DANISH MINISTRY
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Environmental
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The EU Eco-label and Health

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Summary

The objectives of the EU eco-label (the Flower) are to promote the production and marketing of products and services that leads to less impact to the environment compared to products and services having similar uses.

Since its first adoption in 1992, the regulation has been revised once in 2000. The revision lead to a higher focus on health aspects: From a statement that the elaborated criteria must not at the same time reduce the protection of occupational health (1992) - to general requirements that "..considerations shall be given to the net environmental balance between the environmental benefits and burdens, including health and safety aspects…"(Article 3, sec. 2a) (2000).

The present report argues for a more balanced focus on both environmental and health issues. The rationality is that the consumers require a label, which in addition to life cycle aspects also as a minimum covers issues of immediate concern for the consumer: Health and the immediate environmental surroundings.

The actual coverage of health aspects in 6 criteria documents has been analysed. Only chemical related health aspects have been included.

All the analysed criteria documents include additional requirements that go beyond the scope of the Regulation and also the existing chemicals regulation. A gradual move of the coverage of the criteria toward a higher health focus has thus been made. As a rough estimate around three quarters of the chemical related requirements target environmental aspects while around half of the criteria (also) target health issues.

Except for the indirectly coverage due to requirements to the final product, occupational health is not covered beyond the requirements of legislation. There are no requirements to the physical workers environment nor to auxiliary substances.

Should the competent authorities decide that a more systematic coverage of health issues is to be made, there is a need for elaboration of a health life cycle guideline comparable with the existing guidelines for environmental life cycle considerations. A proposal for such a life cycle framework is made in the report. Should health considerations be included in a more systematic approach, the Eco-label holders may be able to use health related arguments in their marketing.

It is proposed that the Eco-label gradually should move from an environmental label to a label for products and services, where appropriate considerations regarding sustainable development have been made. A step stone for such a development is a label covering (chemical related) health and environmental aspects in a balanced way. The report therefore suggests a number of adjustments of the text of the Regulation to be considered by the competent authorities. A stepwise approach may be considered starting with chemical related health issues and in a later revision including also ethical/social aspects (Corporate Social Responsibility issues).

The EU Commission proposal for a new chemicals regulation (REACH) is expected to be implemented during the period 2007-2018. The aim of the regulation is that chemical substances produced or imported above a certain tonnage level are not to be marketed unless the producer or importer is able to guarantee, that the substances may be used without significant risk to health or environment.

It should be analysed how the EU eco-label may be used as documentation that labelled products comply with the principles of REACH, which go beyond the actual legislative requirements, e.g. that all ingredients are in accordance with REACH requirements, not only those imported or produced above the tonnage levels defined in the regulation .

Resumé

EU's miljømærke "Blomsten" har til formål at fremme produktion og salg af produkter og tjenesteydelser, der er mindre miljøbelastende end produkter og tjenesteydelser med tilsvarende anvendelse.

Siden EU-forordningen blev vedtaget i 1992, er der foretaget en revision i 2000. Revisionen medførte en styrkelse af sundhedsaspekterne: Fra en erklæring om at en mindre miljøbelastning ikke måtte medføre en samtidig slækkelse af beskyttelsen af arbejdsmiljøet (1992-forordningen) til en mere generel formulering i den reviderede forordning, at der ved vurdering af produktforbedringer skal tages "hensyn til de positive nettovirkninger for miljøet og de miljømæssige fordele og ulemper, herunder sundheds- og sikkerhedsaspekter" (Artikel 3, stk. 2a).

Nærværende rapport argumenterer for en mere balanceret dækning af både sundheds- og miljøaspekter i forbindelse med den igangværende revision af forordningen. Argumentet herfor er, at forbrugeren i større grad vil efterspørge et produktmærke, der ud over livscyklusforhold også – som et minimum - tager hensyn til forbrugerens primære præferencer, nemlig sundhedsaspekter samt det nære miljø.

Den nuværende dækning af sundhedsaspekter er blevet analyseret for 6 kriteriesæt. Kun kemikalie-relaterede sundhedsaspekter er omfattet af analysen. Kriterierne indeholder alle krav, der går ud over forordningens krav, og i alle tilfælde stilles krav, der er mere stringente end den eksisterende kemikalielovgivning. Et groft estimat viser, at ca. ¾ af kemikaliekriterierne er fokuseret på miljøbeskyttelse, medens ca. halvdelen (også) fokuserer på sundhedsaspekter.

Med undtagelse af den indirekte beskyttelse af arbejdsmiljøet, som de produktrelaterede kriterier medfører, er der ikke egentlige krav til fx det fysiske miljø eller anvendelse af hjælpekemikalier, der ville kunne medvirke til en øget beskyttelse af arbejdsmiljøet.

Hvis det besluttes af myndighederne, at sundhed skal indgå mere systematisk i den reviderede forordning, vil der være behov for en vejledning om livscyklusbaseret sundhedshensyn tilsvarende den nuværende vejledning om livscyklusbaseret miljøhensyn. I nærværende rapport er der opstillet en sundheds-LCA matrix, der i givet fald vil kunne anvendes som udgangspunkt. Et mere systematisk sundhedshensyn vil give mulighed for en mere aktiv sundhedsrelateret markedsføring af mærkede produkter.

Det foreslås, at "Blomsten" gradvist udvikler sig fra et rent miljømærke til et mærke for produkter og tjenesteydelser, hvor der er taget det fornødne hensyn i relation til bæredygtig udvikling. En udviklingsmæssig trædesten vil kunne være et mærke, der balanceret tager hensyn til både miljø- og sundhedsaspekter. Der er i rapporten opstillet en række forslag til justeringer af forordningsteksten, der kan fremme en sådan udvikling. En trinvis måde for dækning af sundhedsaspekter kunne overvejes, hvor den kemikaliebetingede sundhed medtages i den igangværende revision, for senere at udbygge sundhedshensynet til at omfatte sociale/etiske hensyn (Corporate Social Responsibility aspekter).

EU-Kommissionens forslag til ny kemikalieregulering (REACH) har til formål at øge beskyttelsen af miljø og sundhed ved bl.a. at pålægge producenter og importører ansvar for, at kemiske stoffer produceret eller importeret over et vist årligt volumen kan anvendes uden væsentlig risiko for sundhed og miljø. Forordningen forventes implementeret over en 11 års periode. Det foreslås, at der gennemføres en analyse af "Blomsten" og REACH om, hvordan "Blomsten" kan gå længere og signalere en højere grad af miljø (og sundheds)beskyttelse end REACH lovgivningen fordrer, fx ved at alle væsentlige stoffer i et miljømærket produkt er omfattet af REACH-princippet om producentansvar, og ikke kun de stoffer, der produceres eller importeres over lovgivningens minimumkrav.

Table of contents

1 Introduction

Since its adoption in 1992 the Regulation on a Community eco-label award scheme ("the EU eco-label") has been revised in 2000 /1/ and now faces a new revision in 2006.

From its first adoption in 1992, the EU eco-label has been targeting environmental impacts seen in a life cycle perspective. Health aspects were covered in the 1992 regulation in relation to workers environment in the sense that environmental improvements were not to be achieved in a way that would reduce the protection of workers environment (Article 1). Health aspects were also covered in relation to chemicals, as the Eco-label was not to be awarded to substances or preparations classified as dangerous according to the relevant chemicals directives (Article 2, sec. 4)

In practice, however, a number of the criteria documents adopted took considerations of health aspects especially in the area of chemicals beyond the scope of the regulation.

The revision in 2000 led to a higher emphasis on health aspects in the regulation, as it is stated in the environmental requirements of the regulation (Article 3, sec. 2a) that "considerations shall be given to the net environmental balance between the environmental benefits and burdens, including health and safety aspects." Also the term "dangerous" applied in the 1992 regulation was explicitly explained: The label is not to be awarded to substances or preparations classified as toxic, very toxic, carcinogenic, toxic for reproduction or mutagenic according to the relevant EU directives (Article 2, sec. 4).

Since 1992, environmental protection measures have gradually developed from an emission control strategy via a cleaner technology/product focus to a sustainable development concept. In line with this development, the EU eco-label criteria documents have gradually taken on board a broader coverage of not only environmental aspects strictly speaking but also health protection aspects. This was reflected in the regulation revision from 2000 and will presumably be further extended in the revision ahead.

The present report argues for the establishment of a balanced environmental and health label scheme – a "health and eco-label" or ultimately a "sustainable development label".

Chemicals are the primary focus of the report. Health aspects are covered only regarding the direct potential of chemical substances and preparations to influence health. Other issues of relevance for health, i.e. ethical, social and physical health aspects, are not included. As far as possible the definitions applied in the regulation have been used: i.e. the term "chemicals" is applied as a combined term for substances and preparations. The term "goods" is applied synonymously with the term "articles" applied in the REACH proposal

The provisions for the present regulation of chemicals are outlined (chapter 4) and the present coverage of chemical related criteria in a number of rele-

vant criteria documents is analysed (chapter 5). With the objective to promote a more balanced health and environmental focus, a number of amendments to the Regulation are finally proposed (Chapter 6).

The report is targeted at competent bodies and stakeholders involved in EU eco-label work. Thus, the objective of the report is not to explain the background for the development of eco-labels or the present working procedures related to eco-label criteria documents.

2 Background

Various eco-label schemes were established in a number of member countries in the beginning of 1990's and shortly thereafter the EU eco-label regulation was adopted (1992). The background for establishing the schemes was the growing understanding of the need for reducing the environmental impact from the rapidly increasing purchase and use of goods in the member states. Products were recognised to be one of the primary challenges after member states had been able to reduce the direct emissions from industry during the 70's and 80's.

The schemes were established on a voluntary basis, as it was realised to be very difficult to regulate an area characterised by global trade governed by international regulations regarding free trade. It is characteristic for developed countries that most of the products consumed are imported and most of the products manufactured are exported.

The drivers of the various schemes were anticipated to be green frontrunners among the manufactures, a willingness from authorities to select green goods and service for public purchase, and finally that a high percentage of the consumers were willing to select green goods where a choice between similar products were possible.

More than 10 years after the establishment of the labels, the success of the labels are lower than expected for most of them – including the EU eco-label. Some of the reasons are:

- Frontrunners have had difficulties in establishing a financially attractive market and a number of internationally leading companies have refused to apply the labels for their products
- The authorities have not yet used the power of public purchasing to promote the market regarding green products
- In spite of numerous investigations indicating the opposite, consumers have not been willing to purchase labelled products when the product is a valid alternative to existing products, even if the labelled product would be slightly more expensive than the traditional product.

Although a significant increase in the number of sold Eco-label products has been seen during the last 3 years (2003-2005), partly due to the EU-Flower week in 2004, the relative coverage of eco-labelled products in the market is still insignificant compared to the entire marketed products.

Consumer investigations do indicate that consumers are more likely to pay attention to issues regarding their purchase that is related to their immediate surroundings: Health for themselves and their relatives, protection of their immediate environment, etc. Ozone-layer protection, green house gasses and similar issues are of less concern, probably because it is difficult to explain in a few words how this may have impact on their immediate surroundings in a reasonable near future.

Thus, one of the core issues of immediate concern for the consumers is the chemical content of the goods purchased and the risk that they could be harmful to their own or their relatives' health. Consequently, a way for the label to increase its coverage of the market is related to the extent to which the label criteria are able to address the challenge of covering health aspects of the purchased products, so that the producer may advertise the product as being less harmful to the consumer than comparable products.

The reasons for consumer concern are obvious. Today we apply around 100,000 chemical substances in chemical preparations and products of which we have very poor knowledge. Very often newspapers report new findings of hazardous substances in everyday products including children's toys. This information to the consumers causes high concern.

The new chemical regulation, REACH, is expected to be adopted in 2007 and to be fully implemented 11 years later in 2018. In short REACH obliges manufacturers and importers of chemical substances (above a certain yearly tonnage level) to document that the substance may be used without unacceptable risk for man and environment. The documentation will appear in the safety data sheet and in an annexed exposure scenario. Professional downstream users of chemical substances are obliged to use the substances only within the uses identified and to apply the Risk Management Measures (RMM) (protection equipment and measures) prescribed in the SDS and exposure scenario. The outcome for consumers (when implemented) is that articles (goods) purchased will be guaranteed by the producer not to be of significant risk to the consumer in normal (prescribed) uses, provided the substances included in the article are covered by REACH obligations. The applicant for an eco-label will find it easy to identify the data needed to document the compliance with eco-label criteria – as long as the chemicals contained in the products belong to the fraction of the 100,000 chemical substances covered by the regulation.

Once the principles of the new regulation have been adopted, it is anticipated that both consumer organisations and professional downstream users, who have committed themselves in relation to sustainable development, will put pressure on the chemical supply chain to adopt the REACH requirements quicker than what is prescribed by the official implementation period. This has often been seen for other product related chemical regulations. Eco-labels may have a role for the supplier of goods to document the compliance with the principles of REACH. The provisions are that the EU eco-label covers both health and environment in a systematic way regarding chemicals and that updates scheduled for the next 11 years take REACH requirements into consideration.

The Eco-label criteria may also request that all substances above a "level of insignificance" shall be known by the producer and should fulfil REACH requirements despite that they may not all be above the use limits defined in the regulation. The license holder should guarantee the absence of "harmful effects" in the product. In this way the holder of the Eco-label may apply both "health" and environmental arguments in the marketing of the label.

Eco-labels may also support REACH in relation to the requirements to apply substitutes for very hazardous substances (the so-called CMR substances) whenever available. If eco-labelled products have succeeded in applying non-

hazardous alternatives for such substances, authorities may refer to eco-labelled products as examples of relevant substitution possibilities.

REACH targets the regulation of chemical substances. The regulation will also have impact on the content of chemical substances in articles (goods), although hazardous substances used below the threshold volumes per producer and year may still appear. Eco-labels may (and should) play a role to restrict the use of hazardous substances beyond the requirements in REACH in both imported and EU produced goods.

Many industry frontrunners regarding environmental objectives may apply eco-labels in the following ways:

- As a holder of eco-label licenses,
- Purchase of eco-labelled products (to be applied in production or for internal consumption),
- Use of the Eco-label criteria and supporting documentation for their own product design,
- Use of the criteria as part of their purchase policy

During the last 5-10 years the industry frontrunners have moved from a fragmented focus on environment to a sustainable development focus covering health and environment and including social issues and occupational health. Presently, most of these companies' work is targeted at improving the image in the market or/and work regarding "damage control" in relation to being challenged by the news media. The companies need a publicly documented and supported set of product criteria applicable for either marketing of products with an eco-label attached or applied as background documentation for company development of "sustainable" products in its own context.

One of the problems of placing health at the same level as environment is that the complexity increases and makes the development of criteria and the compliance documentation both more difficult and more expensive. However, the label should develop continuously in line with the conceptual understanding in the market and thus fulfil the needs for an applicable market tool. If the label fails to be part of this development, it may be reduced in market importance and instead other (private) labels may fill the gap

3 The EU eco-label

3.1 The purpose of the EU eco-label

The EU eco-label came into existence because of a need for a uniform, reliable, transparent and impartial system regarding information on the environmental properties of products.

The EU eco-label is directed to consumers across the boarders in the EU and it may be awarded to both products and services. The Eco-label is part of a broader EU policy regarding IPP, Integrated Product Policy, that is a key element in the EU environmental policy aiming at promoting sustainable production and consumption. The Eco-label is thus part of the 6th action programme ”Environment 2010: Our Future Our Choice”.

The primary function of the EU eco-label is to stimulate the supply and demand of products and services with a documented lower environmental load than comparable products and services. As a market tool it must be operational and effective for manufacturers, suppliers and consumers in Europe.

3.2 Legislative basis

The legislative basis for the EU eco-label is ”Regulation on a revised Community eco-label award scheme” /1/. The Regulation describes the overall management of the label and requirements for products that may obtain the Eco-label. Both the Regulation and the product criteria are established by the national competent bodies in cooperation with the Commission and an EU stakeholder’s forum (EUEB). The national eco-label competent bodies handle the support and promotion of the label and are also responsible for assignment of the Eco-label to the products that meet the criteria.

The Eco-label may be awarded to products and services primarily intended for consumers except for foodstuffs, beverages, pharmaceuticals, and medical equipment.

Criteria may be established for product groups that have a substantial trade volume in the EU causing significant environmental loads and that contain a potential for significant environmental improvements. At the time of its adoption the criteria should be achievable by part of the existing products on the market.

The criteria are based on life cycle considerations and are updated every 3 to 6 years.

3.3 Methodological basis

The elaboration of proposals for new product criteria is conducted in 4 consecutive steps.

The first step is a feasibility and market investigation with the purpose of establishing whether there is a market basis for an eco-label for the product type in question. Information on market structure, products, and opinions regarding the product type is collected. Primarily information related to the EU is collected, but conditions outside the EU might also be taken into consideration.

In the next step, the most important environmental conditions for the product group are selected based on life cycle considerations according to internationally recognized methods[1]. The Regulation contains an indicative assessment matrix of the environmental factors to be considered. The purpose is to identify the categories of the most important environmental loads.

The third step is an improvement analysis evaluating the improvement potential for the individual environmental load parameters. The technical, industrial, and economic feasibility and market changes are also evaluated and considerations are made about consumer behaviour, perceptions, and preferences that might contribute to the market penetration of the Eco-label.

The final step includes the elaboration of a proposal for the criteria to be applied. The suggestion for criteria might for example contain clearly defined limits for certain ingredients as well as demands for resource consumption and reusability.

The product label consists of 2 boxes. The Eco-label logo “the Flower” is placed in one box and the other contains statements on the primary reasons for awarding the Eco-label.

At present, criteria for 23 different product types including two services have been developed. According to the work programme for the label, the anticipated number of product groups to be covered is between 25 and 35 by the end of 2006.

3.4 Revision of the Regulation

The Regulation has been revised once since 1992. The revision expanded the Regulation to include services. The European Union Eco-Labelling Board (EUEB) was established and it became possible for manufacturers outside the EU to apply directly for the Eco-label.

The present Regulation was to be examined by the Commission no later than 24 September 2005 based on the experience gained in the intervening period. The next ordinary revision is anticipated in 2006.

[1] The principles in EN ISO 14040 and ISO 14024 must be taken into consideration where relevant according to the Annex II of the Regulation

4 Principles for evaluation of chemicals

In the following, the principles for health hazard and risk assessment of chemicals are outlined. Environmental aspects are not covered.

4.1 Hazard assessment

4.1.1 Hazard identification

Health hazardous properties may be divided into acute and chronic effects. Acute effects are effects that may be seen immediately after exposure such as corrosion, damage from contact with skin or narcotic effects from inhalation. Chronic effects are lasting effects appearing after prolonged exposure, e.g. central nervous system damages after long-term inhalation of organic solvents or cancer. Other health hazards include the development of allergy or hormone disruptive effects.

A general list of potential hazards are outlined in Table 1.

Table 1: Parameters included in health hazard identification of substances:

Physical-chemical properties

- Explosion hazard
- Flammable properties
- Fire hazard
- Other properties

Health hazardous properties

- Acute toxic effects
- Other acute effects after a single exposure
- Serious effects after repeated or prolonged exposure
- Corrosive properties
- Irritating properties
- Sensitizing properties
- Carcinogenic effects
- Mutagenic effects (damage to the genes)
- Reproduction toxic effects (damage to foetus or reproduction)

Other properties having indirect health aspects are ozone layer degrading properties (leading to increased frequency of skin cancer), green house impact, persistence and bioaccumulation leading to increased contamination of food stuff.

4.1.2 Classification and labelling of substances and preparations

The EU classification regulations are based on hazard assessment of substances and preparations (chemical products).

The classification of substances and preparations is carried out by comparing information on the properties of the substance (toxicological data, ecotoxicological data, and physical-chemical data) with a number of hazard criteria described in the relevant chemical legislation /3, 4/.

The purpose of classifying substances (and preparations) is to identify all hazardous properties of the substance in the state in which it is marketed in order to inform the (professional) user of the hazardous properties through labelling with hazard symbols, risk and safety phrases. The information is provided for the user in Safety Data Sheets according to the EU directive /5/ and any national implementation requirements. The final hazard labelling of the product helps the consumer to take necessary precautions.

All suppliers of chemical substances are obliged to classify and label the substances in accordance with the Council Directive 67/548/EEC /3/ before they place them on the market (self-classification). This obligation is independent of the quantity manufactured or imported. Presently Community harmonised self-classifications are included in Annex 1 to the Directive. Once REACH has been implemented, manufactures' and importers' self-classifications together with the substance registration numbers will appear on the Agency website (Classification and Labelling Inventory).

Member States will decide the need for harmonizing the various classifications appearing.

For products, the classification is determined on the basis of the classification of the individual ingredients based on calculation rules established by the EU /4/.

Chemicals to be classified as hazardous must be appropriately labelled. The labelling is prepared based on the classification of the chemicals and consists of hazard symbol(s), hazards designation(s) as well as risk and safety phrases (R- and S-phrases) (Table 2 and Annex 2).

Table 2 Overview of hazard classes and the letter designation of the hazard symbol:

Hazard class	Letter designation
Explosive	E
Oxidizing	O
Extremely flammable	Fx
Highly flammable	F
Flammable	R10
Very toxic	Tx
Toxic	T
Harmful	Xn
Corrosive	C
Irritant	Xi
Sensitizer	R42 and/or R43
Carcinogenic	Carc1, Carc2 or Carc3
Mutagenic	Mut1, Mut2 or Mut3
Toxic to reproductive	Rep1, Rep2 or Rep3

health	
Dangerous for the environment	N or R52,R53 or R59

The R-phrases gives information on the inherent properties of the substance or product, i.e. the effects that the substance or product may cause, e.g. ”Harmful if swallowed” or ”Irritating to eyes and skin”.

The S-phrases indicate precautions during use of the product (Risk Management Measures, RRM), e.g. ”Use only in well-ventilated areas”, or instructions for what should be done in case of accidents, e.g. ”In case of contact with eyes, rinse immediately with plenty of water and seek medical advice”.

4.2 Exposure

The risk of health impact of a product does not only depend on the hazardous properties of the substances contained in the product but also on the actual exposure of the substances.

If the hazardous substances in the product are not released from the product or are contained in the product in such a way that the user does not come in contact with the substances, i.e. is not exposed, the substances will not have any harmful effects.

The exposure of the user and thus the potential health impacts of the product is influenced by the physical state of the product (fluid, liquid, or gas), the state in which it is marketed (powder, aerosols, tablets, etc.) together with the way it is used.

Products containing volatile substances may lead to a risk of inhaling the substances during use. Products marketed in a packaging with a spray device or in an aerosol may be harmful to the consumer when inhaling the aerosols (atomized liquid). The risk of inhaling harmful substances will be greater for products applied as a spray than if the similar product is applied as a liquid using a cloth, sponge or brush paint for application (paint, lacquer). Finally, there may be a risk of inhaling dust when using a powder product.

Exposure in the working environment may be reduced via planning of work routines or through technical precautionary measures, such as establishment of ventilation or encapsulation of processes. If it is not possible to reduce the risk of exposure to the employees, appropriate personal protection equipment may be used such as gloves, respirator equipment, etc.

Assessment of exposure includes an evaluation of the duration of the exposure (e.g. hours per day) as well as an evaluation of the concentration of the exposure.

The dosage to which the consumer of the product is exposed may vary a great deal as different consumers have different behaviour, and an exact determination is often almost impossible. However, realistic worst-case estimates may be made based on its various uses.

5 Health aspects presently covered by the EU eco-label

In the following, the extent of the coverage of health aspect is analysed in:

- the Regulation
- the method basis for establishment of criteria
- the criteria for selected product groups
- the demands for the final design of the label for selected product groups.

5.1 Coverage of health aspects in the Regulation

The scope of the regulation contains provisions regarding protection of the consumer and also regarding occupational health:

> Regulation EC No 1980/2000 of 17. July 2000:
> **Article 2, sec. 4:**
> "The eco-label may not be awarded to substances or preparations classified as very toxic, toxic (...) carcinogenic, toxic for reproduction, or mutagenic (...) nor to goods manufactured by processes which are likely to significantly harm man and/or the environment, or in their normal application could be harmful to the consumer."
>
> **Article 3, sec. 2:**
> "(...) in evaluating the comparative improvements, consideration shall be given to (...) health and safety aspects (...)"

The scope of the regulation may be interpreted as follows:

- Preparations containing CMR substances (Carcinogenic. Mutagenic and Repro-toxic) or substances characterised to be toxic and very toxic according to directive 99/45/EEC cannot be labelled with the EU eco-label.
- Eco-labelled goods may not be manufactured in a way that significantly harms man or environment. In practice, a company producing eco-labelled goods should comply with relevant occupational health and environmental legislation. In REACH terminology, the text may read: "The production processes should be in compliance with the identified uses and the risk management measures identified in SDS and attached exposure scenarios".
- An eco-labelled product may not harm the user in its normal application, i.e. the existing legislation should be complied with. An interpretation in REACH regulation terminology would be that there should be no unacceptable risk to man (and environment) by its intended use.
- Health and safety should be considered whenever appropriate, but the main focus is environmental issues.

While the first provision above is clear as it refers to an EU directive, the other three should be more clearly defined. The proposal for a new EU chemical policy (REACH) may be consulted to improve definition of item two and three above.

As a whole the scope may be interpreted as "minimum requirements", i.e. all criteria documents should as a minimum be in compliance with the scope. There are no indications anywhere in the Regulation that these should be interpreted as maximum requirements.

5.2 Method basis

Annex II of the Regulation describes the methodological requirements for establishment of the Eco-label criteria.

> **Extract from Regulation EC No 1980/2000 of 17. July 2000, Annex II:**
>
> **Life cycle considerations (LCC)**
> Key environmental aspects, for which criteria will need to be developed, will be defined through the use of life cycle considerations and will be performed in accordance with internationally recognized methods and standards. The principles laid down in EN ISO 14040 and ISO 14042 will be duly taken into account, where appropriate.

Annex I of the Regulation contains an indicative assessment matrix regarding environmental load assessment in the life cycle of the product.

Environmental conditions	Goods				
	Pre-production/raw materials	Production	Distribution (including packaging)	Use	Recycling/ reclamation/ removal
Air quality					
Water quality					
Soil protection					
Waste reduction					
Energy conservation					
Administration of natural resources					
Prevention of global warming					
Protection of the ozone layer					
Environmental safety					
Noise					
Biodiversity					

Table 3. Indicative assessment matrix for environmental loads of goods.

As may be seen, "noise" is the only condition that is directly related to health although also protection of the ozone layer and prevention of global warming indirectly include considerations regarding health. It may be concluded that "health load" from chemicals is not appropriately considered . Article 3, sec. 2 of the Regulation states that the comparative improvements must consider the positive net effects for the environment and the environmental advantages and

disadvantages, including health aspects. A transparent assessment in relation to the scope of the regulation would require a description of a method or a guideline to cover health aspects in line with the form in annex I (Table 3 above).

5.3 Analysis of selected criteria document

Six criteria sets have been analysed regarding the health aspects covered. Five of these cover chemical products (preparations). In addition, the criteria document for textiles has been selected as representative for an article in which chemicals play a major role regarding environmental aspects.

The selected criteria documents are identified below:

Product groups analysed for health coverage

	Adopted	Next revision
Dish washers detergents /6/	Nov 2002	Dec 2007
Indoor paints and varnishes /7/	Sept 2002	-
Hand dish washing detergents /8/	Mar 2005	2008
Textile products /9/	Feb 2002	May 2007
Laundry detergents /10/	Feb 2003	Feb 2008
All purpose cleaners and cleaners for sanitary facilities /11/	Mar 2005	Dec 2008

Only the health aspects as they appear in the final criteria documents have been analysed. It is outside the scope of the present project to analyse how the health aspects have been dealt with in the preparatory life cycle considerations.

The following aspects have been covered:

- Health considerations in relation to scope of the regulation
- Demands regarding classification of the preparations
- The level of stringency regarding use limitation of ingredients with health concern, e.g. sensitizing substances, and whether relevant official lists and regulations have been applied.
- Demands for declaration of certain ingredients/substance groups
- Demands for measures to reduce exposure of the consumer during use.

A short summary of the results of the analysis is given below. Reference is made to annex 1 for a more detailed description of the analysis.

5.3.1 Health as part of the scope of the criteria document

Health considerations are only explicitly mentioned in criteria set for all purpose cleaners and for hand dish washing detergents.

5.3.2 Scope of the regulation regarding health reflected in criteria documents

Although it is not a prerequisite that the non-supported hazard classes listed in the Regulation under Article 2, sec. 4 should be explicitly mentioned in all criteria documents, there is limited information in many of the documents that these restrictions have actually been part of the technical analysis background documentation or are part of the assessment of compliance of applications with the criteria. This could be part of a checklist used during the application procedure

The criteria document for indoor paints and varnishes support the overall demands in the Regulation to the effect that the preparation may not be classified as acutely toxic (”Very toxic”, ”Toxic”) or with regard to CMR effects (carcinogenic, mutagenic or reprotoxic). For the remaining criteria the demands are limited to restrictions regarding the hazard classes ”Very toxic” or ”Toxic”.

The criteria set for laundry detergents, all purpose cleaners, as well as for hand
dish washing detergents go further than the scope of the regulation, as the criteria do not allow products to be classified with R43 ”May cause sensitisation by skin contact”. The last two mentioned documents also include a ban regarding products classified with R42 ”May cause sensitisation by inhalation”, Xn (harmful) and C (corrosive).

5.3.3 Criteria regarding health aspects of ingredients

All criteria have restricted the use of certain chemicals dangerous to health. These demands include for example limitation in the use of specified fragrance, dyes and/or sensitizing substances. They are all more stringent than the relevant chemical legislation. Various criteria documents require that the products may not contain, or there is a fixed limitation in the content of, substances classified with specific R-phrases. Annex 2 contains an overview of the R-phrases restricted in the selected criteria set.

For some criteria the demand has been formulated as a general ban against or limitation in the use of substances with a specific classification (e.g. substances classified with R48), while for other criteria it has been formulated as a ban against the use of specific substances or substance groups that are otherwise frequently applied in the product groups. Some of the criteria documents contain criteria formulated in both ways. All nitro musk and polycyclic musk compounds considered to be sensitizing and known to occur in washing and cleaning agents are examples of substance groups that are restricted in specific product groups.

No direct reference is made to IARC evaluations of carcinogenic substances in any of the criteria sets, but some criteria include a regulation of substances evaluated by IARC.

5.3.4 Declaration of ingredients hazardous to health in the products

For textile detergents and dish washer detergents criteria regarding declaration of fragrances have been included. The declaration demands refer to Commission Recommendation 89/542/EEC of 13 September 1989 on labelling of detergents.

For hand dish washing detergents and all-purpose cleaners this demand has been omitted in the recent updated criteria of 2005 and instead a reference to the new detergent regulation (648/2004/EC) has been made. The detergent regulation requires that fragrances listed in the Cosmetic Directive (2003/15/EC amending the Council Directive 76/768/EEC) should be declared if the concentration of any of the 26 fragrances listed appears in concentrations above 0.01% (w/w).

The former criteria document for these two product groups contained a list of fragrances along with a demand that it must be clearly stated on the package if the product contains one or more of these substances along with the name or names of the fragrances in question.

Therefore, the two criteria documents are no longer more stringent than the existing regulation regarding these aspects, although presumably it would be possible for products on the market to fulfil more stringent requirements.

5.3.5 Criteria regarding workers environment

To some extent occupational health is indirectly covered through the restrictions on raw materials applied in the production of the eco-labelled product. The exclusion of all fragrances in eco-labelled professional hand dish washing detergent criteria may also be taken as a protection of occupational health. There are no other demands regarding occupational health in any of the criteria documents reviewed.

5.3.6 Criteria regarding exposure to the consumer

None of the criteria documents include demands on reduction of the exposure risk of the consumer, e.g. restrictions of the physical form of the product. The risk of inhalation of certain volatile substances may for example be reduced by requesting that the product may not be sold with a spray device, thus reducing the formation of aerosols.

5.3.7 Summary

The results of the evaluation of the criteria are summarized in table 4.

Table 4 Schematic overview of the result of the evaluation of selected criteria set

Product group / Parameters	Indoor paints and varnishes	Textile products	Laundry detergents	All purpose cleaners	Dish washers detergents	Hand dish washing detergents
Description of purpose						
- Health considerations	-	-	-	+	-	+
Tightened demands for the classification of the product						
- Ban on classification with R42 and/or R43	-	-	+ (R43)	+ (R42,R43)	-	+ (R42,R43)
Regulation of specific ingredients						
- Acutely toxic substances	+	-	-	-	-	-
- Substances with CMR-effects (category)	1,2	(1,2,3)	1,2,3	1,2,3	1,2,3	1,2,3
- Health hazardous substances	+ (R48)	-	-	-	-	-
- Heavy metals	+	+	-	-	-	-
- VOC's	+	+	-	+	-	-
- Negative lists	++	++	+	+	+	+
- Enzymes	n.r.	n.r.	+	-	+	-
Declaration demands[2]	-	-	+	-	+	-
EU's recommendation on detergents	-	-	+	+	+	+
Fragrances	-	-	-	+	-	+
Exposure to the consumer	-	-	-	-	-	-
Exposure during production	-	-	+	+	+	+

+ : The parameter is included in the criteria
- : The parameter is not included in the criteria
n.r.: not relevant for the current product type

The relevance of health and environmentally related limit requirements for chemicals may vary for different product groups. It is interesting, however, to note that around 75% of the specific limit requirements in the 6 criteria documents relate to environmental aspects, while around half of the requirements relate to health aspects. Therefore, in practice there is a relatively high coverage of health aspects, although variations between the criteria are significant.

Based on the evaluation of selected criteria, it may be concluded that:

- Where health-related criteria are present, the criteria are in general more stringent than the demands in relevant chemicals legislation.

- Although not required only one of the selected criteria set (indoor paints and varnishes) lists the requirements of the Regulation that products cannot obtain the Eco-label if they are classified as very toxic (Tx), toxic (T) or with regard to CMR effects.

[2] Declaration demands going beyond the present detergent regulation regarding fragrances

- Workers environment is only indirectly covered by the restriction of substances used as raw materials. The physical environment and auxiliary substances are not covered.

- Exposure of the consumer via the physical application of the products is only indirectly reflected in the criteria.

5.4 Information phrases on the product label

The introduction to the Regulation states that ”the eco-label should contain simple, precise, non-misleading and scientifically based information on essential environmental conditions, that should be taken into consideration in connection with the assignment of the label, so that the consumer can make their choice on a well-informed basis”.

In addition to the logo (the Flower), the label must contain information on the reasons for awarding the Eco-label. The information must include at least one and no more than 3 environmental impact phrases.

Table 5 shows the phrases selected for 6 criteria documents.

Criteria set	Information on the label (box 2)
Indoor paints and varnishes	Suitable for indoor use Restrictions on use of hazardous substances Low solvent content
Textile products	Reduced water pollution Restrictions on use of hazardous substances The entire product chain is included
Laundry detergents	Contributes to reduced water pollution Contributes to reduced resource consumption
All-purpose cleaners and cleaners for sanitary facilities	Reduced impact on aquatic life Reduced use of hazardous substances Clear user instructions
Detergents for dishwashers	Contributes to reduced water pollution Contributes to reduced packaging
Hand dish washing detergents	Reduced impact on aquatic life Reduced use of hazardous substances Clear user instructions

Table 5 Information to be given in label box 2 for selected criteria documents.

It would probably help the consumer to understand the message if the wording of the phrases was more direct and less academic. The problem of formulating the phrases is that they should be clear, use positively loaded words and at the same time be legally valid.

Health is a good example of the problem of phrasing a valid line on health protection. Very few phrases refer to health aspects even though health aspects are an important issue in some of the criteria, e.g. the criteria document for indoor paint and varnishes.

6 Improving the coverage of health aspects

6.1 Strengthening health aspects in the methodology of criteria development

Based on an analysis of the criteria documents for the chemical products selected, it is obvious that the criteria for the health aspects covered in general are more stringent than the requirements of the related chemicals legislation. On the other hand, should health aspects in future be given a higher emphasis in a revised regulation, health should be seen in a life cycle perspective in line with environmental loads.

The assessment of health impacts should cover health aspects related to consumers as well of workers environment.

The experience of including health in life cycle assessments is, however, limited. Although the ISO standard for life cycle inventories includes two impact categories regarding health (human toxicity and occupational health), only two published methods include health aspects /13, 14 / and very often these aspects are excluded during the initial process of system definition.

Based on the indicative assessment matrix for life cycle inventory (Annex 1 of the Regulation) and the ISO principles of LCA, a tentative matrix for health aspects is outlined in table 6.

Health conditions	Goods				
	Pre-production/ raw materials	Production	Distribution (including packaging)	Use	Recycling/ recovery/ removal
Chemical substances					
- acute toxicity					
- chronic toxicity					
- CMR effects[3]					
- sensitization					
- hormone disruptive effects					
- PBT[4]					
- vPvB[5]					
Ergonomic conditions					
- monotonously repeated work					
Health safety					
- accidents					
Physical conditions					
- noise					
- fragrance					
- light					
Indoor climate					
Physical conditions					
- stress					

Table 7. Tentative indicative assessment matrix for health in an LCA perspective (to be considered for the extension of Annex 1 of the Regulation)

For each phase of the product's life cycle it must be considered which of the dominant exposure routes are relevant: Skin contact, inhalation or ingestion. For the consumer, all three exposure routes are usually relevant. For workers environment only skin contact and inhalation are to be included as ingestion is only relevant in connection with accidents.

As the present experience of health life cycle assessments is limited, there is a need for elaboration of a relatively simple approach, which may be further detailed, based on experience from criteria work, the newly established EU Commission IPP LCA platform and from research work.

At the moment a number of initiatives are underway. The most important are summarised below /13/

- Work is carried out on the development of specific characterization methods for all impact categories, including established guidelines for human toxicity.
    - Characterization of each exposure route, ingestion, inhalation and skin contact.
    - Characterization of chronic toxicological effects (both carcinogenic and non-carcinogenic effects).
    - Method development for evaluation of the fate of chemicals in the human environment.
- Method development to tackle multiple humane effects caused by individual chemicals.

[3] Carcinogenic, Mutagenic or Repro-toxic
[4] Persistent, Bioaccumulative and Toxic
[5] Very Persistent or Very Bioaccumulative

- Development of simplified methods that can be used in case of low data availability that is compatible with more advanced models.
- Selection of models and calculation of non-specific factors corresponding to typical exposure situations.
- Further investigation of the possibility of developing the categories of indoor emissions and working environment.

6.2 More stringent health criteria regarding chemical substances?

The analysis of 6 criteria documents indicates varying coverage of health aspects. To basically achieve a more uniform coverage, a health assessment guideline for criteria development should be elaborated. The guideline should include methods of assessment as well as sources for information on international regulation of chemicals.

Many of the criteria documents only relate to the EU classification system, which is a well-known and well-harmonized system, for evaluation of the hazardous properties of chemical substances. However, this could be supplemented by references to other official lists of substances, such as:

- The EU list of hormone disruptive substances
- Substances evaluated by IARC as belonging to categories 1, 2A and 2B /12/
- The SCCNFP list of allergenic substances
- The EU list of PBT and vPvB substances and the OSPAR list of substances that might potentially give rise to concern
- The EU list of azo-dyes that may not be used in certain textile and leather goods (2003/3/EF)
- The PIC Convention list of harmful substances (applied for elaborating the criteria for textiles)

The scope of the Regulation contains an overall demand that substances which have been classified as acutely toxic or which possess CMR properties according to the EU classification regulations cannot be awarded the Eco-label. In the light of the increased problem with hypersensitivity in the population it seems reasonable that this demand be extended also to include products that are classified as sensitizing. More stringent requirements regarding sensitizing substances should also be considered.

It might also be relevant to expand the general demand for the product classification to include products that are classified as harmful to health or at least as harmful to health with risk phrases related to serious or irreversible effects including R48 (Danger of serious damage to health by prolonged exposure) and R68 (Possible risk of irreversible effects).

Based on the criteria for indoor paints and varnishes, a theoretical example of more stringent criteria regarding content of chemical substances is outlined in Annex 6. An evaluation has not been carried out of the consequences on the number of products that may be able to obtain the Eco-label. The overall result of the analysis is outlined in Table 7

Table 7 Theoretical outline of higher stringency of criteria for ingredients in indoor paints and varnishes

Ingredient	Demand	
	Existing	Tentative proposal
Acutely toxic substances	Ban on substances classified with R23, R24, R35, R26;R27, R28 however ≤ 0.1% for preservatives	Unchanged
Substances harmful to health	No criteria	≤ 25% of substances classified with R20, R21 and/or R22 Ban or limits for substances with R39 R48
Substances with R39, R48	Ban however ≤ 0.1% for preservatives	Unchanged
Substances with CMR effects	Ban on substances classified with R45, R46, R60 and R61	Addition of R49. Addition of < 0.1 % of substances with R40, R62, R63 and R68 (CMR cat. 3) and R64
Heavy metals	Trace of Cd, Pb, Hg, Cr(VI) and As is allowed	≤ 50 ppm for Cd, Pb, Cr(VI), Hg and As, ≤ 100 ppm for Zn, Cr(III), Ni, Co, Mn, V, Mb, Cu
Sensitizing substances	-	Limit corresponding to the classification limit
VOC's	Limit for VOC's w. bp ≤ 250°C	Limit for VOC's w. bp ≤ 280°C
Hormone disruptive substances	-	Ban on content of substances on the EU list of hormone disruptive substances
PBT substances	-	Limit the total volume of PBT substances

6.3 A balanced health and environmental scope of the Regulation?

The Regulation has been examined in order to suggest amendments to the text to include health aspects on equal terms with environmental aspects.

6.3.1 Purpose and principles

Article 1 deals with the purpose and principles of the Regulation. Article 1, sections 1 and 2 may be amended as stated in bold in the text box.

Article 1, sec. 1
The objective of the Community eco-label award scheme (hereafter referred to as the Scheme) is to promote products which have the potential to reduce negative environmental **and health** impacts as compared with the other products in the same product group, thus contributing to the efficient use of resources and a high level of environmental **and health** protection...

Article 1, sec. 2
The environmental **and health** impacts shall be identified on the basis of examination of the interactions of products with the environment **and man** including the use of energy and natural resources, during the life cycle of the product.

6.3.2 Scope

Article 2 deals with the scope of the Regulation. Regulation articles 1 and 2, sec. 2b and c and sec. 3 are suggested to be adjusted as stated below.

Article 2, sec.1
The Community eco-label may be awarded to products available in the Community which comply with the essential environmental **and health** requirements in Article 3 and the eco-label criteria in Article 4...

Article 2, sec. 2b and 2c
b) it shall involve, as one or more stages of the product's life, a significant environmental **and/or health** impact on a global or regional scale and/or of a general nature;
c) it shall present a significant potential for effecting environmental **and/or health** improvements through consumer choice...

Article 2, sec.3
.....and with a view to ensuring the optimal potential of the eco-label for effecting environmental **and/or health** improvements.

Article 2 sec. 4 contains the general demands for classification of products that can obtain the Eco-label.

As discussed in the previous section, the health consideration may be strengthened by extending the general demand for classification of products to also include products classified as sensitizing and harmful to health (possibly only certain R-phrases).

It is suggested that the Regulation article 2 sec. 4 be changed as stated below:

Article 2, sec. 4
The eco-label may not be awarded to substances or preparations classified as very toxic, toxic, dangerous to the environment, carcinogenic, toxic for reproduction, mutagenic**, harmful to health or sensitizing**

When elaborating the general demands for product classification, the basis has been chemical products but it would be possible to cover articles by similar demands, e.g. by adding a demand stating that articles are not allowed to release substances with these classifications.

6.3.3 Environmental requirements

It is suggested to amend the heading of article 3 "Environmental requirements" to "Environmental and health requirements" or "General requirements". Article 3 deals with the methodological basis, and as life cycle methods regarding health are at a preliminary step a demand for life cycle based health assessments should be given a relatively high degree of freedom.

It is suggested to amend article 3 sec. 1and 2 as indicated in the boxes below. It is anticipated that annex 1a and b may refer to the environmental and health assessment matrix respectively (health matrix as suggested in section 6.1).

Article 3 sec. 2a and 2b are suggested to be composed as stated below:

Article 3 sec. 1
The eco-label may be awarded to a product processing characteristics which enable it to contribute significantly to improvements in relation to key environmental **and/or health** aspects, which are linked to the objectives and principles set out in Article 1. These environmental **and health** aspects shall be identified in the light of the indicative assessment matrix in Annex **Ia and Ib** and shall meet the methodological requirements set out in Annex II.

Article 3, sec. 2
a) in evaluating the comparative improvements, considerations should be given to the net environmental and health benefits, including ~~health and~~ safety aspects, associated with the adaptations throughout the various life stages of the products being considered. The evaluation shall also take into account the possible environmental **and health** benefits related to the utilisation of the products considered;
b) the key environmental **and health** aspects shall be determined by identifying the categories of environmental **and health** impacts where the product under examination provides the most significant contribution from a life cycle perspective and among such aspects the ones for which a significant potential for improvement

6.3.4 Annexes

Annex I is suggested to be supplemented by a an assessment matrix regarding health (ref. Section 6.1 of the report).

Annex II describes the methodological requirements for establishment of the eco-label criteria.

ANNEX II
METHODOLOGICAL REQUIREMENTS FOR SETTING ECO-LABEL CRITERIA

Introduction
The process of identifying and selecting the key environmental **and health** aspects as well as setting the eco-label criteria...

Life cycle considerations (LCC)
Key environmental **and health** aspects for which criteria will need to be developed will be defined through life cycle considerations will be performed in accordance with internationally recognized methods and standards. The principles laid down in EN ISO 14040 and ISO 14024 will be duly taken into account, where appropriate.

Improvement analysis
The improvement considerations will take into account in particular the following aspects:

- the theoretical potential for environmental **and health** improvement in conjunction with possible changes in the market structures. This will be based on the improvement assessment from life cycle considerations...
- consumer attitudes, perceptions and preferences **with regard to both environment and health**, which may influence the effectiveness of the eco-label.

Proposal of the criteria
The final ecological criteria proposal will take into account the relevant environmental **and health** aspects related to the product group.

Annex III describes the design of the Eco-label. As mentioned in section 5.3 there is a need for the phrases to be authored in an easily understandable language. It might be relevant to demand that at least one of the phrases be related to health.

Suggestions for amendments and additions to annex III are stated below:

ANNEX III
DESCRIPTION OF THE ECO-LABEL

Shape of the label
The eco-label will be awarded to products which comply with the criteria, for all the selected key environmental **and health** aspects. It will include information for the consumers in accordance with Article 8 and to the following scheme.

Box 2 contains information about the reasons for the award of the eco-label... The information will be in the form of a brief description in words **and will be authored in a clear and easily understandable language. No less than one and no more than three phrases will be stated of which at least one shall pertain to health.**

This is an example:

*	low air pollution
*	energy efficient
*	Low content of **health hazardous** substances

7 Conclusion and recommendations

Analysis of the coverage of health aspects in the EU regulation

The Regulation includes a number of basic requirements regarding health aspects. It is a prerequisite for obtaining an eco-label license for substances and preparations that the substance or preparation is not classified as toxic to human health. Presently, the product groups for which eco-label criteria have been elaborated cover 5 types of preparations (various detergents, paint and lacquer) and no substances. From the text, the base line requirements relate to substances and preparations. Hazardous substances are very seldom purchased by consumers and therefore no criteria would be expected to be elaborated for such substances. The overall coverage of the Regulation could therefore be restricted to preparations alone. It could be worthwhile to try to extend the overall criteria to exclude very toxic substances, PBT, and CMR substances at all from eco-labelled products. This could be a strategic choice to position eco-labels as more stringent than the (forthcoming) REACH regulation.

For goods the requirements are less specific. It is stated that the processes of manufacture "may not significantly harm man and/or environment" and the normal application of the goods may not harm the consumer. In practice, the requirements for preparations are relatively stringent while those for goods are minimum requirements, i.e. that goods shall comply with legislation.

It is recommended, that

- The requirements for substances be specified to cover substances in preparations as it is unlikely that criteria be developed for substances.

- The base line for achievement of eco-label licenses for goods regarding health aspects be made more specific and progressive in line with the base line for preparations.

Analysis of the coverage of health aspects in 6 criteria documents

The analysis of the criteria documents for the chemical preparations and products selected do show that the health-related criteria covered are more stringent for most parameters than the requirements of the related chemicals legislation. The analysis thus supports the conclusion from another study reported in 2004 prepared by BEUC /15/.

The analysis also indicates a varying coverage of health aspects. Although not required only one of the criteria documents actually covers all requirements listed in the scope of the regulation. Some of the criteria documents, however, include other aspects than those listed in the Regulation, e.g. requirements regarding sensitization and hormone disruptive substances.

The relevance of health and environmentally related limits for chemicals may vary for different product groups. It is interesting, however, to note that about

three quarters of the specific limit requirements in the 6 criteria documents relate to environmental aspects, while around half of the requirements (also) relate to health aspects. Therefore, in practice there is a relative balanced coverage between health and environmental issues.

Workers environment is only indirectly covered as the use of highly hazardous substances as raw materials are restricted. There are, however, no requirements regarding auxiliary substances and preparations and no requirements for other aspects related to occupational health (physical environment).

It is recommended that

- A more uniform coverage of health aspects in the criteria documents be achieved. A health impact assessment guideline for criteria development should therefore be elaborated. The guideline should include methods of assessment as well as sources for information on international regulation of chemicals.

- The ongoing revision of the regulation should as a minimum be updated to reflect the state-of-the-art regarding criteria requirements as preparations and goods in general have more limitations regarding classified substances and preparations than those identified in the scope of the regulation, e.g. preparations classified as sensitizing (R42, R43).

- The ongoing revision of the regulation takes note of the present relative balanced coverage in the criteria documents of health and environmental aspects regarding chemicals.

A more balanced focus on environment and health in the regulation

The Eco-label should take into account consumer preferences as an important part of the coverage of criteria documents to facilitate licensees' successful marketing of labelled products.

Although the analysed criteria documents indicate a relative good balance between health and environmental requirements this is not reflected in the Regulation. As a minimum, it should be considered to update the Regulation to cover the state-of-the-art regarding health coverage in the criteria documents.

It is suggested that a succeeding revision of the Regulation be more progressive in order to be in line with consumer preferences and potential applicants' focus on sustainable development.

A number of amendments of the articles of the Regulation are proposed in the present report to balance the scope regarding health and environment. If this balance is to be achieved in the ongoing Regulation revision, also the methodological foundation needs revision. In addition to the guidance regarding health assessment mentioned above, also a life cycle framework for health assessments would be required in the form of a supplement to Annex 1 of the Regulation regarding an "indicative assessment matrix" for both environment and health.

It is recommended that

- The ongoing revision of the Regulation seeks to include health in parallel to environmental issues.

- Health aspects be covered in a life cycle perspective in line with environmental loads.

REACH and the EU eco-label

The new EU regulation for chemical substances (REACH) is expected to be adopted in 2007 with an 11 years' implementation period. The new regulation aims at ensuring that chemical substances produced or imported above a certain tonnage level are not to be marketed, unless the producer or importer is able to ensure that the substance may be used without significant harmful effects to health and environment.

The Eco-label Regulation and criteria documents should be positioned ahead of the implementation of REACH to facilitate those industry branches/companies implementing the regulation ahead of the implementation deadline with an information tool to signalise this proactive measure to the customers.

According to REACH highly hazardous substances will require an authorisation before they may be used. The category of substances to be covered by an authorisation is carcinogenic, mutagenic and repro-toxic substances, highly toxic substances, and persistent and bioaccumulative substances. Other substances of concern may be subject to authorisation as well. The Eco-label regulation should set requirements to facilitate that such substances be gradually eliminated from eco-labelled products (preparations and goods).

It is recommended that

- An analysis of REACH requirements be made to assess the possibilities of the Eco-label to be more stringent and move ahead of REACH.

- The Eco-label regulation set requirements for all hazardous substances in the final product, also at levels of volume where REACH requirements are not enforced.

- The special restrictions to be implemented under REACH in the form of an authorisation of highly hazardous substances be included in the base line (scope) of the Regulation to facilitate that such substances be gradually phased out of eco-labelled product.

8 References

1. Regulation (EC) No. 1980/2000 on the European Parliament and of the Council of 17 July 2000 on a revised Community eco-label award scheme. Off. J. European Com. L237, 21.9.2000.

3. Directive 1967/548/EEC on Classification, Packaging and Labelling of Substances.

4. Directive 1999/45/EEC on Classification, Packaging and Labelling of Substances and Preparations

5. Directive 91/155/EEC as amended by EU Directive 2001/58 on Safety Data Sheets

6. Commission Decision of 29 November 2002 establishing the ecological criteria for the award of the Community eco-label to detergents for dishwashers. 2003/31/EC

7. Commission Decision of 3 September 2002 establishing revised ecological criteria for the award of the Community eco-label to indoor paints and varnishes and amending Decision 1999/10/EC, 2002/739/EC, (2002).

8. Commission Decision of 23 March 2005 establishing the ecological criteria for the award of the Community eco-label to hand dishwashing detergents. 2005/342/EC

9. Commission Decision of 15 May 2002 establishing the ecological criteria for the award of the Community eco-label to textile products. 2002/371/EC

10. Commission Decision of 14 February 2003 establishing the ecological criteria for the award of the Community eco-label to laundry detergents. 2003/200/EC

11. Commission Decision of 23 March 2005 establishing the ecological criteria for the award of the Community eco-label to all-purpose cleaners and cleaners for sanitary facilities, 2005/344/EC.

12. IARC Overall Evaluations of Carcinogenicity to Humans. As evaluated in *IARC Monographs* Volumes 1-82 (a total of 885 agents, mixtures and exposures). 9-1-2004.

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14. Wenzel H, Hauschild M, Alting L. Environmental Assessment of Products. Volume 1: Methodology, tools and case studies in product devel-

opment. Kluwer Academic Publishers; 2000.

15. BEUC 2004. The EU Eco-label - Less hazardous chemicals in everyday consumer products. BEUC/X/010/2004

Annex 1 Analysis of selected criteria sets

1A Indoor paints and varnishes

Purpose

- to promote efficient product use and to reduce the amount of waste to a minimum
- to limit the environmental risk and other risks (such as tropospheric ozone degradation) by reducing the emissions from solvents
- to reduce discharges of toxic and in other way polluting substances to aquatic environments.

Area

The product group ”indoor paints and varnishes” includes indoor decorative paints, varnishes, stain and similar products meant for consumers or professional users, and that primarily have been developed for indoor use and are marketed as such.

Corrosion protection agents, anti-fouling paints, wood preservatives and special surface coatings for special industrial uses (e.g. thick-film paints and two-component products) are not included in the product group.

Health-related criteria

Classification:
The product may not be classified as toxic (T), very toxic (Tx) and/or carcinogenic, mutagenic or repro-toxic (CMR).

Regulation of specific ingredients:
The product may not contain *substances* that are classified as

- acutely toxic (R23, R24, R25; R26, R27, R28, R39[6]) unless the substance is a preservative and is found in a concentration of $\leq$ 0.1%.[7]
- CMR[8] in categories 1 and 2 (R45, R46, R60, R61)
- R48 (Danger of serious damage to health by prolonged exposure)

The product may only contain traces from raw materials of Cd, Pb, Cr(VI) and As, but a more accurate limit has not been specified.

[6] See annex 3 for the wording of the R-phrases.
[7] R68 ” Possible risk of irreversible effects” is not regulated R68 is included in Directive 1999/45/EC /5/, but in the previous Directive 88/379/EEC R40 had this wording (Possible risk of irreversible effects). However, R40 (in its previous meaning) has neither been regulated in the criteria for indoor paints and varnishes.
[8] **C**arcinogenic, **M**utagenic, **R**epro-toxic

Some of the regulated substances have been evaluated by IARC /12/. Cd, Cr(VI) and As have been evaluated by IARC as belonging to group 1, formaldehyde has been categorised in group 2A and Pb is in group 2B[9].

Exposure:
Exposure during use has only been regulated indirectly through the demands for ingredients. There are no special demands for physical state of the product (liquid, aerosol) or for application method (brush, spraying).

The effect of the product during the application phase and through the indoor climate has been indirectly regulated through the criteria for volatile organic compounds (VOC's), volatile aromatic hydrocarbons (VAH's) and free formaldehyde. There are limit values for the content of VOC's with a boiling point of < 250°C at normal pressure and VAH's with a boiling point of < 250°C at normal pressure and at least one aromatic ring. In addition, there is a limit value for the content of free formaldehyde.

There are no special criteria for the working environment during production apart from the indirect benefit appearing from the criteria for the substances that may be used as raw materials. For products containing the white pigment TiO_2, limit values have been established for the discharge of SOx for air, sulphate and chloride waste.

Summary

The point of origin for all the criteria are environmental considerations, but several of the criteria also cover health aspects (table A).

Criteria	Environment	Health
1. White pigments	x	
2. Volatile organic compounds	x	x
3. Volatile aromatic hydrocarbons	x	x
4. Heavy metals	x	x
5. Dangerous substances	x	x
6. Fitness for use	x	

Table A. Indoor paints and varnishes. Environment and health coverage.

	Ban	Limitation	Declaration
Product level	T, Tx and CMR	-	-
Substance level	CMR cat. 1 and 2 R48	≤ 0.1% preservatives with T or Tx VOC VAH Free formaldehyde Cd, Cr(VI), As, Pb Isothiazolinons	-

The criteria establishes requirements regarding the content of toxic and very toxic substances as well as certain carcinogenic, repro-toxic and mutagenic substances in categories 1 and 2. The demands for the content of VOC's, VAH's and formaldehyde will benefit the indoor climate properties of the products.

[9] See the meaning of the IARC groups in annex 5.

There are no direct limits for the content of substances that may cause cancer or allergy through inhalation(R49: may cause cancer by inhalation). No demands have been established for the content of substances with R68 (possible risk of irreversible effects).

1B Textile products

Purpose

- to limit the water pollution in connection with the central processes of the textile production chain including fibre production, spinning, weaving, knitting, bleaching, dying and aftercare
- to promote labelling of textile products with a lower environmental load.

Area

The product group ”textile products” includes furnishing fabrics, accessories (such as bags) and clothing fabrics including fibres, yarn and fabrics sold by the metre.
Wall and floor coverings are not included in the product group.

Health-related criteria

The criteria document covers 40 different specific requirements in 3 areas: textile fibres, processes and chemicals and usability. Most of the requirements are environmentally based but a considerable number of the requirements also cover health considerations (Table B).

Regulation of specific ingredients:
The product may not contain dyes, flame retardants and aftercare agents that may be classified as

- CMR in categories 1, 2 and 3 (R40, R45, R46, R49, R60, R61, R63, R68) unless the substance/mixture/agent is found in a concentration of $\leq$ 0.1%

Limit values have been established for the content of the metals Ag, As, Ba, Cd, Co, Cr, Cu, Fe, Hg, Mn, Ni, Pb, Se, Sb, Sn, Zn when they are found as impurities in dyes and pigments. When the metals are included as an integrated part of a metal-complex dye or a reactive dye, there is no limit value. A limit value has been established for the content of formaldehyde in the product and the product may not contain a number of specified dyes – including azo-compounds that are carcinogenic, or that may split off carcinogenic amines.

Some of the regulated substances are found on the IARC list of carcinogenic substances. Chlordane, DDT, toxaphene, hexachlorobenzene, certain organic tin compounds and PCB are furthermore on the EU list of hormone-disrupting substances.

Biocides are only to be used as a preservative of the product.

Exposure:
The product’s influence on the indoor climate is only regulated through the criteria for formaldehyde.

For the manufacturing of various *fibre types* there are demands for emissions to the air for the substances acrylnitril, aromatic diisocyanates, S, N_2O, VOC

Criteria	Environment	Health
Textile fibre criteria:		
1. Acrylic	x	x
2. Cotton and other natural cellulosic seed fibres	x	x
3. Elastane	x	x
4. Flax and other bast fibres	x	
5. Greasy wool and other keratin fibres	x	x
6. Man-made cellulose fibres	x	
7. Polyamide	x	
8. Polyester	x	x
9. Polypropylene	x	x
Processes and chemical criteria		
10. Auxiliaries and finishing agents for fibres and yarns	x	x
11. Biocidal or biostatic products	x	x
12. Stripping or depigmentation	x	x
13. Weighting	x	x
14. Auxiliary chemicals	x	
15. Detergents, fabric softeners and complexing agents	x	
16. Bleaching agents	x	
17. Impurities in dyes	x	x
18. Impurities in pigments	x	x
19. Chrome mordant dyeing	x	x
20. Metal complex dyes	x	
21. Azo dyes	x	x
22. Dyes that are carcinogenic, mutagenic or toxic to reproduction		x
23. Potentially sensitising dyes		x
24. Halogenated carriers for polyester	x	x
25. Printing	x	x
26. Formaldehyde		x
27. Waste water discharges from wet-processing	x	
28. Flame retardants	x	x
29. Shrink resistant finishes	x	x
30. Finishes	x	x
31. Fillings	x	x
32. Coatings, laminates and membranes	x	x
33. Energy and water use	x	

Table B. Textile products. Environment and health coverage.

	Ban	Limitation	Declaration
Product level	-	-	-
Substance level	Azo-compounds 9 dyes Aromatic diisocy-anates* Heavy metals (minus Fe)* Formalde-hyde* Ce*	< 0.1% CMR* Ag* As* Ba* Cd* Co* Cr* Cu* Fe* Hg* Mn* Ni* Pb* Se* Sb* Sn* Zn* Formaldehyde Pesticides Acrylnitril* Aromatic diisocyanates* VOC* Chlorphenoles* PCB* Organic tin compounds* 18 dyes	-

*: Only certain ingredients or processes

The criteria document includes a high number of very specific criteria. The demands are related to specific substance groups instead of substances with specific properties. A number of substances applied for textile production have been banned – including certain azo-dyes.

Chronic health effects have been considered through the ban against content of dyes, flame retardants and aftercare products classified as CMR in categories 1, 2 and 3. However, there is no demand that the product may not contain other types of substances classified regarding CMR effects. Polyester for example may contain up to 260 ppm Sb – SbO_3, which is used as catalyst in polyester manufacturing, and classified as carcinogenic in category 3.

Sensitizing substances and substances classified as R48 have not been restricted and the content of toxic, very toxic and irritating substances is not considered.

1C Laundry detergents

Purpose

- to reduce the transport and energy consumption by favouring compact textile detergents
- to reduce contamination of water by reducing the amount of chemicals used in the product and by limiting the use of potentially harmful ingredients
- to minimize the production of waste by limiting the amount of packaging.

Area

Detergents primarily intended for use in household. The detergent may be powder, liquid or any other physical form for washing of textiles.

Health-related criteria

Classification:
The product may not be classified as R43 (may cause sensitisation by skin contact).

The product may not contain *substances* classified as

- CMR in categories 1, 2 and 3 (R40, R45, R46, R49, R60, R61, R62, R63, R68) unless the substance is found in a preparation in a concentration of $\leq$ 0.01% of the final product
- R64: "May cause harm to breastfed babies" unless the substance is found in a preparation in a concentration of $\leq$ 0.01% of the final product.

All criteria are based on environmental considerations, but a few criteria also include health aspects (table C).

Criteria	Environment	Health
1. Total chemicals	x	x
2. Insoluble inorganic ingredients	x	
3. Toxicity to aquatic organisms	x	
4. Phosphates	x	
5. Biodegradability of surfactants	x	
6. Dangerous, hazardous or toxic substances or preparations	x	x
7. Purity of enzymes	x	x
8. Packaging requirements	x	

Table C. Laundry detergents. Environment and health coverage.

	Ban	Limitation	Declaration
Product level	R43	-	-
Substance level	Nitromoskus and polycyclic musk compounds NTA Micro-organisms	$\leq$ 0.01% CMR and R64	Enzymes Preservatives Disinfectants Perfume (unspecified, but shall fulfil detergent regulation)

The restrictions regarding the total amount of chemicals will also be a benefit to health. The criteria also lists demands the content of carcinogenic, reprotoxic and mutagenic substances.

There are no criteria for the content of toxic, very toxic, irritating and sensitizing substances. There are no considerations regarding the physical state of the product – e.g. a recommendation for tablets and liquid instead of powder.

Chronic health effects have been considered as the product may not contain substances classified as CMR in categories 1, 2 and 3. However, the Eco-label may be awarded to products classified with R42 (may cause sensitisation by inhalation) and products with a content of allergens as well as substances with R48. Content of the allergenic nitromusk and polycyclic musk compounds as well as NTA suspected of being carcinogenic is, however, not allowed.

1D All purpose cleaners and cleaners for sanitary facilities

Purpose

- to reduce the environmental impact by limiting the amount of harmful ingredients, detergents used and the amounts of packaging
- to reduce or prevent environmental or *health* risks related to the use of hazardous substances
- to provide information enabling the consumer to use the product efficiently to minimize the environmental impact.

Area

The product group ”all-purpose cleaners & cleaners for sanitary facilities” is divided into 2 parts – all-purpose cleaners and cleaners for sanitary facilities. The criteria include products for both private and professional use.

All-purpose cleaners include products that are dissolved or diluted in water for regular cleaning of floors, walls, ceilings and other solid surfaces. Also window cleaners are included.

Cleaners for sanitary facilities include products for regular removal of dirt or deposits in sanitary facilities such as washrooms, bathrooms, shower rooms and toilets as well as kitchens.

Health-related criteria

Classification:
The product may not be classified as R42 (may cause sensitisation by inhalation) and R43 (may cause sensitisation by skin contact).

The product may not contain *substances* classified as
- CMR in categories 1, 2 and 3 (R40, R45, R46, R49, R60, R61, R62, R63)
- R68 “Possible risk of irreversible effects”
- R64 ”May cause harm to breastfed babies”
- R31 ”Contact with acids liberates toxic gas”
- R42 and R43

The requirements apply to ingredients that exceeds 0.01% by weight of the final product (0.1% regarding substances classified by R42 and R43)

Regulation of specific ingredients:
The use of the nitromusk and polycyclic musk compounds as well as NTA suspected of being carcinogenic is not allowed. The overall content of other allergens and substances classified with R48 ”Danger of serious damage to health by prolonged exposure” are not regulated.

A limit on the content of VOC’s with a boiling point of < 150^{o}C has been established. Biocides may only be used for preservation of the product.

All fragrances must be manufactured and handled according to the International Fragrance Association guidelines. The criteria require the compliance with the Detergent regulation (648/2004/EC) where requirements regarding fragrances are included. The criteria is thus reduced in relative stringency related to the regulation compared to the former criteria document.

Dyes and colouring agents must comply with the cosmetic and food stuff regulation.

The majority of the criteria is motivated by environmental concern, but a significant part are also relevant for health (table D).

Criteria	Environment	Health
1. Eco-toxicity and biodegradability	x	
2. Phosphorus and phosphonates	x	
3. Anaerobic biodegradability of surfactants	x	
4. Hazardous substances or preparations	x	x
5. Volatile organic compounds	x	x
6. Dyes or colouring agents		x
7. Fragrances		x
8. Sensitizing substances		x
9. Biocides	x	x
10. Packaging requirements	x	

Table D. All-purpose cleaners and cleaners for sanitary facilities. Environment and health coverage.

	Ban	Limitation	Declaration
Product level	R42 and R43	-	-
Substance level	Nitromusks and polycyclic musks NTA Glutaraldehyde	≤ 0, 01% CMR, R64 and R31 VOC Biocides	-

There are no direct demands for absence of toxic, very toxic and allergenic substances. The product may not be classified as sensitizing, but this does not exclude a content of allergenic substances as the general limit for substances with R43 is 0.1%.

Acute health effects have not been taken into account based on the classification criteria.

Chronic health effects have been taken into account as products are not allowed to contain substances classified as CMR in categories 1, 2 and 3.

There are no considerations regarding the physical form of the product such as a recommendation of paste and liquid instead of powder and spray.

As for laundry detergents no requirements have been included, that a product awarded the Eco-label may not belong to hazard classes T and Tx /8/. A reason may be that products belonging to these classes do not appear at the market.

1E Dish washers detergents

Purpose

- to reduce water pollution by both limiting the amount of detergent used as well as its content of harmful substances

- to reduce energy consumption by promoting detergents working at low temperatures
- to minimize the production of waste by limiting the amount of packaging.

Area

All detergents for automatic dishwashers in the household along with all detergents for automatic dishwashers for professional use. For professional use only as long as the dishwasher is similar to those used in private households.

Health-related criteria

Classification:
There are no demands for the classifications of *the product*.

The product may not contain *substances* classified as
- CMR in categories 1, 2 and 3 (R40, R45, R46, R49, R60, R61, R62, R63, R68) unless the substance is found in a preparation in a concentration of $\leq$ 0.01% of the final product
- R64 unless the substance is found in a preparation in a concentration of $\leq$ 0.01% of the final product

Acute health effects:
Acute health effects have not been considered based on the classification criteria.

Chronic health effects:
Chronic health effects have been considered as the product is not allowed to contain substances classified as CMR in categories 1, 2 and 3.

There are no demands regarding substances classified as sensitizing, allergenic substances or substances classified with R48.

Regulated ingredients:
The allergenic nitromusk and polycyclic musk compounds as well as NTA, which is suspected of being carcinogenic, are not allowed.

	Ban	Limitation	Declaration
Product level	-	-	-
Substance level	Nitromusk and polycyclic musk compounds NTA Micro-organisms	$\leq$ 0.01% CMR and R64	Enzymes Preservatives Perfume (unspecific)

The majority of the criteria is motivated by environmental considerations but a minor part also relate to health considerations (table E).

Criteria	Environment	Health
1. Environmental scoring matrix	x	
2. Biodegradability of surfactants	x	
3. Dangerous, hazardous or toxic substances or preparations	x	x
4. Fragrances		x
5. Packaging	x	
7. Purity of enzymes	x	x

Table E. Detergents for dishwashers. Environment and health coverage.

1F Hand dishwashing detergents

Purpose

- to reduce the discharge of toxic and otherwise polluting substances to the aquatic environment
- to reduce or prevent risks to *health* and environment related to the use of hazardous substances
- to minimize packaging waste
- information enabling the consumer to use the product efficiently to minimize environmental impact.

Area

The product group include all detergents intended to be used for hand dish washing and cover products for both private and professional use.

Health-related criteria

Classification:
The product may not be classified as R42 and R43.

The product may not contain *substances* classified as
- CMR in categories 1, 2 and 3 (R40, R45, R46, R49, R60, R61, R62, R63)
- R68 "Possible risk of irreversible effects"
- R64 "May cause harm to breastfed babies"
- R31 "Contact with acids liberates toxic gas"
- R42 and R43

The requirements apply to ingredients that exceeds 0.01% by weight of the final product (0.1% regarding substances classified by R42 and R43)

Regulation of specific ingredients:
The use of the nitromusk and polycyclic musk compounds as well as NTA suspected of being carcinogenic is not allowed. The overall content of other allergens and substances classified with R48 "Danger of serious damage to health by prolonged exposure" are not regulated.

A limit on the content of VOC's with a boiling point of < 150°C has been established. Biocides may only be used for preservation of the product.

All fragrances must be manufactured and handled according to the International Fragrance Association guidelines. The criteria require the compliance with the Detergent regulation (648/2004/EC) where requirements regarding fragrances are included. The criteria is thus reduced in relative stringency related to the regulation compared to the former criteria document.

Dyes and colouring agents must comply with the cosmetic and food stuff regulation.

The majority of the criteria is motivated by environmental concern, but a significant part are also relevant for health (table F).

Criteria	Environment	Health
1. Toxicity to aquatic organisms	x	
2. Biodegradability of surfactants	x	
3. Dangerous, hazardous or toxic substances or preparations	x	X
4. Fragrances		X
5. Dyes or colouring agents		X
6. Biocides	x	X
7. Sensitising substances		X
8. Limitations of surfactants per wash	x	
9. Packaging requirements	x	

Table F. Hand dishwashing detergents. Environment and health coverage.

	Ban	Limitation	Declaration
Product level	R42 and R43 Any fragrances in professional products	-	-
Substance level	Nitromusk and polycyclic musk compounds NTA	$\leq$ 0.01% CMR and R64 Biocides	13 fragrances

There are no direct demands regarding the content of toxic, very toxic and allergenic substances.

Annex 2 Schematic overview of criteria

The coverage of environmental and health classifications according to /3,4/ is outlined below for the product groups analysed.

Product	Classification - Substance level																																	
	R23	R24	R25	R26	R27	R28	R31	R39	R40	R42	R43	R45	R46	R48	R49	R50	R51	R52	R53	R50/53	R51/53	R59	R60	R61	R62	R63	R64	R68	Tx	T	N	Carc	Mut	Rep
Paint & varnish	x	x	x	x	x	x		x				x	x	x		x	x	x	x	x	x		X	x										
Laundry detergents									x			x	x		x					x	x	x	X	x	x	x	x	x						
All-purpose cleaners & cleaners for sanitary facilities							x		x	x	x	x	x		x					(x)	(x)	x	X	x	x	x	x	x						
Hand dishwashing detergents									x	x	x	x	x		x					(x)	(x)	x	X	x	x	x	x	x						
Detergents for dishwashers									x			x	x		x					x	x		X	x	x	x	x	x						
Textile									(x)			(x)	(x)		(x)	(x)	(x)	(x)	(x)	(x)	(x)		(x)	(x)	(x)	(x)		(x)						

Product	Classification - Product level																																	
	R23	R24	R25	R26	R27	R28	R31	R39	R40	R42	R43	R45	R46	R48	R49	R50	R51	R52	R53	R50/53	R51/53	R59	R60	R61	R62	R63	R64	R68	Tx	T	N	Carc	Mut	Rep
Paint & varnish																													x	x	x	x	x	x
Laundry detergents											x																							
All-purpose cleaners & cleaners for sanitary facilities										x	x																							
Hand dishwashing detergents										x	x																							
Detergents for dishwashers																																		
Textile																																		

Product	Effects		LCA - raw material	LCA - product			Use phase (consumer)	Working environment	Waste	Indoor climate	Exposure	LOUS	Endocrine disrupters
	Chronic	Acute	Effluents/emissions	Effluents/emission	Transport & storage	Packaging							
Paint & varnish	x	x	x				x	x		x	x	x	
Laundry detergents	x						x	x	x		x	x	
All-purpose cleaners & cleaners for sanitary facilities	x					x	x	x		x	x	x	
Hand dishwashing detergents	x						x	x	x		x	x	
Detergents for dishwashers	x						x	x	x			x	
Textile	(x)		x	x	x		x	x		x		x	x

Annex 3 List of R- and S-phrases

R-phrases

R1 Explosive when dry.
R2 Risk of explosion by shock, friction, fire or other sources of ignition.
R3 Extreme risk of explosion by shock, friction, fire or other sources of ignition.
R4 Forms very sensitive explosive metallic compounds.
R5 Heating may cause an explosion.
R6 Explosive with or without contact with air.
R7 May cause fire.
R8 Contact with combustible material may cause fire.
R9 Explosive when mixed with combustible material.
R10 Explosive when dry.
R11 Highly flammable.
R12 Extremely flammable.
R14 Reacts violently with water.
R15 Contact with water liberates extremely flammable gases.
R16 Explosive when mixed with oxidising substances.
R17 Spontaneously flammable in air.
R18 In use, may form flammable/explosive vapour-air mixture.
R19 May form explosive peroxides.
R20 Harmful by inhalation.
R21 Harmful in contact with skin.
R22 Harmful if swallowed.
R23 Toxic by inhalation.
R24 Toxic in contact with skin.
R25 Toxic if swallowed.
R26 Very toxic by inhalation.
R27 Very toxic in contact with skin.
R28 Very toxic if swallowed.
R29 Contact with water liberates toxic gas.
R30 Can become highly flammable in use.
R31 Contact with acids liberates toxic gas.
R32 Contact with acids liberates very toxic gas.
R33 Danger of cumulative effects.
R34 Causes burns.
R35 Causes severe burns.
R36 Irritating to eyes.
R37 Irritating to respiratory system.
R38 Irritating to skin.
R39 Danger of very serious irreversible effects.
R40 Limited evidence of a carcinogenic effect.
R41 Risk of serious damage to eyes.
R42 May cause sensitisation by inhalation.
R43 May cause sensitisation by skin contact.
R44 Risk of explosion if heated under confinement.
R45 May cause cancer.
R46 May cause heritable genetic damage.

R48 Danger of serious damage to health by prolonged exposure.
R49 May cause cancer by inhalation.
R50 Very toxic to aquatic organisms.
R51 Toxic to aquatic organisms.
R52 Harmful to aquatic organisms.
R53 May cause long-term adverse effects in the aquatic environment.
R54 Toxic to flora.
R55 Toxic to fauna.
R56 Toxic to soil organisms.
R57 Toxic to bees.
R58 May cause long-term adverse effects in the environment.
R59 Dangerous for the ozone layer.
R60 May impair fertility.
R61 May cause harm to the unborn child.
R62 Possible risk of impaired fertility.
R63 Possible risk of harm to the unborn child.
R64 May cause harm to breastfed babies.
R65 Harmful: may cause lung damage if swallowed.
R66 Repeated exposure may cause skin dryness or cracking.
R67 Vapours may cause drowsiness and dizziness.
R68 Possible risk of irreversible effects.

S-phrases

S1 Keep locked up.
S2 Keep out of reach of children.
S3 Keep in a cool place.
S4 Keep away from living quarters.
S5 Keep contents under... (suitable liquid to be specified by the manufacturer)
S6 Keep under ... (inert gas to be specified by the manufacturer)
S7 Keep container tightly closed.
S8 Keep container dry.
S9 Keep container in a well ventilated place.
S12 Do not keep the container sealed.
S13 Keep away from food, drink and animal feeding stuffs.
S14 Keep away from ... (incompatible materials to be indicated by the manufacturer)
S15 Keep away from heat.
S16 Keep away from sources of ignition - No smoking.
S17 Keep away from combustible material.
S18 Handle and open container with care.
S20 When using do not eat or drink.
S21 When using do not smoke.
S22 Do not breathe dust.
S23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer)
S24 Avoid contact with skin.
S25 Avoid contact with eyes.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S27 Take off immediately all contaminated clothing.
S28 After contact with skin, wash immediately with plenty of ... (to be specified by the manufacturer)
S29 Do not empty into drains.
S30 Never add water to this product.

S33 Take precautionary measures against static discharges.
S35 This material and its container must be disposed of in a safe way.
S36 Wear suitable protective clothing.
S37 Wear suitable gloves.
S38 In case of insufficient ventilation, wear suitable respiratory equipment.
S39 Wear eye/face protection.
S40 To clean the floor and all objects contaminated by this material use ... (to be specified by the manufacturer)
S41 In case of fire and/or explosion do not breathe fumes.
S42 During fumigation/spraying wear suitable respiratory equipment (appropriate wording to be specified by the manufacturer)
S43 In case of fire use ... (indicate in the space the precise type of fire-fighting equipment. If water increases the risk add - Never use water)
S45 In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).
S46 If swallowed seek medical advice immediately and show this container or label.
S47 Keep at temperature not exceeding ...°C. (to be specified by the manufacturer)
S48 Keep wet with ... (appropriate material to be specified by the manufacturer)
S49 Keep only in the original container.
S50 Do not mix with ... (to be specified by the manufacturer)
S51 Use only in well-ventilated areas.
S52 Not recommended for interior use on large surface areas.
S53 Avoid exposure - obtain special instruction before use.
S56 Dispose of this material and its container to hazardous or special waste collection point.
S57 Use appropriate containment to avoid environmental contamination.
S59 Refer to manufacturer/supplier for information on recovery/recycling.
S60 This material and its container must be disposed of as hazardous waste.
S61 Avoid release to the environment. Refer to special instructions/safety data sheet.
S62 If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.
S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.
S64 If swallowed, rinse mouth with water (only if the person is conscious).

Annex 4 List of abbreviations

ADI	acceptable daily intake
Ag	silver
AHWG	ad hoc working group
AOX	absorbable organic halogens
APEO	alkylphenol ethoxylate
As	arsenic
Ba	barium
Cd	cadmium
CMR	carcinogenic, mutagenic and reprotoxic
Co	cobalt
COD	chemical oxygen demand
Cr	chromium
Cu	copper
DDT	dichlorodiphenyltrichloroethane
DHTDMAC	di(hardened tallow)dimethyl ammonium chloride
DSDMAC	distearyl dimethyl ammonium chloride
DTDMAC	bis(hydrogenated tallow alkyl)dimethyl ammonium chloride
DTPA	diethylentriaminopenta acetic acid
EDB	ethylene dibromide
EDTA	ethylendiamintetraacetat
EUEB	The European Union Eco-labelling board
Fe	iron
Hg	mercury
IUPAC	International Union of Pure and Applied Chemistry
LCA	Life cycle assessment
Mn	manganese
Ni	nickel
NOAEL	no observed adverse effect level
NTA	nitrilotriacetate
N_2O	nitrous oxide
Pb	lead
PCB	polychlorinated biphenyls
PEC	predicted exposure concentration
PNEC	predicted no effect concentration
S	sulphur
Sb	antimony
Se	selenium
Sn	tin
T	temperature
TDI	tolerable daily intake
V	vanadium
VAH	volatile aromatic hydrocarbons
VOC	volatile organic compounds
Zn	zinc

Annex 5 Overview of IARC groups

Group 1	Substances on the list in group 1 are carcinogenic due to sufficient evidence of carcinogenic properties in humans.
Group 2A	Substances on the list in group 2A are probably carcinogenic based on limited data for carcinogenic properties in humans but sufficient evidence from animal testing.
Group 2B	Substances on the list in group 2B are possibly carcinogenic based on limited data for carcinogenic properties in humans and less than sufficient evidence from animal testing.

Annex 6 Theoretical proposal for amendments to criteria for paints and varnishes to improve health coverage

This annex contain a theoretical exercise with the aim to illustrate how the criteria for paints and varnishes may be supplemented to cover health aspects.

The existing criteria regarding chemicals in indoor paints and varnishes are supplemented with requirements regarding health aspects as outlined below..

Ingredients/ classification	Criteria Requirements	
	Existing criteria	Supplementary Health aspects
Toxicity class. R23 – R28	Ban or ≤ 0.1% for preservatives	Ban or ≤ 0.1% for preservatives
Health hazard R20 – R22	-	≤ 25%
CMR	Ban for categories 1 and 2 (minus R49)	Ban for categories 1 and 2, ≤ 0.1% for category 3
Prolonged exposure R39, R48	Ban or ≤ 0.1% for preservatives	Ban or ≤ 0.1% for preservatives
Heavy metals	Traces from raw materials for Cd, Pb, Hg, Cr(VI) and As are allowed	≤ 50 ppm for Cd, Pb, Cr(VI), Hg and As, ≤ 100 ppm for Zn, Cr(III), Ni, Co, Mn, V, Mb, Cu
Allergens R42, R43	-	≤ 0.01% corresponding to the classification limit
VOC's	Limit values for VOC's w. bp ≤ 250°C	Limit value for VOC's w. bp ≤ 280°C
Corrosive and irritating subst. R34 – R38, R41	-	Possible declaration demand

Very toxic and toxic substances:
Toxic and very toxic substances are completely banned in the present set of criteria unless they are preservatives for which there is an allowed content of up to 0.1 %. This demand is more stringent than the limit for classification in the hazard class "Harmful", which is 3 % for substances classified in hazard class "Toxic" and 1 % for substances classified in hazard class "Very toxic", respectively. Formaldehyde classified as T;R23/24/25 C;R34 Carc3;R40 R43 has a limit of 0.001 % for free formaldehyde. The requirements of the existing criteria thus cover health in an appropriate way.

Health hazardous substances:
There are no demands for the content of health hazardous substances in the existing criteria. A limit of max 25 % is suggested which is the limit for a classification of the product as health hazardous. The consequence of this will be that products classified as health hazardous to health cannot obtain the Ecolabel.

CMR-substances:
Except for substances classified with R49 (”May cause cancer by inhalation”), the present criteria contain bans on content of CMR substances in categories 1 and 2. It is suggested that the ban is supplemented by a ban on substances classified with R49 and a limit of 0.1% for substances in category 3. The demand for formaldehyde, which is Carc3, is already lower than this limit and will therefore not be in conflict with this new demand.

Effects from prolonged use (R39, R48):
The same demands are made for content of toxic and very toxic substances. The requirements of the existing criteria thus cover health in an appropriate way.

Heavy metals:
Cadmium (Cd), lead (Pb), chromium IV (Cr(VI)), mercury (Hg) and arsenic (As) may not be used as ingredients in the product – neither as substances nor as part of a preparation according to the present criteria. However, there is no ban on trace amounts of the metals in the raw materials. It is suggested that this is specified through a ban on occurrence of Hg and Cd above the detection limit as well as a maximum limit value of 50 ppm for Pb, As and Cr(VI) for the content in the raw materials in the same way as is demanded for the Dutch eco-label.

It is suggested that the demand be extended to cover zinc (Zn), chromium III (Cr(III)), nickel (Ni), cobalt (Co), manganese (Mn), vanadium (V), molybdenum (Mb) and copper (Cu) and a limit of maximum 100 ppm is suggested. The heavy metals mentioned are used in pigments and siccatives. The suggestion may be problematic with regard to siccatives as they often contain Co.

Allergenic effects (R42 and R43):
The present criteria do not include requirements regarding the content of allergenic substances except for regulations on content of isothazolinons, which are known allergens, and used as preservatives. For the combined content of isotiazolinons, a limit of 500 ppm (0.05 %) has been established as the content of kathon (a mixture of 5-chlor-2-methyl-2H-isothiazol-3-on and 2-methyl-2H-isothiazol-3-on in the ration 3:1) may not at the same time exceed 15 ppm. Instead of isothiazolinons it is possible to use sodium benzoate or parabens as preservative. As an example, methylparaben – E218 – is used in natural paint.

It is suggested that the criteria be supplemented by a general demand that the product may not contain more than 1 % of substances classified with R43.

Volatile substances (VOC’s):
In the present criteria, VOC’s are defined as all organic compounds with a boiling point of $\leq 250^{\circ}C$. It is suggested that this limit be raised to $280^{\circ}C$ in order to include the glycol ether Texanol in the criteria. Natural paint contains no VOC’s as linseed oil has a boiling point above $316^{\circ}C$.
A number of fragrances will be included in this criteria, as they are volatile but they are probably not added in the same amounts.

Corrosive and irritating substances (R35, R34; R38, R41):
The content of corrosive and irritating substances are not regulated in the existing criteria. Some preservatives such as aldehydes, nonylphenoles and a number of solvents such as toluene, xylene and some glycol ethers are irritat-

ing. It is difficult to evaluate whether it is possible to manufacture a paint with these requirements unless most is replaced by linseed oil as in natural paint.