About Nordic Ecolabelled

Cosmetic products

Version 3.0

Background to ecolabelling
18 January 2016
Proposal for hearing

Nordic Ecolabelling

Content

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This document is a translation of an original in Swedish. In case of dispute, the original document should be taken as authoritative.

Addresses

In 1989, the Nordic Council of Ministers decided to introduce a voluntary official ecolabel, the Nordic Ecolabel. These organisations/companies operate the Nordic ecolabelling system on behalf of their own country's government. For more information, see the websites:

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1 Summary

This background document contains a brief description of the product group and the impact of cosmetic products on health and the environment, a market overview and background to the requirements set out in the criteria document.

The product group comprises all the products covered by the EU Cosmetics Regulation 1223/2009 with subsequent amendments and rinse-off products for animals (not covered by the Cosmetics Regulation).

Nordic Ecolabelling has come to the conclusion that the most relevant environmental parameters for cosmetics are:

- emissions of hazardous, non-degradable and/or bioaccumulative substances in the environment, which place a burden on treatment works and/or recipients,
- the amount of packaging material and
- extraction of raw materials

Setting criteria on the toxicity and degradability of the ingoing substances, the amount of packaging and sustainable extraction of raw materials can reduce the burdens on our external environment.

There are also certain health-related problems associated with cosmetic products, such as allergies and unnecessary exposure to substances that may be harmful to health. The criteria also cover these aspects.

This version of the criteria contains a number of changes compared with version 2. The main changes in this version are as follows:

- Requirements on renewable raw materials
- New substances added to the list of prohibited substances
- Ban on nano UV filters
- Restriction on the use of phenoxyethanol in children's products
- Restriction on aluminium in leave on products
- Stricter packaging requirements
- New requirement on the residual amount of the product in the container after use
- CDV can be calculated based on the DID list from 2014

With the help of the above, the environmental benefits from version 2 to version 3 can be summed up as new substances on the list of prohibited substances, plus a total ban on nanomaterials and limitations on the use of phenoxyethanol, guaranteeing better cosmetics from an environmental and health point of view. Stricter packaging requirements restrict the use of packaging material and improve resource efficiency. A new requirement on the emptying level limits waste, leading to environmental benefits. Requirements on the sustainable extraction of raw materials are a major global issue with a huge environmental impact.

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2 Basic facts about the criteria

Products that can be labelled

All cosmetic products covered by the EU Cosmetics Regulation 1223/2009 with subsequent amendments, such as skin care products, hair care products, decorative cosmetics, perfumes and hygiene products can be Nordic Ecolabelled.

According to the Regulation, "cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. Wet wipes are included in the definition of product group, as the liquid on the wipe is intended for functions as described above. Washing up liquid with added skin protection, perfumed toilet paper or tissues with lotion, for example, do not meet the above criteria and are therefore not considered to be cosmetic under the Cosmetics Regulation or Nordic Ecolabelling criteria for cosmetic products.

Mix-it-yourself products (cosmetics kits), in which all the ingredients together with instructions for mixing the product are sold as a combined unit/single product are covered by the Cosmetics Regulation and can be Nordic Ecolabelled.[1]

Rinse-off products for use on animals can be Nordic Ecolabelled although these are not covered by the Cosmetics Regulation.

Products covered by the Biocides Regulation 528/2012 cannot be Nordic Ecolabelled. These are often marketed as antibacterial, antiseptic and/or disinfecting. It is the agencies in the Nordic countries who decide whether a product is a biocide or not – but irrespective of this, such products will not be able to be Nordic Ecolabelled because we do not permit the addition of biocides for purposes other than to preserve the product.

Justification for Nordic Ecolabelling

To achieve environmental gains, each individual requirement must be relevant to the inherent environmental problems of the product group. There must also be a proven potential to differentiate between the environmentally better products and others (there must be a difference and it has to be large enough that it "pays" to set the requirement). There must also be scope to steer the environmental problem in question via ecolabelling requirements.

These three parameters are to be seen together and as such are referred to as Relevance-Potential-Steerability, RPS. Choosing the requirements that together have the greatest relevance, potential and steerability in terms of the product's life cycle achieves the greatest environmental gain.

[1] (EU, 2013)

Nordic Ecolabelling believes that there are many different products and players in the cosmetics industry and that they differ in various ways, which means that Nordic Ecolabelling can separate out the best products in environmental terms.

Nordic Ecolabelling has carried out a quantitative MECO analysis (i.e. summarising the impact of materials, energy, chemicals, etc. on the basis of a total evaluation of the products, from production of raw materials to waste, plus transport). The MECO analysis helps to evaluate what the relevant health and/or environmental impacts are linked to materials, energy and chemicals (and other substances) in the different life cycle phases of cosmetic products. The evaluation is based on studies of the literature plus Nordic Ecolabelling's knowledge of the products, their constituents and production. It has been divided into rinse-off cosmetics and leave-on cosmetics, which have different usage patterns. The MECO analysis for the two product types differs in the production, usage and waste phases. The two MECO analyses are set out in a table in Appendix 2.

The important parameters according to the MECO and life cycle analyses[2] are the extraction and production of raw materials, packaging, the usage phase and emission of chemicals in the usage and waste phases. Transport is normally a minor impact. The impact is described in more depth of the different phases below using the RPS tool.

Relevance

Relevance is assessed based on which environmental problems the product group causes and how extensive those problems are.

Raw materials

Most of the raw materials used in cosmetic products are organic substances. Inorganic raw materials are also used, e.g. salts, alkalis, TiO2 and mineral pigments but with fewer variations and in smaller quantities. Cosmetic products use both renewable and non-renewable organic raw materials. There are limited amounts of non-renewable materials because they are extracted from fossil oil while renewable raw materials are re-established through natural processes. The fact that renewable raw materials are re-established is an important argument for promoting the use of renewable raw materials, i.e. it is relevant to introduce requirements encouraging the use of renewable materials.

The use of renewable raw materials instead of non-renewables on a larger scale in fuel, etc. has raised some important issues. The main issues concern the destruction of rain forests and potential competition with food production.

Packaging

Packaging is a relevant environmental burden in cosmetics, and for some products it is more relevant than the product itself. This naturally primarily concerns products with more packaging than contents. There are many examples of cosmetic products that use more packaging than necessary, e.g. small amounts of

[2] (Herron, June 18 2013), (Annette Koehler, 2009)

cream sold in heavy glass jars, and it is therefore relevant to set requirements on packaging in terms of the amount and the materials used.

Manufacture of ingoing substances and cosmetics

Manufacturing ingoing substances and products consumes energy in the factories. Life cycle assessment of cosmetic products shows that the manufacture of ingoing substances in cosmetic products or the manufacture of the cosmetic product does not account for the dominant environmental impact in the life cycle of the product.[3] Raw materials producers state that the part of the life cycle of the product that accounts for the greatest environmental impact differs from product to product based on production processes, e.g. drying and fermenting demand energy.

Even if the environmental impact from the manufacture of cosmetics/ingoing substances is not the dominant environmental impact in the product's life cycle, it can sometimes be thought to be relevant because cosmetics are manufactured in large amounts.

Use phase

Cosmetics can contain over 26 000 substances and constituent parts according to the European Commission's inventory of cosmetic ingredients.[4] The overall relevance of the product group in terms of chemicals requirements is based on the fact that the Cosmetics Regulation does not contain requirements on the use of the substances that may impact on the environment (toxic, persistent or bioaccumulative). Nor does it exclude the use of allergens, for example. There is currently no definition of endocrine disruptors in the EU and therefore nor are these extensively limited/prohibited in cosmetic products. Nor are there any requirements that cosmetic products should be classified, e.g. in the same manner that laundry and cleaning products are classified.

Allergens are a major concern for many consumers, and are found in very many cosmetic products. Media attention is also often focussed on cosmetic products and their component substances, something which gives rise to concern among consumers. Large amounts of cosmetic products are sold, and these products can be used by consumers up to several times a day. Large amounts of cosmetic products are used, which also makes it relevant to set ecolabelling requirements for cosmetics. Sales of cosmetic products are high throughout the Nordic countries, amounting to a total of over EUR 4 800 million. [5]

When a cosmetic product is used, the amount that is used is relevant and in the product types where it is possible to steer the consumer towards using the "right dose", it is relevant to limit overdosing. This applies, for example, to liquid soap which can be dosed with a pump, ensuring that only products with a low environmental impact per functional unit (washing hands) are able to meet the requirement.

[3] (Herron, June 18 2013), (Annette Koehler, 2009)
[4] (European Comission)
[5] (TY, 2014), (Kosmetikkleverandørenesforening, 2012), (SPT), (KTF, KTF/Statistik)

A relevant environmental impact in the use of many cosmetic products is the consumption of hot water, due to the energy required to heat the water.

Waste phase

Cosmetic products and their ingoing substances can take different routes from the consumer to the surrounding environment after use. Some volatile ingredients evaporate to air from hair and skin, other ingredients disappear with the washing water when bathing/showering or washing clothes. Some ingredients are absorbed by the skin and finally disappear the natural way or are accumulated in the body. Some products (e.g. wet wipes, facial cleaning products and nail varnish remover) are likely to be disposed of with the household waste. Sunscreens partly end up in the sea/aquatic environment when people go swimming. It is therefore relevant to set requirements on the inherent characteristics of the substances included in the products, such as degradability and aquatic toxicity and to prohibit or reduce problematic substances such as microplastics.

Potential

Potential is assessed based on the potential environmental gains within the specific product group and for each area in the criteria where requirements are set.

Raw materials

There is potential to introduce requirements on renewable raw materials to safeguard their origin and their sustainable cultivation. Systems such as RSPO are currently available, which distinguish between raw materials production. Nordic Ecolabelling experiences a desire both from consumers and certain licence-holders that Nordic Ecolabelling should broaden this area and consider introducing requirements for renewable raw materials.

Packaging

There are major differences in both choice of material and amount of material in the packaging of cosmetic products. There is therefore potential for requirements on packaging. The majority of cosmetic products that are Nordic Ecolabelled today have plastic packaging, but there are also other types of packaging on the market, e.g. glass and metal.

Manufacturing ingoing substances and cosmetics

Energy use and environmental impact from manufacturing are reduced by optimising processes and using renewable energy, for example.

We also have the potential to influence the production of ingoing substances when we set requirements on residues from the production of ingoing substances.

Use phase

Cosmetic products involve a large number of different substances. As cosmetic products are used directly on the body, it is relevant to set stringent health requirements such as avoiding or limiting substances that are sensitising,

endocrine disruptors and similar. There is also potential for such requirements where the manufacturers of the products are able to select which raw materials are to be included in their products.

The potential for health benefits in the product group has been shown in a large number of tests carried out by the Finnish consumer organisation Kuluttaja, the Swedish Testfakta, the Danish consumer organisation Forbrugerrådet Tænk and the German magazine Öko-Test, which have also found differences between the products in recent years: In recent years Testfakta has found allergenic substances and parabens in skin lotions[6], and allergens in mascara[7]. The Finnish consumer magazine Kuluttaja compared BB and CC creams in 2014[8] and found sensitising fragrances in several products and in 2012 found the carcinogenic nitrosamine in one mascara.[9] The Danish consumer organisation Forbrugerrådet Tænk[10] has tested wrinkle cream. It found that 2 of the 14 products tested contained the preservative MI. They have also tested wet wipes,[11] children's sunscreen,[12] and found substances such as methylisothiazolinone and propylparaben in both and body lotions[13] and hand soap[14] and found undesirable ingoing substances in these too. In August 2014 Fremtiden i våre hender[15] in Norway carried out a test of deodorants. 13 of the 28 products tested were found to contain triclosan. An increased incidence of allergies in conjunction with the use, e.g. of fragrances and preservatives also indicates potential for differentiating products with a good health profile.

Nordic Ecolabelling carried out a small survey of cosmetic products in stores during its evaluation of cosmetics in 2014 and found that non-Nordic Ecolabelled products contain a large proportion of substances that Nordic Ecolabelling excludes, which shows that it is relevant to exclude or limit the substances that have been found here.

These articles, tests and survey show that there is a difference between the products and thus potential. Similarly, the ban on microplastics is one way to differentiate Nordic Ecolabelled products from non-Nordic Ecolabelled products in the segments in which microplastics are used. This would enable Nordic Ecolabelling to help to guide consumers to choose products that are best for the environment.

With regard to correct dosages, there is potential to make a difference as it is possible to choose different pumps and vary the viscosity of the products. However, it is hard to steer how the end consumer handles the products and, for example, how much shampoo they use.

[6] (Testfakta, 2015)
[7] (Testfakta, 2011)
[8] (Kuluttaja, 2014)
[9] (Kuluttaja, 2012)
[10] (Forbrugerrådet Tænk)
[11] (Forbrugerrådet Tænk)
[12] (Testfakta, 2014)
[13] (Forbrugerrådet Tænk Kemi, 2015)
[14] (Forbrugerrådet Tænk Kemi, 2015)
[15] (Lindahl, 2014)

Unlike, e.g. detergents, there is little potential for concrete improvements in terms of hot water used in conjunction with cosmetics because "cold water shampoo" would not be relevant as a product from a consumer point of view.

Waste phase

Reducing problematic substances such as microplastics and non-degradable and/or endocrine disrupting preservatives is important for the waste phase too, and from the above it is clear that potential exists.

Requirements on e.g. information on correct waste management, are both relevant and have potential as they give the consumer opportunities to handle the waste correctly and so reduce its environmental impact.

There are also products on the market that are hard to empty without extra work, and a pair of scissors, for example. The requirement on the emptying level therefore has the potential to reduce the amount of waste.

Steerability

Steerability is assessed based on the scope to set requirements concerning the relevant environmental parameters with potential for improvement.

There is steerability in Nordic Ecolabelled cosmetics in that many consumers demand cosmetic products that constitute a good choice in terms of health and the environment. There is growing awareness of environmental aspects among the general public, which increases demand for Nordic Ecolabelled cosmetics. Those consumers who are expected to be most interested in Nordic Ecolabelling are those that have an extra focus on the products they use not being damaging to health or the parents of children or infants. The latter group are particularly aware of the contents of the products they use. A growing number of consumers choose natural cosmetics for health and environmental reasons.[16] However, there are no guarantees that natural cosmetics are free from classified allergens, for example. Therefore, these consumers might also be interested in Nordic Ecolabelled cosmetics if these took health issues into account.

Raw materials

Promoting renewable raw materials in Nordic Ecolabelled cosmetics requires that the production of renewable raw materials, and the production of vegetable oil in particular, is sustainable. RSPO[17] is one of the initiatives that seeks to promote the production of sustainably grown palm oil.

Steerability of requirements on the origin of raw materials should be OK regarding palm oil. Major actors in the market, manufacturers of cosmetics and raw materials producers alike, have stated that they will switch to certified palm oil in 2015 and 2016.[18]

[16] (Organic Monitoring, 2011)
[17] (RSPO, http://www.rspo.org/)
[18] e.g. (P&G), (Unilever), (Henkel)

Other problematic vegetable raw materials such as soya and sugar cane also have certification systems.[19] These are used to a lesser extent than RSPO in cosmetics. These certification systems have the same problem as the RSPO standard.

Although standards have their deficiencies, Nordic Ecolabelling considers that for the product groups where there are no alternatives and palm oil/soy derivatives are used in large quantities, they are a good start.

There is no such system for fossil raw materials and their origin is not steerable.

There is EU legislation on animal fats: These are covered by EU Regulation 1774/2002 of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption, which ensures traceability to the point of origin of waste and residues.

Packaging

Packaging can partly be steered towards reduced use of packaging and also towards packaging material that places less of a burden on the environment than others. This can also be verified by certificates and calculations of packaging material.

Manufacture of ingoing substances and cosmetics

It is difficult to set steerability requirements on the manufacturing process of cosmetics, such as on energy use. One reason for this is that the factories often manufacture both Nordic Ecolabelled and non-Nordic Ecolabelled products on the same production line.

Quality procedures can safeguard good quality. Requirements on pollutants ensure purer input substances.

Use phase/waste phase

When it comes to the use of cosmetic products, it is difficult to steer how the consumer will finally use their product, but demanding clear user instructions and dosing systems (for the products where this works) increases the chances of less over-use and similar. If a large amount of product remains in the packaging when it is thrown away, this results in great product wastage.

Consumer interest in cosmetics is predominantly about their contents. In some consumer categories, Nordic Ecolabelled products are very important, such as, for example, families who buy children's and baby products. When it comes to input substances for these products, Nordic Ecolabelling can steer towards products whose contents place less of a burden on the environment by applying requirements that limit/exclude substances due to their characteristics. Licensing Nordic Ecolabelled products has resulted in changes to the products' raw materials.

The producers of Nordic Ecolabelled cosmetics also have steerability over the raw materials they use in their products and the materials used in the packaging, i.e.

[19] (Bonsucro), (RTRS)

they can influence the contents and thus the use and waste phases in their products to a large extent.

When it comes to the business to business market, environmental aspects are often involved in procurement in various ways. Nordic Ecolabelled hotels and restaurants are examples of businesses that often demand Nordic Ecolabelled soap.

Common Nordic bullet points

It is important that Nordic Ecolabelling keeps up-to-date with the world of cosmetics and remains a safe choice that stands for stringent environmental and health requirements and that this is clearly communicated to consumers via the consumer platforms currently available. The following Nordic bullet points have been created for this reason:

- Strict requirements on chemicals (harmful to health and the environment), including
    - No parabens
    - No MI (an allergenic preservative)
    - No fragrances in baby/children's products
    - No ingredients on the EU's list of potential endocrine disruptors
- Strict requirements on degradability and bioaccumulation, including
    - No microplastics
- Strict requirements on the amount and type of packaging

Version and validity of the criteria

Nordic Ecolabelling's criteria for cosmetic products were originally introduced as two separate criteria documents for soap and shampoo, version 1, adopted 1996, (cosmetic products that are rinsed off, "rinse-off"), and cosmetic products version 1, adopted 2004, (which covers all other cosmetic products other than those which are rinsed off).

The criteria for shampoo and soap were revised twice. Table 1 in Appendix 1 contains a history of the criteria documents.

In 2008 Nordic Ecolabelling decided to merge the criteria documents into a combined document containing the criteria for Nordic Ecolabelling of cosmetic products, covering both "rinse-off" and "leave-on" products. The obvious reason for this is that the products consist of similar substances with similar uses and functions, whether or not the products are intended to be rinsed off or left on the skin. In addition, all products are covered by the same legislation (Council Regulation 1223/2009 on Cosmetic Products). The criteria document was called cosmetic products and it was version 2.

Table 2 in Appendix 1 contains a history of the cosmetics criteria.

The Nordic Market

Industry and producers

In all the Nordic countries, there are global cosmetics manufacturers, such as Unilever, L'Oréal, Biotherm, Clarins and Clinique, but there are also smaller national companies, including some natural cosmetics.

Sales of cosmetic products are high throughout the Nordic countries, amounting to a total of over EUR 4 800 million, based on the following:

- Finland EUR 940 million (€171/person according to TY[20], 2014, multiplied by a population of 5.5 million)
- Norway NOK 9 790 million (based on information from KLF[21] on net sales from 2012)
- Denmark DKK 7 792 million (based on information from SPT[22] for 2012)
- Sweden SEK 15 330 million (based on information from KTF[23] from 2012)

There are many companies manufacturing in the Nordic countries, such as Cederroth, NOPA Nordic, Allison, Persano, DermaPharm, Lumene, Lilleborg, Kiilto, Teampac, Aco, etc. The companies vary from small, to medium-sized or large. There are both private-label products and those that are sold under their own product name in all Nordic countries.

Retailers

Cosmetic consumer products are mainly sold in supermarkets and in specialist shops. Some are also sold at pharmacies, hairdressers salons and through direct selling. The distribution between the different sales channels varies in the different countries.

Some cosmetics are also sold via the internet and in various tax-free outlets (ferries, airports, etc.) These sales points are harder to monitor.

When it comes to Nordic Ecolabelled cosmetic products for consumers, they are mainly found in supermarkets and pharmacies. Sometimes these include a number of products bearing the store's own name, e.g. Coop (Änglamark), Matas, Rema, Pirkka, Tusinfryd and many products for various pharmacy chains.

Products sold to commercial customers, business to business, mainly sold by direct sales and public procurement, where the environment plays an important role for many.

On the business to business side many of the products sold globally are Nordic Ecolabelled, such as soaps Tork, Katrin, Rentokil and Sterisol.

[20] (TY, 2014)
[21] (Kosmetikkleverandørenesforening, 2012)
[22] (SPT)
[23] (KTF, Kemtekniska Leverantörsförbundet)

The market

The view of Nordic Ecolabelled products is positive in the Nordic countries. A Finnish dissertation[24] in 2012 found the following regarding the purchases we make "When using cosmetics the women in the survey appreciated the price, the quality and the products which are tested to be good in the use. In cosmetics the women appreciated also the products which are recommended by friends, suitable for allergic skin, against animal testing and eco-friendly cosmetics. Ingredients of cosmetics caused slightly a caution in the women in the survey and they wanted to be more accurate what products they use in the future..."

In Denmark in particular, consumers are health-conscious and focus on ecolabelled products as they are judged to be better products from a health point of view. Many equate eco-labelling with cosmetic products that are better for health. The media often highlight the ability to avoid the most problematic substances by choosing ecolabelled cosmetics. This is particularly true for products for babies and children.

The trends in society in which people are increasingly visible on social media, where wellness and fitness plays a major role, means that interest in cosmetic products is increasing. There is increasing interest in the substances included in or excluded from products.

In the last few years, changes have also taken place on the issue of cosmetics and gender. There are now products for men, such as skin creams, hair dye, etc. which did not exist to as large an extent a number of years ago.

During the evaluation in 2014, several manufacturers cosmetics were contacted by e-mail and asked to answer some questions. Several of the manufacturers stated that they believe that demand for renewable raw materials will increase and similarly they believe that organic ingredients are a growing trend. Some already use Ecocert, Cosmos or RSPO-certified raw materials. One manufacturer states that they require an analysis certificate under GMP (Good Manufacturing Practice) for their raw materials.

Other issues that emerge from the e-mail survey was that work is in progress within the industry to produce more environmentally friendly packaging and that one company is working to produce airless packaging.

Nordic Ecolabelling licences

The number of Nordic Ecolabelling licences has increased in recent years. The market share, however, remains quite small. There are products in all the Nordic countries. Baby products, primarily baby wipes, and Nordic Ecolabelled B2B soaps are product types where a larger proportion is Nordic Ecolabelled than in other categories. Similarly, there is a larger proportion of ecolabelled products in the fragrance-free category then in the fragranced category.

In March 2015 there were 126 licences for cosmetics in the Nordic market, covering 2 199 products. These are distributed as shown in Table 1 below.

[24] (Jokela, 2012)

Table 1. Number of licences in respective Nordic country (March 2015)

	No. of licences	No. of products
Denmark	71	1 845
Finland	3	34
Norway	10	29
Sweden	42	291
Iceland	0	0

Other labels

Statutory requirements

Regulation 1223/2009/EC on Cosmetic Products

The Cosmetics Regulation 1223/2009 replaced the Cosmetics Directive on 11 July 2013.[25]

The Cosmetics Regulation is European law and is directly applicable within the Community and must therefore be complied with. One completely fundamental requirement for cosmetic products is that they shall be safe for human health when used under normal or reasonably foreseeable conditions. The requirement on safety, however, is a general requirement and does not prevent cosmetic products containing substances that may be harmful to people with a particular sensitivity (allergy) or substances that are risk classified as hazardous to health.

The Regulation sets out a long list of substances that are prohibited in cosmetics products or that may only be included in limited amounts or for limited purposes. A large number of substances are prohibited under Annex II, limited under Annex III and approved under Annexes IV to VI. CMR substances are prohibited as previously, but there is now an opportunity for exemptions under CMR categories 1A, 1B and 2 (under the CLP Regulation). As before, CMR category 2 must be risk assessed and approved by the Scientific Committee for Consumer Safety. Similarly to this requirement, CMR categories 1A and 1B must be approved for foodstuffs, where no suitable alternative substances exist and where the substance has a particular use in the product category.

Nanomaterials are covered separately in Article 16, which requires that nanomaterials are notified and their safety evaluated; however not when used as a colourant, UV-filter or preservative. In the Cosmetics Regulation nanomaterials have a separate definition, and it is this that the producers must comply with when stating on the packaging whether the product contains nanomaterials.

One new element compared with the previous directive is the introduction of rules on product claims (Article 20). The intention is that standardised claims are to be developed, in which what the claim covers is well-defined. This work is currently being carried out.

[25] (EU, 2009)

Ecolabelling type 1

EU Ecolabel

The EU Ecolabel has criteria for rinse-off cosmetics.[26]

The criteria exclude certain ingredients and classifications of ingredients, and have similar CDV, aNBO and anNBO calculations to the Nordic Ecolabel. The criteria also include requirements on packaging and the emptying level.

The EU Ecolabel also includes requirements on sustainable procurement of palm oil, palm kernel oil and their derivatives.

According to the EU Ecolabel[27] there are no products currently labelled under the new criteria for rinse-off cosmetics. However, there are >500 products with the EU Ecolabel under their old shampoo and soap criteria. These licences are valid up to December 2015.

Good Environmental Choice (Bra Miljöval)

The Swedish Society for Nature Conservation, the organisation that manages the Swedish ecolabel Good Environmental Choice, has an open criteria document for chemical products. Approval for all types of cosmetic products can be given through this document.[28]

The criteria exclude certain ingredients and classifications of ingredients. There are particular requirements on surfactants, complex reagents and solvents, preservatives, thickeners, whiteners, acids, colorants, perfumes, biological substances, enzymes, fillers, rubbing alcohol and other substances. The criteria also include requirements on water content and packaging, and general requirements governing the companies that manufacture these products. There are also a number of product-specific requirements. In soaps, for example, only vegetable fatty acids may be used.

According to the Good Environmental Choice website, there are 16 cosmetic products with the Good Environmental Choice label and all are rinse-off products, the majority soaps.[29]

Good Environmental Choice Australia (GECA)

GECA has criteria for “Personal care” products, which include soap, shampoo, oral hygiene products, skin care, decorative cosmetics and deodorants. [30]

The criteria include requirements on effectiveness, palm oil, VOCs, phosphorus, degradability, claims, toxic and ecotoxic ingoing substances, packaging and minimising waste.

[26] (EU Ecolabel, 2014)
[27] (EU Ecolabel)
[28] (Bra Miljöval, 2014)
[29] (Bra miljöval)
[30] (GECA, 2014)

Other private labelling

Natural/organic cosmetics

There are different standards for natural cosmetics. Some of these are national and some international. They differ from each other somewhat, but what they all have in common is that the raw materials must be of natural (vegetable, animal) origin. Most of these require that the raw materials are 95% or 100% (with some exceptions) of natural and/or organic origin. There are limitations/positive lists for the remaining raw materials and particular chemical and physical processes are usually permitted. The processes that are normally not permitted are ethoxylation, propoxylation, sulphonation, gene technology and radiation.

There are few or no requirements on the extraction of raw materials. Organic raw materials must be certified, GMO is prohibited and some standards have requirements that the raw materials must not come from species threatened with extinction, for example.

The systems are not regulated by the Council Regulation on organic production (834/2007/EEC).

The most important standards are:

- NaTrue[31]
- COSMOS[32] (Developed by the Soil Association, BDIH, Cosmebio, Ecocert and ICEA)
- Ecocert[33]
- BDIH[34]

The fundamental starting point with natural/organic cosmetics is different from that of Nordic Ecolabelling. In natural cosmetics (almost all) raw materials must be from vegetable or animal sources. Nordic Ecolabelling also accept synthetic materials but has requirements stating that raw materials, irrespective of their origin, must be degradable and must not be ecotoxic or bioaccumulating. Classifications and groups of substances that are harmful to health or the environment are also prohibited or limited under Nordic Ecolabelling. Nordic Ecolabelling also has requirements on the origin of palm oil.

Asthma and Allergy Association

The Asthma and Allergy Associations in the Nordic countries also label cosmetic products. Sunscreens, haircare products, skin care products, soaps, wet wipes and deodorant as well as make-up, for example, can be labelled by the Asthma and Allergy Association in the Nordic countries. The requirements are not available to the public in all Nordic countries and products are assessed on a case-by-case basis by allergy experts, but some fundamental principles are similar and public.

[31] (NaTrue, 2014)
[32] (Cosmos, 2013)
[33] (Ecocert, 2012)
[34] (BDIH)

Perfumes and allergens, for example are not permitted.[35] The requirements may differ in the different Nordic countries.

For example, soaps, haircare, skin care and sun protection products, as well as make up are allergy labelled in the Nordic countries.[36]

AllergyCertified

AllergyCertified was launched in 2014 as a competitor to the Nordic Asthma and Allergy Association labelling systems[37]. AllergyCertified is a global label. The products awarded the label have been checked and undergone an allergy risk assessment. The individual requirements for awarding the label are not publicly available but fragrances and allergens are not permitted.

As this is a new label, at the current time there are only very few cosmetic products approved under AllergyCertified.

Green Public Procurement (GPP)

Products, primarily such as soap, are included under the public procurement criteria of the Swedish Competition Authority [38]in the category chemical products. There are requirements for cosmetics similar to the Nordic Ecolabelling requirements on cosmetics.[39] Motiva's procurement advice in Finland also contains general instructions on sustainable procurement for chemical products and cleaning services.[40] The requirements are a selection from the Nordic Ecolabelling criteria for chemicals. These also include soap. In Denmark there are no specific procurement criteria for cosmetics or other chemical products. In Norway DIFI (the Agency for Public Management and eGovernment)[41] has no procurement criteria for cosmetic products.

There are no specific requirements for public procurement of cosmetics in the EU.[42] However, through the directive, in the future it will be possible to demand ecolabelled products in public procurement in the EU.

Industry labels

The European industry organisation Cosmetics Europe does not have an industry label covering environmental issues.[43] However, they state that they are in favour of sustainable development. The global system ICCA responsible care[44] is a global initiative in which companies constantly work on health, safety and the environment and communicate this to other stakeholders.

[35] (Allergia- ja astmaliitto), (Astma- och Allergiförbundet), (NAAF, 2013), (Astma allergi Danmark)
[36] (Astma- och allergiförbundet) (Allergia- ja astmaliitto) (NAAF, 2014)
(Astma allergi Danmark)
[37] (Certified Allergy & Asthma Consultants)
[38] (Konkurensverket)
[39] (Upphandlingsmyndigheten)
[40] (Motivas upphandlingsrådgivning, 2014)
[41] (Direktoratet for forvaltning og IKT)
[42] (European Comission, 2015)
[43] (Cosmetics Europe)
[44] (ICCA)

Raw materials labelling and traceability systems

Palm oil

	Deforestation	Peatland	HCS	HCV	FPIC	Traceability
RSPO	Allowed Subject to HCV &Legal requirements	Allowed Subject to HCV &Legal requirements Avoid planting on peat >3m	Encourages avoidance of HCS (incl. Peat)	Required, HCVs cannot be converted	Required	Separate standard
ISPO	Permitted Subject to Legal requirements	Allowed where >70 % of the concession is < 3m deep	Not explicit	Not explicit	Not explicit	In future
MSPO	Permitted Subject to Legal requirements		Not explicit	Not explicit	Not explicit	
ISCC	Strictly prohibited	Strictly prohibited	No HCS land can be converted	Required	Not Explicit	Separate standard

Figure 1 Different certification schemes for palm oil [45] (HCS: High carbon Stock, HCV: High Conservation Value, FPIC: Free Prior and Informed Consent)

Bonsucro (previously the Better Sugar Initiative)[46] is a collaborative project between a number of actors, including sugar cane producers, investors, retailers and NGOs. It is also supported by environmental organisations, such as WWF. The first standard was adopted in 2010. The production standard contains rules on the environment, social development and economical and good business practice.

Round Table on Responsible Soy Association (RTRS)[47] is an initiative from stakeholders throughout the soya production and distribution chain. It is also supported by environmental organisations, such as WWF. The first RTRS standard was adopted in 2010 and the first RTRS soya was produced in 2011. The RTRS standard contains, for example, requirements on improved production methods in agriculture, working conditions, reduced use of plant protection products, respect for local societies and protection of areas with high biodiversity. RTRS has been criticised because it is technology neutral, i.e. it allows both GMO and GMO-free soya and it does not ban dangerous plant protection products. Under RTRS it is not permitted to certify land which changed land use after May 2009.

[45] (Jervan, 2014)
[46] (Bonsucro)
[47] (RTRS)

Nordic Ecolabelling's views on raw materials labelling and traceability systems

Nordic Ecolabelling's raw materials group has examined the standards in relation to the requirements we set for individual parameter labels and come to the following conclusion:

At the current time, these two systems do not fully meet Nordic Ecolabelling's requirements for sustainability labels.

The RSPO standard:

It is unclear whether this extends further than legislation (seeks to satisfy particularly the international conventions), there were absolute requirement but with opportunities for exceptions, and the standard provides too poor protection for important biological areas. There were no concrete requirements on setting aside protected areas (i.e. it appears to be more on the same level as environmental management). Clear-felling is permitted, secondary forest is not protected. It is permitted to establish plantations on peat bogs, which are an important carbon sink.

The RTRS standard:

The generic standard is general, with individual clearer requirements, e.g. 4.4 Expansion of soy cultivation, which states in subordinate points that after 2009 soya plantations must not be expanded in native habitat. However it also introduces an opportunity for exceptions here: "After May 2009 expansion for soy cultivation has not taken place on land cleared of native habitat except under the following conditions….." and "In areas that are not native forest, expansion into native habitat only occurs according to one of the following two options:….".

It refers only to local and national legislation and rules, not to international conventions. Requirements are set that all legislation/rules must be complied with (1.1 There is awareness of, and compliance with, all applicable local and national legislation) and that the owner of the land must be made clear (1.2 Legal use rights to the land are clearly defined and demonstrable.)

Apart from this, there are no specific requirements that protect protected areas, etc.

As the production of these plant raw materials currently has major environmental consequences, Nordic Ecolabelling takes these two raw materials very seriously and wishes to introduce as stringent requirements as possible within the framework of the respective product group.

In the product groups where there are alternative raw materials and steerability to exclude these without the consequence of a "Burden Shift", Nordic Ecolabelling wishes to exclude the use of palm oil and soya oil. (This is the case with candles).

In product groups where there are no alternatives and no steerability for Nordic Ecolabelling to avoid these raw materials, Nordic Ecolabelling wishes to set as stringent requirements as possible. This is to ensure that the most environmentally friendly alternative is used in Nordic Ecolabelling's products. In these cases Nordic Ecolabelling judges that RSPO and RTRS, with their associated traceability systems,

the best tools in the market and will therefore require these. (This is the case with Hygiene products, for example).

Both RSPO and RTRS are systems that point in a positive direction and Nordic eco-labelling wishes to keep an eye on this development, in order to potentially accept and use these in all criteria in the future.

3 About the criteria development/revision

Purpose of the criteria revision

The main aim of the revision has been to submit a proposal for revised criteria for cosmetics with more stringent environmental and health requirements compared with the existing version. The focus of the revision has been on:

- packaging requirements
- pack requirements and dosability
- updating in line with the DID list 2014
- requirements on (renewable) raw materials
- the new sensitising fragrances and evaluating prohibiting them
- requirements on functionality and claims
- new SCCS opinions

Other requirements have been reviewed and some have been slightly adjusted.

About this criteria revision

The project has been run as a Nordic project. At the start of the project all countries produced national documentation on criteria, industry information and other national information. During the course of the project, manufacturers, industry associations and other stakeholders in the various countries have been contacted in order to tap into the knowledge, experience and interests of the industry.

Project participants:

Project Manager	Terhi Uusitalo (FI)
Project Consultant:	Trine Pedersen (DK)
Product specialist NO:	Ingvild Kvien
Product specialist SV:	Ulf Eriksson
Product specialist FI:	Heidi Vaarala
Product specialist DK:	Michael Christensen
Internal expert	Lina Harström
Internal expert (nano)	Ingvild Kvien
Internal expert (raw materials)	Terhi Uusitalo and the Raw Materials Group
Product Development Manager	Karen Dahl Jensen (DK)

4 Justification of the requirements

4.1 General requirements

The definition of ingoing substances is included to explain what is meant by ingoing substances and impurities. All substances that are added intentionally are considered ingoing substances irrespective of concentration. See the definition below. The definition has not been changed compared with the previous version of the criteria. The requirements apply to all ingoing substances in the cosmetic products (including all ingoing substances in a raw material) unless otherwise stated.

Ingoing substances are defined as all substances in the product – including additives (e.g. preservatives or stabilisers) in the raw materials/ingredients, but not residuals from production, incl. production of raw materials).

Residuals from production, incl. production of raw materials are defined as residuals, pollutants and contaminants derived from the production of the raw materials, which are present in the final rinse off product in amounts less than 100 ppm (0,0100 w-%, 100 mg/kg), and in final leave-on products in amounts less than 0.001% (10 ppm), but not substances added to the raw materials or product intentionally and with a purpose – regardless of amount.

Residuals in the raw materials above 0,1 % (1000 ppm) are regarded as ingoing substances. Known substances realised form the raw materials are also regarded as ingoing substances.

O1 Formulation/recipe and description of product

The applicant must give detailed information on the cosmetic product to which the application relates. The following information is required:

- Description of the product
- A complete recipe for the product. The recipe must include for each ingoing substance:
    - Trade name
    - Chemical name
    - INCI name (International Nomenclature of Cosmetic Ingredients)
    - Amount (both with and without solvents, e.g. water)
    - CAS no. and/or EC number
    - DID number for substances that can be placed in the DID list
    - Function
- A safety data sheet for each ingredient

If an ingredient consists of several substances, data for all ingoing substances is to be stated in the recipe.

✉ Description of the product, e.g. label or other documentation.

✉ Complete recipe in line with the requirement, Nordic Ecolabelling's calculation sheet can be used. If information about the composition of ingredient is confidential, this information can be sent directly to the ecolabelling body

☒ Safety data sheet for each raw material in line with prevailing legislation in the country of application, e.g. Annex II to REACH (Regulation 1907/2006/E2EC).

Background to requirement O1

A licence application must be accompanied by a complete description of all the products covered by the licence. This information is required in order to check compliance with the following requirements. Another reason for this requirement is to provide additional and more detailed knowledge about the individual product types. This will enable more relevant and detailed requirements in future criteria documents but also ensure that the requirements can be adapted to new knowledge in the area. The requirement has been modified slightly compared with the previous version of the criteria and a description of the product has been added.

O2 SCCS

Recommendations from the EU's Scientific Committee on Consumer Safety, SCCS Opinions, must be complied with where there is an unambiguous conclusion from SCCS. In cases where there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies.

SCCS recommendation, SCCS/1459/11 on fragrance allergens, is exempted from this requirement. HICC, chloroatranol and atranol are not, however, permitted in the product, see O9.

SCCS Opinions can be read at http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

Background to requirement O2

The EU's Scientific Committee on Consumer Safety (SCCS) has published a large number of opinions, including a large number of opinions on cosmetic products. Their opinions are based on thorough examination of available scientific information and particular attention should therefore be paid to them and they should be complied with. If there is a direct conflict with other requirements in this criteria document, it is always the most restrictive requirement that applies. The requirement has been clarified in version 3 such that it is only once SCCS has reached an unambiguous conclusion that this must be complied with.

In June 2012 the EU's Scientific Committee (SCCS) issued an opinion on fragrance allergens, which recommends that a total of 127 fragrance allergens must be declared on cosmetic products, if they are included in amounts over 100ppm. These 127 substances include the 26 that are already subject to declaration under the Cosmetics Regulation and which may not be used in amounts subject to declaration in Nordic Ecolabelled products (Requirement 10). In addition to this, the opinion also recommended that three named fragrances (HICC, chloroatranol and atranol) should not be included in cosmetic products due to their very high potential for sensitisation.

Notwithstanding the requirement that opinions from SCCS must always be complied with, Nordic Ecolabelling has judged that it is not yet appropriate to introduce such an amendment. This assessment is based on an analysis of the situation in the market in combination with the fact that the Commission has not yet given signals on whether and to what extent the recommendation from SCCS is

to be implemented in legislation. So far, there is a lack of analysis methods for many of these fragrance substances, but work is in progress to develop new analysis methods. 7 of these new fragrance substances with the highest allergy risk are limited, however, in these criteria in the same way as other sensitising fragrances (O10).

In the light of this, an exception is made for SCCS opinion 1457/11 on Fragrance Allergens. However, the recommendation that HICC, chloroatranol and atranol are not permitted in the products has been implemented.

O3 Renewable raw materials

At least 50% by weight of all raw materials for ingoing surfactants (irrespective of function), emulsifiers and emollients in the product must be renewable.

Raw materials from oil palms (palm oil, palm kernel oil and their derivatives) in tensides and emollients:

- raw materials must be Roundtable on Sustainable Palm Oil (RSPO) certified
- the producer/supplier must be traceability certified under RSPO's Supply Chain Certification Standard
- the traceability of the raw material must be guaranteed via mass balance as a minimum
- the certified raw materials must be deducted from the producer's/supplier's Chain of Custody account for the Nordic Ecolabelled product.

✉ The producer of surfactants (irrespective of function), emulsifiers and emollients must declare which renewable raw materials are included and their amounts, appendix 2 can be used.

✉ Valid RSPO CoC certificate.

✉ The producer of surfactants (irrespective of function), emulsifiers and emollients or the producer of the Nordic Ecolabelled product must show by means of a balance calculation and/or invoices that the proportion of certified surfactants/emulsifiers/emollients corresponds to the amount of certified palm oil raw materials. Alternatively, a declaration from the producer of surfactants (irrespective of function), emulsifiers and emollients that all purchased palm oil raw materials are certified.

Background to requirement O3

Cosmetic products use ingoing substances from both renewable and non-renewable organic raw materials. In addition, there are minerals as parts of organic raw materials, and e.g. in pigments. There are limited amounts of non-renewable organic raw materials because they tend to be extracted from fossil oil which is non-renewable.

We have chosen to encourage the use of renewable raw materials in the ingoing substances that are most relevant in cosmetic products, i.e. tensides and emollients that are usually found in the majority of cosmetic products. These ingoing substances can only be manufactured from fossil and from vegetable raw materials and from a mixture of both. Nordic Ecolabelling also wishes to allow those ingoing substances that are manufactured from mixed raw materials and therefore sets a limit that 50% of the raw material must be renewable. The requirement prevents producers switching to fossil raw materials to avoid the requirements set for renewable raw materials. In addition, it is required that any

palm oil included is certified, in order to encourage a move towards more sustainable production of raw materials.

The renewable base materials used in cosmetics are normally various oils and fats. By far the most common raw material is from oil palms: palm oil, palm kernel oil and their derivatives. Nordic Ecolabelling judges that destruction of rain forest as a consequence of increased demand for renewable oils and fats and unsustainable agriculture can be combatted with the help of certified sustainable plantations. The most used certification system is RSPO, whose standard for sustainable palm oil production is judged by Nordic Ecolabelling to meet satisfactory environmental requirements in such products where palm oil cannot be replaced by other valid alternatives.

Nordic Ecolabelling carried out a survey of manufacturers of Nordic Ecolabelled cosmetics and raw materials suppliers on the opportunity of setting requirements on raw materials. The majority (>95%) of the respondents considered that sustainable raw materials are and will continue to be important in cosmetics. The majority also considered that sustainable renewable alternatives for important raw materials already exist. According to several producers there is currently a satisfactory range of certified palm oil raw materials. For example, BASF stated at the Sustainable Cosmetics Summit in 2015[48] that they are very close to attaining their goal[49] of all palm kernel oil they buy coming from RSPO certified production.

EU Ecolabel[50], Good Environmental Choice[51] and Australia's Good Environmental Choice[52] set ambitious requirements on the proportion of sustainable palm oil and palm kernel oil derivatives in cosmetic products.

This version concentrates on certified palm oil because this is the highest amount of raw material used in cosmetics.[53] The proposed requirement is ambitious as it sets traceability requirements on the minimum mass balance (i.e. Book and claim certificates are not accepted).

No requirements are set in this version for other potentially problematic vegetable raw materials such as soya or sugar. Other vegetable raw materials are used considerably less than palm oil products and the production of these is less problematic compared with palm oil or not problematic at all. Animal fat is used in small amounts and use is restricted by EU legislation (1774/2002).

In theory it may be possible to manufacture a Nordic Ecolabelled product that is entirely based on fossil raw materials (e.g. mineral-based powder). However, we judge that these constitute an insignificant proportion of the products currently found on the market and the opportunity to set good environmental requirements today is small, partly because there are currently no good traceability systems.

[48] (BASF, 2015)
[49] (BASF, 2014)
[50] (EU Ecolabel, 2014)
[51] (Bra Miljöval, 2014)
[52] (Good Environmental Choice Australia, 2014)
[53] (AAK, 2014), (BASF, 2013), (Cosmetics Design Europe, 2014)

4.2 Requirements on ingoing substances

O4 Classification of ingoing substances

Ingoing substances (se definition above) in the product must not be classified as shown in Table 1:

Table 1 Classification of ingoing substances

CLP Regulation 1272/2008:		
Hazard class	**Hazard class and category**	**Hazard phrase**
Carcinogenicity	Risk, Carc. 1A or 1B Warning, Carc. 2	H350 H351
May cause genetic defects	Risk, Muta. 1A or 1B Warning, Muta. 2	H340 H341
Toxic for reproduction	Risk, Repr. 1A or 1B Warning, Repr. 2 -	H360 H361 H362
Respiratory or skin sensitising*	Risk, Resp. Sens. 1 Warning, Skin Sens. 1	H334 H317

*The following substances are exempt:

- Enzymes (including stabilisers and preservatives in the enzyme raw material) can be included if they are liquid form or as granulate capsules, see requirement O12 for enzymes.
- Fragrance can be included in the final product, see requirements O7-9 on fragrances.

☒ Safety data sheet for each raw material in line with prevailing legislation in the country of application, e.g. Annex II to REACH (Regulation 1907/2006/E2EC).

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

Background to requirement O4

There is no requirement that cosmetic products must be classified. For this reason, requirements are set for ingoing substances. The Cosmetics Regulation[54] permits the use of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) in category 1, 2, and 3 if the EU's Scientific Committee (SCCS) has assessed the substances and drawn the conclusion that they are safe to use in cosmetic products. Nordic Ecolabelling applies the precautionary principle and prohibits all CMR substances to increase reassurance and safety for the user. This will also exclude potentially mutagenic and/or toxic for reproduction effects in the environment.

Examples of ingoing substances used in cosmetics today but excluded by this requirement:

- Siloxane D4 (octamethylcyclotetrasiloxane, CAS 556-67-2) which is used, for example, as an emollient or solvent, is prohibited in Nordic Ecolabelled cosmetics due to its classification as Repr. 2; H361f.
- Because Nordic Ecolabelling's definition of ingoing substances counts release products as ingoing substances, preservatives which give off

[54] (EU, 2009)

formaldehyde, such as sodium hydroxymethylglycinate and 2-Bromo-2-nitropropane-1,3-diol and azo dyes that release arylamine are excluded.
- BHA (CAS 25013-16-5) is classified carc[55] and is therefore excluded.

The Cosmetics Regulation allows several sensitising substances in cosmetic products. However, allergies are a growing problem[56]. For this reason, Nordic Ecolabelling has chosen to exclude substances classified as sensitising from Nordic Ecolabelled cosmetics (with two exceptions). This excludes certain preservatives (e.g. methylisothiazolinone (MI) and glutaral) which are commonly used in cosmetic products, and common substances in hair dye, e.g. p-phenylenediamine (CAS 106-50-3). Fragrances are partly exempt from this requirement, because the working group has drawn the conclusion that demand for fragrance-free cosmetics is limited and the range of fragrances that do no contain allergens is limited. Thus, if perfumes or fragrances that contain allergens were to be completely prohibited, this would have a negative effect on the brand's market coverage, which would be disproportionately high compared with the potential environmental impacts of small amounts of fragrances. Substances in enzyme preparations are exempt from this requirement because all enzymes are classified as respiratory sensitisers (H334) and some stabilisers, etc. may be classified as skin sensitisers (H317). Enzymes are used in toothpaste, for example. Enzymes in cosmetics, however, are not expected to cause allergies in the consumer as the ingredients of the enzyme are included in the product and do not exist as "free dust". On the other hand, we have drawn up relevant requirements for good practice when using enzymes in Nordic Ecolabelled products (see O12). Similar exemptions for preservatives have been evaluated. However, Nordic Ecolabelling considers that it is possible to manufacture functional products with a sufficiently good shelf-life without sensitising preservatives. Allergies to preservatives, particularly MI (CAS 2682-20-4) have risen in recent years[57] and Nordic Ecolabelling does not want to contribute towards unnecessary exposure. SCCS finds that also for leave-on products (including wet wipes) there is no safe concentration for MI med in terms of sensitising/allergies.[58]

O5 Prohibited substances

The following substances must not be present in the product or appear as impurities.

- D4 (octamethylcyclotetrasiloxane, CAS 556-67-2), D5 (decamethylcyclopentasiloxane, CAS 541-02-6) and D6 (dodecamethylcyclohexasiloxane CAS 540-97-6)
- BHT
- Borates and perborates
- Perfluorinated and polyfluorinated substances
- Nitro musks and polycyclic musk compounds
- EDTA (Ethylenediaminetetraacetic acid) and its salts (see however exception for solid soap O21).
- Triclosan

[55] (ECHA)
[56] e.g. (Svedman, ym., 2012), (Videncenter for allergi)
[57] (Svedman, ym., 2012), (SCCS, 2013)
[58] (SCCS, 2013)

- Hypochlorite, chloramine and sodium chlorite
- Benzalkonium chloride
- Parabens (4-Hydroxibenzoic acid and its salts and esters).
- Phthalates
- Substances considered to be (potential) endocrine disruptors in accordance with the European Union's reports concerning endocrine disruptors (see Appendix 8 for definition).

  The EU's reports on potential endocrine disruptors can be read in their entirety at http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf
- Substances that have been judged in the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated but which meet these criteria.
- Substances on the Candidate List (SVHC)*.
- Microplastics**
- Halogenated and/or aromatic solvents***
- Nanomaterials/particles as defined in the Cosmetics Regulation****

  An exception is made to this requirement for hydrated silica, which is used as an abrasive in toothpaste.

** The Candidate List can be found on the ECHA website at: http://echa.europa.eu/candidate-list-table*

***Microplastics are here defined as insoluble plastic particles that are 1 µm - 5 mm and are not biodegradable under OECD 301 A-F.*

**** Solvents are defined under Commission Directive 1999/13/EC: organic substances with a vapour pressure of at least 0.01 kPa at 20 °C*

*****Insoluble or biopersistent and deliberately manufactured material with one or more external dimensions or an internal structure in the region of 1-100 nm*

☒ Recipe.

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

Background to requirement O5

There are several problematic substances which cannot be excluded from our general requirements due to the product chemistry of the ingoing substances. For this reason Nordic Ecolabelling has drawn up a list of substances that must not be included in the product, see the definition under general requirements. The aim is only to list the problematic substances which are not excluded due to other requirements and which are relevant to the product group. The requirement has changed compared with the previous criteria document: the substance group of perfluorinated compounds and pthalates has been added to the list. This requirement is to a certain extent a "double entry" for certain substances: a substance can be, for example, both PBT and on the Candidate List.

This requirement has a significant impact on the difference between Nordic Ecolabelled products and other products on the market because it excludes, e.g. D4 and D5, parabens, triclosan and EDTA, which are currently generally used in cosmetics.

Silicones and siloxanes (D4, D5 and D6)

Siloxanes and silicones (including polysiloxanes, which are also called silicones, but in purely chemical terms are not genuine silicones) are used to a considerable extent in cosmetic products, e.g. as softeners, solvents, anti-static agents, moisturisers, anti-foaming agents and to control viscosity in hair care products and anti-perspirants, in creams/liquids, liquid soaps and gels and decorative cosmetics. Siloxanes used in cosmetic products are structurally diverse; cyclical, linear, polymers, can bind to longer and shorter carbon chains, etc. The search term siloxane produces 300 hits in the EU's CosIng database on ingredients in cosmetics. The term "-methicone" is often used for siloxane compounds, particularly in cosmetics.

Some of the siloxanes used in cosmetics are found in the environment and in plants and animals although in low concentrations. This indicates that the compounds are bioaccumulative. Siloxanes are first and foremost found close to densely populated areas.[59] Low-molecular, volatile siloxanes (e.g. D4, D5 and HMDS) evaporate when they are used and can be spread over large distances in the air. Non-volatile siloxanes (higher molecular weight) which are also used in cosmetic products mainly reach the sea in treatment works, where they are accumulating in the sludge because they are slowly degradable and have high bioaccumulation potential. Cyclic siloxanes have the greatest degree of spread in the environment, particularly D4 (octamethyl cyclotetrasiloxane, CAS 556-67-2) and D5 (decamethyl cyclopentasiloxane, CAS-no. 541-02-6). D4 is classified Aquatic Chronic 3 with H413 and Repr. 2 with H361f. D5 is structurally related to D4 and is on the Norwegian authorities' list of prioritised hazardous substances[60]. D5 is also under evaluation as a PBT substance but no conclusion has yet been reached. D4, D5 and the linear siloxane, HMDS (hexadimethyl siloxane, CAS 107-46-0) is categorised as an HPVC chemical (high production volume chemical) in the EU. HMDS does not, however, seem to be used in cosmetic products according to CosIng.[61]

An SCCS opinion states that D5 is not safe to use in skin cream, hair styling products or products that cause exposure via the airways.[62]

D6 was also studied. It is bioaccumulative with BCF = 39874 / logKow = 9.06 and is not biodegradable (4.47% in 28 days).[63] In a Swedish study D4, D5, D6 and HMDS were found in the breastmilk of 11 out of 39 women[64] and D4 in trials carried out on rats has a certain tendency to affect hormone production in female rats.[65] There is no ecotoxicological data but it is expected that D6 has some characteristics that correspond to D4 and D5. For example, it is expected that D6 will affect the liver on repeated exposure[66].

[59] (TemaNord, 2005) (Miljøstyrelsen, 2005)
[60] (Miljøstatus , 2014)
[61] (CosIng)
[62] (SCCS, 2015)
[63] (ECHA, 2015)
[64] (Miljøstyrelsen, 2014)
[65] (Miljøstyrelsen, 2014)
[66] (Environment Canada, Health Canada, 2008) (Miljøstyrelsen, 2014)

For the majority of siloxanes there is only limited data on their toxicity, degradability and bioaccumulation potential. Available data indicates that siloxanes are toxic to aquatic organisms and slowly biodegradable.[67] Because there are many silicones and siloxanes in the market which are suspected to be particularly harmful, we therefore only exclude D4 and D5. For D4 this is a double requirement because it was already prohibited under the requirement to classify ingoing substances (O5), but it is logical to mention it here together with D5. The other silicones and siloxanes must meet relevant environmental requirements in the criteria and if no data on degradability or toxicity is available, they are judged under a "worst case" like all other substances without sufficient data. The requirement is the same as in version 2.

BHT

BHT (CAS 128-37-0) is classified by some[68] as muta., carc. and repr. and BHA (CAS 25013-16-5) as carc[69] and they are thereby excluded. It is added to the list of prohibited substances to make it clear that these cannot be included in Nordic Ecolabelled cosmetic substances.

Borates and perborates

Borates and perborates are used in cosmetics, e.g. as oxidisers and buffers in oral hygiene products and as whiteners. A number of these substances and boric acid are classified as toxic for reproduction and are limited or prohibited in cosmetic products The requirement on classification of ingoing substances prohibits the use of these classified borates and perborates in Nordic Ecolabelled cosmetic products. However, we know that e.g. magnesium ascorbylborate[70] (a magnesium salt from the reaction product of boric acid and ascorbic acid) is not classified as toxic for reproduction and is not limited in cosmetics under the Cosmetics Regulation, but there is no guarantee that it does not break down into boric acid, which is toxic for reproduction.[71] The prohibition on the use of all borates and perborates in Nordic Ecolabelled products is therefore justified by Nordic Ecolabelling's precautionary principle. The requirement is the same as in version 2.

Perfluorinated and polyfluorinated compounds (PFC)

Perfluorinated compounds are used in cosmetics, such as hair and skin conditioners and as solvents.[72]

The OECD has published a repport[73] listing a number of known problematic PFAS substances (Perfluorinated and polyfluorinated alkylated substances). The list shows a number of relevant substances, which are excluded by a ban on the use of PFCs. Note however, that Nordic Ecolabelling's term PFC is broader than the OECD's PFAS.

[67] (TemaNord, 2005)
[68] (ECHA)
[69] (ECHA)
[70] (CosIng)
[71] (SCCS, 2013)
[72] (Kemikalieinspektionen, 2015)
[73] (OECD, 2007)

Per and polyfluorinated compounds (PFCs) constitute a group of substances that have harmful properties. Certain per and polyfluorinated compounds can be broken down into the very stable PFOS (perfluorooctane sulfonate) and PFOA (perfluorooctanoic acid) and similar substances. These substances are found throughout the globe, from large oceans to the Arctic. PFOS have also been found in birds and fish and in their eggs. The substances are extremely persistent and are easily absorbed by the body.[74] The substances in this group impact on the biological processes of the body and are suspected to be endocrine disruptors, carcinogenic and have a negative impact on the human immune system.[75] PFOA, APFO (ammonium perfluorooctanoate) and some hydrofluoric acids are on the Candidate List in the light of the fact that they are toxic for reproduction and PBT, see the section later in this chapter.

There are new research results showing that shorter chains (2-6 carbon atoms) have been discovered in nature.[76] It is therefore difficult to defend and communicate the fact that Nordic Ecolabelled products are able to contain perfluorinated compounds at all. For this reason a more general ban than purely on PFOS or fluorine surfactants is relevant for cosmetics The requirement is new.

Nitro musks and polycyclic musk compounds

Nitro musks and polycyclic musk compounds are suspected to be or are classified as carcinogenic. [77] In addition, nitro musks and polycyclic musk compounds may be bioaccumulating and potentially have long-term effects on the aquatic environment.[78] Nitro musk compounds may also have reproductive and endochrinological effects. Surveys show that they are often found in waste water[79] and in a Spanish study[80] several nitro musk and polycyclic musk compounds were found in the treated waste water and galaxolide and musk ketone in river water. In communication with suppliers of fragrances[81] it has emerged that many companies across Europe continue to use polycyclic musks in consumer products. E.g. nitro musk musk ketone can be used in cosmetics with certain restrictions.[82] The use of nitro musks is clearly extremely limited, but manufacturers outside Europe still produce substances such as musk ambrette that are prohibited under IFRA. Excluding nitro and polycyclic musks is therefore still considered to be relevant as a preventive measure.

The requirement is the same as in version 2.

EDTA

EDTA is a powerful complexing agent which can bind metal ions and is therefore also suspected to be able to mobilise heavy metals in the aquatic environment. However, industry has questioned this latter property, mainly in areas such as the

[74] (Borg, 2013)
[75] e.g. (Philippe Grandjean, 2013), (Arlene Blum, 2015)
[76] (Perkola, 2014)
[77] (ECHA), (ECHA)
[78] (TemaNord, 2004)
[79] (Carballa, ym., 2004)
[80] (Fernández C., 2010)
[81] (Leccia, 2009)
[82] (CosIng)

majority of Nordic waters (CEFIC, 2009).[83] EDTA is not readily biodegradable and the EU's risk assessment[84] shows that conditions in municipal treatment works are such that EDTA is not broken down or is only broken down to a limited extent. Alternatives that are degradable and thus better from an environmental viewpoint are now available and can replace EDTA. The use of EDTA is therefore excluded, with the exception of solid soaps (see O21) in which EDTA is considered necessary. The requirement is the same as in version 2.

Triclosan

Triclosan is an antibacterial disinfectant used in many different products, such as toothpaste and deodorants. There is a certain amount of concern that the use of antibacterial and disinfecting substances such as triclosan can play a role in increasing bacterial resistance to antibiotics.[85] Triclosan is bioaccumulating but a BCF value below 500 has been documented in some sources. It is classified as environmentally hazardous with H400[86], and is on the Norwegian Prioriteringslistan[87] (a Norwegian list of substances that cause environmental and health problems and the use of which should be reduced). Triclosan has been found in a number of different places, e.g. in waste water and water from treatment plants,[88] which indicates that the use of triclosan leads to exposure in the environment.

SCCS finds[89] that "Thus, the continued use of triclosan as a preservative at the current concentration limit of maximum 0.3% in all cosmetic products is not safe for the consumer because of the magnitude of the aggregate exposure.". It is therefore relevant to ban this disinfectant in Nordic Ecolabelled products. The requirement is the same as in version 2.

Hypochlorite, chloramine and sodium chlorite

Calcium and sodium hypochlorites, chloramine and sodium chlorite can be used in cosmetics as oxidising and antimicrobial substances.[90]

Inorganic chlorine compounds such as sodium hypochlorite may be or lead to the formation of toxic, bioaccumulative substances that are hard to break down. They can also lead to resistance in bacteria, both to biocides and against antibiotics. Sodium hypochlorite can constitute an environmental risk due to the risk of creating organic chlorine compounds.

The requirement is new.

[83] (European Chemical Industry Council (Cefic))
[84] (European Chemicals Bureau, 2004)
[85] (Miljøstyrelsen)
[86] (ECHA, 2015)
[87] (Miljøstatus , 2014)
[88] (TemaNord, 2007)
[89] (SCCS, 2011)
[90] (Cosing), (CosIng), (CosIng), (CosIng)

Benzalkonium chloride

Benzalkonium chloride can be used in cosmetics to perform several different functions, e.g. as a preservative, surfactant and deodorant.[91]

Unlike many of the other quaternary ammonium compounds, it is readily degradable, but it is undesirable in Nordic Ecolabelled cosmetics due to its toxicity and risk of creating resistance, as benzalkonium chloride, like other quaternary ammonium compounds, is linked to bacterial resistance to antibiotics and can lead to certain types of allergies.[92]

New requirement, in line with other chemical criterial.

Parabens

Parabens (4-Hydroxibenzoic acid and its salts and esters) have been found to be (potential) endocrine disruptors in different studies and may also have endocrine disrupting effects in nature.[93] Ethyl, methyl, propyl, and butylparaben are all categorised as potential endocrine disruptors (Cat 1) under the EU's strategy for endocrine disruptors. In a Spanish study, butyl, ethyl and benzylparaben were found in treated waste water.[94] However, SCCS has stated that methyl and ethylparabens and propyl and butylparabens in rinse-off products are safe to use in the concentrations permitted by the Cosmetics Regulation.[95] Isopropyl and its salts, isobutyl and its salts, benzyl, pentyl, and phenylparaben are prohibited by the Cosmetics Regulation.[96] All parabens and their salts are not prohibited, however, or on the list of potential endocrine disruptors, such as sodium and calcium paraben. These parabens are structurally related to the above and can thereby be expected to have equivalent effects. In the light of the precautionary principle, the use of all parabens is thus excluded in Nordic Ecolabelled cosmetics.

Phthalates

Phthalates are used in cosmetics in different functions, such as film formation, masking and solvents.[97]

Many phthalates have negative effects on health and the environment. Some phthalates are inscribed on the EU's priority list of substances that should be investigated more closely for endocrine disruption – and some have already been identified as endocrine disruptors.[98] Some phthalates can be found on the EU's Candidate List[99] and some on the Danish "Listen over Uønskede Stoffer" (List of

[91] (CosIng)
[92] (Even Heir, 2001)
[93] (European comission, 2015)
[94] (Fernández C., 2010)
[95] (SCCS, 2010)
[96] (European comission, 2014)
[97] (CosIng)
[98] (European comission, 2015)
[99] (ECHA, 2015)

undesirable substances).[100] Some phthalates are prohibited in cosmetics but some can be used.[101]

As a precaution, Nordic Ecolabelling has chosen to exclude phthalates as a group, since this group includes many different phthalates with various different characteristics. Nordic Ecolabelling is aware that this entails that several of these phthalates are excluded by both the CMR requirement and the requirement concerning Candidate List substances, but still considers it important to highlight phthalates in this requirement. New requirement.

Endocrine disruptors

The Cosmetics Regulation does not limit the use of substances seen as (potential) endocrine disruptors, other than with a general statement that a product must not damage human health under normal or reasonably predictable conditions. The EU's strategy for endocrine disruptors[102] defines an endocrine disruptor as an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. Nordic Ecolabelling consequently prohibits the use of substances that are considered to be (potential) endocrine disruptors (categories 1, 2 and 3b: "Category 1 - evidence of endocrine disrupting activity in at least one species using intact animals"; "Category 2 - at least some in vitro evidence of biological activity related to endocrine disruption"; "Category 3b - no data available") in the EU, according to the EU's report on endocrine disruptors[103] or other studies.[104] An Access database listing all the evaluated substances can be downloaded at http://ec.europa.eu/environment/chemicals/endocrine/strategy/index_en.htm. These lists are also used to assist the European Commission in completing its work of creating a definition for endocrine disruptors so that they can start to be regulated through REACH.

The importance of excluding category 3b substances can be discussed because there is insufficient scientific evidence for endocrine disruption. However, because these products have a higher exposure compared with other chemical product groups, e.g. because they are applied directly to the skin and the majority is spread down to the environment without being first metabolised in the body, we have proposed applying the precautionary principle and prohibiting these substances in category 3b. Once more information has been gathered, substances in category 3b can be moved to category 3a "no evidence of endocrine disrupting activity", and can then be used in Nordic Ecolabelled cosmetic products.

The requirement is the same as in version 2.

[100] (Miljøstyrelsen, 2009)
[101] (SCCS, 2007)
[102] (European comission, 2015)
[103] (DG Environment, 2000)
[104] (DHI water and environment, 2007) (DG Environment, 2002), (European Comission / DG ENV / WRc-NSF, 2002)

PBT and vPvB

PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) organic substances are defined in Annex XIII to REACH (Directive 1907/2006/EC). Cosmetic products are not covered by the REACH legislation but many ingredients used in cosmetics are, however, used in other areas which are covered by REACH. Although the PBT and vPvB criteria are not included in the Cosmetics Regulation, such substances are considered to be undesirable in Nordic Ecolabelled products.

Only a few of the ingoing substances in cosmetics would meet the criteria for PBT or vPvB, mainly silicones/siloxanes. Siloxanes D4 and D5 have been excluded however, due to their inherent properties as described earlier in this document, irrespective of whether they are PBT or vPvB.

Over time it is expected that more substances will be assessed under the PBT and vPvB criteria and added to the Candidate List, i.e. the list of SVHC substances. Generally excluding PBT/vPvB substances guarantees that all substances that meet the PBT or vPvB criteria will also be excluded from Nordic Ecolabelled cosmetics as more data is produced. The majority of PBT/vPvB substances are automatically excluded from Nordic Ecolabelled cosmetics due to restrictions on environmentally harmful substances (see requirement O17). However, it may be the case that vPvB substances in particular are not restricted by requirement O17, despite their continuing to be considered undesirable in the environment.

The requirement is the same as in version 2.

Substances of Very High Concern (SVHC)

SVHC are defined in Article 57 of REACH[105] as substances meeting the criteria for classification as CMR category 1A or 1B, PBT and vPvB substances, substances with endocrine disrupting properties and substances which give rise to an equivalent level of concern and for which there is scientific evidence of probably serious effects to human health or the environment.

Cosmetic products are not covered by the REACH legislation but many ingredients used in cosmetics are, however, used in other areas which are covered by REACH. Although the SVHC criteria are not included in the Cosmetics Regulation, such substances are considered to be undesirable in Nordic Ecolabelled products.[106]

New requirement, in line with other chemical criteria.

Microplastics

Microplastics are small plastic particles less than 1 mm. They may appear in some cosmetic products to produce an exfoliant (scrubbing) effect, such as toothpaste, soaps, shower gels and body scrubs. When microplastics are rinsed own the drain, they often pass through treatment works due to their very small size and are not filtered out (ECHA, 2015)[107],[108]. The particles then continue on to lakes and seas

[105] (EU, 2006)
[106] (ECHA, 2015)
[107] (Stockholms universitets Östersjöcentrum, 2015)

where they are eaten by mussels, fish and other animals, causing injury. Some microplastics are then gradually broken down to even smaller particles by sunlight. They can also absorb harmful substances.[109]

The microplastics found in cosmetics include the following plastics[110]:

- Polyethylene (PE)
- PMMA
- Nylon - 12
- PET
- Polyethylene terephthalate (PET)
- Polystyrene (PS)

There are biodegradable alternatives to microplastics such as PLA (=Polylactic acid), Mater-bi[111], crushed apricot kernels, salts and sugar. It is therefore judged to be possible to exclude microplastics without making it impossible to ecolabel products such as toothpaste, soaps, etc. Plastics that can be broken down and can demonstrate this under tests such as OECD 301 A-F are exempt from the requirement, because it is non-degradable plastics which are undesirable in ecolabelled products.

Halogenated and/or aromatic solvents

Several halogenated or aromatic solvents are banned from use in cosmetics according to CosIng, but some are not prohibited[112]. Some of these substances are classed CMR and are also therefore prohibited in Nordic Ecolabelled cosmetics.

Halogenated and aromatic organic compounds include many substances harmful to the environment and to health, which are very toxic to aquatic organisms, carcinogenic or otherwise harmful to health. The halogenated organic compounds are normally hard to degrade in the environment, which increases the risk of harmful effects from these substances. Liquid organic solvents can cause increased ground ozone content, which can damage vegetation, among other things.

For many of the substances in the group, the requirement is a double requirement, but due to the precautionary principle we choose to prohibit all halogenated and/or aromatic solvents. The requirement is new.

Nanomaterials/particles

Nanomaterials/particles are defined in the Cosmetics Regulation as an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm. Note that emulsions and liposomes are not covered by the definition of nanomaterials in the Cosmetics Regulation and are thus not covered by the requirement.

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[108] (DR DK, 2013)
[109] (Mtv3, 2015)
[110] (Noordzee, 2013)
[111] (Novamont)
[112] (CosIng)

On the page of the Cosmetics Regulation entitled "Preamble to Annexes II to VI", item 3, it is worth noting that this states that the substances listed in Annexes III to VI do not cover nanomaterials, except where specifically mentioned. Annexes IV, V and VI list colorants, preservatives and UV filters, respectively.

Nordic Ecolabelling views this as indicating that compounds which are not specifically labelled with the nano form can no longer be included in their nano form following the introduction of the Cosmetics Regulation in 2009. The prohibition applies until the nano form is specifically stated. At the same time Nordic Ecolabelling assumes that nanomaterials continue to be included in cosmetics products on the market, for example it is assumed that carbon black and silica are extensively used.

Silica

According to SCCS' opinion, silica is extensively used in cosmetic products.[113]

Silica as an abrasive in nano form can be used in Nordic Ecolabelled toothpaste for the following reasons:

- almost all toothpaste on the market contains hydrated silica, which is in nano form (Hydrated silica is a nano-structured material built up from nanoparticles/"nano objects" which form an aggregate of SiO2 which is larger than 100 nm (and contains fairly few particles under 100 nm). However, hydrated silica meets the Cosmetics Regulation's definition of nanomaterial due to the material's internal structures, which are < 100 nm and in terms of the particles' surface layer (confirmed by the Danish Environmental Protection Agency).)
- this abrasive has been used for the past 30–50 years without any evidence of harmful effects being demonstrated.[114] The advantage of hydrated silica is firstly that it is transparent and so can be used in both gel toothpastes and white and coloured toothpastes, and secondly that it is compatible with fluoride.
- the use of hydrated silica was evaluated as safe by the expert panel in Cosmetic Ingredient Reviews (CIR) 2009[115]. SCCS concluded in 2015, however, that the data they had received was not sufficient to be able to conclude whether the ingredients are safe for use in cosmetic products. [116]

In the proposed requirement, silica can be included in Nordic Ecolabelled cosmetic products only in toothpaste.

Carbon black

Carbon black is now counted as a nanomaterial. According to the SCCS opinion[117] the addition of carbon black to cosmetics varies between 0.001% and 10%, with 0.001% (= 10 ppm) in skincare products, 5% in nail varnish and 10% for other eye

[113] (SCCS, 2015)
[114] (SCCS, 2015)
[115] (Cosmetic Ingredient Review Expert Panel, 2009)
[116] (SCCS, 2015)
[117] (SCCS, 2013)

make-up. In the proposed requirement, carbon black and other nanomaterials cannot be included in Nordic Ecolabelled cosmetic products.

Ban on nano UV filters

In the experience of Nordic ecolabelling, it is possible to manufacture functioning and user-friendly sunscreens without nano UV filters. In this generation of the criteria, Nordic Ecolabelling therefore chooses to ban the use of UV filters in nano form. Note that TiO_2 in non-nano form can be used.

In version 2 of the criteria Nordic Ecolabelling approved UV filters as long as they had undergone a risk evaluation by SCCS and were included in Annex VI to the Cosmetics Regulation. These risk evaluations are only health-related, however.

Nordic Ecolabelling is concerned about the environmental consequences of extended use of nanomaterials. In 2004 the Danish Environmental Protection Agency published a report which investigated 9 different nanomaterials and their fate and behaviour in the environment. [118] In conclusion, it was found that for surface-treated or functionalised nanomaterials, their environmental fate and behaviour cannot solely be predicted based on the properties of the nanomaterial's core Instead an individual evaluation is necessary, taking into account the coating, surface modifications and the existence of stabilising agents. The report concluded that a number of defects were found in the current knowledge of transformation processes for nanomaterials which prevent a valid qualitative and quantitative assessment of their fate and behaviour in environmental matrices.

The OECD's Working Party on Manufactured Nanomaterials (WPMN) has started publishing new data on nanomaterials[119], but so far has only published that for titanium dioxide and zinc oxide[120].

There are also individual studies which have examined the environmental consequences of nanomaterials in sunscreen. A recently published Spanish study of sunscreen containing nano titanium dioxide as a UV filter from 2014[121] showed that photoexcitation of inorganic UV filters (TiO_2 and ZnO nanoparticles) produces a considerable amount of hydrogen peroxide (H_2O_2) when subjected to solar radiation. H_2O_2 is a strongly oxidising substance which generates high levels of stress in marine plant plankton. The authors concluded that TiO_2 nanoparticles are largely the reason for the major increase in H_2O_2 levels in the sea in the summer, with potentially dangerous consequences for aquatic organisms.

Reports from the Danish Environmental Protection Agency from 2015 find that the current use of nano titanium dioxide does not constitute an environmental risk in Denmark but that it must be monitored further so that we do not encounter environmental problems at a later date.[122] [123]

[118] (Hartmann;Skjolding;Foss Hansen;Kjølholt;& Gottschalck, 2014)
[119] (SafeNano, 2015)
[120] (OECD)
[121] (David Sánchez-Quiles, 2014)
[122] (Miljøstyrelsen, 2015)
[123] (Miljøstyrelsen, 2015)

As yet, therefore, there is insufficient information on environmental evaluations and the impact of nano to set environmental requirements on nano. Precautionary principle is therefore used and nanomaterials/particles are forbidden.

The requirement has been made more stringent since the previous version of the criteria and it has been moved to the list of prohibited substances.

O6 Surfactants

All surfactants, irrespective of their function must be readily aerobically degradable and anaerobically degradable in line with the testing methods in Appendix 8.

The following are exempt from the requirement on anaerobic degradability:

- Emulsifiers
- Surfactants in toothpaste

Toothpaste must not contain sodium lauryl sulphate (SLS).

✉ Reference to the DID list dated 2014 or later versions. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

DID list: "Detergent Ingredient Database" list, see Appendix 8 for a more detailed description.

✉ For toothpaste: Appendix 1 or equivalent declaration completed and signed.

Background to requirement O6

Surfactants are found in high volumes in liquid soap, shampoo and conditioner. Surfactants are often toxic to aquatic organisms.

Unlike laundry and cleaning products, which are covered by the Detergent Regulation[124], there are no legal requirements on rapid degradability of surfactants in cosmetic products. A condition on rapid aerobic degradability and anaerobic degradability of surfactants is therefore considered relevant for this product group. The requirement has been introduced to ensure that the use of substances in such high volumes does not place a burden on the aquatic environment, irrespective of whether aerobic or anaerobic conditions prevail. The surfactant content is also regulated by requirements on critical dilution volume (CDV).

Special requirements for toothpaste: Some organisations are critical of the use of sodium lauryl sulphate (SLS) in toothpaste because it is believed that it delays the healing of or causes mouth ulcers. A Norwegian study[125] found a statistically significant reduction in the number of mouth ulcers when they changed to an SLS-free toothpaste. The study assumes that the denaturing effect of SLS on the oral mucin layer causes an increased incidence of recurring mouth ulcers. In general, sodium lauryl sulphate is added to toothpastes to generate more foam. It is possible to manufacture toothpaste without SLS by, for example, using sodium-C14-C16 oleofin sulphonate, sodium lauryl sarcosinate, cocamidopropyl betaine or Stearath 30, all of which are less irritating to the skin. For this reason SLS is not permitted in Nordic Ecolabelled toothpaste.

[124] (EU, 2004)
[125] (Herlofson BB, 1994)

Toothpaste is exempt from the requirement on anaerobic degradability of surfactants. The requirement on anaerobic degradability of surfactants has been a major obstacle to Nordic Ecolabelling of toothpaste. The exception for surfactants in toothpaste benefits the market share of toothpaste without triclosan or SLS.

Surfactants are also used in cosmetics as an emulsifier, and here information on anaerobic degradability is sparse. This means there is a lack of potential and steerablity and surfactants with the function of emulsifiers are exempt from the requirement. Emulsifiers are defined in CosIng as follows: "Promotes the formation of intimate mixtures of non-miscible liquids by altering the interfacial tension". Softeners have been removed from the exemption because they are often not surfactants.

Quaternary ammonium compounds are cationic surfactants which are often used in conditioner but can also be used as biocides. Even when they are used as preservatives, they must fulfil the requirements on degradability of surfactants. In this case they must fulfil both the requirement on surfactants and the requirement on preservatives (O13). They must also be approved as preservatives in the Cosmetics Regulation.

The content of the requirement has not changed compared with the previous versions of the criteria. In our view there is a difference between Nordic Ecolabelled and other products because non-degradable surfactants under anaerobic conditions are used in the market.

Fragrances and aromatic additives

The requirement on fragrances has been updated in relation to Nordic Ecolabelling's Fragrance Policy 2012, which was updated in 2015. It is the job of Nordic Ecolabelling to ensure that only the fragrances which are least harmful to health and the environment are added to products. In conjunction with this revision, Nordic Ecolabelling has been in dialogue with several fragrance producers and IFRA.

Requirements 07-9 also apply to aromas and fragrances in plant extracts.

O7 IFRA

Fragrances must be added in line with the IFRA's guidelines.

The IFRA's (International Fragrance Association) guidelines can be read at www.ifraorg.org/

☒ Appendix 1 or equivalent declaration completed and signed.

Background to requirement O7

IFRA stands for the "International Fragrance Association" and represents the fragrance industry. The association conducts safety assessments of individual fragrances and blends, and has public standards/guidelines for the use of fragrances. The requirement for compliance with IFRA's guidelines[126] ensures that the manufacture, handling and use of fragrances in the products meets specific standards in terms of prohibited substances, restricted use and purity. IFRA's guidelines support the industry in offering products that are safe for consumers

[126] (IFRA)

and for the environment. The guidelines apply to the manufacture and handling of all fragrance materials for all applications and contain the complete IFRA standards.

O8 Products for infants, babies and children

Fragrances/perfumes/flavourings/fragrance substances in plant extracts may not be added to infant, baby or children's products.

Exceptions: Flavourings are allowed in children's toothpaste, see O22. O9 must be met.

Infant, baby and/or children's products are considered to be products that are marketed for or have words such as baby and/or children (<12) on the label.

Note that the 26 fragrance substances that are subject to declaration are covered by this requirement.

☒ Appendix 1 or equivalent declaration completed and signed.

☒ Recipe

☒ Label

Background to requirement O8

The requirement covers product specially marketed for babies or children, e.g. with the words "bebis", "baby", "barn", "kids" or "child". Children up to the age of 12 are considered to be children in this context. The main argument is that children are more sensitive than adults and tend to have fewer opportunities to choose a product themselves. This requirement will distinguish between Nordic Ecolabelled and other products. Products marketed as family products or geared towards teenagers do not need to meet this requirement. The requirement exists to attempt to reduce the risk of infants, babies and/or children developing allergies to fragrances.

All the requirements also apply to flavourings which contain equivalent substances as fragrances and fragrances in plant extracts. Many different plant-based ingredients are used in cosmetic products. These can contain allergens such as fragrances subject to declaration. Sensitising fragrances in plant extracts are handled in the same way as fragrances. Otherwise plant extracts containing sensitising substances cannot be used. All plant extracts must be assessed on a case by case basis with the help of specifications on the content. If an extract contains substances that have the function 'perfuming' in CosIng[127] (The European Commission's database with information on cosmetic ingredients) the extract must not be accepted in a children's product.

There are grounds to assess flavourings in the same way and ban them in children's products[128]. No Nordic Ecolabelled toothpaste is currently available for children without a flavour/aroma. This means that consumers are not actually able to make a good choice in health and environment terms when choosing toothpaste for their children. The consumer can either choose to use Nordic Ecolabelled adult toothpaste for children but adult toothpaste often contains more fluoride than is recommended for children's toothpaste, see O36. This is therefore not a good alternative to non-Nordic Ecolabelled children's toothpaste in health terms. As Nordic Ecolabelling sets a requirement that aromas in toothpaste must be approved for food products, see O23, it is ensured that the only flavourings that

[127] (European comission)
[128] (Farage;Bjerke;Mahony;Blackburn;& Gerberick, 2003)

are used in children's toothpaste are those that are approved in terms of health. An exception is therefore made for toothpaste for children, such that aromas approved for food are added.

O9 Amount of fragrance

A fragrance substance/flavouring/fragrance substance in plant extract which is judged to be sensitising with the hazard statement H317 and/or H334, or covered by the fragrance substances subject to declaration may be included at a maximum of 0.001% (10 ppm) in leave-on (see section 2 Biodegradability and aquatic toxicity for definition)products and a maximum of 0.01% (100 ppm) in rinse-off products.

The fragrance substances in table 2 may be included in products with a maximum of 100 ppm (0.010%) for rinse-off products and a maximum of 10 ppm (0.0010%) for leave-on products per substance:

Table 2 other fragrance substances that may be included to a maximum 100 ppm for rinse-off and 10 ppm for leave-on.

INCI name (or, if none exists, perfuming name according to Cosing)	**CAS number**
Cananga Odorata and Ylang-ylang oil	83863-30-3; 8006-81-3
Eugenia Caryophyllus Leaf / Flower oil	8000-34-8
Jasminum Grandiflorum / Officinale	84776-64-7; 90045-94-6; 8022-96-6
Myroxylon Pereirae	8007-00-9;
Santalum Album	84787-70-2; 8006-87-9
Turpentine oil	8006-64-2; 9005-90-7; 8052-14-0
Verbena absolute	8024-12-02

HICC, chloroatranol and atranol are not permitted in the product.

☒ Appendix 1 and 2 or equivalent certification completed and signed plus fragrance specifications.

☒ Recipe

Background to requirement O9

The aim of the requirement concerning sensitising fragrances in Nordic Ecolabelled products is to provide as much protection against new allergies as possible. Nordic Ecolabelling has decided that it is appropriate to go further than the legislation in terms of both limiting sensitising substances and declaring them.

The Cosmetics Regulation currently lists 26 fragrance compounds that must be declared on the packaging when the concentration exceeds > 0.0100%/100 ppm ("rinse-off" products) or 0.0010%/10 ppm ("leave-on" products). Because Nordic Ecolabelling does not see a reason to distinguish between the fragrances that are subject to declaration and other fragrances with an official classification of H317 (May cause sensitisation by skin contact) or H334 (May cause allergy or asthma symptoms or breathing difficulties if inhaled) the requirement is now set out for all these substances. This is because allergies (and allergies to fragrances in particular)

constitute a growing problem and there is every reason to minimise the risk of increasing the number of hypersensitive consumers.

In June 2012 a new opinion was issued by the EU's Scientific Committee, SCCS, stating that 127 substances should be declared on products instead of the current 26, "Scientific Committee on Consumer Safety SCCS OPINION on Fragrance allergens in cosmetic products (SCCS/1459/11)[129]". In this report, SCCS recommends that all the fragrance substances that they have found evidence for being potential allergens must be declared by name on the cosmetics product. Among the 127 fragrance substances, 26 are already restricted under the Cosmetics Regulation, and in total 20 are classified as health hazards with H317. SCCS refrains from recommending decided maximum limits for the content of all the fragrance substances in cosmetic products, particularly due to a lack of underlying data. However, SCCS states that the general limit of 100 ppm is tolerated by the majority of consumers, and wishes to guard against the development of new allergy sufferers both within generally tolerant and sensitive people.

SCCS also recommends that three substances Chloroatranol, Atranol2 and Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) are not included in cosmetic products. Chloratranol and Atranol occur in Oak moss (Evernia Prunastri) and Tree moss (Evernia Furfuracea) extract. These three substances are also included under requirement O2 SCCS Opinions.

Nordic Ecolabelling has conducted a dialogue with IFRA and fragrance producers and checked the status of IDEA (International Dialogue for the Evaluation of Allergens)[130] concerning the 127 allergenic fragrances. SCCS and IDEA are working to develop methods for quantifying more substances of these 127. This work has not been completed and the earliest date in which there is expected to be a declaration requirement in European legislation is 2019. In the light of this, Nordic Ecolabelling has chosen to tighten up the requirement on fragrances by adding a requirement to restrict the 7 substances (see table 2), with the greatest risk of sensitisation in the SCCS report (SCCS/1459/11)[131]. Most of these 7 substances do not have a harmonised classification under ECHA's summary of classification[132], but many are classified by some under H317. The fragrance producers can then avoid these substances when mixing fragrances, if it is not possible to quantify these substances. Nordic Ecolabelling sees this as the first step towards more stringent requirements to restrict fragrance allergens.

[129] (SCCS, 2013)
[130] (IDEA)
[131] (SCCS, 2013)
[132] (ECHA)

Table 2 The 7 substances with the greatest risk of sensitisation under the SCCS report (SCCS/1459/11)[133].

INCI name (or, if none exists, perfuming name according to Cosing)	CAS number
Cananga Odorata and Ylang-ylang oil	83863-30-3; 8006-81-3
Eugenia Caryophyllus Leaf / Flower oil	8000-34-8
Jasminum Grandiflorum / Officinale	84776-64-7; 90045-94-6; 8022-96-6
Myroxylon Pereirae	8007-00-9;
Santalum Album	84787-70-2; 8006-87-9
Turpentine oil	8006-64-2; 9005-90-7; 8052-14-0
Verbena absolute	8024-12-02

According to the Videnscenter for Allergi (the Danish centre for research into allergies) there is in principle no limit for when an allergy causes problems[134] . It would not be realistic, considering the prevailing situation in the market, to prohibit the use of fragrances in the products. So far, the demand for fragrance-free cosmetics is low and if fragrances were to be prohibited entirely, this would probably have a negative effect on the market presentation of the brand, which would be disproportionate compared with the limited impact that fragrances in Nordic Ecolabelled products have on the environment. Particularly because the amount of environmentally hazardous substances (including fragrances) is strictly limited in O17 Environmentally hazardous substances. Consumers can choose between fragranced and fragrance-free products because the existence of fragrance must always be declared on the packaging. In purely general terms, there is demand for both fragranced and fragrance-free products both as consumer products and B2B products, something which is clear among current Nordic Ecolabelled products and the market in general.

In addition, the possible consequences of a total ban on fragrances may lead to a general problem of how to define a fragrance. It is possible that fragrances would simply be replaced by different vegetable oils, which would hardly be a step forwards because information on the environmental impacts or allergies related to these substances is usually limited. We consider a fragrance to be substances intended to perfume a product. If a fragrance without sensitising substances were to be used by another function, it can be accepted. On the other hand, plant extracts or other ingredients with sensitising substances are only used for perfuming the product.

Fragrances which have two functions, e.g. benzylalcohol, which can both have a function as a scent and as a preservative, must continue to comply with our requirements for fragrance substances subject to declaration, whether or not it is stated by the producer that the purpose of its use is other than fragrance. If the purpose is stated to be other than fragrance, the substance must also comply with the requirements we make for the function in question.

[133] http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf
[134] (Duus, 2009)

All fragrance substances subject to declaration are considered to be fragrances irrespective of their function in the product.

If a product has instructions on the packaging such that it can be seen either as "leave-on" or "rinse-off", the product is considered to be "leave-on" in relation to the content of sensitising fragrance substances. Toothpaste is counted as rinse-off.

Colorants

The Cosmetics Regulation[135] defines colorants as substances which are exclusively or mainly intended to colour the cosmetic product, the body as a whole or certain parts thereof, by absorption or reflection of visible light; in addition, precursors of oxidative hair colorants shall be deemed colorants; A colourant covers salts and substrate pigments and when a colourant is expressed as a specific salt its other salts and substrate pigments are also covered.

The content of colorants in cosmetics varies considerably depending on the type of cosmetic and runs from hundredths in soaps etc., up to at least 15% in lipsticks.[136]

All cosmetic products and all colorants irrespective of function are covered by the requirement.

O10 Bioaccumulation

Organic colorants must not be bioaccumulating in line with the testing methods in Appendix 8 BCF<500/logKow<4).

Alternatively the colour must be approved for use in food.

✉ Specification of an experimentally determined BCF value (bioconcentration factor) or logKow value (logarithmic octanol-water partition coefficient), see description in Appendix 8.

✉ Alternatively an E-number (allocated number in conjunction with approval of foodstuffs). Appendices 1 and 2 can be used.

Background to requirement O10

A study carried out by Nordic Ecolabelling in 2003 of 48 colorants approved for use in cosmetics (equivalent to 30% of the approved colours) showed that several of these had bioaccumulation potential and were toxic or very toxic to aquatic organisms. Relevant environmental requirements can and should therefore be introduced for these colorants. The study showed that colorants approved for use in food do not constitute a major environmental problem. Where colours are approved for use in food, their safety is evaluated by the European Food Safety Authority (EFSA). The evaluation also discusses absorption, distribution, metabolism and excretion (ADME) in line with various animal tests. The EFSA has no official guidelines on when colours can be approved and evaluates them on a case by case basis. They can also state ADI (Acceptable Daily Intake) values for approved colours. The background to the ADI values is an ADME evaluation, plus toxicity data such as gene toxicity or sensitisation. Nordic Ecolabelling relies on the EFSA's evaluation that it is likely that highly bioaccumulating colours will not be approved for use in food. Therefore, and on the basis of our own study described

[135] (EU, 2009)
[136] (Naughton, 2003)

above where logKow or BCF values were lacking, we also accept E-numbers as documentation of low bioaccumulation potential.

The requirement excludes about ten colorants with logKow values up to 17, which are approved under the Cosmetics Regulation.[137] In addition, the requirement on environmentally hazardous substances also excludes the use of more toxic colorants.

The BCF and LogKow values are used as indicators for bioaccumulation in line with the definitions in the CLP Regulation.[138]

The requirement only covers organic colorants as bioaccumulation cannot be used for organic compounds. Inorganic colorants such as titanium dioxide can therefore be used in Nordic Ecolabelled cosmetics without special requirements when these are approved for use in cosmetics and meet our classification and toxicity requirements.

O11 Metals in colorants for decorative cosmetics and hair dyes

None of barium, lead, mercury, cadmium, six inhalant chromium or bismuth may be found in colourants for decorative cosmetics and hair dye in concentrations above 10 ppm (0.0010%).

Colours that are approved for use in foodstuffs in accordance with Commission Directive 2008/128/EC may be used without further documentationof the metals listed above.

✉ Appendix 2 or equivalent declaration completed and signed and/or specifications/analysis results of the colour.

✉ Specification of E-number and/or a declaration from a supplier confirming that the colour complies with the purity criteria for colours for use in foodstuffs in accordance with Commission Directive 2008/128/EC.

Background to requirement O11

The purpose of setting requirements on heavy metals in colours is to protect the consumer from unnecessary exposure to heavy metals when using cosmetic products.

A particular limit has been set for a number of relevant heavy metals in colorants. Lead, for example, has been found in lipstick in concentrations of up to 0.65 ppm [139] and in 2015 cadmium was found in a lipstick in the EU[140]. Because lipstick is in fact consumed, to a certain extent[141] and lead is stored in the body over time, this can lead to significant exposure levels combined with lead from other sources. Because 39% of the lipstick tested in the American study does not contain any measurable amounts of lead, it is possible for cosmetics to be manufactured without dubious metals in their colorants.

Bismuth is used in make-up in the form of bismuth chloride oxide (BiClO) as a colour with the aim of providing a shimmering surface. Gunnar Guzikovski from the Swedish Medical Products Agency also stated that the Agency had received an

[137] (EU, 2009)
[138] (EU, 2008)
[139] (Safe Cosmetics)
[140] (European comission - Rapex, 2015)
[141] (Kuluttaja, 1996)

increasing number of questions about bismuth in recent years and that this may be due to increased use of what is known as mineral make-up in which bismuth chloride oxide is often a ingoing substance.[142] According to the ECHA's summary of classification, approximately 20% of notifiers classify bismuth chloride oxide as an irritant to skin and eyes (H315 and H319). Internet searches show that certain make-up producers have chosen to market make-up products as bismuth-free.

A limit of 10 ppm (0.0010%) of lead, barium, mercury, cadmium, bismuth or hexavalent chromium in colourants and other raw materials is judged to be acceptable, according to information from the colorant industry. The addition of less than 0.20%, or raw materials that contain less than 10 ppm of these metals, will result in products with less than 0.02 ppm of these metals (detection limit for lead in the study). The limit of 10 ppm is therefore considered relevant.

Commission Directive 2008/128/EC[143] laying down specific purity criteria concerning colours for use in foodstuffs can also be used because the colourants used in food have been safety evaluated on the basis of an exposure scenario in which they are "closer" to the body than cosmetic products. This directive lists all the colours approved for use in food and sets threshold values for the content of heavy metals, among other things. Where heavy metals are specifically mentioned, the threshold values are lower or equal to the limit set in O12. While not all metals from O12 are included, for the majority of colours the Directive contains a collective criterion covering "other heavy metals" where the limit is above that of the requirement in O12, however. 40 ppm is, however, still considered to be a very low limit. Colours that are approved for use in foodstuffs (under Directive 2008/128/EC) do not need further documentation on their metal content.

The requirement has been changed so that it only concerns colorants in decorative cosmetics and hair dye. For other products the requirement is not considered to be relevant: soap and other cosmetic products contain very small amounts of colours (normally <1%). Documentation is weighty and there are risks in decorative cosmetics that are based on colorants, where impurities are also included in products at very high amounts.

O12 Enzymes

Enzymes must be capsulated granulates or in liquid form. Enzymes in powder form may be used, however, provided that:

- The finished product is a product that does not give off dust (excludes products in powder form and similar)
- Manual handling of powder enzymes must take place in a separate, screened off area (e.g. weighing room or a ventilated fume cupboard)
- Special work instructions must be available regarding the use of protective equipment when manually handling enzymes and regarding the collection and disposal of any spilled enzyme powder.
- Everyone who handles enzymes must wear protective clothing, gloves, a mask with dust filter (minimum: P31 dust filter) and protective goggles

Enzymes must not be added to spray products.

[142] (Läkemedelsvärket, 2009)
[143] (EU, 2008)

✉ Declaration from the enzyme manufacturer or information on a safety data sheet/product data sheet regarding the form of the enzyme. For enzyme powders in particular: Documentation regarding the handling of powder enzymes in production as stated in the requirement.

✉ Declaration from the manufacturer of spray products that enzymes have not been added, Appendix 1 can be used.

Background to requirement O12

It may be necessary to add stabilisers and preservatives to liquid enzyme ingredients to prevent the enzymes breaking down and so losing their activity. This applies, for example, to proteases, where a protease inhibitor is added. Preservatives in enzyme ingredients will solely be aimed at preserving the ingredient, not the finished products. Such preservatives are excluded from the requirement which excludes sensitising substances in the finished product, as the amount of preservatives in the finished product is very low and the preservative performs an important function in an important ingredient.

The requirement made of enzymes concerns the protection of health and safety in the production of cosmetic products in that enzymes must be liquid or a granulate that does not produce dust. This is to prevent workers manufacturing cosmetics from being exposed to the potential effect of enzymes sensitising the airways.

Enzyme preparations must not be found in spray products. This is intended to protect consumers from breathing in spray containing enzymes.

In other cosmetic products, substances in enzyme preparations may be classified H334 and H317, see O4 Classification of ingoing substances. They are not expected to cause allergies in the consumer as the ingredients of the enzyme are included in the product and do not exist as “free dust”.

The requirement has been changed so as not to permit enzymes in powder form.

O13 Preservatives

- The use of preservatives for purposes other than preservation of the product itself is prohibited.
- Preservatives must not be bioaccumulating as specified by Appendix 8 (BCF<500/logKow<4).
- Phenoxyethanol (CAS 122-99-6) may be present to a maximum limit of 0.4% in baby products (children <3) and cannot be used in products intended for the nappy area (e.g. wet wipes for babies or products intended for diaper rash).

These requirements also apply to antibacterial disinfecting and microbial substances.

✉ Appendix 1 and 2 or equivalent declaration completed and signed.

✉ Specification of BCF value or logKow value, see description in Appendix 8. Appendices 1 and 2 can be used.

Background to requirement O13

All antibacterial, disinfecting and microbial substances must comply with the requirements that cover preservatives. This is to ensure that the substances are not added to products unless they comply with the requirements that apply for preservatives.

Preservatives may only be used with the aim of preserving the product to avoid products that are said to be biocides. Household use of biocides is not considered to be beneficial and can increase bacterial resistance.

The requirement that preservatives must not be bioaccumulating reduces the serious environmental impact associated with bioaccumulative substances.

Oral hygiene products may contain substances that produce an "antibacterial" effect. These substances must comply with the requirements for preservatives.

Different dandruff shampoos may contain different substances specifically designed to have an antimicrobial effect against fungus (fungicides). Some of these substances are associated with a risk of environmental damage. As we have seen that in consumer products it is possible to create sufficient antidandruff effect by combining non-fungicidal substances, we wish to promote these. Therefore we make no exceptions for antimicrobial substances in dandruff shampoo. The most effective products have indications against seborrhoea and are sold as non-prescription drugs, which our requirements do not cover.

These requirements have been merged but are otherwise unchanged since version 2.

As a new requirement the use of phenoxyethanol (CAS 122-99-6) is limited in products for children. SCCS agrees to investigate phenoxyethanol[144] due to concern aroused by a report by the French Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM).[145] According to the French report, phenoxyethanol should be limited in products intended for children under the age of three and should not be used by the nappy area because it has systematic effects such as blood and liver toxicity and the safety margins are insufficient for children under three.[146] While awaiting SCCS' opinion on the matter, we have chosen to apply the precautionary principle and follow the French recommendation. By products intended for the nappy area, we mean e.g. wet wipes for babies and zink creams and other products intended for diaper rash etc.

In addition the choice of preservative is limited by many other requirements: preservatives that are sensitising, endocrine disruptors or release formaldehyde are banned (O5 and O6).

O14 UV filter

UV filters may only be added to leave-on products and only to protect the user – not the product. Products with UV statements must comply with O35 Performance, UVA and UVB

All organic UV filters contained in the product:

- must not be bioaccumulating as specified by Appendix 8 (BCF<500/logKow<4).

or

- must have a lowest toxicity with NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l

☒ Appendix 1 and 2 or equivalent declaration completed and signed.

[144] (SCCS, 2014)
[145] (ANSM, 2012)
[146] (ANSM, 2012)

☒ State one of the following: BCF value/logKow value or lowest available NOEC/EC_x/EC/LC50 value.

Background to requirement O14

UV filters can be divided into two types of filter: physical organic filters such as titanium dioxide and chemical organic filters such as benzophenone-3.

UV filters can be problematic from an environmental and health point of view (see e.g. O7 on nanoparticles and O6 on endocrine disruptors).

UV filters provide protection against the sun and thus reduce the risk of skin cancer, so there are also advantages to using sun protection products with UV filters.

UV filters should only be used to protect the user, not the product. The reason is that certain products on the market contain UV filters for reasons that could be described as debatable (for example deodorants in metal holders or shampoos and soaps).[147] In addition, UV filters used to protect the user are the only filter covered by Annex VI to the Cosmetics Regulation and are approved there. Introducing requirements on the function of the UV filter will ensure that Nordic Ecolabelled products only contain approved UV filters and only to protect the user (skin/hair).

The number of available UV filters allowed in cosmetic products is limited by the Cosmetics Regulation and a number of our general requirements (e.g. the requirement on potential endocrine disruptors) restrict this number further.

With the aim of restricting the available UV filters in Nordic Ecolabelled products even more and only accepting those which have a better environmental performance in general, we have reached the conclusion that the UV filters must not be bioaccumulative or toxic to aquatic organisms. Note that O17 further limits the amount of substances that are harmful to the aquatic environment. We realise that the requirement on stability for organic UV filters in the product and on application is not necessarily compatible with rapid or even potential degradability of the substances. An NOEC/EC_x/EC/LC50 value is sufficient but the lowest available value must be used. If Nordic Ecolabelling has access to a lower value than that on e.g. a safety data sheet, this is to be used instead.

The above requirement excludes UV filters such as 4-methylbenzylidene camphor (4-MBC, LogKow = 5.92; molar weight = 254 g/mol; LC50 = 0.13 mg/l) which has been found in lakes in Switzerland.[148]

For substances where logKow >4 and where the acute toxicity for the aquatic environment cannot be measured due to low water solubility, other tests should be considered. Such tests can include studies of chronic toxicity, with a test concentration under the solubility of the substances (results in a concentration without observed effect (NOEC)). A sediment toxicity test should also be considered for substances potentially capable of being deposited or absorbed in sediments to a significant extent, or if logKow is >3.

[147] (Öko-Test 2009a), (Öko-Test 2009b), (Forbrugerrådet Tænk Kemi, 2015)
[148] (Balmer A, 2010)

NB! Nano UV filters are banned under O7 Nanoparticles.

The requirements are the same as in version 2, an opportunity to use data on chronic ecotoxicity has been added.

O15 Polymeres

For all polymers, the total content of residual monomers classified as one or more of the following may be a maximum of 100 ppm/dry substance per classification per polymer, measured on newly produced polymer dispersion.

- Acute tox 1-3 with H300, H310, H330, H301, H311, H331,
- CMR with H350, H351, H340, H341, H360, H361,
- sensitising with H334, H317
- environmentally hazardous with H410, H411
- potential endocrine disruptors (see Appendix 8 for a definition).

✉ When stating the residual monomers in the polymer that are classified according to the requirement above, Appendix 2 can be used, as can a declaration from the polymer producer stating that the requirement is met, e.g. accompanied by specifications and/or analysis results.

Background to requirement O15

Polymers can exist in large quantities in certain types of product.

Monomers in the polymer can involve a health burden, for example due to their characteristics that are harmful to health such as being allergenic or carcinogenic. This burden is considered to be so high, partly because monomers are often very reactive substances, that it is relevant to set a separate requirement limiting the total content of residual monomers in the polymer.

Polymers must have a low monomer content (less than 100 ppm per classification per polymer) if the monomer is classified as acutely toxic category 1-3 (H300, H310, H330, H301, H311, H331), carcinogenic (H350, H351), mutagenic (H340, H341), toxic for reproduction (H360, H361), sensitising (H334, H317) or environmentally harmful under H410/H411 or is considered to be an endocrine disruptor. This requirement limits the content of monomers that pose a risk to health or the environment. Other monomers that we know often occur in cosmetics are not limited because they do not pose any environmental or health problems. Acute toxicity was added to the list in version 2 such that the requirement is identical to other chemical criteria.

Non-synthetic polymers (vegetable), such as polysaccharides do not contain monomer residues but they may instead contain residues from extraction – typically organic solvents. These are not covered by the requirements. However, if it starts to become evident that solvent residues in these are a problem, this is an issue that may need to be reviewed.

O16 Aluminium

Aluminium may only be included in leave on products to a maximum level of 0.6% (Al).

✉ Formulation and calculation of the amount (%) of aluminium (Al).

Background to requirement O16

Aluminium in antiperspirants has caused debate recently. An SCCS opinion on aluminium was issued in March 2014.[149] This stated that aluminium is toxic in high doses but that there is insufficient data on entry through the skin to estimate exposure, whereby a risk assessment cannot be made.

The French authorities have recommended a limit value for aluminium in antiperspirants/deodorants.[150] Due to the precautionary principle, Nordic Ecolabelling has chosen to use this limit value of 0.6%. We are aware that the conventional antiperspirants with aluminium zirconium or aluminium chlorohydrate contain more aluminium than this and will not meet the requirement. Deodorants based on alum (KAl(SO4)2) may meet the requirement. We welcome comments on this during the consultation period.

According CosIng[151], French Ansm[152] and SCCS[153] different aluminum compounds are used for other purposes and in other products as well. These include thickener or viscosity controlling of lotions and creams or makeup.

The French rapport[154] focused in only aluminum in antiperspirants and did not take into account exposure from other cosmetic products and has not estimated exposure or risk from them. Due to the precautionary principle the Nordic ecolabel extends the French recommendation to all leave-on products even if exposure is perhaps less and less frequent.

4.3 Biodegradability and aquatic toxicity

O17 Environmentally hazardous substances

Substances classified as environmentally hazardous according to Regulation 1272/2008/EEC may be included in the product to a maximum:

$100 \cdot c\,H410 + 10 \cdot cH411 + cH412 \leq 2.5\%$

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

Compounds of zinc (classified H410) may however be included in zinc ointment/cream marketed to heal irritated skin to a maximum of 25 % and may, in these cases, be exempted from the calculation.

Surfactants classified with H411 or H412 are exempted from the requirement, on condition that they are readily degradable and anaerobically degradable in line with the test methods in Appendix 8.

✉ A declaration of potential dangers posed to the environment (acute toxicity, biodegradability and/or bioaccumulative potential), in the form of either a product safety data sheet (e.g. Annex II to REACH 1907/2006/EC) or other documentation.

[149] (SCCS, 2014)
[150] (Ansm, 2011)
[151] (CosIng)
[152] (Ansm, 2011)
[153] (SCCS, 2014)
[154] (Ansm, 2011)

- ✉ A calculation of the quantity (percentage by weight) of H410, H411 and H412 in line with the requirement above. If data on the potential dangers posed to the environment by the product (degradability, acute toxicity, and/or bioaccumulation) is not available, the substance is assessed according to a worst case scenario (H410).
- ✉ Declaration of surfactants that are to be exempted from the requirement (quantity, classification, degradability) and declaration of zinc compounds that are to be exempt from the requirement (quantity, label with marketing claims).

Background to requirement O17

Substances that are toxic to the environment and are also not readily biodegradable or substances that are chronically toxic (H410, H411 and H412) constitute a potential problem for the aquatic environment. The majority of ingredients in cosmetic products finally end up in the aquatic environment through the wastewater system, either directly when they are used (e.g. soap, toothpaste, shampoo, hair dye) or after they have been used (rinsing in the shower) (e.g. make-up, deodorant, hair care products, fragrances). Certain products/ingredients are also released directly into the environment (both the aquatic environment and air) during use (e.g. sunscreen, hair care products, creams). Applying the precautionary principle reduces the use, spread and flow in society of substances with these properties as only some of the substances reach the aquatic environment in a harmful form and cause environmental risks.

The Cosmetics Regulation does not prohibit or limit the use of substances in cosmetic products due to their environmental properties. Nordic Ecolabelling has thus identified a need to limit environmentally harmful substances by means of a "cut-off" value for these substances. The requirement is based on a weighted method: the classification H410 is limited the most. The requirement excludes or limits, e.g. certain fragrance blends, colours and high content of any hazardous impurities in cosmetic ingredients. The limit enables proper storage of the products and acts as a guideline for the use of fragrances including fewer and lower content of blends classified as environmentally hazardous. The limit has not been changed because new substances have been classified as environmentally hazardous following the review of CLP, in practice the requirement may have become stricter.

From 1 December 2012 the CLP Regulation changed the criteria used as its basis for classification as environmentally hazardous. This means that some substances which were not previously classified as environmentally hazardous have now become so. This primarily concerns surfactants, which in the new classification are classified with H411 or H412. This is a problem, as surfactants have an important irreplaceable function in many rinse-off products and also as an emulsifier in leave-on cosmetics. There is therefore an exception for surfactants in calculating the content of environmentally hazardous substances in requirement O17.

Zinc compounds that are classified as environmentally hazardous are permitted in higher concentrations when they are used in zinc creams to heal irritated skin and nappy rash with documented effects. For such products, where we see a lack of high-quality alternatives, Nordic Ecolabelling is still able to make a positive difference. In a market screening on the Internet and in some stores in 2010 we found that besides zinc, baby products for red skin can also contain, e.g.

- essential oils and other fragrances – excluded by the ban on fragrances in products intended for children.
- Problematic preservatives – (various parabens – excluded due to suspected endocrine disruptive effects, chlorphenesin – the vast majority of producers classify it with H319 or H315 under the ECHA's classification and labelling inventory [155].)
- Balsam of Peru & TeaTree, allergy risk – excluded by classification/self-classification – allergenic.
- BHA – excluded as it is on the list of potential endocrine disruptors.
- Tetrasodium EDTA – excluded by the prohibition on EDTA and its salts.

The limit for zinc compounds is the same as in version 2: 25% to ensure that it is possible to manufacture products that are highly effective without preservatives. High effectivity can lead to fewer applications, making it not necessarily a higher load per functional unit.

A) Products rinsed off with water immediately after use (e.g. shampoo, conditioner, solid and liquid soap, cleanser, exfoliant and bath foam/gel, hand soap for industry and cleansing gel).

These requirements concern products that according to the usage instructions on the product are rinsed off with water immediately after use (e.g. shampoo, conditioner, soaps, toothpaste, bath foam and scrubs, cleansing products/gels, hair treatments and peels). If a product carries instructions on the packaging stating "...and/or rinse the product from the skin", the product is subject to requirements O18-O19. If, according to the instructions, the user is to rinse the skin after first having used cotton wool, the product is subject to requirement O20 but not requiremnts O18-O19.

O18 aNBO (Aerobic Non-Biodegradable Organics) and anNBO (Anaerobic Non-Biodegradable Organics)

Organic substances that are not readily biodegradable according to Appendix 8, must not exceed the limits indicated in Table 3. For foam soap it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in O19.

Table 3 Threshold values for aNBO och anNBO

Type of product	aNBO (mg/g AC*) DID2007/2014	anNBO (mg/g AC*) DID2007/2014
Liquid soap, hand soap for industry, shampoo, shower gel, conditioner, bath foam, cleanser, exfoliant	15	15
Solid soap	5	5

Type of product	aNBO (mg/dose**) DID2007/2014	aNBO (mg/dose**) DID2007/2014
Foam soap	2.5	2.5

[155] (ECHA, 2015)

"Active content" (AC) refers to the amount (weight) of all organic substances in the product excluding the water content of the ingredients. Abrasives in handwash and exfoliants are not included.

**One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product. If the product is not sold with a particular dispenser, a standardised dose of 0.75 g is used*

Note that surfactants must be degradable under O6.

✉ Calculation of the quantity (mg) of aNBO and anNBO/g AC.

✉ Reference to the DID list dated 2007, 2014 or later versions. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

Background to requirement O18

Restrictions on the content of organic substances that are not rapidly and anaerobically degradable reduce the total level of non-degradable organic substances to a minimum for Nordic Ecolabelled rinse-off products.

The levels for these threshold values are based on Nordic Ecolabelling's experiences from current licences. The documentation submitted under the licensing process has shown that this requirement is already quite strict and that it is one of the most important parameters that distinguishes Nordic Ecolabelled products from other products in this category and therefore the level of the requirement is the same as in version 2.

The limit for solid soaps is more stringent than for other products because solid soap has very high levels of active content and the requirement is based on the active content of the product. In addition, the relative content of aNBO/anNBO substances in general is lower in solid soap compared with liquid products.

The requirement for soap and shampoo is stricter than for other cosmetic products because their composition differs from other cosmetics and so can fulfil more specific requirements. Liquid products that are rinsed off ("rinse-off") such as soap and shampoo generally have a lower active content compared, e.g. with liquids, creams, etc.

Foam soaps have found it difficult to meet our requirements per active ingredients (AC) despite the fact that they were better for the environment from a functional unit perspective. Therefore, for foam soap it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in O19 (CDV).

A dose is defined as the largest amount that the dispenser for which the product is sold produces, or the maximum dose from the product's pump mechanism.

If a dose cannot be determined (if the product is not sold for a particular dispenser or does not have a pump) a standard dose of 0.75 g can be used (a foam soap from Berendsen Textile Service at 500 ml with a matching dispenser produces, for example, approximately 1 250 doses, which is equivalent to between 0.4 and 0.5 g per dose).

Version 2 of the criteria contained two alternatives for aNBO/anNBO calculations for liquid soap and liquid hand cleanser for industry. Experience shows that l/g AC is used to calculate CDV for the majority of liquid soaps and hand cleanser for industry. Liquid soap is the only type of product where aNBO/anNBO is solely calculated on the basis of dose per wash (l/dose), which is why this calculation option has been retained. The requirement has been changed such that only aNBO/anBNO for liquid soap is calculated on a dose basis.

O19 Critical dilution volume (CDV)

The product's critical dilution volume (CDV) must not exceed the threshold values in Table 3 for CDVchronic for the product type in question.

For foam soap it is permitted to choose between applying the limits per AC (active content) or per dose. The unit used shall be the same as in O18.

Table 4 Threshold values for CDV

Type of product	**CDVchronic (l/g AC*) DID2014**	**CDVchronic (l/g AC*) DID2007**
Solid soap	2 000	3 000
Other rinse-off products	12 000	13 000

Type of product	**CDVchronic (l/dose**) DID2014**
Foam soap	1 000

The calculation of CDV is based on information provided regarding the toxicity and biodegradability of the individual substances in an aquatic environment and must be obtained from the DID list dated 2014 or 2007. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

CDV is expressed as litre/g of AC or litre/dose, and is calculated for all substances in the product using the formula given in Appendix 4.

**Active content (AC)*

**One dose = the quantity dispensed per full depression by the dispenser or pump supplied with/designed for the product (0.5 g minimum). If the product is not sold with a particular dispenser, a standardised dose of 0.75 g for foam soap is used.*

✉ Calculation of CDVchronic for the product. (A spreadsheet for this calculation is available from Nordic Ecolabelling).

Reference to the DID list dated 2007, 2014 or later versions. For substances not on the DID list, the parameters must be calculated based on the guidance in part B of the DID list and associated documentation must be presented.

DID list: "Detergents Ingredients Database" list, see Appendix 8 for a more detailed description.

Background to requirement O19

This requirement covers only rinse-off products which must be rinsed off with water after use. Other types of cosmetics constitute a very varied group of products such as liquids, toothpaste, make-up, wet wipes, et. for which it is not appropriate to set common CDV values. Instead the potential content of ecotoxic and non-biodegradable substances is regulated by requirement O20 on the degradability of "other cosmetic products".

The critical dilution volume of the product (CDV) must be calculated for all ingoing substances. CDV is a theoretical value which takes into account the toxicity and aquatic degradability of each substance. The method has been developed for the EU Ecolabel. Chronic data must be used because it better describes the environmental impact. When chronic data is unavailable, acute data can be used combined with higher safety factors.

Rinse-off products are a mixed group of products and in conjunction with the revision it was assessed whether there should be separate CDV requirements for several product types, e.g. conditioner, liquid soap, shampoo, hand cleanser for industry, etc. Immediately this complicates the criteria, making it more difficult to assess which CDV value should be used in each individual case if a product is calculated, e.g. as shampoo and as body wash. Therefore it has been decided to continue with the same two types as today: solid soap and other rinse-off products.

The threshold values have been set based on Nordic Ecolabelling's experience of existing rinse-off licences. In conjunction with this revision the DID list 2014 (Detergent Ingredient Database) was introduced as an alternative to DID2007. The limit in version 3 of the criteria is set for solid soap, CDVchronic (l/g AC) ≤ 2 000, and other rinse-off products ≤ 12 000 according to DID2014. According to DID2007 the limits are: CDVchronic (l/g AC) ≤ 3 000, and other rinse-off products ≤ 13 000.

Version 2 of the criteria contained two alternatives for CDV calculations for liquid soap and liquid hand cleanser for industry. Experience shows that l/g AC is used to calculate CDV for the majority of liquid soaps and hand cleanser for industry. Liquid soap is the only type of product where CDV is solely calculated on the basis of dose per wash (l/dose), which is why this calculation option has been retained. The requirement has been tightened up to CDVchronic (l/dose) ≤ 1 000 for liquid soap.

For liquid soap it is permitted to choose between applying the limits per active content or per dose. The unit used shall be the same as in O18.

The water content of the product in relation to the CDV value has been studied. The water content varies from 50% to 95% depending on the product type, but can within the same product type, e.g. conditioner, vary considerably (75% to 92%). There is no clear correlation between water content and CDV value. It is therefore judged that the environmental benefit would be relatively small if a requirement on the water content in liquid products were introduced in relation to the advantages of the CDV requirement. The water content of today's products would not change markedly and a limit on the water content could lead to more concentrated products, leading to irritation problems, and to handling and dosing problems when viscosity increases. In addition mild products (often containing more water) are needed for children/infants and liquid soaps also often have a high water content.

In conjunction with processing applications for cosmetics and shampoo/soap, and the revision of these criteria documents, it has been made clear that the DID list is insufficient when it comes to handling the many vegetable oils/fats used in cosmetic products. Until now, normal practice has been to use the chemicals list's data for fatty acids in the absence of specific data for vegetable oils. However,

fatty acids are judged to have higher toxicity than many vegetable oils – which is why a high content of vegetable oils, e.g. in conditioner or liquid soap can determine whether the CDV requirement can be complied with. Because degradation products are not included in the CDV calculation for all other raw materials, we accept own toxicity and degradability data for vegetable oils instead of the DID list's data for fatty acids.

B) Other cosmetic products

O20 Biodegradability and aquatic toxicity

At least 95% by weight of the total content of organic ingoing substances must be:

- readily biodegradable (OECD 301 A-F), and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioaccumulable (logKow < 4 or BCF < 500), and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l and be potentially biodegradable (OECD 302 A-C) and/or
- lowest aquatic toxicity NOEC/EC_x > 0.1 mg/l or EC/LC50 > 10.0 mg/l and not be bioavailable (molar weight > 700g/mol)

Exempt are

- UV filters in sun products
- fibre material in wet wipes

Note that surfactants must be degradable under O6.

✉ Calculation as above as well as reference to DID list 2014. For substances not listed on the DID list a specification is required of biodegradability/toxicity/potential for bioaccumulation/bioavailability according to Appendix 8. The lowest available NOEC/EC_x/EC/LC50 value must be used. If chronic values are available, they must be used instead of acute ones.

Background to requirement O20

Cosmetic products are largely washed off the body and clothes and therefore end up to a certain extent in the aquatic environment via waste water treatment. Some are washed directly into the aquatic environment. It is therefore important to set requirements on degradability and/or toxicity/bioaccumulation potential for all ingoing substances.

In addition to readily degradable substances, substances are approved which have

- low chronic toxicity and potential degradability or
- low chronic toxicity and are not bioaccumulating or
- low chronic toxicity and low bioavailability
- If chronic data is not available, acute values may be approved and they must, in such cases be > 10 mg/l, see requirement text.

Colours, antioxidants, preservatives, etc. must be stable in the products and perhaps not meet the requirement for rapid degradability. In addition, long carbon chains such as paraffin, which is often used in cosmetics, are not rapidly degradable. For this reason a strict requirement on rapid degradability of all organic substances will be a major obstacle for Nordic Ecolabelling and drastically reduce the number and type of ingredients that meet the criteria, so reducing the

flexibility of manufacturers. For example, in our own market survey of seven different lipsticks, we found that they often contain a high proportion of non-readily degradable ingredients such as binders, polymers, siloxanes and waxes. Hair care products often contain polymers and waxes that are not rapidly degradable.

Reference is now made to chronic toxicity exceeding the acute values. Otherwise the requirement remains unchanged compared with version 2. The "cut-off" limit is set on the basis of Nordic Ecolabelled cosmetic products and a limited examination of the products on the market. The purpose of the requirement is to exclude the worst products on the market.

Molar weight > 700 g/has been chosen as the "cut-off" value for bioavailability. An examination of the literature[156] judged the opportunity to estimate bioaccumulation potential on the basis of molecular size and solubility. According to this examination, substances with a molar weight > 600 g/mol cannot have a bioconcentration factor > 300. However, a certain amount of uncertainty prevails regarding high molecular hydrophobic substances due to a lack of data. The combination of a "cut-off" value for molar weight with a requirement of low toxicity is not expected to lead to harmful effects because a molar weight > 700 g/mol will probably prevent a high accumulation level, even if a substance has a high LogKow value.

UV filters in sun products are exempt from the requirement because they are needed in sun products in amounts greater than 5% and they must be stable in the products so that they do not meet the criteria for rapid degradability. Because UV filters are often not potentially degradable and due to their molecular size cannot be counted as non-bioavailable substances, they do not comply with the alternative to degradability either. In O15, however, we require that UV filters must not be bioaccumulating and have a lowest toxicity of NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l. This limits the worst UV filters and they can be exempted from the requirement. Several chemical UV filters permitted in non-ecolabelled sunscreens do not comply with our requirements.

In this requirement toothpaste is counted as leave-on, although the Danish Environmental Protection Agency considers that toothpaste must be considered a rinse-off product. In other requirements toothpaste is counted as rinse-off.

4.4 Specific requirements relating to certain product types

This section sets requirements on certain selected product types. The requirements described in this section apply only to the specified product types but it should be emphasised that all products, even those set out in section 4.4 must comply with the requirements in all the other chapters.

Solid soap

O21 Content of EDTA and phosphonates in solid soap

Ethylene diamine tetraacetate (EDTA) and its salts (e.g. CAS no. 64-02-8) are permitted in solid soap.

[156] (Frauenhofer Institut Molekularbiologie und Anwandte Oekologie, 2007)

The total added quantity of EDTA, EDTA salts and phosphonates must not exceed 0.6 mg/g Active content (AC).

✉ Calculation of the quantity (mg) of EDTA and phosphonates per gram of AC.

Background to requirement O21

EDTA is permitted in limited amounts in solid soap because its use can reduce the need for preservatives. Without EDTA and phosphonates, the soap will be of poorer quality and will go off more quickly (see soap on the right in picture 1).

Picture 1 Soap containing EDTA (left) and without EDTA (right)

A limit for the accepted amount of phosphonates has been introduced as phosphonates, in the same way as EDTA, are hard to break down. The amount of phosphonates is limited by O18 (aNBO and anNBO) but is limited further here. When they are ultimately broken down into phosphorus, phosphonates also contribute towards eutrophication.

We have information that the soap producers can use as much as 0.5% of both EDTA and phosphonates and that this can be lowered to as little as 0.02% of each, for example by using high quality fatty acids,[157] see picture 2.

[157] (Frejl, 2009)

Picture 2 Interval of EDTA and phosphonates in solid soap

A limit value of 0.6 mg/g AC (or 0.06 % of AC) for the total EDTA content and phosphonates is strict but within reasonable limits.

The requirement has not been changed compared with the previous version of the criteria.

Lip products, toothpaste and oral hygiene products

O22 Flavourings, colours and preservatives

Flavourings, colours and preservatives used in these products must be approved for use in foodstuffs.

✉ Specification of E-number. For flavourings, specification of FL-number.

Background to requirement O22

Because the consumer is exposed to these products via the mouth, flavourings, colours and preservatives in the product must be approved for use in foodstuffs. According to the Finnish consumer magazine Kuluttaja, applying lipstick three times a day can lead to an intake of up to 15-20 g lipstick a year through absorption and swallowing.[158]

Flavourings do not have E-numbers (under Regulation 1333/2008 on food additives, substances should not be seen as food additives when they are used to add aroma and/or flavour) but they are now listed in Regulation 872/2012 and can be found in an on-line database: https://webgate.ec.europa.eu/sanco_foods/main/?sector=FFL&auth=SANCAS. For this reason a declaration from the manufacturer stating that the flavouring is approved for foodstuffs is no longer accepted as documentation and instead the substance's unique identity number (FL-number) in the EU's list of flavourings (Annex to 872/2012) is required. Otherwise the requirement is the same as in the most recent version of the criteria.

Hair dyes

O23 Hair dyes

Lawsone (CAS no. 83-72-7) may not be included in the product.

Hair dyes judged to be sensitising/allergenic by the SCCS may not be included in the product, even if they are not classified as such with H317 and/or H334.

✉ Appendix 1 or equivalent declaration completed and signed.

[158] (Kuluttaja, 1996)

Background to requirement O23

The EU's Scientific Committee SCCS/SCCP/SCCNFP has investigated Lawsone and henna several times. Among other things, in 2001 they found that Lawsone (the colour in henna, CI 75480, CAS 83-72-7) is mutagenic in vitro and in vivo and that it is not possible to be used as a non-oxidising colour in hair dye.[159] Later SCCS/SCCP stated that they consider that the information submitted is insufficient to allow safe use of the substance as a hair dye.[160] The most recent opinion from 2013[161] finds, however, that henna containing max 1.4% Lawsone is safe to use as 100 g henna powder is mixed with 300 ml boiling water. They also call for a re-evaluation of the genotoxicity of Lawsone. On the precautionary principle, Nordic Ecolabelling excludes the use of Lawsone (the colour in henna, CI 75480, CAS 83-72-7).

Several hair dyes are sensitising. Many, however, do not have a harmonised classification as sensitising with H317 and/or H334 even if SCCS has judged them to be sensitising/allergenic. Hydroxyethyl-3,4-methylenedioxyaniline HCl (CAS 94158-14-2) and hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl, (CAS 128729-28-2) are examples of such hair dyes. Nordic Ecolabelling therefore prohibits all hair dyes judged to be sensitising/allergenic by the SCCS, even if they are not classified as such with H317 and/or H334.

It is also uncertain whether we, given the requirement above and considering what hair dyes currently look like, will be able to obtain Nordic Ecolabelled hair dyes. But through product development, we hope in the future to be able to have the best hair dyes Nordic Ecolabelled.

Wet wipes

O24 Material

Material in wet wipes must meet at least one of the following requirements for the relevant fibre type (other fibre types cannot be used):

Viscose, non-woven, polymers (PE, PP, PET):
Materials must meet the requirements in Nordic Ecolabelling's criteria for Hygiene products version 6.0 or later, or the EU Ecolabel's criteria for absorbent hygiene products 2014/765/EU of 24 October 2014 or later, see Appendix 5.

NB! The requirement also covers viscose based on bamboo fibre.

Additional requirements for materials that meet the criteria of the EU Ecolabel:

Binding agents, ink and colorants, fragrances, lotions or silicone as specified in Criterion 6: Other materials and components must not be included in the material.

Textile material made from viscose, cotton and other natural fibres:
Textile fibres used in Nordic Ecolabelled wet wipes must be licensed under or meet the requirements in Nordic Ecolabelling's criteria for Hygiene products version 4.2 or later, or the EU Ecolabel for Textile products 2014/350/EC of 5 July 2009 or later, see Appendix 5.

[159] (SCCNFP, 2001)
[160] (SCCP, 2005)
[161] (SCCS, 2013)

Process water:

Sensitising substances with H317 and/or H334 can be used in the process water of the wet wipe material only if the concentration in the carrier material/wipe is <0.10 ppm per sensitising substance.

☒ All materials:

A copy of any licence from Nordic Ecolabelling or a contract for the EU Ecolabel* showing the material.

* including additional requirements stated above

Alternative documentation under, see Appendix 5.

- Nordic Ecolabelling's criteria for hygiene products version 6.0 or later

- EU Ecolabel for absorbent hygiene products 2014/763/EU of 24 October 2014 or later and additional requirements described above

- Nordic Ecolabelling's criteria for textiles version 4.2 or later

- EU Ecolabel for textile products 2014/350/EU of 5 June 2014 or later

☒ Process water:

Signed declaration on the use of sensitising substances in the process water for material in wet wipes, Appendix 6 can be used.

If sensitising substances are used, an analysis report is to be enclosed showing <0.10 ppm for each sensitising substance, see Appendix 5 for a more detailed description.

Background to requirement O24

Wet wipes are cosmetic products consisting of a carrier material and chemical ingredients (possibly stated as "liquid"). The carrier material is often made using non-woven technology and often consists of textile/fibre material (viscose, polyester) but can also be made from paper or other natural fibres (e.g. bamboo). Because several studies have shown that the production of these types of material/products can have a significant effect on the environment, requirements have been introduced on the carrier material.

Criteria for the Nordic Ecolabel and the EU Ecolabel exist for both textiles and hygiene products where requirements have already been set for relevant types of carrier materials. Thus we refer to these criteria documents for requirements on the carrier materials. If the material in the wet wipe can be included in several product criteria, the applicant can choose the criteria document whose requirements they wish to meet.

Through analysing wet wipes, Nordic Ecolabelling has become aware that substances such as MI (methylisothiazolinone), CMI (methylchloroisothiazolinone) and glutaraldehyde can be used in process water in the manufacture of non-woven and viscose. MI, CMI and glutaraldehyde are sensitising substances and the Nordic Ecolabel does not permit sensitising substances classified with H334 or H317 in cosmetic products, see requirement O5. The ecolabelling criteria for textiles, hygiene products and paper/tissue do not set requirements on process chemicals, and it cannot consequently be ruled out that the wipe material/carrier material may contain residues of sensitising substances from the process water.

The requirement has been changed such that it is no longer possible to use the paper criteria. Reference is also made to version 6 of Nordic Ecolabelling's Hygiene criteria.

To ensure that no sensitising substances are found in Nordic Ecolabelled wet wipes, producers of all carrier materials/wipes must declare any use of sensitising substances such as MI, CMI and glutaraldehyde or other substances classified with H334 or H317 in process water. If use of sensitising substances is declared, the carrier material/wipe must be analysed for the sensitising substance(s) concerned. An analysis must show a content of < 0.10 ppm of each sensitising substance.

Proposed analysis method for MI/CMI:

The detection limit must be <0.10 ppm of the substance concerned.

The analysis must be carried out on a standard wipe, approx. 4.8 g.

Liquid chromatography - Mass spectrometry/Mass spectrometry (LC-MS/MS)

Gas chromatography/Mass spectrometry (GS/MS)

Rinse-off products for animals

O25 Fragrances and colouring agents in rinse-off products for animals

Fragrances and colouring agents may not be included in rinse-off products intended for use on animals.

Products must comply with the EU's Cosmetics Regulation 223/2009/EC regarding ingoing substances and declaration of ingoing substances.

☒ Label

☒ Appendix 1 or equivalent declaration completed and signed.

Background to requirement O25

Nordic Ecolabelling wishes to continue to Nordic Ecolabel rinse-off products for animals even though these are not covered by the Cosmetic Products Regulation.

Shampoo and soap for animals is rinsed into the waste water system just like shampoo and soap for humans. Also the user is exposed to the same chemicals. These products should therefore meet the same general requirements as ordinary cosmetic products.

Neither fragrances or colours are permitted in shampoo for animals. There is no functional reason or safety reason to add these substances to shampoo and therefore they are not permitted. Even though this argument could reasonably also apply to products aimed at humans, we consider that there are strong consumer needs that encourage the use of cosmetics with colours and fragrances.

Because the owner of the animal comes into contact with the product in the same way as with shampoo or soap for humans, they must meet the same requirements as ordinary cosmetics in terms of ingoing substances and declaration of ingoing substances. In other words, we permit, for example, only the preservatives listed in

the Cosmetics Regulation[162] in the amounts listed (provided that they meet other requirements). The user's health is the justification behind the requirement.

The requirement has not been changed compared with the previous version of the criteria.

4.5 Packaging requirements

Packaging often accounts for a relatively large proportion of a cosmetic product. Products with several layers are common, especially luxury products. It is considered important to limit the amount of packaging materials with a general requirement setting a limit on the total amount of packaging compared with the packaging's contents.

O26 Amount of packaging

- More than one layer of packaging is only permitted where more than 1 product/unit are sold together. More than two layers of packaging are not permitted.

  Exceptions: For spray and pump products with an "airless" system that reduces waste, double packaging (container + bag inside) is permitted. For aerosol products for hairstyling and shaving foam/gel, which do not use gas, double packaging is permitted (metal container + bag with valve).

- The packaging must meet the following calculation. See more information and calculation examples in Appendix 4. A spreadsheet for this calculation is available from Nordic Ecolabelling.

$$\frac{\sum\left(\mathrm{mf_i}\cdot Weight_{\text{material i}}\cdot\frac{(2-\mathrm{rf_i})}{2}\right)-\frac{Weight_{\text{pump}}}{2}}{\mathrm{t}}\leq 8\cdot\ln\left(\mathrm{Vol_{product}}+1\right)+0.004\times\mathrm{Vol_{product}}+4$$

  mf_i = material factor for type of material divided into the following 4 groups of materials:

  mf_{glass} = 0.2

  $mf_{paper/cardboard}$ = 0.6

  $mf_{laminate}$ = 1.1

  $mf_{other\ materials}$ = 1.0

  $Weight_{material\ i}$ = weight of the packaging component (including label + information sheet) in grams

  rf_i = the fraction of the amount of post consumer recycled material i.

  $Weight_{pump}$ = weight of pump (if applicable) in grams.

  t = reuse factor, t=1 for packaging which is not reused for the same purpose.

  ln = natural logarithm

  Volproduct = volume of the product in ml

[162] (EU, 2009)

The following are exempt:

- For decorative cosmetics the following apply:

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

  $W_{packaging}$, i = the weight of the packaging component i

  $W_{non\text{-}recycled,\ i}$ = the weight of non-recycled material in packaging component i (if it is not recycled material in the packaging is $W_{non\text{-}recycled} = W_{packaging}$)

  $W_{product,\ total}$ = the weight of the end product (packaging plus content)

  Note: Decorative cosmetics are mascara, eye liner, eye primer, eyebrow pencil, eyeshadow, powder/blusher, concealer, primer, nail varnish, lipstick, lip gloss and similar products.

- B2B packaging with a volume > 2 litres, no calculation is needed.

✉ Description of the packaging.

✉ The weight of the primary packaging and the calculation as above (A spreadsheet for this calculation is available from Nordic Ecolabelling).

Background to requirement O26

The requirement has been tightened up in two different ways: the formula has been made more stringent and two layers of packaging are now only permitted when two products are sold together. This is to avoid unnecessary use of packaging. According to our own measurements the transport volume of tubes also increases if they are contained in extra cardboard.

There are two exceptions, however.

1) To reduce waste (see also requirement O29) we allow two layers in spray/pump products with an "airless" system (see e.g. http://da.pt-dispensers.com/produkter/skoenhed-personlig-pleje/airless, http://ampulla.eu/AIRLESS-DISPENSERS/c-1-236/) or similar system where there is a bag on the container and the content is sucked out when the pump is pressed.

2) The second exception is for a similar system to aerosols where aerosol is not needed:

Packaging for aerosol products can consist of metal (aluminium, iron, tin) or of plastic (PET). A new type of packaging consisting of metal + a bag with a valve (BOV=Bag-On-Valve) has come onto the market.

Traditional metal and plastic packaging uses gas as a propellant. The most common propellants are the volatile gases propane-butane (LGP), isobutane and dimethyl ether (DME), and the inert gases CO2 and N2. DeMythe®LDD is a new variant of DME based on bioethanol[163], but it is a relatively expensive gas which is not yet widespread. Propane-butane (LGP), isobutane and dimethyl ether (DME) are flammable gases. CO2 and N2 are inert gases, which are only used in combination with propane-butane or isobutane. Depending on the cosmetic product, the gasses are used alone or in combination, e.g. propane-butane + CO2. The relationship between product and gas is important to waste. If there is too little gas in relation to product, there will be product left in the container which will have to be thrown

[163] (AkzoNobel)

away. If there is too much gas in relation to product, there will be gas left in the container which will have to be thrown away. As the ratio between product and gas varies from product to product (typically 40-70% gas, if propane-butane and DME are used) Nordic Ecolabelling cannot set a steerable requirement for the ratio between product and gas.

The BOV system consists of a container containing a bag with a valve, see figure 3.[164] The container is made from aluminium or tin and the bag is coated with aluminium. The BOV system can be used for sunscreen, shaving foam, gel and hairstyling products. The advantages of the BOV system is that gas is not used to get the product out of the container, and that the packaging can be emptied 100%. In the light of this, an exception is made for double packaging for aerosol products which do not used gas.

Figure 3 the BOV system[165]

It is difficult to compare the packaging needs of different cosmetic products. Products with a low volume, such as eye shadow, have much more packaging per product volume compared with high volume products such as most shampoos.

A formula which takes into account the volume of the product, the amount of recycled materials after the consumer stage, reusable/refillable packaging and a potential pump to make correct dosage easier was created for version 2. This has now been made considerably more stringent for version 3. The basis for determining the constants was data from current Nordic Ecolabelled products (140 of them). All the data was entered in a diagram and the constants were determined iteratively considering that the requirements should be realistic but strict. The packaging calculation for wet wipes must be made by measuring the volume of the content (carrier material) as a block, l x b x h.

[164] (AURENA Laboratories)
[165] (AURENA Laboratories)

The material factor value produces a rough “environment weight” which represents energy consumption per kg of different materials. Because metals are only allowed for special types of products, no separate material factor was developed for them.

$\sum\left(\mathrm{mf_i} \cdot \mathit{Weight}_{\text{material i}} \cdot \frac{(2-\mathrm{rf_i})}{2}\right)$ expresses a wish to limit the total weight of the packaging and encourage the use of e.g. recycled plastic after the consumer stage and take into account the type of material used (mf_i) and the fraction of recycled material (rf_i).

$\frac{-\mathit{Weight}_{\text{pump}}}{2}$ means that only “half” of the weight of a dosage pump is included in the calculation. We want to allow this extra weight because correct dosage is an important aspect in the environmental burden of the products and a dosing pump can make correct dosing easier.

$\frac{1}{t}$ is included in the formula to encourage direct recycling of the packaging material, e.g. with the help of refill products. The reuse figure t is as standard 2 when refilling is offered, but if, for example, sales statistics can show that more refills than products are sold, a higher value can be used in the calculations. If, for example, two refills are sold for each product, t can be 3. A corresponding amount of refill packs must be included in the calculations to ensure that refills lead to a total reduction in the amount of packaging.

$10 \times \ln\left(\mathrm{Vol_{produkt}} + 1\right)$ describes the logarithmic increase as a function of the volume of the product. This is equivalent to the relative need for more packaging per volume for products with a small product volume, e.g. 20 ml cream compared with 500 ml shampoo. The constant (8) is determined iteratively. It has been changed compared with version 2.

$0.008 \times \mathrm{Vol_{produkt}} + 8$ is a linear function that takes into account the fact that increased product volume requires larger packs. The constants (0.004 and 2) are determined iteratively. They have been changed compared with version 2.

Decorative cosmetics are a type of product that differs considerably from creams, lotions and shampoo. The requirement above has not taken into account the fact that small products (decorative cosmetics) have a relatively larger proportion of packaging even if the amount of packaging itself is very small. Nordic Ecolabelling has carried out an internal survey of the type and amount of packaging used in decorative cosmetics collected from employees at Nordic Ecolabelling. This survey showed that there are large differences in both the type and amount of packaging between the different product types and within the same product type. This means that it is possible to set requirements that certain products can meet and others cannot meet. Based on the survey, the requirement was set permitting an amount of packaging in decorative cosmetics amounting to 80% of the total weight of the product.

Very large packs, which can be used, for example, in B2B soaps or shampoos are also hard to take into account in the tougher requirement above. This concerns large containers, and similar. However, these have much less packaging compared with their content than other cosmetic products. Nor is packaging used as a marketing method in B2B products and excess packaging is therefore not a problem. B2B packaging > 2 litres is therefore exempt from the requirement.

O27 Type of packaging

All parts of the packaging must be able to be sorted separately (paper, cardboard, plastic, metal, glass) without using a tool. Parts comprising mixed materials that cannot be separated are prohibited, with the exception of pump parts.

This requirement does not apply to pressurised containers and packaging for decorative cosmetic products.

✉ Specification of materials, including description of all components (cap, pump, lid, etc.)

Background to requirement O27

With the requirement that all parts of the packaging must be able to be sorted separately (with the exception of plastic and plastic-paper laminates) Nordic Ecolabelling wants to promote the recycling of packaging and the development of packaging that is recyclable, because this is important for a sustainable society. Packaging for decorative cosmetics often consists of several materials (glass, metal, plastic) which cannot be separated from each other, but here too there are alternatives. The requirement is that paper, cardboard, plastic, metal and glass must be able to be separated, even if we realise that not all municipalities in the Nordic countries collect the different materials. Pumps and spray bottles are excluded because there are no alternatives to these.

The pigment/printing ink in/on plastic packaging can mean that the recirculated product cannot be used as recirculated clear plastic,[166] but so as not to reduce consumer demand for Nordic Ecolabelled cosmetics, we have chosen not to set a requirement on pigments and printing ink, which also applies to the use of e.g. metal silver as a pigment in plastic or hot foils. Plastic laminate and plastic-paper laminate are accepted in the light of the fact that even if they cannot be material sorted as plastic, they can be a light-weight alternative to plastic bottles in certain applications. Both laminates can be used as energy waste. Laminate is a material that consists of several different layers that sit on top of each other. In plastic laminate all the layers are plastic while in plastic-paper laminate there are paper and plastic layers. In the light of the limited capacity to reuse laminate, these have a separate material factor of 1.1 which is to be used for plastic laminate. Decorative cosmetics are exempt, due to the complex nature of the packaging.

O28 Emballagematerial - Metall

Metal packaging may only be used in spray bottles/propellant bottles for hairstyling products and shaving foam.

Small metal parts, e.g. parts of a hand pump or sealing foil across the opening are permitted.

[166] (Plastindustrien i Danmark, 2010)

Metal parts are permitted in decorative cosmetics if the amount of metal does not exceed 15% of the weight of the packaging. Metal elements are permitted in decorative cosmetics if the combined weight of all the metal parts per individual product unit is less than or equal to 15 grammes. Mirrors are not permitted as part of the packaging.

☒ Appendix 8 or equivalent certification completed and signed.

☒ For metal packaging: Packaging sample/product sample/photo of packaging. Account of the content of metal in packaging for decorative cosmetics

Background to requirement O28

Plastic

PVC and other halogenated plastic is excluded due to unwanted environmental effects in the disposal of these types of plastic, and because they can contain substances with undesired health effects[167]. This is particularly true for stabilisers and softeners. In addition, some of the manufacturing techniques for manufacturing chlorine gas for the production of PVC can place more of a burden on the environment than other techniques.

The majority of bottles used for packaging chemical products consist of polypropylene (PP) or polyethylene (PE), but certain types of packaging can theoretically consist of PVC. Auraprint, which delivers labels for Finnish chemical producers, which has a Nordic Ecolabel licence, considers that the most common materials used in labels are PP, PE, PET and paper.[168] Auraprint has stopped making labels from PVC, and considers that most other producers have also stopped using PVC in labels. The risk of PVC in packaging especially for cosmetic products and PVC labels is considered to be so small that the requirement has been deleted.[169]

Paper, cardboard packaging or paper packaging

Bleaching with elemental chlorine releases a significant amount of chlorinated organic substances and dioxins in waste water. Due to this it has been banned from use in the Nordic countries since 1994. The alternative bleaching methods that replaced bleaching with elemental chlorine are TCF (totally chlorine free) and ECF (free from elemental chlorine). There is a very small risk that bleaching with elemental chlorine still takes place in other countries. For this reason the requirement banning the use of bleaching methods using elemental chlorine when manufacturing packaging for Nordic Ecolabelled cosmetics has been deleted.

Metal packaging

Metal spray bottles are usually used, e.g. for hair care products, shaving foam, etc.

Nordic Ecolabelling does not wish to exclude spray bottles in situations where they are needed and so totally exclude certain product types from Nordic Ecolabelling.

[167] (COMMISSION OF THE EUROPEAN COMMUNITIES, 2000)
[168] (Ääritalo, 2012)
[169] Examples of packaging in plastic: http://www.arcabox.it/en/pvc-pet-plastic-packaging.html# (website visited 3 December 2012)

New metal has considerably higher CO2 emissions (up to 95% more, depending on the metal and the process) and their production requires considerably larger amounts of energy (up to 95% more, depending on the metal and the process) than secondary metals (from scrap).[170] All use of metal, however, has an effect on the net use of new metal. Metals must therefore only be used where no other alternatives are available. As we see it, these areas of use are hair care products and shaving foam (foam and gel). Small pieces of metal such as sealing foil at the opening are also permitted.

The use of CFC and HCFC compounds as a propellant are limited in the Montreal Protocol on Substances that Deplete the Ozone Layer, which has been introduced in the EU through Regulation 2037/2000/EC. CFC and HCFC compounds are only permitted in certain specific functions (cosmetic packaging is not included). CFC compounds as a propellant have been replaced by hydrocarbons (e.g. N-Butane/Isobutane), dimethyl ether (DME), N2 or trans-1,3,3,3-Tetrafluoroprop-1-ene. Mixtures of propane and butane (LPG)m, Propane-butane and CO2 as well as Isobutane and DME are also used. In addition, F-gases (e.g. HFC-152a) have been used as a replacement for CFCs. The use of F-gases is also restricted in EU Regulation 842/2006/EC. Most of the fluorinated greenhouse gases identified in this regulation have a high global warming potential. Because these compounds are already banned, no requirements have been set on propellant gases.

The internal survey of decorative cosmetics carried out by Nordic Ecolabelling found that the majority of packaging contained metal for various reasons. To provide an opportunity to ecolabel a wide range of products, it has been decided to permit up to 15% metal in packaging. This would make it possible to stabilise the product without too high a use of metal. Mirrors are not permitted, however, as they are considered unnecessary and contribute a lot of extra metal and weight to the packaging.

Metal elements are permitted in decorative cosmetics if the combined weight of all the metal parts per individual product unit is less than or equal to 15 grammes.

Glass

Glass is a heavy material that is restricted by requirement O26 Amount of packaging. However, no particular requirements on glass have been set.

O29 Dosability/Dosing systems and emptying level

For liquid soap no pump or dispenser sold with the product may provide more than 2 g soap per full press

The emptying level must be 90% and must be calculated according to the formula and taking into account the emptying methods in Appendix 4.

✉ Description of dosing system and weighing results for liquid soap/industrial soap per full press.

✉ Documentation of emptying level according to Appendix 4

[170] (Metal Packaging Europe)

Background to requirement O29

Dosability

Over-dosing of the product increases its environmental impact but does not improve its efficiency. The requirement on dosability/dosing systems has been judged not to be steerable other than for liquid soap with a dispenser. For this reason the requirement has been deleted in version 3. The maximum dose at 1 press for liquid hand soap is the same as in version 2. The maximum dose is related to the CDV requirement (O19).

Emptying level

If a large amount of product remains in the packaging when it is thrown away, this results in great product wastage. To reduce this wastage a requirement on the emptying level of the product was introduced. According to a report from the Institute for European Environmental Policy the following help to minimise waste: a large opening, transparent packaging, opportunity to turn the packaging upside down and it being easy to close.[171]

According to the EU Ecolabel's technical report on criteria for cosmetics [172] there is however no universal truth on the matter and packaging must be adapted to different products and situations. Because there was no methodology on how the parameters such as product design and minimising the product remaining in the packaging can be defined, the EU Ecolabel developed its own system, which can also be used for Nordic Ecolabelling. The amount of product remaining in the packaging (R), which must be less than 10% is calculated using the following formula:

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

where:

m1= mass of primary packaging and product (g)

m2= mass of primary packaging and remainder of product in normal conditions (g)

m3= mass of empty and clean primary packaging (g)

Normal conditions are defined as:

Normal conditions of use are defined as:

- Tube: Applying pressure succesively on the body of the primary packaging until it appears to be empty. The test is considered complete when no amount of liquid will flow after five successive pressures on the body of the primary packaging in direct contact. Neither the cap is dismantled, nor water is introduced inside the packaging.

[171] (Institute for European Environmental Policy, 2004)
[172] (EU Ecolabel, 2013)

- Spray: Applying pressure succesively on the tip of the spray by pressing the spring down entirely. Wait until the spring has returned to its initial position prior to applying a new pressure. Repeat until no amount of product flows from the spray after five successive pressures. Neither the cap is dismantled, nor water is introduced inside the packaging
- Pot: The product is removed using the index and middle fingers carefully but relentlessly. Neither the cap is dismantled, nor water is introduced inside the packaging
- Vial/flask: The vial is turned upside down, with the cap in downward position. After the trickle is not continuous, the bottle is left in the same position for another two minutes. Neither the cap is dismantled, nor water is introduced inside the packaging
- If another type of packaging is used, the emptying method would be accepted by Nordic Ecolabelling.

The requirement is new and comments on it are requested in this consultation. The requirement is the same as for the EU Ecolabel.

4.6 Consumer information requirements

The purpose of the requirements on consumer information is to further reduce the environmental impact of the product and guarantee safe use for the consumer.

O30 Organic claims

If it is stated on the product that the product is/contains organic ingredients, EU Regulation 889/2008 on organic production must be complied with.

This is stated, for example, with an asterisk following the substance on the INCI list and with the following text: “Organic under EU 889/2008”

☒ Label

☒ Certificate of organic ingoing ingredients

Background to requirement O30

Cosmetics are often sold today with marketing claims on organic ingredients. For Nordic Ecolabelled products, these claims must be based on facts in order to maintain the trustworthiness of the ecolabel and the labelled products. Therefore it is required that cultivation complies with the EU’s Regulation 889/2008 on organic production, which must be documented by a certificate. The EU regulation only covers the labelling of food.

O31 Information text – Sunscreen

The recommended dosage of sunscreen must be stated and the sunscreen must bear the following or an equivalent information text on the label (according to 2006/647/EC, EU, 2006)

- “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.”

Contact Nordic Ecolabelling for information texts applicable for the country in question.

The labelling of a sunscreen product with its SPF factor must follow the European Commission recommendations of 22 September 2006 (EU, 2006). The product must be labelled with the following declaration:

- Sun protection factor 6 and 10: Low protection
- Sun protection factor 15, 20 and 25: Medium protection
- Sun protection factor 30 and 50: High protection
- Sun protection factor 50+: Very high protection

✉ Label or packaging sample.

Background to requirement O31

One common misconception among consumers is that sunscreen enables them to spend longer time in the sun, and that they are sufficiently protected. To increase consumer safety, they should be informed that the use of sunscreen is a good idea but that it is not the best protection against the harmful rays of the sun. In addition, many consumers do not know how much sunscreen they should use to attain the level of protection stated by the sun protection factor on the product. It is thus a requirement that Nordic Ecolabelled sunscreen bears a compulsory text drawing the attention of consumers to these points and providing dosage information. An exception is made for day cream/face cream with UV filters and low sun protection (SPF 6-10), where texts on dosage need not be given on the packaging while information on the SPF factor must be stated. Applies to hair products too??? The applicant can express these sentences in a different way as long as the content is clear and the meaning is retained. The above sentences are in line with the EU's general recommendations on efficiency and labelling of sunscreens[173]

O32 Information text - specific products

The following products:

- cleaning products, e.g. cleansing lotions and eye make-up remover
- nail varnish remover
- wet wipes

must bear the following or an equivalent information text on the label: "Do not discard product, cotton wool or paper carrying this product in the lavatory or drain. Dispose of in a rubbish bin instead." Pictograms are also accepted.

The following products:

- nail varnish
- nail varnish remover

must bear the following or an equivalent information text on the label: "Do not throw out-of-date/unwanted product in the lavatory, drain or rubbish bin. Please leave at a collection point for hazardous waste instead."

Contact Nordic Ecolabelling for information texts applicable for the country in question.

✉ Label or packaging sample.

[173] (EU, 2006)

Background to requirement O32

To reduce the effects of paper/cotton and cosmetic products in the aquatic environment and waste water treatment plants an information text is required about correct disposal of paper/cotton in the packaging. The same applies to material in wet wipes

Nail varnish and nail varnish remover contain solvents and should therefore be sorted as hazardous waste. Solvents used as a propellant in aerosols remain in the bottle when the product runs out and should therefore be sorted as hazardous waste. For this reason an information text is required advising correct handling when the packaging contains remains of the product. The requirement has not changed compared with the previous versions of the criteria.

4.7 Performance/quality requirements

O33 Performance/quality and marketing claims

The performance/quality of the product must be satisfactory. This can be demonstrated by sending in documentation according to Appendix 8. Tests must at a minimum test the characteristics with which the product is marketed, in terms of performance/quality. Cosmetics Europe's guidelines on "Efficacy Evaluation of Cosmetic Products" can be followed. For other test reports the information in Appendix 7 needs to be included.

If there is a recognised test (see, for example, K38 for sunscreen products) this must be used. For other products a test could be:

- The applicant's internal quality test, a consumer test with at least 10 independent testers, 80% of whom think the product is as good or better than the reference product.
- A test where comparisons are made with an equivalent product, e.g. a triangle test.
- For existing products that have been on the market for at least 3 years, sales figures can be used as documentation of the primary function. Sales must be increasing or stable to be used as documentation for the primary performance/quality.
- The product's properties/marketing claim can also be documented via the properties of the raw materials (with the exception of mild/gentle, etc.) see Appendix 7.

✉ Description of the documentation in line with Appendix 7.

✉ If an internal quality test is used, a copy of the test description, the results and the conclusion must be enclosed.

✉ If a consumer test is used, a copy of the completed and signed test reports must be sent in. In addition, a report that describes which and how many people were asked and a summary of the results must be enclosed. At least 8 out of 10 consumers must be satisfied with the product.

If sales figures are used, documentation for at least 3 years showing stable or rising sales must be enclosed.

If the properties of the raw materials are used for marketing claims, raw materials documentation must be enclosed.

Background to requirement O33

The performance/quality of Nordic Ecolabelled products must be satisfactory. Because cosmetic products covered by the criteria document cover so wide a range of different products and there are no international standardised tests in this area (with the exception of sunscreens), Nordic Ecolabelling has decided to leave the requirement as open as possible. Cosmetics Europe's (formerly Colipa's) guidelines for evaluating the performance of cosmetic products provide advice on what should be taken into account when products are evaluated using sensory tests on people, either by consumers or in expert panels/by experts. Guidelines are also given for laboratory tests, both for ex vivo and in vitro tests. Guidelines are also given on which information is to be included in the test procedure and in the test report. Cosmetics Europe's guidelines[174] can be followed as they meet the minimum requirements set. Appendix 8 sets out the minimum requirements made of test reports as documentation of the performance/quality of the products.

Cosmetics Europe's guidelines also state that substantiating cosmetic claims should be an integrated part of product development and design and should not be carried out after development merely to support communication of the product's performance and advantages. This is also the background to Nordic Ecolabelling's requirement that the test as a minimum includes testing of the properties that the product is marketed with.

Most cosmetic products state marketing claims praising the products' function and properties. The test should therefore cover the functions that the product is marketed for in addition to performance/quality. This ensures that claims of specific benefits offered by the products are documented and that the products do not give misleading information.

Where there is no standardised test, the evaluation is often subjective, e.g. in user tests. The background to the performance requirement is that the applicant demonstrates that they have made active efforts to judge the performance of the product. If a test panel is used, at least 10 people must test the product, which should then be assessed in comparison with a reference product. The marks from at least 80% of the testers should indicate that the product is as good as or better than the reference product. User tests for shampoo should at least assess capacity to clean and usability (dosage and how easy it is to spread on the hair). For skin cream, for example, tests should be carried out on how easy it is to spread on the skin and ability to moisturise the skin. A triangle test can also be used in which consumers/users test the product such that they use three products simultaneously; two of these products are identical and the third differs from the other two.

Documentation on the performance/quality of the ingredients is not sufficient to demonstrate product performance and quality but can be used to document a marketing claim. The following documentation can be used as documentation of the properties of ingredients and marketing claims:

[174] (Cosmetics Europe, 2008)

- Data sheets/product sheets/presentations of ingredients, which state who made the material and when
- Scientific articles and reports

In principle, all products that are Nordic Ecolabelled are gentle and mild, but there are differences between them. For example, there is less risk of allergy if a product is fragrance-free compared with a fragranced product, even if the Nordic Ecolabel sets strict requirements on fragrances. And a product that contains surfactants classified with H318 will sting more if it comes into contact with the eye, than a product without H318 classified surfactants. A product with a pH which is close to the skin's natural pH (4.7-6.5), will be seen as mild, while a product with a considerably lower or higher pH will be seen as less mild.

There are many types of claims made of cosmetic products and in conjunction with the revision, claims were investigated for 138 Nordic Ecolabelled products. Approximately 30% have no claims on the product's properties or function. Claims for the remaining 70% are categorised in groups stating whether the claim's effect must be documented.

Mild/gentle/safe/sensitive/minimal or minimises the risk of allergy (all types of product). This can be documented by expert assessment or by testing methods to document mildness, e.g. HET-CAM or a test for red blood cells (RBC test) (Brantom PG et al, 1997, Ronald E. Hester et al., 2006), and these tests or tests/expert assessments that give similar results should be used. Note that animal testing is not permitted. In RBC tests Nordic Ecolabelling accepts non-irritant and slightly irritant and in HET-CAM non-irritating and slightly irritating. Claims of "gentle/mild" and similar cannot be documented via a consumer test but can be shown, in addition to the above tests, by meeting the following three points:

- not containing fragrances
- containing < 10% surfactants classified with H318
- pH between 4 and 8.

The following properties/claims must be documented via the properties of the raw materials or alternatively the property can be asked about in a consumer test:

- Moisturising/silky smooth/moist
- Caring/kind to skin/cares/protecting/protects/skin protection/ maintains the skin's natural protective function/protects against damage/effective fluoride protection/protects against decay, tartar and gum problems/protects and strengthens tooth enamel and against decay
- Moisturising/retains the moisture balance/does not dry out/does not dry out the skin/hair/protects the skin's natural moisture balance
- Soothing/calming effect on the skin/counters irritation/soothes irritation
- Nourishes/strengthens/strengthens the mouth's own defences/strengthens hair/rebuilds (poor skin)/rebuilds fat and moisture balance/strong and flexible skin/regenerating (skin)/repair (skin)
- Shine/shining

- Longer lasting hair colour
- Self-tanning
- Water-resistant
- Effective against stretch marks
- Soothing/cooling
- Combats odour/sweat
- Smooths or removes dead skin cells

The following properties/claims must be documented via the applicants internal quality test or via consumer tests by asking about the properties:

- Washes clean
- Detangler
- Easy to brush out
- Stiffening
- Combats static electricity
- Natural volume
- Revitalising
- Healthy
- Long-lasting

For existing products that have been on the market for a long time, it is judged that the product has already undergone consumer testing by the consumers that have bought the product. Here sales figures can be used as documentation of the primary function. Primary function means what the product is designed for or the product's function. E.g. Shampoo - it must be expected that it washes hair clean, Conditioner – it must be expected that it makes hair soft and easy to detangle, Lotion/cream – it must be expected that it moisturises the skin, Deodorant - prevents the smell of sweat. Note that sales must have been ongoing for at least 3 years. Sales must be increasing or stable to be used as documentation for the primary performance/quality. Note that sales figures can only be used as documentation of the product's primary function and not as documentation of claims.

For many of the frequently used ingredients, the claims are well-known, which is why there is no need for further documentation of the properties and claims, see Appendix 7.

Special requirements for sunscreen products

O34 Performance, UVA and UVB

For sunscreen products it must be documented that Commission Recommendation of 22 September 2006, and Cosmetics Europe's guidelines are complied with in terms of effective protection against both UVB and UVA.

✉ Description of the test and test results.

Background to requirement O34

The performance requirement states that "available tests should be used where possible". This is relevant for sunscreen products and it is emphasised that the products are expected to meet the Commission's recommendation of 22

September 2006[175] on UVA and UVB protection, and other recommendations on labelling etc. plus the Cosmetics Europe guidelines.[176]

UVB test: To ensure reproducibility and comparability regarding the recommended minimum protection against UVB radiation, we recommend standard EN ISO 24444:2010 Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF)

UVA test: To assess minimum protection against UVA radiation, we recommend standard EN ISO 24443:2012 Cosmetics – Sun protection test methods – In vitro determination of sunscreen UVA photoprotection.

The UVB/UVA ratio can be determined with ISO 24443:2012 and Water resistance with Guidelines for Evaluation of Sun Product Water Resistance, COLIPA December 2005.

Test methods have been developed since version 2 and the background text now refers to the most recent test methods. An addition has been made to the text of the requirements stating that Cosmetics Europe's (formerly Colipa's) guidelines must be used

Special requirements for toothpaste

O35 Performance, fluoride

Toothpaste must contain fluoride in line with the national recommendations on fluoride content. If the toothpaste is fluoride free or has a lower fluoride content than recommended, there must be evidence that the effect is nevertheless equivalent to the effect of a fluoride toothpaste. This is documented through scientific publications, recommendations from experts (dentists) and in-vivo testing.

✉ Formulation or copy of publications, recommendations and test results as above.

Background to requirement O35

In recent years, toothpastes which do not contain fluoride and which are marketed as natural, environmentally friendly and/or good for the health have increased their market share. This is due to concern that a high fluoride intake causes fluorosis which is a developmental disruption in tooth enamel caused by chronic exposure to high fluoride content during tooth development, which leads to enamel with a lower mineral content and higher porosity.[177] Once teeth are fully developed, there is no risk. Fluorosis is often linked to fluoridation of water, which does not take place in the Nordic countries. The risks of chronic exposure to high amounts of fluoride at an early age is well documented.

However, it is also well documented that fluorine prevents caries[178] and in all the Nordic countries the respective dental organisations recommend using toothpaste that contains fluoride[179], although the amounts vary.

[175] (EU, 2006)
[176] (Cosmetics Europe, 2013)
[177] (Jenny Abanto Alvarez, 2009)
[178] e.g. (NHMRC (Australia), 2007)

It is therefore appropriate to require that toothpaste that is not intended for infants contains an amount of fluoride in line with the national recommendations as evidence of sufficient performance. Alternatively a level of protection equivalent to the recommended fluoride amount should be demonstrated for the same use of toothpastes without fluoride through scientific publications, approval for use by dentists and documented in-vivo testing.

4.8 Quality and regulatory requirements

Quality and regulatory requirements are general requirements that are always included in Nordic Ecolabelling's product criteria. The purpose of these is to ensure that fundamental quality assurance and applicable environmental requirements from the authorities are dealt with appropriately. They also ensure compliance with Nordic Ecolabelling's requirements for the product throughout the period of validity of the licence.

These requirements have been expanded/amended in line with the standard formulations in the criteria template.

O36 Responsible person and organisation

The company shall appoint individuals who are responsible for ensuring the fulfilment of Nordic Ecolabel requirements, for marketing and for finance, as well as a contact person for communications with Nordic Ecolabelling.

✉ Organisational chart showing who is responsible for the above.

O37 Documentation

The licensee must archive the documentation that is sent in with the application, or in a similar way maintain information in the Nordic Ecolabelling data system.

🔑 Checked on site as necessary.

O38 Quality of Cosmetic product

The licensee must guarantee that the quality of the Nordic Ecolabelled product does not deteriorate during the validity period of the licence.

✉ Procedures for archiving claims and, where necessary, dealing with claims and complaints regarding the quality of the Nordic Ecolabelled cosmetic products.

🔑 The claims archive is checked on site.

O39 Planned changes

Written notice must be given to Nordic Ecolabelling of planned changes in products and markets that have a bearing on Nordic Ecolabel requirements.

✉ Procedures detailing how planned changes in products and markets are handled.

O40 Unplanned nonconformities

Unplanned nonconformities that have a bearing on Nordic Ecolabel requirements must be reported to Nordic Ecolabelling in writing and journalled.

✉ Procedures detailing how unplanned nonconformities are handled.

[179] (Suomen hammaslääkäriliitto), (Sveriges Tandläkarförbund), (Tandlægeforeningen), (Den norske tannlegeforenings Tidende)

O41 Traceability

The licensee must be able to trace the Nordic Ecolabelled Cosmetic products in the production.

✉ Description of/procedures for the fulfilment of the requirement.

O42 Take-back system

Relevant national regulations, legislation and/or agreements within the sector regarding the recycling systems for products and packaging shall be met in the Nordic countries in which the Nordic Ecolabelled Cosmetic products are marketed.

✉ Declaration from the applicant regarding adherence to existing recycling/take-back agreements.

O43 Legislation and regulations

The licensee shall ensure compliance with all applicable local laws and provisions at all production facilities for the Nordic Ecolabelled product, e.g. with regard to safety, working environment, environmental legislation and site-specific terms/permits.

✉ Applications must state which supervisory authorities they are covered by, and the plant-specific conditions and environmental permits issued by the authorities.

✉ Duly signed application form.

🔑 The requirement is checked on site.

5 Changes compared to previous version

The main changes compared with the previous version are:

- Requirements on renewable raw materials
- New substances added to the list of prohibited substances
- Ban on nano UV filters
- Restriction on the use of phenoxyethanol in children's products
- Restriction on aluminium in leave on products
- Stricter packaging requirements
- New requirement on the residual amount of the product in the container after use
- CDV can be calculated based on the DID list from 2014

Additional changes are listed in Table 3 below.

Table 3 Overview of changes to criteria for cosmetics version 3 compared with previous version 2.

Proposed requirement version 3	Requirement Version 2	Same require ment	Change	New require ment	Comment
Product group definition	Product group definition		x		clearer definition, no real changes. Tighter limit on impurities at raw material level.
O1 Description of the product and INCI list	R1		X		Description of the product added to the requirement
O2 SCCS	R4	X			

O3 Sustainable raw materials	-			X	Requirement on origin of palm oil in surfactants and emollients
O4 Classification of ingoing substances	R2	X			-
O5 New substances added to the list of prohibited substances	R5		X		New substances added to the list of prohibited substances
O6 Nano	R6		X		Nano prohibited with exception only for silica as an abrasive in toothpaste
O7 Surfactants	R7		X?		Softeners no longer exempt?
O8 Fragrances	R13	X			-
O9 Fragrances	R14		X		Flavourings allowed in children's toothpaste
O10 Fragrances	R15		X		New fragrances that must be declared
O11 Colours	R11	X			-
O12 Metals in colours	R12		X		Requirements on metal now only apply to decorative cosmetics and hair dye
O13 Enzymes	R21		X		The requirement has been modernised to bring it into line with other criteria and the latest information from the industry
O14 Preservatives	R16+17		X		The requirements have been merged restriction on phenoxyethanol added
O15 UV filters	K18+K19		X		The requirements on UV filters have been merged and chronic toxicity values can be used
O16 Polymers	R20		X		The requirement has been harmonised with other criteria and with CLP and new risk statements have been added
O17 Environmentally hazardous substances			X		The level of the requirement on environmentally hazardous substances is the same. The requirement has been harmonised with CLP
O18 aNBO and anNBO (rinse-off)	R8		X		The requirement level is the same, also refers to DID 2014, opportunity to use dose remains only for liquid soap
O19 CDV (rinse-off)	R9		X		The requirement level has been increased slightly, DID list from 2014 can be used. Opportunity to use dose remains only for liquid soap
O20 Degradability and toxicity (leave-on)	R10				The requirement level is the same but chronic values can be used in line with the CDV requirement.
O21 Solid soap	R22	X			-
O22 Lip products, toothpaste and oral hygiene products	R23		X		Opportunity to use declaration for flavourings deleted, approved flavourings now listed in EU
O23 Hair dye	R24	X			-

O24 Hygiene products, wet wipes	R25		X		The requirement has been modified with new criteria versions and it is clearer which requirements in these apply
O25 ”Rinse off” products for animals	R26	X			-
O26 Amount of packaging			X		Level of requirement (packaging calculation) considerably higher. More than one layer of packaging is only permitted where more than 1 product/unit are sold together.
O27 Type of packaging	R28		X		Interpretation on plastic-paper laminate included
O28 Packaging material	K29, K30, K31	X			The requirements have been merged The requirements on DIN labelling, PVC and chlorine bleaching have been removed
O29 Dosability/Dosing systems and emptying level	R32		X		Emptying level is a new requirement, dosability requirement has been deleted
O31 Organic claims	R36	X			-
O32 Information test – Sunscreen	R35	X			-
O33 Information text - specific products	R34	X			-
O34 Performance/quality and marketing claims	R37		X		It has been specified which claims must be documented and how
O35 Performance, UVA and UVB	R38	X			-
O36 Performance, fluorine	R39	X			-
O37-O41 Quality and regulatory requirements	K40-K46		X		Small adjustments in line with the criteria template
-	R33		X		Requirement on declaration of contents removed
-	K48				Requirement on marketing removed

6 New Criteria

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Appendix 1 History of the criteriadocuments of soaps and shampoos and cosmetics

These are available in Swedish.

Appendix 2 MEKA-Schema

These are available in Swedish.

Appendix 3 Minimum requirements for the content in test reports as documentation of performance/quality and raw materials documentation for marketing claims

The product group covers a large number of different products and it is therefore not possible to write a concrete requirement specifying what a test report is supposed to look like. This appendix describes the minimum information required in a test report. The test can be performed as a user test or as a laboratory test, see below for the information required for each test.

Test reports following Cosmetics Europe's guidelines "Guideline for Efficacy Evaluation of Cosmetic Products" are always considered to fulfil the requirement for a test report.

For existing products that have been on the market for a long time, it is judged that the product has already undergone consumer testing by the consumers that have bought the product. Here sales figures can be used as documentation of the primary function, see below under section 3 "Sales figures".

1. User test

Points to be described in the report

- When was the test performed?
- Who performed the test?
- Who ordered the test?
- Which products were tested?
- How were the testers chosen?
- How many testers participated in the test?
- What parameters/properties were tested? Why were they chosen?
    - Primary function
    - Secondary function
    - Claim
- Test results
- Conclusions of the test

Note that the test shall be a consumer test with at least 10 independent testers. At least 80% of the testers must be satisfied with the performance/quality. This applies for each individual parameter in the test. It is therefore important to describe why each testing parameter/property has been included in the test. Some parameters/properties may have been included in the test for reasons other than performance (e.g. the scent of the product or similar).

The test needs to have a conclusion. This must clearly state how the results of the test document each individual test parameter/property.

Claims saying that the product is mild/gentle and similar can also be demonstrated by means of a user test. The claim can be documented by expert assessment or by testing methods to document mildness, e.g. HET-CAM or a test for red blood cells (RBC test) (Brantom PG et al, 1997, Ronald E. Hester et al., 2006), and these tests or tests/expert assessments that give similar results should be used. Note that animal testing is not permitted. In RBC tests Nordic Ecolabelling accepts non-irritant and slightly irritant and in HET-CAM non-irritating and slightly irritating. Claims of "gentle/mild" and similar can alternatively be shown by the product meeting the following three points:

- not containing fragrances
- containing < 10% surfactants classified with H318
- pH between 4 and 8.

2. Laboratory test

Points to be described in the report

- When was the test performed?
- Who performed the test?
- Who ordered the test?
- Which products were tested?
- How was the test method chosen and how can it be used to document the product's performance/quality?
- What parameters/properties were tested? Why were they chosen?
    - Primary function
    - Secondary function
    - Claim
- Test results
- Conclusions of the test

Note that the test needs to have a conclusion. This must clearly state how the results of the test document each individual test parameter/property.

3. Sales figures

Points to be described in the report

For existing products that have been on the market for a long time, it is judged that the product has already undergone consumer testing by the consumers that have bought the product. Here sales figures numbers can be used as documentation of primary performance, provided that the product has been on the market without changes in the recipe in relation to the product for which a Nordic Ecolabelling licence has been applied.

- What time period is covered by sales of the product?
- Are the sales figures in volume, number of products or in price?
- Conclusions of the summary

Note that sales must have been ongoing for at least 3 years. Sales must be increasing or stable to be used as documentation for the primary performance/quality.

Note that sales figures can only be used as documentation of the product's primary function and not as documentation of claims.

A conclusion is required for the sales figures. It must be clear how the sales figures document the primary performance/quality. If there are fluctuations in the sales figures, they need to be satisfactorily explained.

4. Raw materials documentation

The following documentation can be used to document the properties of the raw materials and marketing claims:

- Data sheet/product sheet/presentations of raw materials showing who produced the material and when
- Scientific articles and reports

For the following raw materials and claims, no documentation is required as the properties of the raw materials are well-known:

Raw material/substance	Property
Glycerine	Moisturiser
Aloe Vera	Moisturising, anti-aging, soothing, regenerating, moisture-retaining
Tocopherol	antioxidant
Jojoba oil	moisturising
Lactic acid	moisturising (humectant)
Creatine	skincare
Collagen	haircare, skincare
Panthenol	skincare, moisturising
Allantoin	Moisturising, reduces skin irritation
Bisabolol	soothing effect

Blueberries	antioxidant
Sea buckthorn	antioxidant
Camomile	soothing effect
Caprylic/Capric triglyceride	Moisturising
Shea butter	moisturising, elasticity, UV protection, anti-inflammatory
Beeswax (Cera Alba)	Provides a protective layer
Eucalyptus	antibacterial, stimulates the immune system.
Menthol	cooling
Camphor	cooling effect, healing extremely dry or broken skin
Oils	moisturising
Wheat extract	Moisturising
Keratin	protein for skin and nails
Ethanol	cooling
Aluminium chlorhydrate	rapid penetration
Polyacrylate	Gives hair hold
Chlorhydrate	antiperspirant