

# **Nordic Ecolabelling of cosmetic products**

**Version 2.0**

**Background document regarding ecolabelling**

**18 november 2009 – draft for comment**



**Nordic Ecolabelling**

# Cosmetic products - Background document regarding ecolabelling

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# 1 Summary

This background document contains a brief description of the product group and its impacts on health and the environment, an overview of the market and the background to the criteria for cosmetic products.

The main environmental impact of cosmetic products is associated with the release of hazardous, non-degradable and/or bioaccumulative substances into the environment, thus putting a strain on waste-water treatment plants and/or natural recipients. Imposing requirements regarding the toxicity and degradability of the constituent substances allows the strain on our external environment to be reduced.

There are also certain health-related problems associated with cosmetic products, e.g. allergies and unnecessary exposure to substances that can be harmful to health. The criteria additionally address these issues.

The product group includes all products covered by the Cosmetics Directive EEC/76/768 and similar products for animal use.

## 2 About the criteria

### **What products are eligible for an ecolabel?**

All cosmetic products encompassed by the EU's Cosmetics Directive EEC/76/768 with subsequent amendments and adaptations (see Article 1), e.g. skin-care products, hair-care products, decorative cosmetics, perfumes and hygiene products, qualify for a Nordic Ecolabel. In accordance with the Council's directive on cosmetics, a 'cosmetic product' is any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the oral mucous membrane with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition. For example, hand dishwashing detergents containing skin-care compounds do not meet the above criteria and therefore do not qualify as cosmetics in accordance with the Cosmetics Directive or Nordic Ecolabelling criteria.

In this criteria document we have combined the previously separate criteria documents for 1) Cosmetics and 2) Shampoos, conditioners, body shampoos, liquid and solid soaps (later referred to as soaps and shampoo). Products for use on animals also qualify for the Nordic Ecolabel. Consumer products that are marketed as being anti-bacterial/antiseptic/disinfectant do not qualify for the Nordic Ecolabel. This is because household use of biocidal products has not been found beneficial and may increase resistance to bacteria. Nordic Ecolabelling finds that use of such products in households is unnecessary and should be avoided, so as to reduce the burden on health and the environment.

**Justification for Nordic Ecolabelling of cosmetics**

The preliminary study (Nordic Ecolabelling, 2003a) in 2003 concluded that not only are cosmetic products relevant as a product group but the vast majority of the products also display potential and steerability (RPS). Background documents for and evaluations of different criteria versions of soaps and shampoos also conclude that the product group displays relevance, potential and steerability. (Nordic Ecolabelling, 1995, Nordic Ecolabelling, 2008a, b, etc.)

The relevance of the product group is based on the fact that the Cosmetics Directive does not include requirements regarding the use of substances that may have an impact on the environment. Furthermore, the Cosmetics Directive does not exclude the use of sensitising substances as such. Sensitising substances are of great concern to many consumers, and cosmetic products and their constituent substances frequently attract media attention, thus causing consumers concern. Large quantities of cosmetic products are sold, and these products may be used up to several times a day by consumers. In an American study from 2006 (Loretz, 2006) it was concluded that five widely used personal-care products (spray perfume, hairspray, liquid foundation, shampoo and body wash) were each used on average more than once a day by women aged 18-65. Sales of cosmetic products have been growing in Nordic countries since the preliminary study in 2003 (see Table 1).

**Table 1 Sales of cosmetic products in Nordic countries since 2003 in million€**

	Norway <sup>1</sup>	Sweden <sup>2</sup>	Finland <sup>3</sup>	Denmark <sup>4</sup>
2003	782 (NOK 6,975m)	918 (SEK 9,436m)	320	840 (DKK 6,240m)
2004	830 (NOK 7,400m)	920 (SEK 9,463m)	336	788 (DKK 5,866m)
2005	872 (NOK 7,780m)	966 (SEK 9,927m)	359	859 (DKK 6,406m)
2006	1,000 (NOK 8,920m)	1,028 (SEK 10,569m)	391	928 (DKK 6,919m)
2007	992 (NOK 8,845m)	1,077 (SEK 11,069m)	410	1,011 (DKK 7,533m)
2008	1,023 (NOK 9,130m)	No data	409	No data

<sup>1</sup>(KLF, 2009)<sup>2</sup>(KTF, 2009)<sup>3</sup>(TY, 2009)<sup>4</sup>(SPT, 2009)

The product group's potential environmental and health benefits have been demonstrated in a long series of tests conducted by the German magazine Öko-Test and the Danish consumer organisation Grøn Information (now the Information Centre for Environment and Health). These tests have shown that the product areas examined include a range of products that consumers are recommended not to use, as well as products that are recommended because of their chemical composition. The German

magazine Öko-Test is continuing its comparative test on cosmetics, and also recently has found differences between products (e.g. Ökotest, 2009a; Ökotest 2009b, Ökotest 2009c). In 2004 the Finnish magazine Kuluttaja compared ingredients lists for 20 shampoos (Kinnunen-Moilanen, 2004). EDTA and BHT, for example, were present in several products. The former substance is not readily degradable, and the latter has been classified as being very toxic to aquatic environment, may cause long-term adverse effects. These articles and tests indicate that there is a difference between the products, and hence that a potential exists. The increasing occurrence of allergies associated with the use of fragrances and preservatives also indicates a potential for differentiation of products with a good health profile. Thus Nordic Ecolabelling could help guide consumers towards choosing products that are best in terms of the environment and health.

It was concluded that the product group offered steerability, as many consumers wish to be able to choose cosmetic products that represent good choices in terms of health and the environment. The public is generally becoming more aware of environmental concerns, thus increasing the demand for Nordic Ecolabelled cosmetics. The consumers who are expected to be the most interested in the Nordic Ecolabel are allergy sufferers and parents of children and infants. This latter group is particularly aware of product contents. A growing number of consumers choose natural cosmetics for health and environmental reasons (Organic monitoring, 2009), though natural cosmetics are no guarantee that the products are free from classified allergens. Thus these consumers might also be interested in cosmetics carrying the Nordic Ecolabel.

The evaluations carried out in 2007/2008 (Nordic Ecolabelling, 2008a and b) stated that the relevance, potential and steerability study conducted in the preliminary study for cosmetics in 2003 as well as background studies for shampoo and soaps were still relevant. The licensing of the Nordic Ecolabelled products has resulted in changes in the raw materials and minimising of the amount of packaging material used.

### **The version and validity of the criteria**

The Nordic Ecolabel criteria for cosmetic products were originally established as two separate criteria documents for soaps & shampoos (rinse-off cosmetic products) and cosmetic products (covering all other cosmetics besides rinse-off products). Tables 1 and 2 in Appendix 1 summarise the history of the two criteria documents.

In 2008 the criteria documents for Soaps & Shampoos and Cosmetics were evaluated prior to the revision of the documents. During this process Nordic Ecolabelling decided to merge the criteria documents to form a combined Nordic Ecolabel criteria document for cosmetic products, covering both rinse-off and leave-on products. The obvious reason for this was that the products consist of similar ingredients with a similar use and function, regardless of whether they are intended to be washed off or left on the skin. Furthermore, the products are all covered by the same legislation (the Cosmetics Directive EEC/76/768).

### **The Nordic Market**

There are many different operators active on the Nordic market. In Finland the industry association The Finnish Cosmetic, Toiletry and Detergent Association (TY) has 31 members in the field of cosmetics (TY, 2009). Many of these are importers, but the member list also includes Finnish producers, and there are additionally some

smaller producers who are not members of TY. The Danish industry association (SPT) has 55 members in the field of cosmetics (SPT, 2009). In Sweden the industry association (KTF) has 44 members in the areas of hygiene and cosmetic products (KTF, 2009). KTF estimates that there are approximately 10 major manufacturers on the Swedish market with large market shares and approximately 15 manufacturers with small shares of the market. In Norway the industry association (KLF) has 19 members in the field of cosmetic products (KLF, 2009). KLF estimates that the members account for 75% of sales by the industry in Norway. According to KLF 4-5 of the 25 members account for approximately 80% of sales.

Overall there appear to be 5-10 large and medium-sized manufacturers in the Nordic countries, and numerous small businesses. The majority of product volume on the market is manufactured outside the Nordic countries. Table 2 shows the most recent sales figures for the product group. The Finnish figures solely comprise sales by TY members.

**Table 2 Sales figures for cosmetic products in 2008 in million€**

	Norway (EUR) <sup>1</sup>	Sweden (EUR) 2007 data <sup>2</sup>	Finland (EUR) <sup>3</sup>	Denmark (EUR) 2007 data <sup>4</sup>
Fragrances	66 (NOK 575m)	113 (SEK 1,160m)	18.9	166
Decorative cosmetics	190 (NOK 1,660m)	241 (SEK 2,473m)	63.4	127
Skin care	288 incl. sunscreen lotions (NOK 2,510m)	264 incl. sunscreen lotions (SEK 2,718m)	105.6	203
Hair care	262 (NOK 2,280m)	209 (SEK 2,153m)	134.4	324
Personal hygiene products	242 (NOK 2,105m)	250 (SEK 2,565m)	84.9	191

<sup>1</sup>(KLF, 2009)

<sup>2</sup>(KTF, 2009)

<sup>3</sup>(TY, 2009)

<sup>4</sup>(SPT, 2009)

Statistics Sweden (2009) stated that 40,000 tonnes of cosmetics and hygiene products were sold in Sweden in 2005.

The number of Nordic Ecolabel licences has also been growing in recent years, though the market share is still rather small, with the exception of Nordic Ecolabelled I&I soaps, which have a respectable market share. Table 3 summarises the licences and registrations in the Nordic countries in August 2009.

**Table 3**

	Licences – Cosmetics (090)	Registrations – Cosmetics (090)	Licences – Shampoo and soap (027)	Registrations – Shampoo and soap (027)
Norway	6	16	1	22
Sweden	6	13	11	13
Finland	0	7	2	13
Denmark	25	3	29	7

It should be noted that most licences cover multiple products/trade names. On the Danish market, for example, the 29 licences for ‘cosmetics’ include 355 Nordic Ecolabelled products and the 36 licences for ‘soaps/shampoos’ cover 229 Nordic Ecolabelled products.

### **Other labelling schemes and regulatory systems Cosmetics Directive 76/768/EEC**

Cosmetic products are regulated by the Cosmetics Directive 76/768/EEC with amendments and adaptations (EU, 1976). They are not subject to the rules on classification provided for in the Dangerous Preparations Directive 67/548/EEC.

In general terms the Cosmetics Directive imposes requirements regarding substances that may be present in cosmetic products. Substances that are classified as carcinogenic, mutagenic or toxic to reproduction in Categories 1 or 2 must not be present in cosmetic products. Substances classified in Category 3 must be assessed by the EU Scientific Committee to determine whether consumers can safely use them. The annexes to the Directive specify the substances that must not be present in cosmetic products and those that may be used in limited quantities (Annexes II and III). Colourants (Annex IV), preservatives (Annex VI) and UV filters (Annex VII) are approved in separate annexes, and only the substances listed in the annexes may be present in cosmetic products, subject to the restrictions in the annex in question. Annex V is a list of substances not covered by the Directive.

None of the above annexes limits or prohibits the use of substances on the basis of their environmental properties.

A proposal for a new cosmetics regulation has been under public consultation in spring 2008 (EU, 2008c). It is expected to enter into force in late 2009 and apply as from late 2012. No major changes are expected. One of the main objectives is to remove the legal uncertainties and inconsistencies caused by the many amendments to the present legislation. The directive has been changed into a regulation and will thus be binding in its entirety and directly applicable in all member states.

### **The Flower**

The European Union Ecolabelling scheme, The Flower, includes criteria for soaps, shampoos and conditioners covered by the Nordic Ecolabelling criteria for cosmetic products, but not for other cosmetic products (EU, 2007).

The Flower limits toxicity to aquatic organisms by means of the critical dilution volume (CDV). It also limits the amount of substances classified as environmentally harmful. Surfactants must be degradable under both aerobic and anaerobic conditions,

and there are limits for the content of ingredients that are not readily biodegradable and for ingredients that are not anaerobically degradable. There are also requirements for fragrances, dyes and biocides. No constituent substance must be classified as carcinogenic (Carc), mutagenic (Mut) or toxic for reproduction (Rep), and certain ingredients such as APEOs and borates are excluded or limited. The Flower also imposes requirements regarding packaging and fitness for use.

### **Bra Miljöval**

The Swedish Society for Nature Conservation, the body that manages the Swedish ecolabel Bra Miljöval (Good Environmental Choice), has an open criteria document regarding chemical products. Approval for all types of cosmetic products may be granted through this document (SNF, 2006).

The criteria exclude certain ingredients and ingredient classifications. There are specific requirements for surfactants, complexing agents, solvents, preservatives, thickening agents, bleaches, acids, colourings, fragrances, biological substances, enzymes, filling materials, rubbing/abrasive agents and other substances. The criteria also include requirements for water content and packaging, as well as general requirements for the company manufacturing the product. There are also product-specific requirements. In soaps, for example, only vegetable-based fatty acids can be used.

### **Natural/Organic cosmetics**

There are several different national and international labelling schemes for natural/organic cosmetics (BDIH, Cosmos, Ecocert, NaTrue, Soil Association, 2009). Only some of these schemes have criteria that are accessible to the public. These schemes are not regulated by the Council regulation on organic production (834/2007/EEC).

Labelling schemes include:

#### National

- BDIH
- Naturland
- SOIL ASSOCIATION
- AIAB
- USDA
- NASAA

#### International

- ECOCERT / Cosmebio ECO/BIO
- NaTrue
- Cosmos (proposal)

Most of these standards (with some exceptions) require that 95% or 100% of raw materials be of natural and/or organic origin. Restrictions/positive lists apply to the

remaining raw materials, and some chemical/physical processes are usually allowed. Examples of the processes often not allowed are ethoxylation, propoxylation, sulphonation, genetic engineering and irradiation.

### **Allergy and Asthma Federations**

Allergy and asthma federations in the Nordic countries also label cosmetic products. Sunscreen lotions, hair- and skin-care products, soaps, deodorants and make-up, for example, can be given the allergy and asthma federations' symbol in the Nordic countries (Allergia- ja astmaliitto [Finnish Allergy and Asthma Federation], 2009; Astma- och Allergiförbundet [Swedish Allergy and Asthma Federation], 2009). The requirements are not accessible to the public, but some basic principles are public, for example the fact that perfume compounds and sensitising compounds are not allowed (Allergia- ja astmaliitto, 2009).

## **3 About the revision**

### **The aim of the revision**

The 2008 evaluation of cosmetics, soaps and shampoos stated that the RPS and criteria for both product groups are basically still relevant and up to date (Nordic Ecolabelling, 2008a and b).

Some adjustments are necessary, and it was decided that the two criteria should be revised, the emphases being as follows:

- Merging the present criteria for cosmetics, soaps & shampoos
- Nordic Ecolabelling's recent projects regarding perfume and preservatives
- The possibility of imposing requirements regarding renewable raw materials
- The possibility of imposing requirements regarding raw materials that are classified as being hazardous to aquatic environments
- The possibility of setting limitations regarding nanomaterials
- The possibility of excluding silicone/siloxanes and other PBT substances

The following subjects were also considered in the revision:

- Use of and reference to the official lists; handling/standardising transition periods included
- The relevance of requirements that depend on ingredient function
- Adjusting the requirements where interpretations have been made
- Adjusting the requirements regarding the materials for wet wipes
- Adjusting/tightening up the packaging requirements
- Adjusting/defining the effectiveness requirements
- Tightening up the CDV requirements (primarily for conditioners), plus the possible addition of CDV (chronic)

- Evaluation of adjustment of the effectiveness requirements, taking into account 'mildness'
- Connection between ILN/IAN and product's 'mildness'
- Relevance of the requirements regarding products for animals in combined criteria for cosmetics

### **About this revision**

The criteria were revised by a Nordic Ecolabelling project group from March 2008 and are expected to be finished in March 2010. The revision was based on an evaluation of the existing criteria and a compilation of information and data from the industry (primarily licence holders) and other stakeholders.

The revision process has involved a dialogue with several producers, consumer organisations, authorities and national trade organisations.

In addition to this a stakeholder meeting was organised in Denmark in March 2009. All licence holders and other stakeholders were invited, and 26 stakeholders took part in the meeting, at which future and planned changes to the criteria were discussed.

The working group has comprised: Eline Olsborg Hansen (Norway), Ulf Eriksson (Sweden), Trine Thorup Andersen (Denmark), Anja Keller (Denmark, Project Manager until autumn 2008) and Terhi Uusitalo (Finland, Project Manager from autumn 2008). Jeppe Frydendal (Denmark) is the Nordic Criteria Manager.

## **4 Justification for the requirements**

### **4.1 General background for the product group**

#### **Life cycle of cosmetics**

The life cycle of cosmetics comprises production of raw materials, production of packaging materials, transportation of raw materials and packaging, manufacture of the product, distribution of the product, use of the product, waste-water treatment and management of the waste packaging.

Some of the most important aspects of cosmetic products' life-cycle stages are presented below, so as to provide an overview of our basis for setting requirements in a life cycle perspective.

#### **Raw materials and sustainability**

Nordic Ecolabelling deems it to be essential that the raw materials be sustainable wherever possible, e.g. through requirements regarding renewable raw materials and reduced effect on biodiversity. Social and ethical considerations are also taken into account, usually by requiring that the raw materials used be in line with the certification systems approved by Nordic Ecolabelling, e.g. FSC and PEFC.

In chemical products, Nordic Ecolabelling has so far focused on the characteristics of chemicals and not their origin, though the origins of raw materials for chemical products will also become increasingly important because of the growing ecological and social problems and the increasing demand for agricultural products for other purposes, e.g. biofuels for cars.

In cosmetics the majority of the raw materials used for products are organic substances. Inorganic raw materials are also used, e.g. salts, alkali and TiO<sub>2</sub>, but there are fewer varieties and the quantities are smaller. In cosmetic products both renewable and non-renewable organic raw materials are used. Limited amounts of non-renewable materials are available, as they are extracted from fossil oil, whereas renewable raw materials are replenished through natural processes. This alone supports promotion of the use of renewable raw materials.

However, use of renewable rather than non-renewable raw materials on a larger scale in fuels etc. has caused major concern (WWF, 2009; RSPO, 2009) – chiefly because of rainforest decline and increased food costs. The former is being caused by an increase in demand and unsustainable agriculture, and the latter by use of edible oils in non-food products, as well as replacement of other crops with oil plants. The Roundtable on Sustainable Palm Oil (RSPO) states that between 1990 and the present day the area under palm-oil cultivation has increased by about 43% – most of this increase being in Malaysia and Indonesia. Development of new plantations has resulted in the conversion of large areas of forests with a high conservation value, and has threatened the rich biodiversity of these ecosystems. It has been reported that the use of fire to prepare land for oil-palm planting contributed to the problem of forest fires in the late 1990s. The expansion of oil-palm plantations has in many instances also given rise to social conflicts between the local communities and project proponents. RSPO is one of the initiatives that aims to promote the growth and use of sustainable vegetable oils. Similar initiatives regarding other renewable products, e.g. soya beans and sugar cane, are currently being developed. Promotion of renewable raw materials in Nordic Ecolabelled cosmetics would require sustainable production of renewable raw materials –especially vegetable-oil production.

The project group has decided not to set general requirements regarding renewable raw materials (though a voluntary requirement has been 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. It is unclear whether the production and use of cosmetics contributes significantly to global warming. It is assumed that cosmetics manufacture involves a very limited proportion of the total use of fossil fuels, and the by-products from extraction and refinement of fossil fuels (NationMaster, 2009). The sustainability and traceability of renewable raw materials constitute a challenge, and it is expected to be difficult for manufacturers to get proper documentation for sustainable raw materials, especially since the raw materials are often mixtures originating from different sources. This will greatly limit the quantity of raw materials available to the manufacturers. Since compliance with sustainability requirements regarding renewable raw materials is in practice expected to be difficult for many manufacturers, this might lead to greater use of non-renewable raw materials than is currently the case. Nordic Ecolabelling does not wish to promote use of non-renewable raw materials, and it has decided not to set a general requirement for renewable raw materials yet.

Nordic Ecolabelling has, however, experienced a need to broaden their territory to consideration of renewable raw materials from both consumers and licence holders, thus in the revised criteria document for cosmetics a voluntary labelling requirement is suggested in order to gain more information and experience.

We would very much like to receive your feedback on this voluntary requirement at the hearing.

According to feedback received in the stakeholder meeting in March 2009 there seems to be very little variation in energy consumption during manufacture of raw materials and products, and during transportation of both, thus there is no potential, and Nordic Ecolabelling has not set any requirements regarding these factors.

## **Manufacturing and packaging**

As far as the life cycle is concerned, product manufacture itself is normally far less relevant than the other life-cycle stages. Many cosmetics production processes are not very energy-consuming, and although some of them, e.g. production of solid soap or extraction of minerals, involve major reactions, they cannot be used in differentiating between end products. This is because the overall impact is still too small, and too hard to control in terms of creating a substantial environmental benefit.

Packaging, however, may be relevant to environmental burden – and for some products it might even be of more relevance than the product itself. Of course this mostly applies to products with a high packaging/content ratio. There are many examples of cosmetic products that use far more packaging than necessary, thus we have found it relevant to set requirements related to the use of packaging materials.

Quality considerations are of great importance to Nordic Ecolabelling. In its guidelines for Nordic Ecolabelling (NMR, 2001) the Nordic Council of Ministers states that Nordic Ecolabelling should not be at the expense of product quality. There are thus requirements to ensure the quality and efficiency of the Nordic Ecolabelled cosmetic products. For example, we require traceability of our licence holders with regard to manufacture of Nordic Ecolabelled products, to facilitate tracing of quality problems and to prevent future occurrence of such problems.

## **Use**

The environmental burdens from use are in many cases not direct, though many factors related to consumer behaviour are of great relevance, e.g. the quantity of shampoo used, but Nordic Ecolabelling's steerability is low.

Where possible, however, we have set requirements that relate to consumer behaviour. In general we require that the packaging makes it easier to use the 'correct' dose, so that unintentional overdosing is as far as possible avoided.

For liquid soaps we have set the requirements per actual dose (1 push in a dispenser), to make sure that only products with a low environmental impact per functional unit (hand wash) can meet our requirements.

There are also other requirements, e.g. regarding information on correct disposal, so as to try to exert a positive influence on consumer behaviour.

For many cosmetic products a relevant burden from usage is use of hot water, because of the energy used to heat the water. However, there is no potential for real improvements as there is for textile detergents, since a product like a 'cold-water shampoo' would not be relevant from a consumer standpoint.

The media and consumers have focused on several problematic substances in cosmetics. Nordic Ecolabelled cosmetics should represent a good choice for consumers, without their having to worry about questionable ingredients. Cosmetics are smeared or sprayed onto skin and hair, and come into contact with the mucosa. Some products, e.g. lipsticks, might end up being ingested. Generally the products come into direct contact with the skin and mucosa, and will to some extent be absorbed into these surfaces. This means that cosmetics should contain as few skin irritants, allergens and other harmful ingredients and pollutants as possible. Thus health considerations are also extremely important in Nordic Ecolabelling of cosmetics. Several health requirements go further than the Cosmetics Directive, as the aim of Nordic Ecolabelling is to increase the user's sense of safety and security when using Nordic Ecolabelled cosmetics. Nordic Ecolabelling imposes more strict health requirements than the Cosmetics Directive, e.g. regarding classification of constituent substances, use of sensitising substances, substances that are considered to be (potential) endocrine disruptors and nanoparticles.

### **After use**

Cosmetic products and their constituent ingredients may have different routes from the consumer to the surrounding environment. Some volatile ingredients, for example, will evaporate from the hair and skin into the air; other ingredients will be eliminated with the washing water during a bath/shower or whilst washing clothes, and some ingredients will be absorbed by the skin and finally be eliminated through human excretion or accumulated in the body (WWF, 2005; personal dialogue with the industry). Some products (e.g. wet wipes, nail-polish remover) will likely be eliminated via household waste. Cosmetic products also end up in the aquatic environment when clothes containing product rub-off are washed. Sunscreen lotions partly end up in the environment during swimming. This is a problem, since organic UV filters cause bleaching of coral, which in turn has a negative impact on biodiversity and the functioning of reef ecosystems (Danovaro et al. 2008, etc.). Some organic UV-filters are also potential endocrine disruptors (EU 2007b).

In the Scandinavian countries, where most households are connected to a sewage system, it is expected that the majority of rinse-off and leave-on products will eventually end up in the sewage system, as a result of being washed off during bathing/showering. Depending on the level of sewage treatment and on the properties of the ingredients, a certain fraction of the ingredients from cosmetic products may end up in the aquatic environment via the waste water, or be adsorbed into sludge during waste-water treatment (Guang-Guo Ying, 2007; Shaoyuan Zhang, 2007; Carballa, 2004 etc.). Properties such as biodegradability, bioaccumulation and toxicity to the aquatic environment are thus important. The Cosmetics Directive does not prohibit use of substances in cosmetic products on the basis of their environmental properties, thus it is highly relevant to set criteria related to the environmental properties of ingredients in cosmetic products.

## 4.2 Background to the requirements

### General requirements

The requirements imposed in this chapter must be met by all products for which a licence is being applied for. The justification for the requirements can be found below.

A limit of 100 ppm is set for constituent substance/contaminant in wash-off products as is commonly set for Nordic Ecolabelled chemical products. In leave-on cosmetics a lower limit of 10 ppm has been proposed, since 100 ppm is considered high. It is recognised that contaminants from production lines (carry-over) and from the manufacturing of certain raw materials are to some extent unavoidable. With the 10/100 ppm limits the manufacturers are encouraged to select materials of a high standard that contain very low amounts of trace materials from raw-material production. We would be interested in your opinion on a reduction of the limit from 100 to 10 ppm for leave-on products.

General requirements also apply to known degradation products of ingredients.

Since this criteria document includes references to external lists and bodies (SCCP opinions, R4 and endocrine disruptors, R5), changes may take place during the validity of the licence – sometimes without any prior warning. Because of that, Nordic Ecolabelling has introduced a sentence in the section ‘How long is the licence valid?’, stating that if the content of the lists and opinions changes regarding a matter that affects the licences, a standard transition period of three months will be granted unless Nordic Ecolabelling decides on another (typically longer) transition period, depending on the complexity of changes from the producer's point of view and the assessed relevance of the changes. If other transition periods apply, Nordic Ecolabelling will give instructions and advice to all licence holders and applicants. Licence holders are solely responsible for complying with the criteria at all times.

### R1 Declaration of content

A licence application must be accompanied by a full formulation for all products that are to be encompassed by the licence. This information is needed in order for compliance to be controlled by the subsequent requirements. Another reason for imposing this requirement is to allow greater and more detailed knowledge of the individual product types. This will enable more relevant and detailed requirements to be imposed in the future criteria documents, and will also permit the requirements to be adjusted to reflect new knowledge gained in the field. The requirement remains the same as in the previous criteria versions.

### R2 Classification of constituent substances

The Cosmetics Directive (EU, 1967) does not restrict the use of substances that are classified as carcinogenic, mutagenic or toxic to reproduction (CMR substances) in Class 3 when the EU Scientific Committee (SCCP) has assessed substances and concluded that they are safe for use in cosmetic products. In the proposal for the new cosmetics regulation, even substances in Classes 1 and 2 could be allowed after SCCP evaluation, under certain conditions (EU, 2008). The precautionary principle is used to restrict CMR substances in Classes 1, 2 and 3 in order to increase the sense of

safety and security for the user. This will also exclude the possible mutagenic and/or reproduction-toxic effects in the environment.

The Cosmetics Directive allows several sensitising substances in cosmetic products, though allergies are a growing problem (Videncenter for allergi [National Allergy Research Centre], 2009). Nordic Ecolabelling has thus chosen to exclude sensitising substances from Nordic Ecolabelled cosmetics. This excludes certain preservatives (e.g. chloromethylisotiazolinone) commonly used in cosmetic products. Perfumes are partly exempted from this requirement, since the working group has concluded that there is little demand for fragrance-free cosmetics and the supply of allergen-free perfumes is limited. Thus if fragrances or fragrances containing allergenic compounds were to be banned completely, this would have a negative effect on market penetration of the label, which would be out of proportion to the possible impact of low amounts of fragrances on the environment. Enzymes are exempted from this requirement because all enzymes are classified as respiratory sensitisers (R42/H334), and some are also classified as skin sensitisers (R43 / H317). Enzymes are used in toothpaste, for example, but enzymes in cosmetics are not expected to cause allergy in consumers, as the enzyme ingredients are incorporated into the product and will not be present as 'free dust'. However, we have set relevant requirements for good practice when using enzymes in Nordic Ecolabelled products (see R20).

Nordic Ecolabelling excludes constituent substances that are classified as sensitising, carcinogenic, mutagenic and/or toxic for reproduction according to regulations in force in any of the Nordic countries or to European regulations (Directive 67/548/EEC with amendments and adaptations and/or CLP regulation 1272/2008/EC). Both classification regulations have been included, as the revised criteria will come into force during the implementation period for the CLP regulation (transition period during 2010-2015). The requirement otherwise remains the same as in the previous criteria versions.

### **R3 Environmentally harmful substances**

Substances that are toxic to the environment and are at the same time not readily degradable (R50/53, R51/53 and R52/53 or H410, H411 and H412) represent a potential problem for the aquatic environment. Most ingredients in cosmetic products eventually end up in the aquatic environment through sewage treatment systems, either directly when they are used (e.g. soaps, toothpastes, shampoos, hair dyes) or after use (wash-off during showering) (e.g. make-up, deodorants, hair-styling products, perfumes). Some products/ingredients are also released directly into the environment (both the aquatic environment and air) upon use (e.g. sunscreen lotions, hair-styling products, creams) (WWF, 2005; personal dialogue with the industry).

The Cosmetics Directive does not prohibit use of substances in cosmetic products on the basis of their environmental properties. Nordic Ecolabelling has thus identified a need to restrict environmentally harmful compounds, and has introduced a cut-off level for these substances. The limit has been set after inspection of Nordic Ecolabelled soaps, shampoos and cosmetic products. The requirement has been suggested so that R50/R53 (forthcoming CLP classification: H410) compounds are chiefly restricted by a weighting of the various classifications. The requirement is new, and is based on a weighted approach that regulates the content of the most environmentally hazardous substances. It will thus exclude or restrict certain perfume compounds and colours, and will restrict them and high levels of possible hazardous

contaminants in cosmetic raw materials. The limit ensures, however, that proper preservation of the products is possible, and guides towards use of perfumes that contain fewer and smaller amounts of compounds classified as environmentally harmful.

Zinc compounds classified as environmentally hazardous are allowed (up to a concentration of 15%) when used in zinc creams. Zinc creams are used for itchy-skin disorders and nappy rash, and have a documented soothing effect. A brief market-research measure in two stores in Denmark (Matas and Føtex) showed us that non-ecolabelled zinc creams in some cases contain high amounts of nonbiodegradable organic substances such as petrolatum. Therefore Nordic Ecolabelling can make a positive difference as high-quality alternatives to zinc creams do not exist to our knowledge.

Zinc originating from cosmetic products only contributes marginally to the total Zn contribution from municipal waste water, and it is removed with the sludge. The biggest Zn contribution comes from human excretion (Water UK, 2001). It is thus argued that the total environmental benefit of ecolabelling these indispensable cosmetic products, e.g. by ensuring that the remaining compounds are biodegradable and not classified as being environmentally harmful, justifies inclusion of zinc creams, despite the content of environmentally hazardous zinc compounds.

#### **R4      SCCP Opinions**

The European Scientific Committee on Consumer Products (SCCP) has published many opinions – many of them regarding cosmetic products. These opinions are based on thorough reviews of the available scientific information, thus they should be given special attention (Nordic Ecolabelling, 2004b). The working group still agrees on the importance of compliance with SCCP's opinions, and has kept the requirement specifying that SCCP's opinions must be adhered to unless they contradict any of the other requirements. The requirement remains the same as in the previous criteria versions.

#### **R5      Substances that must not be present in the product**

There are several problematic substances that cannot be excluded by our general requirements regarding the ingoing substances' product chemistry. Nordic Ecolabelling has thus drawn up a list of substances that must not be added to the product or be present as contaminants at concentrations equal to or exceeding 10/100 ppm. The aim is to only list those problematic substances relevant to the product group that are not excluded by other requirements. Compared to the previous criteria documents the requirement has been changed. Several requirements were combined and some compounds were left out, as they are excluded by other requirements. Silicones and siloxanes, nanomaterials/particles and PBT and vPvB compounds were added to the list. This requirement has a considerable impact on differentiation of Nordic Ecolabelled products from other products on the market, since it excludes substances such as siloxanes, BHT, parabens, triclosan and EDTA, which are widely used.

Siloxanes have many synonyms and are often referred to as '**silicones and siloxanes**'. Especially in cosmetics '-methicone' is a suffix often used for siloxane compounds, e.g. dimethicone (dimethylsiloxane), cyclomethicone (octamethylcyclotetrasiloxane/D4), phenyl trimethicone (phenylated trisiloxane).

Siloxanes are used in various functions in cosmetics, e.g. as emollients, solvents, antistatics, moisturisers, viscosity controllers, antifoamers, and skin and hair conditioners. Siloxanes are mostly used in hair-care products and antiperspirants, but also in creams/lotions, liquid soaps and gels and decorative cosmetics. D5 (decamethylcyclopentasiloxane), for example, is frequently used in cosmetics. There are alternatives to siloxanes in cosmetics (EPA, 2005).

Silicone and siloxanes are excluded from Nordic Ecolabelled products since they are generally considered to be persistent in the environment. Some of the siloxanes that are used in cosmetics and other consumer products have been found in the environment and biota (though in low concentrations). This indicates that the compounds accumulate. Siloxanes are primarily found near densely populated areas and major sources (TemaNord, 2005). The cyclic siloxanes are the most widespread in the environment, especially D4 (Octamethylcyclotetrasiloxane, CAS 556-67-2) and D5 (Decamethylcyclopentasiloxane, CAS 541-02-6). D4 is classified as PBT and vPvB as well as Rep3, R63, R53, and is therefore already not allowed in Nordic Ecolabelled cosmetics (R2). D5 is structurally related to D4 and is on Norwegian authorities' prioritised hazardous-substances list (SFT, 2007). D4, D5 and linear siloxane HMDS (hexadimethylsiloxane, CAS 107-46-0) are High Production Volume Chemicals in the EU. A risk assessment is currently being conducted for D4 and D5 in the EU.

Low-molecular volatile siloxanes (such as D4, D5, HMDS) evaporate when used, and are able to spread over great distances through the air. Non-volatile siloxanes (of a higher molecular weight) also used in cosmetics will primarily end up in waste-water treatment plants (WWTP), where they will accumulate in sludge since they are slow to degrade/persistent and have a high bioaccumulation potential. Only limited data is available on the toxicity, degradability and bioaccumulation potential of the majority of siloxanes. The data available indicates that siloxanes are toxic to aquatic organisms and are slowly degradable. Likewise, only a limited amount of data is available on health considerations concerning siloxanes (TemaNord, 2005). It is has therefore been decided not to allow siloxanes and silicone in Nordic Ecolabelled cosmetics, in accordance with Nordic Ecolabelling's precautionary principle.

**Borates and perborates** are used in cosmetics (e.g. as oxidising agents), in buffering and oral care, and as bleaching agents. In addition to boric acid, a number of these substances are in the process of being classified as being toxic for reproduction (EU, 2008a). The classification has not yet entered into force, and until such time as it does prohibition of the use of these substances in Nordic Ecolabelled products will thus be a preventive measure.

Some **nitromusk and polycyclic musk** compounds are suspected of being carcinogenic or are even classified as such. Furthermore, nitromusks and polycyclic musks may be bioaccumulable and have the potential to cause long-term effects on the aquatic environment (Nordic Ecolabelling, 2002a). Nitromusk compounds may

also have reproductive and endocrinological effects on women. They are furthermore often found in waste-water effluents in screening studies (Carballa, 2004 etc.). Their use in Nordic Ecolabelled products is thus prohibited. Communication with suppliers of fragrance (Leccia, 2009) has confirmed that many companies all over Europe still use polycyclic musks in consumer products. The use of nitromusks is apparently very limited, but manufacturers outside Europe still produce Musk Ambrette, for example, which is prohibited by IFRA. Exclusion of nitro- and polycyclic musks is thus still considered relevant as a preventive measure.

**Triclosan** is an antibacterial disinfectant used in a wide range of products, e.g. in toothpastes. There is some concern that the use of antibacterial and disinfectant substances such as triclosan may play a part in increasing the resistance of bacteria to antibiotics (Miljøstatus i Norge, 2008A). Triclosan is bioaccumulable, though a BCF value of under 500 has been documented in certain sources. It is classified as environmentally harmful – N; R50/53 (Dye et al, 2007), and is on the Norwegian Pollution Control Authority's Priority List – a list of substances for which the Norwegian authorities are seeking to bring about a significant reduction in use (Miljøstatus i Norge, 2008A). It is also on the Danish EPA's 'List of undesired substances' (EPA, 2004). Studies have been conducted that show that triclosan breaks down into harmful dioxins when it comes into contact with sunlight (Bakke, 2003). Triclosan has been found in a number of different locations, e.g. in sewage and in waste water from treatment plants (Dye et al, 2007), indicating that use of triclosan results in exposure in the environment.

As triclosan is used in the cosmetic products on the market (e.g. toothpastes), this requirement differentiates Nordic Ecolabelled from non-ecolabelled products on the market.

**BHT** (CAS No. 128-37-0) is used as an antioxidant in cosmetic products. It is excluded because of its hazardous effect on the environment. The Danish EPA's advisory list for self-classification (EPA, 2001) classifies BHT as being environmentally hazardous – N; R50/53 (Very toxic to aquatic environment, may cause long-term adverse effects). The requirement limiting the amount of environmentally harmful substances restricts the use of substances classified as N; R50/53, but BHT is not yet officially classified as being environmentally hazardous, and Nordic Ecolabelling wishes to prohibit it completely.

**EDTA** is a powerful complexing agent that is capable of binding metal ions and is therefore also suspected of being capable of mobilising heavy metals in the aquatic environment. The industry, however, has questioned this latter property, especially in compartments such as most Nordic waters (Cefic, 2009). EDTA is not readily degradable, and the European Union's risk assessment concludes that conditions in municipal treatment plants are such that EDTA will not break down or will only break down to a limited extent (Cefic, 2009). More environmentally friendly alternatives are now available that are degradable and can replace EDTA. The use of EDTA is therefore excluded with the exception of solid soaps (see R20), where EDTA is considered necessary.

**NTA** will be classified as Carc Cat. 3 in future amendments to the CLP regulation (EU, 2008b). Until this classification enters into force, the use of NTA is prohibited as a preventive measure.

The Cosmetics Directive (EU, 1976) does not restrict the use of substances that are considered to be (potentially) **endocrine disruptors** (the Community Strategy for Endocrine Disruptors defines endocrine disruptors as exogenous substances or mixtures that alter function(s) of the endocrine system and consequently cause adverse health effects in an intact organism, or its progeny, or (sub)populations) other than with a general statement that a product must not cause damage to human health under normal or reasonably foreseeable conditions. Substances that cause endocrine disruption are substances that may affect the endocrine balance in humans and animals. Hormones control a number of the body's vital processes and are of particular importance in the growth and development of humans, animals and plants. Changes in the hormone/endocrine balance may have undesired effects, and attention has in particular been focused on hormones that affect sexual development and reproduction. A number of studies have shown effects on animals which are assumed to have been caused by changes in the hormone balance. Emissions into the aquatic environment constitute one of the main sources of the spread of substances that cause endocrine disruption (Miljøstatus i Norge, 2008b). Nordic Ecolabelling thus prohibits the use of substances that are considered to be (potential) endocrine disruptors (Cat. 1, 2 and 3b for either human health or wildlife) in the EU in accordance with the EU's report on endocrine disruptors (EU, 2000) or further studies (EU, 2002a and b, 2007b) (see [http://ec.europa.eu/environment/endocrine/index\\_en.htm](http://ec.europa.eu/environment/endocrine/index_en.htm)).

The relevance of excluding Category 3b substances can be discussed, because there is not sufficient scientific evidence showing endocrine disrupting effects. However, as cosmetics have a higher exposure than other chemico-technical product groups because they are applied directly to the skin, we have proposed use of the precautionary principle and banning of these Category 3b substances. We would very much appreciate your feedback on this at the hearing.

**PBT** (Persistent, bioaccumulable and toxic) and **vPvB** (very persistent and very bioaccumulable) organic substances are defined in Annex XIII to REACH (Directive 1907/2006/EC). Cosmetic products are not covered by the REACH legislation, but the ingredients used in cosmetics are. Even though PBT and vPvB criteria are not included in the Cosmetics directive, such substances are generally considered undesirable in Nordic Ecolabelled products.

Substances that already meet the PBT or vPvB criteria, or substances forming other substances that meet these criteria, can be found on the European Chemical Bureau website: <http://ecb.jrc.it/esis/index.php?PGM=pbt>. Substances that are 'deferred' or substances 'under evaluation' are not considered to have PBT or vPvB properties.

When existing Nordic Ecolabelled cosmetics were screened for possible content of PBT/vPvB substances it was concluded that only a few of the ingredients would meet the criteria for PBT or vPvB, namely silicones/siloxanes. However, silicones/siloxanes are excluded because of their inherent properties as described

earlier in this document, regardless of whether they have officially been evaluated as PBT or vPvB.

With time, more substances are expected to be evaluated in accordance with the PBT and vPvB criteria. A general exclusion of PBT/vPvB substances will ensure that candidate substances meeting the PBT or vPvB criteria will also be excluded from Nordic Ecolabelled cosmetics as more data emerges. Most PBTs/vPvBs are automatically excluded from Nordic Ecolabelled cosmetics because of the restrictions on environmentally harmful substances (see requirement R3). However, the vPvB substances in particular may not be restricted by requirement R3, but they are still considered undesirable in the environment.

## **Nanomaterials/particles**

### **R6 Nanomaterials/particles**

Nanomaterials/particles are defined in the proposed new cosmetics regulation as being insoluble or biopersistent and intentionally manufactured materials with one or more dimension of less than 100 nanometres. Many terms are used to describe nanomaterials in cosmetic products: nanoparticles, nanoemulsions, nanoliposomes/nanosomes and nanocapsules. There are also patents on products that contain quantum dots and nanotubes, and there are reports that fullerenes (C60) are used in creams (Friends of the Earth, 2006; EWG, 2006; Stuer-Lauridsen, 2007; SCCCP, 2007b).

Nanomaterials can be used in cosmetic products because of the properties of the particles themselves (e.g. mineral nanoparticles such as TiO<sub>2</sub> and ZnO), or they can be used to 'carry' specific molecules across tissue barriers or to penetrate further into the tissue, e.g. the skin. The following are functions of nanomaterials (SCCCP, 2007b):

- UV filter in sun lotions
- Accumulating specific ingredients in skin layers
- Increasing ingredients' capacity to penetrate tissue
- Acting as 'storage' for long-term release of dermal active ingredients

The main route for exposure to nanomaterials in cosmetics is via the skin, but uptake through the respiratory system and orally also needs to be considered. The size of the nanomaterials can make it possible for these materials to penetrate and react with cells, subcellular structures and macromolecules, proteins included (Friends of the Earth, 2006; Kemikalieinspektion [Swedish National Chemicals Inspectorate], 2007). Limited information is available on exposure and skin uptake (especially in damaged skin), absorption, transport across membranes, systemic uptake and accumulation in secondary target organs, and the possible consequences thereof (Friends of the Earth, 2006; EWG, 2006; SCCCP, 2007; Handy, 2008). Considerable uncertainty obtains regarding the behaviour and fate of nanomaterials in nature, and little research has been carried out in this field (Kemikalieinspektion [Swedish National Chemicals Inspectorate], 2007; Norges Forskningsråd [Norwegian Research Council], 2005; Ministeriet for Sundhed og Forebyggelse [Ministry for Health and Prevention], 2007). Governments, consumers and environmental organisations are concerned about the lack of knowledge regarding the damage nanomaterials may cause.

Nanomaterials are characterised by a high surface/volume ratio, and their properties may differ from those of the same material on a larger scale. Several reports point out

that today's classification system is not suitable or adequate for evaluation of the risks of nanomaterials. The methods used in current toxicological and ecotoxicological risk assessments may not be adequate to evaluate risks related to nanomaterials. There are no current internationally standardised tests or measuring methods for nanomaterials (SCENIHR, 2005; The Royal Society, 2004; Ministeriet for Sundhed og Forebyggelse [Danish Information Centre for Environment and Health], 2007).

There are already many cosmetic products on the market that contain nanomaterials (EWG, 2006). For the consumer it can be difficult to see whether a product contains ingredients on the nanoscale, because this information is seldom written on the product. Consumers therefore only have a limited possibility of selecting products without nanomaterials if they so wish.

Sunscreen lotions are problematic if the precautionary principle is used and nanomaterials are banned. Nanosized titanium dioxide is used in sunscreen lotions as a physical filter. Without nanosized physical filters it is not possible to manufacture sunscreen products with high sun-protection factors (SPFs) that also appeal to the consumer (Mørch, C., 2008). This is because only nanosized particles do not leave a white layer on the skin when the product is applied. The risk of skin cancer as a result of exposure to sunlight is well established (e.g. EPA, 2009).

SCCP's opinion from 2007 (SCCP, 2007) states that 'The SCCNFP opinion from 2000 (SCCNFP/0005/98) is on micro-crystalline preparations of TiO<sub>2</sub> and preparations of coarse particles. However, since this opinion new scientific data on nanosized particles, including TiO<sub>2</sub>, has become available. Therefore the SCCP considers it necessary to review the safety of nanosized TiO<sub>2</sub> in the light of recent information. Also, a safety assessment of nanosized TiO<sub>2</sub>, taking into account abnormal skin conditions and the possible impact of mechanical effects on skin penetration, needs to be undertaken.

The American non-profit organisation Environmental Working Group (EWG) conducted a sunscreen test in 2009 (EWG, 2009), concluding that the risk entailed by UV radiation is bigger than that entailed by nanosized UV filters, and recommended use of sunscreen lotions containing nanoparticles.

Nordic Ecolabelling thus wishes to apply the precautionary principle when the risk entailed by nano is unknown but the risk entailed by UV radiation is well documented, and A) either ban the use of nanoparticles except in suntan lotions or B) ban the use of nanoparticles for all purposes but be open to the possibility of changing the criteria if data on their safety for humans and the environment has been collected and evaluated.

Comments on Options A and B are welcomed during the hearing. We would like to stress that we do not expect to make our final decision until the updated opinion for the EU's scientific committee is available.

## **Biodegradability**

### **R7 Surfactants**

Surfactants are high-volume ingredients in liquid soaps, shampoos and conditioners. Surfactants are often acutely toxic to aquatic organisms.

Unlike washing and cleaning products, which are covered by the Detergents Regulation (Regulation 648/2004/EC), there are no legal requirements regarding the ready biodegradability of surfactants in cosmetic products. A requirement regarding ready aerobic degradability and anaerobic biodegradability of surfactants is thus considered relevant for this product group. The requirement is being imposed in order to ensure that the use of such high volumes of substances does not place a burden on the aquatic environment – irrespective of whether aerobic or anaerobic conditions prevail. The content of surfactants is furthermore regulated by the requirements regarding CDV and aNBO/anNBO, which will limit the overall toxicity of the product and ensure an optimal biodegradability profile.

Special requirements apply to toothpaste: Some organisations are critical about the use of sodium lauryl sulphate (SLS) in toothpaste, as it is believed to cause blisters in the oral cavity or retard the healing of such blisters. A Norwegian study (Herlofson, 1994) found that switching to an SLS-free toothpaste led to a statistically significant decrease in the number of aphthous ulcers. The study assumes that the denaturing effect of SLS on the oral mucin layer induces an increased incidence of recurrent aphthous ulcers. Generally, sodium lauryl sulphate is added to toothpastes in order to make them generate more foam. It is possible to produce toothpaste without SLS, e.g. by using sodium C14-16 olefin sulphonate, sodium lauryl sarcosinate, cocamidopropyl betaine or steareth-30, all of which irritate the skin less. SLS is thus not allowed in Nordic Ecolabelled toothpastes.

The requirement regarding anaerobic degradation of surfactants has been excluded for toothpaste. The requirement regarding anaerobic biodegradability of surfactants has been a major barrier to ecolabelling of toothpaste. It is anticipated that the exception for surfactants in toothpastes will have a positive effect on this product group as a whole, as it will promote the market share of toothpastes without triclosan and SLS.

Anaerobic biodegradability data exists for a large range of surfactants used in household products, though for other organics used in cosmetics such as emollients and emulsifiers, data on anaerobic degradation is scarce. Hence there is a lack of steerability, and requirements regarding anaerobic degradation of emollients and other ingredients in cosmetics are not included in these criteria.

The requirement remains the same as for the previous criteria versions. In our opinion it differentiates between Nordic Ecolabelled and other products, since surfactants not degradable under anaerobic conditions are used on the market.

## **R8 Shampoos, conditioners, shower gels, soaps, cleansers, exfoliants and bath gels/foams - aNBO and anNBO**

Restrictions regarding the content of organic substances that are not readily and anaerobically degradable reduce the overall level of non-biodegradable organic substances to a minimum in Nordic Ecolabelled shampoos, conditioners and soaps. It has been clarified that bath foams are also covered by the requirement, and cleansers and exfoliants have been added to the requirement. The requirement regarding biodegradability of organics promotes Nordic Ecolabelled products as a whole having an optimal biodegradation profile, and a reduction in the possible accumulation of non-biodegradable substances in waste-water sludge and the relevant environmental compartments.

The levels for these threshold values have been imposed on the basis of Nordic Ecolabelling's experience from present licences. The limits for shampoos, shower gels and soaps have not been made more stringent. The documentation submitted during licensing has shown that this requirement is already quite strict, and one of the most important parameters differentiating Nordic Ecolabelled products from other products in this category. However, the limit for conditioners has been tightened up, and it is now the same as for other liquid products.

The limit for solid soaps is more stringent than that for other products, since solid soaps have a very high active content and the requirement is based on the active content of the product. Furthermore, the relative content of aNBO/anNBO substances is generally lower in solid soaps than in liquid products.

The requirement regarding soaps and shampoos is more stringent than that for other cosmetic products, since the composition of soaps and shampoos differs from that of other cosmetics and stricter requirements can thus be met. Liquid rinse-off products such as soaps and shampoos generally have a lower active content than lotions, creams etc.

'No tears' products need to be more viscous and at the same time non-irritating for the eyes (Hansen, 2008). This combination results in difficulties meeting the same aNBO and anNBO requirement as is imposed for other soaps and shampoos. Polymers in 'No tears' products are thus exempted from this requirement, provided they are inherently degradable in accordance with OECD 302 and provided the products pass a test documenting their 'mildness' (see R40 such as HET-CAM or the red blood cell test (RBC test) (<http://www.hetcam.com/>, Ronald E. Hester et al., 2006). See also R40.

## **R9 Lip products, sunscreen products, hair styling products and lipid creams**

As will be explained below in R10 we wish to set requirements in order to decrease the use of non-degradable organic substances in cosmetics.

In some types of products such as lip products, sunscreen products, hairstyling products and lipid creams the content of non-degradable organic ingredients is typically higher than in other cosmetics. As Nordic Ecolabelling can still make a difference for these products, as indicated below, we have set less strict requirements for these product types than for R10.

Lip products are all products that are intended to be applied to the lips, e.g. lipsticks, lip gloss and lip balm. Based on our own screening in Matas of seven different lipsticks, we found that they often have a high content of ingredients that are not easily degradable, e.g. binders, polymers and waxes. All of the analysed products furthermore contained one or more problematic substances, such as:

- Siloxanes
- Various non-allergenic perfumes
- Preservatives (parabens) and UV filters (ethylhexyl methoxycinnamate) that are suspected endocrine disruptors

In another study (Safe Cosmetics, 2007) lead was found in lipstick products (see R12).

Sunscreen products are all products that use UV filters and meet the requirements R19, R37 and R41. Products with high UV-protection factors will typically have a

high content of organic UV filters that are not readily biodegradable. Many of the permissible chemical filters and other ingredients of non-ecolabelled sunscreens do not meet our requirements.

Hair-styling products are used in the hair as leave-on products, to provide volume, hold etc. Examples are hair waxes, hair sprays, gels and hair foams.

These products often contain polymers and waxes that are not readily biodegradable. On looking at a few products in Matas we also found ingredients such as:

- Preservatives (parabens) that are suspected endocrine disruptors
- Oakmoss extract
- Other allergenic perfumes

Lipid creams are defined as products with a 70% fat content (Andersen, 2006), but according to Informationscenter for Miljø og Sundhed [Danish Information Centre for Environment and Health] (2003) creams with a 60% fat content will have a similar functionality. Our definition is thus creams containing 60% fat or more. In our own screening in Matas and Føtex we only found one product called a 'lipid cream' ('fedtcreme') (this was labelled with the Nordic Ecolabel), but we also found many products with a high fat content and the same functionality, so we assume that these non-labelled products fall under our definition. In the four products we found and investigated we discovered many different problematic substances, such as:

- Siloxanes including cyclopentasiloxane
- BHT
- Various non-allergenic perfume substances
- Preservatives (parabens) that are suspected endocrine disruptors
- EDTA
- Bronopol (can form formaldehyde)

None of these substances were present in the Nordic Ecolabelled 'fedtcreme'.

All in all, in its consideration of products with a high content of substances that are not readily biodegradable Nordic Ecolabelling is able to point to the better products that contain less problematic substances. This is shown above, and we can still make a positive difference, even though we do not impose very strict requirements regarding the biodegradability of these products.

The cut-off levels in the requirement were based on screening of existing licences in cosmetics, soaps and shampoos and on screening of existing products on the market. Since this is a new requirement introduced for cosmetics, the cut-off levels have been set so as to rule out the worst products, but they are not very differentiating.

## **R10 Other products and organic compounds**

Cosmetic products are largely washed off the body and clothes, thus they to some extent end up in aquatic environments through waste-water treatment. It is therefore essential to impose degradability requirements for all the constituent organic ingredients. However, some types of ingredients used in cosmetics, e.g. UV filters, colours, antioxidants and preservatives, are required to be stable in the products and might not meet the requirements for ready biodegradability. In addition, long-chained carbon structures such as paraffins, which are often used in cosmetics, are not readily biodegradable. Thus a strict requirement stipulating ready biodegradability of all organics will be a major barrier for Nordic Ecolabelling and will drastically reduce the number and types of ingredients meeting the criteria and thus decrease flexibility for the manufacturers. In recognition of the fact that most cosmetic ingredients will eventually end up in a sewage treatment plant, a certain quantity of ingredients that are not readily biodegradable may thus be allowed, based on a combination of

- low acute toxicity and inherent biodegradability or
- low acute toxicity and low bioavailability

Substances that are inherently biodegradable are generally assessed as having a good potential for degradation under favourable conditions, e.g. in a well operated WWTP (waste-water treatment plant) (OECD, 2006). In combination with a low aquatic toxicity (EC/LC50 > 10.0 mg/l) the risk of effects on the aquatic environment is limited. Likewise, a combination of low acute toxicity and low bioavailability will limit the risk of affecting the aquatic ecosystem, as persistent substances are already exempted by the restrictions for environmentally harmful substances and PBT/vPvB substances.

Molecular weight and other molecular-size descriptors such as molecular diameter or molecular length have often been proposed as cut-off triggers for bioaccumulation potential. In a literature review published by the Fraunhofer Institute in 2007 (Fraunhofer 2007) this subject was evaluated on the basis of the available scientific data on bioaccumulation, logKow, and molecular properties. Regarding the use of molecular mass as a descriptor for bioaccumulation potential, analysis of the available data supported the hypothesis that compounds with a molecular mass > 600 g/mol may not have a BCF > 300. However, there are some uncertainties about high-molecular lipophilic substances because of a lack of data. It was concluded that molecular weight may be a potential candidate for use as a cut-off trigger for bioaccumulating substances, if substantiated with valid BCF data for large lipophilic compounds.

Based on the above sources, the assumption is that a molecular mass > 700 g/mol is likely to preclude a high accumulation level, even if a substance has a high logKow. Substances with a molecular weight > 700 g/mol are thus not generally expected to be bioavailable for aquatic organisms. In the Guidance Document for assessment of PBT properties (ECHA, 2008), molecular size is also used as a weight-of-evidence approach for assessment of the bioaccumulation potential – although not as a single descriptor. If a cut-off value for molecular weight is combined with a low-acute-toxicity requirement, harmful effects are not expected.

The cut-off levels in the requirement were set on the basis of screening of existing licences in cosmetics and soaps and shampoos. As this is a new requirement for cosmetics the set cut-off levels are designed to rule out the worst products, but are not very differentiating.

## Colours

### R11 Bioaccumulation

A study performed by Nordic Ecolabelling (Nordic Ecolabelling, 2003b) of 48 colourants approved for use in cosmetics (corresponding to 30% of the approved colourants) revealed that several of them had bioaccumulation potential and were toxic or very toxic to aquatic organisms. Relevant environmental requirements can and should thus be imposed regarding these colourants. The study revealed that colourants approved for use in foodstuffs do not represent a major environmental problem. Based on this investigation a decision was made to impose requirements as to the bioaccumulability of the colourants in the first-generation criteria for cosmetics. The working group saw no reason to change this. The requirement excludes a dozen or so colourants with  $\log K_{ow}$ s up to 17 approved by the Cosmetics Directive. Furthermore, a new requirement restricting the use of environmentally harmful substances in cosmetics will also restrict the use of more toxic colourants.

The limit values of  $\log K_{ow}$  and BCF are higher than in the previous criteria version. Within the framework of REACH and the new regulation for classification and labelling, the descriptors of bioaccumulation potential have been reassessed and the levels increased. Thus the BCF and  $\log K_{ow}$  values used as indicators of bioaccumulation potential are in line with the definitions in the CLP regulation.

Since requirements have only been set for organic colourants, inorganic colourants such as titanium dioxide can be used in Nordic Ecolabelled cosmetics without any specific requirements when they are approved for use in cosmetics.

### R12 Metals

Since lead has recently been found in lipsticks at concentrations ranging from 0.03 to 0.65 ppm (0.02 ppm having been the detection limit) (Safe Cosmetics, 2007), a special limit for a number of relevant heavy metals in colourings and other raw materials has been set. Since large amounts of lipstick are ingested (Koskinen, 1996) and lead builds up in the body over time, this could add up to significant exposure levels when combined with lead from other sources. As 39% of the lipsticks tested in the US study did not contain detectable amounts of lead, cosmetics without questionable metals in colourings can be manufactured.

The content of colouring agents in cosmetics varies a great deal depending on the type of cosmetics, ranging from a few per cent in soaps etc. to at least 15% in lipsticks (WWD, 2003).

A limit of 0.1 ppm (0.0001%) of lead, barium, mercury, cadmium or hexavalent chrome in colourings and other raw materials is considered appropriate. Additions of under 20% or raw materials containing under 0.1 ppm of these metals will result in products with under 0.02 ppm of these metals (the detection limit for lead in the study). The limit of 0.1 ppm is thus considered relevant.

At the hearing we would appreciate your feedback on the relevance of setting this requirement for all raw materials instead of the requirement focusing on colouring agents.

## **Perfumes and aromatic additives**

### **R13 IFRA**

### **R14 Products for infants, babies and children**

### **R15 Quantity of perfume**

The original formulation of the fragrance requirements was based on Nordic Ecolabelling's cross-product group project on Fragrances (Nordic Ecolabelling, 2002). A new cross-product group project on Fragrances is in progress, and results are expected in 2009 (Nordic Ecolabelling, 2009).

The Cosmetics Directive lists 26 perfume compounds that must be declared on the packaging when the concentration exceeds > 0.01% (rinse-off products) or 0.001% (leave-on products). The working group wishes to impose further requirements regarding perfumes. The requirement regarding Version 1 was formulated as a ban on the 26 perfume compounds that legislation prescribes must be declared on the label. Since Nordic Ecolabelling sees no reason to differentiate between 'the 26 fragrances' and other fragrances bearing the official classification R43/H17 (skin contact may cause sensitisation), the current formulation of the requirement applies to all of these substances. This is because allergies (and fragrance allergies in particular) represent an increasing problem, and there is every reason to minimise the risk of increasing the number of sensitised consumers. According to Videnscenter for Allergi (Danish Allergy Research Centre) there is basically no limit as to when allergy causes problems (Jeanne Duus, 2009). Given the current market situation it would not be realistic to ban use of fragrances in the products. The demand for fragrance-free cosmetics has hitherto been low, and a complete ban on fragrances would presumably have a negative effect on the label's market penetration that would be out of proportion to the limited environmental impact of fragrance in Nordic Ecolabelled products, since the quantity of environmentally harmful substances (incl. fragrances) is strictly limited in R6 'Environmentally harmful substances'. Consumers have a choice between perfumed and perfume-free products, as any perfume must always be declared in the packaging. In general there is a demand for both perfumed and perfume-free products in both consumer products and B2B products, as can be seen from current Nordic Ecolabelled products and from the market in general.

A total fragrance ban could also lead to a general problem regarding definition of fragrances. It is possible that fragrances would simply be replaced by various plant oils, which would hardly represent a step forward, since information on environmental effects or allergies associated with these substances is usually scant.

Fragrances and aromatic additives, e.g. certain plant oils, are not permitted in products marketed for use in infants, babies and/or children. These groups are especially sensitive to potentially allergenic fragrance substances, and the aim of the requirement is to reduce the risk of infants, babies and/or children developing fragrance allergies. This requirement has been made more stringent than in Version 1 or the criteria for soaps and shampoos, in which fragrances were not allowed for products marketed for infants/babies. The requirement has now been expanded to include products that are specially marketed for babies or children, e.g. using the words 'baby', 'kid' or 'child'. Children aged 12 or under are considered to be kids/children in this context. The main

argument is that children aged 0-12 are more sensitive than adults and usually have little opportunity to select a product voluntarily. This requirement will differentiate Nordic Ecolabelled products from other products. Products that are marketed as family products or products for teenagers need not comply with this requirement.

## Preservatives

### **R16 Use of preservatives**

### **R17 Bioaccumulation**

Antibacterial disinfectant and microbial substances must meet the requirements for preservatives. This is to ensure that these substances are not added to products if they do not meet the requirements applying to preservatives.

Preservatives are only allowed for preservation of the product, in order to avoid products that claim to be biocidal. Household use of biocidal products has not been found beneficial and may increase resistance to bacteria (STTV, 2001).

The requirement that preservatives must not be bioaccumulable has been imposed in order to reduce what represents a serious environmental impact associated with bioaccumulative substances.

Oral-hygiene products may contain substances that provide a so-called 'antibacterial' effect. These substances must meet the requirements for preservatives, though it should be noted that consumer products marketed as being antibacterial/antiseptic/disinfectant do not qualify for the Nordic Ecolabel.

The requirement remains the same as in the previous criteria version for cosmetics.

## UV filter

### **R18 Function of the UV filter**

### **R19 UV filter's environmental characteristics**

UV filters can be divided in two types: inorganic filters such as titanium dioxide and organic filters such as benzophenone-3. Inorganic filters are normally known as physical filters, whilst organic filters are known as chemical filters.

UV filters can be problematic with regard to health and the environment (see, for example, R6 on nanoparticles and R5 on endocrine disruptors, and Chapter 4.1.1 'General background for the product group', which states that UV filters can harm coral reefs when swimmers wear sunscreens when swimming in sensitive areas.

UV filters provide protection from the sun, thus reducing the risk of skin cancer, so there are also benefits from using sunscreens with UV filters.

UV filters should only be used to protect the user – not the product. This is because some products on the market contain UV filters for reasons that might be described as questionable (e.g. deodorants in metal containers, or shampoos (Öko-Test, 2009)). Furthermore, UV filters for protection of the user are the only filters covered by Annex VII to the Cosmetics Directive and approved therein. Imposing the requirement regarding the function of the UV filter will ensure that Nordic Ecolabelled products only contain approved UV filters.

The number of available UV filters allowed in cosmetic products is limited by the Cosmetics Directive, and a number of our general requirements (e.g. requirements regarding potential endocrine disruptors) further limit this number.

It is difficult to set requirements that take into consideration all the potentially relevant environmental impacts of UV filters, because of a lack of data and thus a lack of steerability. Damage to coral reefs through bleaching is not expected to be a major concern in the relatively cold waters around the Nordic countries. This is because cold-water corals live deeper and are not as widespread as warm-water corals (UNEP, 2004). Cold-water corals normally live at depths of 200-1,000 metres (but can occur at depths of as little as 40 metres) (UNEP, 2004). The greater depths mean that the concentration of UV filters as a result of bathing is not expected to be significant, since bathing takes place in shallow areas far from the cold-water corals. The threat to cold-water corals is far more closely associated with fishing (UNEP, 2004).

In order to further restrict the number of UV filters that can be used in products carrying the Nordic Ecolabel to filters that in general display better environmental performance, we have concluded that UV filters must not be bioaccumulable or toxic to aquatic organisms. Note that R3 further restricts the quantity of substances that are harmful to the aquatic environment. It is recognised that the requirement regarding stability for organic UV filters in the product and upon application is not necessarily associated with ready or even inherent biodegradability of the substances. See requirements R6-R8 on biodegradability.

Given these requirements, it should be possible for applicants to document one of the points and thus reduce the risk of a harmful environmental impact.

The above requirements exclude UV filters such as 4-methylbenzylidene camphor (4-MBC, logKow= 5.92, molar weight =254 g/mole, LC50=0.13 mg/l).

See also requirement R5 regarding nanoparticles.

The requirements have been modified somewhat on the basis of the information gained during licensing, and so as to be appropriate to the new combined criteria document.

## **Polymers**

### **R20 Monomers**

Large quantities of polymers are permissible in certain types of product.

Polymers must have a low monomer content (less than 100 ppm) if the monomer is classified as being carcinogenic, mutagenic, toxic to reproduction, sensitising with R42 and/or R43 (H334/H317) or environmentally harmful with R50/53 or R51/53 (H410/H411), or is deemed to be endocrine-disruptive. This requirement limits the content of monomers that pose a risk to health or the environment. There is no limit on use of other monomers known to occur often in cosmetics, as they do not pose environmental or health problems. The requirement comes from the criteria for cosmetics, supplemented by the ban on environmentally harmful monomers.

## **Enzymes**

### **R21 Classification of enzymes**

To prevent problems with the working environment when using substances classified as R42 (May cause sensitisation by inhalation) (H411), enzymes used must be dust-free granulates or liquids. Enzymes in cosmetics, however, are not expected to cause allergy in consumers, as the enzyme ingredients are incorporated into the product and will not be present as 'free dust'. In addition to the previous version of criteria for cosmetics, a further requirement is that enzymes must not be present in aerosol spray products, in order to protect the consumer from inhalable aerosols containing enzymes.

### **Specific requirements relating to certain product types**

This chapter sets requirements for certain selected product types. The requirements outlined in this chapter only apply to the specified product types, but it should be stressed that all products, including those mentioned in Chapter 1.2, must meet the requirements in Chapter 1.1.

## **Shampoos, conditioners, solid and liquid soaps, cleansers, exfoliants and bath foams/gels**

### **R22 Critical dilution volume (CDV)**

The critical dilution volume is a theoretical value that takes into account the toxicity and degradation of each individual substance in the product. The method was developed for the EU Flower Scheme, and replaces what was known as the TD (Toxicity and Degradability) calculation, and was formerly used by Nordic Ecolabelling. Chronic data should be used, since it better describes environmental impact. When no chronic data is available, acute data combined with the higher safety factors can be used.

The threshold values are based on Nordic Ecolabelling's experience of existing shampoo and soap licences. The requirement for conditioners has been made far more stringent, since licensing has shown that there was room for this. The requirement for soaps and shampoo has not been significantly changed. The requirement for liquid soaps has been changed to the effect that the cut-off level is based on dose instead of active content (AC). A dose is determined as the greatest quantity of soap dosed by any of the dispensers for which the product is sold – or as the maximum dose administered by the pump mechanism for the product.

If the dose cannot be determined, and if the product is not sold for specific dispensers or does not use a pump, a standard dose of 1.5 g can be used. This is higher than a normal dose (Danish Environmental Protection Agency, 2006). For foam soaps the standard dose has been set at half of 0.75 g, as the quantity of soap dosed by a foam-soap dispenser is normally much lower than for cream soaps – a 500 ml Berendsen Textile Service foam soap with matching dispenser, for example, yields approximately 1,250 doses – corresponding to between 0.4 and 0.5 g per dose. Including a safety margin as for other liquid soaps, 0.75 g seems reasonable.

A dose is used to relate the requirement much more to the functional unit than in the previous criteria, where we have seen examples of foam soaps having difficulty

meeting our requirements, though they from a point of view of a functional unit were better for the environment.

For other products such as shampoos and conditioners we have not found a smarter and more steerable way of relating the requirements to the functional unit, thus these requirements are still related to the content of active ingredients.

In comparison with the present criteria, it has been clarified that bath foam is covered by the requirement and cleansers and exfoliants have been added to it.

Compared to the benefit of the CDV requirement there would be little environmental benefit in setting a water-content requirement for liquid products. The water content of current products would not change considerably, and limiting the water content might lead to more concentrated products that cause irritative problems and problems with handling and dosage when viscosity is increased. Moreover, mild products (often containing more water) are needed for children/babies, and foam soaps typically have a high water content.

The requirement only applies to shampoos, soaps, bath gels and cleansers (rinse-off products). Other types of cosmetics comprise a very diverse group of products, e.g. lotions, toothpastes, make-up, wet-wipes, for which establishment of common CDV values is not appropriate. The possible content of ecotoxic and non-biodegradable substances is instead regulated by the requirement R4 regarding degradability of 'other cosmetic products'.

### **R23 EDTA and phosphonates in solid soap**

A limited amount of EDTA is permitted in solid soaps, since its use may reduce the need for preservatives. Without EDTA and phosphonates soap becomes rancid more quickly, leading to poor quality.

A limit is imposed to the quantity of phosphonates, since like EDTA they do not degrade well. The quantity of phosphonates is restricted by R7 (aNBO and anNBO), and is further restricted here. When eventually degraded into phosphor, phosphonates also contribute to eutrophication. The requirement remains the same as in the previous criteria version for shampoos and soaps.

According to the information available to us, soap producers may use as much as 0.5% of each EDTA and phosphonate; this can be reduced to as little as 0.02% of each, e.g. by using high-quality fatty acids (Frejl, 2009).

Setting a limit of 0.6 mg/kg AC (or 0.006% of AC) for the total content of EDTA and phosphonates seems strict, but is feasible.

## Hair-care products

### R24 Colorants in hair dyes

It has been specified that hair dyes must meet the general requirements for colourants, since hair dyes do not normally need to be approved for use in cosmetics in the same way as other colourants in cosmetics. The working group has concluded that it is relevant for hair dyes to meet these requirements in order to minimise the possible impact on health and the environment. This requirement also excludes the use of Lawsone (colourant in Henna, C.I. 75480), since it is not on the list of approved colours for cosmetics. The EU Scientific Committee (SCCP (2001)) has stated that 'Lawsone is clearly mutagenic and clastogenic in vitro and in vivo (genotoxic substance, Category 3 in accordance with Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances).' SCCP furthermore states that Lawsone is not suitable for use as a non-oxidising colouring agent for hair dyes (SCCP, 2001). The SCCP opinion dated 13 December 2005 (SCCP, 2005) states that 'The SCCP is of the opinion that the information submitted is insufficient to assess the safe use of the substance as a hair dye.'

The requirement has been modified somewhat, but the outcome remains unchanged, since use of Lawsone is still prohibited.

## Lip products, toothpastes and oral-hygiene products

### R25 Aromas, colorants and preservatives

Since the consumer is exposed to these products via the oral route, aromas, colourants and preservatives in the product should be approved for use in foodstuffs. According to the Finnish consumer magazine Kuluttaja (Koskinen, 1996), applying lipstick three times a day may result in an annual intake of up to 15-20 g of lipstick through absorption and swallowing.

Since aromas do not have E-numbers, and since a comprehensive database on aromas approved for use in foodstuffs is currently still being prepared, a declaration by the aroma manufacturer that the aroma is approved is also accepted as documentation. The requirement is the same as in the previous criteria version, but several requirements were combined to create one requirement for several types of cosmetics. The documentation requirement has been clarified.

## Wet wipes

### R26 Material

Wet wipes are cosmetic products consisting of a carrier material and chemical ingredients (possibly designated as a 'lotion'). The carrier material often consists of textile/non-woven material (viscose, polyester), but it can also be made of paper or other natural fibres (e.g. bamboo). As several studies have shown that production of these types of materials/products may have a significant impact on the environment, requirements have been introduced regarding the carrier material.

EU Flower and/or Nordic Ecolabelling criteria exist for both paper/tissue paper and sanitary products, requirements already having been set for the relevant types of carrier material. Please see these criteria documents for requirements regarding the carrier material.

The requirement has been adjusted somewhat, since the criteria referred to have been revised.

## **Renewable raw materials in cosmetics (voluntary requirement)**

### **R27 Labelling with 'Based on sustainable natural raw materials'**

An additional set of requirements applies to products that promote the use of renewable and sustainable raw materials. These are voluntary, and are only valid if the producer wishes to use the additional text 'Based on sustainable natural raw materials' under the Swan logo on the product. The aim of this requirement is to meet the demands of consumers and producers and to provide an alternative to the more or less misleading marketing of natural and organic cosmetics.

Even though cosmetics may not have that big an effect on climate change and it is not always clear whether non-renewable raw materials have a greater potential for global warming than renewable raw materials, promotion of cosmetics based on renewable and sustainable raw materials is desirable, as there is only a limited quantity of non-renewable raw materials on the planet. The renewable base materials that might be used in cosmetics are typically various oils and fats. The rainforest decline caused by the increased demand for renewable oils and fats and unsustainable agriculture can be tackled by using products from certified sustainable agriculture, e.g. RSPO-certified palm oil (see chapter 'Raw materials and sustainability').

A requirement that controls the quantity of renewable raw materials in the product has thus been introduced. If >50% of the active ingredients is of vegetable origin and >95% is from sustainable renewable sources (as defined in the appendix), the Nordic Ecolabelled product can bear the text 'Based on sustainable natural raw materials' under the Swan logo. 50% was proposed so as to ensure that a sufficient proportion of the product is made from raw materials to which the sustainability requirements in Appendix 7 apply, and 95% was chosen since existing labelling schemes for natural cosmetics widely use this percentage. The background for the requirements is given in detail in Appendix 7.

Cosmetics made from renewable ingredients, i.e. 'natural cosmetics', are not necessarily safer or better than synthetic cosmetics. Nordic Ecolabelled renewable cosmetics thus need to meet all the requirements in this document as well as stringent requirements regarding the sustainability of the raw materials.

This is a proposal for a new but voluntary requirement. We would like you to evaluate it and give us your feedback at the hearing, emphasising the relevance of such a requirement, the level of the requirement and, last but not least, whether the text for positioning under the Swan logo should be changed.

## **Products for animals**

### **R28 Fragrances and colourings in products for animals**

There has been some interest in the ecolabelling of shampoos for pets, even though there are no products on the market at the moment. Nordic Ecolabelling thus wishes to retain the option of Nordic Ecolabelling animal products in the new combined criteria document, even though these products are not covered by the Cosmetics Directive.

Products for animals are washed off to the sewage systems just in the same way as shampoos and soaps for people. Users are also exposed to the same chemicals. Another example of animal products is paw creams. These products should thus meet the same general requirements as ordinary cosmetic products.

In addition to this, no fragrance or colouring is allowed in shampoos for animals. There is no functional or safety reason for adding these ingredients to the product, thus they should not be permissible. Although this argument could reasonably also apply to human products, it is appreciated that there are strong consumer needs in favour of cosmetics containing colouring and fragrance.

The requirement remains the same as in the previous criteria version for shampoos and soaps.

## **Packaging requirements**

Packaging often constitutes a relatively high proportion of the overall product.

There are two requirements for all the packaging types, namely: 1) An overall requirement to reduce the amount of packaging and promote use of recycled materials and 2) Making recycling of packaging easier.

It is difficult to set requirements regarding the effect of cosmetic products on climate because of the diversity of the products (as discussed earlier), but it is easier to take this into account in packaging. In terms of global warming, paper/cardboard generally have the lowest global warming potential (GWP), and aluminium the highest of the various packaging materials (Klimatmärkning för mat [Climate-labelling of food], 2008). We exclude the use of metals, except for a few specific product types for which no alternative is available.

Glass also has a low GWP per kg, but since it is a very dense material the global warming potential of the packaging as a whole is higher than that of other materials of which smaller quantities are needed (Klimatmärkning för mat, 2008). Thus cosmetics packed in glass will typically not meet our requirements related to weight by volume.

### **R29 Amount of packaging**

### **R30 Type of packaging**

Packaging often constitutes a relatively large proportion of the overall product in cosmetics. Multilayered products are common, especially with luxury products. It is considered important to reduce the amount of packaging by applying a general requirement that sets a limit for the total amount of packaging in relation to the content of the packaging.

It is difficult to compare the packaging requirements for different cosmetic products. Products with a low volume, e.g. eye shadow, involve much more packaging in relation to the volume of the product than high-volume products such as shampoos.

A formula has been created, taking into account the volume of the product, the quantity of post-consumer recycled materials, reusable/refillable packaging, and where applicable a pump to facilitate correct dosing.

$$\frac{\text{weight}_{\text{total}} + \text{weight}_{\text{not post consumer recycled}} - \text{weight}_{\text{pump}}}{2 \times t} \leq 7 \times \ln(\text{Vol}_{\text{produkt}} + 1) + 0.045 \times \text{Vol}_{\text{produkt}} + 5$$

$\frac{\text{weight}_{\text{total}} + \text{weight}_{\text{not post consumer recycled}}}{2}$  expresses that we wish to limit the total weight of the packaging and reward use of post-consumer recycled plastics.

$\frac{-\text{weight}_{\text{pump}}}{2}$  means that only ‘half’ of the weight of a dosing pump is included in the calculation. We wish to allow this extra weight, as correct dosage is a key environmental factor regarding the environmental burden of such products, and a dosing pump can support correct dosage.

$\frac{1}{t}$  is included in the formula to promote direct reuse of the packaging materials, e.g. by using refills. T is set to 2 as standard when offering refills, but if sales statistics can show that more refills than products are sold, a higher value can be used in the calculations. If 2 refills are sold for every product, t can be set to 3. However, the corresponding mass of refill packaging must be included in the calculations, to ensure that use of refills leads to a total reduction in packaging.

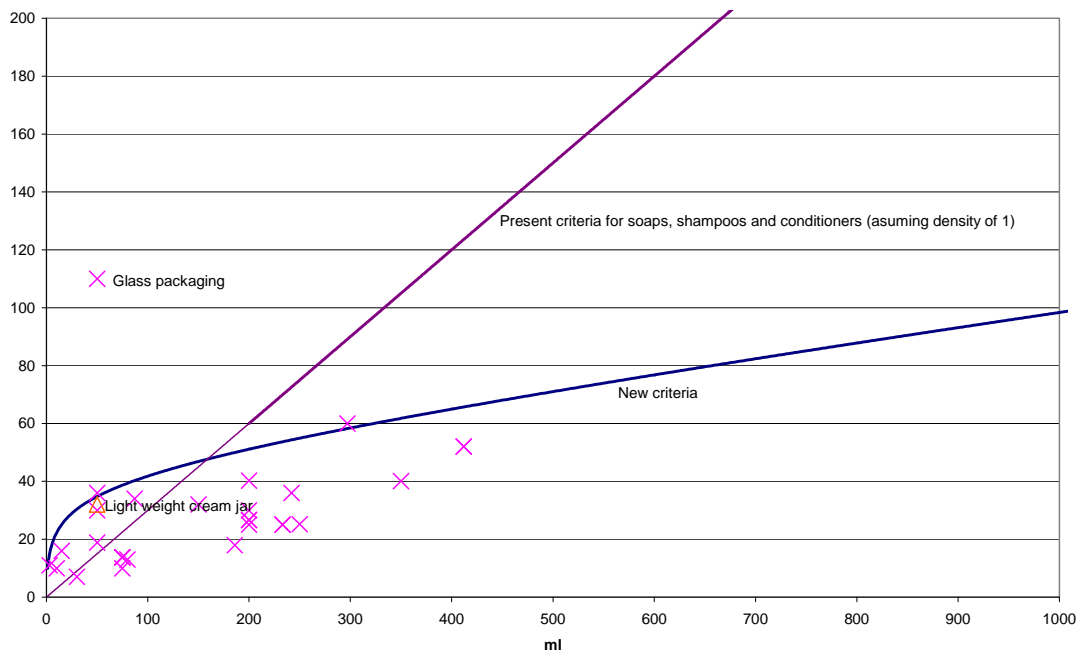
$7 \times \ln(\text{Vol}_{\text{produkt}} + 1)$  describes a logarithmic increase as a function of the product volume. This represents the need for more packaging per unit volume for small-volume products such as a 2 ml eye shadow than for a 500 ml shampoo. The constant (7) is iteratively determined as explained below.

$0.045 \times \text{Vol}_{\text{produkt}} + 5$  is a linear function taking into consideration the fact that more packaging is needed when product volume increases. The constants (0.045 and 5) are determined by means of iteration.

The basis for determining the constants was packaging data on existing Nordic Ecolabelled products. All data was plotted on a graph, and the constants were determined by means of iteration, taking the following factors into consideration:

- The requirements should be realistic
- Unnecessary heavy packaging should be avoided
- We assume that the packaging weight of the existing Nordic Ecolabelled products is not representative, but at the lower end of the scale, because of packaging restrictions in previous criteria
- A 50 ml light-weight cream jar (~32 g) should meet the criteria (shown as an orange triangle in the figure below)

Figure 1 below shows the plotted data and suggested criteria – and the present requirements for soaps, shampoos and conditioners can also be seen. Note that such products are primarily sold in volumes of over 200 ml/bottle.



**Figure 1 Plotted data and suggested criteria**

The requirement regarding the amount of packaging also restricts use of multiple layers of packaging, since the primary packaging as a whole must not exceed the maximum weight. There is thus no need for a separate requirement prohibiting multiple packaging. However, more than two layers of packaging over one product is not permissible. Use of dense glass is also restricted by this requirement.

The requirement also promotes use of post-consumer recycled raw materials for packaging, since the limit is easier to achieve if they are used.

With the requirement that all parts of packaging must be mono-materials and/or easy to separate, Nordic Ecolabelling wishes to promote recycling of packaging and development of packaging that is recyclable, since this is important for a sustainable society. Packaging for decorative cosmetics often consists of several materials (glass, metal, plastic) that can not be separated from each other, but there are also alternatives. The requirement is that paper, cardboard, plastic, metal and glass need to be separable, even though it is recognised that not every municipality in the Nordic countries collects all these fractions. Pumps and pressurised spray bottles are exempted, as there are no alternatives.

These are new requirements for cosmetics. There used to be requirement for weight/content ratio for packaging of shampoos and soaps. This has now been changed, so that cosmetics can also meet the requirement. Approximately 40 different packagings for various cosmetic products were studied, and the requirement level was set on the basis of these packagings.

There are also additional requirements that apply to various types of packaging.

### **R31 Plastic packaging**

Plastics must not consist of halogenated materials, since this may result in environmental problems during waste disposal, particularly during incineration

(Videncenter for Affald [Waste Centre Denmark], 2009). Manufacture of these materials also causes environmental problems, involving the related production of large amounts of waste and the handling of vinyl chloride during production.

The requirement that packaging be labelled in accordance with DIN 6120, Part 2 ensures that recycling, when possible, is easier.

The requirements have been combined into one requirement, and in addition to chlorinated materials other halogenated materials have also been excluded.

### **R32 Metal packaging**

Aerosol sprays made of metal are commonly used, e.g. for hair-styling products, shaving mousse etc.

Nordic Ecolabelling does not wish to exclude spray bottles where they are needed and thereby totally ban certain types of products from the Nordic Ecolabel. Thus restrictions on use of metal packaging have been imposed, contrary to the previous criteria document for cosmetics.

Primary metals create substantially higher CO<sub>2</sub> emissions (up to 95% more, depending on metal and process) and their production requires substantially higher amounts of energy (up to 95% more, depending on metal and process) than secondary metals (derived from scrap) (Nordic Ecolabelling, 2008c). All use of metal, however, has an effect on net withdrawal of primary metals. Metals can thus only be used in applications for which no real alternative is available. These applications are in our opinion hair-styling products and shaving foam. Small pieces of metal such as sealing foil on the opening are also permissible.

CFC and HCFC compounds used as propellant gases are restricted by the Montreal Protocol on Substances that Deplete the Ozone Layer, which has been implemented in the EU through regulation 2037/2000/EY. CFC and HCFC compounds are only permissible in certain specific functions (packaging of cosmetics not included). CFC compounds as propellant gases have been replaced by hydrocarbons or a mixture of water and dimethyl ether. A mixture of propane and butane is also used. In addition to this, F-gases (e.g. HFC-152a) have also been used as replacements for CFC. There is an EU regulation – 842/2006/EC (EU, 2006b) – that restricts the use of F-gases. Most fluorinated greenhouse gases identified by this regulation have a high global-warming potential. HFC compounds in novelty aerosols were banned as from July 4 2009. Since these compounds are already banned, no requirements have been set for the propellant gases.

### **R33 Paper, cardboard and board packaging**

Elemental chlorine bleaching produces substantial emissions of AOX and dioxin into effluents (KnowPulp, 2009). For these reasons it has not been used in the Nordic countries since 1994. The alternatives that replaced elemental chlorine bleaching are TCF (total chlorine free) and ECF (elemental chlorine free) bleaching. Elemental chlorine bleaching may, however, still be used in other countries. There is thus relevance and potential in setting a requirement that bans use of elemental chlorine bleaching in the manufacture of packaging for Nordic Ecolabelled cosmetics. The other requirement for paper/cardboard/board packaging (quantity of recycled

materials) from Version 1 of the criteria for cosmetics has been omitted, since this has been taken into account in R28.

### **R34 Dosage**

Overdosing the product increases its impact on the environment, but does not result in better efficiency. Nordic Ecolabelling thus wishes to promote packaging that facilitates correct dosage. In shampoo and soaps, for example, this means that the mouthpiece should be designed so that it is easy to retrieve only the needed amount of product. The cap also needs to be easy to use. For products designed for specific dosing systems, these systems must be such that it is easy to operate them without overdosing. A maximum dose for liquid soaps with one push/squeeze has also been set. The maximum dose is related to the CDV requirement (R21).

For creams, lotions and other products the producer should put forward arguments illustrating how correct dosage can be promoted.

### **Requirements for consumer information**

The requirements related to consumer information are aimed at further reducing the product's environmental impact and ensuring safe use for the consumer.

### **R35 Informational text**

In order to reduce the impact of paper/cotton wool and cosmetic products on the aquatic environment and waste-water treatment plants, an informational text advising on the correct disposal of paper/cotton wool is required in the packaging.

Nail polish and nail-polish removers contain solvents and should thus be sorted as hazardous waste. Solvent used as propellant gas stays in the bottle when the aerosol product is finished and it should therefore be sorted as hazardous waste. An informational text advising on correct disposal of these products when there is some of the product remaining in the packaging is thus required on the packaging. This second part of the requirement is new.

### **R36 Informational text – Sunscreen lotions**

### **R37 Labelling – Sunscreen lotions**

Consumers are often under the misapprehension that using a sunscreen lotion will allow them to stay in the sun longer whilst still enjoying the necessary protection. To increase the safety of the consumer, information is required stating that even though use of a sunscreen lotion is a sensible idea it does not provide optimal protection against the harmful rays of the sun. Moreover, many consumers do not know how much sunscreen lotion to use in order to achieve the protection indicated by the SPF factor on the product. There is thus a requirement that Nordic Ecolabelled sunscreen lotions should feature a mandatory text that draws the attention of consumers to these points as well as providing guidance on dosage. The proposed sentences are:

- The most effective protection against the sun's rays is achieved by staying in the shade or wearing clothes.

- It is important to apply the recommended dose, otherwise you will not achieve the expected level of protection.
- Re-apply frequently to maintain protection, especially after perspiring, swimming or towelling.

It should be stressed that the applicant can phrase these sentences differently, as long as the meaning is clear and corresponds to the above. The above sentences are in line with the general EU recommendations regarding efficiency and labelling of sun-protection products (Commission Recommendation of 22 September 2006)

In addition to the actual use of a sunscreen lotion, the perception of the degree of protection afforded by the lotion is very important. Here most consumers use the SPF factor for guidance. The problem with this is that many consumers think the sun-factor figures are linear, whereas this is in fact not the case. Colipa issued a recommendation (No. 11) in June 2002 on the subject of the linear understanding of the SPF factors, and this is even clearer in the Commission Recommendation of 22 September 2006. There is a requirement that the products comply with the Commission Recommendation, whereby only specific sun-protection factors are allowed together with a corresponding 'protection category': low, medium, high and very high.

### **R38 Marketing claims**

The marketing of cosmetics currently on sale often includes claims that ecological (organically farmed) ingredients are used. These claims in Nordic Ecolabelled products need to be based on fact in order to maintain the credibility of the label and the products labelled. Thus a test result or a certificate backing up the claim is required. Marketing of products that contain small amounts of organic raw materials cannot include claims of organic content without referring to the quantity of organic raw materials in the product.

### **R39 Efficiency/quality**

The efficiency/quality of Nordic Ecolabelled products must be satisfactory. Since the cosmetic products covered by the criteria document constitute such a wide range of products and since there are no internationally standardised tests in this field (except for sun-protection products), the working group has decided to leave the requirement as open as possible, though the Colipa Guidelines for Efficacy Evaluation of Cosmetic Products must be followed. This means that documentation of the efficiency of the product will largely be left to the applicant, though it has been pointed out that if acknowledged tests are available they should be used. For example, the efficiency of a sunscreen lotion must be measured by the amount of radiation penetrating the skin, using standardised tests, whereas the efficiency or quality of toothpaste will be assessed using entirely different criteria. The applicant must nevertheless be able to document that the efficiency of the product has been assessed sensibly. The test should also cover the features the product is marketed for. This ensures that claims of specific benefits of the products are documented and that the products do not carry misleading information. Documentation of the efficiency/quality of the ingredients is not sufficient for demonstrating the efficiency/quality of the product.

If a user test is used, a minimum of 10 people must have tested the product and it should be judged against a reference product. At least 80% of the test subjects should evaluate the product as being as good as or better than the reference product.

#### **R40 Security**

The Cosmetics Directive requires cosmetic products placed on the market to undergo a safety assessment, and requires the results to be available for inspection. Thus safety assessments are not necessarily evaluated by the authorities before the product is placed on the market. The proposal for the new Cosmetics Regulation suggests that the requirements regarding the content of the safety assessment should be tightened up. Imposition of a requirement stipulating that the safety assessment be made available to Nordic Ecolabelling will add to the trustworthiness of the Nordic Ecolabel and document that the health aspects of Nordic Ecolabelled cosmetics are taken seriously.

## **Special requirement for sunscreen lotion**

#### **R41 Efficiency, UVA and UVB**

The efficiency requirement states that 'If acknowledged tests are available they should be used'. This is relevant to sun-protection products, and it is emphasised that these products are expected to comply with the Commission Recommendation regarding UVA and UVB protection, as well as the other recommendations regarding labelling etc. (Commission Recommendation of 22 September 2006, EU, 2006).

**UVB test:** In order to ensure reproducibility and comparability of the recommended minimum protection against UVB radiation, the International Sun Protection Factor Test Method (2006) as updated in 2006 by the European, Japanese, American and South African industries should be used. Note that there should be between 10 and 20 valid SPF values. The actual number of subjects tested is defined as the number required to produce a mean SPF with a 95% confidence interval (CI) within a range of +/-17% of the measured mean SPF.

**UVA test:** The Commission Recommendation (EU, 2006) proposes the persistent-pigment darkening method applied by the Japanese industry and modified by the French health agency Agence française de sécurité sanitaire des produits de santé (Afssaps) and the critical wavelength test for assessment of minimum protection against UVA radiation. These testing methods have been submitted to the European Committee for Standardisation (CEN) in order to establish European standards in this field, but the Commission Recommendation also states that in-vitro test methods producing similar results are preferable for ethical reasons. In-vitro methods such as the Colipa Ratio (2007) may thus be used (Colipa, 2007) for assessment of UVA radiation.

## Special requirement for toothpaste

### R42 Efficacy, fluoride

Non-fluoride toothpastes marketed as products that are natural, environmentally friendly and/or good for your health have recently increased their market share (Organic monitoring, 2009). This is because of a concern that excess fluoride intake causes fluorosis, which is a developmental disturbance of dental enamel caused by successive exposures to high concentrations of fluoride during tooth development, leading to enamel with a reduced mineral content and increased porosity (Abanto Alvares et al., 2009). After teeth have developed there is no risk. Fluorosis is often linked to water fluoridation, which is not practised in the Nordic countries (Fluoride Alert Network, 2009). The risk of successive exposures to high concentrations of fluoride at an early age is well documented.

However, it is also well documented that fluoride prevents dental caries (e.g. NHMRC, 2007), and the dental associations in all the Nordic Countries recommend toothpastes containing fluoride (Suomen hammasli, 2007; Tandlægeskolen i København, 2009). The amounts of fluoride recommended for toothpaste vary from one Nordic country to another, the lowest recommended amount (1,000 ppm) being that in Finland, and the recommendation in Denmark is 1,100 ppm up to the age of about 3½ and 1,450 ppm from the age of 3½. Fluoride is not recommended for children under 12 months old.

It is thus appropriate to require that toothpastes not intended for babies have a fluoride concentration in accordance with the national recommendations, as proof of sufficient efficacy. Alternatively, a protection level equivalent to the recommended fluoride concentrations for the same level of usage should be demonstrated for fluoride-free toothpastes through scientific publications, approval by professionals (dentists) and documented in-vivo testing.

## Special requirement for mild products

### R43 Efficacy, mildness

If a product claims to be mild, R40 stipulates that it pass a test documenting its 'mildness'. This test must also be passed if the product is invoking the exemption regarding degradability of polymers stated in R7. There are existing methods of documenting mildness, e.g. HET-CAM and the red blood-cell test (RBC test) (<http://www.hetcam.com/>, Ronald E. Hester et al., 2006), and these tests or tests that provide equivalent results should be used. Note that animal testing is not permissible.

HET-CAM is a qualitative method of assessing the potential irritancy of chemicals. Fertile, 10-day-old, white Leghorn eggs are used in HET-CAM. This means complete tissue containing arteries, veins and capillaries. Occurrence of lysis, haemorrhaging and/or coagulation are observed. The eggs are scored according to the severity of the reaction.

The red blood-cell test (RBC test) is part of the COLIPA Validation Project on Alternatives to Draize Eye Irritation. It is used to assess acute ocular irritancy caused by certain classes of chemicals (mainly surfactants) and formulations. The test (Pape, 1999) reveals cellular lysis and changes in protein conformation that can be correlated to inflammatory responses induced by initial tissue-injury events.

## **Quality requirements and regulatory requirements**

The requirements described in Chapter 4 have been imposed in order to ensure that applicants meet authorities' requirements and exercise satisfactory control over the production of their Nordic Ecolabelled products - including correct notification of the Nordic Ecolabelling organisation. It must be stressed that certification of the quality and ecomanagement systems is not a requirement.

Finally, the intention of the requirements in Chapter 4 is to ensure that the relevant persons within the enterprise awarded the Nordic Ecolabelling licence are familiar with the rules applicable to marketing of Nordic Ecolabelled products.

## **Validity of the licence**

We refer to external lists in some of our requirements (SCCP opinions, R4 and endocrine disruptors, R5) and therefore have no control over the actual contents of the lists. We have thus introduced a clause stating that if the content of the lists and opinions changes regarding a matter that affects the licences, a standard transition period of three months will be granted unless Nordic Ecolabelling decides on another (typically longer) transition period, depending on the complexity of changes from the producer's point of view and the assessed relevance of the changes. If other transition periods apply, Nordic Ecolabelling will give instructions and advice to all licence holders and applicants. Licence holders are solely responsible for complying with the criteria at all times,

## **Appendices in the criteria document**

Appendix 1 – Declaration on the marketing of Nordic Ecolabelled cosmetic products

Appendix 2 – Test methods

Appendix 3 – Declaration from the producer of the cosmetic product

Appendix 4 – Declaration from the supplier of raw materials

Appendix 5 – Declaration from the perfume supplier

Appendix 6 – Declaration from the packaging producer

Appendix 7 – Requirements for renewable cosmetics

Appendix 8 – Calculations

## **Requirements discussed but omitted**

Easy-to-use packaging was discussed when The Finnish Rheumatism Association approached with their 'Easy to open' campaign. However, a decision was made not to incorporate this into the criteria, since there is currently no standard that could be referred to, and without any external help it would be impossible to set requirements.

According to feedback received at the stakeholder meeting in March 2009, there is no significant variation in energy consumption during production and transportation of raw materials and products. Thus Nordic Ecolabelling does not set any requirements regarding these factors. It is questionable whether it is relevant to set requirements regarding energy consumption during raw-material production.

## 5 Changes relative to the previous version

Since the last version we have:

- Combined the two criteria documents (cosmetics and soaps & shampoos)
- Introduced a general requirement regarding biodegradability of all organic ingredients
- Introduced a limit for the content of environmentally harmful substances
- Excluded the 'legal requirements' to make the document simpler and shorter. These should automatically be met by all products placed on the market.
- Simplified the criteria where possible
- Introduced new substances to the list of substances not permissible in the product
- Introduced new packaging requirements and removed some of the old requirements
- Tightened up and changed the CDV requirement
- Introduced voluntary requirements regarding cosmetics made of renewable and sustainable raw materials
- Removed the requirement regarding animal testing, since the EU's 2004 Cosmetics Directive banned animal testing of cosmetics, and since bans on ingredient testing on animals will come into force in 2009 and 2013. There are no longer any cosmetic products on the market that have been tested on animals within the last five years.

## 6 New criteria

The future criteria will evaluate the following subjects:

- The possibility of only using of renewable raw materials, and the sustainability of the latter
- Ecological (organically farmed) raw materials

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## Appendix 1 History of the criteria documents of Nordic Ecolabelled Soaps & Shampoo and Cosmetics

<i>Table 1 Soaps &amp; Shampoos</i>			
<b>Version no.</b>	<b>Adopted</b>	<b>Valid until</b>	<b>Major changes</b>
Version 1.0	May 1996	May 1999	<i>First generation criteria</i> Requirements for certain classified substances, product classification, packaging requirements (Weight/utility relationship, PVC and labelling), CDV, biodegradability of surfactants and individual ecotoxicological requirements for certain substances/groups of substances. Environmental matrix coupling CDV and packaging requirements. Documentation of performance.
Version 1.1	Dec 1996	May 1999	The term 'active matter' replaced the term 'dry matter' throughout the document
Version 1.2	Oct 1998	May 2000	Prolongation of Version 1.1
Version 1.3	Apr 1999	Nov 2000	Prolongation of Version 1.2
Version 1.4	June 1999	Nov 2000	The list of chemicals was separated from the criteria document
Version 1.5	March 2000	Nov 2001	Prolongation of Version 1.4
Version 1.6	Oct 2000	May 2002	Prolongation of Version 1.5
Version 2.0	March 2001	May 2005	<i>Second-generation criteria</i> Major changes from Version 1: Requirements regarding product classification removed, limits for content of non-biodegradable organics, more stringent biodegradability/toxicity points, exclusion of certain substances (e.g. LAS, APEO, boronic acid), uncoupling of packaging requirements from matrix.
Version 2.1	May 2002	May 2005	Plastic pumps and caps were exempted from the requirement regarding labelling of plastic packaging (5.3)
Version 3.0	March 2004	May 2008	<i>Third-generation criteria</i> Major changes from Version 2: Increased stringency regarding health requirements (classification of substances incl. sensitising substances, limitations for

			perfume/perfume ban in baby products, ban on potential endocrine disrupters), inclusion of products for animal use, differentiation of cut-off values for different types of products.
Version 3.1	Dec 2004	May 2008	Change of perfume requirement (R18)
Version 3.2	March 2007	March 2010	Prolongation of Version 3.1. Introduction of CDV acute as a calculation parameter (as an alternative to calculation of the Biodegradability and Toxicity parameter (R23))
Version 3.3	Dec 2008	March 2011	Prolongation of version 3.2

**Table 2 Cosmetics**

<b>Version no.</b>	<b>Adopted</b>	<b>Valid until</b>	<b>Major changes</b>
Version 1.0	March 2004	March 2007	<i>First generation criteria</i> Requirements for certain classified substances (no CMR, no sensitising substances except perfume), ban on endocrine disrupters, biodegradability of surfactants and individual ecotoxicological requirements for certain substances/groups of substances, requirements regarding packaging, labelling and performance.
Version 1.1	Dec 2004	March 2007	Change in perfume requirement (R11)
Version 1.2	March 2005	March 2008	Prolongation of Version 1.1 and addition of requirements for wet wipes (R40-41)
Version 1.3	March 2007	March 2010	Prolongation of Version 1.2. Change of requirements regarding UV filters (R16), labelling and performance of sunscreen products (R30 and R49)
Version 1.4	May 2007	March 2010	Change of requirements for surfactants in toothpaste (R21 and R38)
Version 1.5	Dec 2007	March 2010	Requirement R16 regarding a limit for organic UV filters in sunscreen products for babies and children was omitted
Version 1.6	Dec 2008	March 2011	Prolongation of Version 1.5.

## Appendix 2

Background to the voluntary requirement on renewable and sustainable ingredients in cosmetics.

The popularity of natural cosmetics is growing rapidly. Demand is growing from health and environmentally conscious consumers and several cosmetic companies have launched their own lines of natural cosmetics.

Natural cosmetics are strongly promoted:

*“Natural cosmetics serve to beautify and care for the human body by means of ingredients from nature. This is made possible with natural raw materials, friendly to both the skin and the environment.”<sup>1</sup>*

*“A new trend is spreading like wildfire through the cosmetics industry. Informed customers wish to care for their appearance with pure, natural ingredients. Tired of synthetic and even toxic substances, we are becoming increasingly interested in what products actually contain. Natural cosmetics are now the in thing.”<sup>2</sup>*

*“Natural cosmetics care for and improve your skin with ingredients and substances taken from nature. This is achieved through health promoting ingredients that are kind to your skin and nature and that stimulate and support the skins natural functions. The natural ingredients offer mild, natural care for your skin, whatever its age.”<sup>3</sup>*

There is currently no common definition for the term natural cosmetics. Nor are there any regulations regarding the marketing of natural cosmetics. There are however several systems that have guidelines/standards, among these German BDIH ([www.bdi.de](http://www.bdi.de)) and French Ekocert/Cosmebio (<http://www.cosmebio.org>). There is a desire to establish a Europe-wide standard.

At present, many of the requirements regarding natural cosmetics are somewhat vague. Complete criteria and standards are not generally available. There is also a lack of transparency in the development of the guidelines/standards. The link between the constituent natural substances, the production processes and the claimed health and environmental effects are often poorly documented and unverified. For example, a natural fragrance (“nature-identical flavouring”) of unknown origin is not necessarily better to health than a synthetic fragrance, possibly the opposite. It is also unclear how binding the requirements are. For example, regarding vegetable raw materials it may be stipulated that these *as far as possible* should originate from controlled organic sources. There is no clear indication of what “possible” is or how adherence is checked. A common feature of all natural cosmetics is however that they shall primarily compose ingredients from renewable sources.

Nordic Ecolabelling wishes to enable the ecolabelling of natural cosmetics. This will allow the consumer to choose high-class, controlled cosmetic products manufactured from a high proportion of sustainably produced renewable raw materials. The principle is that Nordic Ecolabelled natural cosmetics shall fulfil all the base requirements for the ecolabelling of cosmetics. These cover production, constituent chemicals, quality and health. In addition, strict requirements on the origin of the raw

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<sup>1</sup> [http://www.kontrollierte-naturkosmetik.de/e/natural\\_cosmetics.htm](http://www.kontrollierte-naturkosmetik.de/e/natural_cosmetics.htm)

<sup>2</sup> [www.lifebutiken.se/](http://www.lifebutiken.se/)

<sup>3</sup> [www.gronadraken.com/](http://www.gronadraken.com/)

materials must be fulfilled. Such cosmetics can then be marketed as "Based on sustainable natural ingredients." The existing guidelines for natural cosmetics cannot be accepted since many are not public and it is thus unclear how sustainable the renewable ingredients are.

The table below compares The Nordic Ecolabel requirements with common requirements/guidelines for natural cosmetics in other systems. There are some differences between the Nordic Ecolabel criteria for cosmetics and other systems for natural cosmetics. There are also differences between systems, depending on which direction the system has chosen to promote.

Area of requirement	Example of common requirements on "natural cosmetics"	Nordic Ecolabel requirements on cosmetics
<b>Constituent chemicals</b>	<p><b>Silicones are often prohibited.</b> <b>Synthetic colouring agents are often prohibited.</b></p> <p><b>Synthetic fragrances are often prohibited.</b></p> <p><b>Preservatives are permitted, but must be nature-identical.</b></p>	<p><b>Silicones are prohibited.</b> <b>Colouring agents may be synthetic but must not be bioaccumulating.</b> <b>The use of fragrances is severely limited due to health/allergy issues. Only products with a low and known content of allergens may be used, which is advantageous from an allergy viewpoint. Natural fragrances are often strong allergens and their exact chemical composition unknown. Accordingly, these may only be used if the content of allergens is known.</b> <b>Requirement limiting the content of preservatives. Bioaccumulating, formaldehyde forming or allergenic preservatives are prohibited.</b></p>
<b>Production</b>	<p><b>The transition from raw material to cosmetic product shall be performed with as few chemical processes as possible.</b></p>	<p><b>The quality requirements encompass the production process.</b></p>
<b>Animal testing</b>	<p><b>Testing on animals is most often prohibited.</b></p>	<p><b>Testing on animals is prohibited (as in EU legislation).</b></p>
<b>Raw materials</b>	<p><b>Reusable and biodegrading materials are preferred.</b></p> <p><b>Paraffins and other products of fossil origin are often prohibited.</b> <b>Animal fat is prohibited.</b> <b>Requirements on the collection and production of raw materials. Impact on nature shall be minimised and endangered species protected.</b> <b>GMOs often prohibited.</b></p>	<p><b>No requirements in the main criteria document for cosmetics.</b> <b>Additional requirements for Nordic Ecolabelled natural cosmetics</b> <b>95% of raw materials must be renewable. I.e. max. 5% may be petroleum based.</b> <b>Stringent requirements on the origin of raw materials that ensure that primary production is checked and sustainable.</b> <b>GMOs are prohibited through requirements on organic cultivation and forest standards.</b></p>

Further justification for the additional requirements for Nordic Ecolabelled natural cosmetics:

### **Proportion of renewable vegetable ingredients**

At least 50% of active ingredients must be of vegetable origin and at least 95% of the ingredients in the product must be based on renewable raw materials of vegetable origin. The requirement ensures that the majority of ingredients are natural (i.e. not of fossil origin, such as paraffins) and renewable (i.e. able to reproduce in nature within a period of 100 years). It also ensures that cosmetics that consist mostly of inorganic salts and water with some essential oil etc cannot be claimed to be based on sustainable renewable raw materials. No animal fats are permitted. The proportion is set to 95% since there are no renewable alternatives to some substances such as some preservatives, colouring agents and fragrances. This limit is common in other guidelines for natural cosmetics. Nordic Ecolabelling does not set requirements on the chemical processes that may be used to refine the raw materials since Nordic Ecolabelling maintains that it is most important that the raw materials are renewable and sustainable.

### **Sustainable production of vegetable raw materials**

Vegetable raw materials must be produced in a sustainable manner. They must not originate from forest environments meriting protection due to high biological and/or social value. It is not necessary to document this requirement, but Nordic Ecolabelling may revoke a licence if there is reason to believe that this requirement is not observed. This requirement is set to ensure that non-certified raw materials are not, for example, derived from rain forest areas meriting protection. The licensee must also know the origin and ensure the traceability of all vegetable raw materials.

### **Proportion of certified raw material**

All constituent raw materials derived from oil palms, soya and sugar cane, and 70% of wood raw materials (e.g. for the production of tall oil) must be certified in accordance with a standard and certification system that fulfils Nordic Ecolabelling requirements for the certification of biomass. Alternatively they may be organically cultivated. The requirement is set to ensure sustainable primary production, which also has positive climatic effects. Regarding palm oil, for example, the RSPO standard has been developed to ensure that production observes the principles of sustainability. Equivalent standards for soya and sugar cane are under development. Nordic Ecolabelling's general forestry requirements apply for wood raw material. Certification shall comply with a forestry standard or other standard approved by Nordic Ecolabelling. Other cultivated plants must be cultivated organically. The requirement is equivalent to those often used in the guidelines for natural cosmetics in other systems but is clearer and more controllable.

### **Marketing**

A cosmetic product that has been awarded a licence in accordance with Nordic Ecolabelling criteria for cosmetic products and fulfils the additional requirements on natural cosmetics may be marketed as a Nordic Ecolabelled cosmetic product based on sustainable natural ingredients. The product must display the Nordic Ecolabel and the mandatory subtext "Based on sustainable natural ingredients".

The requirement on renewable and sustainable raw materials in cosmetics also aims to help consumers with allergies who wish to use renewable and sustainable cosmetic products with ingredients of low toxicity and ready biodegradability.