmental impacts which results in a potential underestimation and final underrepresentation of the calculated environmental impacts.

**Distribution process** has been not deeply studied in this study and secondary and literature data has been used in this stage. This stage is responsible for 5% on average of the total impact of products studied, considering average European distribution scenario. Measures of promoting efficiency of transport and improvement in logistics could contribute to reduce this impact, as well as reduction of products' weight.

**Manufacturing of the products** (for which data was derived based on average standard processes as found in the European Databases) shows also an important load in the total environmental impact of products (8% on average). According to LCA results obtained, impacts from manufacturing process come mainly from the use of non-renewable energy for heating and electricity. The main environmental impacts resulting from this stage are found for the impact categories of global warming and use of non-renewable energy. This stage is considered difficult to be regulated via the Ecolabel scheme and other policy tools may be more relevant and more effective. Nevertheless, this information is important for future actions i.e. indicating the areas in which the industry could contribute to improvement of environmental performance (through increase of efficiency in manufacturing and production processes in plants).

**Treatment of packaging waste** stage represents low share of the total environmental impact of products (0.5 % – 0.2 % depending on each product). The waste treatment scenario has been defined according to current European statistics. For plastic bottles (liquid soap, shampoo and hair conditioner), 30% of waste is recycled, 27% is energy valorized and 43% goes to landfill. For paper/cardboard packaging (solid soap) the 81% of waste is recycled, 8% is energy valorized and 6% goes to landfill. Impacts from recycling have been included in a system but balanced with environmental benefits occurring due to avoidance of use of virgin materials (LCA processes pre-defined products life cycles allocation rule).

The incorporation of recycled material or energy recovery allow avoiding some environmental impacts in first stages of manufacturing (energy saving) and packaging (virgin material saving).

Recycling processes have then low environmental impact. Most of the impacts coming from this stage are due to the fraction of waste that goes to landfill disposal.

Introduction of good environmental practices and requirements in the Ecolabel criteria have been analysed in order to estimate and measure the improvement potential and the resulting environmental impact minimization. In the following Table 19 a general overview of how the following information elements are related to each other:

1. Outcomes of the environmental performance of the product group
2. Appropriateness and potential to regulate this area through the policy tool of Ecolabel
3. Ecolabel criterion that is taken or is now proposed per area of action.
4. The environmental savings and improvement that is expected from the Ecolabel criterion is given.

**Table 19. General overview of Environmental performance of the products and Ecolabel criteria. Outcomes of environmental impacts in the life cycle, Ecolabel relevance to take an action, Ecolabel criteria action proposal with introduction of good environmental practices, and environmental savings potential due to the Ecolabel criteria.**

| STAGE         | Environmental impact  | Potential regulation by EU Ecolabel | Good environmental practices /restrictions   | Improvement potential   |
|---------------|---|-------------------------------------|--|---|
| Chemicals     | 24% of the total environmental impact for solid soaps, 19% for hair conditioners, 7% for shampoo , 5% for liquid soaps  | <i>High</i>                         | Select for each functional group of those substances less pollutant (Ecotoxicity factors, CLP, biodegradability)<br><br>Select substances with less energy and non-renewable consumption | <ul style="list-style-type: none"> <li>- Improvement of the environmental performance of ingredients used, including during stages of manufacturing, use and release to water.</li> <li>- Minimize potential ecotoxicity effects if products are released to different environmental compartments.</li> <li>- An important part of environmental impact of substances comes from energy and resources used during its manufacturing.</li> </ul> |
| Manufacturing | 8% on average of the total environmental impact   | <i>Moderate / Medium</i>            | Improvement in manufacturing processes efficiency, mainly in energy use  | <ul style="list-style-type: none"> <li>- Reduction of impacts from manufacturing process, which come mainly from the use of non-renewable energy for heating and electricity.</li> <li>- Minimization of environmental impacts in categories of global warming, use of non-renewable energy.</li> </ul>   |
| Packaging     | 25% of the total environmental impact for liquid soaps, 36% for hair conditioners, 32% for shampoo , 6% for solid soaps | <i>High</i>                         | Minimize packaging weight  | <ul style="list-style-type: none"> <li>- 70% environmental impact of packaging is due to the material used (the rest is generated by manufacturing of packaging)</li> <li>- Decreases in weight (amount of material) have direct decreases in environmental impacts.</li> </ul>   |
|               |   |                                     | Increase recycled material sources   | <ul style="list-style-type: none"> <li>- 70% environmental impact of packaging is due to the material used</li> <li>- Decrease of virgin material has environmental impact savings.</li> </ul>  |
|               |   |                                     | Materials selection:<br>- Use materials with a minor environmental impact  | <ul style="list-style-type: none"> <li>- 70% environmental impact of packaging is due to the material used (the rest is generated by manufacturing of packaging)</li> <li>- Select plastic with low environmental impact along its life cycle (including production phase and recycling phase). Consider potential for reusability and recyclability.</li> </ul>  |
|               |   |                                     | Labelling / information system   | <ul style="list-style-type: none"> <li>- Packaging without label has a 3% of less impact.</li> <li>- Packaging without label is more easily recycled.</li> </ul>  |
|               |   |                                     | Refilling systems  | <ul style="list-style-type: none"> <li>- Refilling system can provide a packaging saving of the 79% of weight</li> </ul>  |
|               |   |                                     | Guarantee recyclability:<br>- Use recyclable materials   | <ul style="list-style-type: none"> <li>- Recycling of waste is in general environmentally preferable than other treatments (energy recovery</li> </ul>  |

|                              |  |  |   |  |
|------------------------------|--|--|---|--|
|                              |  |  | - All parts separable or compatible   | or landfill), nevertheless it can differ for various materials. Recycling allows producing material which can enter again to the system enabling environmental impacts saving in first stages of life product. |
| Distribution                 | Average of 5% of total product environmental impact                                      | Low  | Improve efficiency in logistic and transport processes.<br>Decrease weight of packaging (lower weight of transported product)             | - Environmental improvement due to saving of fossil fuel.  |
| Use                          | 34-17% of total product environmental impact depending on each product                   | Low  | Improvements in products performance: dosage, more easily rinse-off.<br>Communication and awareness messages to users                     | - Reducing dose/washing action<br>- Reducing water consumed /washing action<br>- Reducing product and water consumed/washing action  |
| Release to water             | 27-13% of total product environmental impact depending on each product                   | <i>Impacts from this stage depend on raw materials and use stage</i> | Use substances which are not toxic for the environment or the humans.   | - Environmental impact minimization related to from wastewater treatment.  |
| Treatment of packaging waste | 0.5 % – 0.18 % of the total environmental impact of products (depending on each product) | <i>Impacts from this stage depend on packaging stage</i>             | Increase recycling rates in packaging waste.<br>Reduce amount of waste generated by packaging (refilling systems, lower packaging weight) | - In general, recycling of waste is environmentally preferable than other treatments (energy recovery or landfill), nevertheless, differences among materials exist in this respect.                           |

#### 14. APPENDIX IV: CONCLUSION ON IDENTIFICATION AND ANALYSIS OF ALTERNATIVES FOR HAZARDOUS SUBSTANCES

In this analysis we have provided information on some of the most commonly used substances in soaps, shampoos, hair conditioners and packaging. Based on the information provided by or contained in ESIS, ECHA, CLP, scientific literature<sup>97</sup> and other ecolabels, a priority list of substances which are determined to pose the most significant potential threat to human health and environment in this product group has been prepared. The identification of hazardous substances is based on ingredients inherent properties. The environmental and human health effects are referred in the classification status according to CLP regulation.

In conclusion, the main substances that are proposed to be restricted or excluded from ecolabelled products are mentioned below:

- **Hazardous substances:** According to the Article 6(6) of EU Ecolabel legislation EC/66/2010<sup>98</sup>, the product or any part of it thereof shall not contain substances or mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with CLP Regulation (EC) No 1272/2008, nor to goods containing substances referred to in Article 57 of REACH Regulation.

Hazardous substances can be classified through the hazard statements provided in Annex II.

**Substances considered PBT (persistent, bioaccumulativ and toxic) and vPvB (very persistent and very bioaccumulativ) and/or those having endocrine disrupting properties** according to article 57 of REACH regulation.

- **Substances included in the candidate list<sup>99</sup> of Substances of Very High Concern (SVHC) for authorization.** Currently there are 73 substances in the candidate list.

Some specific substances that are proposed for consideration to be restricted are:

- **Triclosan (5-chloro-2-(2,4-dichlorophenoxy)phenol )** - Triclosan<sup>100</sup> is a preservative added to soaps, hair conditioners and shaving cream products. Triclosan is classified as an agent that may cause adverse environmental effects<sup>101</sup>. Based on its classification<sup>102</sup>, triclosan should be restricted: H410: very toxic to aquatic life with long lasting effects, H315: causes skin irritation and H319: causes serious eye irritation. Some other studies<sup>101</sup> have shown that the use of triclosan in cosmetic products is also a matter of concern from a toxicological point of view.

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<sup>97</sup> Risk Assessments reports

<sup>98</sup> Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:027:0001:0019:EN:PDF>.

<sup>99</sup> 73 substances in the Candidate List are available from:

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp#download](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp#download)

<sup>100</sup> Scientific Committee on Consumer Products SCCP opinion on Triclosan, COLIPA n° P32,

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_166.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf)

<sup>101</sup> Risk assessment on the use of triclosan in cosmetics prepared by the Scientific Committee in cooperation with the Panel on Biological Hazards and the Panel on Food Additives, Flavourings, Processing Aids, Materials in contact with Food and Cosmetics, available online at: <http://vkm.no/dav/117573d6c4.pdf>.

<sup>102</sup> [http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031/AGGR-09e9b0f0-bf29-4975-8fba-a3a2dd0ac2be\\_DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031.html#L-137752f6-fbea-4638-b8d8-acce5e212979](http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031/AGGR-09e9b0f0-bf29-4975-8fba-a3a2dd0ac2be_DISS-9ea3b5cc-80fb-15ea-e044-00144f67d031.html#L-137752f6-fbea-4638-b8d8-acce5e212979).

- **Formaldehyde** - Formaldehyde is used as a preservative. It is a known sensitizer and a known carcinogen, based on its classification<sup>103</sup>: 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, it should be restricted.

Formaldehyde is already regulated and specifically excluded in Ecolabelling criteria for Thai Green Label.

- **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** – 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<sup>104</sup>. There are some studies that demonstrate that people exposed to formaldehyde releasers may experience allergic reaction<sup>105</sup>.
- **Fragrance** - Fragrances are sensitizers and known triggers of allergic reactions such as asthma and contact dermatitis<sup>106</sup>. In 1999, the Scientific Committee on Cosmetic Products and Non Food Products intended for Consumers (SCCP) based on criteria restricted to dermatological data reflecting the clinical experience<sup>107</sup>, identified a list with the 13 most frequently reported contact allergens.

Sensitizing substances classified as H334 (R42): respiratory sensitization and/or H317 (R43): skin sensitization or is one of the 13 fragrances mentioned in this table, are proposed to be restricted to 0.01% (100 ppm) in rinse-off products.

<sup>103</sup> [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](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).

<sup>104</sup> Eskeland M. B., Svanes E.: Final report EU Ecolabel for shampoo and soaps, Ecolabelling Norway, 2006.

<sup>105</sup> Groot et al., Formaldehyde-releasers in cosmetics: relationship to formaldehyde contact allergy, Contact Dermatitis 2010: 62: 18–31, available online at: [http://share.eldoc.ub.rug.nl/FILES/root2/2010/Formretof/de\\_Groot\\_2010\\_Contact\\_Dermatitis.pdf](http://share.eldoc.ub.rug.nl/FILES/root2/2010/Formretof/de_Groot_2010_Contact_Dermatitis.pdf).

<sup>106</sup> Wijnhoven et al., Allergens in Consumer Products, RIVM Report 320025001/2008, available online at: <http://www.rivm.nl/bibliotheek/rapporten/320025001.pdf>.

<sup>107</sup> [http://ec.europa.eu/health/archive/ph\\_risk/committees/sccp/documents/out93\\_en.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out93_en.pdf).

Table 20. Fragrances chemicals most frequently reported as contact allergens

| SUBSTANCES                                   | 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   |
| 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    |

Nordic Swan<sup>108</sup> restricts the use of multiple fragrances in their criteria for shampoo, conditioners, body shampoo, liquid and solid soap.

- **Phthalates** - Some phthalates can be found in rinse-off cosmetic formulations. It is assumed that they are added in the perfume mix. Phthalates such as Bis(2-methoxyethyl) phthalate, diisobutyl phthalate, dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP), should be restricted because they are classified as toxic for reproduction and present in the candidate list of Substances of Very High Concern for authorisation according to REACH regulation.

On February 17, 2011 the European Commission named 6 chemicals as the first entrants on the Authorization list<sup>109</sup> (see Table 21), known as Annex XIV, which means that the next substances: dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and bis (2-ethylhexyl)phthalate (DEHP) were moved from the candidate list to the authorisation list under the REACH regulation.

<sup>108</sup> Nordic Ecolabelling of cosmetic products Version 2.1 • 12 October 2010 – 31 December 2014

<sup>109</sup> COMMISSION REGULATION (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals ('REACH'), <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2011R0143:20110221:EN:PDF>.

**Table 21. Substances subjected to authorization, Annex XIV of REACH regulation**

| Substance name                                    | EC Number | CAS Number | Classification                       |
|---|-----------|------------|--------------------------------------|
| Bis(2-methoxyethyl) phthalate <sup>110</sup>      | 204-212-6 | 117-82-8   | Toxic for reproduction (article 57c) |
| Diisobutyl phthalate <sup>111</sup>               | 201-553-2 | 84-69-5    | Toxic for reproduction (article 57c) |
| Dibutyl phthalate (DBP) <sup>112</sup>            | 201-557-4 | 84-74-2    | Toxic for reproduction (article 57c) |
| Benzyl butyl phthalate (BBP) <sup>113</sup>       | 201-622-7 | 85-68-7    | Toxic for reproduction (article 57c) |
| Bis (2-ethylhexyl)phthalate (DEHP) <sup>114</sup> | 204-211-0 | 117-81-7   | Toxic for reproduction (article 57c) |

- **Ethyl-, methyl-, propyl- and butyl-Parabens** - Parabens are used as preservatives. 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<sup>115</sup>. 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 alternatives to parabens exist<sup>116</sup>, and around 5,4% of products are now marketed as “paraben-free”.

Therefore, based on precautionary principle ethyl-, methyl-, propyl- and butyl- Parabens should be restricted.

<sup>110</sup> Support document for identification of Bis(2-methoxyethyl) phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/d60da5c8-85de-4cb2-b95a-fada9451373b>.

<sup>111</sup> Support document for identification of Diisobutyl phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/d418f8b0-ba93-402a-97fd-1e340d22c541>.

<sup>112</sup> Support document for identification of Dibutyl phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/5196d655-7b11-41b2-acba-c8709064fac8>.

<sup>113</sup> Support document for identification of Benzyl butyl phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/19fd114d-eb69-4012-a107-8ceb97787733>.

<sup>114</sup> Support document for identification of Bis (2-ethylhexyl)phthalate as a substance of very high concern: <http://echa.europa.eu/documents/10162/b8395d41-b6d5-427c-8294-d46997e8835d>.

<sup>115</sup> [http://ec.europa.eu/environment/endocrine/strategy/short\\_en.htm](http://ec.europa.eu/environment/endocrine/strategy/short_en.htm).

<sup>116</sup> See table with different variants that fulfil equivalent function: preservatives.

- **D4 (octamethylcyclotetrasiloxane)** (CAS 556-67-2) is used as an emollient or solvent although is not in the list of most commonly used substances. Based on its classification<sup>117</sup> 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 since this substance is generally 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)** – Butylated Hydroxy Toluene (BHT) is used as an antioxidant in cosmetic products. BHT is classified as H410 (R50/53) very toxic to aquatic life with long lasting effects<sup>118</sup>.

Based on its classification, it should be restricted.

There are also several substances identified in packaging materials, which are mentioned in the below section:

- **Packaging requirements in function of the material used:** plastic, metal, paper, cardboard and related to the environmental performance of the material:
  - **Plastic:** should not contain the following substances included in the candidate list of Substances of Very High Concern (SVHC) for authorization: phthalates: benzyl butyl phthalate, bis (2-ethylhexyl)phthalate, Dibutyl phthalate and Diisobutyl phthalate, monomers such as: 2,4-Dinitrotoluene, 4,4'-Diaminodiphenylmethane, Acrylamide, flame retardants: Hexabromocyclododecane (HBCDD) and all major diastereoisomers, Tris(2-chloroethyl)phosphate, Short Chain Chlorinated Paraffins: Alkanes, C10-13, chloro, Chromium trioxide, pigments: Lead chromate, Lead chromate molybdate sulphate red (C.I. Pigment Red 104) and Lead sulfochromate yellow (C.I. Pigment Yellow 34).
  - **Paper/cardboard packaging:** Chlorine should not be used to bleach. Chlorine gas is classified as<sup>119</sup> 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 dioxin. Dioxins are recognized as a persistent environmental pollutant, regulated internationally by the Stockholm Convention on

<sup>117</sup> [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](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).

<sup>118</sup> [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](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).

<sup>119</sup> [http://apps.echa.europa.eu/registered/data/dossiers/DISS-a6516d11-7da2-57f1-e044-00144f67d249/AGGR-585ca394-3912-4434-bd0f-a9a1fddb4e48\\_DISS-a6516d11-7da2-57f1-e044-00144f67d249.html#section\\_1.1](http://apps.echa.europa.eu/registered/data/dossiers/DISS-a6516d11-7da2-57f1-e044-00144f67d249/AGGR-585ca394-3912-4434-bd0f-a9a1fddb4e48_DISS-a6516d11-7da2-57f1-e044-00144f67d249.html#section_1.1).

Persistent Organic Pollutants<sup>120</sup>. According to EU Ecolabel for tissue paper<sup>121</sup> and for copying and graphic paper<sup>122</sup>, chlorine gas shall not be use as a bleaching agent.

DRAFT WORK IN PROGRESS

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<sup>120</sup> Listing of POPs in the Stockholm Convention, <http://chm.pops.int/Convention/ThePOPs/ListingofPOPs/tabid/2509/Default.aspx>

<sup>121</sup> Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community Eco-label for tissue paper, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:197:0087:0095:EN:PDF>.

<sup>122</sup> Commission Decision of 7 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel for copying and graphic paper, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:149:0012:0024:EN:PDF>.