THE PATH TO SUSTAINABLE USE OF CHEMICALS IN PRODUCTS: THE EUROPEAN ECOLABEL AS A SIGNPOST

Discussion paper

Öko-Institut e.V.
Institut für angewandte Ökologie
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The EEB's work on the European Ecolabel began in the mid-1990s, a few years after the Ecolabel was created. EEB is a member of the European Ecolabel Board and is involved in the criteria development process, with both policy and expert representation. This work forms part of a larger focus on waste and product policy, aiming to reduce negative environmental and human health impacts at the source and not only or predominantly once a product has become a waste. www.eeb.org

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BEUC has been involved in the Ecolabel scheme since its creation and is a member of the European Ecolabelling Board, contributing actively to the development of Ecolabel criteria for different product groups. This work is part of a broader implication of BEUC and its members in sustainable consumption and production policies. The Ecolabel is important for BEUC and its members to help promote sustainable consumption and help consumers choose products that are better for the environment and their own health. www.beuc.eu

Öko-Institut (Institut für angewandte Ökologie / Institute for Applied Ecology) was founded in 1977 by 27 concerned citizens. Their concern was to preserve an environment that was being exploited and protect the natural life-support systems on which human existence depends. At first, Öko-Institut was a small science centre with its own engineers, physicists, chemical industry experts, lawyers and theologists who analysed, assessed, and brought their findings to the attention of a wider public. Today, Öko-Institut is a leading European research and consultancy institution working for a sustainable future. It employs more than 120 staff, including 80 researchers, at three locations: Freiburg, Darmstadt and Berlin. www.oeko.de

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1. Executive Summary

The European Ecolabel, like many ecolabels, was created as a tool to be complementary to environmental industrial legislation, to provide a market-based incentive to companies to make improvements to their environmental performance beyond being compliant with legislation.

Despite the European Ecolabel's creation in 1992, it remained the only European product policy mechanism taking a full lifecycle approach until 2005, when it was joined by the Ecodesign of Energy-Using Products Directive (EuP). In July 2008, the European Commission produced its Action Plan on Sustainable Consumption and Production and Sustainable Industrial Policy, which had a very strong product focus and included a proposal for the revision of the EU Ecolabel Regulation[1]. This revision is taking place now and its adoption is scheduled for 2009.

This changing product policy landscape is further affected by the more specific introduction of the EU Regulation regarding Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[2]. REACH changed historical chemicals policy by introducing the concept of chemical safety testing *before* a chemical is put on the market and shifting the burden of proof from public authorities to industry.

With these key changes in broader policy areas, EEB and BEUC decided to assess the approach to chemicals which is used in the European Ecolabel. The aim of this assessment was to identify how the Ecolabel could better anticipate future developments in chemicals policy, and could develop a more coherent and systematic approach to chemicals in products.

THE EUROPEAN ECOLABEL – A MARK OF "ENVIRONMENTAL EXCELLENCE" BEYOND LEGISLATION

The European Ecolabel (Ecolabel) aims to reduce the negative environmental impacts of products, taking into consideration the whole lifecycle of the product. On chemicals, the Ecolabel aims to reduce the harm that chemicals might cause to the environment and human health, applying the precautionary principle. The guiding principles are exclusion of substances with problematic inherent properties and substitution of problematic substances as far as possible.

Given the important role of the Ecolabel as one of the instruments for achieving sustainable consumption and production, it is fundamental that the Ecolabel be guided by a coherent, overarching approach setting the principles and operational guidelines for sustainable chemistry in Ecolabelled products. REACH, despite its ground-breaking changes to historical chemicals management, does not have sustainable use of chemicals as a key objective. Instead, it aims to improve the safe use and management of chemicals.

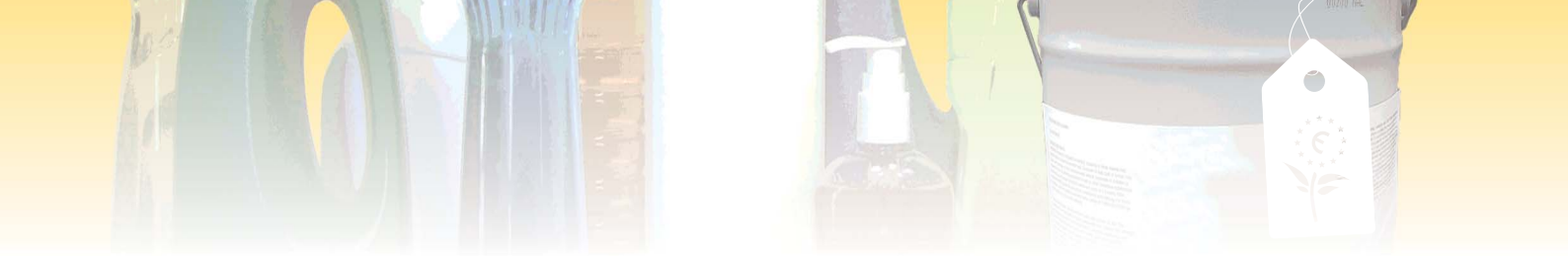
A CONSISTENT AND COHERENT APPROACH TO CHEMICALS – ECODESIGN AND GREEN CHEMISTRY

Since EU policy has not yet provided coherent or systematic detail on ecodesign or sustainability criteria for products, we have taken the fundamental principles of **ecodesign** and **green chemistry** as useful guides for future policy formulation. Some examples of sustainable design that could serve as a starting point for such European principles include ecodesign practices (see Box 1) agreed by the Industrial Designers Society of America (IDSA), which form a good starting point for the Ecolabel to use, at least until similar (or better) guidelines are prepared at EU level.

Box 2 details the 12 Principles of Green Chemistry, originally published by Paul Anastas and John Warner in *Green Chemistry: Theory and Practice* (Oxford University Press: New York, 1998).

[1] Regulation (EC) No 1980/2000 of the European Parliament and of the Council of 17 July 2000 on a revised Community Eco-label Award Scheme

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction Of Chemicals (REACH).



GUIDELINES FOR THE SUSTAINABLE USE OF CHEMICALS IN THE ECOLABEL

In line with the Ecolabel principles, all main phases of the chemical and product lifecycle would be taken into account: design, manufacture, use and end-of-life. Some general principles that we suggest should be more systematically taken into account are the following:

- The chemicals are needed for the necessary function of the product
- Use of chemicals which are inherently safe
- The chemicals readily degrade in the environment.
- Structures which have been shown to cause problems later on are avoided.
- No emissions of problematic substances take place during the use phase or in end-of-life management.
- The different parts of the product can be safely recycled and hazardous chemicals are avoided in product wastes.
- The chemicals are well characterised on their physico-chemical, toxicological and ecotoxicological properties.

Using the Ecolabel principle of the substitution of hazardous substances with less hazardous substances or by non-chemical alternatives promotes safer products. We propose a list of substances to be excluded from the Ecolabel due to their inherently problematic nature:

- Substances classified as dangerous to human health and to the environment according to specific risk phrases;
- Substances classified as carcinogens, mutagens or toxic to reproduction (CMR 1,2,3);
- Neurotoxic substances, immunotoxic substances, allergens and sensitisers;
- Endocrine disrupting substances;
- Persistent or bioaccumulative substances;
- Substances with other problematic hazardous properties;

Other substances for which exclusion should be the starting point for Ecolabel criteria are:

- **Groups of substances of concern to health and the environment** - a single substance approach only does not allow identification of all areas of concern which could occur during the whole lifecycle of a substance or product;
- **Manufactured nanomaterials and nanostructures** - fundamental knowledge gaps on the environmental and human health risks are in direct conflict with the precautionary principle and the approach of the Ecolabel.

By providing guidelines to be developed within the European Ecolabel scheme, EEB and BEUC hope to stimulate a more strategic discussion on the Ecolabel's approach to sustainable use of chemicals in products. The Ecolabel needs a consistent and coherent approach to maintain its status as a mark of "environmental excellence". It should also continue to develop its pioneering approach to products, despite gaps in the policy and regulatory framework that currently surround it and are likely to continue to do so in future.

2. Introduction: the European Ecolabel as a signpost for sustainable use of chemicals in products

The European Ecolabel, like many ecolabels, was created as a tool to be complementary to environmental industrial legislation, to provide a market-based incentive to companies to make improvements to their environmental performance beyond being compliant with legislation.

According to the current European Regulation on the Ecolabel, its objective is "to promote products which have the potential to reduce negative environmental 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 protection." On chemicals specifically, the Regulation says: "The eco-label may not be awarded to substances or preparations classified as very toxic, toxic, dangerous to the environment, 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."

Due to its notional status as a "mark of environmental excellence", the Ecolabel scheme needs to go beyond regulation. This means it makes exclusions where substances are otherwise allowed in other relevant European legislation.

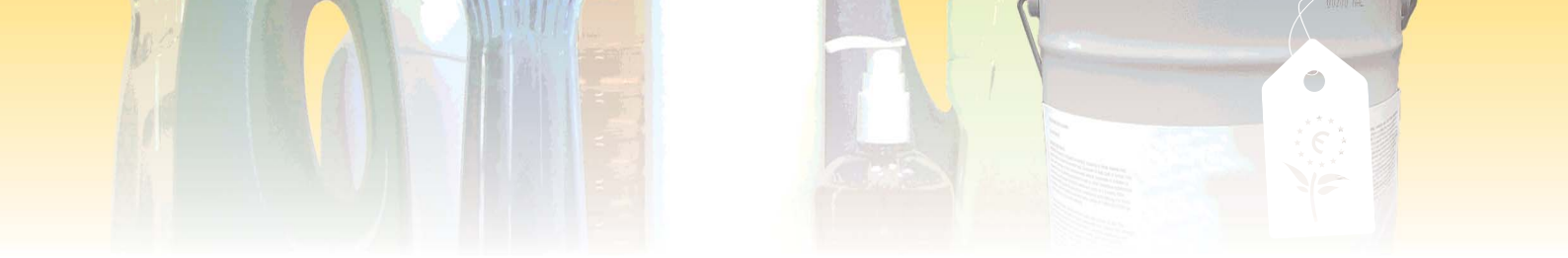
In 2006, the European Union's policy and legislative approach to chemicals management was greatly changed through the adoption of the Registration, Evaluation, Authorisation and Restriction of Chemical substances Regulation (REACH). This piece of legislation modernised chemicals policy by achieving paradigm shifts: it applies the "no data, no market" principle which requires industry to provide health and safety data on chemicals they want to start or continue marketing in Europe and to show how they can be used safely. Previously, the burden of proving that chemicals might harm health and the environment before they could be restricted was on the authorities.

This change in approach marks a more responsible and preventive attitude to human and environmental exposure to substances. However, with more than 100,000 chemicals being used in the products or in the processes making the products we use in our daily lives, REACH will only partly lead to more sustainable products. Various human illnesses, from respiratory diseases and skin complaints to cancers, thyroid problems, and reduced sperm levels (amongst other illnesses or negative effects) are increasingly being linked to exposure to chemical substances. Since it is hardly possible to be exposed to a chemical substance on its own, chemicals regulation based upon testing of an individual substance in isolation has serious limitations. Additionally, chemicals legislation on its own cannot be expected to address the negative impacts to human and environmental health, so other policies and legislation need to act in conjunction with it.

The Ecolabel takes into consideration the whole lifecycle of the product. In relation to chemicals, the Ecolabel aims to reduce the harm that chemicals might cause to the environment and human health. The guiding principles to reach this aim are exclusion of substances with problematic inherent properties and substitution of problematic substances as far as possible. This approach applies the precautionary principle, avoiding the use of chemicals which, due to their hazardous properties, have the potential to cause harmful effects.

Given the important role of the Ecolabel as one of the instruments for achieving sustainable consumption and production (see section 4 on the Ecolabel and Sustainable Consumption and production/Sustainable Industrial Policy)., it is fundamental that the Ecolabel be guided by a coherent, overarching approach setting the principles and operational guidelines for sustainable chemistry in Ecolabel products.

Although the Ecolabel to date has tended to take a similar approach to chemicals between the different products within the scheme, the introduction of REACH as the overarching chemicals legislation, coupled with developments in product policy within the broader context of sustainable consumption and production, warrant a reconsideration of the approach taken to chemicals in the Ecolabel, particularly in the area of ecodesign and eco-innovation.



3. Aims of the discussion paper

This discussion paper aims to make a contribution to establishing a much-needed framework of guidelines that could support a more systematic and coherent approach towards chemicals in the European Ecolabel scheme.

The descriptions and background information supporting the recommendations of this discussion paper build upon experiences within the present Ecolabel scheme. Placing the Ecolabel more strategically in the sustainable consumption and production and sustainable industrial policy agendas and reducing the use of unnecessary chemicals and hazardous chemicals are major goals of this document. By filling in some gaps in the current approach taken by the Ecolabel, the Ecolabel scheme could become an even more effective driver of sustainable chemistry in products than it is at present.

Our proposed approach includes specifications for the following horizontal issues relevant to all product groups that contain chemicals or use them in production:

- The relationship between the Ecolabel and REACH;
- How to address persistent and bioaccumulative substances;
- How to address endocrine disrupting chemicals;
- How to address manufactured nanomaterials and nanostructures;
- How to address the incompleteness and the quality of the data which are available for characterising the substances.

We propose some guidelines on handling these horizontal issues in a systematic and coherent way. By doing this, we hope to stimulate a broader discussion within the Ecolabel scheme on how to identify commonly accepted criteria and how to put them into practice. The guidelines take **ecodesign** and **green chemistry** as starting principles. More details on these principles can be found in the next section.

4. Sustainable consumption and production and sustainable industrial policy - the Ecolabel as a mark of 'environmental excellence'

The European Ecolabel was created in 1992[3], long after the first ecolabel, the German Blue Angel, was created in 1978. Following in the footsteps of the Blue Angel, other countries or regions and 'private' bodies created similar ecolabels, most notably the Nordic Swan (1989), and Sweden's Bra Miljöval/Good Environmental Choice (1988). In Europe, there are also national ecolabels in Austria, the Czech Republic, the Netherlands, France, Hungary, Poland, the Slovak Republic and a Spanish regional one in Catalonia.

Each label has varying levels of market penetration, depending upon cultural 'openness' to, or general public awareness of, ecological issues, and the level of marketing support provided to the label. Regardless of success rates of the individual labels, the proliferation of these 'stamps of environmental performance' is based upon general government acceptance of such mechanisms as a means of stimulating industry to go beyond legislation and to set a notional 'benchmark' performance level which companies can seek to attain.

A similar multiplication of industry-led labels also followed, in reaction to these 'third party' labels and as a means of communicating similar messages to the public and to corporate purchasers. The International Standardisation Organisation (ISO) agreed differentiation of the various types of labels, to distinguish between:

- Type I: a voluntary, multiple-criteria based, third party program that awards a license that authorises the use of environmental labels on products indicating overall environmental preferability of a product within a particular product category based on life cycle considerations
- Type II: informative environmental self-declaration claims
- Type III: voluntary programs that provide quantified environmental data on a product, under parameters set by a qualified third party and based on life cycle assessment, also verified by a qualified third party

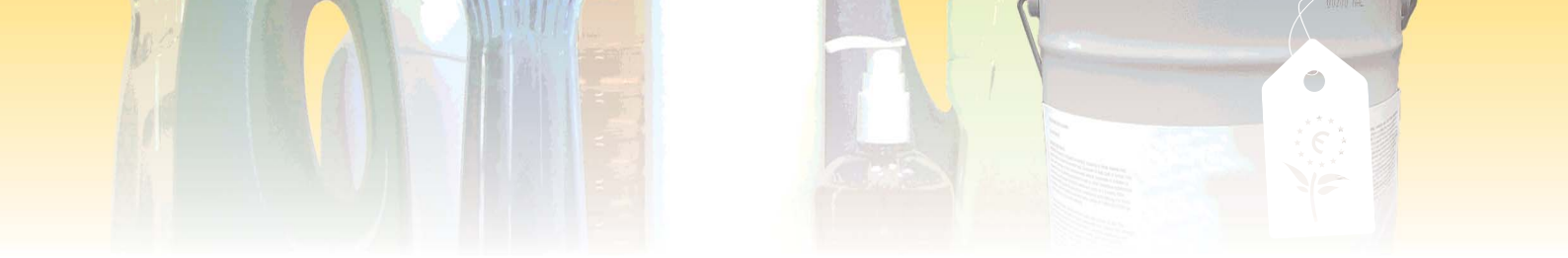
The Ecolabel is a Type I label which are considered the most credible due to the third party involvement of societal representatives such as consumer and environmental NGOs. EEB and BEUC are official members of the Board and take active part in the development of criteria providing expert technical support and societal and policy perspectives.

The Ecolabel was a pioneer in European environmental product-focused policy, as the only policy mechanism addressing the environmental performance of a range of unrelated products across their lifecycle for more than a decade, until the arrival of the Ecodesign for Energy-using Products Directive (EuP) in 2005.[4] In implementing the EuP Directive, the European Commission has created a Consultation Forum of stakeholders discussing possible options for improving the environmental performance of products, some of which were already addressed by the Ecolabel. Both BEUC and EEB are members of this Consultation Forum, aiming to better integrate EuP and Ecolabel approaches, objectives and outcomes. However, given the limited focus of EuP on use-phase improvements in only energy-using product groups, the Ecolabel still remains the only pan-product, lifecycle-focused mechanism operating at European level.

The Ecolabel currently deals with various elements of production (such as emissions to different media, energy and water and some production materials), end-of-life management and packaging. For many of these issues, the Ecolabel uses as reference points Directives such as Integrated Pollution Prevention and Control BREFs (Best Available Technique Reference documents), sustainable forestry labels, and the waste hierarchy and waste Directives. However, the Ecolabel has more difficulty addressing issues where there are no clear environmental or sustainability policies, including chemicals.

[3] The European Ecolabel takes the form of a European Regulation meaning that European Union Member States need to transpose the Regulation in its entirety with no variations according to national legislation. This theoretically ensures full harmonisation of the legal basis for the mechanism. The first European Ecolabel Regulation entered into force in 1992 (Regulation (EEC) No 880/92), with a subsequent revision in 2000 (Regulation (EC) No 1980/2000) and is under revision again in 2008 and 2009.

[4] Directive 2005/32/EC establishing a framework for the setting of ecodesign requirements for energy-using products (EuP).



The diminished product policy landscape is now, slowly, starting to change. At EU level, policy discussions have recently been taking place in the new areas of sustainable consumption and production (SCP) and sustainable industrial policy (SIP), and on existing areas such as natural resources and waste management. At last, the Ecolabel has the opportunity to be supported by a wider sustainable product policy framework, within which it can be positioned to set clearer benchmark levels.

The difficulty inherent in a policy tool such as the European Ecolabel is that it needs clear policy objectives on which it can base typically, very detailed criteria requirements. Due to its lifecycle-based approach, this means that its needs extend from policies on natural resources and chemicals to production efficiency, emissions limits and end-of-life management.

Since the EU policy framework has not yet provided coherent or systematic detail on ecodesign or sustainability assessment of products, EEB and BEUC take the fundamental principles of ecodesign and green chemistry as useful guides. Many different ecodesign strategies, approaches, guidelines, etc. exist, some of which deal with selected aspects of product design, such as design for recycling. Since the EU has also not yet developed agreed principles on ecodesign, we have provided a small number of examples which could be the starting point for European principles.

BOX 1: IDSA recommends the following ecodesign practices

Use ecodesign strategies appropriate to the product

- Reduce overall material content and increase the percentage of recycled material in products
- Reduce energy consumption of products that use energy
- Specify sustainably grown materials when using wood or agricultural materials
- Design disposable products or products that wear out to be more durable and precious
- Eliminate unused or unnecessary product features
- Design continuously transported products for minimal weight
- Design for fast, economical disassembly of major components prior to recycling, and
- Design products so that toxic components (electronics, etc.) are easily removed prior to recycling.

Perform comprehensive environmental assessment

- Consider all of the ecological impacts from all of the components in the products over its entire life cycle, including extraction of materials from nature, conversion of materials into products, product use, disposal or recycling and transport between these phases
- Consider all ecological impacts including global warming, acid rain, smog, habitat damage, human toxicity, water pollution, cancer causing potential, ozone layer depletion and resource depletion
- Strive to reduce the largest ecological impacts, and
- Conduct life cycle impact assessment (LCA) to comprehensively identify opportunities for improving ecological performance.

Encourage new business models and effective communication

- Support product 'take back' systems that enable product up-grading and material recycling
- Lease the product or sell the service of the product to improve long-term performance and end-of-life product collection
- Communicate the sound business value of being ecologically responsible to clients and commissioners (*people commissioning design work*)
- Discuss market opportunities for meeting basic needs and reducing consumption, and
- Present superior product quality claims ('energy saving', 'contains less toxic waste', etc.) along with other performance features.

The IDSA Ecodesign Section distilled these practices and principles and the IDSA Executive Committee adopted them in November 2001.

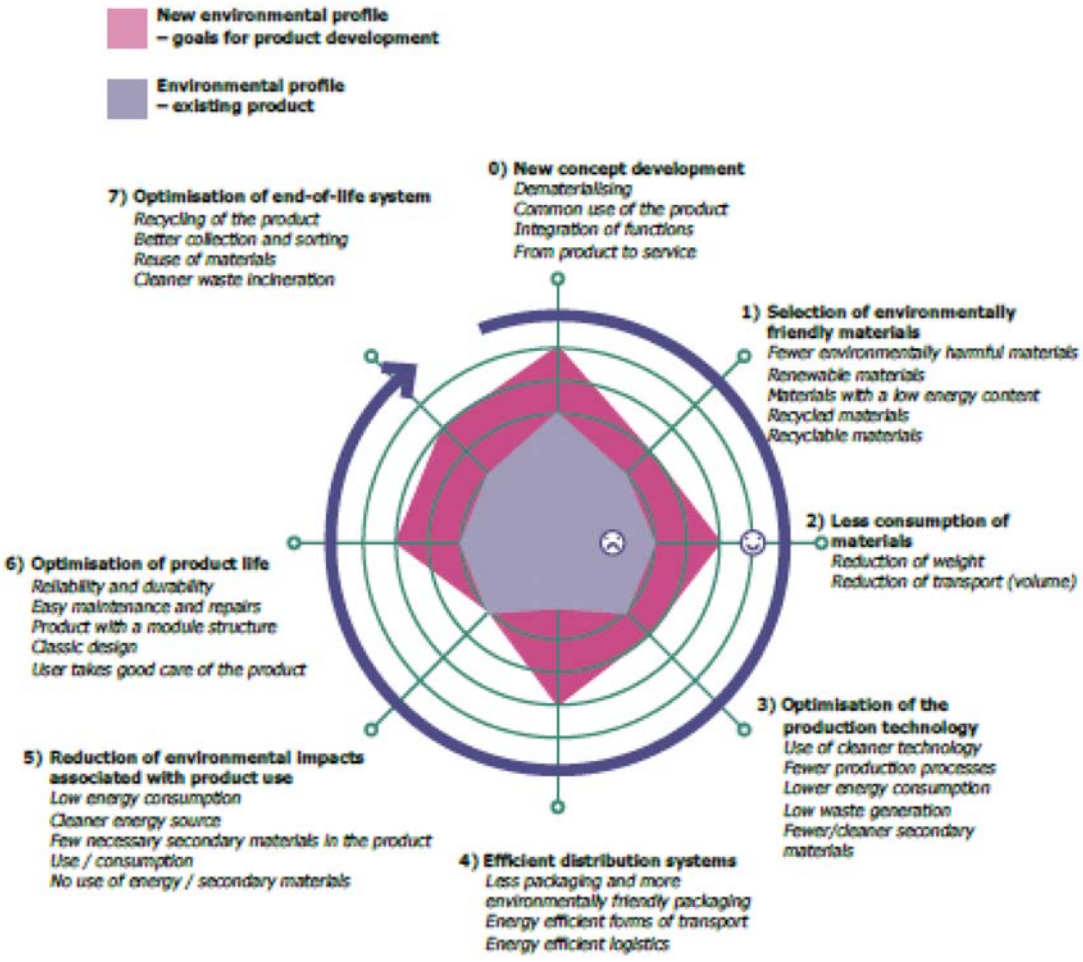
ECODESIGN

The Bureau of European Design Associations produced a report in 2004 called "*Design Issues in Europe Today*" which considered key issues such as sustainability, ethics and corporate social responsibility. However, it did not go as far as identifying principles of sustainable design or eco-design. In 2001, the Industrial Designers Society of America (IDS A) agreed some ecodesign practices which provide a good foundation for more general ecodesign principles (see Box 1). These recommendations refer to the design phase of products, comprehensive assessment of products, new business models as well as effective communication about these products.

Similarly, the United Nations Environment Programme (UNEP) in its 2007 report "*Life Cycle Management – A business guide to sustainability*"[5] outlined 6 principles to describe eco-design:

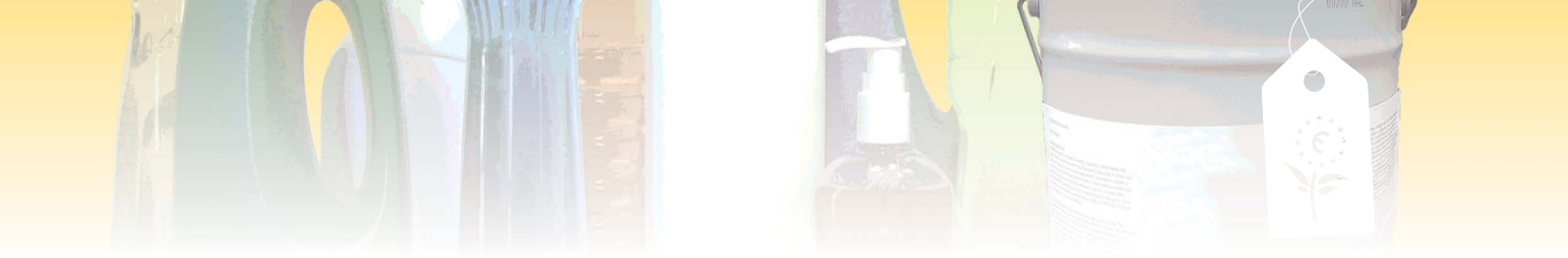
- RE-think: the product and its functions. For example, the product may be used more efficiently.
- RE-duce: energy, material consumption and socio-economic impacts throughout a product's life cycle.
- RE-use: Design the product for disassembly so parts can be reused.
- RE-cycle: Select materials that can be recycled.
- RE-pair: Make the product easy to repair e.g. via modules that can easily be changed.
- RE-place: harmful substances with safer alternatives.

It also included the following wheel to illustrate a product's environmental profile:



Source: UNEP, 2007

[5] *"Life Cycle Management: A Guide to Sustainability"* was produced as part of UNEP's Life Cycle Initiative work. It can be downloaded from the website at: http://lcinitiative.unep.fr/



GREEN CHEMISTRY

Any discussion on chemicals within the Ecolabel scheme necessarily starts from an implicit or explicit aim to reduce the use of chemicals generally and particularly those with problematic inherent properties (e.g. toxicity). In this context, REACH provided big changes to chemicals regulation, the most important being the more comprehensive coverage of chemicals and shifting the burden of proof of safety onto producers.

However, REACH, despite its ground-breaking features, does not have sustainability at its heart. It aims to phase out the worst of the chemicals, defining "substances of very high concern" (SVHC),[6] and to create a registration system for chemicals to be placed on the European market. Nevertheless, even under REACH, hazardous chemicals will stay on the market – on the basis that companies will argue that safe use can be demonstrated. Moreover, apart from the most problematic substances which fall under the authorisation regime, a systematic search for less hazardous substances (based on their inherent properties) is not foreseen.

Although REACH helps to put some Ecolabel discussions into a broader context, it does not provide sustainability or benchmark points of reference. For sustainability criteria, we therefore turn to the concept of green chemistry.

Green chemistry includes chemicals and chemical processes designed to reduce or eliminate negative environmental impacts. The use and production of these chemicals may involve reduced waste products, non-toxic components, and improved efficiency. It is a highly effective approach to prevention of negative impacts on the environment and human health because it applies innovative scientific solutions to real world environmental situations. The box below details the 12 Principles of Green Chemistry, originally published in *Green Chemistry: Theory and Practice* in 1998.

BOX 2: Twelve Principles of Green Chemistry

1. **Prevent waste:** Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.
2. **Design safer chemicals and products:** Design chemical products to be fully effective, yet have little or no toxicity.
3. **Design less hazardous chemical syntheses:** Design syntheses to use and generate substances with little or no toxicity to humans and the environment.
4. **Use renewable feedstocks:** Use raw materials and feedstocks that are renewable rather than depleting. Renewable feedstocks are often made from agricultural products or are the wastes of other processes; depleting feedstocks are made from fossil fuels (petroleum, natural gas, or coal) or are mined.
5. **Use catalysts, not stoichiometric reagents:** Minimize waste by using catalytic reactions. Catalysts are used in small amounts and can carry out a single reaction many times. They are preferable to stoichiometric reagents, which are used in excess and work only once.
6. **Avoid chemical derivatives:** Avoid using blocking or protecting groups or any temporary modifications if possible. Derivatives use additional reagents and generate waste.
7. **Maximise atom economy:** Design syntheses so that the final product contains the maximum proportion of the starting materials. There should be few, if any, wasted atoms.
8. **Use safer solvents and reaction conditions:** Avoid using solvents, separation agents, or other auxiliary chemicals. If these chemicals are necessary, use innocuous chemicals.
9. **Increase energy efficiency:** Run chemical reactions at ambient temperature and pressure whenever possible.
10. **Design chemicals and products to degrade after use:** Design chemical products to break down to innocuous substances after use so that they do not accumulate in the environment.
11. **Analyze in real time to prevent pollution:** Include in-process real-time monitoring and control during syntheses to minimize or eliminate the formation of byproducts.
12. **Minimize the potential for accidents:** Design chemicals and their forms (solid, liquid, or gas) to minimize the potential for chemical accidents including explosions, fires, and releases to the environment.

Originally published by Paul Anastas and John Warner in **Green Chemistry: Theory and Practice** (Oxford University Press: New York, 1998).

[6] The REACH definition of substances of very high concern refers to the inherent properties of the substances. This group is made up of several sub-groups including persistent, bioaccumulative and toxic ("PBT substances"); carcinogenic, mutagenic or of reproductive toxicity (CMR); and very persistent and very bioaccumulative ("vPvBs substances").

In addition, the United States' Environmental Protection Agency (US EPA) provides information on green chemistry, including a sustainable chemistry hierarchy. According to the US EPA, chemical products and processes should be designed to the highest level of the hierarchy and be cost-competitive in the market as shown in Box 3:

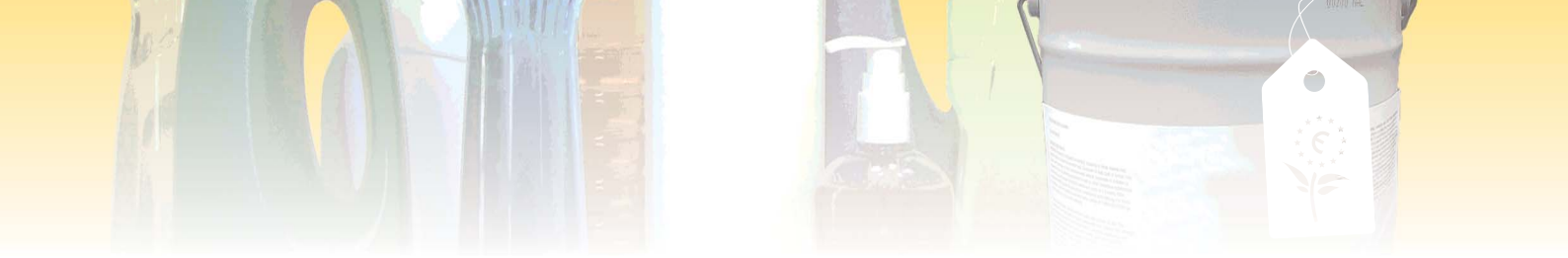
BOX 3: Green Chemistry:

1. Source Reduction/Prevention of Chemical Hazards
   a. Design chemical products to be less hazardous to human health and the environment*
   b. Use feedstocks and reagents that are less hazardous to human health and the environment*
   c. Design syntheses and other processes to be less energy and materials intensive (high atom economy, low E-factor)
   d. Use feedstocks derived from annually renewable resources or from abundant waste
   e. Design chemical products for increased, more facile reuse or recycling
2. Reuse or Recycle Chemicals
3. Treat Chemicals to Render Them Less Hazardous
4. Dispose of Chemicals Properly.

* Chemicals that are less hazardous to human health and the environment are:
- ➔ Less toxic to organisms and ecosystems
- ➔ Not persistent or bioaccumulative in organisms or the environment
- ➔ Inherently safer with respect to handling and use

Source: USEPA website.

Taking these broader principles as the starting point for a more systematic and coherent approach to chemicals in the Ecolabel, we now turn to a closer focus on REACH and its relationship to the Ecolabel to see what can be incorporated already from REACH and why and where the Ecolabel needs to go further.



5. REACH, chemicals and the European Ecolabel

We have already stated that REACH will play a major role to set a new framework for the safe use of chemicals in the European Union (and arguably, internationally). In particular, company registration of more than 2,000 substances of high production volume (with a production volume of at least 1,000 tonnes per year) needs to be completed by the end of 2010. This includes data on the substance properties as well as descriptions of their safe use. Substances with a smaller production volume (from one tonne to less than 1,000 tonnes per year) will follow. In the process of evaluation, registration data will be assessed by the European Chemicals Agency and the Competent Authorities in each EU Member State.

REACH will improve the safety data base for many chemicals. This will stimulate the generation of data on substance properties and uses as well as on exposures. In parallel, the classification and labelling of the majority of existing chemicals (with production volumes of 10 tonnes per year and more) related to their hazardous properties will change due to new available data.
The data required for the registration of a substance under REACH can be used as reference in the Ecolabel process.
REACH obliges producers to communicate along supply chains, through safety data sheets and exposure scenarios, the conditions of safe use for "intended uses". In future, it will therefore be an important criterion for the Ecolabel whether a substance has been registered or not and whether a risk characterisation for the intended uses of the substance has been prepared.

REACH defines "substances of very high concern" (SVHC) and it sets criteria to assess the toxicity, the persistency and the bioaccumulation potential of substances. SVHC can cause a high risk to humans and the environment.

The Ecolabel scheme can benefit from exploring synergies with REACH, by making reference to the concepts and methodologies defined and using new data. REACH will generate a high amount of substance-specific data that can be used for calculating theoretical environmental impacts. This is currently done in several Ecolabel product groups, although it is performed on the basis of less robust data.

However, at the same time, REACH on its own cannot ensure that the production and use of chemicals in products move in a more sustainable direction. Even under REACH, hazardous chemicals will stay on the market – on the basis that companies will argue that safe use can be demonstrated (taking into account application of the necessary risk management measures). Apart from the most problematic substances which will be prioritised for authorisation, a systematic search for less hazardous substances (based on their inherent properties) is not foreseen.

REACH cannot be the only reference point for assessing chemicals in products for several important reasons:

- It does not cover all substances relevant to the Ecolabel (e.g. biocides and pesticides).
- In principle, according to the European Commission and the European Chemicals Agency, nano-sized substances are covered by REACH. However, there are still questions on the limitations of the methods for assessing the possible risks of nanomaterials (see section 10 on nano-sized materials).
- REACH does not cover all chemicals which are used on the EU market: data requirements have been lowered especially for substances with a low production volume (1-10 tonnes/year), and substances produced in volumes lower than 1 tonne/year will not have to be registered.
- REACH connects persistency, bioaccumulation potential and toxicity. Therefore substances fulfilling only one or two of these three criteria are not considered as SVHC under REACH.
- REACH defines very narrow criteria for persistency, bioaccumulation potential and toxicity. Only a small number of substances fulfil these criteria.
- Substitution of hazardous substances by less dangerous ones will be stimulated by REACH mainly in the case of SVHC but not for all and not for hazardous substances in general.
- Substances in consumer products are poorly covered by REACH and additional information for consumers will only focus on the SVHC on the "candidate list". At present the candidate list only includes 15 substances.[7]

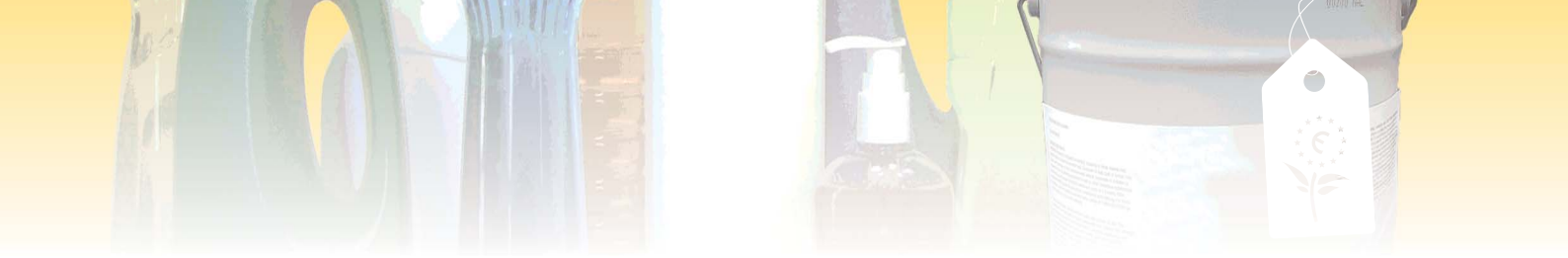
[7] The candidate substances can be subjected to the REACH authorisation regime which prohibits the use of these substances unless an authorisation is granted. Through this mechanism, substitution of these substances is supported.

- REACH has long implementation periods (e.g. the deadline for registration of low volume chemicals between 1-100 tonnes annual production is June 2018).

Therefore, since REACH does not automatically deliver the appropriate reference point for sustainable chemistry and for a voluntary Ecolabel scheme aiming to support innovative products. It is necessary for the Ecolabel scheme to develop a coherent and more ambitious approach to chemicals that goes beyond legislation, including REACH, and promotes a more precautionary use of chemicals.

Some ways in which the Ecolabel will need to go beyond REACH include:

- Ecolabelled products should not contain SVHC, as defined by REACH as persistent, bioaccumulative and toxic (PBT-substances) or as Very Persistent and Very Bioaccumulative. In addition, the Ecolabel needs to develop an approach which excludes all problematic substances, whether or not they are considered SVHC under REACH. Therefore, it should also address these properties individually (e.g., solo-P, solo-B).
- For a proper assessment of the hazardous potential of a low production volume chemicals substance (less than 100 tonnes per year), more data should be required for the Ecolabel than required by REACH.
- REACH focuses on substances while the Ecolabel focuses on products. The substance approach gives important information, but cannot replace a complete product assessment which typically covers additional criteria.
- While assessing products, the Ecolabel should consider the complex mixture of all substances contained in the product and/or which might be released from the product. Little is known on the interactions between individual substances and the mixture of substances already present in the environment or in the product. The classical methods of risk assessment for a specific substance used in REACH cannot adequately cover the real multiple exposure situations during the whole lifecycle of a product.



6. Criteria for chemicals in the European Ecolabel: from case-by-case decisions to a systematic approach

The current EU Ecolabel Regulation text states an aim to exclude problematic chemicals[8] and is based on the application of the precautionary principle. However, criteria development tends not to be systematic or harmonised among the various product groups, partly because the criteria are developed by different 'leading competent bodies'[9], and partly due to lack of clear guidelines on criteria development for everyone to use. Such guidelines are necessary in order to strengthen the delivery of the scheme as a policy mechanism that goes beyond legislation. Without wishing to propose that too strict and prescriptive an approach be developed for the Ecolabel, there is a need to support a more systematically coherent approach. Guidelines, therefore, play an important role.

At present, the Ecolabel includes several types of criteria to assess the use of chemicals in the products under discussion, including:

- specific substances
- specific properties of formulations composed of several substances;
- the emissions of substances during the product production phase;
- product functions;
- the use of renewable substances.

Specific substances with hazardous properties for human health or the environment (e.g. substances which are toxic, irritating, allergenic, sensitising, carcinogenic, etc.) are excluded from Ecolabelled products. However, if these substances are deemed fundamental to the product, they are severely restricted. The criteria used to exclude or restrict them usually refer to *risk phrases* (so-called R-phrases) defined in key chemicals Directives[10], or name the specific substances or groups of substances which have problematic inherent properties or may raise specific environmental or health problems during their lifecycle. Examples of this include:

- individual substances such as EDTA and formaldehyde;
- groups of substances such as biocides, phthalates, nitromusks, and organotin compounds;
- substances having undesirable properties not adequately addressed by risk phrases such as bioaccumulative, persistent or endocrine-disrupting.

Below, we characterise some of the difficulties or tensions raised by the under-development of the European chemicals policy framework.

Persistency, bioaccumulative potential and toxicity as well as **endocrine-disruption** have been identified as properties needing to be addressed in a horizontal way (in all products) by the Ecolabel. However, although they have been introduced into criteria discussions on various products, they have not been the subject of systematic exclusion.

Nano-materials and nano-structures have become the subject of an intense discussion regarding their potential impacts on human health and the environment, but the specific risks posed by nano-materials and nano-structures have not yet been addressed by the Ecolabel scheme. During the recent revision of the Ecolabel criteria for paints and varnishes, the leading Competent Body recommended that this issue should be dealt with in a horizontal way. At present a coherent system to deal with engineered nano-materials and nano-structures is not in place in the Ecolabel, nor in European legislation generally.

Substances with problematic properties are usually excluded as a first step. If this is not possible for functional reasons, it is discussed on a case-by-case basis to achieve a maximum reduction, usually by setting a concentration limit. In future, it could be that **positive** lists of substances (or properties, more likely since this is less prescriptive) could be used.

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[8] EC Regulation 1980/2000 states; *"The eco-label may not be awarded to substances or preparations classified as very toxic, toxic, dangerous to the environment, carcinogenic, toxic for reproduction, or mutagenic in accordance with Council Directive 67/548/EEC (1) or Directive 1999/45/EC of the European Parliament and of the Council (2) 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,".*

[9] Member State representatives that are contracted to deliver the new or revised criteria of a product group.

[10] The two key Directives are the Directive on Dangerous Substances (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC).

Criteria on specific substances in Ecolabel are supplemented by criteria on the **properties of formulations** (composed of several substances). For example, in the case of household washing agents, all ingredients are assessed according to their impact on aquatic ecosystems, using a ranking system; and for wooden furniture, criteria include limits on substances reducing indoor air quality[11].

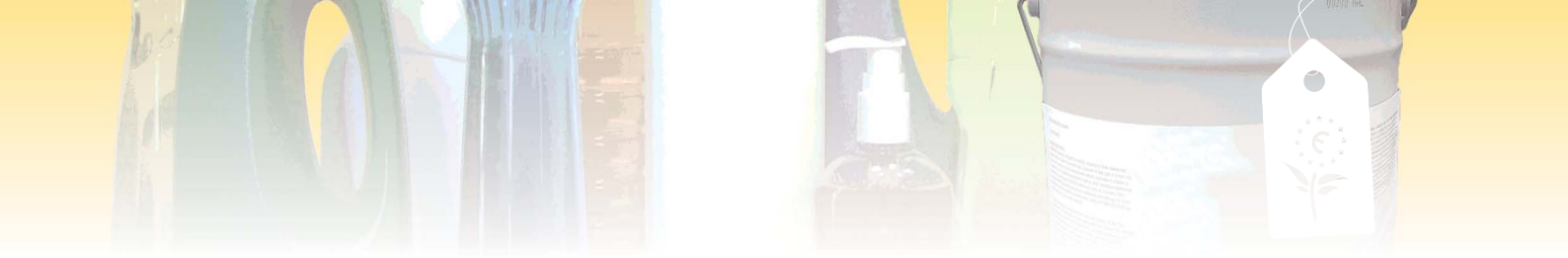
Further aspects considered in Ecolabel criteria, although not systematically, are those related to the **lifecycle analysis of materials**, e.g. the use of renewable materials versus synthetic substances, and the emissions and formation of hazardous substances or degradation of products during the production and end-of-life phase. Recently, the **quality and the completeness of the data available for the assessment** of a given substance have been brought to the discussion on criteria development.

At present the criteria are selected, arranged and detailed on a case-by-case basis according to the specific product being discussed. This can lead to time-consuming and less effective discussions, often repeated several times and create inconsistent ambition levels between product groups. In addition, due to the sharing of responsibility amongst European country "Competent Bodies" for the development of criteria, and a lack of clear guidelines on criteria development, a harmonised approach cannot be assumed since different Member States have different approaches to the Ecolabel.

Discussions on some products containing substances with properties identified for exclusion have been introduced on an ad-hoc basis, although these have not managed to be excluded in the final criteria documents.. This is due more to political decisions, rather than lack of support of such exclusions. Indeed, Member States have expressed strong interest in advancing the Ecolabel in this way. For example, a proposal to exclude allergenic fragrances in the soaps and shampoos product group was made by some Member States even though it was eliminated from the final criteria because it was deemed to run counter (or to threaten) the approach taken in the Cosmetics Directive. This is a good example of how tension can arise relative to the Ecolabel's 'beyond legislation' approach.

Systematic guidelines would not completely eliminate the current product-specific approach. Rather, they would help to provide an 'institutional' approach or framework to form the starting point for a general approach to chemicals, which could then be adapted according to factors relating to the specific product in question.

[11] In this case, reference is made to emission modelling and specific assessment methods (e.g. emission chamber tests and the AgBB scheme for the assessment of emissions of volatile organic compounds to indoor air).



7. Guidelines for the sustainable use of chemicals in the Ecolabel

This section sets out some general principles as the starting point for Ecolabel chemicals guidelines. Proposals for exclusion of substances with problematic inherent properties are described in more detail in sections 8 – 10. First considerations regarding the assessment of the completeness and quality of data are given in section 11.

The guidelines followed by the Ecolabel when addressing chemicals need to be based on general principles of sustainable chemistry. These principles should conform to a robust framework ensuring the use of chemicals that are necessary and safe for the environment and human health. In this way, the European Ecolabel could support innovative product design approaches. In line with Ecolabel principles, all phases of the chemical and product lifecycle would be taken into account: design, manufacture, use and end-of-life.

Ecodesign and green chemistry offer approaches which could help set the path towards more sustainable ecolabelled products. Although many of the principles are not new to the criteria development process, they would help to develop the coherent and systematic approach being proposed in this document.

BOX 4: Proposed general principles of sustainable chemistry for systematic use in the Ecolabel:

- ***The chemicals are needed for the necessary function of the product***

The necessary functional or technical properties of a product can often be achieved by different means. The Ecolabel scheme should support non-chemical solutions provided that they have lower or at least equal impacts on humans and the environment. By this approach the number and the amount of substances which may cause adverse effects can be reduced, production processes and the energy used in these are reduced or simplified, and detailed assessments of the safety of the substances and the related exposures are not required.

Therefore RE-thinking the product and its function as suggested by the UNEP guidelines is of great importance for a more sustainable product design, including sustainable use of chemicals. This reflects the need for simplification of the design of the products in line with the principles of green chemistry. For instance, we need to question whether optical brighteners, biocides or certain colorants are necessary for the product function and if so, whether they can be replaced through technological innovation (e.g. protection of wood from beatles can be done by physical means, through heat, instead of biocides).

- ***Use of chemicals which are inherently safe***

If chemicals are necessary in Ecolabelled products, the approach should be to allow only substances which have no potential to harm the environment and human health, based on testing rather than the absence of proof. These are called "substances which are inherently safe". With this as a starting point, substitution of hazardous substances by less hazardous ones needs to be one of the key principles of a sustainable approach to chemicals in the Ecolabel[12]. In addition, the precautionary approach and the goal of optimal environmental quality care takes further important factors into account, including:

- emissions of a substance from products;
- exclusion of substances with problematic properties'
- interaction between different substances;
- avoidance of exposure of humans and the environment to a complex mixture of substances through the final product.

- ***The chemicals are readily degraded in the environment.***

The ready degradation of substances ensures that no harmful effects from long-term exposure and/or the transboundary effects can occur. At the same time, it prevents accumulation of substances in environmental media.

Persistent but non-toxic ingredient(s) generating stable metabolites in the course of biodegradation have negative impacts on environmental quality. They can cause long-term environmental contamination, which in many cases, is irreversible. They can also have negative impacts on human or ecosystem health on endpoints which cannot be foreseen by conventional testing of the substances. Therefore the starting point for Ecolabel criteria should be to exclude these.

- ***Structures which have been shown to cause problems at a future time are avoided.***

Safer substitutes that offer the same functionality without having problematic structures should be favoured in Ecolabel.

[12] In this context, risk assessments for dangerous substances including hazard and exposure assessment are seen as important tools to describe the safe use of hazardous substances. Demonstration of conditions for safe use (including implementation of risk management measures) at the same time does not replace the central requirement to use substances which have less or – in the best case – no problematic inherent properties.

- ***No emissions of problematic substances take place during the use phase and in end-of-life management.***
- ***The different parts of the product can be safely recycled and hazardous chemicals are avoided in product wastes.***

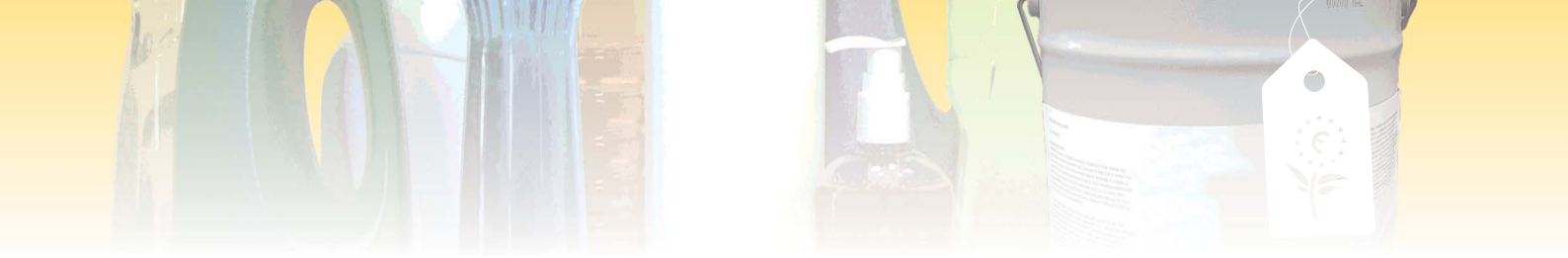
Since the Ecolabel takes a lifecycle approach, the use and end-of-life phases also need to be considered. Several substances cause formation of hazardous substances e.g. dioxins and furans when incinerated, and others make recycling activities difficult and are dangerous to human and environmental health. In such cases, these should be excluded. In any case, this approach has already been introduced in European legislation, albeit in a limited way, through waste-related legislation on electrical and electronic appliances, precisely to reduce the production of hazardous waste.

- ***The chemicals are well characterised on their physico-chemical, toxicological and ecotoxicological properties.***

The assessment of harmful effects on human health and the environment of substances requires sufficient data on substance properties. For the majority of the existing substances, this data does not exist. REACH will improve the data base, but not for all chemicals.
The Ecolabel should support the use of substances for which data is available on all relevant properties (e.g. physico-chemical properties, acute and chronic toxicity for humans and the environment, including long term effects due to continuous low level exposures).

Box Source: EEB, BEUC, OKO-Institute, 2008.

These green chemistry principles should apply to substances, to preparations and the final products in the Ecolabel. Ideally, the design of the products should also be assessed according to these principles and ecodesign principles. Of course, this will raise issues of "trade-offs" between different environmental and human health issues. For example, in order to avoid the use of chemicals a process might be needed which uses more energy or uses a non-renewable resource. Without a clear policy framework to help guide decisions between such trade-offs, a more coherent and systematic approach will help in deciding which trade-off to make.



8. Exclusion of inherently problematic substances

In this section, we consider in more detail the problematic substances to be excluded or severely limited. For specific products groups, with current production processes or technologies it might not be possible to completely avoid the use of substances with problematic inherent properties for human health and the environment, even if the most innovative products designs have been chosen. In these cases, the Ecolabel should set concentration limits in order to support innovative product systems which fulfil the required product functionality with a minimum content of problematic substances. However, this option should only be used if no products free of the hazardous substance(s) in question are available on the market. In these cases, the intention to phase-out these hazardous substances from the product-group under consideration should be defined in the Ecolabel criteria as a middle term objective for the next five years.

Additionally, several products can cause emissions of hazardous substances (e.g. to indoor air or groundwater). In these cases, the Ecolabel should include criteria setting limit values to these emissions and stimulate the use and development of low-emission-products. These criteria will make reference to emission measurements and related assessment schemes[13].

In this section we propose a list of problematic inherent properties of substances which should be excluded from Ecolabelled products. By using this approach, the Ecolabel scheme could stimulate the substitution of hazardous substances by less hazardous substances or by non-chemical alternatives. Avoiding the use of problematic substances wherever possible would also support the safe use of products. This approach has several advantages:

- Hazardous substances require, during their life time, risk reduction measures for safe handling which are not necessary for less hazardous substitutes or non-chemical alternatives. Therefore, substitution is the preferred option for worker protection – ahead of technical, organisational and personal protection measures.

- Systematic substitution of problematic substances helps to reduce the overall exposure of humans and the environment to a complex mixture of a high number of chemicals. The aggregated risk posed by chemicals today is difficult and complex to assess, particularly as numerous substances are released in small quantities from a large number of products. The effects of this complex exposure cannot be assessed by means of classical risk assessment and require a precautionary approach[14].

In several European national legislation and international programmes, such as the OSPAR Convention[15], the inherent properties of substances are the starting point for measures to protect human health and the environment. The definition of substances of very high concern in REACH also refers to the inherent properties of a substance.

We propose the exclusion of inherently problematic substances with the following properties:

- Substances classified as dangerous to human health and to the environment according to specific risk phrases;
- Carcinogenic and mutagenic substances and substances of reproductive toxicity (CMR 1,2,3);
- Neurotoxic substances, immunotoxic substances, allergens and sensitisers;
- Endocrine disrupting substances;
- Persistent or bioaccumulative substances;
- Substances with other problematic hazardous properties.

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13 An example for such an assessment scheme is the evaluation procedure for in-door-air-emissions developed by the Committee for Health-related Evaluation of Building Products, Germany (AgBB scheme).

14 Even the exposure assessment and risk characterisation of a single substance have inherent uncertainties.

15 The OSPAR Commission is in charge of managing the work of the OSPAR Convention, legal instrument for international cooperation on the protection of the marine environment of the North-East Atlantic. The OSPAR Commission is made up of representatives of the Governments of 15 Contracting Parties and the European Commission, representing the European Community.

Substances classified as dangerous to human health and the environment according to specific risk phrases

As mentioned earlier, exclusion criteria for chemicals in the Ecolabel use R-phrases established in the EU Directive on Dangerous Substances[16] and the Directive on Dangerous Preparations[17]. However, recent international efforts have been made to harmonise chemicals management under the United Nations. This has resulted in the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), implemented in the EU via a Regulation[18].

The R-phrase reference system is very valuable because it excludes substances on the basis of their inherent properties and should continue to be used in the Ecolabel scheme. In future, the Ecolabel should reflect both the R-phrase approach and the corresponding characterisations from the GHS, to allow easier use of the Ecolabel criteria at international level (that is, by companies not based in the EU).

Additionally, at present, the specific set of R-phrases which are not accepted for substances in Ecolabelled products varies from one product to another. Although comparison between products is considered during the criteria revision process, a list to be used as a starting point has not yet been established. For a more transparent approach, we recommend the creation of a consistent set of R-phrases in order to cover all relevant dangerous properties that should be excluded. We recommend excluding the following set of R-phrases (Box 5).

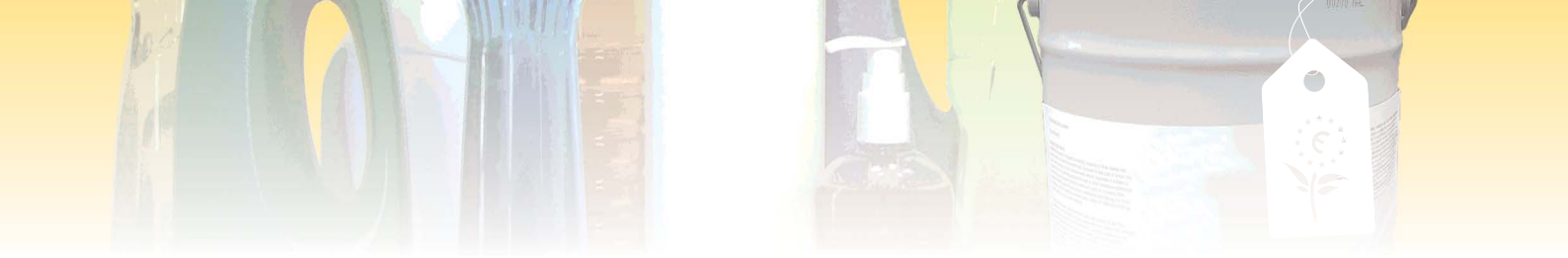
BOX 5. R-phrases for problematic inherent properties of substances which should not be allowed in the Ecolabel

Human health impacts	Environmental impacts
• 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) • R32 (Contact with acids liberates very toxic gas) • R33 (danger of cumulative effects) • R35 (Causes severe burns) • R39 (danger of very serious irreversible effects) • R40 (limited evidence of carcinogenic effect) • R42 (may cause sensitisation by inhalation) • R43 (may cause sensitisation by dermal contact) • 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) • 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) • R68 (possible risk of irreversible effects).	• N R50 (very toxic to aquatic organisms) • N R50/53 (very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment) • N R51/53 (toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment) • N R52/53 (harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment) • 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)

16 Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

17 Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.

18 The EU's Classification, Labelling and Packaging (CLP) Regulation aligns EU legislation to the United Nations Globally Harmonised System (GHS). This new system will ensure that the same hazards will be described and labelled in the same way all around the world.



Recommendations:

Ecolabelled products should not contain substances which are required to be labelled with at least one of the R-phrases given in Box 5 (or the related classifications of the GHS system). The classification of substances according to Directives on Dangerous Substances[19] and Dangerous Preparations[20] and/or according to the GHS should remain the basis for the criteria development according to the classification of the substances or preparations. This should therefore apply to substances and to the preparations.

If in specific product groups, ingredients or synthesis by-products which correspond to the above mentioned R-phrases cannot be avoided, concentration limits, which probably will be in the parts per million (ppm) range, should be set.

CMR substances Category 1, 2 and 3

Carcinogenic substances, mutagenic substances and substances of reproductive toxicity ("CMR") can cause severe, serious and irreversible health damage to humans and should therefore be excluded from Ecolabelled products.

Recommendations:

The Directives 67/548/EEC and 1999/45/EC and the corresponding categories of the GHS take account of the CMR properties of substances. **Therefore these substances should be excluded through the related R-phrases R40, R45, R46, R49, R60, R61, R62 and R63**.

Directive 67/548/EEC distinguishes between substances with effects that have been proven to be relevant for humans (CMR Category 1 and 2) and substances which are suspected to have these effects, on the basis of animal tests (CMR Category 3).

The Ecolabel scheme should exclude CMR category 1, 2 and 3. CMR category 3 substances have shown severe chronic toxicity in animal tests and cannot be excluded with certainty that no effects will take place if humans are exposed.

In addition, Ecolabelled products should not contain substances which are included in the IARC[21] reports on cancer causing chemicals, as substances that are human carcinogens (IARC1), probable human carcinogens (IARC 2A) and possible human carcinogens (IARC 2B). The scientific evidence behind IARC reports is strong enough to include these substances in the priority list as they raise a level of comparable concern to that substances classified as carcinogenic category 1 or 2, in accordance with Directive 67/548/EEC.

Neurotoxic substances, immunotoxic substances, allergens and sensitisers

Allergens, sensitisers and substances which are neurotoxic or immunotoxic should not be found in Ecolabelled products. These properties are already partly covered by the R-phrases (see the section on substances classified as dangerous, above). Substances which can cause sensitization are classified as R42 and R43. Many substances included in Annex I of Directive 67/548/EEC have different neurotoxic effects. However there is no unique method for classifying them. Substances with risk phrase R67 for vapours which may cause drowsiness and dizziness, is the only identifier of some of the substances with these properties.

Recommendations:

In specific cases, where information from toxicological studies is available that substances have these properties without already being classified, such information should also be taken into account.

19 Ibid

20 Ibid

21 International Agency for Research on Cancer: http://www.iarc.fr/

Endocrine disrupting substances

Substances which disrupt the endocrine system of living organisms have caused severe damage to wildlife populations and there is growing scientific concern on harmful effects on humans. They can disrupt or damage the body's or organisms' endocrine glands, affect the metabolism of hormones or disturb the interaction of hormones with their target organs. Due to the complexity and sensitivity of the endocrine system, such substances can cause severe effects even in very low concentrations.

The problematic inherent properties of endocrine disrupting activity, persistency and bioaccumulation potential are not adequately addressed by the above mentioned Directives[22] nor by the GHS. Therefore, the R-phrases approach needs to be complemented by additional criteria covering these properties. They are described in this section and the following section.

Since 1999, the European Commission has been developing a Strategy on Endocrine Disrupting Chemicals[23] with the aim of addressing the potential problems posed by these substances and ensuring better protection of the environment and human health. The short term action plan of the EU Strategy on endocrine disrupters involves setting up a priority list of endocrine disrupting substances. Until now, the Commission has published two Communications as part of the strategy. In the Strategy on Endocrine Disrupting Chemicals, substances have been identified which show endocrine disrupting effects in living organisms (Category I) or which have shown the potential of endocrine disrupting effects in in-vitro studies (Category II). Lists of these substances have been published recently by the European Commission[24].

Recommendations:

Endocrine disrupting chemicals (EDCs) can cause a multitude of harmful effects, which are not all taken into account by the R-phrases of Directive 67/548/EEC, Directive 1999/45/EC and the corresponding categories of the GHS. The use of R-phrases is therefore not sufficient to exclude endocrine disrupting chemicals.

Substances classified as endocrine disruptors Category I or Category II, within the EU Strategy on endocrine disrupters, should be excluded from Ecolabelled products. In addition, all EDCs which have been identified as chemicals of equivalent concern on a case-by-case basis in the context of REACH and further investigations on endocrine disrupting chemicals should be also excluded.

Persistent and bioaccumulative substances

Chemical substances which are persistent and bioaccumulative contribute to the complex chemical burden which is already present in the environment and which should be reduced as far as possible.

An international agreement on persistent and bioaccumulative toxicants, the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic, aims to eliminate the release of these dangerous substances into the marine environment by 2020. The European Union has signed OSPAR. The scientific evidence behind OSPAR Persistent, Bioaccumulative and Toxic substances list is strong enough to exclude these substances from the Ecolabel.

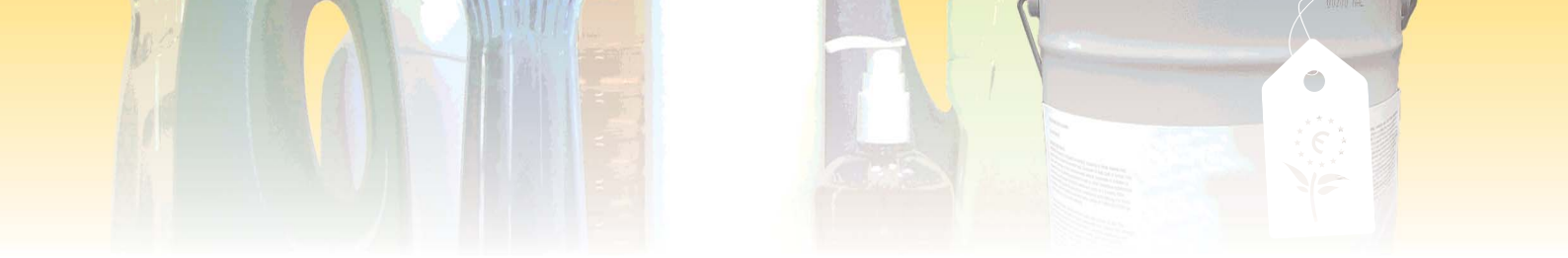
PERSISTENT SUBSTANCES

Substances which degrade slowly in the environment, or do not break down at all, can cause long-term damage to humans and wildlife. The release of such substances into the environment is irreversible in nearly all cases. Persistent chemicals often reach even remote areas, for example the Arctic region. For most substances, long-term toxicity is not or is only partly known. The use and release of persistent substances should therefore be avoided.

22 Directive 67/548/EEC and Directive 1999/45/EC

23 "Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife" COM(2001) 262 , which covers the time period 1999 to 2001. http://ec.europa.eu/environment/endocrine/index_en.htm

24 http://ec.europa.eu/environment/endocrine/documents/final_report_2007.pdf



In this context, Ecolabelled products should not contain persistent organic compounds[25] – independent from the toxicity and the bioaccumulation potential of the substances. The assessment of the persistency of a substance in the Ecolabel should include its degradation products and, if relevant, its combustion products of a substance (i.e. if the substance, or a product which contains the substance, is incinerated).

The property of persistency is not reflected in the existing R-phrases of Directives on Dangerous Substances and Dangerous Preparations[26] and the corresponding categories of the GHS. REACH does not refer to persistency as a discrete property. In REACH, persistency is taken into account if the substance is also bioaccumulative and toxic (PBT substances) or if the substance is very persistent and very bioaccumulative (vPvB). Therefore exclusion of PBT and vPvB substances does not automatically cover all persistent substances. The analysis of the EU PBT working group[27] has shown that there are a number of substances which are persistent, but do not fulfil the criteria for bioaccumulation and/or toxicity as given in Annex XIII of REACH.

Recommendations:

From a precautionary point of view, the property of persistency has to be considered as problematic, especially in the case of organic substances. Criteria to assess persistency have been developed by several EU Institutions[28]. The criteria for identifying substances that are Persistent, Bioaccumulative and Toxic (PBT) or that are Very Persistent and Very Bioaccumulative (vPvB) of REACH Annex XIII are currently undergoing revision. **For the Ecolabel, criteria related to results of laboratory test methods, as well as results from measurements of substances in the environment including indications of long range transport should be taken into account to decide whether a substance is persistent and should be excluded from Ecolabelled products.**

BIOACCUMULATIVE SUBSTANCES

Bioaccumulative substances have the potential to accumulate in living organisms. This can cause high concentrations even if the initial emissions of the substances have been low. There are several examples of bioaccumulating substances (e.g. dioxins, furans and polybrominated diphenylethers) which have been found even in remote areas of the world and as body burden of humans and in wildlife. Bioaccumulation is a problematic property of a substance which results in an enhanced and long-term exposure. For many substances the long-term toxicity is not or is only partly known. Therefore the use of bioaccumulative substances should be avoided independent of the question whether these substances have been classified as dangerous or not.

The property of bioaccumulation is not reflected by the existing R-phrases of Directives on Dangerous Substances and Dangerous Preparations[29] and the corresponding categories of the GHS. Also, REACH does not refer to bioaccumulation as a discrete property. Instead bioaccumulation is taken into account if the substance is also persistent and toxic (PBT) or if the substance is very bioaccumulative and very persistent (vPvB). Therefore exclusion of PBT and vPvB substances does not automatically cover all bioaccumulative substances. The analysis of the EU PBT working group[30] has shown that there are a number of substances which are bioaccumulative, but do not fulfil the criteria for persistency and/or toxicity as given in Annex XIII of REACH.

25 Organic compounds consist of several elements and contain carbon.

26 Ibid

27 The results of the EU PBT working group are published from the European Joint Research Centre (http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt).

28 "Non-hazardous chemicals – proposals for implementing of new guidelines on chemicals policy". Sweden, SOU 2000:53 (http://www.chemicalspolicy.org/SwedenGov.shtml)

29 Ibid

30 The results of the EU PBT working group are published from the European Joint Research Centre (http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt).

In addition, REACH defines in Annex XIII very narrow criteria for bioaccumulation in comparison to criteria which are set by other regulations such as OSPARCOM. Only a small number of substances fulfil these criteria. The REACH Annex XIII is currently under revision. Even substances which are known to be bioaccumulative by other mechanisms than bioconcentration are not detected by the REACH bioaccumulation criteria.

Recommendations:

Ecolabelled products should not contain substances which have the potential of bioaccumulation or which already have been found as body burden organisms.
Within the Ecolabel scheme, less narrow criteria to assess bioaccumulation should be used in order to avoid substances of a moderate bioaccumulative potential. Several criteria for assessing the bioaccumulation potential have been developed within the EU[31]. We recommend using criteria as given in OSPAR Annex XII[32] and, additionally, taking into account uptake mechanisms through the food chain and through air and whether there are rising trends in humans and the environment. Such substances should not be used for Ecolabelled products[33].

Substances with other problematic hazardous properties

Substances having the potential to harm the environment and human health should not be allowed in Ecolabelled products. This refers to substances having one of the properties described in the five preceding sub-sections, but should also be the case for substances which are acting by different mechanisms. Under REACH hazardous chemicals which are identified on a case by case basis for authorisation are called "substances of equivalent concern".

The "Substitute it now" (SIN) list[34] recently published by the International Chemical Secretariat (ChemSec), a non-profit organisation dedicated to working towards a toxic free environment, is a very good starting point for substances with other problematic properties (some of them are already covered by the properties formulated in the last five subsections). It lists 267 high concern substances that fulfil the REACH criteria for substances of very high concern, based on the combined efforts of public interest groups, scientists and technical experts. The list is based on credible, publicly available substance information from existing data bases, scientific studies and new research.

In the framework of this discussion paper we have not been able to address all aspects related to chemicals in Ecolabelled products. The focus of this study has been set on hazardous properties of substances. For this reason, the following issues should be considered in a wider study on chemicals and the Ecolabel:

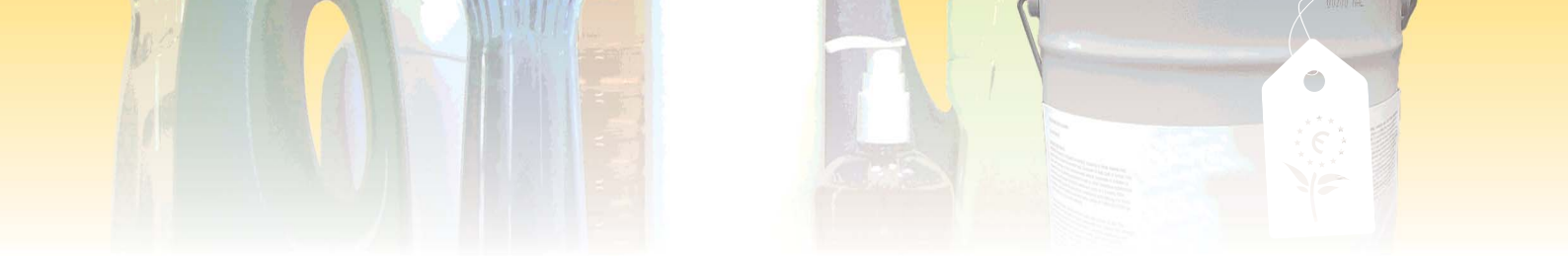
- Their production should not cause environmental burdens such as excessive energy/material use;
- Their production should not cause potential adverse effects such as impacts on biodiversity;
- Their production should not lead to the release of GMOs;
- They should be based on renewable materials.

31 "Non-hazardous chemicals – proposals for implementing of new guidelines on chemicals policy". Sweden, SOU 2000:53 (http://www.chemicalspolicy.org/SwedenGov.shtml).

32 Substances should not have a bioconcentration factor > 500 or a figure >= 4 for the logKow (logarithm of the partition coefficient n-octanol/water. (This factor describes the partition of a substance between an aqueous and a liquid phase).

33 Reineke, N.; REACH must allow use of "real world" PBT evidence. Chemical Watch November 2008 (http://www.panda.org/about_wwf/where_we_work/europe/what_we_do/wwf_europe_environment/initiatives/chemicals/index.cfm?uNewsID=150362)

34 ChemSec's SIN list can be found at their website at: http://www.chemsec.org/



9. Exclusion of groups of substances of concern to health and the environment

Several groups of substances have been shown to cause or have the potential to cause severe damage to human health or the environment. For this reason, they should be excluded from Ecolabelled products and production processes. Some of these substances are already excluded due to their problematic inherent properties covered by the criteria given in section 8 (e.g. toxic heavy metals), but not all.

Focusing on the inherent properties of a single substance does not allow identification of all areas of concern which could occur during the whole lifecycle of a substance or a product. Examples for such areas of concern are:

- use of hazardous substances for the production of the substance;
- emissions of hazardous substances during production of the substance;
- formation of hazardous degradation products in the environment;
- formation of hazardous substances during metabolism in the human body;
- release of hazardous substances in case of incineration;
- formation of hazardous substances during recycling or in waste treatment steps;
- interaction between several substances.

The Ecolabel must continue to take into account inherent hazardous properties of substances as well as additional problematic areas of concern. Therefore, Ecolabelled products should not contain substances which are linked to one or several of the areas of concern listed above, such as:

- Alkylphenolethoxylates (environmental toxicity/endocrine disrupting activity of degradation products);
- Halogenated flame retardants (human toxicity, environmental toxicity, persistency, bioaccumulation potential, hazardous incineration products, problems during recycling phase/ waste treatment);
- Halogenated organic solvents (human toxicity, environmental toxicity, volatile organic compounds with the potential for formation of photo oxidants);
- Phthalates (human toxicity, environmental toxicity);
- Biocides and pesticides (human and environmental toxicity), e.g. organotin compounds;
- Persistent fluorinated compounds (human toxicity, persistency);
- Nitromusks and polycyclic musks (persistency);
- Azo dyes which can release carcinogenic amines (human toxicity).

The Ecolabel guidelines would need to clearly identify how exceptions for individual substances would be allowed. For example, an exception could be made if a substance (which structurally belongs to one of the above groups) does not show any problematic properties, or do not have the potential to raise problems linked to the areas of concern listed above, throughout its whole lifecycle. Also in this case it should be clarified that the use of the substance cannot be avoided by a different design of the product (see section 7).

10. Manufactured nanomaterials and nanostructures

Leading scientific organisations have warned that nanomaterials may present serious risks to human health and the environment. One of the first of these opinions came in 2004 from the UK Royal Society. It recommended that nanomaterials be treated as new chemicals and be subject to new safety assessments prior to their inclusion in consumer products. It also advised to adopt the precautionary approach in technology development and applications because of knowledge gaps in key safety areas: *"Until more is known about environmental impacts of nanoparticles and nanotubes, we recommend that the release of manufactured nanoparticles and nanotubes into the environment be avoided as far as possible"*.[35]

Since then, different governmental bodies in several Member States[36] have assessed current legislation and concluded, to varying degrees, that considerable gaps and limitations exist in assuring the further safe development and application of nanotechnologies in consumer products. The legislative gaps need to be clearly identified, analysed and closed in advance of any further developments.

While there is an urgent need for more research to ensure that environmental and health risks presumably posed by certain nanomaterials are addressed, there are fundamental knowledge gaps on how to assess their safety. Nanosized materials are currently not sufficiently characterised and the methods for overcoming this problem (analytical methods and test methods for ecotoxicological and toxicological properties) are not sufficiently developed and harmonised. The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded that: *"Current risk assessment methodologies require some modification in order to deal with the hazards associated with nanotechnology"*.[37]

The EU regulatory framework currently also inadequately addresses the possible nano-related risks. While existing legislation is in principle ensuring for the safe use and development of nanomaterials, practical application is unclear. The existing gaps associated with current scientific risk assessment methods prevent current legislation such as Directive 67/548/EEC, GHS or REACH from ensuring proper consideration of engineered nanomaterials. These substances cannot be assessed based on how similar compounds behave in their larger particle forms, nor is it possible to properly identify the risks that they pose. Furthermore, volume production of many nano-particles (less than one tonne/year) means that registration under REACH is not required, but even if it is required, the set of tests is likely to be insufficient to determine the related risks.

Recommendations:

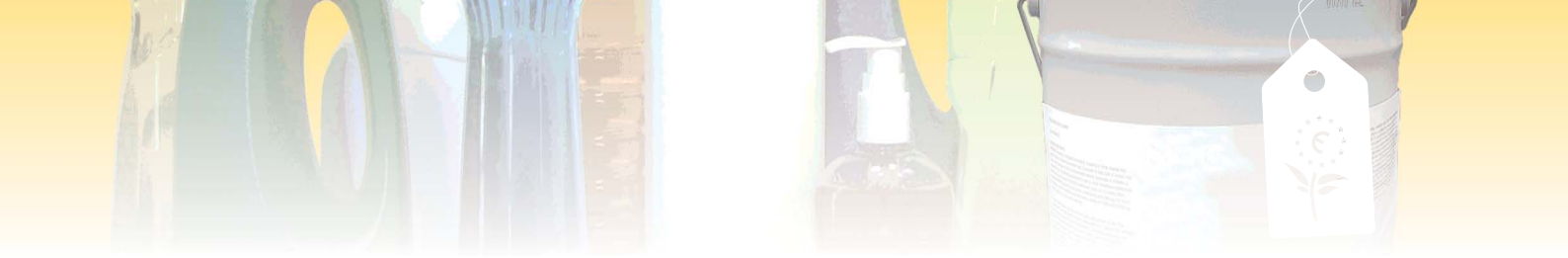
It is true that nanomaterials may offer consumer benefits. However, the huge uncertainties of the scientific understanding about the risks presented by nanomaterials might outweigh these benefits. Given the growing body of toxicological evidence showing that in specific cases manufactured nanomaterials may present serious risk to human health and the environment, we consider that the precautionary approach should be followed by the Ecolabel. **Until a proper toxicological and ecotoxicological assessment framework for nanomaterials is in place, the Ecolabel should not be given to consumer products which contain manufactured nanomaterials and structures which could be released into different environmental media**[38].

[35] *Nanoscience and nanotechnologies: opportunities and uncertainties*; The Royal Society & Royal Academy of Engineering, 2004; pg. 50.

[36] Countries such as Austria, Germany, Ireland, Sweden and the UK have undertaken regulatory analysis or have provided public commentary on existing legislation.

[37] Scientific Committee on Emerging and Newly Identified Risks (SCENIHR), Modified Opinion (after public consultation) on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, 10 March 2006.

[38] An exception from this general exclusion could only be made if in the future, a proper detailed assessment of individual nanoparticles shows, on the basis of adequate test methods, that a safe use for humans and the environment is possible, taking into consideration the whole lifecycle. Also in this case it should be clarified that the use of the substance cannot be avoided by a different design of the product.



11. Completeness and quality of the substance specific data

For a good and robust characterisation of the hazardous potential of a substance, a sufficient amount of data is required on its toxicological and ecotoxicological properties. In addition, adequate data is an essential condition in making comparisons between substances of concern and substances which can be recommended as substitutes.

In practice, for most of the substances available on the market, these data are missing, one of the major reasons for the development of REACH. Fortunately, registration under REACH will increase the knowledge regarding properties and uses of many substances within the next 10 years. The priorities and the timelines set by of REACH are outlined in the following table.

BOX 6: Registration under REACH: Priorities and time lines.

- End November 2010: Deadline for registration of high production volume chemicals (at least 1,000 tonnes/year), chemicals classified as dangerous for the environment (R-phrases R50 -53) with a production of more than 100 tonnes/year) and of substances classified as carcinogenic, mutagenic or of reproductive toxicity (with production volumes of greater than one tonne/year);
- End June 2013: Deadline for registration of substances with a production volume between 100 and 1,000 tonnes/year;
- End June 2018: Deadline for registration of substances with a production volume chemical between 1 tonnes/year and 100 tonnes/year.

Recommendations:

The Ecolabel should support the use of well-characterised substances for which the inherent properties have been assessed taking into account all relevant endpoints for human health and the environment (independent from the registration state and the data requirements as given by REACH). At present, for the majority of substances, neither the data on hazardous properties nor risk characterisations for the intended uses are available.

The quality and the completeness of the data available for a substance should become an important criterion within the Ecolabel scheme. This criterion does not yet exist and has to be developed. **Therefore, within the Ecolabel scheme an incentive can be given to close data gaps as soon as possible.**

In order to make an assessment, for all ingredients of an ecolabelled product the following information should be declared:

- The chemical name including CAS number and concentration;
- REACH registration relevance of the substance (e.g. polymers,and substances listed in Annex IV have not to be registered);
- Indication if registration is not required due to a low production volume of less than one tonne/year;
- Production volume of the substances which has to be registered;
- Registration already completed (documented by the registration number given by ECHA) or registration missing;
- Availability of data as described in REACH Annex VII; (1 tonne/year and more);
- Availability of data as described in REACH Annex VIII; (10 tonnes/year and more);
- Availability of data as described in REACH Annex IX; (100 tonnes/year and more);
- Availability of data as described in REACH Annex X; (1000 tonnes/year and more);
- Availability of risk characterisations of the intended uses (with documentation of safe conditions of use by exposure scenarios).

12. Conclusions

The guidelines and recommendations in this document should help formulate a more strategic discussion on the Ecolabel's approach to sustainable chemicals use in products. The Ecolabel needs a consistent and coherent approach, including to chemicals, in order to maintain its status as a mark of "environmental excellence". This approach must include going beyond existing regulations, including REACH.

Such a discussion needs also to consider elements that we have not been able to address in the preparation of this paper. Such elements extend to the production phase of substances, most notably the use of energy and impacts on biodiversity and an environmental preference for renewable materials.

The European Ecolabel can only remain a 'pioneer' in product policy if it continues to develop its forward-reaching approach to products, despite gaps in the policy and regulatory framework that currently surround it and are likely to continue to do so in future.

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