About Nordic Ecolabelled

Cleaning Agents for Use in the Food Industry



Version 2.0

Background to ecolabelling
08 June 2016
Draft for consultation

Nordic Ecolabelling

Contents

1	**Summary**	**3**
2	**Basic facts about the criteria**	**3**
3	**The Nordic Market**	**5**
4	**Other labels and controls**	**7**
5	**About the revision**	**11**
6	**Environmental impact of the "product group"**	**12**
6.1	MECO - charting of environmental impacts	12
6.2	Relevance, potential and steerability (RPS) of cleaning agents for use in the food industry	15
7	**Justification of the requirements**	**18**
7.1	Product group definition	18
7.2	Overall requirement area, description of products	21
7.3	Performance, packaging and information text	41
7.4	Quality and regulatory requirements	43
7.5	Areas that are not subject to requirements	45
8	**Changes compared to previous version**	**45**
9	**New criteria**	**46**
10	**Document version history**	**46**
11	**Terms and definitions**	**47**

Appendix 1 MECO form for cleaning agents for use in the food industry

070 Cleaning Agents for Use in the Food Industry, version 2.0, 8 June 2016

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

Addresses

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

Denmark
Ecolabelling Denmark
Fonden Dansk Standard
Göteborg Plads 1
DK-2150 Nordhavn
Tel: +45 72 300 450
info@ecolabel.dk
www.ecolabel.dk

Iceland
Ecolabelling Icelan
Umhverfisstofnun
Suðurlandsbraut 24
IS-108 Reykjavik
Tel: +354 591 20 00
ust@ust.is
www.svanurinn.is

Finland
Ecolabelling Finland
Box 489
FI-00101 Helsingfors
Tel: +358 9 61 22 50 00
joutsen@ecolabel.fi
www.ecolabel.fi

Norway
Ecolabelling Norway
Henrik Ibsens gate 20
NO-0255 Oslo
Tel: +47 24 14 46 00
info@svanemerket.no
www.svanemerket.no

Sweden
Ecolabelling Sweden
Box 38114
SE-100 64 Stockholm
Tel: +46 8 55 55 24 00
svanen@ecolabel.se
www.ecolabel.se

This document may only be copied in its entirety and without any type of change. It may be quoted from provided that Nordic Ecolabelling is stated as the source.

1 Summary

Cleaning agents for use in the food industry are products that are used in various food producing industries and catering kitchens. The products are effective in removing grease, proteins and other types of soiling from machine parts, pipe systems and other surfaces in production premises used to produce food.

The ecolabelling of cleaning agents for use in the food industry contributes to reducing environmental emissions of substances that are hazardous to health and the environment by setting more stringent requirements for the constituent substances and by reducing overdosing, since the products' performance at the recommended dosage is tested. Nordic Ecolabelled cleaning agents for use in the food industry are characterised as:

- Effective and with low environmental impact.
- The products contain substances which are not bioaccumulative, which reduces the impact on the environment when they are discharged.
- Performance tested for use in specific application areas.

The most significant changes made in this generation of the criteria are:

- Updated definition of constituent substances
- An updated product group definition in order to clarify what is included and not included in this product group
- Updated requirements of the classification of products and constituent substances (O2-3)
- More stringent requirements of environmentally hazardous substances (O4), phosphorus (O7) and biodegradability (O10)
- New substances added to the list of prohibited substances (O8)
- Inclusion of requirement for CDV - critical dilution volume (O11)
- The requirement of performance testing has been expanded from three to five test sites (O12)

With the help of the above, the environmental gains from generation 1 to 2 can be summarised as: the new requirements are tighter concerning the constituent substances and more extensive efficacy testing. The introduction of the CDV (critical dilution volume) requirement is also new in this generation. These more stringent requirements entail environmental gains in terms of reduced discharges of the most environmentally hazardous substances in the products.

2 Basic facts about the criteria

Products that can be labelled

The product group concerns cleaning agents intended for the cleaning of production premises (surfaces, walls and floors) and production equipment (pipe systems and other equipment) within the food industry, as well as cleaning agents for catering kitchens.

The criteria do not include personal hygiene products, disinfectants, band lubricants, dishwasher detergents, products with microorganisms, or two-component products. With regard to products that cannot be ecolabelled according to this criteria document, reference is made to Nordic Ecolabelling's other criteria documents, such as machine dishwasher detergent for professional use, cleaning agents and industrial cleaning and degreasing agents.

Disinfectants are not included in the product group as they are covered by the Biocides Directive. See also section 7.1 for a description of what is included, or not included, in the product group definition.

Justification for Nordic Ecolabelling

Environmental impacts from cleaning agents for use in the food industry mainly come from discharges to drains when the products are used, which means that requirements concerning the constituent substances' environmental and health-related aspects are considered to be very important. Another parameter to ensure the lowest possible environmental impact for this product group is to reduce the risk of overdosing, which is achieved with the requirement of clear dosing instructions, and that the performance of the products at the recommended dosage can be shown. See also section 6 concerning the background to the requirements for this product group.

The Nordic aspects determined for this product group are:

- Effective and with low environmental impact.
- The products contain substances which are not bioaccumulated, leading to a lower environmental impact on their discharge.
- Efficacy tested for use in specific application areas.

Version and validity of the criteria

The first version of the criteria for cleaning agents for use in the food industry was adopted by the Nordic Ecolabelling Board (NMN) in October 2005. This is the first revision of the criteria.

Generation 1 (approved in October 2005) concerned cleaning agents for use in production premises and for production equipment in the food industry. At the The Secretariat Managers Meeting in September 2010, it was decided to expand the product group to include cleaning agents for machine dosage, which are intended for use in professional kitchens.

Generation 2 This revised version is planned to be submitted for consultation in June 2016. The final version is to be adopted in March 2017.

Nordic Ecolabelling licences

Currently (February 2016) there are eight licences within the product group comprising cleaning agents for use in the food industry. The table below shows their distribution on the various countries.

Table 1. Overview of Nordic Ecolabelled cleaning agents for use in the food industry (2016-02-02 from CRM)

Country	Number of licences
Denmark	3
Finland	1
Iceland	0
Norway	2
Sweden	2

The Nordic Ecolabel has not had any particularly great impact on the market within this product group. One reason for this may be that many product series for the food industry include disinfectants. Since disinfectant products cannot be ecolabelled according to these criteria, there is less interest in ecolabelling than in other product groups, in which entire product series can be ecolabelled. Nonetheless, several manufacturers state in response to enquiries from the project group that there is increasing interest in ecolabelling their products.

3 The Nordic Market

In the Nordic region, the market for cleaning agents for use in the food industry is dominated by a few large producers and suppliers. As a general rule, cleaning agents for use in the food industry constitute a small part of a larger range. Even though the market is dominated by a few large companies, there are also many small producers of cleaning agents for use in the food industry, especially for smokeries, meat-processing enterprises (charcuterie products), and fish processors.

Nordic Ecolabelled cleaning agents for use in the food industry can be briefly summarised as the following types of products:

- detergents for circulatory cleaning (CIP) for dairies and other food industries (alkaline)
- foam cleaning agents for catering kitchens (alkaline)
- foam cleaning agents (alkaline)
- basic cleaning agents for e.g. abattoirs (alkaline)

Cleaning in the food production sector is extensive and there are strict requirements concerning execution and documentation. Within all food production, it is important to prevent the growth of bacteria colonies, which makes cleaning very important. Regular bacteria samples are taken from production and equipment. Rinsing to remove soiling and residue is an important stage before an appropriate cleaning agent is applied to the surfaces or parts that are to be cleaned. Cleaning is followed by the element of the process which concerns disinfecting surfaces and equipment, see Figure 1 below.

Figure 1 - Cleaning process in the food industry



Below is a description of some of the areas in which cleaning agents are used in the food industry.

Meat production

Cleaning in an enterprise which produces meat products will typical concern removing waste (meat residue, fat, etc.) by rinsing (basic cleaning), before using cleaning agents suitable to remove fat and proteins. During basic cleaning it is important that all areas have been cleaned before cleaning agents are applied. Usually foam cleaning is applied. Foam cleaning makes it easy to identify to which areas a cleaning agent has been applied. Disinfection is the last cleaning stage. Not only the surfaces of machines and counters must be cleaned, but also boxes, vats, floor grates and so on.

Dairy operation and production

Throughout the Nordic region, milk is produced from cows and goats, for example. Milking takes place at the farms and generally tankers carry the milk to the dairies, where it is processed into various dairy products. Milk production requires good routines and good hygiene practices. Cleaning of milking systems involves removing manure and feed, as well as water deposits such as chalk and limescale, and milk residue.

Stationary systems are cleaned using water and cleaning agents, as cleaning in place, which means that the equipment is not dismantled.

The cleaning agent helps to loosen the contaminating substances and suspend them in the solution so that they can be rinsed out with the cleaning solution. In addition, the cleaning agent must prevent calcium and magnesium from forming limescale (limescale is a deposit which mainly consists of calcium and magnesium). The cleaning agent may be acidic or alkaline. Alkaline cleaning agents are often the standard type of agent used. Acidic cleaning agents are used subsequently, for example once a week, to remove limescale. Disinfectants are used to kill bacteria. Disinfectants often consist of chlorine or chlorine compounds. In some alternative washing systems, disinfection is replaced by high heat.

Production of dairy products such as cheese, beverages, ice cream, desserts and so on requires effective cleaning and disinfection of machines, equipment and production premises. Surfaces that are in direct contact with food products and processing equipment require cleaning in order to reduce surface bacteria and to prevent contamination during production.

Highly alkaline liquid detergents to remove proteins, fat and limescale are used to clean milking equipment.

Fish industry

As a rule, the processing of fish, either on board fishing vessels or at land-based catch-landing facilities entails anaesthetisation, slaughtering, gutting and possible

filleting of the fish. This soils production premises, machines and equipment with fish entrails, blood and fat.

After production, the production premises, machines and equipment must be rinsed off to remove fish debris, fish residue, fat and blood. It is customary to rinse in cold water before draining off and adding detergent, preferably with foam, which is left for a time before pressure rinsing with heated water. Washing is followed by disinfection.

Breweries

Breweries produce beer, cider and mineral water. Breweries producing beer consist of a malt house, brewing house and a fermentation house, in addition to the actual bottling plant. All of these processes concern products for human consumption and require hygiene and cleaning routines. Cleaning agents are needed especially in the bottling plant, where Nordic Ecolabelled products can be used. In bottling plants there is a need to clean pipe systems, tanks, conveyor belts, surfaces and equipment.

4 Other labels and controls

Many labelling systems have criteria for cleaning agents, although these labelling systems usually concern products to clean offices, institutions, storerooms and industrial plant. The following labelling schemes have no specific criteria for cleaning agents for use in the food industry: EU Ecolabel[1], Astma & Allergi-förbunden (Swedish Asthma and Allergy Association)[2,3,4,5]. There are no Green Public Procurement (GPP)[6] requirements concerning cleaning agents for use in the food industry.

The Swedish Society for Nature Conservation has the "Bra Miljöval" (Good Environmental Choice) ecolabelling criteria, which cover a number of product areas. Like the Nordic Ecolabel, "Bra Miljöval" is a Type 1 labelling scheme. This scheme has no separate requirements concerning cleaning agents for use in the food industry, but has criteria for chemical products[7] which include everything from shampoo to cleaning agents and autocare agents. Today, a small number of products are labelled[8] for the food industry.

Voluntary systems do not seem to be so common for this type of product.

[1] EU Ecolabel: www.ecolabel.eu (visited 2016-03-01)
[2] Astma och Allergiförbundet (Swedish Asthma and Allergy Association): http://astmaoallergiforbundet.se/svalanmarkt/ (visited 2016-03-01)
[3] Astma og Allergi DK (Danish Asthma and Allergy Association): http://www.astma-allergi.dk/producent/kriterier (visited 2016-03-01)
[4] NAAF No (Norwegian Asthma and Allergy Association): www.naaf.no (visited 2016-03-01)
[5] Allergia Fi (Finnish Allergy and Asthma Federation): www.allergia.fi/ (visited 2016-03-01)
[6] http://ec.europa.eu/environment/gpp/pdf/toolkit/cleaning_GPP_product_sheet_da.pdf (visited 2016-03-01)
[7] "Bra Miljöval" criteria for chemical products, version 2006:4, www.snf.se (visited 2016-03-01)
[8] http://www.naturskyddsforeningen.se/bra-miljoval/register (visited 2016-03-01)

Official requirements, national industry schemes and other control schemes

Regulations which are relevant for this product group:

- The REACH Regulation
- The CLP Regulation
- The Detergent Regulation (EC) No. 648/2004*
- Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs, Articles 7 and 8

* *Since cleaning agents for use in the food industry are products for professional use, it is possible to grant dispensation from requirements concerning the biodegradability of surfactants, so that it is still relevant for Nordic Ecolabelling to require surfactants to be aerobically and anaerobically biodegradable in this product group, see O11.*

HACCP (Hazard Analysis and Critical Control Point)

The HACCP system is an internationally recognised hazard analysis and risk assessment system[9] within the food industry. The system helps companies to document, assess and evaluate their own quality systems.

HACCP is an internal control programme to help to ensure that food which is produced and served is safe in terms of health. The programme requires a number of basic routines or basic conditions to be in place. The method is based on seven principles[10]:

- Identification of health hazards
- Identification of critical handling steps
- Determination of the threshold value for each critical handling step
- Determination of monitoring of the critical handling steps
- Determination of measures to take if threshold values are exceeded
- Verification that the system is functioning and is complied with
- Creation of documentation

All hazards that are discovered must then be prevented, minimised and reported. Based on the hazard analyses, a risk assessment is then performed to examine the probability of a recurrence of the hazard, and the consequences.

Biocides Regulation

Nordic Ecolabelling of disinfectants is limited by the Biocides Regulation (EU 528/2012), which replaces the Biocides Directive (98/8/EU). The Biocides Regulation prohibits biocides that present an unacceptable health and/or environmental risk. The Regulation also states that disinfectants may not be marketed as ecofriendly. The criteria for cleaning agents for use in the food industry solely include the parts related to the cleaning of surfaces, systems and equipment in production premises for food products and catering kitchens.

[9] Anticimex: www.anticimex.se (2016-02-08)
[10] www.anticimex.se (2016-02-08)

Denmark

In Denmark, the Danish Environmental Protection Agency has a guide for the assessment and regulation of industrial process water's content of various different substances[11]. This is based on three lists: A, B and C. In brief, this concerns the substances' potential hazardous effects on humans, biological degradability and potential risk for aquatic organisms.

In Denmark, cleaning agents and disinfectants used on board fishing vessels with storage of fish for more than 24 hours, and in food production enterprises handling fish and fish products, must be approved by the Danish Veterinary and Food Administration[12]. This does not apply to fish retailers.

Products used for udder hygiene are approved by the authorities. In practice, this means that virtually all cleaning agents (also without disinfecting effect) intended for other areas of the food industry, are approved by the Danish Veterinary and Food Administration in accordance with the requirements for use in the fishing industry. This makes it easier for producers to market and sell the products to the overall food industry. This also makes requirements of cleaning routines, such as rinsing with water after using cleaning agents, as well as the temperature of the rinsing water.

Finland

The municipalities hold the primary responsibility for the practical work in the control of food products. The municipal supervisory authorities (inspectors and veterinary officers) perform inspections of primary production, as well as all facilities and retail outlets engaged in the commercial production, handling, storage, serving and/or sale of food products.

The regional administrative agency manages and evaluates the municipalities' inspection of food products and monitors compliance with the food regulations within its area. The regional administrative agency compiles an annual summary for the Finnish Food Safety Authority Evira[13] on the basis of reports on the municipalities' inspection, and according to these reports assesses how the regional food inspection has been performed. Evira is the central government agency and is tasked with planning, managing, developing and performing food inspection on a national basis. As part of the programme for the national food inspection, every third year Evira sets up a national environmental and health safety inspection programme. Evira writes on its website that cleaning agents and disinfectants used to clean food premises should be suitable for their purpose. The cleaning agent must be soluble in water and must not leave traces of cleaning agents on surfaces that are in contact with food[14].

The Finnish Ministry of Agriculture and Forestry is the highest authority with the task of preparing, planning and monitoring food inspection legislation.

Norway

[11] Danish Environmental Protection Agency, Tilslutning af industrispildevand til offentlige spildevandsanlæg (Connection of industrial wastewater to public wastewater systems), 2006,
[12] Order no. 1004 of 15/12/1999: Order on the approval of disinfectants and certain cleaning agents in food production companies, etc.
[13] Evira: http://www.evira.fi (2016-03-08)
[14] http://www.evira.fi/portal/fi/elintarvikkeet/hygieniaosaaminen/tietopaketti/puhtaanapito/puhdistusaineet (2016-03-08)

Up to 2011, the Technical Committee for Cleaning and Disinfection Agents for the Food Industry (TKVDN) served as a voluntary registration and labelling body for cleaning and disinfection agents for the Norwegian food industry. The regulations are now assessed to be so good and adequate that TKVDN's registration scheme is superfluous.

In today's hygiene regulations it is expected and required that the company has internal inspection that is based on HACCP[15] (see the above section concerning HACCP). The regulations state that operators must keep premises clean, disinfect as necessary and inspect cleanness, but does not specify any concrete official requirements concerning the actual agents used.

In Norway, the term "IK Mat" denotes an internal inspection system which all food production companies are obliged to have introduced. This is a system requirement that is well-established in most companies and is subject to regulation no. 1187 of 15.12.1994 on internal inspection of compliance with food product legislation (the internal inspection regulations)[16]. The Norwegian Food Safety Authority has retained the internal inspection regulations in order to maintain the system requirement since HACCP is not a direct system requirement.

Approved disinfectants are only approved for use in the disinfection of aquaculture systems, transport units and equipment[17]. No approval is required for cleaning agents (which are not disinfectants).

Sweden

The relevant official requirements are official requirements concerning hygiene. Several authorities, such as the Swedish National Food Agency, the Swedish National Board of Social Services and the Swedish Board of Agriculture have hygiene regulations and requirements. The authorities set requirements concerning cleaning and disinfection, especially concerning the food production industry and other enterprises with commercial handling of food products. The responsibility for control of food products is shared between the Swedish National Food Agency, the county councils and the municipalities.

The Swedish National Food Agency[18] prescribes that commercial operators which handle food products are obliged to perform self-inspection that is adapted to the nature and extent of the business enterprise. The Swedish National Food Agency also describes how premises, equipment and tools must be kept clean and in satisfactory condition so as not to contaminate raw materials and products. Good hygiene in the production of milk and other food products is also subject to the Swedish Board of Agriculture's regulations[19]. Disinfectants are also subject to specific requirements.

National industry guidelines The Swedish Food Federation's industry organisations also create industry guidelines[20], which are assessed by the Swedish National Food

[15] Food hygiene regulations, which among other things implement regulation EC 852/2004: http://www.lovdata.no/cgi-wift/ldles?doc=/sf/sf/sf-20081222-1623.html (visited 2016-03-09)
[16] https://lovdata.no/dokument/SF/forskrift/1994-12-15-1187 (visited 2016-03-09)
[17] Regulation no. 821 of 17 June 2008 on the use and approval of disinfectants in aquaculture systems and transport units: https://lovdata.no/dokument/SF/forskrift/2008-06-17-821 (visited 2016-03-09)
[18] www.livsmedelsverket.se (visited 2016-03-09)
[19] Swedish Board of Agriculture: www.jordbruksverket.se (visited 2016-03-09)
[20] http://www.livsmedelsverket.se/produktion-handel--kontroll/branschriktlinjer2/ (visited 2016-03-08)

Agency. The industry guidelines advise companies within the respective industries on how to fulfil the legislative requirements, and also on the design of their own control of the company. The Federation of Swedish Farmers, LRF[21], has general requirements and recommendations concerning the choice of chemicals and use of chemicals in, for example, dairies[22].

5 About the revision

Purpose of the revision

The main objective of the revision has been to present a proposal for revised criteria for cleaning agents for use in the food industry which ensure positive environmental benefits via ecolabelling, and that the criteria are also useful and clear to the industries at which they are targeted. The revision considered the areas that were revealed during the evaluation of the criteria. The evaluation indicated that the criteria should be revised with focus on:

- General assessment of the requirement levels and possibility of tightening the requirements.
- Assessment of whether the criteria are correct in relation to the market and the development trend for the market.
- Product group delineation: Definition and assessment of expansion to, for instance, disinfectants, highly-concentrated products and use of micro-organisms in products. The product group delineations must also be assessed against products for the industry, such as the fisheries industry.
- Updating in relation to chemical-technical guidelines
- Assessment of requirements of complexing agents and NTA content
- Challenge test. Assessment of whether to retain this. The feedback is that this takes time and resources and that it should be possible to choose a preserving agent that is not bioaccumulative and to follow the supplier's conservation recommendations.
- Review of problems in the food industry with protein deposits on equipment and the risk of microbial growth and assessment of the requirements on this basis.
- Assessment of the possibility of setting requirements for CDV calculation or other requirements of the content of substances that is toxic to humans.
- Updating of the background document and preparing an updated and thorough RPS analysis on the basis of the MECO analysis from the evaluation in 2011.
- Review of the requirements of preserving agents and bioaccumability, especially for products with neutral pH.
- Assessment of the consequences of a prohibition of DTPA and more stringent phosphorus requirements.

[21] www.lrf.se (visited 2016-03-09)
[22] http://www.lrf.se/foretagande/verktyg/bra-kemrad (visited 2016-03-09)

- Review of the user report requirements. Producers of cleaning agents for use in the food industry tend to specialise, so that one producer may possibly only supply two to three different users/areas of use. It can therefore be a challenge to get more than three user reports from various areas of use. This requirement should be reviewed when any revision is made.
- Development of joint Nordic bullet points for the product group's environmental characteristics.

About this criteria review/revision

The project group comprised the following persons/roles.

Project Managers: Anne Kristine Feltman/Susanna Vesterlund

Project Consultants: Lina Harström/Terhi Uusitalo and Caroline Karlsson

During the revision, the project group was in ongoing contact with the industry, including producers, raw materials producers and licence holders.

6 Environmental impact of the "product group"

The most important environmental parameters for cleaning agents for use in the food industry have been assessed to be the inherent characteristics of the constituent substances (such as biodegradability, ecotoxicity and potential health hazard) and the products' dosing and performance. Nordic Ecolabelling has therefore focused on setting requirements of the constituent substances' environmental and health-related characteristics. Requirements are also made of the dosing instructions and performance tests, to reduce the risk of overdosing.

6.1 MECO - charting of environmental impacts

In order to assess which requirements should be made of Nordic Ecolabelled cleaning agents for use in the food industry, a simplified LCA analysis has been performed. It is called a MECO analysis, which compiles the impacts from Materials, Energy, Chemicals and Other factors (such as waste, transport and so on), in order to assess the environmental impact of cleaning agents for use in the food industry in five "phases" of the life cycle.

The MECO matrix helps us to assess where relevant health and environmental impacts are related to materials, energy and chemicals in the various life cycle phases of cleaning agents for use in the food industry. Appendix 1 presents a more detailed MECO matrix. Below, the impacts are described in further detail for the various phases.

Materials phase

A number of different raw materials, such as surfactants, solvents, polymers, inorganic substances, preserving agents, colourants and complexing agents are included in chemical-technical products. Raw materials such as surfactants, polymers and solvents originate from non-renewable fossil materials (oil and

natural gas), but can also originate from renewable resources such as vegetable and animal oils.

Plastic for packaging mainly comes from fossil sources such as oil and gas. Crude oil is an important resource as it is used for heating, fuel and production of raw materials for plastics, cleaning agents, paint and pharmaceuticals. The environment is affected among other things by oil emissions to lakes in conjunction with production. In addition, oil and gas consumption leads to emissions of the climate gas CO_2 and gases such as NOx and SO_2 which have acidifying effects.

Renewable raw materials can also present environmental problems when, for example, tropical forests are cut down to make way for plantations. Production of biomass and other renewable raw materials can result in significant environmental impacts. The renewability of renewable resources as such is an important argument in promoting the use of renewable resources.

Cleaning agents for use in the food industry usually consist of inorganic acids and alkalis. Organic raw materials are used less extensively. For this product group it is not currently relevant to set requirements concerning the origin of raw materials or the ratio of renewable resources.

Recovery of raw materials requires energy and water, and produces waste. In addition, production of raw materials such as surfactants requires further chemical processing.

Increased population growth will require increased consumption of raw materials, both renewable and non-renewable, and future raw material requirements will have a considerable environmental impact.

Production phase

In the manufacture of constituent substances, products and packaging, energy and water are used in the factories, and waste is produced. Life cycle assessments of various chemical-technical products show that the manufacture of constituent substances and/or the manufacture of the final products generally does not account for the dominant environmental impact in the life cycle of the products.[23] This is also supported by the MECO performed on the revision of the Nordic Ecolabelling criteria for cleaning agents in 2013[24], when the energy consumption to recover raw materials was not assessed to be a significant parameter in the overall assessment.

Chemicals are used in the production of plastic for packaging, in order to achieve the required end-product.

In production, there is a risk of the employees being exposed to the raw materials and end-products. Both skin contact and inhalation can have detrimental health effects for the employees, unless safety equipment is used. The processes are often automated and in normal production management the risk of hazardous emissions from production is considered to be small.

[23] AISE 2001: The Life-Cycle Assessment of European Clothes Laundering. Report 2: LCA of Compact Fabric Washing Powder & main wash process
[24] The background document for Nordic ecolabelled Cleaning Agents, Version 5, was adopted on 13 March 2013

Use phase

Cleaning agents for use in the food industry are applied to the areas to be cleaned as part of the overall cleaning process, which involves rinsing with water, applying the cleaning agent, waiting time, rinsing and disinfecting. Often, foam cleaning (sprayed on) is used, as this makes it easier to see where the products have been applied. Hot water is often used for cleaning in the food industry.

There is no full overview of the volume of cleaning agents for use in the food industry used in the Nordic region. Overdosing will increase consumption and result in increased extraction of raw materials, besides a higher environmental impact from discharging chemicals to the drains or recipients after use.

For users of cleaning agents for use in the food industry it is very important that the products are effective, especially due to the hygiene requirements in the food industry. Low product performance increases the risk of overdosing, as the user will not be satisfied with the result of a specific dose.

Cleaning agents for use in the food industry are used in premises which are connected to municipal drainage systems, but may also be used on board fishing vessels where fish is slaughtered and processed. These vessels must have their own cleaning systems (biological). The drainage network leads to treatment plants (or other processing), but since these treatment plants mainly remove nitrogen and phosphorus, and do not degrade other than easily biodegradable organic compounds, it is relevant to set requirements of ecotoxicology and biodegradability. Products with constituent substances that are easily biodegradable will therefore lead to fewer negative consequences.

For the constituent raw materials/chemicals in cleaning agents for use in the food industry, ecotoxicity and biodegradability are the most important parameters for assessing the products' environmental impact in the use phase.

Waste phase

Packaging for cleaning agents for use in the food industry is often bulky and designed to serve the function of packaging, i.e. without aesthetic decoration to the same extent as consumer packaging. There are also good recovery systems in the industry. Packaging waste is not the most relevant environmental problem for this product group.

Transport phase

Nordic Ecolabelling lacks concrete details of how transport affects the various stages of the life cycle of cleaning agents for use in the food industry, but our experience indicates that the raw materials are often produced in other countries than where the products are later sold and used, and may be transported over long distances on lorries, trains or ships. Life cycle studies[25] of the transport of raw materials and end-products show that the transport phase often has a lower environmental impact, with lower energy consumption, than the recovery of raw materials.

[25] Golsteijn et al, A compilation of life cycle studies for six household detergent product categories in Europe: the basis for product-specific A.I.S.E. Charter Advanced Sustainability Profiles, 2015, http://enveurope.springeropen.com/articles/10.1186/s12302-015-0055-4 (visited 2016-04-20)

The products may be ready-to-use or concentrated, which affects both the amount of packaging and the energy used in transport. Concentrated products require less packaging and also less energy for transport.

6.2 Relevance, potential and steerability (RPS) of cleaning agents for use in the food industry

To assess the health and environmental requirements for various products, Nordic Ecolabelling uses the parameters Relevance, Potential and Steerability (RPS).

- Relevance - Is there an environmental problem?
- Potential - Is it possible to address the problem?
- Steerability - Can environmental labelling do anything to address the problem?

To achieve environmental benefits, each requirement must be relevant, according to the environmental problems for the product group. There must also be potential to distinguish the environmentally superior products. It must also be possible to steer the relevant environmental problem using the requirements made.

The next stage is to assess the potential for reducing health and/or environmental effects in the products' life cycle, before finally assessing whether Nordic Ecolabelling offers the steerability required to be able to realise the environmental improvement potential.

In order to set relevant requirements that promote real environmental gains, all three parameters (RPS) must be assessed to establish the overall existence of Relevance, Potential and Steerability.

6.2.1 Relevance

Relevance is assessed according to the environmental problems caused by the product group and the extent of each problem. The environmental impact of cleaning agents for use in the food industry is described exhaustively in chapter 6.1, in conjunction with the MECO analysis.

6.2.2 Potential

Potential is assessed according to the potential environmental benefits within the specific product group and for each area of the MECO form, as well as for each area of the criteria in which requirements are made.

Raw materials

The relevance of setting requirements for the origin of raw materials or share of renewable raw materials has been assessed to be small for this product group, and therefore the potential is not discussed here.

Since the raw materials chains are very long, the steerability of setting requirements of energy use or water consumption in the production of raw materials is assessed to be very low.

Plastic can be produced from fossil or renewable sources, such as maize and sugar cane. Recycled plastic can be used to reduce environmental impacts by conserving fossil resources and reducing CO_2 emissions. Today, however, the available range of biobased plastic is limited. It accounts for approximately 1% of the world's production of plastic, equivalent to the use of approximately 1,150,000 tonnes of biobased plastic for various packaging globally in 2014[26]. There is thus no potential to require the specific use of biobased plastics in packaging for cleaning agents used in the food industry. Biobased plastics are mainly used in food packaging, since consumers require biobased food packaging.

Production phase

The production phase is assessed to be less relevant in terms of the cleaning agent's entire life cycle, so that the potential is not discussed.

Use phase

Products containing raw materials with low ecotoxicity and which are biodegradable, both aerobically and anaerobically, have a lower environmental impact than products with less biodegradable, toxic raw materials. Nordic Ecolabelling is aware that there are variations in the content of various products in the market, for example in terms of their content of substances that are very harmful to health (such as fragrances), and their toxicity and biodegradability.

Products requiring dilution in hot water lead to higher energy consumption than products which do not require hot water. Many cleaning agents for use in the food industry are diluted in hot water. There may be potential in requiring recommended water temperatures for the products.

Cleaning agents for use in the food industry vary in terms of both performance and environmental characteristics. High volumes of the products are used, and effective products that are dosed correctly would contribute to reduced consumption, lower costs and reduced environmental impacts.

Clear dosing instructions, dosing equipment, and automatic dosing, would reduce the risk of overdosing and thereby reduce chemical emissions. Reduced extraction of raw materials would reduce energy consumption for the extraction and processing of the raw materials, and reduce consumption of packaging materials for the raw materials. The use of products for circulatory cleaning in pipe systems (CIP) is usually dosed automatically, making it possible to reduce overdosing of the products.

Products which tests have shown to be effective at the stated doses will increase the likelihood of the user being satisfied with the result, also at correct low/correct dosage. The products in the market have varying performance.

[26] http://www.european-bioplastics.org/market/market-drivers/ and http://www.european-bioplastics.org/market/ (visited 18.3.2016)

Waste phase

Reduced packaging volumes present savings in the transport stage and in terms of the volumes of plastic raw materials required for packaging. Cleaning agents for use in the food industry are often packaged in bulk, with a relatively small amount of packaging per dose. There is thus limited potential for setting the traditional WBR (weight-benefit ratio) requirement.

Transport phase

Reduced transport of both raw materials and end-products should result in lower energy consumption and CO_2 emissions. It is difficult to set figures for this impact, since transport takes place in many different stages of the products' life cycle. In general terms, energy consumption can be said to be related to whether the packaging contains many or few doses, which means that more concentrated products entail less transport per dose. Bulk packaging containing more doses is also preferable, rather than small packaging units with few doses. Encouraging the use of concentrated products may reduce transport and energy consumption.

6.2.3 Steerability and summary of RPS

Steerability is assessed on the basis of the opportunity to set requirements of the relevant environmental parameters with improvement potential.

Raw materials

The raw materials phase is not assessed to have very great potential and therefore steerability is not discussed.

Nordic Ecolabelling will monitor the development in the industry and in its ongoing criteria development will assess opportunities to set requirements of the ratio of biobased plastic in packaging, and also the ratio of renewable raw materials in the products, and the traceability of the renewable raw materials.

Production phase

The production phase is not assessed to be particularly relevant and therefore steerability is not discussed.

Use phase

Producers have a great impact on which raw materials are used in products, and are aware of the respective raw materials' environmental and health impacts. There are thus good opportunities to set fully steerable requirements concerning ecotoxicity and biodegradability.

Setting requirements to limit allergens and prohibit the use of fragrances in cleaning agents for use in the food industry will make it possible to reduce the number of new allergy sufferers. Nordic Ecolabelling can therefore see an opportunity to distinguish between the various products, and only label those with the lowest health impact. Exposure can be reduced further by using protective equipment and automatic dosing.

Nordic Ecolabelling can require clear dosing instructions, in order to facilitate correct dosing. Concentrated products often have dosing devices offered by producers and suppliers. This can help to ensure more correct dosing. User tests

and performance testing requirements ensure effective products, and correctly dosed effective products reduce the overdosing need.

Nordic Ecolabelling therefore regards dosing requirements and dosing instructions as a means to steer towards more effective products that are used correctly, resulting in reduced overdosing.

Waste phase

The production phase is not assessed to have very great potential and therefore steerability is not discussed.

Transport phase

The steerability of transport used by raw materials producers and producers of cleaning agents is low for Nordic Ecolabelling. Many producers do not own the means of transport (vehicle, train or ship) and for certain sections have no other transport options than, for example, lorries.

7 Justification of the requirements

This chapter presents proposals for new and revised requirements, explains the background to the requirements, the selected requirement levels and any changes from generation 1. The appendices referred to can be found in the criteria document "Nordic Ecolabelling of Cleaning Agents for Use in the Food Industry".

7.1 Product group definition

The product group concerns cleaning agents intended for the cleaning of production premises (surfaces, walls and floors) and production equipment (pipe systems and other equipment) within the food industry, as well as cleaning agents for catering kitchens.

The food industry is defined as the following activities:

- *Food production*
- *Production of beverages*
- *Processing and preserving of meat and meat products*
- *Processing and preserving of fish and crustacean and molluscan shellfish*
- *Processing and preserving of fruit, berries and vegetables*
- *Production of vegetable and animal oils and fats*
- *Production of dairy products and ice cream*
- *Production of grain mill products and starches*
- *Production of bakery and flour products*
- *Other food production*
- *Production of prepared animal feeds*

The definition of the food industry is taken from the EU's statistical classification of economic activities, NACE, which is a statistical standard used to classify entities such as companies and workplaces according to their economic activities[27].

Catering kitchens are kitchens intended for the preparation of a small number of dishes for many people at the same time, such as hospitals and schools. For products for restaurants, reference is made to the criteria for cleaning agents.

Products for both automatic and manual dosing can be Nordic Ecolabelled within the product group. Nordic Ecolabelled cleaning agents for use in the food industry can only be marketed to professional users.

The criteria do not include personal hygiene products, disinfectants, band lubricants, dishwasher detergents, products with microorganisms or two-component products. Disinfectants are not included in the product group since they are covered by the Biocides Directive.

With regard to products that cannot be Nordic Ecolabelled according to this criteria document, reference is made to Nordic Ecolabelling's other criteria documents, such as machine dishwasher detergents for professional use, cleaning agents or industrial cleaning and degreasing agents.

The aforementioned text is the product group definition found in the criterion document.

Cleaning agents are used in various areas in the food industry and may include:

- Cleaning of floor and wall surfaces in production premises and catering kitchens
- Foam cleaning of floors, exterior cleaning of machines
- Removal of proteins and vegetable/animal fat, blood and albuminoids from machines, production equipment and surfaces
- Removal of limescale in dairies
- Cleaning of boxes, barrels and containers
- Cleaning of pipe systems (CIP - clean in place)
- Cleaning of smoking ovens, especially in the fish and meat industry[28]
- Cleaning of tanks, vaporisers, pasteurisers, pipelines, centrifuges and other food industry equipment
- Membrane cleaning

The product group definition has been specified in terms of catering kitchens, in relation to generation 1 of the criteria. The primary difference between a catering kitchen and a restaurant kitchen is that in a catering kitchen a small number of dishes are prepared for many people at the same time. In addition, individual pans are seldom used. Instead, griddles and boiling pans with built-in heating and stirring are used. For products for restaurants, reference is made to the criteria for cleaning agents. The product group has also been expanded to include manually dosed products for catering kitchens. In the preceding generation, only

[27] SCB: http://www.scb.se/SNI2007/, (visited 2016-03-07)
[28] Arcon: www.arcon-as.no (visited 2016-03-07)

automatically dosed products for catering kitchens could be ecolabelled. Manual dosing usually takes place in smaller enterprises such as farm slaughterhouses and farm packing units, but also in catering kitchens. The product group definition has been expanded to meet the demand in the industry, but also to enable small enterprises to also achieve environmental benefits.

Products which cannot be Nordic Ecolabelled as cleaning agents for use in the food industry

The criteria do not include personal hygiene products, products with microorganisms or two-component products.

Disinfectants are not included in the product group since they are covered by the Biocides Directive. Products that are marketed with disinfectant properties are assessed to be biocides in accordance with the Biocides Directive, EU 528/2012. The Biocides Directive restricts marketing of these types of products as, for instance, "ecofriendly"[29].

Band lubricants (products for the lubrication of conveyor belts in e.g. dairies and breweries) are not cleaning agents and are therefore not included in the criteria for cleaning agents for use in the food industry.

Microorganisms

Some cleaning agents in the Nordic market contain microorganisms to give the products extra cleaning performance. Microorganisms are living organisms which are used to degrade organic materials such as proteins, fat and starch in soil deposits.

The EU Ecolabel excludes microorganisms in its criteria for cleaning agents, while in its criteria for cleaning agents Nordic Ecolabelling permits cleaning agents for certain types of professional products to contain microorganisms. These products are required to fulfil a specific requirement concerning microorganisms besides all the other requirements in the criteria document.

For this revision, Nordic Ecolabelling contacted several producers of cleaning products for use in the food industry. Most of these producers have stated that they do not manufacture products with microorganisms for this product segment. A few of them answered that they have products for certain specific application areas within the food industry. Since the industry has not shown very much interest in these product types, Nordic Ecolabelling has chosen not to include products with microorganisms in this product group, but requests comments if there is still an interest in expanding the product group with specific requirements concerning microorganisms.

[29] Biocides Directive EU 528/2012, Article 72, Advertising, http://eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:02012R0528-20140425&from=SV (visited 2016-03-07)

7.2 Overall requirement area, description of products

The requirements in Chapter 1 apply to all constituent substances in the product (cleaning agent), unless otherwise specified.

The requirements in Chapter 1 of the criteria apply to all constituent substances in the product (cleaning agent), unless otherwise specified. The calculations are based on the highest recommended dose stated as grammes of the product/litres of water.

Constituent substances and impurities

All substances in the product are counted as constituent substances, unless otherwise stated, including additives (e.g. preservatives and stabilisers) in the raw materials, but not impurities deriving from production, including raw materials production.

Impurities are residues from production, including raw materials production, which may be found in the product at concentrations below 100 ppm (0.0100% by weight, 100 mg/kg), but not substances that have been added to a raw material or product actively and for a particular purpose, irrespective of quantity. Impurities in concentrations exceeding 1.0% in of the raw material are considered to be constituent substances. Known degraded substances/products (such as formaldehyde or and arylamine) from constituent substances are also considered to be constituent substances.

O1 Information about the product

a) The applicant must give detailed information on the cleaning agent to which the application relates. The following information is required:
   - Description of the product's area of use, in accordance with "What can be Nordic Ecolabelled?"
   - Description of the product type (e.g. alkaline, acidic, CIP) and the product's use, in terms of whether it must be diluted or used without dilution.

b) The applicant must provide detailed information on the formulation of the product, and enclose a safety datasheet for each raw material. The information on the product's formulation must include:
   - Trade name
   - Chemical name
   - Amount (both with and without solvents, e.g. water)
   - CAS number of each constituent substance (if a raw material has several constituent substances, this must be stated)
   - Function
   - DID number for substances that can be placed in the DID list
   - Classification

The DID number is an ingredient's number on the DID list, which is used on calculating chemical requirements. The DID list can be obtained from Nordic Ecolabelling's websites, see addresses on page 2.

✉ A complete declaration of the formulation of the product with information as set out in the requirement.

✉ Safety datasheet for each constituent raw material in accordance with the REACH Chemicals Regulation (1907/2006) Annex II.

☒ Signed and completed declaration of compliance with the product requirement, Appendix 2 or similar documentation.

Background to requirement O1

The product must be described so that it can be ensured that the product is subject to the product group definition. It is important that Nordic Ecolabelling has a good knowledge of the ecolabelled cleaning agents for use in the food industry. Without this knowledge, it will not be possible to determine which criteria are relevant and which criteria should be set for the products in the future. Nordic Ecolabelling therefore requires information on the products' formulation and intended application method.

O2 Classification of the product

The final product (cleaning agent) may not be classified according to table O2 below, according to the CLP Regulation 1272/2008 with subsequent amendments.

Table O2 - Classification of the product

CLP Regulation 1272/2008		
Hazard class	**Signal word, Category code**	**Hazard statement**
Toxic to aquatic organisms	Warning, Aquatic acute 1 Warning, Aquatic chronic 1 -, Aquatic chronic 2 -, Aquatic chronic 3 -, Aquatic chronic 4	H400 H410 H411 H412 H413
Hazardous to the ozone layer	Warning, Ozone	H420
Carcinogenicity*	Risk, Carc. 1A or 1B Warning, Carc. 2	H350 H351
May cause genetic defects*	Risk, Muta. 1A or 1B Warning, Muta. 2	H340 H341
Toxic for reproduction*	Risk, Repr. 1A or 1B Warning, Repr. 2 -, Lact.	H360 H361 H362
Acute toxicity	Risk, Acute Tox. 1 or 2 Risk, Acute Tox. 1 or 2 Risk, Acute Tox. 1 or 2 Risk, Acute Tox. 3 Risk, Acute Tox. 3 Risk, Acute Tox. 3 Warning, Acute tox 4** Warning, Acute tox 4** Warning, Acute tox 4**	H300 H310 H330 H301 H311 H331 H302 H312 H332
Specific target organ toxicity	Risk, STOT SE 1 Warning, STOT SE 2 Risk, STOT RE 1 Warning, STOT RE 2	H370 H371 H372 H373
Aspiration hazard	Risk, Asp. Tox. 1	H304
Airway or skin sensitising	Risk, Resp. Sens. 1, 1A or 1B Warning, Skin Sens. 1, 1A or 1B or products labelled EUH208: “Contains (name of sensitising substance). May cause an allergic reaction.”	H334 H317
Highly flammable	Flammable Aerosols 1, 2 or 3 Flammable Liquids 1, 2 or 3	H222, H223, H229 H224, H225, H226

[*] *The classifications in the Table concern all variants within the respective classification. For example, H350 also covers classification H350i.*

[**] *Exceptions: Products may be labelled as Acute tox, Cat 4 with H332, H312 and/or H302 if the packaging is designed so that the user is not in contact with the product.*

Please note that the producer/supplier is responsible for the classification.

☒ Safety datasheet for the end-product in accordance with the REACH Chemicals Regulation (1907/2006), Annex II.

☒ Description of the packaging design showing that the user is not in contact with the product for the products for which an exemption is made from the requirement of classification as H332, H312 and/or H302. Documentation in the form of a technical description and user instructions showing how the user avoids contact with the product.

Background to requirement O2

Nordic Ecolabelling strives to ensure that the health and environmental effects of the products are as low as possible. It is therefore a requirement that the products are not classified as hazardous to the aquatic environment, CMR, acutely toxic, specifically toxic, with specific target organ toxicity, sensitising or flammable.

As a rule, cleaning agents for use in the food industry must be able to remove a certain type of soil at a high concentration. The products in the market are often highly alkaline or acid-based and they are often classified as caustic, irritating to the skin or harmful to the eyes. These classifications are not limited by Nordic Ecolabelling's criteria in this product group, since highly alkaline or acidic products are needed, in order to have effective products for certain application areas.

According to a market survey during the revision, there are, however, products in the market that are classified as, for example, environmentally hazardous. It is thus relevant to exclude products that are classified as environmentally hazardous.

The requirement has been updated from the previous generation, i.e. the classifications in the table in the requirement have been updated to be more relevant for the types of products labelled by Nordic Ecolabelling in this product group.

The exemption for products classified as Acute tox, Cat 4 with H332, H312, H302 to be ecolabelled if the packaging is designed to minimise contact with the user also existed previously, but in this case it was partly subject to the information text requirement. Examples of how packaging can be designed to minimise contact with the user are that there may be dosing systems or pump devices or other solutions which, for example, entail that the user does not need to pour from one package to another on dilution.

O3 Classification of a product's constituent substances

The cleaning agent may not contain substances which are, or can give off substances that are carcinogenic (Carc), mutagenic (Muta) or reprotoxic (Repr) with the following hazard codes or risk phrases, or combinations thereof, see table O3 below. The cleaning agent may not contain substances which are classified as sensitising with H334 or H317, respectively, according to table O3 below.

Table O3 - Classification of a product's constituent substances

Classification under CLP Regulation 1272/2008	
Carcinogenic*	Carc 1A or 1B; H350 Carc 2; H351
Mutagenic*	Muta 1A or 1B; H340 Muta 2; H341
Reprotoxic*	Repr 1A or 1B; H360 Repr 2; H361 Lact. H362
Sensitising	Resp. Sens. 1, 1A or 1B H334 Skin Sens. 1, 1A or 1B H317

* *The classifications in the Table concern all classification variants. For example, H350 also covers classification H350i.*

Exemptions:

- Enzymes (including stabilisers and preservatives in enzyme raw materials) are exempt from the requirement concerning sensitising substances, provided that the enzymes are in liquid form or as non-dust-forming granulates.
- Complexing agents of the MGDA and GLDA type may contain NTA impurities in the raw material in concentrations of less than 0.2%, if the concentration of NTA in the cleaning agent is below 0.1%.

✉ A signed and completed declaration of compliance with the requirement for the product (Appendix 2 or equivalent documentation) and the raw materials (Appendix 3 or equivalent documentation).

✉ Safety datasheet for each constituent raw material in accordance with the REACH Chemicals Regulation (1907/2006) Annex II (see O1).

✉ Documentation on the safety datasheet or similar that the enzymes are in liquid form or in the form of non-dust-forming granulate.

Background to requirement O3

For the same reason as described under requirement O2, there is a requirement that none of the constituent substances may be classified as carcinogenic, mutagenic, reprotoxic or sensitising. In the previous generation, not all CMR classifications were listed explicitly, as here, but the requirement still ruled out all CMR-classified substances, so that the requirement has not been reworded in terms of what is included.

The requirement to prohibit sensitising substances is a tightening in relation to the previous generation of the criteria. The substances that are often classified as sensitising are fragrance substances, preservatives and enzymes. Fragrances are excluded under requirement O8 below. Enzymes are exempted here as there is a need for enzymes in a number of types of cleaning agents in order to degrade proteins, etc. Preservatives are often problematic compounds that are classified as sensitising. This requirement limits the use of preservatives and contributes to ensuring products that are less harmful to health for users of the product.

Within the product group of cleaning agents for use in the food industry, it is mainly ready-to-use products that contain preservatives. Some of the preservatives in the products in the market are classified as sensitising, but there are also non-classified preservatives. Dialogue with the industry has shown that mainly isothiazolinones and phenoxyethanol are used as preservatives in products for the food industry. Many products are completely without preservatives as they

have high or low pH values, and are thereby self-preserving. The preservatives used must also fulfil requirement O5 concerning Challenge test and bioaccumability.

Exemptions

Enzymes

Enzymes, including stabilisers and preservatives in the enzyme raw material, are exempted from the requirement concerning sensitising substances, H317, since enzymes are already classified as sensitising. Enzymes are used in a number of cleaning agents for use in the food industry, such as products for membrane cleaning.

Previously, there was a separate requirement for enzymes, which has now been removed. Another new aspect is the requirement for the enzymes to be in liquid form, or as non-dust-forming granulate. This requirement is to prevent the people who work in cleaning agent production from being exposed to the enzymes' potential sensitisation of the respiratory system. There are rules and guidelines for handling enzymes, to protect people working with enzymes in production. One example is AISE's guidelines[30].

The requirement text is now more harmonised with the criteria for both machine dishwasher detergents for professional use and cleaning agents. The requirement in the preceding generation stated that the enzymes had to be free of microorganism residues from production, but this has been adjusted to the requirement that the enzymes are in liquid form, or in the form of non-dust-forming granulates, in order to protect the people working with the enzymes in the production of the cleaning agent.

Complexing agents

NTA (Nitrilotriacetic acid) and its salts are good complexing agents[31] and have previously been used in many chemical-technical products, but have now been phased out for most products. NTA has been classified as carcinogenic cat.2, H351. NTA is thus prohibited on the grounds of its classification. Complexing agents that replace NTA (e.g. GLDA and MGDA) may, however, contain small quantities of NTA as synthesis residues from raw materials production (as attested in various safety datasheets for the raw materials). Nordic Ecolabelling's review of licensed products shows that there is a need to use these complexing agents in cleaning agents for use in the food industry, as an alternative to, for example, EDTA. NTA as a contaminant in complexing agents is therefore exempted from the requirement, but subject to the limitation that the concentration of NTA in the raw materials must be below 0.2% by weight. and that the concentration in the end-product must be below 0.1% by weight. The content in the raw material has been tightened after discussion with the industry. The EU Ecolabel's proposed revised criteria for technical chemicals, including cleaning agents, now also includes the same stipulation that 0.1% NTA may be found in raw materials of the GLDA and MGDA types.

[30] A.I.S.E's guidelines for Safe handling of enzymes: https://www.aise.eu/our-activities/standards-and-industry-guidelines/safe-handling-of-enzymes.aspx (visited 2016-04-26)
[31] Lindquist, Information om kompleksbindingspotentialer (Information on complexing agent potential), submitted by Hans Lindquist in conjunction with the development of the criteria for machine dishwashing agents for professional use. 2002

O4 Long-term environmental effects

The use of substances which are classified with any of the hazard statements H410, H411 or H412 is limited as follows:

$100*C_{H410} + 10*C_{H411} + C_{H412} \leq 0.0010$ grammes/litre in-use solution

where

C_{H410} = concentration of substances with H410 in grammes/litre in-use solution

C_{H411} = concentration of substances with H411 in grammes/litre in-use solution

C_{H412} = concentration of substances with H412 in grammes/litre in-use solution

Exemptions

- Protease/Subtilisin classified as Aquatic Chronic 2 (H411) is exempt from the requirement, see also the requirement concerning enzymes in O3.
- Surfactants classified as H412 are exempted from the requirement, on condition that they are readily biodegradable* and anaerobically biodegradable**.

* *In accordance with the DID list. If the substance is not on the DID list, or data on the DID list is lacking, the substance is documented in accordance with test method no. 301 A-F or no. 310 in the OECD guidelines for testing of chemicals, or other equivalent test methods.*

** *In accordance with the DID list. If the substance is not on the DID list, the substance is documented in accordance with ISO 11734, ECETOC no. 28 (June 1988) or other equivalent test methods, where biodegradability of at least 60% is achieved in anaerobic conditions.*

If information about the substance being hazardous to the environment (in the form of data concerning toxicity and biodegradability, or toxicity and bioaccumulability) is not available, the substance is treated as a worst case, i.e. as environmentally hazardous, H410.

☒ Report on surfactants that are to be exempted from the requirement (quantity, classification, biodegradability).

☒ Summary of the product's content in % by weight of substances classified as H410, H411 and H412.

☒ Appendices 2 (product) and 3 (raw material) signed and completed, or alternatively equivalent signed information.

☒ Calculation according to the above formula showing that the requirement is fulfilled.

Background to requirement O4

Substances that are classified as environmentally hazardous may be present in cleaning agents in limited quantities. Substances with poor biodegradability may cause environmental problems today or in the future. The effect will be very serious if poorly degradable substances are also toxic. Limitation of these adverse characteristics will reduce the risk of negative environmental impacts. A requirement is therefore made concerning the products' maximum content of environmentally hazardous substances. By weighting the parameters, substances classified as H410 are subject to the greatest limitation. The weighting in the formula below is connected to classification limits for environmentally hazardous substances (CLP, table 4.1.2, Classification of compounds in terms of the risk of long-term adverse effects by summarising the concentrations of the classified constituents).

Experience from ecolabelled cleaning agents for use in the food industry shows that there are many different types of products, with great variation in their dosing. There are both ready-to-use and concentrated products in the market. Nordic Ecolabelling therefore considers it important to set requirements of environmentally hazardous substances based on grammes/litre of in-use solution, rather than the product's percentage content. The cleaning agents for use in the food industry which are ecolabelled today contain very small quantities of environmentally hazardous substances. However, there are many products in the Nordic market within this product segment which contain environmentally hazardous substances such as classified surfactants, hydrogen peroxide, fragrances, colourants, hypochlorites, preservatives and amine oxides. Nordic Ecolabelling has decided to set the requirement concerning environmentally hazardous substances according to the following weighted formula, so as to limit the most environmentally hazardous substances the most.

The threshold values are set on the basis of Nordic Ecolabelling's licensing experience with this product group. Consultation input is therefore extra important in this respect.

$100*C_{H410} + 10*C_{H411} + C_{H412} \leq 0.0010$ grammes/litre in-use solution

This threshold can be compared with the threshold in cleaning agents, which is currently 0.0020 grammes/litre in-use solution for concentrated products for professional use, and 0.10 grammes/litre in-use solution for ready-to-use professional products.

The requirement is a tightening from generation 1 of the criteria, since the requirement was not a weighted formula, but separate threshold values for the respective classifications (H410, H411 and H412). In generation 1 there were also requirements limiting substances classified as H400. Nordic Ecolabelling has moved away from setting requirements for substances classified as H400 and instead focuses on the substances which are more persistently environmentally hazardous substances, i.e. which are classified as H410-H412. The requirement that the product may not be classified as H400 is maintained, see O2.

For this generation of the criteria, Nordic Ecolabelling has decided not to include M-factors, multiplication factors*, in the requirement, since most of the substances included in cleaning agents in this product group have M-factor 1. This also entails that substances for which there is no data and for which a "worst case" assessment is made are counted as H410 with M-factor=1.

* *An M-factor is applied to the concentration of a substance classified as hazardous to the aquatic environment in the categories of acute 1 and chronic 1, on classification in accordance with CLP*[32].

Exemptions

On the 2nd ATP of CLP the basis for environmental risk classification was amended (as from 1 December 2012). Previously, substances were classified with the environmental risk classification "long-term environmental effects" (R50/53, R51/53 and R52/53) if they were not easily biodegradable. But in the CLP system, substances can have a risk classification in the "long-term effects for aquatic

[32] ECHA: http://echa.europa.eu/documents/10162/13643/pg_7_clp_notif_sv.pdf (visited 2016-05-03)

organisms" (H410, H411, H412) category solely for the substance's chronic toxicity (if data exists), even if the substance is easily biodegradable. This mostly affects surfactants, which often have low toxicity values, but are biodegradable. Yet there are also other substances, such as the protease enzyme, which are also classified as H411 according to the new classification rules.

Protease

Protease (Subtilisin, EINECS 232-752-2, CAS 9014-01-1) is an effective enzyme which is mainly used to degrade protein-based stains. Protease cannot be replaced by other enzymes. Chronic tests have shown that protease must be classified as Aquatic Chronic 2 (H411), event though protease is easily biodegradable. In this criteria generation, Nordic Ecolabelling has decided to exclude protease from the environmentally hazardous substances requirement.

Surfactants

Nordic Ecolabelling has decided to exempt aerobic and anaerobic biodegradable surfactants with the H412 classification (Harmful to aquatic life with long-lasting effects) from the requirement, in the same way as in the criteria for cleaning agents. In the next revision, Nordic Ecolabelling will review the products in order to investigate the need for this exemption.

O5 Preservatives

a) Preservatives that are included in the end product or in one of the constituent substances may not be bioaccumulative. Preservatives are assessed to be non-bioaccumulative if BCF < 500 or logKow < 4. If both values are available, the value for the highest measured BCF is to be used.

b) The concentration of the preservative must be optimised and a Challenge test or equivalent must be performed to show this.

c) Preservatives are only permitted to conserve products or raw materials and not to give the product an antibacterial or disinfecting effect.

☒ Documentation of BCF or logKow (e.g. safety datasheet, see requirement O1).

☒ Appendices 2 (product) and 3 (raw material) signed and completed, or alternatively equivalent signed information.

☒ Test report for the completed Challenge test or equivalent showing that an optimum concentration of the preservative is used in the product. See Appendix 1 concerning test laboratory requirements and for information on Challenge tests.

☒ Signed and completed declaration that preservatives have only been added to conserve the product or raw material (Appendices 2 and 3, or equivalent documentation).

Background to requirement O5

Preservatives are added to products to prevent bacterial growth in the products. The composition of the products may also affect the need for preservatives.

Preservatives are generally toxic to aquatic organisms and can cause hypersensitivity and allergies. Preservatives may only be used in products and in constituent raw materials if they are not bioaccumulative. This is because bioaccumulative compounds accumulate in the fat tissue of living organisms and can cause long-lasting damage to the environment.

Unless otherwise proven, substances are considered to be bioaccumulative if logKow ≥ 4.0 under the OECD's guidelines 107 or 117, or equivalent. The substance in question may be tested on fish in line with the OECD's testing instructions 305 A-E. If the substance has a biological concentration factor (BCF) ≥ 500, the substance is considered to be bioaccumulative, and if BCF < 500 the substance is considered to be non-bioaccumulative. If there is a measured BCF value, the highest measured BCF is always the deciding factor on any assessment of a substance's bioaccumulative potential.

To avoid unnecessary addition of preservatives and to ensure that the amount of preservative is sufficient, the amount of preservative added must be optimised in relation to the product's volume. This is documented via a Challenge test (provocation test, load test) or equivalent test, which is performed in conjunction with the development of the product. The project group has received enquiries from some contacts in the industry concerning whether it is relevant to require Challenge tests for the products in this product group which use preservatives, as they do not consider this test to be particularly relevant. Nordic Ecolabelling still considers it relevant to require a Challenge test for the products which are preserved within this product category, in order to ensure that the amount of preservative is correct for the specific products.

Challenge test is a mass designation for tests to determine the correct/necessary volume of preservative in products. This is performed by adding varying concentrations of preservative (e.g. 2%, 1%, 0.5% and 0.25%) to a series of samples, and to a sample with no added preservative. A mixture of bacteria, yeast and mould fungi are added to the samples and tested for growth. The duration of a test can vary according to what is being tested and the test conditions, such as which organisms are tested (depending on how the product is ultimately to be used), pH, temperature, and so on (these parameters are not specified in Challenge tests). The lowest concentration of preservative for which there is no growth is the correct/optimum amount of preservative for the product. Various producers and suppliers of preservatives have various Challenge tests/methods which they use to determine the correct preservative content. These tests include: Koko Test (Test Method SM 021), USP Challenge Test (US Pharmacopoeia) and CTFA Challenge Test (Cosmetics, Toiletries and Fragrance Association).

There is no wish for Nordic Ecolabelling to ecolabel products with an antibacterial or disinfecting effect. Producers of products/raw materials containing preservatives must therefore declare that the preservative is added with a preserving effect, and not an antibacterial or disinfecting effect.

Within the product group of cleaning agents for use in the food industry, it is mainly ready-to-use products that contain preservatives, see also the justification under requirement O3.

The requirement has been tightened from the previous criteria generation with regard to how preservatives are only permitted to preserve the product or raw material, and not to give an antibacterial or disinfecting effect. The requirement has now been harmonised with the requirement for cleaning agents. In combination with the requirement in O3 that sensitising substances may not be included, this exclude many preservatives, however.

O6 Colourants

Colourants included in the product or constituent substances may not be bioaccumulative. Colourants are assessed to be non-bioaccumulative if BCF < 500 or logKow < 4.0. If there is information on both BCF and logKow, the value for the highest measured BCF must be used. Colourants approved for food products are also accepted (with E number).

✉ Documentation of the colourant's BCF or logKow (e.g. safety datasheet, see O1) or state E number.

✉ Appendices 2 (product) and 3 (raw material) signed and completed, or alternatively equivalent signed information.

Background to requirement O6

Colourants are primarily added to the products for aesthetic reasons, but some raw materials may also be coloured. Colourants may also be added to fulfil a specific function. Within the professional market, for example, colour coding may be used to distinguish which products are used for which purposes. Colourants are added in extremely small quantities and are not considered to be one of the major environmental impact factors for cleaning agents. Colourants are also subject to the CDV requirement, the requirement concerning environmentally hazardous substances and the requirement concerning non-biosubstances.

The requirement excludes bioaccumulative colourants. This means that the requirement limits the risk of the colourant being absorbed into the food chain. Bioaccumulative substances collect in the fat tissue of living organisms and can cause long-lasting damage to the environment.

Unless otherwise proven, substances are considered to be bioaccumulative if logKow ≥ 4.0 under the OECD's guidelines 107 or 117, or equivalent. The substance in question may be tested on fish in line with the OECD's testing instructions 305 A-E. If the substance has a biological concentration factor (BCF) ≥ 500, the substance is considered to be bioaccumulative, and if BCF < 500 the substance is considered to be non-bioaccumulative. If there is a measured BCF value, the highest measured BCF is always the determining factor in the assessment of a substance's bioaccumulative potential.

Colourants that are approved for use in foods are not considered to be environmentally hazardous and are therefore approved.

O7 Phosphorus

The total amount of phosphorus from phosphates, phosphonates and other phosphorus compounds may not exceed 0.50 g P/litre of in-use solution, calculated as grammes of phosphorus per litre of in-use solution. The highest recommended dose must be used to calculate phosphorus.

Observe the national legislation concerning phosphorus where the product is to be sold/marketed. In Norway, phosphorus is subject to the "Regulation on restrictions to the use of health- and environmentally-hazardous chemicals and other products (Product Regulations)", Sections 2-12.

✉ Calculation of the total volume of phosphorus (calculated as elementary phosphorus, P) in the in-use solution.

Background to requirement O7

Phosphate (DID no. 2504) is a reasonably good complexing agent[33]. Phosphate would appear to have good environmental characteristics since it is not hazardous for aquatic organisms, and as it is inorganic there is no reason to consider biodegradability. But phosphate is a nutrient and contributes to eutrophication of the aquatic environment. Phosphate is therefore not unproblematic. It would also seem that phosphorus reserves have been depleted and that phosphorus may become a limited resource in the future.

Phosphonates (DID no. 2512) are a range of phosphorus compounds that are good complexing agents[34]. They are also covered by the phosphorus requirement. Phosphonates are not harmful to aquatic organisms, but they are persistent and are not anaerobically biodegradable. Phosphonates contain phosphorus and are therefore a nutrient that can lead to eutrophication. Phosphonates are used as complexing agents to a lesser extent than phosphate, since phosphate is a very strong complexing agent.

Norway has specific national limitations for phosphorus, which should be taken into account for this product group[35]. In the Norwegian regulation, phosphorus is limited as follows:

a) Special agents for dairies and the food industry: 10.0%

b) Special agents for milk production and other industry: 2.5%

For concentrates for commercial use in closed systems with automatic dosing, the threshold values apply after dilution to a in-use solution.

After review of licensed products and in dialogue with the industry it has been found that mainly phosphate, phosphonate and phosphoric acids are used in these products which contain phosphorus. The licensed products and comparison with other product groups lead Nordic Ecolabelling to the conclusion that the threshold value for phosphorus in this product group can be tightened considerably and at the same time allow for the ecolabelling of well-functioning products. The new threshold value is 0.50 g P/litre of in-use solution and includes phosphorus (P) from phosphate, phospohonate, phosphoric acids and phosphonic acids. The threshold value is thus at the same level as in the criteria for industrial cleaning agents and degreasing agents.

In the previous generation of the criteria, the limit was 10.0 g P/litre of in-use solution. The new limit is thus a significant tightening, which has nonetheless been reconciled with licence data and thereafter assessed to be reasonable.

[33] Lindquist, 2002: Lindquist, Information om kompleksbindingspotentialer (Information on complexing agent potential), submitted by Hans Lindquist in conjunction with the development of the criteria for machine dishwashing agents for professional use, 2002.
[34] Lindquist, 2002: Lindquist, Information om kompleksbindingspotentialer (Information on complexing agent potential), submitted by Hans Lindquist in conjunction with the development of the criteria for machine dishwashing agents for professional use, 2002.
[35] Product regulation: FOR 2004-06-01 no. 922 : Regulation on restrictions in using health- and environmentally hazardous chemicals and other products. Chapters: 2-12. Detergents - phosphorus content

O8 Substances prohibited from products

The following compounds may not be included in the product or exist as actively added substances in the raw materials:

- Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)
- EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)
- Organic chlorine compounds and hypochlorites
- Volatile organic compounds (VOC)

  Volatile organic compounds are defined in accordance with the European Commission's directive 1999/13/EC on the limitation of emissions of volatile organic compounds with steam pressure > 0.01 kPa at 20°C.
- Fragrances
- Benzalkonium chloride (CAS 8001-54-5)
- Fluorine surfactants and other per- and polyfluorinated compounds (PFC)
- Substances on the Candidate List (SVHC)*.
- Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects. The full list can be seen at
- http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf (Annex L, page 238ff.)
- Substances evaluated by the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bioaccumulative), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated, but which meet these criteria.
- Nanomaterials/particles**

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

** *Nanomaterials/particles are defined in accordance with the European Commission's definition of nanomaterials dated 18 October 2011, with the exception that the limit for the particle size distribution is reduced to 1%. "Nanomaterial means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm." Examples are ZnO, TiO2, SiO2, Ag and laponite with particles of nanosize in concentrations exceeding 1%. Polymer emulsions are not considered to be nanomaterial.*

☒ Signed and completed declaration that the aforementioned substances are not included in the end-product (Appendix 2 or equivalent), nor actively added to the raw material (Appendix 3 or equivalent).

Background to requirement O8

Environment-related problems concerning cleaning agents for use in the food industry are primarily handled by Nordic Ecolabelling setting requirements of the characteristics, but also by prohibiting a number of problematic substances. This in particular concerns substances that are not limited by other requirements such as classification, and which might occur in products such as cleaning agents for use in the food industry.

Nordic Ecolabelling prohibits the following substances from cleaning agents for use in the food industry.

Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD)

Alkylphenol ethoxylates (APEO) and/or alkylphenol derivatives (APD) are a group of surfactants that have proved to be hazardous to health or less easily biodegradable. Individual substances also have endocrine disruptive effects. The degradation products nonylphenol, octylphenol and also nonylphenol ethoxylate are on the EU's priority list of substances to be investigated further for endocrine disruptive effects.

APEO have previously been used in washing and cleaning agents, but have been subject to phasing out for some time, on the basis of a voluntary industry agreement. They are still used in some specialised products, however, such as cleaning agents for the pharmaceutical and food industries.

Some octylphenol compounds have problematic characteristics in accordance with the Advisory List for Self-Classification: H410 and one compound also has H317. The substances are only partly subject to limitations on use, but other applications are also considered to be environmentally questionable[36]. In addition, octylphenol ethoxylates and nonylphenol ethoxylates are included on the Candidate List due to their serious environmental effects. The reason that Nordic Ecolabelling has nonetheless retained APEO and APD on the negative list is that akyl covers more than just octyl and nonyl compounds, and on precautionary grounds related compounds are also excluded, even though these are not identified as problematic substances.

The requirement is the same as in generation 1.

EDTA (Ethylene diamine tetraacetate and its salts) and DTPA (Diethylenetriamine pentaacetate)

EDTA and DTPA have previously been used extensively for cleaning agents for use in the food industry and are still included in a number of products. EDTA and DTPA are complexing agents which are under suspicion of being able to mobilise heavy metals in certain environments, since they can be complexing agents for these. In the industry, problems with this characteristic have raised questions concerning EDTA[37].

EDTA are not easily biodegradable and the EU's risk assessment states with the prevailing conditions in municipal treatment plants, EDTA will not be degraded at all, or only degraded to a small degree[38]. DTPA has the same characteristics as EDTA. In the first version of the criteria for cleaning agents for use in the food industry, limited amounts of EDTA and DTPA were permitted (0.6 g/litre of in-use solution of EDTA or DTPA) since when the criteria were adopted it was not considered possible to completely replace EDTA and DTPA with other complexing agents. Today there are environmentally better alternatives that are degradable and that can replace EDTA. Examples are MGDA (methyl glycine diacetic acid) and GLDA (glutamic acid diacetic acid tetrasodium salt), although polycarboxylates, citrate, gluconates and phosphonates are also used as complexing agents.

[36] List of adverse substances 2009. Information from the Danish Environmental Protection Agency no. 3 2010 http://www2.mst.dk/udgiv/publikationer/2010/978-87-92617-15-6/pdf/978-87-92617-16-3.pdf
[37] CEFIC, 2003: Internet information about EDTA, found at http://www.cefic.org/Documents/Other/B013.doc, memo from European Aminocarboxylates Committee (EAC), March 2003.
[38] CEFIC, 2002: Internet information about EDTA, found at http://www.cefic.org/Documents/Other/C014.doc, memo from European Aminocarboxylates Committee (EAC), June 2002

Conversations with producers have shown that EDTA and DTPA have been phased out for most product types within this product group. Nordic Ecolabelling has therefore in this generation decided to exclude EDTA and DTPA from this product group, which is a tightening compared to previous generations of the criteria. Nordic Ecolabelling welcomes consultative comments on this.

NTA has been classified as Carc. 2 with H351 and is thereby prohibited via requirement O3. NTA is, however, still permitted to occur as a residual substance in complexing agents of the MGDA and GLDA types, see the exemption in O3.

Organic chlorine compounds and hypochlorites

Sodium hypochlorite or organic chlorine compounds such as triclosan are often used as disinfecting/antibacterial substances, but can also be used to dissolve tough protein coatings in, for example, the dairy industry, where they help to break down protein-based soiling. Sodium hypochlorites are inexpensive and effective, so they are often used within this product group. From the dialogue with producers, Nordic Ecolabelling understands that enzymes can also be used to dissolve protein coatings, see O3 concerning enzymes, and the exemption in O4. Other alternatives that may be used are strongly alkaline products, which are used in combination with disinfectants. Nordic Ecolabelling prohibits hypochlorites since they may be or lead to the formation of toxic, less biodegradable and bioaccumulative substances. They can also lead to resistance in bacteria, both to biocides and against antibiotics. On this basis, Nordic Ecolabelling wishes to exclude these substances from cleaning agents for use in the food industry, even though there is a need for hypochlorites within certain areas of use, such as dairies. The requirement appears differently to generation 1, but the content is unchanged.

Volatile organic compounds (VOC)

Volatile organic compounds are particularly adverse due to their inherent characteristics. They can be absorbed via the lungs and skin, and damage various organs. Prolonged exposure to certain organic solvents can cause chronic damage to the brain and nervous system, while other organic solvents can cause cancer or reproductive damage. In addition, solvents can be detrimental to health, causing headaches and irritation of the eyes and respiratory system. They can also have negative effects on the earth's ozone layer and are also often less easily biodegradable in the ecosystem.[39]

Experience shows that the content of VOC in ecolabelled cleaning agents for use in the food industry has been low. On this basis, as well as the adverse characteristics of volatile organic compounds, Nordic Ecolabelling has decided to prohibit their use in generation 2. VOCs can, for example, be replaced by glycol ethers, which have low vapour pressure.

VOC are defined in accordance with VOC Directive 1999/13/EC[40]: Volatile organic compounds (VOC) are organic compounds with vapour pressure > 0.01 kPa at 20°C).

The requirement is new in generation 2.

[39] Miljøvejledninger Ordbog (Environmental guides, Glossary), 2009: Section on organic solvents in the glossary at Miljøvejledninger.dk, found at http://www.miljoevejledninger.dk/ordbog/uddybendeforklaringer/o/organiskeoploslashsningsmidler.
[40] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0013&from=SV (visited 2016-03-22)

Fragrances

Fragrances can contain substances with characteristics that are hazardous to health and the environment. Nordic Ecolabelling has always focused on fragrance in Nordic Ecolabelled products and has noted an active debate concerning allergenic fragrances, particularly in Denmark. Allergies are a growing problem, and people with allergies can have allergic reactions on contact with products containing substances that we know are allergenic. Many fragrance substances are classified as sensitising with H317 or H334. Fragrances have no function in the product other than to give a fragrance, and since they are often also classified as environmentally hazardous with H410/H411/H412, Nordic Ecolabelling has decided not to permit fragrance in cleaning agents for use in the food industry. This requirement was also included in the preceding version generation.

Benzalkonium chloride

Quaternary ammonium compounds are often cationic surfactants and often have adverse environmental effects. They are used in washing and cleaning agents and are usually non-biodegradable. There are subgroups (such as esterquats) with better environmental characteristics, which means that they are easily biodegradable. Quaternary ammonium compounds (QAS) are often highly toxic for aquatic organisms. Combined with their non-biodegradability, this results in long-term effects in the aquatic environment and possible accumulation in the environment. They are excluded by the requirement for surfactants to be biodegradable. Among the better known and often adverse quaternary ammonium compounds are the biocide benzalkonium chloride (classified as Aquatic Acute 1 with H400), which is easily biodegradable, in contrast to many of the other compounds. Benzalkonium chloride is unwanted due to its toxicity and the risk of causing resistance, and how it can promote certain types of allergies.[41] Benzalkonium chloride is therefore retained on the list of adverse substances. The requirement appears differently to generation 1, but the content is unchanged.

Fluorine surfactants and other per- and polyfluorinated compounds (PFC)

Per- and polyfluorinated compounds (PFCs) constitute a group of substances that have harmful properties. Certain per- and polyfluorinated compounds can be broken down into the very stable PFOS (perfluorooctane sulphonate) and PFOA (perfluorooctanoic acid) and similar substances. These substances are found all over the globe, from the large oceans to the Arctic. PFOS have also been found in birds and fish and in their eggs. The substances are extremely persistent and are easily absorbed by the body.[42] The substances in this group impact on the biological processes of the body and are suspected to be endocrine disruptors, carcinogenic and to have a negative impact on the human immune system.[43] PFOA, APFO (ammonium pentadecene fluoro octanoate) and certain fluoride acids are on the Candidate List due to their reprotoxicity, as well as PBT.

[41] Heir et al, 2001: Kan desinfeksjionsmidler bidra til bateriell antibiotikaresistens (Can disinfectants contribute to bacterial antibiotics resistance)? The Journal of the Norwegian Medical Association, no. 27, 2001, Even Heir, Solveig Langsrud, Maan S. Sidhu & Martin Steinbakk, 2001.

[42] Borg, D., Tissue Distribution Studies And Risk Assessment Of Perfluoroalkylated And Polyfluoroalkylated Substances (PFASS), Doctoral thesis, Institute Of Environmental Medicine (IMM) Karolinska Institutet, Stockholm, Sweden 2013
http://publications.ki.se/xmlui/bitstream/handle/10616/41507/Thesis_Daniel_Borg.pdf?sequence=1

[43] For example, Heilmann, C. et al, Persistente fluorbindelser reducerer immunfunktionen, Ugeskr Læger 177/7, 30.3.2015 OSPAR 2005: Hazardous Substances Series, Perfluorooctane Sulphonate (PFOS), OSPAR Commission, 2005 (2006 Update), MST, 2005b: Environmental project no. 1013, 2005, More Environmentally Friendly Alternatives to PFOS-compounds and PFOA, Danish Environmental Protection Agency, 2005.

There are new research results showing that shorter chains (2-6 carbon atoms) have been discovered in nature.[44] It is therefore difficult to defend and communicate the fact that Nordic Ecolabelled products may contain perfluorinated compounds at all. For this reason a more general prohibition than for PFOS or fluorine surfactants alone, is relevant. A Swedish report shows that the compounds are used in certain cleaning agents[45].

This is a new requirement that was not included for the preceding generation.

Candidate List and SVHC, Substances of Very High Concern

SVHC, Substances of Very High Concern, is a term to describe the substances which fulfil the criteria in article 57 of the REACH Regulation, which states: substances which are CMR (categories 1A and 1B in accordance with the CLP Regulation), PBT substances, vPvB substances (see the section below) and substances which are endocrine disruptors or environmentally hazardous without fulfilling the requirements for PBT or vPvB. SVHC can be included on the Candidate List with a view to subsequent inclusion in the Approval List. This means that the substance is subject to regulation (prohibition, phasing-out or another type of restriction). On the basis of these adverse characteristics, Nordic Ecolabelling prohibits substances on the Candidate List. Other SVHC substances are addressed via the prohibition of PBT and vPvB substances, and the requirement of classification and prohibition of endocrine disruptors.

This is a new requirement in generation 2.

Potential endocrine disruptors

Potential endocrine disruptors are substances which can affect the endocrine balance of people and animals. Hormones control a number of vital processes in the body and are particularly important to the development and growth of people, animals and plants. Changes in the hormone balance can have adverse effects, and there is special focus on hormones which affect sexual development and reproduction. Several studies have shown effects on animals that can be assumed to be due to changes in the hormone balance. Discharges to the aquatic environment are one of the biggest sources of the spreading of endocrine disruptors[46]. Nordic Ecolabelling prohibits the use of substances that are considered to be potential endocrine disruptors, category 1 (there is evidence of a change in endocrine activity in at least one animal species) or category 2 (there is evidence of biological activity related to changes in the hormone balance), in line with the EU's original report on "Endocrine disruptors"[47] or later studies[48].

---

[44] Perkola, Noora, Fate of artificial sweeteners and perfluoroalkyl acids in aquatic environment, Doctoral dissertation Department of Environmental Sciences, Faculty of Biological and Environmental Sciences, University of Helsinki, Finland 2014-12-12, https://helda.helsinki.fi/bitstream/handle/10138/136494/fateofar.pdf?sequence=1

[45] Kemikalieinspektionen, 2015 http://www.kemi.se/global/rapporter/2015/report-7-15-occurrence-and-use-of-highly-fluorinated-substances-and-alternatives.pdf (visited 2016-03-22)

[46] Miljøstatus i Norge (2008): Endocrine disrupters: http://www.miljostatus.no/Tema/Kjemikalier/Noen-farlige-kjemikalier/Hormonforstyrrende-stoffer/#D (dated February 26 2009)

[47] DG Environment (2002): Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption. FINAL REPORT. European Commission DG ENV / BKH Consulting Engineers with TNO Nutrition and Food Research. 21 June 2000

[48] DG Environment. (2002): Endocrine disrupters: Study on gathering information on 435 substances with insufficient data. http://ec.europa.eu/environment/endocrine/documents/bkh_report.pdf#page=1, European Commission / DG ENV / WRc-NSF. (2002): Study on the scientific evaluation of 12 substances in the context of endocrine disrupter priority list of actions, http://ec.europa.eu/environment/chemicals/endocrine/pdf/wrc_report.pdf#page=29

The European Commission is now developing criteria for endocrine disruptors.[49] Nordic Ecolabelling is monitoring this development and may change the requirement when the EU criteria for the identification of endocrine disruptors are published.

The requirement concerning endocrine disruptors is new for this generation of the criteria.

PBT and vPvB

PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) are organic substances as defined in Annex XIII of REACH (Directive 1907/2006/EC)[50]. Nordic Ecolabelling does not generally wish to have these substances.

Most PBT/vPvB are excluded automatically from cleaning agentsfor use in food industry due to the restrictions on environmentally hazardous substances (see O4). Since some of them, primarily vPvB, may possibly not be excluded in accordance with O4, they are prohibited by Nordic Ecolabelling.

This is a new requirement in generation 2.

Nanoparticles

Nanotechnology, which also includes nanoparticles, is being used to an increasing extent in many product areas, including those for which Nordic Ecolabelling has criteria. The greatest cause for concern is the use of nanoparticles, which can be released and thereby affect health and the environment. There is concern among public authorities, environmental organisations and others about the lack of knowledge regarding the potential detrimental effects on health and the environment.

On 18 October 2011, the European Commission made a recommendation for a definition of nanomaterials, stating that a nanomaterial is a "natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm." Nordic Ecolabelling adheres to the wording in this definition, but assesses which threshold value should be set for various product groups. In the new, revised requirements for ecolabelling of cleaning agents, Nordic Ecolabelling has set the threshold value at 1%, to include more materials with an element of nanomaterials. Nanoparticles may not be included in Nordic Ecolabelled cleaning agents for use in the food industry. This is a new requirement in this version of the criteria.

DHI water and environment. (2007): Study on enhancing the Endocrine Disrupter priority list with a focus on low production volume chemicals. DG Environment.
http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf

[49] Chemical watch, News, Andriukaitis promises EDC criteria 'before the summer', 4.2.2016, https://chemicalwatch.com/44841/andriukaitis-promises-edc-criteria-before-the-summer

[50] REGULATION (EC) No. 1907/2006 of the EUROPEAN PARLIAMENT AND THE COUNCIL of 18 December 2006 concerning the registration, authorisation and restriction of chemicals (Reach) http://eur-lex.europa.eu/legal-content/sv/TXT/PDF/?uri=CELEX:02006R1907-20160203

Other substances discussed under this requirement

LAS (linear alkylbenzene sulfonates) are excluded via requirement O10 (requirements for surfactants) since it is not anaerobically biodegradable. LAS is therefore no longer on the list in this requirement.

Halogenated and aromatic compounds have been discussed as to whether to exclude them or not. The project group has assessed that it is not relevant to exclude these explicitly since this generation of the criteria has classification requirements, requirements that volatile organic solvents may not be included, and biodegradability requirements, which significantly limit such substances, if they should prove to be relevant in any specific application. Halogenated and aromatic compounds were not excluded from generation 1 of the criteria either.

O9 Surfactants, easily aerobically and anaerobically biodegradable

All surfactants must be easily biodegradable according to test method no. 301 A - F in the OECD guidelines for testing of chemicals or other equivalent testing methods.

All surfactants must be anaerobically biodegradable in accordance with ISO 11734, ECETOC no. 28, DIN 38414 part 8 or equivalent testing methods.

✉ Reference to the DID list dated 2014 or later versions. If the DID list lacks the relevant data for surfactants, data may be taken from the safety datasheet on condition that the data is reliable and that the test methods are in agreement with Appendix 1. Section B of the DID list shows how to make the calculations of the various factors. It is also permitted to refer to analogous observations, as long as they are carried out by a competent third party, and refer to relevant data from literature that has been subject to scientific scrutiny.

Background to requirement O9

The durability/persistence in nature of substances is an important environmental parameter. The extent to which substances are degraded in the aquatic environment indicates how long the substance may affect the environment.

Compounds that accumulate in the environment can pose a risk both now and in the future if they are acutely toxic. Knowledge of the longterm effects of non-readily biodegradable substances is often in short supply. Rapid biodegradability under oxygenrich (aerobic) and oxygenpoor (anaerobic) conditions is therefore of major environmental importance. Surfactants are considered to be of central importance in this respect as they constitute a group of organic compounds that are found in large quantities in cleaning agents for use in the food industry. In addition, many surfactants are toxic to aquatic organisms.

The detergent regulation prescribes that surfactants must be aerobically biodegradable, but there are opportunities for exemptions from the detergent regulation for products for professional use. The fact that products are launched in the market does not entail that they comply with legislation, even though this should naturally be the case. It is therefore very important to require surfactants (irrespective of function) to be degradable in both aerobic and anaerobic conditions for this product group.

The test method DIN 38414 part 8 has been added as an alternative test method. This is a test method which indicates the anaerobic biodegradability of organic substances, such as surfactants. If the test has a result indicating more than 60% biodegradability, the substance is assessed to be anaerobically biodegradable.

The requirement of anaerobic biodegradability entails that LAS (linear alkylbenzene sulfonates) cannot be included in Nordic Ecolabelled cleaning agents for use in the food industry, since LAS are not biodegradable in the anaerobic environment.

The requirement also entails that quarternary ammonium compounds are excluded. Quarternary ammonium compounds of cationic surfactants often have adverse environmental effects. They are usually highly toxic for aquatic organisms and combined with their low biodegradability, this results in long-term effects for the aquatic environment and possible accumulation in the environment.

As LAS and quarternary ammonium compounds are excluded by this requirement, they have been removed from the list of substances which may not be included in requirement O8.

O10 Content of substances which are not aerobically and/or anaerobically biodegradable

The product's total content of substances that are not aerobically (aNBO) biodegradable may not exceed the following limits per litre of in-use solution. The product's total content of substances that are not anaerobically (anNBO) biodegradable may not exceed the following limits per litre of in-use solution.

Note that all surfactants must be aerobically and anaerobically biodegradable in accordance with O9. See also the exemption from the requirement of anaerobic biodegradability for substances which are not surfactants (Appendix 1, item 6, Anaerobic biodegradability).

Table O10: Threshold values for aNBO and anNBO

Category	aNBO (g/litre of in-use solution)	anNBO (g/litre of in-use solution)
Concentrated products	0.40	0.50
Ready-to-use products	0.40	0.50

Note that the following exemptions apply:

- Iminodisuccinate (DID 2555) can be excluded from the calculation of anNBO.

✉ Calculation of the concentration of aNBO and anNBO for the cleaning agent in grammes/litre of in-use solution.

Reference to the DID list, 2014 or later versions. For substances not included on the DID list, the related documentation must be submitted.

Background to requirement O10

Organic substances that are not easily biodegradable may affect the environment even if they do not show any acute toxic effects. Substances which are only slowly biodegradable have a longer toxic effect and entail a greater risk of damaging the environment. Rapid biodegradability in both aerobic and anaerobic conditions is therefore required. The requirement concerning the biodegradability of organic substances gives ecolabelled products as a whole a good biodegradability profile and reduces the potential accumulation of non-easily biodegradable substances in waste sludge and in other relevant pockets in the environment.

The requirement thresholds for aNBO and anNBO have been tightened in relation to generation 1 of the criteria. The new thresholds are based on data which Nordic Ecolabelling has for products that hold ecolabelling licences. The threshold in the

previous generation of the criteria was 0.6 g/litre of in-use solution for substances that were non-aerobically biodegradable, and the same for substances that were non-anaerobically biodegradable. The new thresholds are 0.40 g/litre of in-use solution for substances that are not biodegradable in aerobic conditions, and 0.50 g/litre of in-use solution for substances that are not biodegradable in anaerobic conditions.

Iminodisuccinates (DID 2555), IDS, are aerobically biodegradable, but are exempted from the requirement concerning non-anaerobically biodegradable substances (decided by the Nordic Ecolabelling Board in December 2009) in this version of the criteria. This is because there is a need for alternatives to NTA and phosphates and IDS are assessed to be the preferred complexing agents compared to many others. IDS are exempt from the requirement of anaerobic biodegradability and must thus not be included in the calculation.

On the new DID list, cumene sulphonate has been updated to be aerobically biodegradable. With regard to anaerobic biodegradability, it can be exempted with reference to how it is aerobically biodegradable and non-bioaccumulative, in accordance with the exemption in Appendix 1 of the criteria.

O11 CDV (critical dilution volume)

The critical dilution volume (CDV) is calculated for all constituent substances included in the cleaning agent. CDV is a theoretical value that takes account of each substance's toxicity and biodegradability in the environment.

The product's critical dilution volume (CDV) is calculated on the basis of the highest recommended dosage stated on the packaging.

The product's critical dilution volume (CDV) may not exceed the following threshold value for $CDV_{chronic}$.

Table O11. CDV threshold value

Category	$CDV_{chronic}$
Concentrated products	30000
Ready-to-use products	300000

CDV is calculated using the following formula for all substances in the product:

$CDV_{chronic} = \sum CDV_i = \sum (dose_i \times DF_i \times 1000 / TF_{i\ chronic})$

$dose_i$ = the constituent volume of each individual substance "i", in g/l in-use solution

DF_i = biodegradation factor for substance "i", in accordance with the DID list

$TF_{i\ chronic}$ = chronic toxicity factor for substance "i", in accordance with the DID list. If $TF_{i\ chronic}$ is lacking, $TF_{i\ acute}$ can be used.

There are calculation sheets for the calculation of CDV on the respective secretariats' websites.

☒ Calculation of CDVchronic for the cleaning agent.

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

Background to requirement O11

There are several ways of handling a product's overall toxicity and biodegradability. Nordic Ecolabelling has decided that for chemical-technical products, the primary

method is to assess the product's critical dilution volume. CDV requirements should therefore be made for products which end in the aquatic environment. The critical dilution volume is a theoretical value which takes account of the individual substances' chronic toxicity and biodegradability in the environment. The critical dilution volume (CDV) is calculated for all chemicals included in the cleaning agent. See the definition of constituent substances at the beginning of section 7.2.

No CDV requirements have previously been made for cleaning agents for use in the food industry. To be able to assess any such requirement and its level, it has been necessary to perform CDV calculations for a selection of products. Cleaning agents for use in the food industry have different functions. Experience from other product areas for which Nordic Ecolabelling has criteria shows that the CDV values are often reflected in the product's function and level of dilution. Nordic Ecolabelling has calculated CDV for products that are currently licensed within this product category. With the help of these calculations, and a degree of comparison with cleaning agents, Nordic Ecolabelling has arrived at the following threshold values:

CDVchronic for concentrated products ≤ 30,000

CDVchronic for ready-to-use products ≤ 300,000

The requirement levels in this consultation draft are set on the basis of calculations for products in the Nordic market. Nordic Ecolabelling wishes to receive consultative comments on these threshold values.

7.3 Performance, packaging and information text

Performance tests are primarily a quality requirement to ensure that a good cleaning result is achieved at the stated dose of the ecolabelled product. A product that shows good performance at the dose stated on the label reduces the risk of overdosing, since the user can see that the product is effective, and has no need to use more than is recommended.

O12 Performance and user test

Products must show satisfactory performance/quality within the application areas for which they are intended. The product's performance/quality must be documented by user tests, see Appendix 4.

The user test must be performed by at least five test sites, which include the majority of the areas of use for which the product is intended. Dosing must be in accordance with the producer's recommendations for normal soiling. The test period must be at least four weeks.

At least 80% of the test sites must assess the product's performance/quality as "satisfactory" or "very satisfactory", compared to the product which they normally use (see Appendix 4), for the requirement to be fulfilled.

✉ At least five user tests designed in accordance with Appendix 4.

A report that describes which and how many test sites were asked and a summary of the results.

Background to requirement O12

Nordic Ecolabelled cleaning agents for use in the food industry must show satisfactory performance/quality within the application areas for which the product is intended. This must be documented by a user test. Since there are no

standardised tests and professional users are a demanding user group, Nordic Ecolabelling believes that user tests are the best way of documenting the product's performance.

User tests must be performed by at least five test sites. Dosing must be in accordance with the producer's recommendations for normal soiling. If dosing for normal soiling is stated as an interval, the lowest dose must be indicated unless otherwise clearly justified by the licence applicant. The test period must be at least four weeks.

If at least 80% of the test sites assess the product's performance/quality as "satisfactory" or "very satisfactory" (see Appendix 4), compared to the product which they normally use, the product will be considered to fulfil the Nordic Ecolabel's performance requirement.

In the previous generation of the criteria, the user test had to be performed by three test sites. Nordic Ecolabelling believes that three test sites are not a sufficiently large selection to show that the product has satisfactory performance. In this generation of the criteria, the requirement has therefore been changed to include at least five test sites. In the dialogue with the industry, opinions have differed on increasing the number of test sites to five, and a number of companies believe that this will be very difficult, while others believe that this should function well. Nordic Ecolabelling therefore welcomes comments on this during the consultation.

O13 Labelling of packaging

Plastic packaging must be labelled in accordance with DIN 6120 part 2, ISO 11469 1469:2000 or the equivalent. Plugs, caps and pumps are exempt from this requirement.

✉ Documentation of primary packaging showing that the labelling is in accordance with DIN 6120 or equivalent labelling, images of the product's labelling, or datasheets showing the labelling. Labelling can also be shown on an attached label, if this is supplemented with documentation of the type of plastic from the packaging producer.

Background to requirement O13

Plastic materials are to be marked in line with DIN 6120 part 2, ISO 11469:2000 or the equivalent in order to ensure easier sorting and recycling of plastics once the product has been consumed.

Modern plastic recovery enterprises no longer use manual sorting of plastic waste, but sort the waste optically using NIR (Near Infrared Spectroscopy) or with the help of water bath density. Large volumes of composite plastic thus appear to undergo automatic sorting, although DIN labelling is still used in certain situations.[51] The environmental relevance of the requirement can therefore be discussed, but there are also reasons to retain the requirement. In Norway and Sweden, a lot of commercially-used plastic is still sorted manually, in which case DIN labelling can be useful.

DIN labelling on the packaging of professional products such as cleaning agents for use in the food industry is therefore still required.

[51] Personal contact with IL Recycling, Ragnsells, Norsk Gjenvinning, autumn 2014

O14 Information text and user and dosing information

A technical description of the product or information included with the product, stating the following information:

- Recommended dose for normal use and on normal soiling (applies to products for dilution before use).
- Recommended dose can be stated as e.g. number of ml or dl, pump strokes or caps.
- Description of how the user avoids contact with the product using e.g. protective equipment.
- The information text on the packaging must adhere to the detergent regulations, 648/2004/EC and 907/2006/EC.

✉ Label, draft label or copy of the information (information text and user instructions) on the primary packaging and technical product datasheet (if found), showing the dose and user instructions in accordance with the requirement. The information on labels and/or product datasheets must be in the languages in which the product is marketed.

Background to requirement O14

An important environmental parameter is that the products are used for the purpose for which they are produced, and that products to be diluted before use are dosed correctly. Incorrect use of cleaning products, such as overdosing, will lead to unnecessary and increased environmental impacts. It is therefore important to have clear information concerning the product, so that the user can easily see how much the product needs to be diluted, the areas of use and how the product can be used to achieve the best results.

To avoid overdosing of concentrated products, the packaging must be designed to support correct dosing. For products for dilution there must be clear and concise dosing instructions on the packaging.

It must be clearly stated, e.g. on a technical datasheet or label, which protective equipment the user of the product will need. There may be recommendations for the use of dosing equipment, protective goggles, gloves, etc.

In the previous version of the criteria, it was also a requirement that packaging for concentrated products had to be designed to ensure that the user was in minimum contact with the product. This is now included in O2.

7.4 Quality and regulatory requirements

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

These requirements have been amended in relation to the equivalent requirements in generation 1 of the criteria for cleaning agents for use in the food industry, in order to adjust them to Nordic Ecolabelling's new standard wordings.

O15 Responsible person and organisation

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

✉ Organisational chart showing who is responsible for the above.

O16 Documentation

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

🔎 This is checked on site as necessary.

O17 Quality of the cleaning agent

The licensee must guarantee that the quality of the Nordic Ecolabelled cleaning agent for use in the food industry does not deteriorate during the term of validity of the licence.

✉ The claims archive is checked on site.

O18 Planned changes

Written notice of planned product and marketing changes that affect the Nordic Ecolabelling requirements must be submitted given to Nordic Ecolabelling.

✉ Procedures detailing how planned product and marketing changes are dealt with.

O19 Unforeseen non-conformities

Unforeseen non-conformities that affect Nordic Ecolabelling requirements must be reported to Nordic Ecolabelling in writing and logged.

✉ Routines describing how unforeseen non-conformities will be handled.

O20 Traceability

The licensee must be able to track the Nordic Ecolabelled cleaning agent for use in the food industry in their production.

✉ Description of/procedures for fulfilment of the requirement.

O21 Take-back system

Relevant national regulations, legislation and/or agreements within the sector regarding take-back systems for products and packaging must be complied with in all the Nordic countries where the Nordic Ecolabelled cleaning agents for use in the food industry are marketed.

✉ Declaration from the applicant regarding affiliation to existing recycling/processing agreements.

O22 Laws and regulations

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

✉ Duly signed application form.

7.5 Areas that are not subject to requirements

PVC in packaging

PVC and other halogenated plastic have adverse environmental effects on the disposal of these types of plastic, and furthermore they can contain substances with undesired health effects[52]. This applies especially to stabilisers and softeners. In addition, some of the manufacturing techniques to produce chlorine gas for the production of PVC can impose a greater burden on the environment than other techniques.

Most of the bottles used for packaging chemical-technical products consist of polypropylene (PP) or polyethylene (PE), but certain types of packaging can theoretically consist of PVC. Auraprint, which delivers labels to Finnish chemical-technical producers with a Nordic Ecolabelling licence, believes that the most common materials used for labels are PP, PE, PET and paper.[53] Auraprint has stopped making labels from PVC, and believes that most other producers have also stopped using PVC in labels. Enquiries in the industry have shown that PVC is not used in the industry's packaging for these product types. The producers also indicate that they use plastic materials such as PP, PE and HDPE. The risk of PVC packaging being used for cleaning agents and PVC labels is considered to be so small that the requirement can be removed.

8 Changes compared to previous version

Table 4 below presents a summary of where this generation of the criteria has been tightened and amended compared to generation 1 of the criteria.

Table 4. Changes compared to the previous generation

Requirement number according to the consultation draft for version 2	New requirement/unchanged requirement/amended requirement	Comments
Product group definition	Amended text	The product group definition has been updated in order to clarify what is included and not included in this product group
Constituent substances	Amended text	The text concerning constituent substances has been updated.
O1 Description of the product	New requirement	The requirement of a declaration of the formulation and description of the product has been split off as a separate requirement in this version, whereas before it was included in other requirements.
O2 Classification	Updated	The table of product classifications has been updated.
O3 Classification of constituent substances	Amended	The requirement now also includes sensitising substances. The limit to how much NTA may be present as impurities in complexing agents of the GLDA and MGDA type has been tightened.
O4 Environmentally hazardous	Amended	The requirement has been tightened and

[52] COMMISSION OF THE EUROPEAN COMMUNITIES, 2000. GREEN PAPER Environmental issues of PVC. Brussels.
[53] Ääritalo, 2012. Personal communication between Terhi Uusitalo, Nordic Ecolabelling, and Juha Ääritalo, Auraprint.

substances		a weighted formula has been introduced for the various environmentally hazardous classifications.
O5 Preservatives	Amended	In the previous version, there were two requirements concerning preservatives (bioaccumulability and Challenge), and these have now been combined as one requirement. The requirement has also been expanded with a text that preservatives may only be added to achieve a conserving effect.
O6 Colourants	Unchanged	The requirement was included in the previous version and is the same as in that version.
O7 Phosphorus	Amended	The requirement threshold has been tightened.
O8 Prohibited substances	Amended	The list of prohibited substances has been amended and expanded, and among other things includes the prohibition of EDTA and DTPA, which were previously permitted in small quantities.
O9 Biodegradability of surfactants	Unchanged requirement	The requirement is the same as before.
O10 aNBO and anNBO	Amended	The requirement thresholds have been tightened.
O11 CDV	New requirement	A CDV requirement has been introduced for the first time for this product group.
O12 Performance	Amended requirement	The requirement has been amended in terms of the number of test sites, which has now been increased to five.
O13 Labelling of packaging	Unchanged	The requirement is the same as before.
O14 Information text	Amended	Some of the items in the requirement have been moved to requirements O1 and O2. Some items have been deleted from the requirement.
O15-O22 Quality and regulatory requirements	Amended	These requirements have been updated since the preceding version of the criteria.
PVC in packaging	Removed	Previously there was a requirement that PVC could not be used in packaging, but this has now been removed since it is no longer considered to be particularly relevant, since PVC is not used in this type of packaging.

9 New criteria

This chapter is written after the consultation and must not be included in the consultation document.

10 Document version history

Descriptive text concerning adjustments, extensions and so on must be added to the document on an ongoing basis (as decided).

11 Terms and definitions

Term	Explanation or definition
aNBO	Aerobic non-biodegradable substances
anNBO	Anaerobic non-biodegradable substances
BCF	Bioconcentration factors
CDV	Critical Dilution Volume
CIP	Cleaning-in-place, cleaning of pipe systems
CMR	Substances classified as either carcinogenic, germ cell mutagenic or reprotoxic
PBT / vPvB	Persistent (slowly biodegradable), bioaccumulative (accumulated in living tissue), toxic/ / very persistent and very bioaccumulative (Persistent, Bioaccumulative, Toxic/very Persistent and very Bioaccumulative)
SVHC	Substances of very high concern
GHS	”Globally harmonised system of classification and labelling of chemicals”. The CLP regulation implements GHS in the EU/EEA.
VOC	Volatile Organic Compounds

Appendix 1 MECO form for cleaning agents for use in the food industry

	Material phase	Production phase	Use phase	Waste phase	Transport phase
Material	Extraction of raw materials (both chemical raw materials and packaging raw materials (plastic)) from petrochemicals (oil/gas). Cultivation, harvesting and refining of biobased raw materials (palm oil)	Production of end-product and packaging.	Equipment for dosing and application of the products. May lead to overdosing, exposure of the products to the user and adverse emissions.	Packaging for incineration or recovery.	Load pallets, wrapping or carton
Energy	Primarily consumption of fossil energy sources. Energy consumption on extraction/cultivation, refining and production of raw materials and packaging.	Energy consumption during production of end-product and packaging.	Equipment for application of products. Products requiring heated water.	Energy from incineration of packaging. Energy for water treatment plant.	Transport of raw materials + final product. Ready-to-use products lead to increased energy consumption during transport.
Chemicals and emissions	Additives, softeners and other chemical treatment in conjunction with raw materials production. Emissions of CO_2 and SO_2. Potential emissions from the extraction and production of raw materials.	Handling of chemicals in production. Exposure risk. Potential emissions from production (cleaning of tanks and the risk of adverse emissions). CO_2 emissions. Use of chemicals such as additives in plastics production.	Risk of exposure on use. Emission to recipient and air. Soiling and oil which cleaning agents bring with them to recipients.	Packaging and residual quantities of products. On discharge to treatment plants, large volumes will entail a risk for the environment, if the products contain toxic and non-biodegradable substances.*	Transport, emissions of NO_x, CO_2, VOC.
Other	Working environment and labour rights at plantations and within the petrochemical industry. Impact on nature of the extraction of raw materials. Risk of net emissions of CO_2 due to deforestation and loss of biodiversity.	Working environment	Performance and dosing. Allergy, VOC, working environment for professional products		

* *Can also be part of the use phase.*