FINAL REPORT
EU ECO-LABEL FOR SHAMPOO AND SOAPS

ECOLABELLING NORWAY
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THE EUROPEAN ECO-LABEL - THE FLOWER

The Flower is the symbol of the European Eco-label - your guide to greener products and services.

It is a VOLUNTARY scheme designed to encourage businesses to market products and services that are kinder to the environment and for European consumers - including public and private purchasers - to easily identify them.

You can find the Flower throughout the European Union as well as in Norway, Liechtenstein and Iceland. The European Eco-label is part of a broader strategy aimed at promoting sustainable consumption and production.

Key aims

- **to achieve significant environmental improvements** - by developing, publishing and promoting criteria that push the market forward, in order to minimise the environmental impacts of a wide range of products and services over their whole life-cycle;
- **to ensure the credibility of the award** – by efficient administration and through criteria which:
  - are environmentally strong;
  - are based on good science, including the precautionary principle;
  - take account of consumer health;
  - require good product performance;
  - are developed transparently and cost-effectively, with the participation of stakeholders;
  - are reasonably attainable;
  - are up to date.
- **to encourage manufacturers, retailers and service providers to apply for the award**, to publicise their own participation in the scheme, and to promote the availability of eco-labelled products and information about them;
- **to encourage purchasers to buy products and services with the award**;
- **to improve consumer awareness and behaviour** regarding the environmentally optimal use of products and services.

How the eco-labelling Scheme works

It takes hard work and commitment to set up criteria. Every product group is designed and crafted to meet high environmental and performance standards. Ecological criteria for each product are defined on the basis of life cycle considerations (LCC) taken from a "cradle-to-grave" view of the environmental impacts of a product group.

How Eco-label Criteria are developed and adopted

Proposals for the definition of product groups and ecological criteria are made either on the request of the EUEB or by the Commission. The Commission gives a mandate to the EUEB (lead Competent Body) to develop or review the eco-label criteria. Priority product groups will be listed in the joint working plan. On the basis of these mandates the appropriate EUEB member, supported by a working group and the Commission will draft appropriate eco-label criteria and the assessment and verification requirements related to these criteria. All interested parties are invited to participate in this process. The Competent Body will take into account the results of feasibility and market studies, life cycle considerations and an improvement analysis. A regular feedback process to the whole EUEB is ensured. Finalised criteria are submitted to the Regulatory Committee of national authorities and voted upon. If the Committee takes a favourable view of the proposal, the Commission proceeds with its adoption and publication. Otherwise, the Committee submits the proposal to the Council of Ministers for decision.

1. Background

Ecolabelling Norway was in 2004 appointed Lead Country for the development of ecolabel criteria for soaps and shampoos. The development of ecolabel criteria for these products is seen as a continuation of the eco-label work with cleaning products, even though soap and shampoo-products, as these are used on the human body, are regulated in the Cosmetic Directive in the European legislation. The Cosmetic Directive regulate only the health aspect of the products, and environmental aspects are not included.

In 1996 the European Commission initiated a first study of the possibilities for ecolabelling of shampoos. As a part of the feasibility study, the French company Ecobilan performed an LCA study in 1997 including the system "cleaning and drying of hair". The study is discussed in detail in chapter 5 of this report. The Competent Bodies did not give priority to this product group at the time. Since then eco-label criteria for shampoos and similar products have been developed in several other ecolabelling schemes: The Nordic Swan, Good Environmental Choice (Sweden) and the Taiwanese, Korean and Thai ecolabels. Interested parties, especially consumer organisations, have welcomed these initiatives and asked for European criteria in the area. Toiletries also came out with a high score in the recently performed study on "Prioritisation of New Ecolabel Product Groups". It was therefore decided to launch a new initiative for soaps and shampoos in 2004. The work would be based on previous LCA-studies and work done in other eco-labelling schemes.

The Proposals for the criteria is given in a separate document. This background document contains:
- A summary of investigations made in the project.
- A summary of external studies of environmental and health effects of soaps and shampoos.
- Background for the proposed requirement
- The results of discussions in the ad-Hoc Working Group (aHWG) meetings
- Comments and information from manufacturers as well as other interested parties

The simplified term "soaps and shampoos" is used all through the document, but in fact all cosmetic rinse-off products were discussed during the criteria development.

2. Introduction

Soaps, shampoos and other rinse-off products such as shower products and conditioners are in the forefront of people's attention. It is the product category with highest turnover in Norwegian grocery stores and these products also feature prominently in advertising of all kinds, especially on TV. The products are used daily by all Europeans.

Ecolabelling Norway set up an ad-hoc working group, inviting all interested parties, including product and ingredient manufacturers environmental
and consumer organisations, test institutes, scientists and government agencies. The working group had 3 meetings: November 8, 2004, March 16, 2005 and June 6, 2005. Based on several studies and on discussions in the group, Ecolabelling Norway developed the proposal for ecolabel criteria.

Many manufacturers have expressed a wish to be informed about the project. Some small- and medium-sized manufacturers have been participating and contributed in the project, and some of them expressed interest in obtaining an eco-label on their products. The organisation of small- and medium sized enterprises (UEAPME) have supported and encouraged our work.

The main manufacturers organisation The European Cosmetic, Toiletry & Perfumery Association COLIPA, organised a committee to follow the work. In front of the third aHWG-meeting however, we were informed that they would end their participation in the project because they did not think the proposed criteria met the environmental requirements in the ecolabel regulation.

In general, companies producing both cosmetics and household detergents express more interest in environmental issues. This can be seen by their environmental policy and openness regarding environmental impacts. This is to be expected because these companies have taken environmental issues into consideration because of the legislation on household detergents. Companies that are purely cosmetic product manufacturers communicate very little on environmental issues presumably because the main focus has been the requirements in the Cosmetics Directive.

Every year a number of consumers experience adverse health effects by the use of cosmetic products, a large percentage of these cases are presumably not reported. Some cases are the result of improper use of the products, but based on information from consumer organisations, health authorities, media coverage and contacts with ordinary consumers the general impression is that some adverse effects arise from the products themselves. Therefore this report address health aspects, as it has been the intention to give consumers an even better protection against adverse health effects than the regulations offers. However, the inclusion of health criteria has been contested by the Commission, claiming all products complying to the Cosmetic Directive are safe for consumers under normal use. Nevertheless, the discussion on health issues in the working group is referred in this report.

The question of animal welfare and ethical aspects of raw-material production have also been discussed for inclusion in the proposal. Unfortunately the Ecolabel Regulation does not open for requirements on ethical issues to be set in ecolabelling criteria.
3. Market

Ecolabelling Norway has contacted a number of manufacturers (small, medium-sized and large), manufacturers organisations and statistical agencies in order to get an overview of the market for soaps and shampoos.

Consumption

Soaps, shampoos and conditioners are high-volume products. The following table shows some key-figures on the European Market. Most of the figures come from COLIPA statistics. Figures from the new member states are unfortunately lacking.

The COLIPA statistics contain accurate data of the sales of cosmetic products in Western Europe. However the categories are quite broad. The segment “Hair Care” contains not only shampoos and conditioners but also other products like hair lotions, hair sprays, setting lotions/mousses, hair creams, colouring shampoos and perms. We do not have the exact figures for shampoo and conditioner sales except for a few countries. Based on figures from these countries we have calculated the fraction of shampoos and conditioners of the total hair care segment to be 37 %.

Soaps and shower products form part of the market segment “Toiletries” which also includes (among others) deodorants, depilatories and products for tooth-brushing, shaving and foot-care. Based on statistics from a few countries we have calculated the fraction of soaps and shower products of the total Toiletries segment to be 11 %.

Table 1. RSP (Retail sales price) volume in some Western European countries

<table>
<thead>
<tr>
<th>Product</th>
<th>Hair care</th>
<th>Toiletries</th>
<th>Shampoos and conditioners</th>
<th>Soaps and shower products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>Million Euros</td>
<td>% of total</td>
<td>Million Euros</td>
<td>% of total</td>
</tr>
<tr>
<td>Europe</td>
<td>13991</td>
<td>100</td>
<td>1376</td>
<td>100</td>
</tr>
<tr>
<td>Italy</td>
<td>1788</td>
<td>12,8</td>
<td>2176</td>
<td>15,8</td>
</tr>
<tr>
<td>UK</td>
<td>2231</td>
<td>15,9</td>
<td>2434</td>
<td>17,7</td>
</tr>
<tr>
<td>Germany</td>
<td>2873</td>
<td>20,5</td>
<td>3316</td>
<td>24,1</td>
</tr>
<tr>
<td>France</td>
<td>2466</td>
<td>17,6</td>
<td>1984</td>
<td>14,4</td>
</tr>
<tr>
<td>Be-Ne-Lux</td>
<td>1110</td>
<td>7,9</td>
<td>975</td>
<td>7,1</td>
</tr>
<tr>
<td>Norway</td>
<td>232</td>
<td>1,7</td>
<td>224</td>
<td>1,6</td>
</tr>
<tr>
<td>Finland</td>
<td>233</td>
<td>1,7</td>
<td>136</td>
<td>1,0</td>
</tr>
<tr>
<td>Denmark</td>
<td>266</td>
<td>1,9</td>
<td>209</td>
<td>1,5</td>
</tr>
<tr>
<td>Sweden</td>
<td>370</td>
<td>2,6</td>
<td>316</td>
<td>2,3</td>
</tr>
</tbody>
</table>

Based on our calculations and the COLIPA statistics we conclude that the total European market for liquid and solid soaps, shampoos, conditioners and shower products seems to be 6680 million Euros for 2003.
Based on an average price of 2 Euros pr 300 ml bottle the total sales volume is 1000 million litres. Assuming a density close to that of water we get a very rough estimate of 1 million tons of soaps, shampoos, conditioners and shower products. Another way of calculating the consumption gives an even higher estimate. It is based on an average daily consumption of 12 grams and a population of 456 millions. This gives a total market of cosmetic products in the 25 EU-countries is 2 million tons. Whether the total market is 1 or 2 million tons it is clear that the volume is significant. A high percentage of the products consist of water. If we assume that 75 % of the lower estimate (1 million tons) is water the total amount of active substance released into European rivers, lakes and seas either directly or via waste water treatment plants is 250 000 tons every year.

There are a number of other cleaning products on the market in addition to traditional soaps, shampoos and shower products. Peeling products and products for cleaning specific parts of the body are examples. We have not succeeded in obtaining specific sales figures for these special product groups.

The amount of packaging for soaps and shampoos is also high. Even if we assume a low amount of packaging (identical to the criteria limit of 0,30 g/g AC) the total amount of packaging material is 75 000 tons. The actual number is probably much closer to 100 000 tons a year.

**Market structure**
The market seems to be dominated by a few large companies. However there are also many small- and medium-sized enterprises that manufacture soaps and shampoos. These companies have traditionally been the ones that are most interested in ecolabelling. Even though soaps and shampoos are quite similar to household detergents it is not typical that the same companies produce household detergents and soaps and shampoos. It is more common that companies that produce soaps and shampoos also produce other cosmetic products.

**Market trends**
Cosmetic products are high value products and the competition is fierce. As a consequence the cosmetics manufacturers are very innovative and quickly responds to consumer preferences. Product development takes place in a fast pace.

Another market trend is that the products are more and more specialized. The consumption of specialized shampoos (for normal, fatty, dry hair, dandruff shampoos) increases while the “general use” shampoos are losing market shares. Another tendency is that liquid soaps increase in market share whereas solid soaps decrease.

**Interest in the label**
As mentioned earlier, a number of small- and medium-sized manufacturers are interested in obtaining the ecolabel for their products,
especially products aimed at children and babies and I´n´I-products.

However, few manufacturers are expected to take an initiative themselves in order to obtain the ecolabel. They will get the label if the market wants it. Hence it is very important to stimulate market demand, e.g. by informing procurers on their possibility, and duty, to take the environment into consideration when buying such products.

4. Legislation

Cosmetic products are regulated through many Directives; the most important is the Cosmetics Directive. The Directive primarily regulates health impacts of cosmetic products but also contain a section on animal welfare. In contrast with regulations on other product groups such as household detergent directive, it does not take environmental issues into consideration. This fact has often been criticised. There are few signs that environmental issues will be addressed in the near future. The last technical updates of the Directive only concern health aspects.

Some degree of environmental protection is assured by the Directives on Hazardous Chemicals (67/548/EEC) and Dangerous Preparations (1999/45/EEC) regulating the cosmetics ingredients. These regulations do not regulate the content of a certain substance or preparation in a cosmetic product, but they at least restrict the use of the "worst" substances and preparations.

REACH, the new chemicals legislation will also concern cosmetics ingredients and might have a considerable impact on the formulation of cosmetic products. However it is unlikely that REACH will be implemented in the validity period of this criteria document.

Some Countries wants to include environmental considerations into the Cosmetics Directive. The Norwegian Government has in its proposal for a new law on cosmetics called for an integration of environmental considerations. In the background document sent with the law on public consultation they cite the example of Triclosan, which has been found to be harmful to the environment but still used extensively in cosmetic products. Triclosan is classified as R50/53 and R36/38 according to the 29th ATP of the Dangerous Substance Directive.

The Swedish Government has contemplated producing an "observation list" of some ingredients found in cosmetic products. The criteria for inclusion on the list are that the compounds have such properties that the government wants to limit their use but have no way of doing that using the existing legislation.

This indicates that ecotabelling might serve a very useful tool for consumers who want to buy products not only "safe" for human health but also for the environment. It could also help manufacturers reduce the environmental impact of their production.
5. Studies on soap and shampoos by external agencies

The environmental impact of rinse-off cosmetic products has been the subject of a few studies. They can roughly be divided into three main categories: Life Cycle Analysis (LCA), Risk Assessments (RA) and studies based on inherent properties. Ecolabelling Norway has assessed the available studies and has also done one quantitative and one qualitative study based on ingredients properties.

The LCAs are 8-9 years old, which means that the background data is still older. However they point at some main trends that should still be valid today. The LCAs are:
- LCA on shampoo performed by Ecobilan commissioned by the European Commission for ecolabelling purposes.
- LCA on shampoos performed by Chalmers Technical University and commissioned by KTF (the Swedish detergent producers organisation).

5.1 Ecobilan Life Cycle Analysis

The French company Ecobilan did their LCA in 1996 commissioned by the European Ecolabel. This study was based on the formulation of one shampoo only, but the analysis included several ways of producing the main surfactants. Because they could not obtain an actual shampoo formulation from the industry, Ecobilan based their study on a very simplified shampoo formulation containing Ammonium lauryl ether sulphate, 3 EO (8 %), Ammonium lauryl sulphate (1 %), Sodium lauryl ether sulphate, 2 EO (9 %) and unspecified Other ingredients (11 %).

The functional unit for Ecobilan was dry weight of organic substances (“using a dose of shampoo containing 3 grams of dry organic matter”), and the LCA was based on the system boundaries “cleaning and drying of hair”. The entire life cycle of the products from production of raw materials to the disposal of the product was included, as well as the energy consumption of a hair dryer together with the associated emissions and the heating of the water in the shower.

The LCA focus on some global and regional effects such as Resource depletion, global warming, acidification, eutrophication and photo-oxidant formation. The study also looked at the production of the surfactants using 4 different source materials (1 petrochemical and 3 of natural origin) and 3 different industrial processes. It is difficult to determine whether the Ecobilan study contains data from the raw material production and refining/processing.

The water and energy consumption assumed for hair cleaning was 7,5 l water heated from 15 °C to 35 °C. For drying the estimate was 5 minutes use of a 1000 W hair dryer.

Conclusions
The study concludes that the main environmental load in the system
comes from the use phase. Ecobilan includes the emissions of shampoo ingredients as being part of the use phase.

The energy consumption and associated resource depletion and emissions from the heating of water were found to cause the main environmental load. The study also finds that the packaging causes a large part of the remaining environmental load (when the use phase is excluded). The energy source used for heating water but also for production processes has a lot of impact on the final results of the analysis.

The study recommends a few requirements for ecolabelling of shampoos based on the findings and some other considerations.

- Consumer information on the bottle urging the consumer to use lower water temperatures and/or less time hair drying.
- Consumer information on the bottle urging the consumer to use less water.
- A requirement limiting the amount of packaging per unit dry weight of shampoo.
- A requirement limiting the use of ingredients with a high Nitrogen-content.
- Use only readily biodegradable surfactants.
- Shampoos containing ingredients classified as carcinogenic, mutagenic and teratogenic should be excluded.

Evaluation
The LCA is important background material for ecolabelling purposes. The main advantage is that it allows the products to be examined from cradle to grave and it enables us to identify the life stages that are major contributors to the environmental benefits studied.

The study could not determine any significant difference in environmental impact between using raw materials of a natural origin rather than of petrochemical origin. This is in part because there are many effects that are difficult to quantify such as land use and loss of species, and if quantified, these parameters are difficult to compare with other parameters, e.g. global warming.

The use phase is found to be the phase with the highest environmental impact. As only one formulation was studied, Ecobilan assumes the impact to be similar for all shampoos.

Some effects are not included in the study. The study does not include local effects such as the toxicological impact on water recipients of the products. This is a serious shortcoming of the study.

5.2 Chalmers LCA
The Swedish technical University Chalmers performed an LCA in 1997 (authored by Lisa Person) that was commissioned by KTF, the Swedish Manufacturers organisation.
3 different shampoo formulations were studied, thus enabling a comparison between different products. Shampoo 1: Caring and conditioning shampoo from a leading branch. Shampoo 2: A basic cleansing shampoo on the market. Shampoo 3: Shampoo 2 reformulated to fulfil the requirements of the Nordic Swan ecolabel criteria by adding an inorganic “inert” salt (Sodium chloride). Shampoos 1 and 2 are products on the market whereas shampoo no 3 is a theoretical product. The quality and user properties of shampoo no 3 are not known nor considered.

Functional unit: Wet weight (The amount of shampoo necessary for 1000 hair washes using a standardized dose of 15,4 grams for simple cleaning shampoo and 15,8 grams for a caring shampoo with several cosmetic functions).

The system boundaries seems to be all processes and products used for cleaning of hair. This means that the consumption of water and energy for heating the water (together with the associated emissions) for the washing process is included, but unlike the Ecobilan-study, hair-drying is excluded.

The study focuses on global and regional effects such as resource depletion, global warming, acidification, eutrophication and photo-oxidant formation. In addition human health effects from air and water emissions are calculated.

The study employs weighting methods in order to compare different kinds of impacts. E.g. EPS weighting is employed to compare depletion of different kinds of resource depletion. In this way Uranium consumption and petroleum consumption can be included in the same parameter.

The Chalmers LCA study concludes:
1. The use phase totally dominates the environmental loadings in the life cycle of shampoo.
2. The environmental impact of the packaging is larger than expected.
3. A shampoo fulfilling the Nordic Swan eco-labelling criteria does not have lower environmental impact than a similar shampoo that cannot fulfil the requirements.
4. There are no significant differences in the environmental impacts between the main product categories studied.

The report summarise by claiming that since the use phase is so dominant it might be assumed that, from an ecological point of view, it does not matter what shampoo is used. The main impacts arrives from the consume and heating of water for the hair wash.

The report also claims that there is practically no difference in environmental impact between shampoos 2 and 3. Shampoo no 2 cannot fulfil the Nordic Swan ecolabelling criteria whereas shampoo no 3 (equal to no 2 except a small addition of Sodium Chloride) fulfil the criteria. They remark that this is hardly surprising since shampoo 2 and 3 are very similar in composition.
Evaluation:
When evaluating the LCA we must bear in mind the following aspects:

1. The study only concerns shampoos. Other products require different water and energy consumption in the use phase. E.g. soap bars for hand washing should require far less water and energy consumption and hence the use phase should be far less dominating.

2. The functional dosage was wet weight, i.e. the whole product. This means that generally more concentrated products will have a higher score than less concentrated products. Hence the comparison of products is of less value.

3. Some environmental impacts were not studied, e.g. local effects. The environmental impact of the ingredients on aquatic recipients is an example. Hence the LCA cannot be said to give a full view of the environmental impact of the products.

4. The shampoos 2 and 3 have very similar environmental impact but only no 3 fulfil the Nordic Swan Ecolabelling requirements at that time (1996). This result is of little interest as it is hardly surprising that a product that barely fulfils the requirements has an environmental impact close to that of a product that barely misses the requirements.

Ecobilan concludes with a much smaller use phase impact than Chalmers when compared to the other life stages. The reason is that Chalmers stipulate much higher water consumption and a lower start temperature than Ecobilan. It is interesting to see the large impact of these basic assumptions.

5.3 Chalmers Risk Analyses
Chalmers University of Technology performed in 1997 an initial risk assessment for the aquatic environment of 24 compounds utilized in shampoo formulations. Out of these 24 compounds, the analysis could not demonstrate environmental safety for the following 5 ingredients in the standard USES environment:

i) Cocoamido propyl betaine
ii) Formic acid
iii) hexyl cinnamic aldehyde
iv) Dipropylene glycol
v) 2-bromo-2-nitropropane-1,3-diol

Three different exposure scenarios were used, one according to a standard USES scenario, the two others Swedish scenarios. The Swedish scenarios yielded a different result: Out of these 24 compounds the analysis could not demonstrate environmental safety for just one compound: 2-bromo-2-nitropropane-1,3-diol.

Evaluation:
The study gives an impression of which ingredients have the greatest potential for creating a negative environmental impact when evaluated
isolated. The study also indicates that the potential for acute impact of shampoo ingredients on the aquatic environment is small. However it is questionable what the study can tell us about the impact of a steady release of shampoo ingredients on aquatic environments where many other pollutants are released and which are adversely affected by other impacts, such as oxygen depletion and eutrophication.

The study should not be interpreted to mean that the use of shampoo and soap do not have negative environmental impacts. However, the effect of emissions of shampoo ingredients is probably of less importance if compared to the total releases of water pollutants in Europe.

5.4 Risk analysis of the Medical Products Agency in Sweden

The Swedish Medical Products Agency has made an official study on the environmental effects of cosmetic products and medicines on behalf of the Swedish Government (Medical Products Agency, 2004). This work is still ongoing. Of the 7000 ingredients found in cosmetic products some groups of ingredients were singled out as giving the worst environmental impact. The basis was some selected indicators (volume of use, toxicity, etc). A risk analysis of a few selected groups of ingredients and assessment of some known or suspected environmentally harmful ingredients were made.

The findings of the report were: Cocoamidopropyl betaine and Parabenes were found to pose little or no risk to the aquatic environment. Bronopol pose a potential risk but only when the total usage was considered (also usage in other products). Cetrimonium salts pose a slight risk whereas Sodium Laureth Sulphate and Triclosan pose a high risk.

The following ingredients were found to be environmentally harmful: Butyl metoxydibenzoylmethane, EDTA, Cocoamide DEA, Isoparaffines, Polyquaternium-10, Resorcinol, Zink oxide and Zink Pyrithione. Sodium Lauryl Sulphate was evaluated as not harmful to the environment:

The main recommendations from that study were:

- Environmental Regulations should be taken more into account in the Cosmetics Directive.
- More, and better, risk assessments should be made.
- The knowledge base on potential environmental risks of cosmetic products should be increased.
- The reporting of product content should be improved and the flows of ingredients better supervised.
- More information should be made available in order to stimulate the environmental awareness.

5.5 Risk Analysis commissioned by the Swedish County Jönköping

In the study "Environmental impact of hygiene products" a risk assessment of selected ingredients were performed. The product groups

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liquid soaps, shampoos, conditioners and toothpaste were studied and three different water scenarios used: single separate releases, wastewater from a treatment plant and one river. The report found risk quotas of > 1 (this indicates an environmental risk) for quarternary ammonium compounds, cocoamido propyl betaine, triclosan, sodium cocoamphoacetate, sodium lauryl ether sulphate and cocoamide DEA. The last ingredient was found to cause a low risk when used only in the studied products but a high risk when considering the total usage. Parabenes were prioritised for risk assessment but could not be studied because of lack of information.

5.6 Analysis for the Swedish drinking water provider Stockholm Vatten

Kristina Johansson (Stockholm Vatten, 2002) studied the environmental effects of hair care products, on behalf of Stockholm Vatten. The study was based on ingredients inherent properties.

She studied 73 products. 21 ingredients were found to be harmful to the environment, while another 40 were suspected to be so. Some ingredients could not be identified and environmental information was lacking in a great number of cases. The study showed that hair colouring products contained most of the environmentally harmful ingredients but many were found in shampoos and conditioners too.

Environmentally harmful ingredients declared in shampoos and conditioners were: Ammonium hydroxide, Behentrimonium chloride, cetrimonium chloride, diazolidinyl urea, diethyl dimonium chloride, disodium laureth sulfo succinate, distearyldimonium chloride, isothiazolinones (MIT and CMI) and thymol. Carbomer, some polyquaternium-compounds (2-, 4-, 6-, 7, 10-, 11-, 30- and 37-), quaternium-52 and some silicone oils and some colours were suspected of being harmful to the environment.

Conclusions:
- The environmental impact have been studied for a large number of ingredients
- Most environmentally harmful compounds were found in shampoos and colouring products
- Many ingredients are suspected to be harmful to the environment
- Some products are inadequately labelled.

5.7 CETOX study of soaps

The Danish Centre for Integrated Environment and Toxicology (CETOX) performed in 1998 a study on the environmental and health impact of 27 liquid soaps and 39 solid soaps. The study was based on ingredients inherent properties. The study focused on the effects of the contents of the products on health and environment.
The environmental effects were measured by the classification status according to the Dangerous Preparations Directive and the anaerobic biodegradability. The ingredients were assessed according to the rules of the Dangerous Substances Directive (67/548/EEC) into a number of classes such as R50/53, R51/53, R52/53, R52, R50 and no classification. The details are given in Appendix 1.

The health impacts were assessed using a safety analysis according to the Cosmetics Directive.

Conclusions of the study:
37 of the 39 studied solid soaps were found not to fulfil the criteria for classification as environmentally harmful according to the Dangerous Preparations Directive. 2 solid soaps could be classified as environmentally harmful. This was due to the fact that these soaps contain synthetic anionic surfactants as main ingredients instead of the traditional saponified fats or oils.

9 out of the 27 liquid soaps could be classified as environmentally harmful. This was due to the content of Cocoamide MEA, Cocoamide DEA, Triclosan, Imidazolidinyl urea and sodium olefin sulphonate.

Assessment of health impact should not be based on the ingredients classifications. The product does not necessarily cause skin irritation just because of a large content of a surfactant with irritative properties; other ingredients may reduce the irritation effects. Hence the health assessment focused on known problematic substances such as perfumes. The study recommended the use of perfume-free products.

5.8 The Substitution Report commissioned by the Danish EPA
The report gives the results obtained in the project "Substitution of surface-active compounds in cosmetic products". The project was carried out by DHI, Water and Environment, in collaboration with three manufacturers. In addition to surface-active compounds some preservatives were studied. The primary aim were to help manufacturers to substitute environmentally problematic ingredients by alternative ingredients with better properties by screening the ingredients eco-toxicological properties, partly by literature reviews, partly by laboratory tests.

The majority of the ingredients were found to have a low potential for causing environmental harm. Only a minor part of the ingredients could be characterized as causing environmental harm. During the project several of these ingredients were phased out or replaced.

In the cases where no test data could be found and the substance was important for the manufacturers, anaerobic biodegradability and chronic toxicity tests were carried out. The connection between bioaccumulation potential and chronic toxicity was also investigated. The results indicate that a high logKow-value does not increase the toxicity of the substance in long-term tests provided the substance is readily biodegradable.
Most of the 24 tested substances were found to be anaerobically biodegradable.

One of the results of the study is that the commonly employed cationic surfactant Cetrimonium Chloride can easily be substituted by the environmentally preferable alternative Behenyl PG-trimonium Chloride.

5.9 Environmental guidance document by the Danish EPA

This study (Danish EPA 1999) contain evaluation of the impact of hair shampoo, body shampoo and liquid and solid soaps on the environment and human health. The study encompasses all the products life-stages.

The study found that these products cause a considerable environmental impact in its life stages. The release of active ingredients to water after use and the release of CO2, SO2 and NOx from energy production were found to be the main environmental impacts. The most problematic ingredients are those who are toxic, poorly biodegradable and prone to bio-concentrate.

The study also concludes that since the products are rinse-off products, the exposure to the skin is low, but many people experience adverse health reactions, probably due to exposure to fragrances and preservatives. Mild products should be used and some specified ingredients avoided.

The study also found environmental impacts that would be difficult to address in this environmental guidance document. They concluded f ex that ingredients based on plant and animals are preferred because raw oil is a limited and non-renewable resource and takes more energy to produce.

The study also found that the use phase accounts for a large part of the total impact and this impact can best be reduced by water-saving equipment and campaigns towards changing consumer behaviour.

It concludes as follows:
- Choose ecolabelled products
- Make sure the users read the ingredients list to avoid unwanted ingredients
- Choose mild products
- Choose products with less packaging
- Choose solid soaps
- Choose mild liquid soaps if the wash frequency is so high that a solid soap doesn't have time to dry in-between
- Choose products that is easy to apply in desired dosage
- Avoid coloured and perfumed products
- Choose only disinfecting soaps in those cases where it is specifically required
- Avoid EDTA and NTA

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- Avoid products with more than 0.1% of compounds who fulfil the requirement to be classified as harmful to the environment with the designation ‘N’. E.g APEO, LAS, quarternary ammonium compounds, secondary alkane sulphonates, sulfosuccinates as well as non-ionic surfactants with more than 30 EO.
- Avoid products with CMR-ingredients.
- Choose products with only readily biodegradable surfactants.
- Avoid the preservation agents 2-bromo-2-nitropropane-1, 3-diol, DMDM Hydantoin, 5-bromo-5-nitro-1,3-dioxane, imidazolidinylurea, isothiazoloinones, triclosan (or other trichlorohydroxyphenyl ethers) and the anti-oxidant BHT.

5.10 Other studies

In a study by the Swedish Society for Conservation of Nature (May 2001) 14 shampoos and 12 soaps for use on babies were examined, and pass/fail requirements on health and environment were set up. (Environment: R50/53, R51/53, low biodegradability and environmentally harmful in other ways (e.g. content of heavy metals), health: risk of allergy, cancerogenic or genotoxic potential and endocrine disruptive properties.)

Only 4 of the 14 shampoos fulfilled the requirements. 10 of the products failed because of perfume content and/or colouring agents. Many products failed because of the use of the following preservatives: Methyl dibromo glutaronitrile, Quatertinum-15, imidazolidinyl urea, Cetrionum chloride, methylchloroisothiazolinone and methylisinthiazoloinone. The poorly biodegradable Cetyl alcohol and ingredients containing monoethanolamines (MEA) and diethanolamines (DEA) are other examples. MEA and DEA are singled out because of warnings from the American government agency FDA regarding possible carcinogenic activity.

Only one of the 12 soaps fulfilled the requirements. It is a solid soap. Another soap would have fulfilled the requirements if it had not contained perfume. 6 products contained perfume and/or colouring agents. The antioxidant BHT is used in several products. Disodium EDTA, Tetrasodium EDTA and Cocoamide DEA are examples of other ingredients that are assessed as harmful to the environment and/or health. Generally, solid soaps were found to contain fewer ingredients harmful to the health and the environment than liquid soaps.

A study carried out by the Danish Green Information Centre in 1999 concluded as follows regarding environmental impact:
- Release of shampoo and soap ingredients to waste water treatment plants and aquatic environments is a major environmental impact.
- Release of CO₂, SO₂ and NO₃ from energy production is the other major environmental impact.
- The most problematic ingredients are those that are poorly biodegradable, toxic to aquatic organisms and not potentially biodegradable.
- Using ecolabelled products ensures that the most harmful substances are not used.

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Conclusions regarding health impact:

- Perfume ingredients are the most problematic ingredients regarding health.
- Soaps and shampoos can dry out skin.
- Many ingredients are known to, or suspected of causing allergies, e.g. BHT, propylene glycol, lanolin, and certain perfume ingredients such as eugenol, isoeugenol, oak moss, geraniol, hydroxycitronellal, α-amyl cinnamaldehyde, cinnamaldehyde and cinnamal alcohol.
- The products impact on health depends on frequency of wash, water temperature, skin type, age of person, health status and ingredients of the product.
- The effect of pH on product health impact is not clear.

5.11 Discussion of the studies

The studies presented above were used as background material for the criteria development project and for the discussions in the ad-Hoc Working Group. In addition the experience of the ahwg-participants were considered, e.g. the experience gained by Nordic Ecolabelling after having ecolabelling criteria for soaps and shampoos for more than eight years.

The European Ecolabelling Scheme is based on life-cycle considerations and the two LCA-studies was important input to the discussions. However, both studies include heating and consumption of water within the system boundaries, and one study also included the use of a hair dryer. Therefore, both studies concluded that the main environmental impacts were found in the use phase, and arose from by the production of energy for heating the water and for the dryer.

The result of an LCAs also depends on the impacts studied. The LCAs focused on global and regional impacts caused by air pollution. Energy is often produced by combustion, hence it is no surprise that energy use is of high importance to the results.

The mandate from the Commission for this project was to develop criteria for the soap and shampoo-products, and did not include the washing or drying of the hair. Therefore, we focused on the environmental impacts of the products, and only parts of the LCA-studies connected to the products were used in the subsequent discussions. Furthermore the ahwg agreed that ecolabels are not the appropriate tool for decreasing environmental impacts connected to heating water for washing or air for drying the hair. The Group agreed that the environmental impacts of the products themselves: extraction of raw materials, refining, production of ingredients, use phase, and impact after use are sufficient to justify ecolabelling of soaps and shampoos.

The Risk Analysis and the reports focusing on ingredients properties show that many ingredients could potentially lead to toxic effects in the environment.
Risk Analysis gives as results Risk Quotients (RQ). An RQ>1 is claimed to indicate a risk for environmental harm. The Risk Analysis performed give low RQ for the vast majority of ingredients that have been examined. Ecolabelling Norway and several Group Members have expressed doubt regarding the results of Risk Analysis. The assessments often give conflicting results, and the complexities of natural ecosystems are generally ignored when the substance toxicity is measured alone and in a pure environment. Generally in ecolabelling, the properties of the ingredients are the basis of the criteria development. This is in accordance with the Chemicals Legislation, which is generally based on inherent properties of chemicals.

The other reports show that ingredients in soaps and shampoos have very different toxicity and biodegradability properties. The Group agreed to use the parameters employed in the ecolabelling criteria for detergents:

- CDV as a measure of total long-term toxic effect
- aNBDO as a measure of potential harm caused by ingredients remaining in aerobic environments because of low aerobic biodegradability.
- anNBDO as a measure of potential harm caused by ingredients remaining in anaerobic environments such as anaerobic sludges and sediments because of low anaerobic biodegradability

6 Studies by Ecolabelling Norway

Ecolabelling Norway studied more than 111 products. These products were selected from both the North and South European markets. Both In´I-products (products for Institutional and Industrial use) and consumer products were represented.

Ecolabelling Norway has made:

- A quantitative study of 81 products based on their exact formulations.
- A semi-quantitative study of 61 products for which we only had ingredients list.
- Quantitative comparison with household detergents

6.1 Quantitative studies of 81 products based on exact formulations

Based on the quantitative study we calculated some parameters to get an impression of the total environmental impacts of the products by using data from the DID-list and a number of other open sources, among them Madsen and Larsen (1998) and Madsen et al (2001). We have not been able to find environmental data for roughly 10 % of the ingredients in the investigated products, either because the ingredients have not been tested or because the data are not published. Based on reports and expert opinions we evaluated the toxicity, biodegradability and (in some cases) the bioaccumulation potential of many of these ingredients without environmental data

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The following table sums up the most important results of the study:

Table 2.

<table>
<thead>
<tr>
<th></th>
<th>CDV</th>
<th>Aerobic not degradable non-surfactants</th>
<th>Anaerobic nor degradable toxic ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average</td>
<td>Range</td>
<td>Average</td>
</tr>
<tr>
<td>Shampoo and shower products</td>
<td>18622 (*)</td>
<td>3600-83000</td>
<td>45</td>
</tr>
<tr>
<td>Solid soap</td>
<td>3925</td>
<td>2000-9300</td>
<td>13</td>
</tr>
<tr>
<td>Conditioner</td>
<td>73735</td>
<td>2300-380000</td>
<td>123</td>
</tr>
</tbody>
</table>

(*) The 2 highest values are not included in the average calculation.

**Toxicity**

The CDV gives a measure of the total toxic impact of the product. The parameter is described in detail later in this report.

The CDVs of the products we have investigated mostly lie in the range 1500 to 30000. Some products have significantly higher CDVs but this commonly due to the presence of ingredients with no documentation on toxicity and degradability.

In the products with highest CDV we found that toxic preservatives and surfactants form a large part of the CDV. These compounds are also often not biodegradable in aerobic and/or anaerobic compartments and this has large impact on the other quantitative requirements. Additionally the preservatives are often allergenic (like methyldibromo glutaronitrile) or formaldehyde-releasing (like 5-bromo-5-nitro-1,3-dioxane).

In the products with a low CDV, a large percentage of the CDV is taken by 3 ingredients:
- Surfactants, for example sodium lauryl ether sulphate (SLES) or sodium lauryl sulphate (SLS), typically accounts for 20-40 % of the CDV. Surfactants are added for its cleaning properties, but are usually hard to the skin and may cause irritation when used alone.
- Cocoamidopropyl betaine is often added to achieve a milder soap or shampoo. This ingredient alone accounts for 50-80 % of the CDV in many of the products.
- Perfume typically accounts for 5-15 % of the CDV but the figure can be much higher, as some products contain a high percentage of perfume. In many products also the preservative accounts for a large part of the CDV.

In many cases the manufacturer can substitute the surfactants and preservatives and perhaps reduce the amount of perfume. However, the proposed criteria allows for the use of the most common ingredients SLES, SLS (Sodium Lauryl Sulphate) or Cocoamidopropyl betaine.
Ingredients classified as environmental harmful

The following table show the amounts of classified ingredients found in the quantitative study of 50 compounds.

Table 3. Average content of classified ingredients

<table>
<thead>
<tr>
<th>Product group (mg/g AC)</th>
<th>R50/53</th>
<th>R51/53</th>
<th>R52/53</th>
<th>R50</th>
</tr>
</thead>
<tbody>
<tr>
<td>All products</td>
<td>12</td>
<td>16</td>
<td>10</td>
<td>450</td>
</tr>
</tbody>
</table>

The high content of classified ingredients in conditioners is probably due to the fact that many of the active ingredients in these products, e.g. cationic surfactants are highly toxic and poorly biodegradable. Additionally the active content is lower in these products which means that many cases perfume is the only ingredient that fulfil the criteria for classification as environmentally harmful. Another important contributor to the content of environmentally harmful compounds is Cocoamide DEA (R51/53) due to its high bioaccumulation potential. The classification has been made by Madsen and Larsen (1998) and is only tentative.

Products classified as environmental harmful

The Directive on Dangerous Preparations does not cover cosmetic products. It is however interesting to find whether the studied products would have been classified as harmful to the environment if the Directive did apply to Cosmetics.

We have only taken into account the combined risk phrases, not the risk phrases that only concern degradability/bioaccumulation or only toxicity. The reason for this is that other requirements will limit the toxic impact (CDV) and degradability (limit on not degradable surfactants).

The symbol ‘N´ means that the product should bear a symbol, in this case a dead tree. If the product would classify for the risk phrases R50/53 or R51/53 the risk phrase and the symbol would have to be printed on the label. If the product would classify for the risk phrase R52/53 only the risk phrase would have to be printed on the label.

\[
\begin{align*}
N, R50/53: & \quad (W_{R50/53}/25 \%) \geq 1 \\
N, R51/53: & \quad ((W_{R50/53}/2,5 \%)+(W_{R51/53}/25 \%) \geq 1 \\
R52/53: & \quad ((W_{R50/53}/0,25 \%)+W_{R51/53}/2,5 \%)+W_{R52/53}/25 \%) \geq 1 \\
\end{align*}
\]

\(W_{R50/53}\) = Weight percent of ingredients that may be classified as R50/53.

\(W_{R51/53}\) = Weight percent of ingredients that may be classified as R51/53.

\(W_{R52/53}\) = Weight percent of ingredients that may be classified as R52/53.

If the Preparations Directive had been valid for cosmetic products, none of the studied products would qualify for the risk phrases R50/53 or R51/53 and labelled ‘N´. However, 6 products would get the risk phrase R52/53 whereas 5 products would be close to the classification limits. This means...
that approx. 10% of the products could be classified as harmful to the environment according to the combined risk phrases alone. 5 of these 6 products are conditioners.

**Biodegradability of the compounds**

We generally wish to encourage the use of biodegradable ingredients. Compounds that are not biodegradable may accumulate in the environment and are a potential environmental risk.

The content of poorly biodegradable non-surfactants lie in the area 0-500 mg/g AC. Most products contain less than 70 mg/g AC. The content of poorly (aerobic) biodegradable surfactants is surprisingly low. Only 19 out of the 81 products contain (11%) such ingredients. The reason might be that surfactant manufacturers have spent much time and effort to develop biodegradable surfactants because of the new detergent legislation. Manufacturers of other ingredients have not faced similar incentives.

Low biodegradability may not be a problem if the toxicity is low. In combined parameters such as the CDV or the risk phrases (R50/53, etc) this has been taken into account. Hence it is of interest to see how large fraction of the anaerobic not degradable ingredients that have a high toxicity.

**Endocrine disrupters**

No ingredients on the EU-list of endocrine disrupters were found. Neither were the two suspected endocrine disrupters benzophenone and butylparaben (not on the EU list) found in the products.

**Preservatives**

Many of the products contain preservatives that will be excluded by the proposed requirements. The majority of these are formaldehyde releasers, such as diazolidinyl urea, 5-bromo-5-nitro-1,3-dioxane and sodium hydroxy methyl glycinate.

Metyldibromoglutaronitrile is allowed in rinse-off cosmetics in amounts less than 0.1%. Many of the products contain this preservative in spite of the fact that the percentage of the population reacting to this ingredient is high and has been rising the last years.

Isothiazolinones are present in a few products. 1,2-benzoisothiazolin-3-one is not allowed in cosmetics but was still found in one product!

**Fragrances**

The fragrance content varies a lot and in general South European products contain more fragrance than North European. A solid soap in the south often contain 1-2% fragrance whereas a Northern soap contain 0.2-0.5%. The liquid rinse-off products contain 0-0.2% in the North, 0.2-0.4 in the South.

**EDTA and phosphonates**
Half of the solid soaps contain EDTA and/or phosphonates, generally in the range 3-5 mg/g AC.

**Biological additives**
More than half of the products contain biological additives, i.e. ingredients from plant or animals that has not been chemically altered. These are generally not documented regarding environmental properties. However they must be tested for human safety according to the Cosmetics Directive.

**6.2 Semi-quantitative studies of 61 products based on ingredients list**
The 61 products are 19 shower products, 7 solid soaps, 10 liquid soaps, 19 shampoos and 6 conditioners. The products contain 250 ingredients. From different sources we found environmental data or evaluations of environmental properties on 68 % of the ingredients. We searched for environmental data in various sources. Some confidential data has been made available to us but most of the data was found in open sources, such as the DID-list. We have no data on biodegradability, bioaccumulation or aquatic toxicity for 32 % of the ingredients.

31 % of the product contained preservation agents that release formaldehyde upon degradation.

None of the endocrine disrupters on the EU-list were found in the products. 5 % of the products contained the suspected endocrine disrupters benzophenone and butylparaben.

Almost half the products (43 %) contained "biological additives" (e.g. plant extracts).

**6.3 Comparison with household detergents.**
In order to get an understanding of the environmental impact of soaps and shampoos, a comparison was made with all purpose cleaners and laundry detergents. The same functional unit as proposed for soaps and shampoos was used.

The all-purpose cleaners have CDVs from 18000 to 30000 l/g AC. The Laundry detergents have CDV from 2500 to 5000 l/g AC.

The content of anaerobically degradable ingredients was 70-190 mg/g AC (laundry detergents) and 60-300 mg/g AC (all-purpose cleaners).

None of the studied products classified for labelling as environmentally harmful.

This study was made on the basis of a few products with the purpose of getting an idea of the magnitude of potential environmental impact of soaps and shampoos compared to household detergents.
Generally we can say that the potential environmental impact of soaps and shampoos are of the same magnitude as that of household detergents.

6.4 Other studies
Manufacturers, experts and test institutes have been asked about test for mildness and efficiency. There exist tests for these parameters but no standard tests. The test institutes and manufacturers are reluctant to give us their test methods. They have invested in the test methods and are not interested in publishing them for free.

We have received the protocol of the Red Blood Cell test (RBC). This is a test that determines the effect of products on erythrocytes (red blood cells). Cosmetic ingredients will have to penetrate the skin in order to have an effect on the blood. Hence it would be more appropriate to test only those components that penetrate the skin. However the penetration properties depends on the other ingredients in the products. It is also important not to require many tests to be performed because this might prevent SME's from applying for an ecolabelling licence.

All in all the RBC test is a simple and cheap method that gives a good indication of the potential for damage to the body outer layers.

The method does not specify a pass/fail-level. Our intention is not to make mildness an important parameter but rather to eliminate the "worst" products. Hence we propose that the product must not be much worse than the average of products on the market. Products are used for different purposes e.g. conditioners and soaps. Even products with the same usage (e.g. soaps) can be used very differently, e.g. hand soaps used by health workers and ordinary consumers.

Accordingly it makes sense to compare the mildness of a product with the mildness of one or several products representing a market average within the same area of usage and user group. The product should not give a significantly worse result than the comparison product(s). "Significantly" could mean 20%.

6.5 Discussion of the studies:
The large number of formulations gives an excellent background material enabling the calculation of parameter values and testing implications of different set of requirement levels. The lack of accurate market data means that it is impossible to precisely define requirement levels that enable 30% of the products to fulfil the requirements without changing their products. The Group discussed whether or not the investigated products were representative of the European market. Some Members argued that products manufactured in Italy and France was more representative of the European Market because these countries are big manufacturing countries. The North European market, especially the Scandinavian market has gotten used to the idea of ecolabelling of soaps and shampoos. Many products now carry the Nordic Swan label or the Swedish Falcon label ("Good Environmental Choice"). Hence it is no Final report for the development of ecolabelling criteria. EU-Ecolabel for Shampoo and Soaps Ecolabelling Norway 3. May 2006
surprise that Northern European manufacturers have taken the environment more into consideration when formulating products than their Southern European counterparts. This can be clearly seen in the much higher incidence of formaldehyde-releasing preservatives, allergenic preservatives and not readily biodegradable surfactants in Southern Europe than in the North. It can also partly explain the fact that the Northern products contain fewer ingredients for which no test data exists. The differences between different parts of Europe are further discussed in the chapters on CDV and biodegradability.

The ranges of CDV, aNBDO and anNBDO values are quite high which indicates that the environmental impact differs a lot from product to product. The high values can to a large extent be explained by poorly biodegradable, very toxic preservatives and surfactants, and a high content of perfume. The range is especially high for conditioners, which is almost entirely caused by poorly biodegradable and very toxic cationic surfactants. Part of the reason for the higher parameter values for conditioners is purely "technical". These products have a smaller active content than the cleaning products, which means that f ex a certain amount of a toxic, and poorly biodegradable surfactant counts much more in a conditioner than in a shampoo.

6 products were found to be environmentally harmful according to the Dangerous Preparations Directive, and this is due to the evaluation of Cocoamide DEA as potentially bioaccumulating. Hence the number of products that could be classified as environmentally harmful may be much smaller, but it is nevertheless interesting to note that there actually are products that could be classified as environmentally harmful or are close to the limits.

The CDV values indicate that the potential environmental impact of soaps and shampoos is comparable to those of household detergents. One important difference between household detergents and soaps and shampoos is that the latter contain many more ingredients, and that a larger fraction of the ingredients are undocumented as concerns eco-toxic properties.

### 7. Definition of the product group

The product group was defined originally as soaps and shampoos. The Group discussed inclusion of other rinse-off cosmetic products for similar purposes. It was agreed that all products for regular cleaning of human hair and body should be included. Hence all kind of shampoos, liquid soaps and solid soaps was accepted without discussion. The proposal to also include bath soaps, conditioners, combined products, anti-dandruff shampoos and special cleaning product such as peeling products was accepted after some discussion.

It can be discussed whether or not conditioners are "rinse-off" products but they require a rinsing off with water after application and they have a low retention (<1 %). They are not cleaning products and are different in composition from the cleaning products. However they are often used in

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combination with shampoos and they score higher on the CDV and the biodegradability parameters than the other products. Hence there is more to gain environmentally in this category than in the others.

Peeling (also called ex-foliating) products are rinse-off products but many products are supposed to stay on the skin for 5-10 minutes before rinsing off. It can also be discussed whether they are for regular use. However some manufacturers have informed us that they are not very dissimilar from other cleaning products apart from some special rubbing/abrasive agents. We also know the ingredients of some products. Many consumers use them regularly.

The rubbing/abrasive agents can be inorganic and inert like f ex bentonite clay. They can also be organic polymers. However they are usually not soluble in water and cannot be expected to be biodegradable. Hence they are exempted from the requirements where biodegradability is included.

There also exist other "niche" products f. ex. washing gels for the face, and hand cleansing gels. The manufacturers we have contacted have not been willing to give exact information so that we could calculate the scores for CDV and other quantitative parameters. The COLIPA frame formulations indicate that these products contain many of the same ingredients that are found in traditional shampoos, soaps, shower products and conditioners.

However, the manufacturers we have contacted have informed us that the products are not very different from the products we have studied. F ex intimate cleaners are very similar to ordinary liquid soaps.

Anti-dandruff shampoos are subject to special rules in the Cosmetics Directive. They contain an active ingredient that often is quite toxic and has even been compared with anti-bacterial products. Zinc Pyrithione is a good example of an active ingredient that is mild to the body but is very toxic for aquatic organisms. Our calculations have shown that anti-dandruff shampoos can fulfil the requirements and still fulfil the quality requirement laid down in the Cosmetics Directive.

The Group wanted to make a distinction between disinfecting products and ordinary cleaning products. Ordinary consumers have no need for disinfecting products. In order to halt the tendency to use cleaning products with anti-microbial action as a sale argument, the Groups decided to exclude disinfecting products from the product group.

**Conclusion**

The Group agreed on a product group definition that includes all cosmetic (see the EU Cosmetics Directive 76/768/EEC with adaptations) rinse-off products for cleaning human body and hair as well as products for conditioning human hair. Products intended for the professional (I`n`I) and consumer market are included.

Disinfecting or antimicrobial products are not included.
8. Functional unit

The quantitative requirements form the backbone of the criteria but the ranking of products depends very much on the functional unit, which they are based on. Ideally the functional unit should be linked with the amount of product necessary to perform a standard "job" like the washing of a pair of hands. This "standard dosage" should then be documented by a standard test. The "standard dosage" should also ideally be stated on the product to make sure that people do not use more product than necessary. According to the manufacturers this is not possible.

For the purpose of risk assessments standard usage volume and frequency has been determined. The surface areas of the body and different body parts have also been determined. The Group discussed the possibility of using the standard dosages in the ecolabelling project but the idea was abandoned because it encourages ecolabelling of diluted products. This could be partially counteracted by a strict requirement on product fitness for use, but as no standard method for fitness for use exists it is difficult to set a strict requirement.

Table 4. Standard dosages and frequency according to Colipa

<table>
<thead>
<tr>
<th>Product</th>
<th>Dosage</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hair conditioner</td>
<td>14 g</td>
<td>0.28 a day</td>
</tr>
<tr>
<td>Shampoo</td>
<td>8 g</td>
<td>1 time a day</td>
</tr>
<tr>
<td>Shower gel</td>
<td>5 g</td>
<td>2 times a day</td>
</tr>
</tbody>
</table>

The retention of these products are all estimated at < 1 %.

Similarly standard measures for the area of the whole body and individual body parts exist.

The approach of Ecolabelling Norway has been to instead encourage the use of efficient ingredients by using the active content as a base for the functional unit. The Nordic Swan has had this approach but has received comments from manufacturers that this encourages the use of inert inorganic salts to dilute products until they fulfil the requirements. This is highlighted in the Chalmers LCA where product no 3 is exactly such a product. Hence it was decided to set the functional unit to 1 gram of organic ingredients. There still exist a possibility to "dilute" the product with biodegradable organic ingredients with low toxicity but the Group did not find this likely to happen.

Not all proposed parameters are linked to this functional unit. The requirement on environmental risk phrases is based on percentage of the whole product because it is specified like that in the Dangerous Preparations Directive. The parameter on packaging weight is based on weight of the whole product, not just active content. This is explained later in this report.

Conclusion

The functional unit is 1 g organic ingredients, hereafter referred to as active content, AC. Rubbing/abrasive agents in hand cleaning agents are not included.
9. Criteria requirements on the different life stages

The LCAs, risk analysis and other studies show that soaps and shampoos have a potential to cause a variety of negative environmental impacts. The market data shows that the consumption is high. The impacts are mostly connected to the production of ingredients and their raw materials, effects of the ingredients after use and impacts from the production of packaging material. Depending on how the products life cycle is defined we may include the air pollution connected to hot water production as a major environmental impact. The environmental impacts are many and include greenhouse gas emissions, ozon layer destruction, formation of photochemical oxidants, depletion of non-renewable resources, acidification, eutrophication, reduction of water quality, loss of biodiversity and various health effects such as allergies.

It is important to note that not all environmental effects can be addressed by ecolabelling. Rather ecolabelling is one of several "environmental policy tools" that must find its place alongside others, e.g. regulations, information campaigns, green taxes and voluntary agreements.

9.1 The early life stages

Experience from ecolabelling of household detergents, have shown that it is difficult to set requirements on the first life phases: Raw material extraction/refining and manufacture of ingredients. One major problem is the difficulty to obtain sufficient information to set the requirements. Even more problematic are the difficulties involved in comparing the environmental effects of ingredients derived from plants and petroleum. Some effects are caused by both sources (e.g. depletion of non-renewable resources, greenhouse gas emissions, acidification, ozone layer depletion) whereas others are specific to one source. Plant sourced ingredients cause for example land degradation, loss of biodiversity and effects of pesticide use. Petroleum sourced ingredients cause for instance local effects of pollution from oil drilling and refining, oil spill effects, etc. Furthermore it is difficult to influence the raw material producers and ingredients producers to change their practises because they do not derive direct benefit from ecolabelling but have to take costs.

Experience has shown that ecolabelling is most efficient in reducing the environmental impact of soaps and shampoos after use and, to a lesser extent the health effects during use. This is done by regulating the inherent properties of the ingredients of the products and the packaging weight and material.

Early in the project the Group discussed the possibility of reducing the environmental impacts of the first life stages of palm oil. Palm oil is mostly used in food but also as raw material for soaps and shampoos. Production of palm oil has lead to large environmental and health problems. After media and NGOs in some countries focused on these problems the general public reacted strongly. The Roundtable of Sustainable Palm Oil (RSPO) was initiated by WWF in 2001. The principal objective of RSPO is “to
promote the growth and use of sustainable palm oil through co-operation within the supply chain and open dialogue between its stakeholders. The RSPO has started development of criteria for sustainable palm oil production but these criteria are yet not finished. Ecolabelling Norway welcomes the initiative taken by the RSPO. It has the potential to make soaps and shampoos more sustainable both ecologically and socially. This would also make it easier to set requirements and check compliance with the requirements. Until the Guidelines are in place however, it is difficult to set requirements. Producers of palm oil and other interested parties can become members of the RSPO. The Group considered making membership of the RSPO obligatory for the palm oil producer or the company refining palm oil into shampoo ingredients. This would ensure that producers are supporting the idea of sustainable palm oil production and that they have access to information on what sustainable production means in practice.

The proposal was withdrawn because the Ecolabelling Directive does not allow ecolabelling criteria to require membership in a voluntary organisation. Furthermore the RSPO is for a great part concerned with ethical issues. Ethical issues are not covered in the Ecolabelling Directive.

The production of other ingredients also causes environmental effects but we do not have the resources to assess these impacts, set requirements and determine verification procedures.

The impact of packaging has been evaluated. There is no impact during use and the impact after use is low because a lot of packaging is material or energy recycled. The largest environmental impact is probably concerned with the production of the packaging materials. The LCAs show that packaging accounts for a significant part of the products environmental impact. This result is probably in part due to the fact that air pollution form a large part of the production impact and hence scores high in the LCA. The efficiency of the packaging has important impacts on transport, and this has therefore indirect environmental impacts. Different ways of reducing environmental impact of packaging was discussed by the Group, but due to limited information we were not able to rank the packaging with quantitative requirements. However the working group agreed on the weight/content-relationship parameter. This parameter generally reduces packaging weight and thus indirectly reduces impacts from material production and transport. For more details see the Packaging chapter.

One important way of reducing overall environmental impact is to reduce the applied product dosage. The Group discussed various ways of reducing the dosage. We cannot force the producers to indicate a standard dosage because the usages vary a lot (sometimes the whole body, sometimes parts of the whole body is cleaned). In some applications, e.g. in soaps for public toilets the amount used can be standardised and limited by a pump system but generally the needs differ and the consumer uses what he or she needs. It was decided to include a requirement that the product must be designed in such a way that makes it easy for consumers to apply the

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desired dosage. That can be achieved by many different means, e.g. a pump, the adjustment of viscosity or the diameter of the tip opening.

Another way of reducing overall environmental impact is to only ecolabel efficient products, e.g. products that perform well. This means that a smaller dosage will be needed for a certain task. See "Fitness for Use" Chapter.

It was also discussed to require an information text urging the consumer to use less product similar to what was done in the AISE "Wash right" campaign for detergents. This is discussed in the Information Text Chapter.

**Conclusion:**
No direct requirements is given for the early life stages of soaps and shampoos, i.e. extraction and refining of raw materials and production of ingredients.

However some requirements reduce overall consumption, which in turn reduces impacts from the early life stages. The requirement on Weight/content-ratio reduces packaging impact and the requirement on package design reduces applied dosage and hence reduces the overall impacts in all life phases.

**9.2 The use phase**
During actual use the consumer may be exposed to health risks, e.g. perfume may affect the skin or lungs. Some products also remove the skin's natural lipid layer leaving it more vulnerable to infections. We have proposed several health related requirements that reduce potential for detrimental health effects even further than the Cosmetics Directive. These include among others ban on CMRs class III, ban on formaldehyde releasing preservatives, limitation on allergenic fragrance compounds and limitation of perfume in baby products. These requirements are discussed in the relevant chapters.

At the final stage of the project, the Commission deleted several of these criteria as these could imply that products only complying with the Cosmetic Directive would be regarded as “not safe”. Ecolabelling Norway regrets these changes. Many consumers experience negative health effects from cosmetic products, and we believe the inclusion of strict health requirements would have improved the criteria significantly.

During use there are few environmental impacts. However, since the product must be applied with, and rinsed away with water it may be argued that the resource use and pollution associated with the washing must be included in the products total environmental impact. In the same manner it may be argued that the energy consumed during transport of the product, ingredients and raw materials must be included. However the LCA authors decided to include the impacts from the washing process in the system but not the transport energy. This just shows how heavily the results of an LCA depend on the system boundaries and other basic tenets.
The Group discussed the possibilities of reducing energy and water consumption associated with the washing process. The proposal to introduce a text urging consumers to use less and colder water during the washing process was rejected. This is discussed in the Information Text Chapter.

The Group decided that it would be very difficult for an ecolabel to reduce the impacts connected with the washing process. Other possibilities such as information campaigns, fossil fuel and energy taxes and subsidies on water saving devices are probably more efficient in reducing these impacts.

**Conclusion:**
During use, the product has no environmental impact but they may have a negative health impact. The potential for negative health impacts could be reduced by some health related requirements on fragrances, preservatives and hazardous compounds, but the Commission deleted these proposals.

The environmental impacts concerned with associated activities such as heating of water for washing of hair is difficult to reduce by ecolabelling of soaps and shampoos.

### 9.3 The disposal phase

The Group agreed that the life phase with the greatest environmental impacts that Ecolabelling could influence was the disposal phase. Ecolabelling Norway proposed parameters with an aim to reduce impact of soap and shampoo ingredients released into the environment. The possible impacts include direct toxic effect, eutrophication, oxygen depletion, loss of species and endocrine disruption.

The amounts of Nitrogen and Phosphorus are not large in soaps and shampoos which means that eutrophication is probably not a big impact from these products. It is difficult to assess the contribution to oxygen depletion of the products but it is probably less important than the huge low toxicity discharges from f ex agriculture. Ecolabelling Norway proposed to focus the criteria on reducing direct toxic impact and the potential environmental risks associated with the accumulation of not biodegradable ingredients in the environment. The Group accepted this.

Very little packaging is reused. Packaging is normally recycled, incinerated or sent to landfill. The Group discussed ways of limiting the effects of packaging in its final life stage. Even though the current proportion of recycling or incineration is quite high in Europe due to the legislation, the picture is not so positive for cosmetic packaging. Soaps and shampoos, especially the liquid products generally come in plastic packaging. Plastics are recycled less than other packaging materials. Also packaging for consumer products have a lower recycling rate than professional products. We have found no data for the recycling or incineration rates for soap and shampoo packaging but we have reason to believe that a high fraction is sent to landfill. Hence the Group has discussed ways of limiting the
potential impacts of packaging after use and has agreed on limitations on the use of certain additives. Additionally the Weight-Content Ratio encourages the use of recycled material by counting virgin material twice but recycled material only once. The environmental impacts of packaging are further discussed in the packaging chapter.

Conclusion:
The criteria focuses on the environmental impacts in the disposal phase for the actual products. Parameters regulating direct toxic impact and accumulation of poorly biodegradable substances were proposed and accepted by the Group. These parameters are quantitative and form the backbone of the criteria.

The disposal phase is not as dominating for packaging. Due to lack of data it has not been possible to assess the effect of the packaging whether it goes to landfill, is incinerated or recycled. However the criteria contains a requirement excluding the worst additives. Additionally the Weight-Content Ratio parameter gives an incentive to use recycled material.

9.4. Animal testing

Products and ingredients have in the past been extensively tested on animals in order to avoid detrimental health effects. This testing have caused a lot of suffering for animals and the Cosmetics Directive contain a ban on animal testing of products from 1 December 2001. The directive also contain a ban of tests performed on ingredients or combinations of ingredients, as soon as an alternative method has been published by the Commission, after endorsement of its scientific validity by the European Center for the Validation of Alternative Methods (ECVAM) and the ECVAM Scientific Advisory Committee.

The Swan criteria contains a requirement regarding testing of the finished product that is more slightly stricter than the Cosmetics Directive. The finished product must not be tested within the last 5 years before the date of application.

Very little animal testing is done on finished product and existing ingredients. However animal testing on new ingredients seems still to be taking place on a large scale. Many consumers are very concerned about animal testing. Some companies do not test products on animals whereas others still do. We have no indications that the products with ingredients not tested on animals are less safe than those containing tested ingredients. Hence a restriction on animal testing was considered. The aHWG supported the idea. However, animal suffering is an ethical question, not a health or environmental issue. Ethical issues are not mentioned in the Ecolabelling Directive and hence we cannot set requirements based on ethical considerations only.

Conclusion:
Because of the Ecolabelling Directive the criteria contains no requirement on animal testing.
10. Critical Dilution Volume (CDV)

This parameter is intended as a measure of the product's total toxic impact. Literally it is the volume of water needed to dilute one functional unit (1 g organic ingredients) to a level where no effects can be seen. The inclusion of very high safety factors from Risk Assessment Directive and accordingly has large safety margins in-built. This means that the numbers are exaggerated but the ranking between products are unaffected by this.

The remains of soaps and shampoos after the washing process is released into the environment either directly or via waste water treatment plants (WWTPs). Depending on the degradability more or less of the ingredients reaches the recipients in different water bodies. There they have a potential to cause harm to organisms according to their toxicity and tendency to accumulate.

The aquatic environments that the ingredients reach are very complex and diverse and it is impossible to foresee the environmental impacts. In the absence of large-scale scientific studies we have to rely on what we know of the ingredients properties.

We have chosen to focus on the toxic effects measured in the OECD standard tests. Soaps and shampoos are released into the environment not in episodes but on a regular basis every day. Hence the chronic toxicity tests (that measure long-term effects) should be used rather than the acute toxicity tests (that measure short-term effects).

The SF is much higher if only acute results, rather than long-term results are used. Thus the production of long-term data, which gives a better picture of the actual environmental impact, is encouraged.

The CDV-parameter is common in ecolabelling criteria for household detergents. It is also used in the soap and shampoo criteria for the Nordic Swan. The amount of each ingredient is divided by its Toxicity Factor giving a number that increases with higher toxicity and with the amount used. The number is then multiplied with a Degradation factor, which is meant to signify the fraction of the ingredient that is not degraded. The sum is then multiplied with a Security Factor (SF) that generally decreases with increasing number of test results. The toxicity factor is determined as the lowest median toxicity factor of the compound divided by a "safety factor" (SF). The SF has been taken from the Risk Assessment Directive Technical Annex and is very high, especially for chemicals where no chronic data were available and the TF is based on acute toxicity. The calculated CDV will be a rather high number and should be used to compare products. It is not correct to interpret the CDV as the volume of water contaminated by one gram organic ingredient.

The CDV enables a precise ranking of products according to very relevant environmental impacts using readily available data from standardised tests. Hence there is good reason to set a very strict limit on the CDV making this one of the most important parameters. The data we have is from products that are relatively "green" that are optimised to give a low

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environmental impact. The majority of the soaps and shampoos on the European market probable have higher CDV values. We choose a cautious approach until we know more of the market.

Different requirement levels were set for different product categories. This mean that we could get ecolabelled products in all categories, increasing the consumer's choice. Even though solid soaps have a lower score for the CDV and other parameters we should not exclude liquid soaps. Many people prefer liquid soaps and in the I´n´l-market they dominate completely. Differentiated requirement levels also enables a "fine-tuning" of the requirement levels so that it is equally difficult for products in all categories to fulfil the requirement.

The Group accepted the CDV parameter and the setting of different levels for different product categories.

The requirement levels were discussed at length. Not only the CDV but also the parameters on aerobic and anaerobic not degradable ingredients were discussed. Some Group Members argued that the requirement levels were too strict, allowing very few products from the South and Central European markets to fulfil the requirements. Others argued that the requirements were significantly less strict than the Nordic Swan requirements and wanted stricter requirement levels.

The documentation of this requirement might pose a challenge since many of the ingredients have not been tested. Testing is expensive but will probably lead to environmental benefits because the producer can evaluate environmental performance together with quality, physical properties and price when developing products. Furthermore we can offer the consumers 100 % transparency, i.e. that all the product ingredients have been thoroughly evaluated not only regarding health but also regarding the environment! The Safety Factor is very high if no chronic data are given or if data for just one (or two) trophic level are given. In this way the production of more data is encouraged which makes a more precise ranking of the ingredients possible.

**Conclusion**
The Critical Dilution Volume ($CDV_{tox}$) is defined as follows:

\[
CDV_{tox} \text{(ingredient i)} = \frac{(\text{Weight (i) x DF (i) x 1000})}{\text{TF}_{\text{chronic (i)}}}
\]

\[
CDV_{tox} = \sum \text{CDV}_{tox} \text{(ingredient i)}
\]

Weight (i) is the weight of the ingredient (in gram) per functional unit (1 gram organic ingredients). DF (i) is the degradation factor and TF chronic (i) is the toxicity factor of the ingredient (in milligram/litre).

Rubbing/abrasive agents in hand cleaning agents are not included.

The CDV must not exceed the following levels:

Shampoo, shower products and liquid soaps: 20 000 l/g AC

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Solid soaps: 3 500 l/g AC  
Conditioner: 30 000 l/g AC

If the product is a combination of two categories, for example a conditioner + shampoo, the limit is calculated as an average value. In the case of conditioner + shampoo the limit is 25 000.

If the ingredient is on the DID-list the parameter values on this list must be used. If not, the licence applicant must supply test results. If no test results are given the ingredient will be assumed to be “worst case” and assigned a toxicity=0.1 mg/l, SF=10 000 and poor biodegradability. This would give a TF=0.000001 mg/l (=1*10^{-5} mg/l) and a DF of 1. The worst-case CDV would thus be 10 000 000 = 10 million l/g AC. An exception for the worst-case scenario is proposed for plant extracts and other ingredients isolated from plants or animals and with little or no chemical alteration. These ingredients are evaluated in the same way as fragrances, i.e. with TF=0,002 and DF=0,5.

### 11. Environmentally harmful products

Cosmetic products are not subject to the provisions of Directive on Dangerous Substances and the Directive on Dangerous Preparations, but cosmetic ingredients are. This means that if a cosmetic product contains classified ingredients, the R-phrases will not appear on the product, but the Cosmetic Directive regulate which ingredients and the amount of these, that can be used in cosmetics.

The Ecolabelling Directive does not allow labelling of products that are classified as environmentally harmful. Hence it makes sense to exclude cosmetic products that would be classified as environmentally harmful if cosmetic products had been subject to the provisions of the Dangerous Preparations Directive. The aquatic organisms cannot distinguish between an environmentally harmful cosmetic product and an environmentally harmful household detergent.

As mentioned earlier, we want to target those ingredients that are both toxic and have a poor biodegradability or are potentially bioaccumulating. They stay in environmental compartments for a longer time than other toxic ingredients (with high biodegradability). Thus their toxic properties have a higher potential for creating negative environmental impacts. At the same time it is important to use existing regulations when setting requirements, i.e. use definitions and standard tests already in existing regulations. Hence, we require that the products should not exceed the limits for classification as environmentally harmful. However it makes more sense to focus on classifications based on mixed risk phrases: R50/53, R51/53 and R52/53. Risk phrases based on toxicity or degradability alone are not necessary because the CDV and biodegradability parameters will exclude these products anyway.

In the same way as the CDV, the documentation will pose a challenge here. The classification is based on the lowest validated toxicity value.
regardless of species. The DID-list toxicity values may unfortunately not be used because the DID-values are based on the lowest median toxicity. The fact that acute toxicity results are required makes it however easier for the licence applicant because acute test results are more available than chronic test results.

A test for bioaccumulation potential is required for ready biodegradable ingredients with a toxicity ≤ 10 mg/l, otherwise the ingredient will automatically be given the classification R51/53 (toxicity between 1 and 10 mg/l) or R50/53 (toxicity < 1mg/l). The BCF-test is the preferred test for bioaccumulation potential. Results from the simpler octanol-water partition coefficient test (log Kow) may be used if no data from a BCF-test is available. However, the octanol-water partition coefficient test is difficult to measure for surfactants because these are bipolar and will stay in-between the phases.

The requirement level is not very strict. The intention is to exclude the "worst" products and encourage the production of more environmental data.

Rubbing/abrasive agents in hand cleaning agents are not included.

If no results are available the ingredient will be regarded as R 50/53. The following exceptions apply:

Fragrances and dyes: R 51/53.
Biological additives (Plant extracts and other ingredients isolated from plants or animals and with little or no chemical alteration): R 51/53.

Conclusion
The product must not fulfil the requirements for classification for any of the following risk phrases according to The Directive of Dangerous Preparations:

\[ N \text{, R50/53: } (W_{R50/53}/25 \%) \geq 1 \]
\[ N \text{, R51/53: } ((W_{R50/53}/2,5 \%)+(W_{R51/53}/25 \%) \geq 1 \]
\[ R52/53: ((W_{R50/53}/0,25 \%)+W_{R51/53}/2,5 \%)+W_{R52/53}/25 \%)) \geq 1 \]

\[ W_{R50/53} = \text{Weight percent of ingredients that may be classified as R50/53.} \]
\[ W_{R51/53} = \text{Weight percent of ingredients that may be classified as R51/53.} \]
\[ W_{R52/53} = \text{Weight percent of ingredients that may be classified as R52/53.} \]

The risk phrases and the classification limits are defined in the same way as in the Directive of Dangerous Substances (67/548/EEC). Some classified compounds have stricter classification limits than others with the same classification. This must be taken into account when doing the calculations. The details will be presented in the Users Manual.

12. Poorly biodegradable ingredients
Ingredients that are poorly biodegradable stay a longer time in water environments than readily biodegradable ingredients. The longer a compound stays in the environment the more damage it may potentially cause. Many compounds have not been tested and other has only been tested on very few test organisms. Hence there is a definitive risk that cosmetic ingredients are much more toxic than the toxicity tests show. Thus it makes sense to reduce the risks by limiting poorly biodegradable ingredients as much as possible. The CDV will indirectly limit the amount of poorly biodegradable ingredients but only those that are relatively toxic and are used in relatively large amounts.

Non-degraded ingredients end up in aerobic water environments but may also end up in anaerobic compartments such as WWTP sludge (especially where anaerobic digesters are used) or sediments. Thus different criteria are set for aerobic and anaerobic degradability. Such requirements are standard feature of EU Flower household detergent criteria.

12.1 Poorly (aerobically) degradable surfactants

The exclusion of surfactants not readily biodegradable in aerobic conditions is a standard feature of household detergent criteria of both the EU Flower and the Nordic Swan. A similar, but not identical requirement is found in the Detergents Directive. Surfactants must be ultimately biodegradable within 28 days. No pre-adaptation is allowed. According to the expert we have consulted (Torsten Källqvist) this corresponds (with the exception of the 10-day window) to the level of the OECD 301 A-F test series.

The Detergent Directive has a derogations clause from this requirement. However, these derogations are only possible for a few of the surfactants used, and a lot of information and test results must be submitted before a derogation is approved. The number of accepted poorly biodegradable surfactants will therefore be small.

In the same way as the Detergents Directive surfactants are regarded as readily biodegradable if they reach the final degradation level even though the 10-day window criterion is not fulfilled. This is in accordance with the principles behind the DID-list. Hence we avoid the exclusion of some surfactants that are very "broad" in their composition, e.g. non-ionic surfactants with a wide range of carbon chains (e.g. C20-28) and a wide range of ethoxylation (e.g. 2-10 EO).

Apart from the possibility for derogation, the exclusion of aerobically poorly biodegradable surfactants is identical to the exclusion given in the Detergents Directive. It seems reasonable to argue that the aquatic organisms cannot "see" the difference between a surfactant from a cosmetic product and a household detergent. Hence there is no reason why we should allow poorly degradable surfactants in f ex soaps and not in f ex laundry detergents. The reason that surfactants are singled out is that surfactants are the main ingredients used in these products and because of their bipolar nature are usually quite toxic. The term "surfactant" is defined in the Detergents Directive.

Conclusion

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Each surfactant used in the product shall be readily biodegradable, according OECD 301 A-F.

### 12.2 Poorly (aerobically) degradable non-surfactants

Although special emphasis is put on surfactants, it is important to reduce the amount of other poorly biodegradable ingredients as well. Other ingredients may be as toxic as, or more toxic than surfactants. However, due to the restriction on poorly biodegradable surfactants in the Detergents Directive the producers of surfactants have had several years to develop degradable alternatives. This has not been the case for the producers of non-surfactants. Furthermore there are some groups of ingredients that probably are biodegradable but for which no tests have been carried out. Perfumes have been assessed by the AISE in collaboration with representatives from EU Ecolabelling as being Inherently, but not Readily biodegradable. Perfumes come from natural sources or are prepared synthetically. Many perfumes from natural sources are probably biodegradable but they have not been tested. Perfumes are often changed, they are often produced in small volumes, they consist of many compounds and it is not required by law to test them. The same problem exists for "natural" ingredients (e.g. essential oils) used for other purposes. A ban on all ingredients not proven readily biodegradable, as proposed by one Industry Representative, would effectively exclude almost all products with natural fragrances or other natural ingredients.

Hence the Group agreed on a limitation on poorly biodegradable non-surfactants, but not exclusion. The prevalence of these ingredients varies a lot in different product groups. Solid soaps contain little, while conditioners contain much more, poorly biodegradable ingredients. Shampoos and liquid soaps are somewhere in-between. The limits are differentiated so that a certain fraction of the products on the market qualifies. Our estimates show that about half the products on the market qualify.

**Conclusion:**
The sum of ingredients that are not readily biodegradable, according to OECD 301 A-F, may not be present in a quantity exceeding the following limits:

- Shampoos, shower products and liquid soaps: 30 mg/g AC
- Solid soaps: 15 mg/g AC
- Conditioners: 50 mg/g AC

If the product is a combination of two categories, for example a conditioner + shampoo, the limit is calculated as an average value. In the case of conditioner + shampoo the limit is 40 mg/g AC.

**12.3 Anaerobic degradability**

Some ingredients in soaps and shampoos have been shown to degrade poorly in the standard test for anaerobic environments. In some cases elevated concentrations of anaerobically not degradable surfactants have...
been measured in e.g. sediments and wastewater sludge from anaerobic digesters. The presence of soap and shampoo residues in wastewater treatment sludge may then reduce the chances of using it for instance for agricultural purposes. As a consequence restrictions have been set on ingredients both in the Swan and the Flower household detergent criteria and in the Swan soap and shampoo criteria.

In the detergent criteria, the policy has been to exclude all non anaerobic degradable surfactants. In this project, we have proposed only to set a limit on all ingredients that are toxic and non anaerobic degradable.

The issue of anaerobic degradability has been the topic of many discussions in the aHWG. Representatives from the manufacturers of cosmetic ingredients have argued against any restriction on anaerobically poorly degradable ingredients. The arguments can be summarized as follows:

- substances that are readily biodegradable (aerobic) and does not have a tendency to adsorb on particles (or easily desorb) will not enter into anoxic compartments.
- un-degraded ingredients found in anoxic compartments do not cause any environmental problems
- the test method is not good enough to evaluate anaerobic degradability
- it is not justified to exclude non anaerobically degradable surfactants and not other non anaerobically degradable ingredients

The issue of anaerobic degradability has been disputed for years in ecolabelling working groups and as well as in other forums. The reasons for why we think a requirement on anaerobic biodegradability is appropriate are given in a separate Annex.

We introduce a requirement that will limit the amount of toxic and not anaerobically biodegradable ingredients for the following reasons:
- Soaps and shampoos consist almost exclusively of organic compounds.
- Many of the non-surfactants are as toxic (or more toxic) as surfactants.
- We primarily want to target ingredients that are both poorly biodegradable and toxic.
- Many surfactants have not been tested. It would place a high burden on the licence applicant if all surfactants (down to a cut-off level) should have to be tested.
- Although the ultimate goal is to exclude all ingredients not anaerobically degradable it makes more sense to start with the most toxic ones.

Many ingredients have not been tested for anaerobic degradability. The documentation can pose a problem. The documentation policy of the Nordic Swan and the EU Flower has been different. The Swan has in some cases (e.g. for non-surfactants in soaps and shampoos) accepted alternative documentation for anaerobic degradability: Ingredients that are readily degradable (aerobic) and do not absorb easily on particles (or easily desorb) or are not potentially bioaccumulating, are accepted as
anaerobically degradable. The idea behind this lenient approach is that ingredients with such properties will not reach anaerobic compartments or they will not stay there long enough to do damage. In the EU-Flower, this lenient approach has not been accepted due to lack of scientific evidence to support it.

We do not have very accurate figures for the products on the European Market. The requirement level has been set very conservatively to exclude the "worst" products. The limits are differentiated in the same way as the CDV in order to ensure a "balanced strictness level".

The effects of these requirements are:
- Most anaerobically non-degradable surfactants are excluded.
- The limit will allow a small amount of non-degradable surfactants either because they are "non-toxic" or are present in very small amounts.
- The limit encourages the use of surfactants with a low toxicity or anaerobic biodegradability and also reduces the burden of documentation for surfactants used in very small amounts.
- Surfactants and non-surfactants are treated equally.

**Conclusion:**
The content of ingredients that are not anaerobically degradable (or have not been tested for anaerobic degradability) and have a lowest acute toxicity \( \leq 100 \text{ mg/l} \) must not exceed the following levels:

- **Shampoos, shower products and liquid soaps:** \( 25 \text{ mg/g AC} \)
- **Solid soaps:** \( 15 \text{ mg/g AC} \)
- **Conditioners:** \( 50 \text{ mg/g AC} \)

If the product is a combination of two categories, for example a conditioner + shampoo, the limit is calculated as an average value. In the case of conditioner + shampoo the limit is \( 37.5 \text{ mg/g AC} \).

**13. Fragrances**
Fragrances are potentially harmful both to human health and to the environment. They are very different from the other categories of ingredients in that they are volatile and that they are:

- used in almost all soaps and shampoos
- different from product to product
- changed more often than other ingredients
- often complex mixtures of many chemical compounds
- not necessary for the function of the product but important for many consumers
- added to disguise the smell of the other ingredients
- most often not tested for environmental properties
- suspected of causing health problems such as allergies
Additionally there are very many different fragrance mixtures in the products on the market.

A large proportion (4 %) of the population has some kind of perfume allergy. The Group discussed various ways of reducing the incidence of such problems. The aim is not only to reduce the number of new allergy cases, but also to help those who already have problems. Several possibilities were discussed:

- Information on specific problematic substances
- Reduction of exposure to specific problematic substances
- Reduction of general exposure to fragrances
- Encouragement of production of new data

The Group decided to reduce the risk of perfume use by making the IFRA Guidelines obligatory. Now they are only voluntary guidelines. The Guidelines contain advice on how to handle and use fragrances in products. The Guidelines are useful as basic requirements but not adequate to protect the consumers. Further ways of reducing risks connected to perfume use was discussed.

A general reduction of perfume exposure is ensured by the CDV and biodegradability limits. Some people are more vulnerable and need more protection, especially small children and babies.

The general exposure to fragrances may be reduced by limiting the use of perfume in products for small children and babies. Perfumed products are not necessary for babies and small children, in the sense that the children themselves will accept non-perfumed products without protest. It is the parents that prefer perfumed products. We also suspect that parents buy the perfumed product because that is what is available on the market. The perfume content in products marketed for babies is generally lower than in products for older children and adults. The products have a weak smell. There are no data available to support the claim that exposure to fragrances at such an early life stage pose a health risk. However we know that babies and small children are very sensitive, and that perfume allergies increases with the exposure. An ecolabel should not endorse a practice that may cause problems for the children later in life.

We believe that the precautionary principle should be applied. The products used on babies should be as mild as possible. The fragrance is not necessary for the function of the products. Hence we want to limit fragrances in products for small children (< 3 years) and babies. Some of the products on the market for small children and babies contain fragrance, others not. The market in some countries seems to accept non-perfumed products for this age group.

The Group agreed that perfume should be limited in products aimed at adults and children below 3 years, but not in products for adults and older children. Products for persons above 3 years almost always contain perfume. In fact the perfume seems to be an important part of the identity of the product. Products without perfume have been available for a long
time but very few consumers buy these products. A ban on fragrances means that very few products can fulfil the criteria and the ecolabel will be marginalized. The allowed amount of perfume will be restricted by the CDV and biodegradability requirements.

This subject was discussed at length in the Group. Some Members claimed that products without perfume would be unacceptable by the consumers, while others supported the requirement. The scientific justification behind this requirement was challenged. As a compromise, 0.1% perfume was proposed by the ad hoc working group, but the Commission did not accept this requirement.

The Cosmetics Directive has recently been revised and now a number of known allergens (the list of 26 compounds) must be declared if they appear in amounts of 0.01% each. The Group agreed to set an exclusion limit at the same level. In other words: if one of the fragrances on this list is present in so high level that the product must be labelled with this known allergen, the product cannot be ecolabelled.

The list has been extensively discussed both in the ecolabel working group and in connection with the Cosmetic Directive. Some argue that the criteria for a compound to be included on the list are not very transparent. According to the IVDK, the Information Center for a number of German Dermatological clinics, (cited in Ökotest (2004)) the list contains both highly potent allergens (e.g. oak moss) as well as compounds that cause few problems when compared to the exposure levels (Geraniol). According to another source (Peter Malaise, Ecover and EDMA) the list contains substances that cause no problems when appearing in a matrix like e.g. plant extract but can be a potent allergen when isolated.

In spite of these claims, the EU Scientific Committee for Cosmetic and Non-Food products have chosen to treat all the 26 compounds in the same way and require declaration on the label if appearing in amounts > 0.01% of the product. It was therefore proposed to limit all the 26 compounds. Through our contacts with manufacturers we know that many producers have already removed these 26 substances from their products or are in the process of doing so. Perfume manufacturers are also in the developing other fragrances for the use in cosmetics.

In order to further reduce the incidence of fragrance-induced allergies the Group decided to exclude fragrance substances with the risk phrase R42 and R43. This is done as a precautionary measure to decrease the incidence of fragrance allergies.

However, Ecolabelling Norway was instructed by the Commission to delete all requirements on perfume that are stricter that the Cosmetic Directive. All products on the EU market shall fulfil the Cosmetic Directive, and this is a guarantee that the products are "safe under normal application". DG Enterprise claims that stricter Ecolabel criteria may imply that not ecolabelled products are not "safe". Ecolabelling Norway regrets this decision in the Commission, and believes that stricter health criteria should be a part of ecolabelling.
The market is already adapting to the new regulation. The Nordic Swan has heard from several manufacturers that they have a policy of not including the 26 compounds or chemicals classified as R43.

**Conclusion**
Any ingredients added to the product as a fragrance must have been manufactured and/or handled in accordance with the code of practice of the International Fragrance Association.

### 14. Dyes or colouring agents

Dyes/colouring agents (from now only called dyes) are often poorly documented as regards environmental properties. Many of them are very toxic but because they are added in very small amounts they are not restricted by any of the other requirements. Therefore the environmental impacts of dyes are small but can be further reduced by excluding the highly toxic, potentially bio-accumulating and at the same time poorly biodegradable dyes. Hence the Group agreed to exclude dyes that may bioaccumulate. Colour is however important for the consumer and could also be important as a help for the consumer to apply the correct dosage. In order to give the producer a reasonable variety of colours to choose from, all dyes approved for use in foodstuffs are accepted. These have been scrutinized closely by the authorities before being accepted.

The requirement level is strict but allows a wide range of colours to be used.

**Conclusion**

a) Any dyes or colouring agents used in the product must be permitted by Council Directive 76/768/EEC relating to cosmetic products 6 and its subsequent amendments.

b) Organic colouring agents must not be potentially bioaccumulating. In the case of colouring agents approved for use in foodstuffs it is not necessary to submit documentation on bioaccumulation.

### 15. Preservatives

Preservatives are added to inhibit micro-organisms and maintain the colour and appearance of the products. They are often very toxic and poorly biodegradable. They are added in so small amounts that they are not affected by the general requirements (CDV, environmental risk phrases, and limits on poorly biodegradable compounds). Environmentally very harmful compounds may cause damage even though they are only used in very small amounts. The combination of high toxicity, poor degradability and bioaccumulation gives a high risk for environmental damage.
Hence the Group agreed to exclude compounds classified with the risk phrases R50-53 or R51-53 and at the same time potentially bioaccumulating.

The Group wanted to make a distinction between disinfecting products and ordinary cleaning products. Ordinary consumers have no need for disinfecting products. In order to halt the tendency to use cleaning products with anti-microbial action as a sale argument, the Groups decided to exclude disinfecting products from the product group.

In the Cosmetics Directive, formaldehyde is accepted as preservative even though it is classified as cancerogenous (Carc3, R40). Our requirements exclude the use of formaldehyde in ecolabelled products. However some preservatives release formaldehyde upon degradation. Sometimes the amount of formaldehyde released is above the classification limits for formaldehyde. The Group agreed to propose a restriction on formaldehyde releasers in order to cover this "loophole".

Examples of formaldehyde releasers:
- 2-bromo-2-nitropropane-1,3-diol
- 5-bromo-5-nitro-1,3-dioxane
- Diazolidinyl urea
- DMDM Hydantoin
- Imidazolidinyl urea
- Sodium hydroxy methyl glycinate

Common preservatives such as phenoxyethanol, methylparaben, ethylparaben and sodium benzoate do not release formaldehyde, and are among the acceptable alternatives.

**Conclusion:**

a) The product may only include biocides in order to preserve the product, and in the appropriate dosage for this purpose alone. This does not refer to surfactants, which may also have biocidal properties.

b) Biocides, either as part of the formulation or as part of any preparation included in the formulation, that are used to preserve the product and that are classified with R50-53 or R51-53 risk phrases, in accordance with Directive 67/548/EEC 4 and its amendments or Directive 1999/45/EC, are permitted but only if they are not potentially bioaccumulating. In this context, a biocide is considered to be potentially bioaccumulating if the experimentally determined BCF > 100 or if no BCF-results are available the log Pow (log octanol/water partition coefficient) > 3.0. ).


c) Preservatives must not release substances that are classified in accordance with the requirements on hazardous ingredients and endocrine disrupters.
16. Hazardous ingredients

16.1. CMR-classified ingredients

The Cosmetics Directive prohibits the use of compounds that are classified as carcinogenic, mutagenic or toxic to reproduction in class 1 or 2. The Scientific Committee, SCCNFP must evaluate compounds in class 3. The proposed requirement is stricter than the Cosmetics Directive and gives consumers an increased "margin of safety".

The working group also proposed to exclude substances classified as sensitizing with R42 and R43, including the rules for self-classification. Again the Commission deleted this requirement with references to the safety of products complying to the Cosmetic Directive.

**Conclusion:**
No constituent substance must be classified as carcinogenic (Carc), mutagenic (Mut) or toxic to reproduction (Rep) including rules for self-classification.

Specific requirements are prescribed for biocides, either as part of the formulation or as part of any preparation included in the formulation (see criterion on biocides).

16.2. Endocrine disrupters

Some compounds are so similar to hormones that they "mimic" them. They can bind to hormone receptors and cause unwanted effects. Both animals and human beings can be affected. The effect is called endocrine disruption (ED). More effects have been reported on animals and other organisms than on human beings. The Commission has worked out, and partly implemented a Community Strategy for Endocrine Disrupters. One part of the Strategy is research, another to develop a series of test methods for some environmental and human effects. A third part is the establishment of a priority list of ED compounds.

The latest status concerning the priority list came October 28, 2004 in the form of a Commission Staff Working Document (Commission 2004). A candidate list of 553 substances has been divided into several sub-categories, depending on usage levels, evidence of ED and whether it is already regulated by other regulations. Evidence of ED or potential ED was found for 118 substances. Of these 118, 109 were already regulated under existing Community legislation. It has been decided to investigate the other 9 substances in depth.
Very few chemicals investigated for endocrine disruption are used in soaps and shampoos. Some ingredients are worth mentioning:

**Parabenes:** Some parabenes have shown to have a weak oestrogenic effect but the effect is too small to warrant a limitation or exclusion.

**Polycyclic musks:** These compounds are part of some synthetic perfumes. HHCB and AHTN are suspected of causing ED. The Group agreed to exclude polycyclic musks for this and other reasons.

**Benzophenones:** Some benzophenones are suspected of ED but the effect is too small to warrant a limitation or exclusion.

**Alkylphenol ethoxylates** have shown to cause ED effects. These compounds are already excluded in another requirement.

By far the largest group of ingredients with ED effects are phthalates. Some are excluded for use in cosmetics because of ED effects or other disturbance of reproductive function. Hence there is no need to exclude Di-n-oktyl phthalate (DOP), Dibutyl phthalate (DBP), Diethylhexyl phthalate (DEHP), Butyl benzyl phthalate (BBP) or Bis-(2-etoxyethyl) phthalate. Dicyclohexyl phthalate (DCHP) and Diethyl phthalate (DEP) are included in the list of 118.

According to our knowledge, out of the 118 ingredients the only substance found to some extent in rinse-off cosmetics formulations is Diethyl phthalate (DEP). The presence of phthalates and musk compounds in cosmetic products has recently bee studied by TNO (TNO 2004) in the Netherlands. The same study reports finding phthalates in 49 out of 55 cosmetic products. 15 out of 19 studied shampoos contained phthalates with diethyl phthalate (DEP) as the most common. The function of phthalates in the products is not known, but it is assumed that they are added in the perfume mix. Another Dutch report (Milieudefensie 2005) contain references to scientific studies which links phthalates to a number of negative health effects: Endocrine disruption, asthma, liver cancer and DNA damage.

The requirement on CDV and environmental risk phrases limits the toxic effect of the products but not all toxic effects are "covered". Lethality and non-lethal effects such as immobilisation are measured in the OECD standard acute toxicity tests but some effects like hormone disruption is not 100 % covered. Effects of hormone disruption on the reproductive system is covered by other regulations, but the effects on other hormone systems, such as the thyroid gland, are not covered.

The Group wanted to ban endocrine disrupters and thereby to eliminate a potential problem and raise awareness of the issue. Ecolabelling Norway supported this view. However the Commission opposed this. The endocrine disruption is not an end-point, and should be regarded as covered by reproductive toxicity in the current legislation. In the future, as standard test methods are being developed and ratified, we hope a requirement based on test results will be accepted. However, the tests
should cover all the relevant end-points. For the time being, the Commission do not allow references to endocrine disruption in connection with voluntary schemes like the Flower. Ecolablling Norway regrets this intervention by the Commission, as endocrine disruption has become an important issue for consumers.

**Conclusion:**
No requirements on endocrine disruptors could be proposed.

### 16.3. Excluded and limited ingredients

Some ingredients are so damaging to the environment that they are explicitly excluded or limited. Most of these are regulated in many criteria documents of the EU Flower and the Nordic Swan.

**Alkyl phenol ethoxylates and other alkyl phenol derivatives** are poorly degradable and endocrine disrupting and are as such excluded by other requirements. However they are included because we want to put special emphasis on them.

**NTA and EDTA** are poorly degradable and are suspected of remobilizing heavy metals in e.g. riverbeds. NTA is in addition a suspected carcinogen and is in Denmark restricted by voluntary agreements between unions and manufacturers.

**Boric acid** (CAS No. 10043-35-3) is on the Danish Environmental Agency’s list of unwanted substances because of its toxicity to the reproductive system. Borates and perborates are easily converted to boric acid in the environment.

**Phosphonates** contain phosphorus and contribute to eutrophication, but the most important reason for limiting them is that they are poorly biodegradable. Phosphonates degrade more easily when influenced by light (photodegradable). However, claims have been made that there are some phosphonates which are readily biodegradable in aquatic environment. Ecolabelling Norway has consulted experts but has not been able to find support for this claim. However it should not be ruled out that such phosphonates will be developed. The use of biodegradable alternatives should be encouraged by ecolabelling. Nevertheless we allow phosphonates in a small amount because they are photodegradable and the complexes they form with metals are insoluble which ensures that heavy metals are not remobilized.

**Nitromusks and polycyclic musks**

Nitromusks and polycyclic musks are groups of chemicals found in perfumes. They are cheap synthetic alternatives to natural musk compounds. Polycyclic musks are used in higher quantities than Nitromusks.

The environmental and health properties of these compounds have been extensively studied for many years.

**Polycyclic musks**

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The Polycyclic musk compounds AHTN and HHCB are high volume chemicals used in a wide range of products. They are high acute aquatic toxicity (<1 mg/l) and they are poorly biodegradable and highly bioaccumulating. Hence they should be limited or banned in ecolabelled products.

Polycyclic musks have been (in 2003) found in a number of samples from wastewater treatment sludge in Norway. AHTN and HHCB were found in high concentrations. Polycyclic musks have also been found in some samples of fox and mussels.

Nitromusks
Musk xylene (MX), musk ketone (MK) and musk moskene (MM) are the most common Nitromusks. They are highly bioaccumulating and persistent. Musk Ketone and Musk Xylene have been proposed for classification as very toxic for aquatic organisms.

Nitromusks have been found in environmental samples from water recipients, sludges, sediments, fish and mussels. The highest levels have been reported in rivers and river sediments.

Regulation
Musk Ambrette, Musk Tibetine and Moskene are, according to the Cosmetics Directive, not allowed to use in perfume products. Musk Ketone and Musk Xylene are allowed in limited quantities.

Other government initiatives
All Nitromusks are on the Norwegian priority list of substances they want to phase out. The target is that the consumption of these substances shall be drastically reduced by 2010. The Nitromusks are also on the Norwegian Governments "Observance List" of compounds that the authorities would like to reduce the usage of, but for which there are no regulatory restrictions.

Voluntary initiatives
Several companies have phased out the use of Nitromusks and Polycyclic Musks in their products. P&G has almost entirely phased out Musk Xylene and several other Nitromusks from its product fragrances and perfumes.

Discussion
The majority of the Group agreed on the proposed exclusion of all Nitromusks and Polycyclic musks. However one Group Member expressed that all compounds in these groups should be evaluated separately and that more emphasis should be put on the available Risk Assessments than the compounds Inherent Properties. This argument was brought up in the discussions of all the other environmentally related requirements. The Group decided that it would be more in line with the current legislation on chemicals and other ecolabelling criteria for this and related product groups to base the requirements on inherent properties rather than risk assessments.
The Group accepted the exclusion of all Nitromusks and Polycyclic musks based on the environmental properties of these compounds.

**Conclusion**

a) The following ingredients shall not be included in the product, either as part of the formulation or as part of any preparation included in the formulation:
- Alkyl phenol ethoxylates (APEOs) and other alkyl phenol derivatives
- NTA (nitrilo-tri-acetate)
- Ethylenediaminetetraacetate (EDTA) and its salts
- Boric acid, borates and perborates
- Nitromusks and Polycyclic musks

b) Phosphonates
Not readily biodegradable phosphonates may be added but only in a maximum content of 0.6 mg/g AC.

**17. Biological additives**

We have defined biological additives as ingredients that have been extracted from plants or animals and used in soaps and shampoos with little or no chemical alteration. They are sometimes called "natural" ingredients, as opposed to synthetic ingredients. Essential oils are typical examples. They are used more and more in soaps and shampoos. These ingredients are specifically addressed because test results on environmental properties are scarce: toxicity, biodegradability and bioaccumulation potential. Manufacturers, organizations and consumers seem to assume that since these ingredients are natural extracts they cannot be harmful to the environment or health. There is no scientific basis for this assumption. Though these compounds exist in nature they are, when used as ingredients in soaps and shampoos, taken out of their context.

The Ecolabelling Criteria for the Swedish Ecolabel "Good Environmental Choice" accept 0.5% biological additives without further testing. The Nordic Swan have the same requirements to natural additives as to all other ingredients, but they are treated as perfume if no documentation is presented.

The working group discussed the issue at length, and agreed that some natural additives probably are bio-degradable, and are not very toxic. We therefore treat biological not tested additives the same way as perfume.

This implies:
CDV: Toxicity factor = 0.002. Degradation Factor = 0.5.
Environmental risk phrases: R 51/53.
Anaerobic degradation: The ingredient is considered as not anaerobically degradable if no data is given. According to the requirement, if the additives is tested and found to be not very toxic, LC50 > 100, the amount of additive is not counted in the anaerobic degradation requirement.

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18. Packaging

The LCAs show that the environmental impact of packaging is quite large compared to that of the soap or shampoo itself. This is perhaps not so surprising when one considers that shampoos mostly consists of water whereas packaging is solid material. The weight of the active content of a shampoo is only 3-4 times higher than the weight of the packaging. Furthermore the packaging may be re-used or recycled. That possibility does not exist for the content of the product.

The impacts come from (in the case of plastics): the extraction/refining of petroleum, production of plastic raw materials, production of plastic, production of bottles and finally the disposal. Packaging is normally made from non-renewable sources, then used once and incinerated or sent to landfill after use. Parts of the product ingredients come from renewable sources. This is the main reason why packaging scores so high on resource depletion as compared to the product itself. Packaging accounts for twice as much resource depletion as the production of the ingredients. Global warming potential shows the same pattern. Acidification and eutrophication is about three times higher for packaging than for ingredients production. In photo-oxidant formation the impact of packaging is especially high, 35 % of the use phase, far higher than for the other parameters.

The most common packaging materials are polyethylene (PE) and polypropylene (PP) and, to a lesser extent Polystyrene (PS). Some producers prefer transparent packaging that is impermeable to volatile compounds, especially perfume. Glass, PET and PVC are the major materials with such properties. According to PVC industry sources, PVC is used as primary packaging for less that 2% of the products on the European market. Secondary packaging contains plastics but in addition cardboard or corrugated board is very common. Tertiary packaging is plastic shrink-film, (very small amounts per product), and pallets which are often reused several times.

The most obvious way of reducing the environmental impact of packaging is to reduce the amount of material used. From our study of 50 products we have a fairly good idea of the weight of primary packaging used. Commonly the ratio of primary packaging to product is in the vicinity of 0,05-0,1 g packaging pr gram product. The shampoos studied in the Chalmers LCA have 0,9-0,15 g primary packaging pr g shampoo and 0,001 g secondary packaging pr g shampoo. Generally these ratios decrease with increasing product size. Based on these numbers we have a requirement called Weight/Content Ratio (WCR). This is a limit on the weight of packaging pr unit product (see the end of this chapter).

It was difficult to set requirements on the earlier life phases for the same reasons as for the ingredients. The required information is not available, and ecolabelling may not influence the producers. Packaging is not the most important issue for this products group and we did not intend to put more emphasis on the packaging than the actual shampoo or soap. Hence we focused on the use phase and disposal phase.
Leaching of additives from the plastic container to the product is one potential environmental (and health) impact originating from the use phase. Plastic packaging contain not only the polymer itself but also some additives and impurities. These may leach into the product during the period from production to the use of the product. We have no indication that this happens in reality, but the possibility should not be excluded. Cadmium, Lead, Mercury and its compounds are sometimes found in plastics. The same applies to organic tin compounds and halogenated organic compounds. Intentional addition of these additives is proposed excluded. Residual monomers and other impurities are not proposed excluded, as this would require testing and put to much emphasis on a potential problem.

Hence the packaging requirements are focused on the production and disposal phases. Packaging constitutes a large part of the garbage from households and professional users. Hence the disposal of packaging is important. Almost all packaging are used only once.

Clearly we should encourage re-use, but it is as yet not much used, except for I˚n˚I-products (used in dispensers, etc). However the WCR-requirement encourages re-use.

The second best alternative is material re-cycling. The extent of packaging recycling is, according to the EEA, increasing but still very low in Europe.

The third best alternative is to utilize the energy content by incineration. This alternative is increasing fast.

The worse, and unfortunately a very frequently used alternative, is landfill.

Recycling of materials is encouraged by the WCR-requirement and also by the labelling of plastic materials. It was discussed to promote re-cycling of cellulose fibers by requiring that all cardboard packaging consist of at least 80 % recycled material. This requirement was dropped because cardboard is mostly secondary packaging forming a very little part of the products environmental impact, and the fact that it might be difficult in some parts of Europe to get enough recycled material.

Incineration is the preferred alternative for packaging that is neither re-used nor recycled. Preferably, the energy gained is recovered, but ecolabelling cannot influence this. Incineration may cause emission of dangerous compounds, and formation of dioxins have been reported in many incinerators although emissions from incinerators throughout Europe are strictly regulated. It is difficult to see how ecolabelling can contribute to reduction of dioxins and other problematic compounds from incinerators. Hence the criteria contain no requirement directly aimed at reducing emissions from incineration.

Landfill is the worst alternative. The energy content is not recovered, the resources are wasted and valuable land is filled up with virtually non-degradable material. This may lead to toxic additives leaching into ground water. Unfortunately a lot of Europe's household wastes are still sent to
landfill. The working group discussed extensively the possibility to include requirements that would distinguish between the different packaging materials. The Nordic Swan has banned the use of PVC for many short-lived applications and environmental organizations want such a ban.

The WCR-requirement can probably be fulfilled by all packaging materials, except heavy materials, notably glass. PVC is different from the other plastic types employed. It is a material that gives rise to a number of negative environmental impacts in all life stages that has made it into a prime target of environmental organisations.

The PVC Industry has responded to the criticism by doing a number of investigations on the environmental and health impacts and by making improvements, e.g. in the production processes and in the additives used.

PVC is used also in shampoo and soap packaging and the issue has been discussed also in this group. The Ecobilan LCA study looked at one case of a shampoo with PVC packaging and the results are actually in favour of PVC because of the lower energy use in the production compared to other materials.

Although PVC causes problems in the production and pre-production phases these are not so important that we find reason to limit the use of the material. We focus on the impact of the material after use.

Because of the problems caused by PVC and not with other materials Ecolabelling Norway initially suggested to exclude the use of PVC in the packaging, as it has been done in the Nordic Swan criteria for many years.

At the ahwg-meeting, the representative from the PVC industry claimed that PVC should not be regarded as more harmful than other plastics. A memorandum had been sent out to the EUEB in front of the meeting, and Ecolabelling Norway has also received comments from ECVM after the meeting. Ecolabelling Norway has also received representatives from the PVC-industry to a meeting where the industry presented their view.

The industry refers to a study on LCA-studies that has been carried out by PE Europe and published by the Commission (“Life Cycle Assessment of PVC and of Principle Competing Materials” April 2004). The study is assessing existing and previously published LCA-studies on PVC. One of the key messages is that LCA comparisons should be undertaken at application level rather that material level, and that PVC should therefore not be judged by the material on its own, but only in the context of specific applications. Ecolabelling Norway believes that this is exactly what has been done. We have looked at PVC as packaging of short-lived consumer products that ends up in the household waste. There are strong initiatives in the EU to prevent landfill, hence the waste should be incinerated, and in the further evaluation of PVC in soap and shampoo-bottles, we will concentrate on the environmental impacts from incineration of municipal waste.
The industry informed us of several possibilities of recycling. Unsorted plastic waste can be used for some purposes like sound isolation along the roads etc. However, the presence of PVC cause problems for the recycling of other plastics and the potential for the use of sorted plastic is bigger that for unsorted fractions. So-called “feedstock” recycling, where mixed plastics can be broken down to synthesis gases is a possibility. HCl is then formed from the PVC. ECVM refers to a Danish recycling plant that is about to be set up at the end of 2004. Ecolabelling Norway has no information about feedstock recycling being performed in other places in the EU, and no indication that this is becoming a widespread process in the near future. Except for in a few countries, the household waste separation is not common in the 25 Member States of the EU, and recycling of soap and shampoo-bottles is assumed not to be taking place to a great extent. We conclude that only a small fraction of the PVC packaging used for consumer products will be recycled in the near future.

By incineration, the formation of dioxin is most likely related to the temperature and the oxygen concentrations in the incinerator. The above-mentioned study indicates that with the current level of chlorine in the waste, and about 2% PVC, the PVC do not increase the dioxin formation significantly. However, there are no indications of the results if the proportion of PVC increases. Another problem is the generation of waste from incineration of PVC. Some incinerators use a cleaning technology for removing HCl and other similar gases from the smoke that produces a lot of waste materials. On an European average the 0,3 kg waste generated pr 1 kg PVC in the incinerated garbage. Ecolabelling Norway has therefore regarded it as important not to encourage an increase in the amount of PVC by encouraging the use in short-lived products like soap and shampoo-bottles.

Ecolabelling Norway agrees that the production plants for PVC in Western Europe have improved significantly regarding emissions and the treatment of hazardous by-products during the last years. We would also like to receive information on the production sites in the new Member States at this point. A lot of the packaging ends up in landfills. Plastic materials will degrade very little. Plastics contain different additives, e.g. UV stabilizers and pigments. These additives are smaller molecules than the polymers and hence may migrate and create a toxic impact in the run-off from waste dumps. Additives based on Cadmium, Mercury and compounds with these elements have been used as stabilizers in plastics. The same applies to organic tin compounds and halogenated organic compounds. These compounds have high potential for negative environmental and health impacts if leached into the environment. Alternatives exist. Hence we exclude these additives.

When we look at the influence on packaging material on the environmental impact in the disposal phase PVC stands out from the other materials.
PVC:
- Cause problems for material recycling
- Causes high levels of waste when incinerated and
- May leach problematic additives when landfill
- Very little is known about the degradation products from the PVC polymer itself.

However the presence of PVC as packaging in this product group is so small and the negative effects of PVC are very difficult to quantify. Hence the criteria contain no restrictions on PVC as packaging material at the present time.

Finally there is one way in which the packaging can reduce the products overall environmental impact, namely by designing the product so that it is easy for the consumer to easily get the desired amount of product out of the bottle. This can be done by adjusting the diameter of the opening of the bottle.

**Conclusion**

a) The Weight/Content Relationship (WCR) must be $< 0.30$ g packaging/g product.

\[
VCR = \sum \left( \frac{(W_i + N_i)}{(D_i \times r)} \right)
\]

- $W_i =$ The weight (grams) of packaging-component $i$ (primary-, secondary- or tertiary packaging) inclusive label.
- $N_i =$ Weight (grams) of not-recycled material of packaging-component (primary-, secondary- or tertiary packaging). If the packaging component does not contain recycled material then $N_i = V_i$.
- $D_i =$ gram product the packaging-component contains.
- $r =$ Return number, i.e. the number of times packaging-component $i$ is used for the same purpose through a system of return or refill ($r=1$ if no reuse occurs).
- If the packaging is reused $t$ is set to 20 for plastics and 10 for corrugated board unless the applicant can document a higher number.

b) Labelling of packaging
To allow for identification of different parts of the packaging for recycling, plastic parts in the primary packaging must be marked in accordance with DIN 6120, Part 2 or the equivalent.
Caps and pumps are not included in this requirement.

c) Dosage
The packaging must be designed to make correct dosage easy, f.ex. by ensuring that the opening at the top is not too wide.

d) The packaging must contain neither additives based on Cadmium, Mercury or compounds with these elements, nor additives that do not fulfil the criterion 8a.
19. Product fitness for use

The quality of ecolabelled products should not be less than non-labelled products. It is important for the reputation of the ecolabel. It is also important that producers are not tempted to "dilute" their products with "inert" organic ingredients (e.g. propylene glycol) in order to fulfil the criteria. Furthermore we wish to promote efficient products in order to reduce overall consumption.

The products perform many functions. Initially the Group decided to concentrate on two main areas: mildness and cleaning efficiency for shampoos, and the effect on the improvement of the condition of the hair for the conditioners. Some Members wanted only to have a mildness test, considering this to be the most important quality aspect. They also argued that the efficiency test would be very expensive, about 3000-4000 Euro.

Later in the project it was decided to replace the mildness and cleaning efficiency test with a fitness for use test where the quality parameters are given by the function of the product. For example for products defined as especially mild, mildness is an important parameter, alongside cleaning efficiency. Furthermore it was decided to allow both laboratory tests and consumer tests to demonstrate fitness for use.

19.1 Mildness

A wide variety of soaps and shampoos on the marked are claimed to be suitable for the use on sensitive skin due to their mildness. Some products even use "Documented Mildness" as a label.

Soaps and bath oils with a high fat-content are considered as being mild to the skin on the assumption that they leave a film of "protective" oil on the surface. Furthermore, soaps with low pH have been claimed as mild in comparison with alkaline soaps. There are mainly products for children and products for intimate hygiene or sensitive skin that claims mildness to the skin.

Today there are no regulations concerning test methods, maximum or minimum levels and so on for establishing mildness of cleansing products. In the Cosmetic Directive article 6, 3 the following is given: "Member States shall take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have". Given that there are no standard methods, this is a difficult requirement for the authorities to control.

The Colipa Steering Committee on Alternatives to Animal Testing (SCAAT) has prepared the guidelines Cosmetic Product Test Guidelines for the Assessment of Human Skin Compatibility. Their main purpose is to show how the safety of finished products can be assessed whilst avoiding new product testing making use of animals. In these guidelines there are given 6 examples of types of testing on human skin, including both visually
assessing (for example redness, scaling) and objective measurements (for example trans-epidermal water loss and redness intensity).

ACO Hud AB have performed two different studies to investigate the possible differences in the irritation potential of different products which claims mildness to the skin (Aco Hud 2003). The first study investigated eight different soaps for intimate hygiene and the second study investigated eight different shower and bath oils (Aco Hud 2004). Detection of the potentially irritant residues was done by occlusion of the treated and rinsed skin area, followed by evaluation of the biological response based on both visual scoring as well as instrumental assessment measuring trans-epidermal water loss and skin blood flow. The study was double blind and randomised on 15 healthy volunteers (23-57 years), and performed with distilled water as negative control and 1% aqueous solution of sodium lauryl sulphate as positive reference. The results from the studies shows that cleansing products marketed as being mild to the skin or to be used in the intimate region show big differences in irritation potential. The same result is valid for bath and shower oils as well, although the majority of the oils were mild to the skin. However, instead of protecting the skin by depositing an oily layer, some oils may also leave irritating substances on the surface.

The Asthma and Allergy Association in Norway recommend special products to consumers with asthma and allergy. Soaps and shampoos from two different producers are recommended. The recommendation is based on an evaluation by medical experts in the Council of physicians. Finn Levy, a leading allergy specialist in Norway has informed us that the recommendation is based on the inherent properties for the different ingredients regarding irritation and allergy potential, and feedback from the consumers. In addition the products must be perfume free. According to the specialist it is very difficult to measure "mildness". The different methods used today, are not well documented and have raised the question "what is mildness"?

Hence we see that it is not easy to define "mildness", let alone find one test method that described this. However many consumers wants to be guided towards finding mild products.

**Conclusion**

It is important that ecolabelled products should not adversely affect consumer's health. The Cosmetics Directive gives some degree of protection. The ecolabelling requirements on health related issues give an additional protection. A requirement on testing of the products impact on human health can further reduce the likelihood for adverse effects. The potential gain from such a requirement must be weighed against the extra time and resources incurred on licence applicants.

From consultations with experts and extensive discussion in the Group it was decided not to include any specific requirement on product mildness. The health related requirements adequately ensure consumer protection.
19.2 Efficiency

Experts within manufacturing companies and test institutes inform us that no standard test for efficiency exists. COLIPA has developed guidelines for testing of efficiency but no branch standards exist.

There seems to be many tests and few of them have been published. Those who have developed the tests are generally not willing to give them away for free. It is not within the scope of this project to finance development of tests.

Some producers claim that cleaning efficiency is not a big topic. It is not difficult to formulate a product that clean well or gives a good hair conditioning. Hence, it was decided to remove the requirement on product efficiency and instead include a general requirement on product fitness for use.

The fitness for use must be demonstrated through a laboratory or consumer test. By fitness for use we mean the most important quality parameters. E.g. if the product is marketed as a shampoo for coloured hair, the shampoos must be shown to clean the hair and preserve the hair colour. Another example: If a soap is marketed towards sensitive skin it must be shown to be mild in addition to clean efficiently.

The requirement is only meaningful if a comparison is made. Quality is a relative concept and does not mean anything in itself. Hence we require that the product be compared to one of the four market-leading products.

Conclusion
The product fitness for use must be demonstrated through a consumer test or laboratory test. The fitness for use signifies the most important quality parameters. The product must be compared to one of the four market-leading products for the same area of usage.

20. Information for the consumer

Ecolabelling is an important tool helping the consumers to reduce the environmental impact of soaps and shampoos. The consumers should be informed about the reasons for ecolabelling of soaps and shampoos. One effective way of communication is to require a text on the label of the products. This is usually done by the text appearing in Box 2, i.e. next to the actual Flower symbol.

The Group rejected proposals pertaining to increased health safety and reduced use of hazardous substances.

The following information shall appear on the ecolabel:

* Reduced impact on aquatic life
* Fulfils strict requirements regarding the environment
* Reduced packaging waste
The text in Box 2 must be short because of practical considerations.

Furthermore we may influence consumer behaviour by additional information text on the label. The information typically contains advice for the consumer on how to reduce the environmental impact of his/her activities.

One possible text could be:
‘Proper dosage saves costs and minimizes environmental impacts’.

This text addresses the fact that few people are aware of the fact that consumer products have an environmental impact. Many consumers have an idea that the fact that a product is marketed as safe for their health it must also be safe for the environment. The problem with this text is that there is no dosage indicated on the products. Hence the consumer is left with the message to minimize product use.

Another possible text is:
‘The use of less water at lower temperatures when using the product gives a very significant environmental benefit’

This text has the potential of reducing the environmental impact of the use phase. According to the LCAs the associated emissions of the use phase gives the largest environmental impact. The Group did not support the inclusion of such advice to the consumer. The first reason is that such a text probably is too big for product labels, which often are small, and already contains a lot of information. The problem is made worse in the cases where a product is sold with the same label in several countries because then the text will have to appear in several languages. The second reason is that the amount of water used and water temperature selected often has more to do with bodily comfort than the actually need to apply and rinse off the product. The third reason is that such a text seems moralizing and might provoke consumers.

Conclusion:
The following text must appear in Box 2 of the ecolabel:

* Reduced impact on aquatic life
* Fulfils strict requirements regarding the environment
* Reduced packaging waste

21. Environmental impact assessment and the selectivity of the proposed requirements

21.1. Environmental impact assessment

Ecolabelling Norway has made an assessment of the quantitative impact of ecolabelling of soaps, shampoos, shower products and other products included in the proposed definition of the products group.
The assessment has been made on the basis of the three main quantitative parameters in the ecolabelling criteria: Critical Dilution Volume (CDV), aerobic non biodegradable organic ingredients (aNBDO) and anaerobic non biodegradable organic ingredients (anNBDO).

The calculation was based on a number of assumptions:

1. The market average of products is identical to the average of products we have investigated. We have also studied the effect of assuming that the average of the product formulations received from UEAPME and APAT represents the market average.
2. The distribution of market volume is: 77% shampoos, liquid soaps, shower products, 8% solid soaps and 15% conditioners.
3. The products that are assumed to be ecolabelled are average in composition and will change their products so that the parameter values will lie exactly on the threshold values proposed by Ecolabelling Norway.

In order to illustrate the reduced environmental impacts we have compared the water volume of decreased CDV impact with the volume of Lake Constance, Central Europe's 3rd largest lake. It has a water volume of approx. 47 cubic kilometres.

The following results (measured as decrease in impact) were obtained:

<table>
<thead>
<tr>
<th>% of the market being labelled</th>
<th>CDV (Cubic kilometres)</th>
<th>CDV (times Lake Constance)</th>
<th>aNBDO(tons)</th>
<th>anNBDO(tons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>21</td>
<td>0,4</td>
<td>160</td>
<td>260</td>
</tr>
<tr>
<td>15</td>
<td>62</td>
<td>1,3</td>
<td>490</td>
<td>770</td>
</tr>
</tbody>
</table>

(#{}) Assuming that the market average equals the average of all the products that Ecolabelling Norway has exact formulation data on.

<table>
<thead>
<tr>
<th>% of the market being labelled</th>
<th>CDV (Cubic kilometres)</th>
<th>CDV (times Lake Constance)</th>
<th>aNBDO(tons)</th>
<th>anNBDO(tons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>127</td>
<td>2,7</td>
<td>700</td>
<td>680</td>
</tr>
<tr>
<td>15</td>
<td>382</td>
<td>6,8</td>
<td>2090</td>
<td>2030</td>
</tr>
</tbody>
</table>

(##) Assuming that the market average equals the average of the products that UEAPME and APAT has sent exact formulation data on.

The impacts depends very much on the threshold values. We have also made calculations based on the threshold values recently proposed by UEAPME. Ecolabelling of 5% of the products on the market yielded an reduced impact of only 4 cubic kilometres CDV (0,1 times Lake Constance), 11 tons anNBDO and no effect of aNBDO. If we assume that

Final report for the development of ecolabelling criteria.
EU-Ecolabel for Shampoo and Soaps
Ecolabelling Norway
3. May 2006
the UEAPME/APAT products represent the market average the reduced impact is higher: CDV reduced by 40 cubic kilometres (0.9 times Lake Constance), aNBDO 36 tons and anNBDO 300 tons.

**These calculations show that ecolabelling can lead to a large reduction in potential environmental impact across Europe.**

As expected the calculations show that the stringent criteria proposed by Ecolabelling Norway give a much higher reduction of potential environmental impact than the much less stringent criteria proposed by UEAPME. The precondition is, of course, that 5% of the products on the market will be ecolabelled.

**21.2. The selectivity**

The requirements are aimed at reducing the main impacts of soaps and shampoos that may be influenced by ecolabelling. The requirement should be strict enough in order to achieve an environmental benefit. At the same time the requirements must not be so strict that it is too difficult for the producers to fulfil the requirements. As a general rule ecolabelling criteria requirements are set so that 30% of products on the market can fulfil them without changing the products.

The European market contains thousands of different products. Ecolabelling Norway does not have access to the sales figures and formulation of every product on the market. Hence it is impossible to be sure of exactly the market share of products that fulfil the proposed criteria. However we have the formulations of a number of products on the European products from a variety of manufacturers. Based on communication with a number of manufacturers we know that the formulation of products is not very different from North, Central and South Europe. The requirement levels are set on the basis of this knowledge and the experience gained by the Nordic Swan in the 9 years their soap and shampoo criteria have existed.

The requirements have been set so that approximately 30% of the products, in each category, can fulfil the criteria.

**References:**


ACO Hud AB, "Irritation potential of bath and shower oils before and after use: a double blind randomised study", Lodén et al, British Journal of Dermatology 2004. 150: 1142-1147


Appendix 1. The DID-list
Appendix 2. Cetox study of soaps

N; R50/53: Coco fatty acid monoethanolamide (Cocoamide MEA), Triclosan, Imidazolidinyl urea, 2-bromo-2-nitropropane-1,3-diol, 5-bromo-5-nitro-1,3-dioxan and methylchloroisothiazolinon.

N; R51/53: Coco fatty acid diethanolamide (Cocoamide DEA), sorbic acid and Potassium sorbate, butylparaben and butylhydroxytoluene (BHT).

R52/53: Tetrasodium EDTA

R52: Tocopheryl acetate.

N; R50: Alkyl ether sulphates, alkyl sulphates, amidopropyl betaines, alkyl- and alkyl ether sulfosuccinates, lauroamphodiacetates and lauriminodipropionates.

No classification: Fatty acid soaps, alkylisethionates, alkyl polyglycosides, PEG (<10 EO), phenoxyethanol, parabenes (ethyl-, methyl- and propyl-) and sodium benzoate.

Assessed as not anaerobically biodegradable: Triclosan, BHT, Tocopheryl acetate, alkyl- and alkyl ether sulfosuccinates, alkylisethionates.

Assessed as anaerobically biodegradable: Coco fatty acid monoethanolamide, Coco fatty acid diethanolamide, Alkyl ether sulphates, alkyl sulphates, Fatty acid soaps, alkyl polyglycosides, PEG (<10 EO) and sodium benzoate.
Appendix 3. **Background for requirement on anaerobic degradability**

Soaps, shampoos and shower products are cleaning products with surfactants as main ingredients. Even though they are defined as cosmetic products they are more similar to household detergents than to most other cosmetic products.

The household detergents criteria (4 product groups) contain requirements that surfactants must be degradable under both aerobic and anaerobic conditions.

The requirement on anaerobic degradability has been contested by Industry often citing the conclusions of the report by the Fraunhofer Institute: "Anaerobic Biodegradation of Detergent surfactant" that was published in July 2003.

Ecolabelling Norway proposes a requirement restricting the total amount of ingredients that are not anaerobic biodegradable and toxic (lowest acute toxicity < 100 mg/l). This Annex presents our reasons for this requirement.

**Why a requirement on anaerobic degradability?**

Organic compounds can be degraded by micro-organisms both under aerobic (in the presence of oxygen) and anaerobic conditions (without the presence of oxygen). Sediments and wastewater treatment sludge are examples of anaerobic compartments.

Based on the precautionary principle we want to limit the use of ingredients with unknown or un-documented long-term effects in the environment. Hence we want to only include biodegradable ingredients in soaps and shampoos whether they are released into sewers or directly into recipients. If the ingredients are easily degraded they will not give negative long-term effects in the environment or for human health.

**Effects of anaerobic biodegradability**

The Fraunhofer-report contains a summary and analysis of available studies regarding anaerobic degradability of surfactants. Most of the studies concern the widely used surfactant group LAS.

The report concludes that there is little risk for negative effects in the environment of surfactants that are readily degradable (aerobic) even though are not anaerobic degradable. However the report contains a number of results and recommendations that indicate surfactants that are readily degradable (aerobic), but not anaerobic degradable, can be problematic. Some citations are given at the end of this document. Furthermore a recent EU Scientific Committee report has reported serious shortcomings of the Fraunhofer report. Thus it should not be considered authoritative.

By using standardised test methods the PNEC (predicted no effect concentration) for different environments/recipient may be calculated.
The actual concentration (PEC) of the compound can either be measured directly or simulated on the computer. A comparison between the PEC and PNEC can then give an indication whether negative effects in the environment can be expected.

The Fraunhofer report mentions several measurements of PEC near or above PNEC. Table 1 contains some PECs in different recipients together with corresponding PNEC-concentrations.

Table 1: PNEC and PEC (measured concentration) of LAS in different recipients (referred to pages in the Fraunhofer report).

<table>
<thead>
<tr>
<th>Ecosystem</th>
<th>Calculated PNEC (p 161)</th>
<th>PEC=Measured concentration (LAS)</th>
<th>Typical concentrations (LAS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earth</td>
<td>4,6 mg/kg dw</td>
<td>1,0 – 5,0 after 1 – 2 months (page 153)</td>
<td>5 – 15 mg/kg dw(^1) directly after sludge distribution (page 129)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3,1 after 6 months, 0,7 after 12 months (page 131)</td>
<td>&lt;0,5 – 2,4 (p 106)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-100 mg/kg dw(^2) (page 103)</td>
<td>&lt; 0,1 (p 108)</td>
</tr>
<tr>
<td>Sediment</td>
<td>8,1 mg/kg</td>
<td>4,0 – 8,4 (no treatment)</td>
<td>0,2 – 0,1 in Polish rivers (p 99)</td>
</tr>
<tr>
<td>Fresh water</td>
<td>0,270 mg/l</td>
<td>0,24 (inadequate treatment)</td>
<td></td>
</tr>
<tr>
<td>Salty water</td>
<td>0,031 mg/l</td>
<td>0,5 (page 137)</td>
<td>&lt; 0,05 mg/l (p 137)</td>
</tr>
</tbody>
</table>

As we can see from the table the measured values are close to the PNEC and sometimes above the PNEC. Negative effects cannot be excluded because:

- high levels/amounts in recipients where there is no connection to a WWTP
- concentration levels have been found, especially in earth/sediments, where the concentration is higher than PNEC

The report proposes a restriction of the amount of the use of sludge with a high content of surfactants. Alternatively it is recommended that the sludge should be treated aerobically before it is used for agricultural purposes.

Sludge is an important resource. An ecolabel should work towards a reduction of contamination of sludge that lead to a need for reduction of the amount used of the sludge.

The report concludes that no environmental effects of poor anaerobic degradability could be determined. On the other hand the report states that it is generally preferable that chemicals used in high volumes should

\(^1\) dw= dry weight
\(^2\)
be degradable also under anaerobic conditions. The report also discusses whether LAS should be replaced with other surfactants. The main focus is economy. The report concludes that a replacement of LAS with other surfactants would lead to increased costs by about 10-15% (see citation no 2). The main argument against replacing LAS is not that lack of anaerobic degradability is irrelevant.

**Conclusion**

The Fraunhofer report contains results from a number of investigations regarding anaerobic degradability of surfactants. LAS is the most thoroughly investigated surfactant. The investigations show that the actual concentration of LAS measured in the environment in many cases is close to, or above PNEC.

According to the Fraunhofer report it is not documented any lasting environmental effects caused by release of surfactants not anaerobic degradable. Based on the precautionary principle it is nevertheless considered relevant to limit the amount of high-volume chemicals that are not anaerobic degradable. This is also mentioned in the Fraunhofer report.

We have no reason to believe that non-surfactants that are not anaerobic degradable are any worse or better than not anaerobic degradable surfactants.

Surfactants are just one of the group of ingredients in soaps and shampoos. A large number of ingredients are found in these products, most of them organic. A large fraction of these compounds are toxic (toxicity < 100 mg/l). Many of these ingredients have not been tested for anaerobic degradability. We believe that it should be our focus to exclude the most toxic ingredients that are not anaerobic degradable. There are surfactants that have low toxicity and these should not be our priority in this case.
Annex. Citations from the Fraunhofer report

Citations from the report that indicates that surfactants with poor anaerobic degradability is or can be a problem:

**Citation 1**
“The PNEC of LAS for soil organisms was determined with 4.6 mg/kg dw. This concentration is exceeded immediately after sludge application and may lead to acute toxic effects, but aerobic biodegradation lead to rapid reduction of the LAS concentration in the soil.” (page 163)

**Citation 2**
(page 204-205) “Anaerobic stabilised sewage sludge, mainly originating from middle and large size WWTP (=waste water treatment plant) often show high concentrations of anaerobic non-degradable surfactants such as LAS.

Prevention of high surfactant load on agricultural soil can be achieved by restriction of sludge application rates. Typical annual application rates used in practice (2 t dw/ha) will not cause adverse long-term effects.

Aerobic treatment is very effective in reduction of surfactant concentrations in sewage sludge. Different treatment techniques are available (composting, sludge mineralisation etc). Such treatment has been already used for general improvement of sludge quality.

Aerobic treatment of sludge is regarded as an option to reduce surfactant concentration in sludge to be used in agriculture. The treatment generates additions expenditure to WWTP. But the costs are less expensive comparing with costs needed for disposal of sludge by incineration.

As benefit, the enhanced acceptance of sludge as fertiliser by farmers can be taken into account due to improvement of sludge quality. Additionally, Aerobically treated sludge is no subject to the above-mentioned restriction of limitation of application rates. “

**Citation 3**
“Although environmental damages caused by lack in anaerobic biodegradability have not been detected so far, it is generally desirable for ecological reasons, that chemicals of large market volumes such as surfactants, which are released into the environment, are also degradable under anaerobic conditions. But the biodegradability is only one issue in terms of the possible impact of surfactants to the environment. There are many other considerations to be taken into account such as weight-effectiveness, performance, stability, processability, cost and availability”. (page 166)

“Since LAS has the best cost/performance ratio among surfactants and the production capacity of LAS is currently very high (1.7 mill tons per year in Western Europe), it may be presumed that a relatively rapid replacement of LAS would mean major cost for the producing industry ...and subsequently for the consumer. A substitution on an equal weight basis by
other surfactants can lead to a 10-15% cost increase for the surfactant system. “(page 178)

“Nevertheless, it may be risky to accept the application of large amounts of surfactants such as LAS to soil, with the hope that the natural biodegradation potential will serve the complete elimination. Biodegradation in the natural environment depends on several factors (temperature, nutrients, pH, oxygen supply, water content etc.), and suboptimal parameters may result in a delay or inhibition of biodegradation.” (page 196)