About Nordic Swan Ecolabelled

Cosmetic products

Generation 4 • 04 November 2024 – 28 February 2030

Nordic Ecolabelling

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090 Cosmetic products, version 4.7, 10 February 2026

Contact information

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

Denmark
Ecolabelling Denmark
www.svanemaerket.dk

Finland
Ecolabelling Finland
https://joutsenmerkki.fi/

Sweden
Ecolabelling Sweden
www.svanen.se

Iceland
Ecolabelling Iceland
www.svanurinn.is

Norway
Ecolabelling Norway
www.svanemerket.no

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1 Summary

This background document contains a brief description of the product group, the impact of cosmetic products on health and the environment, 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, including wet wipes. Also, animal care, sex lubricants and medical lubricants are included even though they are not covered by the Cosmetics Regulation.

Cosmetic products affect the environment over the whole of their life cycle, but life cycle assessments show that the selection of ingredients has a higher environmental impact than the water and energy consumption from the manufacturing of ingoing substances and the cosmetic product. The impact from the ingredients is both from the raw material phase and the end-of-life phase. After use, cosmetic products and their ingoing substances can end up in the environment, and risk harming aquatic organism and the ecosystem. Properties, like biodegradability, bioaccumulability and aquatic toxicity are therefore of great importance for all ingredients.

As cosmetic products are being applied directly to the body, and for leave-on products being completely absorbed into the body, properties like carcinogenic, toxic to reproduction, and allergenic/sensitising are of great importance too.

Packaging also has a high impact on the environment from the consumption of energy and fossil resources, and it is therefore important to lower the total amount of packaging being used, and to ensure that the packaging is designed for recycling. Emissions of hazardous, non-degradable and/or bioaccumulative substances in the environment, which place a burden on treatment works and/or recipients.

This version of the criteria contains a number of changes compared with version 3. The main changes in this version are as follows:

- Palm oil/palm kernel oil must be RSPO certified with trace level Mass Balance or higher
- The new EUH hazard classes for endocrine disruptors, PBT/vPvB, and PMT/vPvM are added to the prohibited classifications along with H410, M>1.
- Updated definition on microplastics and endocrine disruptors.
- The exemption for anaerobic degradation of surfactants for emollients and emulsifiers now only applies to emulsifiers in leave-on products
- Requirement for amount of allergenic fragrance in the product is adjusted to the updated list of regulated fragrances in the Cosmetic Regulation.
- Preservatives must be readily aerobically biodegradable.
- In the requirements for environmentally hazardous substances, surfactants are no longer exempted.
- CDV must be calculated based on the DID-list 2023 or later versions.
- Wet wipes can no longer contain plastic fibres.

- Medical examination lubricants are now included in the product group.
- New requirements have been introduced for primary packaging concerning the packaging's recyclability and design for recycling.

For a full list of changes, see section 6 Changes compared to previous generation.

2 Environmental impact of cosmetic products

The table below shows an overall analysis of the product group in terms of RPS (Relevance, Potential and Steerability). Relevance is assessed based on which environmental problems the product group causes and how extensive those problems are. Potential is assessed in terms of potential for reducing the environmental impact. Steerability is assessed based on the extent to which the Nordic Swan Ecolabel can contribute to a positive change and how this can be verified. The analysis is prepared based on available life cycle assessments and other relevant publications[1,2,3,4].

Table 1 Analysis of the product group in terms of RPS

Lifecycle stages	Area and assessment of R, P, S (high, medium or low)	Comments
Raw materials		
	Fossil oil or plant materials (palm oil etc.) for production of chemical raw materials R: High P: Medium S: High RPS: High	R is high due to a large consumption of energy and fossil resources, and non-sustainable extraction of renewable raw materials. P is medium. There is no potential for minimising the use of fossil resources for chemical raw materials, due to the lack of available renewable raw materials, but there is a potential for excluding plastic fibres in wet wipes and for minimising the negative impacts of extraction of palm oil. S is high as requirements for RSPO certified palm oil origin can be set together with a supply chain policy and code of conduct and plast fibres in wet wipes can be prohibited.
	Plastic and other packaging raw materials R: High P: High S: High RPS: High	R is high due to a large consumption of energy and fossil resources. P is high as the use of too much packaging and non-compatible packaging components is widespread, so there is a potential to limit the total amount of packaging and to promote design for recycling. S is high as requirements can be set for the total amount of packaging, the type of packaging and the combination of packaging materials that enables emptying and recycling.

[1] Herron, S., Life Cycle Impact Study of Leave-on Skin Care Products, 2013, www.sustainabilityconsortium.org

[2] Koehler, A. et. a., Comparing the Environmental Footprints of Home-Care and Personal-Hygiene Products: The Relevance of Different Life-Cycle Phases, 2009, Environ. Sci. Technol, 43, 8643–8651

[3] Cosmetics Design Europe, Croda announces RSPO certification for cosmetics ingredient factories in India and Brazil, 2014, Cosmetics Design Europe

[4] Secchi, M. et. al., Assessing eco-innovations in green chemistry: Life Cycle Assesment (LCA) of a cosmetic product with a bio-based ingredient, 2016, Journal of Cleaner Production, 129, 269-281.

Production/distribution		
	Water and electrical consumption for production of packaging and cosmetic product R: Medium P: Medium S: Low RPS: Low	R is is medium due to consumption of energy and fossil ressources. P is medium as there is a potential to limit the use on non-renewable energy and to lower emissions from production. S is low as the production facilities often manufacture both Nordic Swan Ecolabelled and non-Nordic Swan Ecolabelled products on the same production line.
	Transportation from production to retail and to consumers R: Medium P: High S: Low PRS: Medium	R is medium due to consumption of fossil ressources for fuel and particulate matter and emissions from distribution vehicles P is high as there is a potential to limit the use on non-renewable energy and to lower emissions from trucks. S is low as distribution is carried out by external companies transporting both Nordic Swan Ecolabelled and non-Nordic Swan Ecolabelled products.
Use phase		
	Water and electrical consumption when using the cosmetic product R: High P: Medium S: Low RPS: Medium	R is high due to the use of water and consumption of energy and fossil ressources for heating of water. P is medium as the use of water can be minimsed, but there is limited potential for the consumers to limit the use of energy for heating of water. S is low as energy used for heating of water is not controlled by the consumers.
	Exposure of chemicals harmful to health R: High P: High S: High RPS: High	R is high due to consumers being exposed to chemicals that are harmful to health P is high as the is a potential to limit or exclude ingredients with negative impact on health, like allergens, endocrine disruptors and microplastic which are not sufficiently regulated by the Cosmetic Regulation. There is also a potential to limit overdosing and thereby minimising the exposure. S is high as requirements to prohibit or strongly limit problematic substances can be set. The amount of products used can be limited by clear instructions for use, and for some product types requirements for maximum dosage pr. pump stroke can be set.
End of life		
	Water and electrical consumption for waste water treatment R: Medium P: Low S: Low RPS: Low	R is is medium due to consumption of energy and fossil essources. P is low as there is no potential for the licensees to limit the use on non-renewable energy. S is low as the sewage treatment plants are run by the public sector and they handle waste from both Nordic Swan Ecolabelled and non-Nordic Swan Ecolabelled products together.
	Packaging disposal (incineration, reuse or recycling) R: Medium P: High S: High RPS: High	R is medium due to consumption of energy and fossil resources. P is high as the use of too much packaging and non-compatible packaging components is widespread, so there is a potential to limit the total amount of packaging and to promote design for recycling. S is high as requirements can be set for the total amount of packaging, the type of packaging and the combination of packaging materials that enables emptying and recycling.
	Product emissions from use (degradability and toxicity to aquatic organisms) R: High P: High S: High RPS: High	R is high as cosmetic products and their ingredients can all end up in the environment affecting biodiversity, even though they might take different routes. Cosmetic products therefore risk harming both aquatic organism and the ecosystem, depending on the intrinsic properties of the ingredients. P is high as there is a potential to reduce the content of environmentally hazardous ingredients like, substances toxic to aquatic organism, non-degradable substances, microplastics, endocrine disruptors etc. S is high as requirements to prohibit or strongly limit problematic substances can be set.

Cosmetic products affect the environment over the whole of their life cycle, but life cycle assessments show that the selection of ingredients has a higher environmental impact than the water and energy consumption from the manufacturing of ingoing substances and the cosmetic product[2,3,5]. The impact from the ingredients is both from the raw material phase and the end-of-life phase.

Both renewable and non-renewable organic ingredients are used for cosmetic products, as well as raw materials that are synthesised from both renewable and non-renewable sources. In the long term, the amount of non-renewable materials is limited since they are extracted from fossil oil. Renewable materials, on the other hand, are replenished through natural processes, but it is important that they are produced sustainably to reduce their environmental impact. Possible negative effects of non-sustainable production of renewable materials include the use of environmentally harmful pesticides, genetic modification and use of land that was originally a key biotope, such as rainforest, or that could have been used for food production.

After use, cosmetic products and their ingoing substances can end up in the environment, and risk harming aquatic organism and the ecosystem. Properties, like biodegradability, bioaccumulability and aquatic toxicity are therefore of great importance for all ingredients.

As cosmetic products are being applied directly to the body, and for leave-on products being completely absorbed into the body, properties like carcinogenic, toxic to reproduction, and allergenic/sensitising are of great importance too.

Packaging also has a high impact on the environment from the consumption of energy and fossil resources, and it is therefore important to lower the total amount of packaging being used, and to ensure that the packaging is designed for recycling.

3 Other labels

Type 1 ecolabels

EU Ecolabel[5]

The EU Ecolabel was established in 1992. It has publicly available criteria that includes both leave-on and rinse-off products. The criteria exclude certain problematic ingredients and classifications, and have similar CDV, aNBO and anNBO requirements to the Nordic Swan Ecolabel. The criteria also include requirements on packaging and sustainable sourcing of palm oil.

Good Environmental Choice (Bra Miljöval)[6]

Good Environmental Choise (Bra Miljöval) was established in 1990 by the Swedish Association for Nature Conservation. It has publicly available criteria for chemical products and approval for all types of cosmetic products can be given through this

[5] https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel-home_en
[6] www.bramiljoval.se

document. The criteria exclude certain problematic ingredients and classifications. The criteria also include requirements on water content and packaging, and general requirements governing the companies that manufacture these products.

Other private labels

Asthma Allergy Nordic[7]

Asthma Allergy Nordic was established in 2018 as is a nordic label when the national Asthma Allergy associations in the nordic countries joined forces. The focus is solely minimising the risk of developing skin allergies. It has publicly available criteria and labels cosmetic products, but products are still assessed on a case-by-case basis by allergy experts. Perfumes and allergens are not permitted.

AllergyCertified[8]

AllergyCertified was launched in 2014 as a competitor to the Nordic Asthma and Allergy Association labelling systems. AllergyCertified is a global label. Products are assessed on a case-by-case basis by allergy experts. The complete criteria for awarding the label are not publicly available but fragrances and allergens are not permitted.

Ecocert COSMOS Organic[9]

Ecocert was established in France in 1991 and since 2011 part of the COSMOS standard for organic products. COSMOS is a European standard for organically certified cosmetics, that is used in more than 70 countries. Behind COSMOS are five organic labelling schemes that together have created one common organic label to help obtain the Ecocert COSMOS Organic label. 95% of the product's plant-based ingredients must be organic, while at least 20% of all ingredients must be organic (10% for rinse-off products).

Vegan[10]

The Vegan trademark was established in 1990 and covers cosmetic products. According to The Vegan Trademark they are the oldest, largest, and original vegan verification scheme, managed by a team of vegan experts to give brands and consumers alike confidence in their purchasing decisions. The criteria are not publicly available.

4 Justification for requirements

This chapter explains the background to the requirements and the chosen requirement levels. The appendices referred to are those that appear in the criteria document “Nordic Swan Ecolabelling of cosmetic products".

[7] www.asthmaallergynordic.com
[8] www.allergycertified.com
[9] www.ecocert.com/en/certification-detail/natural-and-organic-cosmetics-cosmos
[10] https://www.vegansociety.com/the-vegan-trademark

4.1 Definition of the product group

All cosmetic products covered by the EU Cosmetics Regulation with subsequent amendments, such as skin care products, hair care products, decorative cosmetics, perfumes, and hygiene products can be Nordic Swan 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. Washing up liquid with added skin protection, perfumed toilet paper or tissues with lotion, for example, do not meet the above criteria and are not included in the definition.

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 Swan Ecolabelled.

Wet wipes can be Nordic Swan Ecolabelled even if there is only lotion in the product, which is covered by the Cosmetics Regulation. Animal care products can be Nordic Swan Ecolabelled although these are not covered by the Cosmetics Regulation.

Lubricants for medical purposes (such as medical examinations with or without e.g. an ultrasound probe) as well as lubricants marketed as “sex products” (such as lube, anal creams, and orgasm gels) can be Nordic Swan Ecolabelled when their formulations are similar to cosmetic products. Lubricants for medical purposes are part of the scope of the Medical Device Regulation, which can also be the case for “sex products”.

Products covered by the Biocides Regulation 528/2012 cannot be Nordic Swan Ecolabelled. Products that are marketed as being antibacterial, antimicrobial, antiseptic and/or disinfectant or claim to have ingredients that have these properties cannot be Nordic Swan Ecolabelled, as this does not comply with the Biocides Regulation 528/2012.

4.2 General requirements

Unless, otherwise stated, the requirements in the criteria document and accompanying appendices apply to all ingoing substances in the Nordic Swan Ecolabelled product, and impurities are exempted from the requirements.

Background to requirement O1 Description of the product

A description of the product (e.g., label) and its areas of use is required to assess whether the product falls within the product group definition. Nordic Ecolabelling needs to know the complete formulation, with all ingoing raw materials. This is necessary to control the individual requirements below and make the calculations necessary in respect of each requirement.

Background to requirement O2 SCCS

The EU's Scientific Committee on Consumer Safety (SCCS) has published many 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.

Background to requirement O3 Supply chain policy and code of conduct

Supply chain management is the handling of the entire process of turning raw materials into a final product. Supply chain policy reflects the companies' requirements and responsibilities for sourcing raw materials along the whole supply chain. This applies both to renewable raw materials and minerals like for instance MICA. The policy must describe how the company sees to respect human rights, compliance with local and international laws and regulations (deforestation risks (EUDR[11]), environmental, health and safety) along the whole supply chain. The policy must also describe the governance processes in place for Due Diligence especially for assessing biodiversity and deforestation risk in the supply chain.

The licensee must in addition also present its supplier Code of Conduct that defines and describes what is expected and required of suppliers in the supply chain. The supply chain policy and code of conduct must be both public and communicated to the supply chain.

The requirement for supply chain management reflects new EU legislation, e.g., due diligence directive (draft proposal) and new forest deforestation legislation, and how commodity companies work today. The EU due diligence directive applies at first hand to companies with +250 employees. Nordic Ecolabelling supports the new legislation but recognizes that this can be a huge workload for small businesses. Companies with less than 10 employees are therefore exempted from the requirement.

Background to requirement O4 Certified raw materials from oil palms

Palm oil plantations are often established at the expense of tropical rainforest and other protected areas. This is one of the biggest threats to biodiversity in Southeast Asia, leading to the loss of valuable species, habitats, ecosystems, and landscapes. Hence, palm oil is part of EU´s Regulation on deforestation-free products.

Palm oil is widely used as an ingredient or feedstock for chemical substances and therefore difficult to exclude in NSE products. Therefore, if palm oil is used in the product the palm oil/palm kernel oil, including by-products or residues, must be RSPO certified. Traceability must be ensured by Mass Balance, Segregated, or Identity Preserved. Book and claim are not accepted as there are no link between the claim for certified palm oil and the product itself.

The manufacturer or supplier of palm oil must present a valid RSPO Supply chain certificate (RSPO SCC certificate). The certificate/RSPO schemes ensures and controls the flow of certified claims throughout the supply chain. The manufacturer of

[11] https://green-business.ec.europa.eu/deforestation-regulation-implementation_en (visited August 2024)

the Nordic Swan Ecolabelled product must by request present invoices/delivery notes/order confirmation that the palm oil purchased is RSPO certified. The type of traceability (Mass Balance, Segregated or Identity Preserved) must be apparent from the documentation.

In cases where the Manufacturer of the Nordic Swan Ecolabelled product is RSPO Supply chain certified, the applicant must by request present a third party-controlled balance sheet showing RSPO certified raw materials being accounted/recorded to the Nordic Swan Ecolabelled product(s). This to ensure that RPSO raw materials (credits) are used in the Nordic Swan Ecolabelled product(s).

Background to requirement O5 Classification of ingoing substances

Excluding carcinogenic, mutagenic, reproduction toxic (CMR), sensitizing substances and endocrine disruptors is an important parameter from a health perspective. For products that can be partly ingested, this also applies to substances that are fatal if swallowed. The list includes classifications that are standard to include in all product groups if we do not get information that they are irrelevant, as we apply the precautionary principle. In that way we include unknown or new problematic ingoing substances or impurities that might be present in cosmetic products.

Enzymes are used in toothpaste, for example. Enzymes that are in liquid form or in solid form as granulates and not used in spray products 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”, and they can therefore be exempted.

Tocopherol and tocopherol acetate are often used as antioxidants in leave-on products. Nordic Ecolabelling has been in dialogue with chemicals producers and experts in the allergy field and checked it with ECHA. In the light of this, tocopherol, and tocopherol acetate are judged not to be allergens, although certain raw materials suppliers classify them with H317.

Amidoamines up to 1% of the active betaine active content is allowed in betaine raw materials, as it is technically unavoidable and without risk in this concentration according to the Asthma and Allergy Nordic.

When classifying a substance as chronic aquatic toxicity category 1, it is mandatory to indicate an appropriate M-factor as stated in the CLP Regulation (EC) No 1272/2008. Nordic Ecolabelling has decided to not allow the most toxic substances in this category with M>1 (i.e., LC50 or EC50 < 0,1 mg/1).

The new CLP classifications is included to align with the European Green Deal's goal of a toxic-free environment. This inclusion reflects the need to establish hazard identification for endocrine disruptors and addresses criteria for environmental toxicity, persistency, mobility, and bioaccumulation. Additionally, the inclusion of PMT and vPvM substances is crucial due to their persistence, mobility, and potential impact on water quality. Nordic Ecolabelling aims for comprehensive hazard identification and protection of the environment and human health.

Background to requirement O6 Microplastics

Microplastics[12] are very small fragments of plastic material, less than 5 mm. They can be harmful to health and the environment due to their size, surface properties and resistance to degradation. They have been found at sea in sediments, sludge from water treatment plants, agricultural soil, Arctic Sea ice as well as Antarctic freshwaters. Microplastics have been detected in various aquatic organisms across the food chain, from zooplankton to vertebrates, and in organisms in the soil. Currently, there are insufficient scientific knowledge and disagreement about the effects of microplastics, especially under natural conditions. Nordic Ecolabelling applies the precautionary principle and strives to limit the use of microplastics where possible.

In cosmetics microplastics are used for example for exfoliation and cleansing (microbeads) and for opacity control, smooth and silky feeling, illumination of the skin and viscosity control[13]. They can be used both in rinse-off and leave-on products, in for example shampoos, soaps, lotions, lipstick and powders and as a carrier for other ingredients[14].

Nordic Ecolabelling is concerned about consequences when microplastics are released into the environment, for example through bathing and showering, and laundering of towels, clothes and linen soiled with cosmetic products. Thus, we do not apply the derogations in paragraph 4 and 5 of Annex XVII to the REACH Regulation (EC) No 1907/2006 when excluding microplastics.

Nordic Ecolabelling is aware that replacing film formers and other ingredients that are microplastics in sun screen products is challenging, and that reformulations and testing of sun screen products is very time consuming. Therefore sunscreen products are exempted from the requirement until October 17, 2029.

A specific type of gel-forming ingredients, commonly referred to as carbomers, are used in many leave-on products and they are also very challenging to replace. Therefore an exemption has been introduced for high-molecular-weight crosslinked acrylate-based polymers that function as rheology modifiers/thickeners (e.g. carbomers and acrylates/C10-30 alkyl Acrylate Crosspolymer) in leave-on products until 17. October 2029.

Background to requirement O7 Excluded substances

There are several problematic substances and substance groups that are difficult to exclude through general requirements concerning the product's chemistry. Nordic Ecolabelling has compiled a list of the substances that must not be present as ingoing substances in the ecolabelled product. The aim of the list is to prohibit substances that are not excluded through other requirements but are associated with environmental and health hazards. Some substances are included in the list for the

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[12] Nordic Swan Ecolabel webtext: https://www.nordic-swan-ecolabel.org/nordic-ecolabelling/environmental-aspects/chemicals-nano-microplastic/microplastics/

[13] Lamprini A. et al. Worldwide actions against plastic pollution from microbeads and microplastics in cosmetics focusing on European policies. Has the issue been handled effectively? Marine Pollution Bulletin Volume 162, January 2021, 111883. https://doi.org/10.1016/j.marpolbul.2020.111883.

[14] European Chemicals Agency (2019) Annex XV Restriction Report. Proposal for a restriction.

sake of clarity, even though they are prohibited under other requirements. The list includes substances that are standard to include in all product groups if we do not get information that they are irrelevant, as we apply the precautionary principle. In that way we include unknown or new problematic ingoing substances or impurities that might be present in cosmetic products.

1,4-dioxane (CAS No. 123-91-1)

1,4-dioxane is an SVHC and meets the classification of carcinogenic, because of this, SCCS recommend that trace levels should not exceed 10 ppm in the final cosmetic product[15]. However, foremost it is of concern because of its PMT properties, leaning to easy distribution in the aquatic environment eventually ending up in drinking water. Because of this, the state of New York limits the amount of 1,4-dioxane to 1 ppm in rinse-of products and 10 ppm leave-on products[16] and the German competent authority for Reach has a proposal for restriction under Reach to limit trace levels of 1,4-dioxane to 1,0 mg/kg in the surfactant active matter. This is because the impurity of 1,4 dioxane is mainly present in organic surfactants. The German proposal targets the surfactant raw materials as the manufacturing is identified as the major source of emissions.

Alkylphenols (AP), alkylphenol ethoxylates (APEO) and other alkylphenol derivates (APD)

Alkylphenols is a group of mainly non-ionic surfactants that are produced in large volumes and their use leads to widespread release to the aquatic environment. APEOs are highly toxic to aquatic organisms and degrade to more environmentally persistent compounds (APDs). Ethoxylated nonylphenol and several other alkylphenols are included in the Candidate List due to endocrine disrupting properties. Other alkylphenols are polyalkylated phenols such as butylated hydroxytoluene (BHT) and butylated hydroxyanisole (BHA) which have antioxidant properties. An exception is made for BHT in perfumes with the limit of ≤100 ppm provided that the amount in the cosmetic products does not exceed 1 ppm. This exemption is made since BHT is used to ensure the stability of the perfume mixture which can affect the stability of the entire product.

Bisphenols and bisphenol derivatives

Several bisphenols with the general bisphenol structure and bisphenol derivatives which have constituents with structural properties common to bisphenols are now prohibited. Based on the potential for widespread use and available information on potential endocrine disruptors, reproductive toxicity and PBT/vPvB properties, the following 34 substances were identified in need for further regulatory risk management in EU[17]: 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5

[15] SCCS (Scientific Committee on Consumer Safety), Opinion on the Report of the ICCR Working Group: Considerations on Acceptable Trace Level of 1,4-Dioxane in Cosmetic Products, 15 December 2015, SCCS/1570/15

[16] Environmental Conservation (ENV) CHAPTER 43-B, ARTICLE 37, SECTION 37-0117 Prohibition of cosmetic products and personal care products containing 1,4-dioxane or mercury, The New York State Senate, 2023

[17] Annex XV restriction report https://echa.europa.eu/documents/10162/450ca46b-493f-fd0c-afec-c3aea39de487

(BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS, 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA).

Benzalkonium chloride

Benzalkonium chlorides (BACs) is part of a group of chemicals with wide applications due to their antimicrobial properties against bacteria, fungi and viruses. There is a risk that frequent and widespread use of BACs in commercial products can generative selective environments for microbes and contribute to resistance to antibiotics. Furthermore, there is a risk to consumer exposure due to their toxicity and allergenic properties.

Boric acid, borates, and perborates

Boric acid, borates and perborates have many uses, such as stain removal, oxidizing and bleaching agents. In cosmetic products they are used as oxidisers and buffers in oral hygiene products and as whiteners. They are classified as toxic to reproduction and poses a risk to consumers.

Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts.

Ethylenediaminetetraacetic acid (EDTA) and diethylenetriamine pentaacetate (DTPA) is used in many products such as liquid soaps and other cosmetics to improve stability. EDTA, DTPA and their salts are not readily degradable, furthermore, they are both classified toxic for reproduction and poses a risk to consumers. for EDTA, the EU’s risk assessment states that under the conditions at municipal water treatment plants EDTA is either not broken down or only breaks down to a slight degree. To-date in Europe, EDTA has been replaced in virtually all consumer products by readily biodegradable alternatives such as MGDA (methylglycine diacetic acid) and GLDA (glutamic acid diacetic acid).

Halogenated and/or aromatic solvents

Halogenated solvents are harmful to health, often not readily biodegradable and can have negative effects on the earth’s ozone layer. Some halogenated solvents are suspected of causing cancer.

Nanomaterials/-particles

Nanomaterials are a diverse group of materials under the size of 100 nm. Due to their small size and large surface area nanoparticles are often more reactive and may have other properties compared to larger particles of the same material. Further, different sizes, shapes, surface modifications and coatings can also change their physical and chemical properties. Nanoparticles can cross biological membranes and thus be taken up by cells and organs. One of the main concerns are linked to free nanoparticles, as some of these – when inhaled – can reach deep into the lungs, where the uptake into the blood is more likely.

There is concern among public authorities, scientists, environmental organisations, and others about the insufficient knowledge regarding the potential detrimental

effects on health and the environment[18,19]. Nordic Ecolabelling takes these concerns seriously and applies the precautionary principle to exclude potentially hazardous nanomaterials from products.

Synthetic amorphous silica (SAS) is an intentionally manufactured silicon dioxide (SiO_2) form that is extensively used in cosmetic products. Almost all toothpaste on the market contains SAS (hydrated silica) as an abrasive in the form of nanoscale particles which form aggregates[20]. It is transparent and can be used in both gel toothpastes and white and coloured toothpastes, and it is compatible with fluoride[21]. SAS is a nanomaterial under the Cosmetics Regulation and is exempted from the requirement due to a lack of alternative substances.

Nano titanium dioxide (TiO_2) is an effective physical UV filter often used in sunscreen. 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[22,23]. We choose to approve the use of TiO_2 as a UV filter as long as SCCS opinion SCCS/1516/1337 is followed, and the UV filter is thus not photocatalytic, and the coating is stable. Nano UV filters can still not be used in spray products, in line with the SCCS recommendation.

Nitro musks and polycyclic musk compounds

Nitro musks and polycyclic musk generally have undesirable properties regarding both health and the environment. Some such compounds are already excluded from use via the requirement concerning CMR substances.

Organic chlorine compounds, hypochlorite and hypochlorous acid

Organic chlorine compounds, hypochlorite and hypochlorous acid can be used as disinfecting and antibacterial substances and as bleaching agents. Chlorine-based substances generally have undesirable health and environmental properties. Both hypochlorite and hypochloric acid can lead to formation of organic chlorine compounds and byproducts that are toxic and bioaccumulative, like trihalomethanes

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[18] UNEP (2017) Frontiers 2017 Emerging Issues of Environmental Concern. United Nations Environment Programme, Nairobi. https://wedocs.unep.org/bitstream/handle/20.500.11822/22255/Frontiers_2017_EN.pdf?sequence=1&isAllowed=y

[19] SCCS (2019) Guidance on the Safety Assessment of Nanomaterials in Cosmetics. SCCS/1611/19. https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_233.pdf

[20] Enax, J.; Meyer, F.; Schulze zur Wiesche, E.; Fuhrmann, I.C.; Fabritius, H.-O. Toothpaste Abrasion and Abrasive Particle Content: Correlating High-Resolution Profilometric Analysis with Relative Dentin Abrasivity (RDA). Dent. J. 2023, 11, 79. https://doi.org/10.3390/dj11030079

[21] Lippert F.An introduction to toothpaste: Its purpose, history and ingredients. Monogr Oral Sci. 2013;23:1-14

[22] Miljøstyrelsen (2015). Environmental assessment of nanomaterial use in Denmark. Environmental project No. 1788, 2015. From http://www2.mst.dk/Udgiv/publications/2015/10/978-87-93352-71-1.pdf

[23] Miljøstyrelsen (2015). Environmental effects of engineered nanomaterials, Estimations of Predicted No Effect Concentrations (PNECs). Environmental project No. 1787, 2015. From http://www2.mst.dk/Udgiv/publications/2015/09/978-87-93352-70-4.pdf

and haloacetic acids. Hypochlorous acid is not classified, and hypochlorite have the classification Very toxic to aquatic life (H400) and thus, they are not covered by the general requirement concerning environmentally hazardous substances. However, both pose an environmental risk due to the possibility of organic chlorine compounds forming.

Parabens (4-Hydroxibenzoic acid and its salts and esters)

Parabens (4-Hydroxibenzoic acid and its salts and esters) have a widespread use as preservatives in cosmetic products. Several parabens are identified- or under evaluation for being endocrine disruptors. Because of the structural similarities among parabens, they can be expected to have equivalent endocrine disruptive properties and therefore there is a ban on this group of substances.

PBT and vPvB substances in accordance with REACH Annex XIII

PBT and vPvB are abbreviations for substances that are persistent, bioaccumulative and toxic, and very persistent and very bioaccumulative, respectively, in accordance with REACH Annex XIII. This means that they are not biodegradable and that they accumulate in living organisms. Based on these adverse characteristics they pose a threat to the environment and human health. They are prohibited in all Nordic Swan Ecolabel products.

Per- and polyfluorinated substances (PFAS)

Perfluorinated and polyfluorinated alkylated substances (PFAS) are a group of substances with undesirable properties. The substances are persistent and are readily absorbed by the body. PFASs are defined as fluorinated substances containing at least one fully fluorinated methyl or methylene carbon atom (without any H / Cl / Br / I atom attached to it), i.e., with a few listed exceptions, all chemicals with at least one perfluorinated methyl group ($–CF_3$) or a perfluorinated the methylene group ($–CF_2–$) is a PFAS as described in the OECD recommendations[24].

Phthalates (esters of phthalic acid)

Several phthalates are identified as endocrine disruptors and some of them are classified as reprotoxic. For these reasons several phthalates are included in the Candidate list. Based on their hazardous properties, phthalates pose a threat to the environment and human health and there is a ban on this group of substances.

Potential or identified endocrine disruptors

Endocrine disruptors (EDs) are chemicals that alter the functioning of the endocrine (hormone) system and consequently cause adverse health effects. The hormone system regulates many vital processes in living organisms and when normal signalling is disturbed, adverse effects may result. EDs raise high concern for their risk of causing serious negative impact on the environment as well as on human health specifically. Special concern is raised for effects on reproduction and development and about possible links to increases in public health diseases. While effects in wildlife populations have been confirmed, evidence is pointing to effects also in humans. By excluding both identified and prioritised potential EDs which are under evaluation, Nordic Ecolabelling ensures a restrictive policy on EDs.

[24] Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and practical Guidance, OECD 2021.

The ED lists I-III on https://edlists.org/ are dynamic, and the companies are responsible for keeping track of updates, in order to keep labelled products compliant with the requirement throughout the validity of the licences. Nordic Ecolabelling acknowledges the challenges associated with new substances being introduced on particularly List II and III, and in some cases also List I. We will evaluate the circumstances and possibly decide on a transition period on a case-by-case basis.

A number of substances that are moved from ED List II to sublist II, but can still be considered potential endocrine disruptors, is also prohibited. It includes the following:

- 2-ethylhexyl (2E)-3-(4- methoxyphenyl)acrylate (CAS No. 83834-59-7)
- Homosalate (CAS No. 118-56-9)
- Kojic acid (CAS No. 501-30-4)
- Octocrylene (CAS No. 6197-30-4)

Quaternary ammonium compounds, which are not readily aerobic biodegradable such as DTDMAC (CAS No. 68783-78-8), DSDMAC (CAS No. 107-64-7), DHTDMAC (CAS No. 61789-80-8) and DADMAC (CAS No. 7398-69-8)*

Quaternary ammonium compounds (QACs) are usually surface-active agents where some of them precipitate or denature proteins and destroy micro-organisms. QACs are toxic to a lot of aquatic organisms including fish, daphnids, algae, rotifer and microorganisms employed in wastewater treatment systems.

Salicylic acid and its salts, benzyl salicylate, and ethyl-hexyl salicylate

Salicylates are commonly used substances in cosmetic products. Salicylic acid is used for anti-dandruff, hair conditioning, preservative, and skin conditioning. Benzyl salicylate and ethyl-hexyl salicylate are mainly used as UV absorber and UV filter. The group of substances are suspected endocrine disruptors.

Siloxanes

Siloxanes are substances that have a widespread use in cosmetic products, such as skin care, hair care and make-up. The most commonly used siloxanes in cosmetic products are the cyclic siloxanes cyclotetrasiloxane (D4), cyclopentasiloxane (D5) and cyclohexasiloxane (D6) and the linear polydimethylsiloxane (PDMS) also known as dimethicone. The cyclic siloxanes D4, D5 and D6 are toxic to human health and the environment having PBT and/or vPvB properties, whereas dimethicone is not considered toxic or bioaccumulative. However, there is a concern that over time, dimethicone will slowly degrade into smaller units exerting the same properties as the cyclic siloxanes[25]. Therefore, the use of both cyclic and linear siloxanes is prohibited with the exemption for leave-on products, where linear siloxanes can be used as the products are intended to stay on the skin and not be rinsed off released directly into the wastewater.

Silver, colloidal silver and nanosilver

Silver is antibacterial agent used in various consumer products, typically in nano form, where it has a greater effect per total amount of silver. Silver is hazardous to

[25] Danish Environmental Protection Agency, Survey, and risk assessment of siloxanes in cosmetic products, Survey of chemical sub-stances in consumer products No. 185, June 2021

health with since it is classified as reprotoxic and under assessment for endocrine disruptive properties. In addition, silver is extremely hazardous to the environment, classified H400 and H410 with an M factor of 10-1000 depending on particle size.

Substances on the REACH Candidate list of SVHC

The Candidate List identifies substances of very high concern which fulfil the criteria in article 57 of the REACH Regulation (EC 1907/2006). The list includes carcinogenic; mutagenic; and reprotoxic substances (CMR, categories 1A and 1B in accordance with the CLP Regulation); and PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) substances (as defined in REACH Annex XIII). In addition, two more substance groups are included if they are of equivalent level of concern (ELoC) as the ones previously mentioned. These are endocrine disruptors and substances which are environmentally hazardous without fulfilling the requirements for PBT or vPvB. Based on these adverse characteristics, Nordic Ecolabelling prohibits substances on the Candidate List. This means that we act ahead of the legislation and ban the substances before they are subject to authorisation and restriction in accordance with REACH.

Titanium dioxide

Titanium dioxide is used as white pigment or opacifying agent in cosmetic products such as make-up, skin- and hair care, oral care, and sunscreen. The classification as a suspected carcinogen through inhalation (Category 2) has been annulled by the European Court of Justice in August 2025.

However, according to SCCS/1661/23, genotoxicity from titanium dioxide cannot be ruled out in oral products and products that can be inhaled, and no safe limit for titanium dioxide can be established in those products. Therefore titanium dioxide remains prohibited for use in loose powder, sprays, toothpaste, and lip products (lip balm, lipstick, lip gloss, lipliner, and similar). Other products which are not expected to be inhaled or likely to be ingest are exempted.

Triclosan

Triclosan is an antibacterial agent used in different products such as toothpaste and deodorants. An antibacterial agent is a substance that inhibits or stops growth of microorganisms such as bacteria, fungi, or protozoa (single-celled organisms) and can be applied on a treated article or constituent in a chemical product. It is suspected that some antibacterial agents are contributing to the increasing resistance to antibiotics in society. Consequently, the bacteria are developing new methods of resisting the effects of the antibiotic. This, in turn, can lead to certain diseases becoming more difficult to treat. Furthermore, they can harm bacteria that are necessary for the treatment of water at water treatment plants. Therefore, products containing antibacterial agents should be avoided.

Background to requirement O8 Surfactants

Surfactants are found in high volumes in liquid soap, shampoo, and conditioner. Surfactants are often hazardous to aquatic organisms and unlike laundry and cleaning products, which are covered by the Detergent Regulation[26], there are no

[26] Regulation (EC) No 648/2004, 2004

legal requirements on rapid degradability of surfactants in cosmetic products. A requirement on rapid aerobic degradability and anaerobic degradability of surfactants is therefore considered relevant for this product group.

A surfactant is defined as any organic substance, which has surface-active properties, and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of reducing the surface tension of water. This means that most emulsifiers also are covered by the definition. There is limited available data on anaerobic biodegradability for emulsifiers, and as emulsifiers have a crucial function in leave-on cosmetics they are excluded from the requirement on anaerobic degradation.

Sodium lauryl sulphate (SLS) is prohibited for use in toothpaste since studies have shown that SLS is irritating to the oral mucous membrane[27] and can contribute to slower healing of recurrent oral aphthous ulcers (RAU)[28]. Furthermore, a scoping review of available literature regarding the side effects of SLS used in toothpastes reported that possible effects of SLS included mucosal desquamation, irritation or inflammation of oral mucosa or the dorsal part of the tongue and ulcerations[29], which further supports the assumption of SLS's ability to irritate the oral cavity. Based on current knowledge this requirement is therefore relevant from a health perspective.

Sodium lauryl sulphate is added to toothpastes to generate more foam and is the most common foaming (and cleaning) agent in toothpastes. Nordic Ecolabelling does not permit the substance in toothpastes because there are alternatives available that are less irritating.

Background to requirement O9 IFRA

IFRA stands for the “International Fragrance Association” and represents the fragrance industry. The association conducts safety assessments of fragrance substances and provide public standards/guidelines for the use of these. The requirement for compliance with IFRA’s guidelines[30] 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 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. Note that the requirement on IFRA guidelines is one of several requirements that must be included to protect the consumer, see also requirements O10 and O11 on regulation of fragrances.

[27] Healy CM, Cruchley AT, Thornhill MH, Williams DM. The effect of sodium lauryl sulphate, triclosan and zinc on the permeability of normal oral mucosa. Oral Dis. 2000 Mar;6(2):118-23.
[28] Herlofson BB, Barkvoll P. Sodium lauryl sulfate and recurrent aphthous ulcers. A preliminary study. Acta Odontol Scand. 1994 Oct;52(5):257-9.
[29] Kasi SR, Özcan M, Feilzer AJ. Side effects of sodium lauryl sulfate applied in toothpastes: A scoping review. Am J Dent. 2022 Apr;35(2):84-88.
[30] Guidance for the use of IFRA Standards, The International Fragrance Association, 2023

Background to requirement O10 Fragrance free products for babies and children

The requirement covers products marketed for babies or children, e.g., with the word “babies”, “baby”, “barn”, “kids” or “child”. Children up to the age of 12 are considered children in this context. Products marketed as family products or towards teenager are not covered by this requirement. The main argument is that children are more sensitive than adults and tend to have fewer opportunities to choose their own products. Thus, the purpose of the requirement is to reduce the risk of babies and children developing allergies to fragrances.

However, an exemption is made for flavourings in children's toothpaste where aromas for use in food are allowed. This is covered in requirement O21 Oral products: Flavourings, colours, and preservatives and ensures that the flavourings that are used in children’s toothpaste are approved in terms of health. Nordic Ecolabelling considers it important to have an ecolabelled option for parents to enable an environmentally sound choice, as toothpaste in these criteria also must fulfil requirements on toxicity (requirement O5 Classification of ingoing substances), limitation on the use of environmentally hazardous substances (requirement O17) and a prohibition of the use of SLS, a known irritant to the oral cavity (requirement O8 Surfactants).

Background to requirement O11 Fragrance allergens

This requirement limits the amount of fragrance allergens in products rather than prohibit the use of them, because fragrance-free cosmetics have a low demand on the market. Prohibiting fragranced products would most likely have a negative effect on the market presentation of the brand, which would be disproportionate compared with the limited impact that fragrances in Nordic Swan Ecolabelled products have on the environment. Particularly because the amount of environmentally hazardous substances (including fragrances) is strictly limited in requirement O17 Environmentally hazardous substances.

The aim of the requirements is to provide as much protection against new allergies in the society 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.

In 2023, the Cosmetic Regulation included 56 new fragrance substances that must be declared on the packaging when the concentration exceeds 0,01% in rinse-off products and 0,001% in leave-on products, leading to a total of 80 substances that are subjected to declaration[31]. These substances are adopted from the EU Scientific Committee on Consumer Safety (SCCS) opinion on fragrance allergens in cosmetic products from June 2012[32]. SCCS refrains from recommending maximum limits for the content of the fragrance substances in cosmetic products but however states that the general limit of 100 ppm is tolerated by most consumers and wishes to guard

[31] Regulation (EC) No 1223/2009, 2009.
[32] SCCS (Scientific Committee on Consumer Safety), opinion on fragrance allergens in cosmetic products, 26-27 June 2012

against the development of new allergy sufferers both within generally tolerant and sensitive people.

Nordic Ecolabelling do not distinguish between fragrance substances that are subject to declaration and fragrance substances that meet the classification H317 (may cause sensitisation by skin contact) or H334 (may cause allergy or asthma symptoms or breathing difficulties if inhaled), therefor the requirement includes all these substances. This is because allergies, particularly contact allergies to fragrances, constitute a growing problem and there is every reason to minimise the risk of increasing the number of sensitised consumers.

Nordic Ecolabelling 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. However, all fragrance substances subject to declaration are a fragrance 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 a leave-on in relation to the content of fragrance substances.

Toothpaste and oral hygiene products are considered as rinse-off products and are exempted from the requirement of maximum 100 ppm for a certain number of fragrance allergens from aromas in the final product; six fragrance allergens in adult products and two in children's products may be included up to <1000 ppm each. In aldult products, menthol (CAS Nos. 2216-51-5, 89-78-1, 1490-04-6 and 15356-60-2) up to a total of <4000 ppm in combination with up to five other fragrance allergens up to <1000 ppm each is also accepted. These exemptions only applies to fragrance allergens that are not classified H317/H334 cat. 1A.

The exemption is needed because, otherwise, these products would have a flavouring profile that cannot be achieved due to the expanded list of fragrance allergens that is covered by this requirement. Menthol is allowed in higher concentrations, as it is the main flavour in mint-flavoured toothpaste, which is the most requested toothpaste on the market. Licence data have showed that this level and number of aromas, is what is needed to reach an acceptable taste profile. The reason for not exempting aromas that are classified H317/H334 cat. 1A, is that levels above 100 ppm are considered such high risk, that they would lead to product classification, if cosmetic products were included in CLP.

The criteria have changed since the previous version. All fragrance allergens and natural extracts added to the Cosmetic Regulation in 2023 are now covered by this requirement, which is 45 more substances than in the previous criteria version. However, many of these substances are already regulated by requirement O17 Environmentally hazardous substances because they are to be classified as hazardous to the aquatic environment or requirement O5 Classification of ingoing substances because they are sensitising. Thus, the inclusion of these new fragrance substances is not a major change to the previous version. The substances Chloroatranol and Atranol are prohibited for use in cosmetics by the cosmetic regulation. These two are the main components of oak moss extract (Evernia prunastri, CAS No. 90028-68-5) and tree moss extract (Evernia furfuracea, CAS No. 90028-67-4) and therefore their use is prohibited in Nordic Swan Ecolabelled products.

Background to requirement O12 Organic colorants

Nordic Ecolabelling carried out a study in 2023 of 103 colorants approved for use in cosmetics (equivalent to 33% of the approved colours in Annex IV of the Cosmetic Regulation at the timepoint)[33], which showed that several of these colorants lack data for bioaccumulation and meet the classification of hazardous to aquatic organisms. Relevant environmental requirements can and should therefore be introduced for colorants to prevent the use of colorants with unknown environmental data.

A study carried out in 2003 by Nordic Ecolabelling showed that colorants approved for use in food do not constitute a major environmental problem. When colourants are approved for use in food, their safety is evaluated by the European Food Safety Authority (EFSA). The evaluation discusses absorption, distribution, metabolism, and excretion (ADME) in line with various animal tests. Based on the ADME study and other toxicity data, such as gene toxicity or sensitisation, EFSA establish ADI (Acceptable Daily Intake) values for the colorants approved for use in food. 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, based on our own study described above where log Kow or BCF values were lacking, we also accept E-numbers as documentation of low bioaccumulation potential.

In addition, requirement O17 Environmentally hazardous substances also exclude the use of more environmentally hazardous colorants. The BCF and log Kow values are used as indicators for bioaccumulation in line with the definitions in the CLP Regulation for classification of chronic aquatic toxicity[34].

Carbon black is prohibited because it is suspected of being carcinogenic. It is part of the ECHA Community Rolling Action Plan (CoRAP) where it is to be evaluated for carcinogenicity and IARC considers that carbon black is possibly carcinogenic to humans (group 2B)[35].

The requirement only covers organic colorants as bioaccumulation cannot be used for inorganic compounds. Inorganic colorants can therefore be used in Nordic Ecolabelled cosmetics if they meet our requirements on classification and toxicity.

Background to requirement O13 Preservatives

This requirement is set to protect the environment and human health from substances with unknown toxicity and behaviour in the environment. Preservatives are included in most cosmetic products with the aim of preventing bacterial growth and extending shelf life. Nordic Ecolabelling carried out a study in 2023 of all preservatives approved for use in cosmetics listed in Annex V[36]. The study showed that several preservatives lack data for persistence and bioaccumulation, and many meet the requirements for classification of hazardous to aquatic organisms.

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[33] Regulation (EC) No 1223/2009, 2009
[34] Regulation (EC) No 1272/2008, 2008
[35] IARC, Carbon Black, Titanium Dioxide, and Talc. Lyon. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 93 2010.
[36] Regulation (EC) No 1223/2009, 2009

The requirement has changed since the previous version as it now requires that preservatives must not be bioaccumulative but also must be readily aerobically degradable. The addition of a requirement on aerobically degradable is made because persistence is considered the biggest cause of concern when looking at the environmental impact of chemicals and bioaccumulation alone is not enough since it mainly prevents bioaccumulation in humans and organisms[37]. This is described by Ian R. Cousins et. al, where they emphasise that persistence alone is a sufficient basis for regulation of a chemical. This is because the release of persistent chemicals leads to increasing concentrations in the environment that can cause known and/or unknown effects. In addition, it can take up to several decades to reverse the contamination.

Since the use of preservatives is common in most cosmetic products and they are often hazardous to the environment, both biodegradation and bioaccumulation are relevant requirements to protect the environment and human health. Especially, since environmental data is not available for all of them.

Background to requirement O14 UV filter

UV filters can be divided into two types: Physical organic filters such as titanium dioxide and chemical organic filters. UV filters can be problematic from an environmental and health point of view, but they also provide protection against the sun and thus reduce the risk of skin cancer.

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)[38]. In addition, UV filters used to protect the user are the only filter covered by Annex VI to the Cosmetics Regulation.

To minimize the environmental impact, UV filters must have at least one of the following two proporties: Not bioaccumulative or not toxic to aquatic organisms. A 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 one will be used instead.

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 which 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 log Kow is >3.

Background to requirement O15 Residual monomers in synthetic polymers

Residual monomers in polymers can cause negative health effects, for example due to the allergic and carcinogenic properties of the monomers. Monomers are often

[37] Ian T. Cousins et al. Environ. Sci.: Processes Impacts, 2019,21, 781-792
[38] (Öko-Test 2009a), (Öko-Test 2009b), (Forbrugerrådet Tænk Kemi, 2015)

very reactive substances, and the risk is considered so great that it necessitates a separate requirement to further limit the level of residual monomers in the polymer.

Monomers tend to reduce over time, as many monomers are volatile compounds. The requirement relates to the newly produced polymer since it is important to reduce the impact at source and to this end it is most practical for the polymer manufacturer to perform the analysis. The limit of 100 ppm of residual monomers in polymers with classification according to the table in the requirement is based on licensing data.

Background to requirement O16 Aluminium

Aluminium is a known systemic toxicant at high doses. The SCCS have evaluated the safety of aluminium in cosmetics for several product categories, including aggregated exposure of cosmetic products. The opinion concludes maximum concentration limits for several products categories and these limits have been adopted by the Nordic Ecolabelling[39].

Since SCCS has not set limit values for all leave-on products, Nordic Ecolabelling asked an external consultant to make worst case safety calculations for make-up, as it is estimated that these products have the highest content of aluminium. The safety calculations were made by the Institute of Public Health in Norway in accordance with the method stated in the SCCS opinion on aluminium. The calculations were made for eyeshadow, blush, and facial powder. The conclusion is that the use of aluminium in these products can be considered safe at concentrations up to 17.5% for all three products. This limit value will therefore apply for all cosmetic products not mentioned in the SCCS opinion. Note that Aluminium Oxide is obliged to fulfil the requirement for nanomaterials (O7 Excluded substances).

4.3 Biodegradability and aquatic toxicity

Background to requirement O17 Environmentally hazardous substances (C_{total})

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. Most ingredients in cosmetic products eventually end up in the aquatic environment through the wastewater system, either directly when they are used or after they have been used (rinsing in the shower). Some products are also released directly into the environment during use (e.g. sunscreen and hair care products). Nordic Ecolabelling has thus identified a need to limit environmentally harmful substances by means of a limit value calculation by a weighted method where 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.

Including the M factor in the calculation have been considered, but instead the most toxic H410 substances with M-factor > 1 is completely prohibited. It is expected

[39] SCCS (Scientific Committee on Consumer Safety), Opinion on the safety of aluminium in cosmetic products - Submission IV, preliminary version of 14 44 December 2023, SCCS/1662/23

almost exclusively to be ingredients in perfume raw materials that have M > 1 and alternative perfume raw materials exist.

From 1 December 2012 the CLP Regulation changed the criteria used as its basis for classification as environmentally hazardous. This meant that many surfactants which were not previously classified as environmentally hazardous now needed to be, and they were therefore at that time exempted from the requirement, as surfactants have an important irreplaceable function in many cosmetic products. Surfactants are no longer exempted in this criteria version, but to mitigate the negative consequences, separate limit values is introduced for the products where licence data has showed that it is needed.

Rinse-off products

Background to requirement O18 aNBO (aerobic non-biodegradable organics) and anNBO (anaerobic non-biodegradable organics)

Restrictions on the content of organic substances that are not rapidly and anaerobically biodegradable reduce the total level of non-degradable organic substances to a minimum for Nordic Swan Ecolabelled rinse-off products. The limit values are based on data from existing Nordic Swan Ecolabel licences.

The limit is lower for solid products compared to other rinse-off products because they have very high levels of active content.

Foam soaps have found it difficult to meet the requirements per active ingredients (AC) even though they are 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 the CDV requirement. 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.

Background to requirement O19 Critical dilution volume (CDV)

CDV is a theoretical value which considers the toxicity and aquatic degradability of each substance. 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. The limit values are based on data from existing Nordic Swan Ecolabel licences.

The limit is lower for solid products compared to other rinse-off products because they have very high levels of active content. For foam soap it is permitted to choose between applying the limits per active content or per dose, as described in the background text for the aNBO/anNBO requirement.

The water content of the product in relation to the CDV value has been studied, and it 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.

Leave-on products

Background to requirement O20 Biodegradability and aquatic toxicity

Most leave-on products are washed off the body and clothes and therefore end up to a certain extent in the aquatic environment via wastewater treatment. Many environmentally problematic ingredients are commonly used in leave-on cosmetics. For instance, long chained vegetable oils or paraffin, that are not rapidly biodegradable. This also applies to many binders, polymers, siloxanes, and waxes. It is therefore important to set requirements on degradability and/or toxicity/bioaccumulation potential. Note that the requirement does not apply to products containing 100% inorganic raw materials.

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

Molar weight > 700 g has been chosen as the limit value for bioavailability. An examination of the literature[40] judged the opportunity to estimate bioaccumulation potential based on 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 limit 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 log Kow value.

UV filters in sun products are exempt from the requirement because they are needed in sun products in amounts greater than 5% and in many cases, they will not meet this. However, requirement O14 UV filter ensures that the most environmentally problematic UV filters are excluded by requiring them not to be bioaccumulating and have a lowest toxicity of NOEC/ECx > 0.1 mg/l or EC/LC50 > 10.0 mg/l.

In the revision of the DID-list into the 2023 version, the substance cera alba (beeswax) was added with worst-case data for aquatic toxicity as there was no available data or structure analogies at the time. This approach is not in line with the principles of the DID-list, where only substances with information on aquatic toxicity should be added. Cera alba is therefore exempt from this requirement until a new version of the DID-list is available.

[40] Frauenhofer Institut Molekularbiologie und Anwandte Oekologie, 2007

4.4 Specific additional requirements relating to certain product types

Lip products, toothpaste, oral hygiene products, and nipple cream

Background to requirement O21 Flavourings, colours, preservatives, and mineral oil

This requirement is set to protect human health by only allowing flavourings, colours and preservatives that are approved for food. This is because consumers are exposed to lip products, toothpaste, and oral hygiene products via the mouth. Nipple creams are included since babies can be exposed during breastfeeding.

By only allowing flavourings that are approved for food their safety has been evaluated by the European Food and Safety authority (EFSA) which conduct a risk assessment based on exposure, metabolism, and toxicity of the ingredient.

Mineral hydrocarbons (mineral oils or waxes) are used as ingredients of cosmetic lip care products and the safety have been discussed. With respect to potential oral exposure, Cosmetics Europe recommends that only particular mineral hydrocarbon fractions for which an Acceptable Daily Intake (ADI) has been identified, should be used in cosmetic lip products. This recommendation applies to all mineral hydrocarbon fractions, i.e. mineral oils and microcrystalline waxes or mixtures thereof, which meet specifications ensuring a safe use in cosmetic lip care products.

Background to requirement O22 Fluoride/hydroxyapatite and zinc salts in toothpaste and mouthwash

The market for fluoride-free toothpaste is growing with products that are marketed as "natural"; however, it is well known that toothpaste without fluoride does not prevent dental caries when compared to fluoride toothpaste[41]. In addition, all the Nordic countries respective dental organisations recommend that both adults and children use fluoride toothpaste for a caries preventing effect. Studies have shown that hydroxyapatite is capable of protecting against caries to the same extent as fluoride[42], and a few products with this alternative are available on the market. There are currently no recommendations for the content of hydroxyapatite in toothpaste, however for fluoride the following national recommendations apply:

- Denmark: 1500 ppm
- Finland: 1450 ppm for adults, 1000-1000 ppm for children
- Norway: 1450-1500 ppm
- Sweden: 1000 ppm

[41] Walsh T, Worthington HV, Glenny AM, Marinho VC, Jeroncic A. Fluoride toothpastes of different concentrations for preventing dental caries. Cochrane Database Syst Rev. 2019 Mar 4;3(3):CD007868
[42] Paszynska E, Pawinska M, Enax J, Meyer F, Schulze zur Wiesche E, May TW, Amaechi BT, Limeback H, Hernik A, Otulakowska-Skrzynska J, Krahel A, Kaminska I, Lapinska-Antonczuk J, Stokowska E and Gawriolek M (2023) Caries-preventing effect of a hydroxyapatite-toothpaste in adults: an 18-month double-blinded randomized clinical trial. Front. Public Health 11:1199728.

Therefore, it is required that toothpaste and mouthwash must include fluoride to the above extents to ensure performance of the products.

Water-soluble Zinc salts in mouthwash is limited to 0,1% based on the scientific opinion of SCCS[43]. The Cosmetic Regulation does not have a specific limit for mouthwash, only a limit of 1% for oral products, which is why the Nordic Ecolabelling adopts the opinion of the SCCS.

Decorative cosmetics and hair dyes

Background to requirement O23 Heavy metals in colourants

The aim of this requirement is to protect consumers from unnecessary exposure to toxic heavy metals which are unavoidable in pigments as they are naturally occurring. All heavy metals except Chromium and Nickel are hazardous to the environment, in addition many of them are carcinogenic, mutagenic, toxic to reproduction and sensitising.

The use of the heavy metals Arsenic, Antimony, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel is prohibited by Annex II in the Cosmetic Regulation (EC) 1223 / 2009 (with exemption for special use of Mercury in Annex V). However, trace levels are allowed without specific limits, hence the Nordic Ecolabelling sees a need to limiting the amount of these heavy metals. The requirement only covers decorative cosmetics and hair dyes since other products such as soap and lotion are not considered relevant, as they contain very small amounts of colours in comparison.

The Food and Drug Administration (FDA) have previously shown that trace levels of these heavy metals can vary from zero ppm to thousands ppm in decorative cosmetics, while in lotions, they are mostly below detection limits. Furthermore, these results showed that trace levels of Nickel and Chromium, in many cases where higher than the other metals[44]. This is also shown in colourants data from the industry where trace levels of these metals are found in higher concentrations, generally in ranges between 10 to 200 ppm. Therefore, to enable the labelling of decorative cosmetics and hair dyes a higher limit for these heavy metals are needed.

The main concern for the public regarding Nickel and Chromium are their sensitisation properties. And to make sure the amount is not too high in the product; the Nordic Ecolabelling have adapted the limit of 10 ppm from a study by Basketter et al. This study suggest that the majority of individuals will rarely react to irritants in levels below 10 ppm in the final product[45].

The use of the Bismuth chloride oxide (BiClO) is to provide a shimmering effect to the make-up. This pigment is prohibited since it can be irritating for sensitive consumers and there is a demand of Bismuth-free make-up on the market. In addition, according

[43] SCCS (Scientific Committee on Consumer Safety), Opinion on water soluble zinc salts used in oral hygiene products - Submission I, preliminary version adopted on 7 March 2017, final version adopted on 21-22 June 2018, SCCS/1586/17

[44] FDA's Testing of Cosmetics for Arsenic, Cadmium, Chromium, Cobalt, Lead, Mercury, and Nickel Content, The Food and Drug Administration (FDA) 2014

[45] Basketter et. al. Nickel, chromium, and cobalt in consumer products: revisiting safe levels in the new millennium. Contact Dermatitis. 2003 Jul;49(1):1-7

to the ECHA's summary of classification, approximately 15% of notifiers classify bismuth chloride oxide as a respiratory, skin and eye irritant (H335, H315 and H319).

Colourants approved for foods can be used because their safety have been evaluated by EFSA based on an exposure scenario in which they are "closer" to the body than cosmetic products. In addition, these colorants need to meet specific purity criteria in the Commission Regulation (EU) No 231/2012 where if relevant, certain heavy metals are limited.

Background to requirement O24 Hair dyes

Lawsone (CAS No. 83-72-7) and Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (CAS No. 928659-47-5 and CAS No. 73793-79-0) are prohibited based on SCCS opinions, suggesting that both have mutagenic potential[46,47], and their use is not regulated by the Cosmetic Regulation.

In addition, hair dyes which are suggested to be sensitising and/or allergenic by the SCCS are prohibited to limit the risk of sensitisation and allergies of hair dye products. Examples of such dyes are methylimidazolium propyl p-phenylenediamine HCl (CAS No. 220158-86-1)[48].

Wet Wipes

Background to requirement O25 Wipe material

Wet wipes are pre-wetted cloths of nonwoven fabric, where the lotion is covered by the EU Cosmetic Products Regulation (CPR). Environmental impact of wet wipes is highly related to raw materials used as carrier material in wipes. According to the RPS, there is relevance and potential for excluding plastic polymers in wet wipes and therefore, plastic fibres are no longer allowed in the wipe carrier material.

Wet wipes are mostly made with nonwoven technology consisting of only viscose or a mixture of viscose and plastic, but it is possible to manufacture wet wipes consisting of a mixture of viscose and other natural polymers. Nonwoven industry has recently had focus on increasing the use of materials made from renewable sources, fully biodegradable, recycled, or non-plastic alternatives where relevant[49]. This is partly driven by EU Directive (EU) 2019/9043[50] also known as the Single-Use

[46] SCCS (Scientific Committee on Consumer Safety), Opinion on Lawsonia inermis (henna), 19 September 2013, corrigendum 12 November 2021
[47] SCCS (Scientific Committee on Consumer Safety), Opinion on Hydroxypropyl p-phenylenediamine and its dihydrochloride salt (A165), preliminary version of 20-21 June 2019, final version of 30-31 October 2019, SCCS/1608/19
[48] SCCS (Scientific Committee on Consumer Safety), Opinion on hair dye Methylimidazoliumpropyl p-phenylenediamine HCl (A166), preliminary version adopted on 29 July 2019, final version adopted on 30-31 October 2019, SCCS/1609/19
[49] https://www.edana.org/how-we-take-action/edana-sustainability-initiatives/edana-sustainability-vision23
[50] https://eur-lex.europa.eu/eli/dir/2019/904/oj

Plastic (SUP) Directive, where any personal care product that is designed to be used once and contains plastic shall be marked with the “dead turtle” on the packaging[51].

Requirements set for relevant types of carrier materials can be found in the Nordic Swan Ecolabel and the EU Ecolabel Criteria for textiles, hygiene products and tissue paper. Carrier material in wipes shall meet the latest updates of these Criteria, presented in the table in the requirement. If the material in the wet wipe is included in several different criteria, the applicant can choose the criteria whose requirements they wish to meet. Reference to EU Ecolabel textile products will be introduced when these Criteria are updated. More information about justification of requirements for carrier material and fibres can be found from relevant Nordic Swan Ecolabel Background documents and EU Ecolabel Final Technical Reports.

Background to requirement O26 Process water

Through analysing wet wipes, Nordic Ecolabelling has become aware that substances such as MI (methylisothiazolinone), CMI (methylchloroiso-thiazolinone) 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 Ecolabelling does not permit sensitising substances classified with H334 or H317 in cosmetic products, see requirement O5 Classification of ingoing substances.

To ensure that no sensitising substances are found in Nordic Swan Ecolabelled wet wipes, producers of all carrier materials/wipes must declare any use of sensitising 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.

Background to requirement O27 User information

Correct disposal of wet wipes ensures the best possibilities for recycling and reduces the risk of problematic substances being discharged into the environment.

According to the EU Directive (EU) 2019/904[52], also known as the Single-Use Plastic (SUP) Directive, wet wipes containing plastics must contain the following “dead turtle” marking on the packaging:

Nordic Ecolabelling no longer allows plastic fibres in the wipe carrier material, but for the sake of recognition and uniformity for products sold within EU, we recommend that the "Do not flush" part of the logo is stated on the packaging. To prevent environmental issues with flushing wet wipes, this part of the logo or a corresponding "do-not-flush" pictogram is required on the packaging of wet wipes.

[51] Regulation (EU) 2020/2151 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R2151
[52] EU Directive (EU) 2019/904: https://eur-lex.europa.eu/eli/dir/2019/904/oj

Sunscreen products

Background to requirement O28 Efficacy and UV protection claims

Sunscreen products are commonly used and trusted by consumers to protect against the health hazards of excessive UV light exposure. It's important that their efficacy is verified and claimed accurately in order not to mislead consumers, who could otherwise be put at an elevated health risk. Whereas the EU regulations on cosmetic products[53] and on cosmetic products claims[54] requires that all claims are substantiated and documented, Nordic Swan Ecolabelled products must also comply with the EU recommendation on efficacy of sunscreen products and the claims used[55]. This means that the recommendation, with suggestions on how to fulfil the cosmetic products regulation's Article 20 about product claims, must be followed.

UVB radiation is defined as sun radiation in the spectrum 290-320 nm and UVA radiation is defined as sun radiation in the spectrum 320-400 nm. The critical wavelength is defined as the wavelength for which the section under the integrated optical density curve starting at 290 nm is equal to 90 % of the integrated. SPF describes the amplitude of protection, and critical wavelength provides a reliable measurement of a product's absorption capability over the entire UV spectrum. The critical wavelength and the efficacy of UVB and UVA protection must be tested according to standardised methods, reach a minimum level, and be consistently communicated. The claims used must be accurate and clear and be accompanied by instructions on how to use the sunscreen product in order to obtain the claimed efficacy.

Products outside the scope of the cosmetic products regulation

Background to requirement O29 Animal care products

Animal care products include rinse-off products such as shampoo, conditioner, and cleanser as well as leave-on products such as sunscreen, much like the corresponding cosmetic products for human use. Products for animals are not covered by the Cosmetic Products Regulation though. There are no declaration/INCI requirements for animal products so animal owners do not know what the products contain. Nordic Swan Ecolabelling can therefore make a difference in declaring constituent substances in ecolabelled animal products, so benefitting both the owners and the animals.

Cosmetic products for animals are often rinsed into the wastewater system just cosmetic products for humans. Also, the user is exposed to the same chemicals.

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[53] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. ELI: http://data.europa.eu/eli/reg/2009/1223/oj.
[54] Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products. ELI: http://data.europa.eu/eli/reg/2013/655/oj.
[55] Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC). ELI: http://data.europa.eu/eli/reco/2006/647/oj.

These products should therefore meet the same general requirements as ordinary cosmetic products.

Neither fragrances nor colours are permitted in cosmetics for animals. There is no functional reason or safety reason to add these substances to animal care products 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 cosmetic products 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 in the amounts listed (provided that they meet other requirements). The user's health is the justification behind the requirement.

Because animal care products are covered by CLP 1272/2008, the requirement includes that products may not be classified as environmentally hazardous.

Background to requirement 030 Sex lubricants

The lubricant "sex product" segment, with products such as lube, anal cream, and orgasm gel, is outside the scope of the cosmetic products regulation (CPR, (EC) No 1223/2009). This is because, for example, the products are not only used on e.g. the external genital organs but also internally. However, the product formulas are similar to cosmetic products. Moreover, in 2018 Nordic Ecolabelling compared different sex lubricants on the Nordic market and concluded that there are differences regarding health and environmental profiles. Thus, there's a potential to differentiate between the products by ecolabelling the more favourable products. The criteria for cosmetic products are suitable since the product formulas and their close-to-body applications are comparable. Therefore, the product group definition was extended in 2018 to include this additional product type.

Sex lubricants may or may not be within the scope of the EU regulation on medical devices (MDR, (EU) 2017/745*), depending on how they're marketed and claimed. If, for example, a product is recommended for use together with a condom it's within the scope of the regulation as an "accessory for a medical device". They may also be regarded as medical devices *per see*, in terms of constituting a "replacement or modification of the anatomy or of a physiological or pathological process or state", especially if they're recommended to help alleviate dryness of mucous membranes.

Since sex lubricants are not subject to the obligations of the CPR, and in some cases neither those of the MDR, the requirement includes reference to selected articles of the CPR that shall apply to the products. The ingoing substances must comply with the restrictions on substances, the products must be safe for human use and a safety assessment must be conducted to confirm it. Also, the products must be manufactured according to good manufacturing practise (GMP), labelled with a declaration of the ingredients for transparency towards the consumer, and the claims used must be clear, accurate and verified.

The safety assessment must be conducted by a specialist with the relevant documented qualifications needed (university level pharmacy, toxicology, medicine or

similar). In addition, for companies who doesn't have internal experience in manufacturing of cosmetics, the safety assessor must also be an independent third party in order to strengthen the robustness of the assessment.

For sex lubricants which are within the scope of the MDR, a safety assessment according to the CPR is not required. Instead, for those products the EU declaration of conformity with the MDR and the CE marking of the product is requested as verification documentation. Compliance with MDR also replaces the need for compliance with some of the selected articles of the CPR.

Sex lubricant products which are not within the scope of the MDR fall within the scope of the EU CLP regulation ((EC) No 1272/2008) as chemical mixtures. The products must not be classified as hazardous to the aquatic environment, which is a standard requirement for Nordic Swan Ecolabelled chemical products.

Fragrances and colourants are excluded since the products are used on intimate and sensitive parts of the body.

Background to requirement O31 Medical examination lubricants

Lubricants used during medical examinations is added as a new product type in this generation of the criteria, as the formulations are similar to those of sex lubricants. From a comparison of different medical examination lubricants on the Nordic market, the potential to ecolabel products that are favourable from an environment and health perspective is also comparable. Such favourable products are desirable to differentiate, since the products are used in a healthcare setting in direct contact with the skin and mucous membranes of patients, including sensitive groups. Also, they are used in quite large volumes.

Medical examination lubricants are not cosmetic products but fall within the scope of the medical devices regulation (MDR). A safety assessment according to the cosmetic products regulation (CPR) in not requested, but the EU declaration of conformity with the MDR and the CE conformity marking of the product is requested as verification documentation. In addition, the requirement includes reference to selected articles of the CPR that shall apply to the products. The ingoing substances must comply with the restrictions on substances, the products must be labelled with a declaration of the ingredients for easy access transparency towards professional users and consumers, and the claims used must be clear, accurate and verified.

Fragrances and colourants are excluded since the products are used on intimate and sensitive parts of the body.

4.5 Packaging requirements

Packaging is a focus area in circular economy, and one of the most important parameters in reducing the climate burden. Nordic Ecolabelling wants to set strict requirements on packaging to ensure the best possibilities for recycling and to reduce the material consumption and transport of packaging.

The packaging requirements target the primary packaging*. Only the packaging materials described in requirement O32 Packaging and materials can currently be used. If you are interested in another packaging type (or e.g., another label type),

please contact Nordic Ecolabelling to find out whether the criteria can be extended to include your format.

Some cosmetic products may be supplied in barrels and in Intermediate Bulk Containers (IBC) that hold up to several thousand litres. Reuse comes higher up in the EU's waste hierarchy than material recycling, and this type of packaging is so strong that it can be reused several times over. Thus, such packaging that is part of a take-back system, is exempted from requirements O32-O37.

** In accordance with EU Directive 94/62/EC on packaging and packaging waste, the term "primary packaging" is defined as consumer packaging, i.e. packaging conceived so as to constitute a sales unit to the final user or consumer at the point of sale.*

Background to requirement O32 Packaging and materials

The requirement specifies what material types may be used in primary packaging: Rigid and flexible plastic, paper-based (e.g. cardboard and corrugated board), cardboard packaging for liquid products, glass containing a minimum of 50% recycled material. Aluminium is allowed under special circumstances.

Very small (miniature-sized) bottles of products such as shampoo and wash soap use an unnecessary high amount of packaging in relation to the amount of product. They are unnecessary in hotel rooms as they are easily replaced by dispensers that are installed in the bathroom. We therefore wish to prohibit the Nordic Swan Ecolabelling of such small products. The prohibition concerns both rinse-off and leave-on products sold to the HoReCa (Hotel, Restaurant and Catering) sector.

The prohibition is not extended to smaller-sized products sold to consumers as these are either long-lasting at smaller volumes (e.g. lip balm, eye cream) or there are no alternatives to them (travel size products need to be less than 100 ml due to flight restrictions), and such sizes should be available on the market.

Nordic Ecolabelling performed an internal comparative LCA screening of the packaging material types that are most commonly used in primary packaging of cosmetic products. The screening showed that aluminium has an impact on the environment that is approximately twofold that of plastic, which is reflected in its' different material factors in requirement O37 concerning WUR. The tough WUR requirement, which takes into account the material's environmental impact and its weight, ensures either that aluminium packaging of very low weight is used or that the product is sold with refills in order to meet the requirements and be eligible for Nordic Swan Ecolabelling. Glass packaging also needs to be sold with refills in order to meet the WUR requirement due to its' heavy weight.

The container should preferably consist of 100% aluminium; other metals and aluminium alloys are at risk of being lost in the recycling process by being oxidized or leaving as slag, or it contaminates the recycled aluminium. In the public consultation, we have received feedback that a small amount of aluminium alloys are required to make the aluminium mouldable. Therefore, we have decided to allow up to 0.5% aluminium alloys in aluminium packaging.[56]. After public consultation, a requirement

[56] Metallförpackningar: En återvinningsmanual från FTI version 2.0 (Accessed 2023-12-12)

on a minimum of 60% recycled material in the aluminium packaging has been introduced.

Metal in packaging of other materials is not allowed because residues cause plastics to be rejected if there are metal detectors on the sorting line. Metal residues can also break down plastics and become a problem in production of the recycled plastic[57,58]. However, small pieces of metal which have a function when used as a metal part in a hand pump, or to protect the product such as sealing foil at small openings of e.g. tubes are permitted.

A majority of packaging for decorative cosmetics contain metal for various reasons. To provide an opportunity to ecolabel a wide range of products, up to 15 w% metal of the total weight of the packaging is permitted. However, mirrors are not permitted as they are considered unnecessary and contribute a lot of extra metal and weight to the packaging.

Background to requirement O33 Plastic packaging: Design for recycling

The EU has adopted a circular economy action plan[59] that has a clear focus on recovery and recycling, particularly with regards to packaging material. Recyclability is an important step in shifting towards a circular economy. This requirement applies to all components of the packaging, except labels that have their own requirement (O36). All parts of the packaging that consist of different materials must be possible to be separate without using a tool and sorted separately, so as to not hinder recycling. Exemptions are made for certain packaging/packaging elements as they are difficult to separate from the rest of the primary packaging and there are no known alternatives to these.

The recyclability of primary packaging made from plastic can be documented either in accordance with the requirements as described in the criteria document, or with a Recyclability certificate from RecyClass showing that the primary packaging is fully recyclable with a minimum recyclability score of B.The Nordic recycling manuals for plastic packaging[60,61] and RecyClass guidelines for design for recycling[62] are the base for the requirement, which state that plastic bottles/containers and closures must be made from ≥99% PE, ≥95% PP or ≥98% PET (not PET-G, cPET or foamed PET) to be compatible with recycling. These three are the best performing plastics from a recycling perspective. Biodegradable plastics are not allowed to be used as they are not suitable in today's recycling systems and can cause problems in the material recovery process.

[57] Plastkretsen and FTI, Bättre förutsättningar för återvinning av plastförpackningar.
[58] http://www.plasticsrecycling.org/hdpe (Accessed 2023-11-24)
[59] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Closing the loop – An EU action plan for the Circular Economy, COM(2015) 614 final, https://eur-lex.europa.eu/resource.html?uri=cellar:8a8ef5e8-99a0-11e5-b3b7-01aa75ed71a1.0012.02/DOC_1&format=PDF (Accessed 2023-11-24)
[60] "Plastförpackningar – En återvinningsmanual från FTI, version 7.0
[61] Miljøstyrelsens Udkast til en dansk model for det miljøgraduerede bidrag for emballage (2024-04-04)
[62] https://recyclass.eu/recyclability/design-for-recycling-guidelines/ (Accessed 2024-09-04)

Pouches or other types of packaging made from plastic films (e.g. flexible pouches may be made from ≥ 95% PE which is in line with RecyClass' guidelines for flexible PE film. An exemption from the requirement has been introduced for pouches sold to the professional market until 30th of June 2028 due to insufficient availability of pouches made from monomaterials on the market that meet the requirements.

Further exemptions from this requirement have been introduced for sealing foil of plastic laminate, pipettes/droppers and small parts in dispensing systems for products sold to the consumer marketas there are few dispensing systems on the market made of monomaterial and these small parts play a crucial role in the function of the dispensing systems. Dispensing systems as a whole for products sold to the professional market are also exempted as these are complex and are built up of multiple components of different material and are not possible to produce of monomaterial today. None of these may contain PVC and other halogenated plastics.

Another exemption has been introduced for closures on upside down squeeze bottles that contain silicone with a density < 0.95 g/cm³ for containers of PET and with a density > 1.0 g/cm^3 for containers of PE and PP, as these are necessary so that the squeeze bottles doesn't leak. Alternative membrane materials exist for squeeze bottles, however they usually fail to ensure leak-proof closures when the bottle is inverted (upside-down). The silicone's density must be compatible with recycling of PE, PP and PET respectively. Furthermore, it is mandatory that the plastic primary packaging[63] is proven fully recyclable according to guidelines established by RecyClass. The packaging must achieve a minimum score of B, as indicated on a Recyclability certificate issued by RecyClass[64]. D4, D5 and D6 can be residues from polymerisation of silicone and are on the Candidate List and Nordic Ecolabelling wishes to limit the use of materials with higher concentrations of these substances, whereby a limit of 1000 ppm for these three substances combined is set.

And an exemption has been introduced for closures used on refill deodorants, or similar liquid products that are refilled from the bottom, which may include membrane made of nitril rubber (NBR). Refill products have an overall favourable environmental profile, and NBR is the most suitable alternative to ensure that the products does not leak after refilling.

Nordic Ecolabelling has decided to accept the following barriers:

For PE and PP packaging components: EVOH and SiOx with a PE or PP binder. For PET packaging components: SiOx or other barriers based on PET. This is in line with what the recycling companies recommend so that the recycling process is not adversely affected.

Colourless plastics have the highest recovery value. Dark colours result in a darker recycled fraction, which is not preferable. Carbon black causes problems in automated sorting plants, as the NIR (near infrared reflectance) detector cannot identify dark colours produced with carbon black. For PE and PP packaging components, carbon black is not allowed, so as to contribute to a visually lighter

[63] In accordance with EU Directive 94/62/EC on packaging and packaging waste, the term "primary packaging" is defined as consumer packaging, i.e., packaging conceived to constitute a sales unit to the final user or consumer at the point of sale.
[64] https://recyclass.eu/get-certified/recyclability/#1

recycled fraction and to avoid issues with NIR-detection. For PET, only transparent and transparent coloured packaging without carbon black is allowed. This means that opaque colours are not allowed for PET packaging. It is desirable to keep the PET stream as clean as possible from colouration, and opaque colours are not compatible with recycling. An exemption has been introduced for white, opaque colours for oil-based products containing unsaturated and polyunsaturated fatty acids. These products need to be especially protected from sunlight as these raw materials readily degrades from light exposure.

During the revision, it has come to our knowledge that surface treatment of the primary packaging with PFAS occurs in the industry. PFAS constitute a group of substances that have highly problematic intrinsic hazardous properties. Therefore, such surface treatment is prohibited.

Nordic Ecolabelling strongly wishes to set a requirement on a minimum amount of recycled material in plastic packaging to further promote circular economy. However, recycled plastic often contains several problematic substances, many of which are hazardous to health, which can migrate into the product. Currently there is no established test protocol for the recycled PE and PP to show compliance for use in packaging for near-food applications, albeit there are developments in the industry, of which CosPaTox's project[65] shows the most promise. In addition to this, Nordic Ecolabelling deems the availability of safe enough raw material(s) as too uncertain to set such a requirement in this generation of the criteria. The availability of e.g. PCR PET is limited to food grade quality, and Nordic Ecolabelling does not wish to promote the use of food grade quality PET for non-food applications.

Therefore Nordic Ecolabelling refrains from setting a mandatory requirement on recycled plastic material in primary packaging in this generation of the criteria. Many advancements are made in this area, both in terms of increased supply and with the coming Packaging and Packaging Waste Regulation (PPWR), where a requirement on a minimum amount of recycled material in packaging is set to come into force in 2030. Nordic Ecolabelling will follow these advancements closely in the coming years and this will be a main focus in the next revision of the critieria, to be published before 2030.

Background to requirement O34 Paper-based packaging: Recycled material and design for recycling

Legislation and infrastructure are in place for paper-/cardboard collection and recycling in the Nordic countries[66]. To promote the use of recycled materials and to save virgin resources, an obligatory requirement on the amount of recycled materials is introduced. The 75% recycled material requirement level is based on correspondence with stakeholders regarding the availability of recycled material of good enough quality in the European region. The remaining proportion of the raw material must be FSC/PEFC certified as Nordic Ecolabelling wishes to promote sustainable forestry.

[65] https://cospatox.com/the-project/ (Accessed 2023-11-24)
[66] http://norden.diva-portal.org/smash/get/diva2:1304371/FULLTEXT01.pdf (Accessed on 2020-12-06).

Two-sided plastic laminate is not allowed since the doble layer impedes the pulpability and leads to a low degree of fibre recovery. Specialized pulpers are required to obtain good fibre recovery for two-sided laminates. A significant proportion of the Nordic board waste is currently not sent to such specialised facilities[67].

PVC and other halogenated plastics are excluded since they lead to adverse environmental impacts in waste handling. Aluminium is not essential in paper-based packaging within this product group.

Solid coloured material other than white is not permitted, as this may lead to discolouration of non-coloured fractions in the pulper.

Background to requirement O35 Cardboard packaging for liquid products: Sustainable material and design for recycling

There seems to be an emerging trend towards liquid chemical-technical products in cardboard packaging. Nordic Ecolabelling will allow the most environmentally friendly packaging within this format to be used for Nordic Swan Ecolabelled products.

The availability of liquid packaging board with PCR materials is very limited. Hence, we accept bio-based material as an alternative to PCR. The requirement promotes sustainable, renewable raw materials (both paper/paperboard and biobased plastics) as an alternative to PCR plastics. The requirement of minimum 60% paper/board is set to ensure a relatively high content of paper/board, which is material recycled in the Nordic countries. The plastic fraction of the liquid packaging board is currently not being material recycled.

PVC and other halogenated plastics are excluded since they lead to adverse environmental impacts in waste handling. Even though aluminium from liquid packaging board is currently separated and material recycled[68], it is excluded due to the energy consumption required in the recirculation process. Direct print instead of labels, and use of water-based inks when printing on cardboard is preferable in the recycling process[69] as non-water-based inks will remain on the fibres in the cardboard and will lower the quality and safety of the resulting recycled fibres. However non-water-based inks are allowed for print on the plastic layer of the packaging as the printink ink will remain with the plastic polymer, which is not recycled.

Background to requirement O36 Labels and print for all packaging materials: Design for recycling

PE and PP containers should preferably have labels of the same plastic material in order to facilitate correct sorting by the NIR sensor. Other label materials could be accepted given that the packaging passes RecyClass' Washing quick test procedure. However, the washing temperature in procedure is set to 40°C, which is not compatible with the area of use for cosmetic products used in a shower or a warm

[67] Personal communication with Johannes Daae, Grønt Punkt Norge (January 2021).
[68] Information from Fiskeby Board AB
[69] Personal communication with Cecilia Halling Linder, Fiskeby Board AB (December 2020)

bathroom, whereby we have not included this in the criteria. Therefore, PE and PP containers must have a label in the same plastic material. Cross-over labels of PP are exempted from this requirement, as it is not possible to produce cross-over labels of PE of good enough quality.

PET containers must have labels with density <1.0 g/cm^3. As a consequence, for the time being, cPET labels are not allowed. Nordic Ecolabelling will consider allowing cPET-labels with the appropriate specifications, if cPET labels become endorsed by EPBP (The European PET Bottle Platform) for PET bottles and/or by RecyClass (www.recyclass.eu). PET-G labels/shrink film labels are excluded on PET containers since PET-G is problematic in recycling in large quantities as it is not compatible with the PET commonly used for containers (A-PET). An exemption is made for PET labels (not PET-G, cPET or foamed PET) on PET packaging for oil-based products, because PE labels or PP labels will fall off the packaging when the product is being handled, as the oil dissolves the glue on the labels.

If the NIR sensor at the sorting facility hits the label instead of the bottle, the bottle may end up in the rejected fraction. Therefore, labels and shrink film labels of different materials than the PET container must not cover more than 50% of the container surface for sizes ≤ 500 ml and more than 70% for sizes > 500 ml in accordance with RecyClass' guidelines. For very small containers there may be issues with sufficient space on the label for regulatory information and proper design, therefore label coverage up to 70% on containers ≤ 500 ml can be accepted if an independent third party waste handling facility can demonstrate NIR-sorting according to RecyClass Sorting Evaluation Protocol[70], step 4.1-4.2 and 4.10-4.11 based on succes criteria described in step 4.13, which is sufficient documentation showing that the packaing is sorted correctly without requiring a full recyclability assessment.

The requirements mean that PVC and other halogenated plastics are excluded since they lead to adverse environmental impacts in waste handling, and paper labels are excluded since they degrade the recycled material.

Metallized labels can be detected by metal detectors causing the packaging to be sorted to reject. Thin metal layers do not seem to possess major problems for the sorting or recycling, if the labels can be separated from the containers[71]. However, these metal materials will not be recycled, and single use of metal is not supportable from a resource point of view.

Direct printing on plastic packaging is not permitted, as ink residues lower the quality of the recycled plastic and it is desirable to keep the recyclate stream as clean as possible. An exemption is made for tubes and flexible pouches, as it is challenging to apply labels to these types of packaging, as well as for aluminium packaging. Furthermore, direct print of date codes, batch codes and UFI (Unique Formula Identifier) are permitted on all types of packaging.

For paper-based packaging, direct print instead of labels is preferable in the recycling process. However, Nordic Ecolabelling has decided to allow paper labels, to provide

[70] https://recyclass.eu/wp-content/uploads/2024/01/SORTING-EVALUATION-PROTOCOL-FOR-PLASTIC-PACKAGING_-V2.0-FINAL.pdf
[71] https://www.epbp.org/design-guidelines/products (Accessed on 2023-11-24)

for flexibility for the producers. For paper labels, water soluble adhesive is preferable in the recycling process[72].

Background to requirement O37 Amount of packaging: Weight-Utility Ratio (WUR)

Packaging often accounts for a relatively large proportion of a cosmetic product. Products with several layers are common, especially for luxury products. It is therefore important to limit the amount of packaging used in relation to the product's volume.

The requirement uses a formula that attempts to take into account the very high variation in cosmetic products from a 5 ml lip balm stick to 5 l B2B soap bottles. It takes into account the volume of the product, the weight of the packaging, reusable/refillable packaging, and a potential pump to make correct dosage easier. The formula works by calculating the amount of packaging on the left-hand side, taking into account return figures and an eventual pump. On the right-hand side, the volume is taken into account by use of a linear equation with different constants. The constants differ for different packaging types such that there are different limits for, e.g. tubes and pump bottles, which ensures a stringent requirement for all packaging types.

The equation on the right-hand side is linear with new constants a and b. The basis for determining the constants was data from current Nordic Swan Ecolabelled products. All the data was entered in a diagram and the constants were determined iteratively considering that the requirements should be realistic but strict.

The limit value for wet wipes now relates to the number of wipes in the packaging, rather than the volume of the packaging, which will give a more accurate representation of the amount of packaging used for a certain amount of product.

Furthermore, the element representing the amount of recycled material in the packaging has been removed due to the issues raised concerning recycled plastic in requirement O33 Plastic packaging: Design for recycling.

The material factor value produces a rough “environment weight” of each material. They are estimated based on a simple screening[73] of the climate impact for 1 kg of cardboard, aluminium, glass and plastic used as packaging material. The screening included both the production and waste management phase, in order to include potential climate impacts/benefits from recycling. All three materials were modelled as monomaterials, containing 0% recycled material, and were assumed to be sorted 100% for recycling by the consumer. The climate impacts of the materials were normalised according to the climate impact for plastic.

[72] Personal communication with Cecilia Halling Linder, Fiskeby Board AB (December 2020).
[73] The screening was based on datasets from the Ecoinvent database and expert knowledge, and the circular footprint formula was used, together with suggested default allocation values from the EU, to allocate impacts between use of recycled material and recycling of material.

Below follows a description of all elements of the formula:

$$\sum(mf_i \cdot W_{material_i})$$

This element limits the total weight of the packaging and includes the material factor (mf_i).

$$\frac{1}{t}$$

This element is included in the formula to encourage direct reuse 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 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.

$$a \cdot Vol_{product} + b$$

This element describes the increase of packaging material 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 constants a and b are determined iteratively for different packaging types.

For examples of what types of packaging pertain to the different categories, please see appendix 6 to the criteria.

After consultation, the factor subtracting half the weight of the pump for pump bottles has been removed as this was deemed unnecessary. The limit value has instead been adjusted to account for the weight of the pump.

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 such small products use a large amount of packaging in relation to their small product volume, therefore a separate formula is developed for decorative cosmetics.

Background to requirement O38 Dosability / Dosing systems and emptying level

Over-dosing of the product increases its environmental impact but does not improve its efficiency. The requirement on dosability/dosing systems has been judged to be steerable only for liquid hand soap with a dispenser. The maximum dose at one press for liquid hand soap is related to the requirement O19 CDV.

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[74].

It has been identified that the products with the lowest emptying level are:

- Viscous products in pump bottles
- Viscous products in tubes
- Viscous products in bottles, especially conditioner and skin cream

Instead of a general requirement on the emptying level, a requirement is therefore set that focuses on only these product and packaging types as far as possible.

Bottles for conditioner and cream, and bottles with a pump, incl. dispenser bottles must have an emptying level of 90%. Pump products with an “Airless” system or similar system, where there is a bag in the container and the content is sucked out when the pump is pressed, always meet the emptying level requirement and therefore do not to be documented in line with the requirement.

4.6 Disposal information requirements

Correct disposal of cosmetic products is an important factor in reducing the environmental impact.

Background to requirement O39 Disposal information

Correct disposal of cosmetic products ensures the best possibilities for recycling and reduces the risk of problematic substances being discharged into the environment.

Marking of plastic parts is aimed at helping with sorting and recycling at end-of life. Marking helps correct sorting at the first line of the recycling process when end-users have to sort the discarded packaging.

The pictograms for recycling according to EUPicto (eupicto.com) is developed in the Nordic countries. DIN 6120-2 is a standard for marking of packaging and packaging materials for recycling purposes. Pictograms recommended by national recycling systems are also accepted, e.g. Grønt Punkt from Norway[75]. Näringslivets Producentansvar (NPA AB) from Sweden recommends using EUPicto[76].

Reference to web pages or QR codes are not accepted.

To reduce the effects of paper/cotton and cosmetic products in the aquatic environment and wastewater treatment plants an information text is required about correct disposal of paper/cotton. For cleansing lotion and eye makeup remover, a reference to using reusable pads is accepted as an alternative, as it helps reduce the use of single-use paper/cotton products. 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 also be sorted as hazardous waste.

[74] (Institute for European Environmental Policy, 2004)
[75] https://www.grontpunkt.no/emballasjedesign/emballasjemerking
[76] https://npa.se/vart-erbjudande/mark-dina-forpackningar

4.7 Licence maintenance

The purpose of the licence maintenance is to ensure that fundamental quality assurance is dealt with appropriately.

Background to requirement O40 Customer complaints

Nordic Ecolabelling requires that your company has implemented a customer complaint handling system. To document your company's customer complaint handling, you must upload your company's routine describing these activities. The routine should be dated and signed and will normally be part of your company's quality management system.

If your company does not have a routine for customer complaint handling, it is possible to upload a description of how your company perform these activities. During the on-site visit, Nordic Ecolabelling will check that the customer complaint handling is implemented in your company as described. The customer complaints archive will also be checked during the visit.

Background to requirement O41 Traceability

Nordic Ecolabelling requires that your company has implemented a traceability system. To document your company's product traceability, you must upload your company's routine describing these activities. The routine should be dated and signed and will normally be part of your company's quality management system.

If your company does not have a routine for product traceability, it is possible to upload a description of how your company perform these activities. During the on-site visit, Nordic Ecolabelling will check that the product traceability is implemented in your company as described.

5 Areas without requirements

Performance/quality

A requirement on verification of the general product performance as well as any claimed specific effect was part of earlier generations of the criteria. The current criteria generation comprises efficacy testing of sunscreen products and declaration of fluorine content in toothpaste only. We have chosen to narrow the scope since the cosmetic products regulation[77] and the claims regulation[78] require that proof of effect is included in the Product information file and that all claims are substantiated. Market surveys by the European Commission[79] and the European Advertising

[77] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. ELI: http://data.europa.eu/eli/reg/2009/1223/oj.
[78] Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products. ELI: http://data.europa.eu/eli/reg/2013/655/oj.
[79] REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on product claims made based on common criteria in the field of cosmetics, 19.9.2016 COM(2016) 580 final https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0580

Standards Alliance (EASA)[80] have shown about 90% overall compliance with the claims regulation's common criteria for claims.

Claims

According to the cosmetic products regulation, no claims shall be used to imply characteristics or functions which the products do not have. For claims on organic origin of products and ingredients, established ISO 14024 type I certification schemes such as Ecocert and COSMOS are available. Nordic Swan Ecolabel criteria do not require proof of verification assessment concerning sustainability aspects which are not part of the criteria. Verification of claims on mild/gentle/sensitive products is also not part of criteria generation 4 since we consider the obligations of the CPR[51] and the claims regulation[52] sufficient, according to the section on Performance/quality above.

6 Changes compared to previous generation

Changes to the requirements for cosmetic products in criteria generation 4 compared with the previous criteria generation 3.

Table 2 Overview of changes to requirements for cosmetic products generation 4 compared with previous generation 3.

Req. gen. 4	Req. gen. 3	Same req.	Change	New req.	Comment
O1 Description of product	O1	X			
O2 SCCS	O2		X		SCCS opinion on perfume allergens are no longer exempted
O3 Supply chain policy and code of conduct				X	
O4 Certified raw materials from oil palms				X	
O5 Classification of ingoing substances	O4		X		EUH hazards, H410 M>1 have been added.
O6 Microplastics	O5		X		Definition of microplastics have been updated
O7 Excluded substances	O5		X		Definitions of endocrine disruptors have been updated. A few new substances and substance groups have been added.
O8 Surfactants	O6				Exemption on anaerobic biodegradability now only applies to emulsifiers in leave-on products.
O9 IFRA	O7	X			
O10 Fragrance free products for babies and children	O8	X			

[80] Cosmetics Europe and the European Advertising Standards Alliance: Cosmetics Advertising Audit, 2015.

O11 Fragrance allergens	O9				All allergens subject to declaration on the updated list in Annex III is included. Higher limits for toothpaste is introduced.
O12 Organic colorants	O10		X		Carbon black is prohibited
O13 Preservatives	O13				Preservatives must now also be readily aerobic biodegradable
O14 UV filter	O14	X			
O15 Residual monomers in polymers	O15				H370-H373 is now also restricted
O16 Aluminium	O16		X		Limits adjusted to SCCS opinion
O17 Environmentally hazardous substances	O17		X		Limits adjusted. Zinc compounds and surfactants are no longer exempted.
O18 aNBO and anNBO	O18		X		Limits adjusted
O19 CDV	O19		X		Limits adjusted
O20 Biodegradability and aquatic toxicity	O20		X		Limit adjusted
O21 Oral products: Flavourings, colours, preservatives, mineral oil	O22		X		Nipple cream is included, and requirements for MOSH and MOAH is added
O22 Oral products: Fluoride and zinc salt	O36		X		Toothpaste and mouthwash must contain fluoride. Water-soluble zinc salts in mouthwash is limited to 0,1%
O23 Heavy metals in make-up and hair dye	O11		X		Arsenic and Antimony is added to the list
O24 Hair dyes	O23		X		Hydroxypropyl p-phenylenediamine and its dihydrochloride salt is prohibited
O25 Wet wipes: Wipe material	O24		X		Plastic fibres no longer permitted. Newer up-to date requirements
O26 Wet wipes: Process water	O24	X			
O27 Wet wipes: User information				X	
O28 Sunscreen products	O31, O35		X		Clarifications on test procedure and SPF claims
O29 Animal care products	O25a		X		Clarifications to which parts of the CPR to comply with
O30 Sex lubricants	O25b		X		Clarifications to which parts of the CPR to comply with
O31 Medical lubricants				X	
O32 Packaging and materials				X	
O33 Plastic packaging				X	

O34 Paper-based packaging				X	
O35 Cardboard packaging for liquids				X	
O36 Labels and print				X	
O37 WUR	O26		X		Limits tightened. Material constants updated.
O38 Dosability	O29	X			
O39 Disposal information	O32		X		Aerosol spray cans included
O40 Customer complaints				X	
O41 Traceability				X	

New criteria

In the next generation of the criteria, the following should be reviewed:

- The possibility for setting a requirement for the maximum allowed content of raw materials based on fossils.
- The possibility for requiring that palm oil/palm kernel oil must be RSPO certified with traceability level Segregated or Identity Preserved, and no longer allowing Mass Balance (or Book and Claim).
- The possibility for setting a requirement for the maximum allowed content of viscose in wet wipes.
- The possibility for setting a requirement for the minimum amount of recycled material in plastic packaging.