BACKGROUND REPORT THIRD AHWG-MEETING

EU ECO-LABEL FOR SHAMPOO AND SOAPS

BACKGROUND REPORT

PREPARED FOR THE THIRD AHWG-MEETING FOR THE DEVELOPMENT OF CRITERIA FOR SOAPS AND SHAMPOOS.

TIME: MONDAY 6 JUNE 10.00-17.00.
PLACE: 5 AVENUE DE BEAULIEU, BRUSSELS

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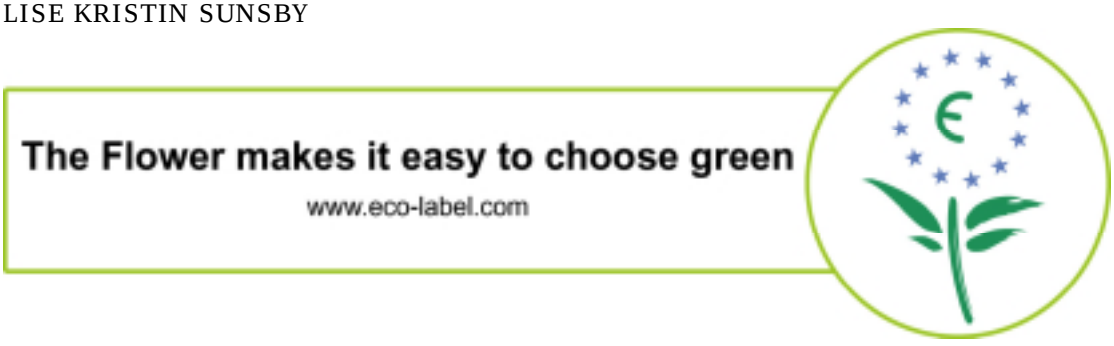

THE EUROPEAN ECO-LABEL- THE FLOWER

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.

More information: http://europa.eu.int/comm/environment/ecolabel/index_en.htm

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1 Background

Ecolabelling Norway is Lead Country for the development of ecolabelling criteria for soaps and shampoos.

Ecolabelling Norway has, based on investigations made by us and others, as well as discussions in the ad-Hoc Working Group meetings of November 8, 2004 and March 16, 2005 proposed a set of ecolabelling requirements. The criteria proposal is given in a separate document.

This document contains:

- a summary of investigations made since the first and second aHWG meeting
- a summary of external studies of environmental and health effects of soaps and shampoos, not mentioned in the background document of the first meeting.
- background for the requirement proposed
- updates on PVC, anaerobic degradation and other disputed topics
- The results of discussions in the ad-Hoc Working Group (aHWG) in its 1st and 2nd meetings.
- Comments and information from manufacturers as well as other interested parties.

This document will be updated and will eventually grow into the Final Report of the project.

The product group now encompasses the following rinse-off products:

- liquid and solid soaps
- shampoos
- conditioners
- shower products
- any combinations of the above mentioned products
- other rinse-off products (solid, liquid or gel) for cleaning human body and hair
- consumer products as well as I´n´I-products

For the sake of simplicity we will later in this document use the simplified term "soaps and shampoos" while referring to all these products.

2 Introduction

Soaps, shampoos, 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 probably in other countries as well. These products also feature prominently in advertising of all sorts, especially TV. The products are used daily by almost all Europeans and they are very closely linked to appearance and hygiene.

Ecolabelling Norway has contacted the manufacturers of these products and the manufacturers of the ingredients. Environmental organisations, consumer organisations, test institutes and government agencies have also been contacted.

Many manufacturers have expressed a wish to be informed about the project. COLIPA, the main manufacturers organisation have organised a committee to follow our work. Very few manufacturers have expressed a negative attitude towards the project, but it has been difficult to get the information or comments on our proposals.

With the exception of a few small- and medium-sized manufacturers we have been met with a neutral and passive attitude. Generally the small- and medium-sized manufacturers have been more positive; some of them expressing interest in obtaining an eco-label on their products. The organisation of small- and medium sized enterprises (UEAPME) have supported and encouraged our work.

Our impression is that companies that produce both cosmetic products and household detergents express more interest in environmental issues. This can be seen by their environmental policy and openness regarding environmental impact. This is only to be expected because these companies have had to take the environmental issues into consideration because of the legislation on household detergents. Companies that are more purely cosmetic product manufacturers communicate very little on environmental issues. The reason for this could be that these companies have been concentrating on fulfilling the requirements of the Cosmetics Directive.

3 Reasons for ecolabelling of soaps and shampoos

Ecolabelling Norway has further studied the evidence or indications on the environmental and health impacts of soaps and shampoos. The possible impacts of cosmetics on human health are discussed at the end of this chapter.

There seems to be a popular belief that because these products are proven as "safe" products, i.e. not harmful to human beings, they must also have little impact on the environment. Household detergents, on the other hand, are more irritant and "harsh" products hence are regarded as harmful to the environment. Ecolabelling Norway has not found scientific evidence to support the notion that household detergents are more harmful to the environment than cosmetic products. On the contrary we have found indications that soaps and shampoos may have a high environmental impact. Some ingredients, such as Zinc Pyrithione (active ingredient in some anti-dandruff shampoos), have a low health impact but a high environmental impact. Additionally, soaps and shampoos contain almost exclusively organic ingredients. Organic ingredients are more prone to bioaccumulate in organisms than inorganic ingredients because of their generally higher lipofilicity (which indicates higher solubility in fats). Ternes et al (2004) also points to the fact that due to the high lipofilicity the ingredients have a high tendency to sorb unto sludge and sediments. Finally the number of ingredients is far higher in soap and

shampoos than in household detergents. More importantly the number of ingredients for which no environmental information (biodegradation, toxicity and bioaccumulation) is available seems to be much higher for soaps and shampoos. Without knowing the data of the ingredients, the manufacturers have less possibility of reducing the environmental impact of the products.

As mentioned in this report and the background report of the first meeting, soaps and shampoos give rise to a number of negative environmental impacts. Some global impacts, like greenhouse gas emissions, are easy to quantify. Other impacts, such as the impact on water quality and biodiversity are more difficult to quantify. It is precisely these local and regional effects that ecolabelling have the highest potential to influence: water quality and biodiversity in rivers, lakes and oceans.

According to the EEA the major environmental problems in European surface waters are microbiological pollution, nitrates pollution, toxins and heavy metals. The problems are unevenly distributed over Europe. For instance microbiological pollution is worse in Eastern Europe while Western Europe suffers from nitrate pollution. Eutrophication is a big problem in large parts of Europe. The situation is generally improving due to better wastewater treatment and increased number of households connected to treatment plants. While we cannot link these problems to soaps and shampoos, it is likely that already polluted water bodies will be vulnerable to further pollution, f ex from soaps and shampoos. It is very difficult (in practise impossible) to assess the impact of soaps and shampoo ingredients on European water bodies, but it is clear that many ingredients are quite toxic. It is not improbable that soaps and shampoo ingredients have a considerable effect on water bodies already weakened by other major pollutants.

The focus in pollution policy across the world has changed from dilution (end of pipe-solutions) to prevention. Hence it makes more sense to reduce the toxic impact of soaps and shampoos rather than just hoping that the ingredients will be degraded and diluted until they cause no significant damage.

The non-degraded remains of soaps and shampoos end up in water recipients, in the sludge in wastewater treatment plant and in sediments. Many of the ingredients used are toxic and have the potential to cause significant toxic effects on different organisms, even though the effects are difficult to quantify. Furthermore it is difficult to determine synergy effects between different ingredients.

The packaging ends up as waste after use
Although increasing amounts of waste is burnt (18 % in Western Europe) or recycled (29 % of the "old" EU) the major part of European waste is still landfilled (57 % in Western Europe). These numbers are from the EEA. We should have this in mind when setting requirements on packaging.

Packaging consists mainly of plastic bottles (primary packaging), cardboard (secondary packaging) and pallets + shrink film (tertiary packaging). Pallets are re-used many times.

Primary packaging largely consists of plastics. The major plastics are polyethylene (PE), Polypropylene (PP) and Polystyrene (PS). Polyethylene terephtalate (PET), glass and Polyvinyl Chloride (PVC) are used to a lesser extent. None of these materials are biologically degradable and hence will last "for ever" if landfilled. It is technically possible to make some plastics biodegradable by adding chemicals. The problem is, according to Industry sources (Borealis) that these materials cannot be recycled and they make recycling of ordinary plastics impossible if mixed together.

Packaging plastics are not only made of polymers. They also contain additives. PE and PP often contain pigments whereas PVC contains UV stabilisers. The additives are smaller molecules than the polymer itself and may migrate. The migration of additives has not been much studied with the exception of plastics for use with foods, e.g. food wrappings.

While recycling is clearly the most sustainable solution for packaging waste, we have to look at the realities today when setting requirements.

The Cosmetics Directive is aimed mostly at protecting consumer's health and, to a lesser extent, it also deals with the ethical question of testing of cosmetics on animals. The Directive specifies an approval procedure for cosmetic products. Products that have been approved through this procedure are labelled as "safe" if used as intended. "Safe" is defined in Article 2 as follows " A cosmetic product put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use,.....". Consumers are additionally protected by other regulations such as the Directive on Dangerous Substances.

No risk analysis can conclude with certainty that there is absolutely no risk concerned with a certain activity or product. It is un-scientific because the number of data is limited. Every possible end-point cannot be studied. The numbers of tests is limited as well as the number of study objects. Scientifically we can only speak of probabilities for damage. We can then define a limit for "safety". The limit will often be defined according to the expected exposure levels as compared to the level at which no damage is found. If the probability for damage is less than the agreed limit the product could be labelled "safe". This distinction is important. When we know that we are discussing probabilities we know that it is possible to further improve the safety of a product. If we believe that a product that is 100 % safe then it is no point in trying to improve the safety of the product!

Every year a number of consumers experience adverse health effects because of use of cosmetic products. Consumer organisations and health workers inform us that a large percentage of these cases are not reported. Some cases are clearly the result of improper use of the products but not all. Based on communication with consumer organisations, media

coverage and contacts with ordinary consumers it is our general impression that consumers want to be even more protected against adverse health effects than the Regulation offers.
The Cosmetics Directive offers protection from adverse health effects but of course it is based on the knowledge we have. New knowledge may show problems with a certain ingredient, f ex high incidence of allergy towards an ingredient. In these cases it is necessary to act fast to stop the damage caused by the use of the ingredient. Based on communication with manufacturers, government agencies, consumer organisations and environmental organisations we conclude that the procedure required to limit or exclude a cosmetic ingredient takes a long time and require a heavy burden of proof.

Hence it seems appropriate and necessary to include health related requirements even though all products are approved according to Community Regulations.

The question of animal welfare is also included in the Cosmetics Directive. This issue and other ethical issues, e.g. the treatment of people working, and indigenous people living, on plantations producing raw materials for the Cosmetics Industry are of high importance and interest for many consumers. Unfortunately the Ecolabelling Directive does not allow requirements on ethical issues to be set in ecolabelling criteria. Thus ethical issues must be handled by other "policy tools".

4 Market

Ecolabelling Norway have contacted a number of manufacturers (small, medium-sized and large) and manufacturers organisations but we have been able to find little more data on the market since the initial study. We would especially like to have data from the new Member States.

The consumption of these products in Western Europe is large. Ecolabelling Norway has calculated a total consumption of approx. 1 million tons in Western Europe. This figure is based on sales figures and on some basic assumptions, f ex the percentage constituted by shampoos and conditioners of the total hair care products market.

The total market of cosmetic products in the 25 EU-countries is 2 million tons based on an average daily consumption of 12 grams and a population of 456 million. Approximately half of this is volume is assumed to be water.

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.

As mentioned earlier in this report, a number of small- and medium-sized manufacturers are interested in obtaining the ecolabel for their products,

especially I´n´I-products or products aimed at children and babies.

However, few manufacturers will take the initiative themselves to get 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.

5 Legislation

The Cosmetics Directive does not take environmental issues into consideration and there are few signs that this will change in the near future. This fact has often been criticised. There are few signs that this situation might change in the near future. The last technical updates of the Directive only concern health aspects. However the ingredients of cosmetics are regulated by the Directives on Hazardous Chemicals (67/548/EEC) and Dangerous Preparations (1999/45/EEC). These regulations does 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 into the Cosmetics Directive. 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 ecolabelling might serve a very useful purpose as a tool for consumers who want to buy products not only "safe" for human health but also for the environment. It could also help manufacturers to reduce the environmental impact of their production.

6 Studies on soap and shampoos

This chapter does not contain all the studies we have on soaps and shampoos. Some studies have not been mentioned because they have already been quoted in the first Background Report (distributed before the

first aHWG-meeting). This report only mentions the studies we have been made aware of since the first meeting.

6.1 Studies by other agencies

Medical Products Agency in Sweden
The Swedish Medical Products Agency has made an official study (Medical Products Agency, 2004) on the environmental effects of cosmetic products and medicines on behalf of the Swedish Government. 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 was 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.

Report for the Swedish drinking water provider Stockholm Vatten
The student Kristina Johansson (Stockholm Vatten, 2002) has made a study of the environmental effects of hair care products on behalf of Stockholm Vatten. She studied 73 products. 21 ingredients were found to be, while another 40 were suspected to be, harmful to the environment. Some ingredients could not be identified and a great number lacked environmental information. 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 sulfosuccinate, 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.

Report commissioned by the Swedish County Jönköping
The study was called "Environmental impact of hygiene products". Risk assessments of selected ingredients was used. The product groups 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 were 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.

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 are 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 the products are rinse-off products and hence the exposure is low. However many people experience adverse health reactions 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
- 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´. F ex 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.

6.2 Studies by Ecolabelling Norway

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

Ecolabelling Norway has made:

- a quantitative study of 71 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

Quantitative studies of 71 products based on exact formulations
Based on the quantitative study we have calculated some parameters to get an impression of the total environmental impact.

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

	CDV		Aerobic not degradable non-surfactants		Anaerobic nor degradable toxic ingredients	
	Average	Range	Average	Range	Aver age	Range
Shampoo and shower products	16100	3600-83000	38	0-460	57	0-410
Solid soap	4400	2000-9300	15	0-47	13	0-39
Conditioner	110000	2300-380000	85	0-310	189	0-530

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 lie mostly in the range 1500 to 30000. Some products have significantly higher CDVs but this commonly due to the presence of ingredients with no documentation of the environmental properties.

A large percentage of the CDV is taken by 3 ingredients: Cocoamidopropyl betaine, lauryl ether sulphate and perfume. Cocoamidopropyl betaine alone accounts for 50-80 % in most of the products where it is used. Lauryl ether sulphate typically accounts for 20-40 % of the CDV. Perfume typically accounts for 5-15 % of the CDV but the figure can be much higher, especially in products without cocoamidopropylbetaine or lauryl ether sulphate. In many products a preservative accounts for a large part of the CDV. One example is 5-bromo-5-nitro-1,3-dioxane. In some cases non-ionic surfactants accounts for a large part of the products total CDV.
In many cases the manufacturer can substitute the surfactants and preservatives and perhaps reduce the amount of perfume. However it is not necessary to leave out SLES, SLS or Cocoamidopropyl betaine, in order to fulfil the requirements.

Some ingredients are not documented. 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

We have used 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 we did not have access to the data.

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

Table 2. Average content of classified ingredients

Product group	R50/53	R51/53	R52/53	R50
All products (mg/g AC)	12	16	10	450

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.

Many products have a very low content of classified compounds. In many cases perfume is the only ingredient that fulfil the criteria for classification as environmentally harmful. Other important contributors to the content of environmentally harmful compounds are Cocoamide DEA (R51/53) and Cocoamide MEA (R50/53). The classifications are made by Madsen and Larsen (1998) and are only tentative.

The Directive on Dangerous Preparations does not cover cosmetic products. It is however interesting to check how many of the studied products would have been classified as harmful to the environment if the Directive on Dangerous Preparations 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 there are other requirements that limits 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.

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

$W_{R50/53}$ = 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. However 5 of these 6 products are conditioners.

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.

- As mentioned earlier 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 9 out of the 71 products contain (13 %) such ingredients. The reason might be that surfactant manufacturers has spent much time and effort to develop biodegradable surfactants because of the impending new detergent legislation. Manufacturers of other ingredients has 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 anaerobically 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. Many are formaldehyde releasers, such as diazolidinyl urea, 5-bromo-5-nitro-1,3-dioxane and sodium hydroxy methyl glycinate.

Methyldibromoglutaronitrile is allowed in 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 content of fragrance in the product is not known to us. The fragrance content vary a lit. 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.

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.

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.

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. 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 SMEs 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, f ex. hand soaps use 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 %.

7 Definition of the product group

The aHWG has agreed that only rinse-of products for human use should be included. 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 %). Soaps, shower products and shampoos have many similarities but conditioners are quite different in composition. However conditioners are often mixed with shampoos in products and the biggest potential environmental benefit seems to be for conditioners.

There exist many "niche" products f. ex. washing gels for the face, hand cleansing gels and peeling product containing abrasives.

The manufacturers we have contacted have not been willing to give us the information we need to evaluate whether these products should be included in the product group. The COLIPA frame formulations indicate that these products contains many of the same ingredients that are found in traditional shampoos, soaps, shower products and conditioners. The fact that we have no exact frame formulations means we cannot make a

quantitative analysis of the products. 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. Bath soaps are similar to the respective solid and liquid soaps. Peeling product and other facial cleaners are, apart from the rubbing agents, not very different from liquid soaps. Hence we propose to include all these "special" cleaning products in the product group and to include them in the same groups as the soaps: Liquid and gel products are evaluated similarly as liquid soaps. Solid products are evaluated similarly as solid soaps.

Some products are for "deep" cleansing and irregular use. These products are often oil based. We propose not to include them in the product group.

Many products on the market are combined products, f ex conditioner and shampoo together. They are included in the product group definition but it must be decided what to do when a product "bridges" the categories with different requirement levels. Our proposal is to use average values. F ex a 2 in 1 product with conditioner and shampoo must have a CDV lower than (16000+20000)/2=18000 l/g AC.

We propose a broad definition covering all products for regular cleaning of human body and hair as well as conditioners.

Proposal
The product group contains liquid, solid and gel-formed cosmetic (see the EU Cosmetics Directive 76/768/EEC with adaptations) rinse-off products used primarily used for cleaning and washing human skin and hair. Liquid and gel-formed rinse-off products for conditioning hair are also included. Combined products are also included.

8 Functional unit

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 . We will not use these standards in the ecolabelling project but they are useful as indicators of use.

Hair conditioner:	Dosage 14 g and use frequency 1-2 times a week.
Shampoo:	Dosage 12 g and use frequency 2-7 times a week.
Shower gel:	Dosage 5 g and use frequency 1-2 times a day.
Soap bar:	Dosage 0,8 g and use frequency 3-6 times a day.

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.

We have received a proposal that the functional dosage should be set equal to these standard dosages. This is a good proposal because it links the environmental effect to the typical dosage actually applied. However

we could risk that products are diluted until the requirements are met. Ideally the functional unit should be linked to a certain task that could be accurately measured. Then a dosage could be accurately defined and specified on the label. According to our knowledge no such test exists.

We propose to set the functional unit to 1 gram of organic ingredients. This solves the problem of diluting the product with water or inorganic ingredients and it is very easy to calculate precisely. Furthermore, no test is required.

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.

Proposal
The quantitative parameters should be based on the weight of organic ingredients. The functional unit is 1 g organic ingredients.
Rubbing/abrasive agents in hand cleaning agents are not included.

9 Proposed requirements

The LCAs, risk analysis and other studies show that soaps and shampoos cause, or have a potential to cause, a variety of negative environmental impacts. Some of these impacts are directly linked to the product e.g. raw material extraction + refining, ingredients manufacture, product manufacture, impact during use and impact after use of the products. Some impacts are indirectly linked, e.g. use of energy for heating washing water in the use phase. Environmental impacts includes 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.

The consumption of these products in Western Europe is large, approx. 1 million tons in Western Europe. The environmental effects are potentially large, but not all environmental effects can be addressed by ecolabelling. Rather ecolabelling is one "environmental policy tool" that should be used alongside others, e.g. regulations, information campaigns, green taxes and voluntary agreements.

Experience from ecolabelling of household detergents, the product groups most similar to soap, have shown that it is difficult to set requirements on the first life phases: Raw material extraction/refining and manufacture of ingredients. Is it difficult to get sufficient information to set the requirements but more problematic: It is very difficult to compare 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 f.ex. land degradation, loss of biodiversity and effects of pesticide use.

Petroleum sourced ingredients cause f.ex. local effects of pollution from oil drilling and refining, oil spill effects, etc.

Experience have 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.

9.1 Requirements on raw materials.

Because of the following difficulties we have decided not to propose any requirements relating the first life phases of the products:

a) Difficulties in getting adequate quantitative information about the production of ingredients and
b) Difficulty in comparing very different environmental impacts

Palm oil is mostly used in food but it is also used 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, as 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. It also makes it much easier for us to set requirements and check compliance with the requirements. Until the Guidelines are in place it is however, difficult to set requirements. Producers of palm oil and other interested parties can become members of the RSPO. We have considered a requirement 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 practise. However, according to the Ecolabelling Directive, it is difficult to require membership in a voluntary organisation.

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

Proposal:
We propose no requirements for the early life stages of soaps and shampoos, i.e. extraction and refining of raw materials and production of ingredients. However the inclusion of such requirements should be considered again in the revision of the criteria.

9.2 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.

Ecolabelling Norway wants to encourage the development of alternatives for animal testing. This also concerns testing of ingredients. We do, however, recognize the manufacturers need and obligation to ensure the safety of their product. A ban of the use of ingredients tested on animals during, let's say the last five years have consequences that are difficult to foresee. European Ecolabelling does not have the competence to accept alternative methods for testing of ingredient safety.

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 should be considered. However animal suffering is a 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.

Proposal
Because of the Ecolabelling Directive we do not propose any requirement on animal testing.

9.3 Critical Dilution Volume (CDV)

What are the worst potential environmental impacts from soaps and shampoos? 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 tests (that measure long-term effects) should be used rather than the acute tests (that measure short-term effects).

The CDV is a parameter that is common in ecolabelling criteria for household detergents. It is also used in the soap and shampoo criteria for the Nordic Swan. It is a measure of the total toxic impact, taking the biodegradability into account, of soaps and shampoos in aquatic environments. 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 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 in the cases where the TF is based on acute toxicity because no chronic data were available. The calculated CDV will be a rather high number and should only be used to compare products.

The CDV is a very good parameter because it 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 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.

There are several possible approaches possible when setting the CDV requirement level. It might seem like a good idea to set the same level for products fulfilling the same function. This would mean that virtually all liquid soaps fail to qualify whereas the solid soaps would easily qualify.

We propose to use different requirement levels for different product categories. This would 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´I-market they dominate completely. Differentiated requirement levels also enables us to "fine-tune" the requirement levels so that it is equally difficult for products in all categories to fulfil the requirement.

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 environment 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 levels are given. In this way the

production of more data is encouraged which makes a more precise ranking of the ingredients possible.

Proposal
The Critical Dilution Volume (CDV_{tox}) is defined as follows:

CDV_{tox} (ingredient i)= (Weight (i) x DF (i) x 1000) / $TF_{chronic}$ (i)

$CDV_{tox} = \Sigma CDV_{tox}$ (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:	16 000 l/g AC
Solid soaps:	3 500 l/g AC
Conditioner:	20 000 l/g AC

If the product is a combination of two categories, f ex a conditioner + shampoo, the limit is calculated as an average value. In the case of conditioner + shampoo the limit is 18 000.

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.

9.4 Environmentally harmful compounds

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). Hence 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.

Cosmetic products ingredients must fulfil the Directive on Dangerous Substances and the Directive on Dangerous Preparations. The products themselves are, however, not subject to the Directive on Dangerous

Preparations. The aquatic organisms cannot distinguish between an environmentally harmful cosmetic product and an environmentally harmful household detergent. Hence we propose to 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 requirement will probably 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 biodegradability 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 use for surfactants because surfactants 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.

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

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

$W_{R50/53}$ = 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.

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.

9.5 Poorly biodegradable ingredients

Ingredients that are poorly biodegradable have the potential to stay a long time in water environments and cause a lot of damage. The requirements mentioned below will reduce the quantity of poorly biodegradable ingredients but only to a certain extent and only in aerobic conditions.

9.5.1 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 but no 10-day window applies. No pre-adaptation is allowed. According to the expert (Torsten Källqvist) we have consulted this corresponds (with the exception of the 10-day window) to the level of the OECD 301 A-F test series. The Directive allow derogations from this requirement. A derogation may be given for a surfactant that is used in low-dispersive applications and in specific industrial and/or institutional applications. Furthermore the risk to the environment or to the health posed by the volume of sales and use pattern must be small compared to the socio-economic benefits, including food safety and hygiene standards. The last condition indicates one probable candidate for derogation
: surfactants used in disinfecting products.
We propose to exclude disinfecting products from the product scope.
Finally it must be mentioned that it is not an easy matter to gain a derogation. Many tests must be performed. Hence it is likely that the number of accepted poorly biodegradable surfactants will be rather small.

In the same way as the Detergents Directive we accept surfactants 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 etoxylation (e.g. 2-10 EO).

Apart from the possibility for derogation, the proposed 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. One problem with this requirement is the definition of surfactants.
The term "surfactant" must be defined. The definition in the Detergents Directive should be used.

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

9.5.2 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. The other ingredients can 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 whom 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 consists 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 we propose a limit on poorly biodegradable non-surfactants, but not an exclusion. The prevalence of these ingredients vary a lot in different product groups. Significantly solid soaps contain little, while conditioners contain much more, poorly biodegradable ingredients. Shampoos and solid soaps are somewhere in-between. The proposed 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.

Proposal:
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:	25 mg/g AC
Solid soaps:	15 mg/g AC
Conditioners:	50 mg/g AC

If the product is a combination of two categories, f ex a conditioner + shampoo, the limit is calculated as an average value. In the case of conditioner + shampoo the limit is 37,5 mg/g AC.

9.5.3 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 sludges from anaerobic digesters. The presence of soap and shampoo residues in wastewater treatment sludges 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.

The policy has been to exclude non anaerobically degradable surfactants and in some cases, but not all, limit non anaerobically degradable non-surfactants. This would mean that we treat surfactants in the same way as other ingredients.

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 other fora. The reasons for why we think requirements on anaerobic biodegradability is appropriate, are given in a separate Annex.

We propose <u>not</u> to exclude surfactants that are not anaerobically degradable. Instead we propose to introduce a requirement that will limit the amount of toxic <u>and</u> not anaerobically biodegradable ingredients. The reasons for this are as follows:

- Soaps and shampoos consist almost exclusively of organic compounds.
- Many of the non-surfactants are as toxic (or more toxic) as surfactants.

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- 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.

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. We find it difficult to support this lenient approach until there is more 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 so as just to exclude the "worst" products. The limits are differentiated in the same way as the CDV in order to ensure a "balanced strictness level".

One effect of the proposed limits is that most anaerobically non-degradable surfactants are excluded. The proposal will allow a small amount of non-degradable surfactants either because they are "non-toxic" or are present in very small amounts. The proposal encourages the use of surfactants with a low toxicity or anaerobic biodegradable and also reduces the burden of documentation for surfactants used in very small amounts.

Another important effect of the proposal is that surfactants and non-surfactants are treated equally.

Proposal:
The content of ingredients that are not anaerobically degradable (or have not been tested for anaerobic degradability) and have a lowest acute toxicity ≤ 100 mg/l must not exceed the following levels:

Shampoos, shower products and liquid soaps:	25 mg/g AC
Solid soaps:	15 mg/g AC
Conditioners:	50 mg/g AC

If the product is a combination of two categories, f ex a conditioner + shampoo, the limit is calculated as an average value. In the case of conditioner + shampoo the limit is 37,5 mg/g AC.

9.6 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.

Of the 118 mentioned compounds, very few 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 to 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. We have proposed to exclude polycyclic musks for this and other reasons.

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

Alkylphenoletoxylates have shown to cause ED effects. We have already proposed to exclude these compounds.

By far the largest group of ingredients with ED effects are phtalates. 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-oktylphtalate (DOP), Dibutylphtalate (DBP), Dietylhexylphtalate (DEHP), Butyl benzyl phtalate (BBP) or Bis-(2-etoxymethyl)phtalate. Dicyclohexylphtalate (DCHP) and Diethylphtalate (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 phtalate (DEP). The presence of phtalates and musk compounds in cosmetic products has recently bee studied by TNO (TNO 2004) in the Netherlands. The same study reports finding phatalates in 49 out of 55 cosmetic products. 15 out of 19 studied shampoos contained phtalates with diethylphtalate (DEP) as the most common. The function of phtalates

in the products is not known to us but it is assumed that they are added in the perfume mix. Another Dutch report (Milieudefensie 2005) contain references to scientific studies which links phatalates 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 not100 % covered. Effects of hormone disruption on the reproductive system is covered by other regulations, but other effects are not covered.

We propose a ban on endocrine disrupters to eliminate a potential problem and raise awareness of the issue. The ban will only effects ingredients that are mentioned in the latest Commission Staff Working Document. In the future, as standard test methods are being developed and ratified, a requirement based on test results would be a better way of handling this problem. However the tests should cover all the relevant end-points!

Proposal:
The product o may not include any ingredient on the EU lPriority list of substances that show evidence of endocrine disruption or potential for endocrine disruption

9.7 Fragrances

Fragrances are very different from the other categories of ingredients.

They:
- are used in almost all soaps and shampoos
- are different from product to product
- are changed more often than other ingredients
- are volatile
- are often complex mixtures of many chemical compounds
- are not necessary for the function of the product but important for many consumers
- hide the smell of the other ingredients
- are most often not tested for environmental properties
- are 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. How can the incidence of such problems be reduced? Not only do we want to reduce the number of new allergy cases, we also want to help those who already have problems. There are several possibilities:

- Information on specific problematic substances

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

One way of reducing the exposure to specific problematic substances is to require that the IFRA Guidelines be followed. These 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. Furthermore they are only mandatory.

One way of reducing the general exposure to fragrances is to limit 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 unperfumed products without protest. It is the parents that prefer perfumed products. We also suspect that they buy the perfumed product because that is what is available on the market. The perfume content seems to be less in such products than in products for older children and adults. The products have a weak smell. We have no data 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. An ecolabel should not endorse a practise that may cause problems for the children later in life?

We believe that the precautionary principle should be applied. The products used on them should be as mild as possible. The fragrance is not necessary for the function of the products. Hence we propose to exclude all 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 seem to accept unperfumed products for this age group.

Perfume should be excluded in products aimed at adults and children below 3 years, but it should not be excluded in product for adults and older children. Products for persons above 3 years almost always contains perfume. In fact the perfume seems to be an important part of the identity of the product. Products without perfume (aimed at people > 3 years) have been available for a long time but very few consumers buy these products. If we ban fragrances the fraction of products that can fulfil the criteria will be very low. We risk to marginalise the ecolabel. Hence we do not propose to exclude fragrances from ecolabelled products. The allowed amount of perfume will anyway be low because of the restrictions affected by the CDV and biodegradability requirements.

One way of reducing the exposure to certain problematic perfume ingredients is to limit their usage. TheCosmetics Directive has recently been revised. Now a number of known allergens (the list of 26 compounds) must be declared if they appear in amounts of 0,01 % each. We propose to set an exclusion limit at the same level. To put it in other words:
If an ingredient is present in so high a level that the product must be labelled with these known allergens it cannot be ecolabelled. The list has

been hotly contested. 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 very few problems when compared to the exposure levels (Geraniol). According to another source (Peter Malaise, Ecover and EDMA) the list contain 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 recommend that they must be declared on the label if appearing in amounts > 0,01 % of the product. It is difficult for Ecolabelling Norway to define which of the 26 compounds should be accepted and which should be excluded. Hence we propose to limit all the 26 compounds.

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

In the Annex we present a list based on the 26 allergenic compounds regulated by the EU but without the compounds classified as R42 and R43, including rules for self-classification. The reason why we omit the classified compounds from the list is that we do not want to give the impression that the list is complete. New R43- or R42-classifications may happen and this should be taken into account by licence-applicants and fragrance formulators.

We propose an additional requirement limiting the amount of R43-labeled compounds not related to the amount of product but related to the fragrance mix. No matter how little perfume is used in the product we do not want the amount of R43-classified ingredients to be so high that the perfume mix will be classified as harmful to the health. It would send the wrong signals to the consumer even though the actual perfume content of might be small.

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 compounds classified as R43.

Some fragrance compounds are banned altogether. They are of special concern because they are persistent and bioaccumulating and found in mothers milk. The substances are: Nitromusks and polycyclic musks.

The proposals regarding fragrances are concerned with health. The requirements on CDV, environmental risk phrases will all strictly limit the environmental impact of fragrances, hence we see little reason to further limit the environmental effects of fragrances.

The Nordic Swan has many years of experience with the requirements and their experience is that the requirement level on fragrances is strict but possible to achieve.

Proposal
a) 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.

b) Fragrances in products for babies/infants
Fragrance must not be added to products that are sold for use on babies/infants.

c) Quantities of fragrance substances
Fragrance substances classified R43 or fragrance substances specified in Appendix 5 may be present in the product in quantities not exceeding 0.01%(100 ppm).

Fragrance substances classified with R43 or found in Appendix 3 may be part of the fragrance mix in amounts below 1%. The total amount of substances classified R43 or found in Appendix 3 may, however, not exceed 5% of the fragrance mix.

d) Excluded fragrances
- Nitromusks and polycyclic musks, including for example:
Musk xylene: 5-tert-butyl-2,4,6-trinitro-m-xylene
Musk ambrette: 4-tert-butyl-3-methoxy-2,6-dinitrotoluene
Moskene: 1,1,3,3,5-pentamethyl-4,6-dinitroindan
Musk tibetine: 1-tert-butyl-3,4,5-trimethyl-2,6-dinitrobenzene
Musk ketone: 4'-tert-butyl-2',6'-dimethyl-3',5'-dinitroacetaphenone
HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta(g)-2-benzopyran)
AHTN (6-Acetyl-1,1,2,4,4,7-hexamethyltetralin)

9.8 Dyes or coloring agents

Dyes/coloring 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. The environmental impact of dyes is small but it can be further reduced by excluding the "worst" ingredients. In this context the worst dyes are those that are highly toxic , potentially bioaccumulating and at the same time are poorly biodegradable. Hence we propose to exclude dyes that may bioaccumulate. Color 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 colors to choose from we propose to accept all dyes approved for use in foodstuffs. These have been scrutinized closely by the authorities before being accepted.

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

Proposal
a) Any dyes or coloring 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 coloring agents must not be potentially bioaccumulating. In the case of coloring agents approved for use in foodstuffs it is not necessary to submit documentation on bioaccumulation.

9.9 Preservatives

Preservatives are added to inhibit microorganisms and maintain the color 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 we propose to exclude compounds classified with the risk phrases R50-53 or R51-53 and at the same time potentially bioaccumulating. Butyl paraben and isopropyl paraben are examples of preservatives excluded on the basis of this requirement.

We would like to make a distinction between disinfecting products and ordinary cleaning products. Ordinary consumers have no need for disinfecting products. We want to halt the tendency to use cleaning products with anti-microbial action as a selling point.

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. We 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

These requirements reduce significantly the number of accepted preservatives. Preservatives such as phenoxyethanol, methylparaben, ethylparaben and sodium benzoate are among the accepted alternatives. Before we make a decision on the requirements we have to make sure

that there exist technically usable preservatives for every product category covered by our definition.

Proposal:
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) It is prohibited to claim or suggest on the packaging or by any other communication that the product has an anti-microbial action.

c) 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.).

The concentration of biocides in the final product shall not exceed the maximum authorized concentration in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products and its subsequent amendments.

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

9.10 Hazardous ingredients

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

Proposal:
No constituent substance must be classified as carcinogenic (Carc),mutagenic (Mut) or toxic to reproduction (Rep)including rules for self-classification. No constituent substance must be classified as sensitizing Xi with R42 and/or R43 including rules for self-classification. See also the specific requirements for fragrances.

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).

9.11Excluded and limited ingredients

Some ingredients 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 cancerogenous 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 which leads to eutrophication but the most important reason for limiting them is that they are poorly biodegradable. However claims have been made that there exists some phosphonates which are readily biodegradable. Ecolabelling Norway has consulted experts but have 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.

Proposal
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)
- Boric acid, borates and perborates

b) EDTA and phosphonates
Ethylenediaminetetraacetate (EDTA) and its salts and not readily biodegradable phosphonates may only be added in solid soaps and only in a maximum content of 0,6 mg/g AC.

9.12 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 is a typical example. They are used more and more in soaps and shampoos. The reason why we need to address these ingredients specifically is that they have seldom been tested for environmental properties: toxicity, biodegradability and bioaccumulation potential. Additionally manufacturers, organizations and consumers seems to think that since these ingredients are from natural environments 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, taken out of their context. The Ecolabelling Criteria for the Swedish Ecolabel "Good Environmental Choice" accept 0,5 % biological

additives with very little indication.

The lack of data for biological additives would mean that we would have to use "worst case"-data when calculating CDV, anaerobic ingredients and environmental risk phrases. Our calculations show that no products containing biological additives would qualify for the ecolabel if we apply the standard worst-case-values. This would mean that almost half the products would be excluded without necessarily be more harmful to the health and the environment.

We propose to treat biological 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.

9.13 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 not much 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 only used once and incinerated or landfilled after use due to resource depletion. Packaging is normally made from non-renewable sources. 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 has 0,9-0,15 g primary packaging pr g shampoo and 0,001 g secondary packaging pr g shampoo. Generally these ratios decreases with increasing product size. Based on these numbers we propose a requirement called Weight/Utility Ratio (WUR). This is a limit on the weight of packaging pr unit product (see the end of this chapter).

Setting requirements regarding the earlier life phases is difficult for much the same reasons as for the ingredients. It is difficult to get the required information and it is difficult to influence the producers.
Packaging is not the most important issue for this products group. Hence we do not intend to put more emphasis on the packaging than the actual shampoo or soap. Hence we focus on the use phase and disposal phase.

One potential environmental (and health) impact originating in the use phase can be caused by leaching of additives from the plastic into the product. 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. Endocrine disrupters such as Bisphenol A also occurs. We propose an exclusion of these compounds but the exclusion is restricted to willfully added compounds. We do not propose to exclude residual monomers and other impurities as this would require testing and put to much emphasis on a potential problem.

Hence we propose that the packaging requirements should focus on the disposal phase. 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 proposed WUR-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 very fast.

The worse, and unfortunately the most frequently used alternative is landfilling.

We propose promotion of re-cycled materials by means of the WUR-requirement. We also propose the promotion of re-cycling by requiring

that all plastic materials be labelled. Furthermore we want to promote re-cycling of cellulose fibers by requiring that all card-board packaging consist of at least 80 % recycled material.

Incineration is the preferred alternative for packaging that is neither re-used or re-cycled Preferably the energy gained is utilized but ecolabelling cannot influence this. One problem with incineration is emission of dangerous compounds .Formation of dioxins have been reported in many incinerators. Incinerators throughout Europe are strictly regulated as regards emissions of dangerous compounds. It is difficult to see how ecolabelling can contribute to reduction of dioxins and other problematic compounds from incinerators. Hence we do not propose any requirement directly aimed at reducing emissions from incineration.

Landfilling is the worst alternative. Not only is the energy content used. Valuable land is filled up with virtually non-degradable material and toxic additives may leach into ground water. Unfortunately a lot of Europes households waste is still land-filled. We propose to limit the impact by the already mentioned restrictions on additives and by the requirements encouraging recycling and re-use.

The most difficult part of the discussions on packaging is whether to include requirements that will ban or restrict certain packaging materials. The Nordic Swan has banned the use of PVC for many short-lived applications and environmental organizations want such a ban.

The requirements already proposed will only exclude heavy packaging materials, notably glass. The other materials are still possible to use.

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, f ex 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 studies 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 that 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 which 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 where plastics are now separated by the households, 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, f ex 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 propose to 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 landfilled
- 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 is very difficult to quantify. Hence we propose 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.

Proposal

a) The Weight/Content Relationship must be < 0,30 g packaging/g product.

$$VCR = \sum ((W_i + N_i) / (D_i \times r))$$

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) Cardboard packaging must consist of at least 80 % recycled material.

c) Labeling 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 excepted this requirement.
d) 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.
e) The packaging must not contain additives based on Cadmium, Lead, Mercury and compounds with these elements, as well as organic tin compounds and halogenated organic compounds. Neither may the packaging contain endocrine disrupters (defined as in requirement 5) such as Bisphenol A

9.14 Product quality

The quality of ecolabelled products should not be less compared to 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 aHWG consider mildness and efficiency the main areas of quality. Mildness is as important, if not more important than, the washing efficiency of the product.

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 an label.

Superfatted soaps and bath oils 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 labeling, 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 transepidermal 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 different products to consumers with asthma and allergy. Soaps and shampoos from two different producers are recommended, and this 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 feed back 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 has risen 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 an important that ecolabelled products should not adversely effect consumers health. The Cosmetics Directive give some degree of protection. The proposed 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.

Ecolabelling Norway has not concluded in this matter. Rather we ask the aHWG to discuss the following alternatives:

1. No extra requirement on product mildness. The health related requirements adequately ensures consumer protection.

2. The products mildness should be tested and compared to one or several products representing the market average for a certain usage and user group.

Test methods

Visual methods
Erythema, oedema, scaling, fissures, chapping, discoloration, burning, stinging etc.
Grading: zero, weak, moderate, strong, very strong.
Type of response: evaluation of number, duration and intensity of response and type of response comparison to effects of known materials.

Objective methods
- **Red Blood Cell Test System.** It measures the products impact directly on erythrocytes.
- **HET-CAM Test.** The potential irritancy of compounds may be detected by observing adverse changes which occur in the chorionallantoic membrane of the egg after exposure to test chemicals.
- **Patch test technique** developed in the 1960s for detection of the corticosteroid reservoir in the stratum corneum. Instrumental measurements of the transepidermal water loss and superficial skin blood flow served as indicators of the injurious effects of the products.
- **Spectroscopic measurements** of redness intensity

The mildness of a product refer to the absence of damage on skin and hair, f ex drying out of skin. There are many possible endpoints that could be used for mildness, and different producers use different test methods. This makes it difficult to compare the different products claiming their mildness, and consumer organizations often rise the questions regarding the validation of these tests.

Proposal:
Alternative 1: No extra requirement on testing of product mildness.

Alternative 2: The following requirement is proposed:
"The mildness of the product must be demonstrated by in vitro or in vivo tests. The product must not be less mild than the market average of

products within the same market segment, i.e. products for the same use and the same target group (i.e. babies). Hence the licence applicant must also test one or more market leading products with the same test(s). The test must conform with the Guidelines laid down by the Colipa "Cosmetic product guidelines for the assessment of human skin compatibility". "

Efficiency
Experts within manufacturing companies and test institutes inform us that no standard test for efficiency exists. COLIPA have 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.

We propose that license applicants must submit laboratory test results for the efficiency and "mildness" of the products. The products should perform as well, or better than, the average of the products on the market. A certain quality control of the tests is necessary. Guidelines for test quality will be proposed at a later stage in the project.

Preferably the tests should be performed by a neutral Third Party.

Proposal
The product must be as efficient as, or better than, the average of the products on the market. The efficiency of the product must be demonstrated by in vitro or in vivo tests. The product must not be less efficient than the market average of products within the same market segment, i.e. products for the same use and the same target group (i.e. babies). Hence the licence applicant must also test one or more market leading products with the same test(s).

The test must conform with the Guidelines laid down by the Colipa "Guidelines for the Evaluation of the Efficacy of Cosmetic Products".

9.15 Information for the consumer

Ecolabelling is an important tool for 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 actual Flower symbol.

We propose the following information on the ecolabel:

* reduced impact on aquatic life
* reduced use of hazardous substances
* increased health safety

The text in Box 2 must be short because of practical considerations.

Furthermore we may influence consumer behavior 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.

Another possible text is:
`The use of less water at lower temperatures when using the product significantly gives a significant environmental benefit´

This text has the potential of reducing the environmental impact of the use phase. According to the LCAs the use phase gives the largest environmental impact. We do not propose any 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.

Proposal:
The following text should appear in Box 2 of the ecolabel:

* reduced impact on aquatic life
* reduced use of hazardous substances
* increased health safety

We propose no further text on the label of the product.

Regarding mildness, …..

10 Effect of the proposed requirements

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 to 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.

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