About Nordic Ecolabelled

Disposable products for peritoneal dialysis (PD) and intravenous (IV) infusion treatment

Version 1.8
Background to ecolabelling

Nordic Ecolabelling

Addresses

In 1989, the Nordic Council of Ministers decided to introduce an official voluntary ecolabelling scheme, the Swan. The organisations/companies listed below administer the Swan ecolabelling scheme on assignment from their respective national governments.

For further information, please visit the respective Web sites:

Denmark
Ecolabelling Denmark
Danish Standard Foundation
Göteborg Plads 1, DK-2150 Nordhavn
Fischersgade 56, DK-9670 Løgstør
Phone: +45 72 300 450
info@ecolabel.dk
www.ecolabel.dk

Finland
Ecolabelling Finland
Urho Kekkosen katu 4-6 E
FIN-00100 Helsinki
Phone: +358 9 61 22 50 00
joutsen@ecolabel.fi
www.ecolabel.fi

Iceland
Ecolabelling Iceland
Umhverfisstofnun
Suðurlandsbraut 24
IS-108 Reykjavik
Phone: +354 5 91 20 00
ust@ust.is
www.svanurinn.is

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

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

Swan labelling of products for PD and IV infusion treatment:
Background criteria version 1.8 – 18 June 2019

Abbreviations used in the criteria document and the background document

BBP	Benzyl butyl phthalate (CAS No. 85-68-7)
CMR	Carcinogenic, mutagenic and toxic to reproduction
DBP	Dibutyl phthalate (CAS No. 84-74-2)
DEHP	Diethylhexyl phthalate (CAS No. 117-81-7)
DG ENV	Directorate General Environment
DIDP	Diisodecyl phthalate (CAS Nos. 26761-40-0 and 68515-49-1)
DINP	Diisononyl phthalate (CAS Nos. 28553-12-0 and 68515-48-0)
DNOP	Di-n-octyl phthalate (CAS No. 117-84-0)
EC	European Community
EKU	Swedish official board for green and public procurement
EMAS	Eco Management and Audit Scheme
EN	European Norm
EU	European Union
ISO	International Standardisation Organisation
IV	Intravenous
LCA	Life cycle assessment
NO_x	Nitrogen oxides
PVC	Polyvinyl chloride
RPC	Relevance, potential and controllability
SFS	The laws of Sweden
SIS	Swedish Standards Institute
SO_2	Sulphur dioxide
TEQ	Toxic equivalent
VOC	Volatile organic compound

1 Summary

The purpose of this document is to outline the background for the first generation of criteria for the ecolabelling of disposable products for peritoneal dialysis (PD) and intravenous (IV) infusion treatment. This allows applicants, consumers and interest organisations to read Nordic Ecolabelling's reasons and justifications for the requirements imposed in the criteria document.

This document describes the reasons behind the choice of product group and the requirements from the perspective of Nordic Ecolabelling's environmental philosophy. Two of the environmental goals defined in Nordic Ecolabelling's Philosophy are of particular relevance to the life cycle of disposable products for the treatment of peritoneal dialysis and intravenous infusion, and relate to the following areas:

- Emissions and effects of substances harmful to health, e.g. on sensitive patient groups.
- Waste and waste generation.

In addition to these environmental targets, the environmental philosophy specifies a number of means by which the vision of sustainability should be achieved. For example, the environment must not be exposed to systematic increases in the concentration of substances deriving from the ground. There is also reference to the Factor Four and Factor Ten concepts, which state that we will have to increase the efficiency of our use of natural resources, materials and energy by a factor of four in the short term and a factor of ten in the longer terms.

Justification for the requirements is also provided by the potential environmental gains offered by the ecolabelling of disposable products for peritoneal dialysis and intravenous infusion treatment and the scope for controlling and documenting the requirements.

2 Introduction

This background document is the first for this product group, and it will serve as a background to Version 1 of the criteria document for disposable products for peritoneal dialysis and intravenous infusion treatment. The criteria were adopted by Nordic Ecolabelling on 13 December 2007.

In 2006, Nordic Ecolabelling was contacted by a manufacturer in the health care industry who wanted us to establish ecolabelling criteria for peritoneal dialysis (PD) bags. Based on that contact, Nordic Ecolabelling conducted a survey of the health care industry in the Nordic countries. In late 2006, it was decided based on the findings of this study that ecolabelling criteria should be drawn up for this product group. During the development of the criteria, disposable products for intravenous (IV) infusion treatment were also included due to interest from industry.

The work of drafting requirements was carried out by an internal work group chaired by Ecolabelling Denmark in 2006-07.

Nordic Ecolabelling's procedures require technical data from operators in the market to be compiled. This product category was no exception, and data from various manufacturers was considered at the meetings of the working group. Proposals for criteria were drawn up with the aid of the expertise provided by experts contacted on an ad hoc basis. The 60-day public review also provided valuable information.

The purpose of ecolabelling disposable PD and IV infusion products is a form of sustainability target, although without the social dimension normally included in the sustainability concept. The criteria are designed to promote the development of products that:

- do not use substances that are harmful to health or the environment.
- contribute as little as possible to generation of problematic waste.

Since criteria are normally revised every three to five years, each version of the criteria document represents a step in the direction of achieving the above-mentioned goals. The goal of this first version of the criteria is to take the first step towards the sustainability target.

Moreover, the background document focuses on discussing the criteria against the background of published life cycle assessments; evaluations of relevance, potential and controllability (RPC); quantitative and qualitative assessments regarding the consequences of the new criteria; etc.

3 Other environmental schemes and legislation

There are at this time no other ecolabelling schemes with criteria for this product group. The Swedish EKU (the official Swedish board for green and public procurement) has, however, developed criteria for dialysis equipment and disposables (haemo- and peritoneal dialysis therapy) as well as for medicinal products (EKU 2007):

- Haemodialysis equipment and disposables
- Peritoneal dialysis equipment
- Peritoneal dialysis disposables
- Medicinal products

In the case of peritoneal dialysis disposables, EKU divide the criteria in two: one covering disposables such as tubes and fittings under the Medical Devices Directive and one covering the bag and dialyse solution under the medicinal products legislation.

The EKU criteria for disposable products exclude chlorinated plastics such as PVC in the packaging. However, PVC is not excluded from the disposables themselves, such as tubes and fittings.

With respect to tubes and fittings, the criteria focus on additives, but they are not compulsory. EKU addresses additives that are dangerous to the environment, carcinogenic, mutagenic or toxic to reproduction (Categories 1 and 2), toxic or very toxic according to EU classification legislation.

As the bag and the dialysis solution together are considered a medicinal product, PVC is not excluded. The reason is that the compulsory criteria for medicinal products do not exclude PVC packaging (i.e. the bag). In the future, EKU will consider excluding PVC.

Claims
Product catalogues for medical devices include some product data, but they often lack information as to whether the material contains PVC. But claims such as “PVC-free” or “phthalate-free” are sometimes communicated on the products or product sheet. This information may give some guidance to the buyer, but such claims have some disadvantages in comparison with ecolabelling:

- Claims by a first party are not as credible as third-party certifications.
- Marketing agreements and regulations in the health care sector might conflict with such claims.
- The claim itself may not be an obvious issue or concern for the customer, whereas a well-recognised ecolabel is much easier to understand.

The international coalition *Health Care Without Harm* works in more than 50 different countries and collaborates with more than 440 organisations (hospitals, healthcare staff, environment organisations, etc.). The objective of Health Care Without Harm is to transform the market for health care materials so that neither people's health nor the environment is harmed. One of Health Care Without Harm's work groups in Europe is working in particular for safer materials and is focusing on phasing out PVC, phthalates and mercury. Health Care Without Harm has a list of manufacturers and products that are PVC-free.

Environmental certification
Some of the manufacturers of medicinal products and medical devices already have certified environmental management systems such as ISO14001 or EMAS in place. In formulating the criteria, we tried to take into account the environmental management systems already used by manufacturers of disposable products for peritoneal dialysis and intravenous infusion treatment, with a view to reducing the administrative burden.

This forms one of the components in the vision proposed by the authors of the Nordic Council of Ministers report on the role of the Swan Label in relation to environmental management (Edlund et al. 2002), which states on page 14:

> *”A significant part of the data necessary to document and confirm the requirements of the eco-labelling scheme is generated by the producer's environmental management system. The environmental management system also organises the necessary documentation, and environmental reporting can be used to report to the eco-labelling organisations.”*

Standards
The IEC 60601-1-9 standard ("General requirements for basic safety and essential performance - Collateral standard; Requirements for environmentally conscious design") contains a clear summary of the different environmental aspects for medical device equipment in a life cycle perspective. According to the standard there must be documentation of how to handle the equipment to minimise the environmental load. Among other things, the documentation must contain information on type and weight of packaging; use of energy, water, disposables and chemicals; and emissions from the equipment.

European directives
The Directive 2001/83/EC on the Community code relating to medicinal products for human use contains provisions about authorisation and control of medicinal products and the companies that manufacture, store or otherwise handle medicinal products.

For instance, the solution and container for peritoneal dialysis must be approved by authorised authorities before marketing and use on patients, according to the medicinal product directive. The authorisation consists of a marketing authorisation.

However, many related items, such as drainage bags, tubing and catheters, are also regulated under the Medical Devices Directive.

Medical devices are regulated by three main directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), e.g. pacemakers.
- Council Directive 93/42/EEC on Medical Devices (MDD), also called the general directive, covers all medical devices except for active implantable medical devices and in vitro diagnostic devices. This directive went into effect on January 1, 1995.
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD), e.g. laboratory equipment.

The Medical Devices Directive, as well as the new rules in the IVDMD Directive, requires CE labelling to demonstrate conformity with certain standards for safety purposes. The CE marking is a visible sign that the manufacturer has complied with the procedures of the Directive and that the products fulfil the requirements that apply to them.

One of the standards is ISO Standard 10993:2003 for the biological evaluation of medical devices. This standard consists of almost 20 parts. The first part of the standard states that the following should be considered of relevance in the overall biological evaluation of the device:

- materials of manufacture
- intended additives, process contaminants and residues
- leachable substances
- degradation products
- other components and their interaction in the final product
- the properties and characteristics of the final product

In January 2007, ISO voted to approve a new project in the area of biological evaluation of medical devices. The title of the project is “Technical Specifications for Development of Tolerable Intake Values for Di-(2-ethylhexyl)-phthalate (DEHP)” (ISO/TC 194 N619), and it is expected to provide more specific guidelines regulating the use of DEHP in medical devices (see the section on SCENHIR).

Medical devices are divided into four different classes (I, IIa, IIb and III). In addition, Class I is subdivided into devices sold in a sterile condition and devices sold with a measuring function. The classification reflects the risks involved in the use of the product, the vulnerability of the parts of the body on or in which the devices are to be applied and the duration of use.

The highest risk class (III) includes products which come into contact with the central nervous system, the heart or the central circulatory system, as well as medical devices incorporating medicines. The classification thus ensures that regulatory control is reasonably proportional to the risk involved in the use of the product.

Testing of medical devices is carried out by the notified bodies; labelling with the CE label is the responsibility of the manufacturer. The subsequent supervision, which ensures that products on the market fulfil the requirements of the Directive, is, on the other hand, the responsibility of the competent authorities. An example of a notified body is DGM: DS Certification/DGM (Danish Medical Devices Certification) is the Danish notified body (www.dgm-nb.org).

A notified body issues certificates documenting compliance with the relevant standards under the Medical Devices Directive. For the revision of the Medical Devices Directive see section 5.1 below.

European Scientific Committee (SCENIHR)
The EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is currently working to comply with a request to review and update the opinion adopted in 2002 by the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD) in order to assess the safety of alternatives to DEHP in PVC-based medical devices and to establish tolerable intake values of DEHP leaching from soft PVC as a basis for assessment of risk to high-risk patient groups, taking into account the route of exposure.

Prior to the publication of its final recommendations, SCENIHR has decided to give its proposal will be given a public review in the autumn of 2007. In the proposal SCENIHR reports very high exposure for patients undergoing medical treatment with devices containing DEHP. Even if there is limited indication of a relationship between DEHP exposure and certain effects in humans, the very high exposure raise a concern. DEHP induces more severe effects in reproductive animal studies compared with some of the alternatives.

Interest in DEHP extends to outside Europe as well. Most recently, the US National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) summarised in a 200-page report scientific progress made since 2000 and commented on its validity in evaluating the risk DEHP represents to human reproduction.

The European scientific committees are expected to reach more or less the same conclusions as other authorities in the world. Two expert panels of the US National Toxicology Program (NTP), the US Food and Drug Administration (FDA), and the Health Canada Expert Panel have all reached the same conclusions: animal studies of DEHP raise serious concerns because they are likely to predict human health impacts.

They therefore recommend avoiding the use of DEHP-containing medical devices and preferential use of safer alternatives, especially for vulnerable groups, including infants, small children, pregnant and nursing mothers, and patients on haemodialysis.

Some EU member state authorities, including the German Federal Institute for Drugs and Medical Devices (BfArM 2004), have also recommended the use of alternatives for vulnerable patient groups and encouraged manufacturers to develop new and safer DEHP-free alternatives.

4 The Market

Medical devices more or less comprise all products with some form of medical connection, except for pharmaceuticals: everything from consumables such as dressing materials, syringes and drainage to implants, x-ray equipment and imaging systems for medical diagnostics.

The medical devices industry is extensive and global, with a large number of international manufacturers often represented at the national level either through subsidiaries or trading companies. From an international perspective, the medical devices industry has a turnover of approximately €184 billion, with approximately €55 billion in Europe. In Sweden, the industry employs roughly 15,000 people distributed among a few very large international companies and many small-to-medium-sized companies.

Of the total use of PVC in the world, it is estimated that a little less than 1% is used in medical devices. The market for medical devices is global, and conditions in the Nordic countries may be assumed to be similar. In Stockholm County alone, more than 200 tons of PVC products were used each year in 1997-2004. Most of the PVC was used for gloves at 170 tons (18.8 million units), followed by infusion materials at 15-20 tons (580,000 units) and urine bags at 13 tons (450,000 units).

There are PVC-free alternatives available today on the market in nearly all areas of use (except for blood bags for red blood corpuscles and tubing for haemodialysis). Latex is an alternative to PVC gloves, but especially those with powder are associated with allergy problems.

The market shares of haemo- and peritoneal dialysis equipment from the three major manufacturers in the world are shown in the table below.

Table 4. Kidney Treatment Equipment: Worldwide Market Share 1999 (Gambro 1999).

Type of Dialysis	Baxter (market share)	Gambro (market share)	Fresenius (market share)
Haemodialysis	5%	22%	26%
Peritoneal Dialysis	71%	2%	16%
Both Haemodialysis and Peritoneal Dialysis	23%	17%	23%

Haemodialysis is the dominant kidney therapy in developed countries and accounts for approximately 70% of worldwide dialysis revenues (Dorland's Biomedical, 1998). In developing nations, lower-cost peritoneal dialysis dominates. For example, peritoneal dialysis accounts for 90% of the dialysis market in Mexico (Leaversuch 1999).

The three world-leading dialysis companies – Fresenius, Baxter, and Gambro – account for approximately 63% of all dialysis revenues (see Table 4). Other, smaller players in the dialysis market include Aksys Ltd., Althin, B. Braun McGaw, Bard, Horizon Medical Products, Medionics International, Minntech Corp., and Vasca, Inc.

Worldwide revenues from dialysis products and services totalled $5.45 billion dollars in 1997, with U.S. revenues equalling $1.39 billion (Dorland's Biomedical 1998). In the U.S., Baxter dominates the peritoneal market with approximately 85% market share. The haemodialysis market is dominated by Baxter, Gambro, and Fresenius.

The IV (intravenous) therapy solutions market in Europe is dominated by the following competitors, who represent a total of 80% of the European market (Frost & Sullivan1996):

- Fresenius
- Pharmacia & Upjohn (today Fresenius Kabi)
- B Braun
- Baxter/Clintech

Based on 1996 figures and the expected growth rate, these companies will generate estimated revenues of 950 million to 1 billion US dollars in 2007.

5 Choice of product group

The idea of ecolabelling disposable health care products stemmed from an inquiry from a manufacturer. Even if Nordic Ecolabelling had not been operating in the health care sector, this product group would be considered relevant due to the simple fact that it comprises single-use products used in large quantities. Nordic Ecolabelling looked at selected disposable health care products with a view to potential ecolabelling (Bergbom 2006); the study is currently available from Nordic Ecolabelling. The product group was initiated as a so-called "environmental pioneer".

The study concluded that there was potential for improvement, particularly in:

- Leaching of plasticisers from polymers, which could affect the long-term health of patients, i.e. sensitive groups such as newborns, children and dialysis patients.
- Reduction in the amount of waste and possibly problematic emissions from incineration plants.

A decisive factor in the choice of product group was the scope for achieving environmental gains in the most important parameters without shifting environmental problems into other areas.

Regarding the quality and security aspect, Nordic Ecolabelling is aware of the extensive legislation in this area. No health care products can be put on the market unless they have been approved by the authorities.

Moreover, Nordic Ecolabelling concluded that professionals in the health care sector wanted more environmentally friendly devices and disposables. One of the problems with PVC that hospitals experienced became apparent when they began sorting their waste: healthcare products did not usually have any markings other than a CE marking.

The fact that a number of PVC-free products were already on the market indicated that good functionality and quality could be delivered, and the prices of these alternatives had recently become increasingly competitive. Other factors also affected price considerations:

- Bags: the alternative polymers are 10-20% more expensive, but cost-competitive due to less material needed for the same size and kind of bag (so-called "down gauging").
- Tubing: can cost more but may have a longer service life.
- Gloves: cost-competitive at large volumes and better quality, which leads to fewer discards.

5.1 Revision of the Medical Devices Directive

In its review of the criteria, Nordic Ecolabelling was criticised on its choice of product group. Several stakeholders wanted to postpone development of the criteria and wait for the revision of the Medical Devices Directive.

The revision is finished, and the new directive was adopted in 2007. It will enter into force in the member states in the beginning of 2010. The new directive contains a requirement that manufacturers should avoid substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs). A total ban of these substances was not possible.

Additionally, the revised directive states that devices which could possibly release phthalates to the body of the patient should be labelled accordingly.

To achieve this, CEN, the European Standards body, will specify a label for phthalate-containing devices on a mandate from the European Commission. However, the labelling requirement will not come into force until 2011.

Nordic Ecolabelling is satisfied with this development, which will lead to better information provided to the users of these products.

The Nordic Ecolabelling requirement goes further than the revised directive because phthalates mentioned in the EU Toys Directive, phthalates that are Category 1, 2 or 3 CMRs as well as phthalates that are endocrine disrupters are totally banned. And not only phthalates are banned but all additives that have the mentioned properties.

However, the Nordic Ecolabelling requirements also cover several aspects of the life cycle other than the use of additives with CMRs and endocrine disruption properties. Examples are additives hazardous to the environment. The requirements also deal with the disposal of the products and are aimed at avoiding production of large amounts of residue that has to be landfilled.

Information on phthalates in products requires the users to understand the information so they can make an informed choice. As reported by several hospitals to Nordic Ecolabelling, users may not have the education to fully understand and react to the information.

6 Background for delimitation of product group and requirements

The background for and rationale behind the requirements is described in the sections below. Reasons are based on Nordic Ecolabelling's goals and the potential for improvement by the health care industry. The cost of compliance with requirements is also discussed, as is the attitude of various interested parties where relevant.

Requirements that have been discussed but not included are also discussed where relevant in the context.

6.1 Definition of product group (what is eligible for Nordic Ecolabelling)

Disposable products for peritoneal dialysis and intravenous infusion treatment have been chosen as eligible for Nordic Ecolabelling due to interest from the industry. Another important reason is the existence of established and priceworthy alternatives on the market for these kinds of health care products.

The description of peritoneal dialysis treatment in the criteria terms and definitions section is based on the information in Appendix 1 below. The intravenous infusion treatment description is based on Lindskog et al. (1975).

In future, Nordic Ecolabelling may consider including other medicinal products or single-use medical devices as well.

6.2 Environmental requirements and other requirements

Nordic Ecolabelling formulated the requirements in consideration of the following:

- The number of requirements was kept small.
- Templates were created relating to the procedures and instructions needed by the manufacturers in order to fulfil the requirements.
- Templates were created for suppliers, so it is less time-consuming to document requirements for chemicals.

The Working Group emphasised that compliance with the requirements should be easy to document, while also encouraging manufacturers to introduce environmental improvements or rewarding manufacturers that have already done so.

Generally, the requirements were selected based on an assessment of the effects of each product on health and the environment during its life cycle. In addition, an assessment was performed of the potential for environmental benefits without gains in one area entailing a problem in another.

Other key factors are the importance of formulating clear criteria that are documentable and offer a high degree of credibility. Where the Nordic authorities have legislation in place or have stated goals or attitudes in an area, this will be taken into account, since it is intended that the ecolabelling requirements be stricter than legislation applicable in that area.

6.2.1 Description of the product (R1)

For reasons of credibility, it is required that the applicant describe how the product is covered by current legislation. The legislation has strict requirements as to the safety and functionality of the product. See more about the legislation for health care products in section 3 above.

6.2.2 Halogenated plastics in product or packaging (R2)

The decision to exclude halogenated plastics such as PVC (vinyl) was made in the light of Nordic Ecolabelling's objective to reduce problems in waste handling.

This requirement was also selected in the light of Nordic Ecolabelling's objective to reduce the risk of health-related problems.

The main waste problems with chlorinated plastics such as PVCs are the production of hydrochloric acid when they are incinerated and the need for expensive equipment to neutralise the acid. The neutralising process generates a large amount of problematic residue in the incineration plant, and this residue must be deposited under special conditions such as landfill.

The generation of dioxin in incineration plants is mostly correlated with the operation and design of the incinerator and the flue gas treatment. Although the amount of PVC may have some influence of the generation of dioxin, it is of less importance because there is normally always chlorine from other sources in municipal waste (see section 7.2.3 below on waste issues).

A similar need for neutralisation with the subsequent generation of large amounts of problematic residue is expected from the incineration of plastics containing other halogens (for instance bromine), so the requirement applies to all halogenated plastics. Halogenated plastics other than PVC are probably not used in medical devices or medicinal products packaging at this time, so the requirement is intended to ensure that halogenated plastics are not used as an alternative to PVC in the future. Other plastics do not generate acid to the same extent in waste incineration plants and therefore are less problematic.

The definition of plastic is taken from the Danish Plastics Federation and covers thermoplastics, thermosets and elastomers (Plastindustrien i Danmark 1999).

Soft PVC, in contrast to other polymers, requires a significant amount of plasticiser, which has the potential to migrate and enter a patient's body. A precautionary approach is therefore to avoid such polymers. Going further than the current legislation by applying the precautionary principle is a strategy supported by the fact that an EU scientific committee on newly identified health risks has taken up the discussion on harmful PVC plasticisers again (see section 7.2.1 on health effects).

PUR is an optional material for tubing; the potential health risk from exposure to isocyanates is far less than that to plasticisers from PVC tubing due to the simple fact that the amount present in the plastic is very small. Any amount present in PUR is unintended, as opposed to the plasticisers in PVC.

Polycarbonate is a stiff material used in small parts of catheters and connections, etc. The potential health risk from exposure to bisphenol A in this connection is also much smaller for the same reasons as for isocyanates in PUR. See more about the environmental profile of PUR and polycarbonates in section 7.3.1 and Appendix 2 below.

The potential health risk from both PUR and polycarbonate in this type of product is assessed to be administered by the legislation (see section 3).

PD and IV bags are made of alternatives to PVC, e.g. a laminate consisting of polyamide and polyolefin or pure polyolefins. The environmental profiles of these materials are dealt in section 7.3.1 and Appendix 2.

6.2.3 Plasticisers, other additives and adhesives (R3-R5)

As the use of PVC is not permitted, it may seem unnecessary to have requirements regarding plasticisers and additives. Normally little plasticiser or additive is used in plastic materials other than PVC.

However, almost all plastics contain additives to which humans, or the environment may be exposed, although the legislation discussed in section 3 is aimed at protecting humans from any unwanted exposure. The requirement is therefore mostly laid down for credibility reasons: to catch possible harmful chemicals used in plastics other than PVC.

The legislation discussed in section 3 is aimed at protecting humans from unwanted exposure to health care products. Most of the waste from disposable plastic health care products is incinerated, and there will thus be no exposure of the aquatic environment to the adhesive used. Thus, the requirement exists mostly for credibility reasons: to catch possible harmful chemicals.

The information needed to show compliance with the additive and adhesive requirements is similar to what is needed for authority approval or authorisation for this kind of products.

Endocrine disruption (R3)
Some of the phthalates used as plasticisers are endocrine disrupters. The requirement is based on the EU implementation of a Community strategy for endocrine disrupters that covers a range of substances suspected of interfering with the hormone systems of humans and wildlife.

In order to prioritise the review of the information on endocrine disrupters, a priority list was developed and reported in the so called “BKH Report” (European Commission DG ENV 2000). Several studies have been performed since the BKH Report and they can be seen on the EU Endocrine Disrupters website:

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm

In Annex 1 in the BKH Report from 2000, a candidate list of 553 endocrine disrupters was identified by the EU as a basis for prioritisation. The candidate list was divided into three separate groupings of substances depending on the level of information available. The candidate list for prioritisation with the 553 substances is available for viewing at the EU Endocrine Disrupters website.

The following studies have resulted in an updated priority list in September 2007. The updated priority list now contains 428 substances and is included in Appendix L in the “Final Report of the DHI-Study” on the EU Endocrine Disrupters website.

The list includes substances with evidence of endocrine disruption, substances considered potential endocrine disrupters and substances still under suspicion. The list is open to change. As new information becomes available, chemicals may either be removed from or added to the list.

Environmental harmfulness (R4)
The requirement that the chemical added to the plastic may not be classified as environmentally harmful is based on the EU classification legislation.

In the review of the criteria, several hospitals wanted improvements in usability of the criteria. Thus, to make it easier not only for manufacturers but also for buyers to use the criteria, Nordic Ecolabelling added a link to a self-classification database. The database is the result of collaboration between the Nordic Council of Ministers and the European Chemical Bureau: *http://apps.kemi.se/nclass/default.asp*

Health-related requirements (R4)
The chemicals to which restrictions apply are those that have or should be allocated a risk phrase indicating that the chemical is carcinogenic, mutagenic or toxic to reproduction (termed 'CMR effects') or is allergenic, toxic or very toxic according to EU classification legislation. All chemicals with CMR R phrases are excluded, irrespective of whether they cover Category 1, 2 or 3 CMR effects. The exclusion of substances that are harmful to health will minimise possible health issues related to the use of the product but will also improve the chemical working environment during the manufacturing of the product.

In their review, several hospitals requested improvements in the usability of the criteria. To make it easier both for manufacturers and for buyers to use the criteria, Nordic Ecolabelling added a link to the European Chemical Bureau's database. This database contains legally binding and recommended classifications of substances in the EU: *http://ecb.jrc.it/esis/index.php?PGM=cla*

Bioaccumulative substances with unpredictable long-term effects (R5)
EU legislation is becoming stricter with respect to eliminating toxic chemicals, so the requirement is based on EU's REACH legislation. This was a suggestion received during the public review process of the criteria development.

The recently adopted REACH chemicals legislation will enable member states not only to regulate CMR (carcinogenic, mutagenic or toxic to reproduction) chemicals in materials, but to some extent also PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) substances. Unfortunately, medical devices will not be subject to this chemical's regulation.

In order not to make it too complicated to document, the requirement refers to the EU list of this kind of substance: http://ecb.jrc.it/esis/index.php?PGM=pbt

The list contains more than 60 substances concluded not to fulfil the criteria for PBT or vPvB and more than 20 substances under evaluation. Therefore, only substances indicated as fulfilling and substances forming PBT and or vPvB substances are excluded in the requirement.

Most of the chemicals satisfying the criteria for PBT or vPvB substances will also be classified as dangerous to the environment. But there might be cases in which chemicals are not classified as dangerous to the environment because the substance is not very acutely toxic and easily soluble in water. If the long-term toxicity (NOEC, no effect concentration) is very high, the substance may qualify for PBT classification. A long-term effect may, for instance, be an endocrine disruption effect.

Phthalates (R6)
Phthalates classified as reproductive toxins – DEHP, DBP and BBP – are prohibited in all children's products according to EU regulations for toys. The other three phthalates – DINP, DNOP and DIDP – are not classified but are banned from products intended for children under the age of three, based on similar concerns as apply for the first three phthalates (see also section 7.2.1).

The requirement is based on the EU Toys Directive. However, requirements R3 and R4 will already exclude DEHP, BBP, DBP, DINP and DNOP, but not DIDP. DIDP is not classified and not regarded an endocrine disrupter according to the EU (see the section on endocrine disruption above).

6.2.4 Recycling system (R7)

There has previously been a voluntary industry agreement on packaging operations in Norway, which has led Nordic Ecolabelling to have a requirement to ensure that licensees for a number of (45) product groups comply with this regulation.

Requirements for return systems have now been incorporated into the Norwegian Waste Regulations, which means that the Nordic Ecolabelling requirement for membership in a return company will be out of date and therefore no longer need to be managed by Nordic Ecolabelling in a separate requirement.

6.2.5 Safety (R8)

For reasons of credibility, the applicant is required to submit documentation for compliance with the legislation regarding the safety and correct functioning of a product. In the case of a medical device, it is a copy of the approval/certificate from a notified body. For a medicinal product, it is a copy of the market authorisation from the reference member state or national authority. The legislation contains strict requirements as to the safety and function of the products. See more about the legislation for health care products in section 3 above.

6.2.6 Requirements that also have been discussed

Several requirements were discussed during the criteria development process. Some of them were not included in the criteria; they are discussed below and may be considered as future requirements (see section 9).

Energy

Nordic Ecolabelling considered the possibility of including requirements regarding energy consumption in the production of plastics (see more about energy consumption in section 7.2.2). Due to the limits in the scope of the criteria development project, this was not done, but it could be a future requirement.

Recycling of materials, labelling and design of packaging

Some materials and products on the market are better suited for recycling than others. Simple polymers with no or a small amount of additives combined with a system for identification may make recycling possible. (See more about the recyclability of various plastic materials in section 7.3.3 and more about waste in section 7.2.3.)

If, however, the waste is considered to be clinical waste (waste contaminated with organic material such as blood, other body fluids and contaminants), recycling may not be suitable, as indicated by some parties in the public review (Nordic Ecolabelling 2007).

The labelling of plastic parts and packaging with harmonised symbols that indicate the type of material used in accordance with the worldwide ISO 11469 standard was also discussed. For example, this kind of labelling would probably help personnel at hospitals and other health care units identify the material if they wanted to sort the waste. If the waste is not clinical waste, different countries handle identified and sorted PVC waste differently. Some send it to landfills and others to hazardous waste incineration (Nordic Council of Ministers 2004).

If non-PVC plastic is labelled, it would be possible to identify and sort it in order to incinerate it in municipal waste incinerators or recycle the plastic. Some hospitals sort packaging of disposables (EKU 2007).

To ensure sterility, there may be a transparent outer packaging of the PD or IV bag. There should be no printing on the outer bag that would limit readability of the text printed on the bag inside.

Labelling of small parts is difficult due to limited space. Examples of small parts are clamps, caps and any plastic labels used. Normally medical devices such as PD sets, including tubing (fill and drain), are not labelled and do not have any written information.

The cost of changing any text on bags or packaging is high, and the product information printed on this kind of product is often the same for many different countries.

Requirements as to the choice of material, product design to enhance recycling and labelling can be discussed again for future versions of the criteria.

Process contaminants and residues
In some plastics, there are small amounts of process contaminants or residues such as traces of catalyst material and monomers from the production of the polymer. These substances can be problematic themselves but are only present in very small amounts. See the discussion and examples in section 6.2.2 above.

In the most common thermoplastics, the content of free monomer is roughly 1-10 ppm or less (Schmidt 2006). (See also the legislation on this listed in section 3.) The area is complex because of the many different production methods and materials, so requirements regarding process contaminants and residues from production may be a future demand.

Working environment
During the review, many stakeholders wanted more requirements to do with working environment. One suggestion was to require forced ventilation and personal protection equipment for workers handling dangerous substances in the manufacturing of plastics.

Workplace health and safety requirements, including forced ventilation and personal protection equipment, can be discussed again for future versions of the criteria.

6.2.7 Other requirements (M1-M5)

This set of requirements is common to most of Nordic Ecolabelling's criteria documents. They are intended to ensure that the requirements are complied with during the validity of the licence and to allow Nordic Ecolabelling to withdraw a licence if legislation is not complied with.

6.2.8 Marketing (M6)

The marketing directions are aimed at ensuring optimal value for the applicant in using the Swan label and avoiding misunderstandings. Among other things, the requirements comprise explanatory texts, additional texts and design directions for the Swan logo.

The explanatory text "The Swan requirements do not apply to the pharmaceutical inside" is intended to make sure no one believes it is the pharmaceutical in the PD bag, for example, that is eco-labelled.

To make it easier for hospitals that wish to separate PVC waste from non-PVC waste, there is a requirement that additional text must include the phrase "Does not contain PVC". See also more about the recycling of materials, labelling and design of packaging in section 6.2.6 above.

Medical devices must also be labelled with the CE mark under EU directives (see section 3). To eliminate the risk of misunderstanding, there is a requirement stating that the Swan label must not reduce the visibility and readability of the CE label.

The Medical Devices Directive contains rules on the relationship between the CE label and other labels. The rules say that other labels can be added as long as they don't mislead the reader in the meaning or presentation of the CE label. To judge whether other labels are misleading, one must consider whether the other label has a different meaning than that of the CE label, and whether it could create confusion about the meaning of the CE label or reduce the visibility and readability of the CE label.

The role of the Nordic Swan is to draw special attention to the precautionary principle and to be more proactive than the official regulations. The Nordic Swan is focused on environmental issues throughout the product's life cycle, and this is not the case with the CE label. The function of the Swan label is thus different from that of the CE label. The Nordic Ecolabel is a label well known in the Nordic countries. The fact that it is an environmental label from the Nordic countries conveys the meaning of the label also to people in other countries because of the reputation for high environmental standards the Nordic countries enjoy.

7 Effects on health and the environment

Because several manufacturers have taken active steps on environmental issues in recent years, there is a growing potential for improvement in health and environmental impacts. This is true not least in light of the size of the industry.

There are several sources of information on effects on health and the environment; life cycle assessments are amongst the published sources. The most well known in this area are discussed below. A further source of published information is the reference document on Best Available Technology (BAT) in the production of polymers: published in October 2006, it contains the generic BAT for all polymers and a specific BAT for each polymer.

An additional source is comments by experts on health and the environment in the health care industry who is contacted during the process. Industry players, including buyers of the products, also represent a source of information on effects on health and the environment. Surveys of interested parties may also represent a means of finding out what these interest groups regard as important.

For the sake of simplicity, a number of general areas have been selected in the following sections, and the most relevant effects in each area described.

7.1 Life cycle investigations

Nordic Ecolabelling evaluated the studies mentioned in this and the following sections and identified the waste-handling problem and the use of harmful additives as the most relevant issues in the life cycle of disposable plastic health care products.

In future versions of the criteria, Nordic Ecolabelling will have the option of covering areas that were considered important enough to be mentioned in the "Future requirements" section, as well as other areas later discovered to be of significant relevance. During the review, several stakeholders mentioned occupational health as an important area, so areas relevant to occupational health have been added to the "Future criteria" section.

There is a compilation of the existing life cycle assessments (LCAs) of PVC and competing materials commissioned by the EU Commission (European Commission 2004). The authors, however, underline that comparisons between the plastic materials were made on an application level and cannot be used on a general material level. The report also states that there are no publicly available LCAs for medical applications.

The PVC industry concludes from the compilation that PVC is as good a material as any other as long as special precautions are taken during the different stages of the life cycle (Vinyl2010 2004).

The Commission’s LCA report can be regarded as an approach to responding to concerns and questions raised in a green paper issued by the Commission four years earlier. However, most of the questions raised by the green paper remain unanswered. As a matter of fact, the LCA report has been heavily criticised as non-conclusive, for example by Mark Rossi in 2004:

> *Through a combination of omitting key data and policy decisions, engaging in the selective citation of studies (or poorly conducting research), and relying upon a method -- quantitative life cycle assessment (LCA) -- unsuited for the task, the result is a study whose conclusions must be read with a healthy dose of scepticism. Given these problems it is impossible to know the validity and relevance of the conclusions reached by the authors. We conclude from this review that the study* -- Life Cycle Assessment of PVC and of Principal Competing Materials -- *is fundamentally flawed and that it should not be used or considered as a relevant comparative analysis of the life cycle problems associated with PVC and its competing materials.*

Rossi explains the limitations and some of the reasons why the study is not conclusive with the fact that many life cycle studies are limited to measurable figures such as energy and raw materials use.

For hazardous chemicals, for example, it is much more complicated to express different risk scenarios and take the precautionary principle into account. He argues that taking the precautionary principle into consideration is relevant for the majority of existing chemicals.

There is, on the other hand, a rating of various polymers and their environmental issues by Lars Pedersen (in Danish). This is a kind of qualitative LCA, followed by an environmental classification considering mainly the content of substances hazardous to health or the environment, energy consumption and waste treatment (see Appendix 2). However, this study is criticised by the PVC industry as outdated.

As stated in section 6.2.2 above, PVC is excluded from the products in question due to problems in waste handling and health-related problems. The two areas are described thoroughly in this document, and it is clear that Nordic Ecolabelling also uses other and more recent references than Pedersen, among which is the industry's own Vinyl2010.org Web site and the study by Schmidt (2006).

The study presented by Pedersen, however, provides a practical picture of various plastics and the potential problems. It does not necessarily mean that Nordic Ecolabelling stands behind all data or rankings.

Nordic Ecolabelling is aware of the changes in PVC technology and knowledge, and the claimed inconsistencies in the study are discussed in other sections of this document. For instance:

> *Incineration and dioxins.* Nordic Ecolabelling reports in section 7.2.3 below on how the content of chlorine ends up in the residue that must be landfilled. The same section reports findings that, apparently, no more dioxin is produced from burning PVC than from incinerating any other material.

Phthalates. Nordic Ecolabelling includes in sections 7.2.1 and 7.3.2 an updated legislative status report and results from the latest risk assessments.

7.2 Health and the environment from the perspective of nature and society

In order to gain an overview of environmental and health effects from the perspective of nature and society, Nordic Ecolabelling opted to describe the effects on health and the environment in the following general areas:

- Health and working environment
- Waste
- Energy consumption
- Air
- Aquatic environment

These areas are particularly relevant for health care products discussed in this document.

7.2.1 Health and working environment

A general overview of exposure to chemicals in the production of the most common plastics can be seen in Schmidt's survey from 2006. He lists different types of plastics and manufacturing methods, together with measurements of degradation products.

Polyvinyl chloride or vinyl (PVC) is a polymer in which more than half of the content by weight consists of chlorine. Plasticisers are added to PVC to make the plastic soft and pliable, the most desirable properties for disposable medical devices and medicinal products.

A problem with plasticisers is that they do not bind to the PVC matrix and can leach out of the product into liquids transferred from medical devices into a patient's body. In general, medical procedures that last for hours or days – e.g. haemodialysis, blood transfusion, extra-corporeal membrane oxygenation (ECMO), total parenteral nutrition (TPN) or enteral feeding – result in higher plasticiser exposure than brief procedures.

Phthalates are the most commonly used plasticisers in PVC plastic. Phthalates have been in the authorities' spotlight because of their CMR and endocrine-disruption effects on human health. Patients that use PVC products internally (tubes, etc.) may be subjected to elevated exposure to phthalates because the phthalates are not bound to the polymer. The potential for DEHP exposure is also higher when the PVC/DEHP product is used invasively and/or when fat-containing liquids such as blood or nutritional formulas are transferred.

Research results on the risks associated with plasticisers and PVC are not unequivocal, and a general prohibition of PVC does not exist. The EU's Scientific Committee on Medicinal Products and Medical Devices examined the issue of PVC in 2002 but did not find any evidence of carcinogenic effects in humans, and so did not provide any specific recommendation on limiting the use of DEHP.

This issue has, however, been taken up again by the EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR 2006). The committee is discussing the safety of medical devices containing DEHP-plasticised PVC or other plasticisers for use with neonates and other groups that may be at risk (see also section 3 above).

Chemical preparations containing DEHP must be labelled with the "skull and crossbones" symbol in the EU. Medical products are not regarded as "chemical preparations" under chemicals legislation and are therefore not covered by the general restrictions in chemical legislation, despite the likelihood of elevated exposure. However, these products are covered by other medical device and medicinal products legislation that takes risk assessment into account (see section 3 above).

There are specific regulations on the use of phthalates in toys. Toys that can be placed in the mouth by children under the age of three may not contain six specific phthalates. But recently the legislation was updated: phthalates classified as reproductive toxins – DEHP, DBP and BBP – are now prohibited in all children's products.

The other three phthalates – DINP, DNOP and DIDP – are not classified thus but are banned from products intended for children under the age of three based on similar concerns as for the first three phthalates.

The use of DEHP in cosmetics, adhesives, paint and other consumer products is prohibited.

Several PVC products that contain DEHP plasticiser are used in health care. Common products include feeding tubes, tubes and catheters, as well as infusion bags for nutrients or dialysis fluids.

Under the EU’s risk assessment process, the risks of different types of DEHP exposure have been evaluated. In the case of medical devices, the conclusion is drawn that risk reduction measures are necessary to decrease the exposure of patients who come into contact with DEHP.

The phthalate DEHP leads to a reduction in the size of testicles in laboratory animals and is classified as toxic for reproduction and teratogenic. The risk of harm to health is greatest among children and patients who experience long-term exposure.

Non-phthalate plasticisers such as trimetallates, citrates etc. are often used as alternatives to phthalates. They may have an advantage in toxicological profile and/or less leaching. Also treated castor-oil is marketed as an alternative to phthalates. This alternative plasticiser consists of acetylated monoglycerides and diglycerides of hardened castor oil, and it has been investigated for hydrolysis, absorption, metabolism and excretion in rats. The results show that the oil is hydrolysed and quickly metabolised and excreted (Vang Sparsø et al 2007).

7.2.2 Energy consumption

The table below demonstrates the energy balance for common polymers used in peritoneal dialysis or IV infusion bags in the health care sector (Pedersen 1999). It can be seen that the plastics are energy-intensive materials to produce. From an energy point of view, polyamide seems to be disadvantageous compared to other plastic materials. This is, however, only one of many environmental aspects, and in a total assessment, this material will have a much better relative environmental profile.

Table 7.2.2 Energy demand and recovery for different plastics.

	Energy demand (MJ/kg)	*Energy recovery from incineration (MJ/kg)*	*Difference*
PVC	66.8	17.8	49
Polyamide	156	28.7	127.3
Polyolefins	80-82	43.5-42.3	36.5-39.7
Polyurethanes	89	27	62

Anders Schmidt (2006) has more detailed figures for the plastics mentioned, as well as for other plastics. Figures for energy consumption can also be found in the EU BAT report (European Commission 2006).

7.2.3 Waste

A large amount of plastic waste ends up in incineration plants, where its energy content is used to produce electricity and heat (see the previous section). Denmark has a long history of using waste to generate electricity and heat and competes with Switzerland and Japan for the position of the country in the world that incinerates most waste per capita. There are approximately 30 incineration plants in Denmark (Kleis et al 2004).

Disposable health care products made of plastic end up in hospital waste incineration plants if the products are not used at home. Peritoneal dialysis often takes place in a patient’s home, which means the disposables end up in the municipal waste incinerator or in a landfill. PVC waste is undesirable in Denmark's incineration plants and is therefore landfilled if identified and sorted out.

Clinical waste (hospital waste) can be classified into general waste, which is similar to municipal solid waste, and specific waste, which contains pathological material. Because of the special measures instituted to handle pathological waste, it is common for hospitals to have their own waste incinerator. Many hospital incinerators have been closed down due to poor emissions performance, and clinical waste is often handled by larger facilities, e.g. hazardous waste incinerators or special furnaces located at municipal waste incinerators (Jacquinot et al 2000).

In Finland, most PVC waste is generally landfilled. Approximately 70% of Sweden's PVC waste is landfilled and the rest incinerated (Nordic Council of Minsters 2004).

Most of the larger waste incineration plants in the EU are designed to handle and minimise emissions from plastics and other waste burned. There is an EU directive for MSW (municipal solid waste) incineration (369/89/EC) and one for hazardous waste incineration (94/67/EC) setting limits for emissions. There are limits for hydrochloric acid (HCl) and dioxins, among others.

Several investigations show that no more dioxin is produced by an extra kilo of PVC in an incineration plant than by one kilo of any other equivalent chlorine-free material. This is based on the fact that chlorine always will be present in organic material in municipal solid waste, which means that dioxin can be formed anyway. But there are also other studies showing that there is a correlation between PVC content and dioxin formation.

However, the parameters with the highest influence on dioxin formation are related to plant operation (e.g. the combustion temperature, the CO concentration, etc.) and plant design. The reduction of PVC thus is expected to have a second- or third-order relationship with dioxin formation (Møller et al 1996).

In Sweden, more than half of the chlorine contribution to incineration plants comes from PVC (Nordic Council of Ministers 2004).

Even if the emissions from the incineration of PVC can be controlled in the bigger plants, burning PVC generates a large amount of problematic residue due to its content of chlorine. The amount is between 0.4-1.7 kg/kg PVC, depending on the purification process used (Schmidt 2006 and Jacquinot et al. 2000). The most common processes used generate more problematic residues than the amount of PVC incinerated. These residues are categorised as hazardous waste by the authorities and must be deposited as landfill under special conditions. If PVC itself is deposited as landfill, it cannot be ruled out that the plasticisers are released over time (Møller et al. 1996).

For this reason, the Danish authorities have since 1999 followed the strategy that PVC should be avoided in the waste incineration process. Thus, the focus has been to limit the use of PVC products that cannot easily be collected after use and will consequently end up in the waste incineration process (Miljø- og Energiminsteriet 1999).

This strategy should be seen in the light of the general waste management policy in Denmark: waste that can be incinerated, including most of the plastics, is not to be deposited as landfill. Instead it should be recycled or incinerated in order to recover its energy content.

7.2.4 Air

The most problematic emissions to air are the gases originating from energy production, e.g. carbon dioxide (CO_2), nitrogen oxides (NOx), sulphur dioxide (SO_2), and volatile organic compounds (VOCs).

Emissions of nitrogen oxides and sulphur dioxide cause environmental problems such as acidification, which results in fish death in lakes and air pollution that is harmful to health. Nitrogen oxides emitted to air also cause environmental problems such as over fertilization and oxygen depletion. Carbon dioxide and volatile organic compounds cause climate change in the form of the greenhouse effect.

7.2.5 The aquatic environment

The effluent water from the Karolinska hospital in Sweden is contaminated, e.g. with phthalates. The levels of DINP are today double those of DEHP (A. Vesterberg, personal communication, January 2007). This probably reflects the shift in plasticisers used in the PVC industry from DEHP to DINP.

All phthalates used to a great extent in PVC can be found throughout our environment today, partly because they are released from PVC products (European Commission 2000). In the environment, the phthalates DEHP, DINP and DIDP decompose slowly and are highly bioaccumulative, which is why "it cannot be ruled out that they accumulate in the food chain" (Danish Environmental Protection Agency 2003).

7.3 Health and the environment from a technical perspective

To gain an overview of environmental and health impact viewed from a technical perspective, Nordic Ecolabelling decided to describe the environmental effects of the following elements:

- Plastic
- Plasticisers and other additives
- Recycling of plastics
- Dioxins

These areas are particularly relevant for health care products discussed in this document. The production of polymers in general is extensively described in the 2006 European Commission BAT document and the different manufacturing processes described in the 2006 Danish EPA report (Schmidt 2006).

7.3.1 Plastic

Initially, PVC products were developed to replace natural rubber and glass. The advantages associated with products made from PVC are that they are easy to sterilise, transparent, soft, physically strong, chemically stable and relatively cheap.

Plasticised PVC often has important functional characteristics, such as ease of use, softness and flexibility, which prevent sensitive human tissue from injury. It also minimises discomfort for patients and ensures free passage through catheters and tubes. PVC also facilitates the collection of whole blood by preventing coagulation.

The alternatives to softened PVC in medical devices or packaging of medicinal liquids are the following. To the right of the plastic name stands the category they belong to according to Appendix 2 (see section 7.1 for a discussion of the study referred in Appendix 2).

- Polyamide In Category 2
- Polyolefins In Category 1 (polypropylene/polyethylene)
- Polyurethanes In Category 3
- Silicone In Category 2
- EVA In Category 1
- Latex/rubber In Category 3

There are many arguments in favour of alternative polymers to PVC, as described by Lars Pedersen in Appendix 2. PVC softened with DEHP belongs to the worst class (Category 4), but otherwise softened PVC belongs to Class 3, together with materials such as polyurethane (PUR) and polycarbonate, which may also be relevant in some health care disposables.

According to Pedersen, PUR is critical mainly due to the use of isocyanates, which is an allergenic raw material in the production of PUR. In the same way, the suspected endocrine disrupter bisphenol A is used as a raw material in the production of polycarbonate. However, these plastic materials are not used in disposable peritoneal-dialysis and IV-infusion treatment products. The common alternative material for this kind of products is polyolefins.

Manufacturers have reacted to purchasers' requests for PVC-free products and increasing numbers of new products are being introduced. There are many manufacturers on the market. The environmental impact of plastic medical devices such as examination gloves, tubes and bags in this context is often associated with the question as to whether PVC is used in the product or not.

Even today, renewable plastic is not yet an alternative for these types of products. Protective gloves have traditionally been made from natural rubber latex, but synthetic rubber has become more common due to the allergic problems associated with latex. Gloves are also available in polyethylene and nitrile, for example.

7.3.2 Plasticisers and other additives

Disposable medical devices and packaging for medicinal products made from PVC normally contain 20–40 per cent plasticiser by weight. The content can be as high as 80 per cent in feeding tubes. There are at least 15 different phthalates, all with similar properties and often used as plasticisers in PVC. Trimetallates, citrates, etc. are used as alternatives to phthalates.

The most widely used phthalate is DEHP (di-ethyl-hexyl-phthalate, CAS No: 117-81-7). (See more about health issues and phthalates in section 7.2.1. 9.) Alternatives to DEHP in PVC for medical devices have been investigated by the Danish EPA: the conclusion was that none of the substances were rejected as alternatives to DEHP. However, the report states that much more data are needed before an actual substitute for DEHP can be suggested for use in medical devices (Danish EPA 2003).

Approximately 80% of IV sets are manufactured with DEHP-plasticised PVC bags and tubes. The leaching of DEHP into IV medications and products is well established. Trissel, for example, identified in 1998 a range of drugs, including the cancer drug Taxol, that have been shown to increase DEHP leaching. DEHP leaching into standard IV products such as glucose (sugar) solutions or electrolyte (saline) solutions is more likely when the bags have been agitated or warmed. DEHP concentrations as high as 0.36 mg/l have been found in glucose solutions and 0.16 mg/l in electrolyte solutions. An infusion of one litre of glucose solution could result in 0.005 mg DEHP/kg bw (Health Care Without Harm 2007).

The phase-out of toxic plasticisers is, however, moving forward. Leading manufacturers are shifting away from DEHP due to its potential hazards for patients. Many countries in the EU as well as outside Europe recommend avoiding DEHP-plasticised PVC devices due to potential reproductive hazards for the most vulnerable populations.

Apart from plasticisers, there are thousands of other additives that can be added to the plastics. They have different functions, acting as stabilisers, antioxidants, UV-stabilisers, flame retardants, dyes, pigments, etc. (Schmidt 2006).

7.3.3 Recycling of plastics

As an example of the difficulty in recycling PVC, especially closed-loop recycling, the automobile industry has targeted PVC for elimination. Driven by end-of-life vehicle directives in Europe and Japan to increase recycling rates for automobiles, automakers are evaluating their use of plastics and selecting plastics that can be recycled back into the same product.

European automaker Opel, for example, classified plastics according to their recyclability. PVC was next to last on the list in terms of recyclability, with PVC only more recyclable than a “mixture of incompatible products” (see Table 7.3.3 below). All of the automakers have reached the same conclusion as Opel: that polypropylene and polyethylene are the easiest plastics to recycle and PVC is among the most difficult.

Table 7.3.3. Opel priority list for plastics with regard to recycling aspects (Opel 2000).

▲	Polypropylene, polyethylene
▲	Polyoxymethylene (POM), polyamide, thermoplastic urethane (TPU)
▲	Acrylonitrile butadiene styrene (ABS), polymethylmethacrylate, styrene maleic anhydride (SMA) copolymer, acrylonitrile styrene acrylate (ASA), styrene acrylonitrile (SAN)
▲	Polycarbonate, polyethylene terephthalate (PET), polybutylene terephthalate (PBT)
▲	Thermoplastic elastomer (TPE)
▲	Polyurethane
▲	Sheet moulding compound (SMC)
▲	Elastomer
▲	Polyvinyl chloride (PVC)
▲	Mixture of incompatible materials

7.3.4 Dioxins

If the technology and safety of production plants are up to scratch, the PVC information council in Denmark claims that most of – but not all – dioxins are removed from emissions. According to the information council, the Swedish environmental protection agency has determined that PVC raw materials account for roughly 1% of the total dioxin emissions in the country (Dammand Nielsen 2005). In small, less modern facilities, dioxin emissions into the environment and in humans are more common (European Commission 2004). Dioxins are also released when PVC is incinerated. See also the section on waste (7.2.3).

The Nordic countries are bound by the Stockholm Convention on Persistant Organic Pollutants (POPs) to omit waste containing POPs at source so that POPs are destroyed or pacified without impacting the environment (www.pops.int). The convention considers the incineration of PVC, for example, to be a source of POPs, in particular dioxins.

Furthermore, there is always a risk of POP emissions (dioxins) from uncontrolled fires that involve PVC and other materials containing chlorine, e.g. houses, hotels and hospitals.

There are many other sources of dioxin emissions to air: dioxins are also released to water and into the ground and can be found in waste products as well. The following sources are listed in a background document for a meeting of the OSPAR Commission in June 2002 (www.ospar.org):

- Incineration of waste and sludge
- Heating of buildings with coal and biomass (straw and wood)
- The metal industry – in particular sintering processes and the recycling of metal waste

Statistics Norway estimated dioxin emissions to air as 29 g TEQ in 2003 (www.miljostatus.no). Of these emissions, 10.5 g originated from households, which were the primary source. Industrial emissions were 8.1 g, of which 7.75 g stemmed from metal processing and 0.01 g from the chemical industry. Industrial emissions in 1990 were 86 g TEQ; household emissions were 8.1 g. Emissions of dioxins from incineration and waste were 0.6 g TEQ (17.6 g in 1990). It is estimated that the burning of wood accounted for one-quarter of all dioxin emissions in 2003.

8 Expected environmental effects

The criteria are intended to encourage manufacturers to avoid:

- substances that are harmful to health and the environment.
- materials that are problematic in waste handling.

Nordic Ecolabelling expects to support and speed up the emerging development of reductions in health and environmental impact from health care products by ecolabelling. Ecolabelling is especially expected to contribute to the reduction in harmful phthalates and waste handling that is unsustainable due to the excessive generation of problematic residue during incineration.

Nordic Ecolabelling estimates that if the dialysis bags on the Nordic market did not contain PVC, approximately 50 tons of phthalates could be avoided on a yearly basis, according to Karolinska University Hospital (Nordic Ecolabelling 2007). According to an EKU (the official Swedish board for green public procurement) background document on disposable peritoneal dialysis products, the figure could be 100 tonnes (EKU 2007). The harmful residue formed when PVC is burned could also be avoided.

Nordic Ecolabelling also expects the criteria to reduce health and environmental impact when used in green procurement in hospitals. During the public review process, several hospitals indicated that they wanted to use the criteria in that way (Nordic Ecolabelling 2007). To encourage this, we tried to formulate the criteria so they can be easily used by buyers of health care products.

9 Future requirements

In future criteria, Nordic Ecolabelling will, among other things, consider whether to include requirements regarding:

- energy
- recyclability of materials, labelling and design
- process contaminants and residues
- working environment such as forced ventilation and personal equipment

See more in section 6.2.6.

10 References and literature

Bergbom, K. (2006). Medicintekniska plastprodukter utan PVC. Förundersökning. Nordisk Miljömärkning. 25 September 2006.
Dammand Nielsen, K. (2005). PVC-notat til NMN fra SLM. Nordisk Miljømærkning, April 2005.
Danish EPA. (2003). *Evaluation of Plasticisers for PVC for Medical Devices*. Written by Kjeld Karbæk, Danish Technological Institute, Plastics Technology, for the Danish Environmental Protection Agency. Environmental project 744.
Dorland's Biomedical. (1998). *Medical and Healthcare Marketplace* (Philadelphia: Dorland's Biomedical).
Edlund, S, Leire, C. and Thidell Å. (2002). *Svanens roll I förhållande till andra miljöinforamtionssystem och miljöledning*. Internationelle Instituttet för Industriell Miljöekonomi, Lunds Universitet for Nordiska Ministerrådet Konsument/Miljö. TemaNords 2002:517.
EKU. (2007). *EKU-kriterier för Läkemedel (2007-06-21)* and *Medicinteknisk utrustning och tillbehör (förbrukningsmaterial till peritonealdialysutrustning: 2007-04-12)*. The Swedish Environmental Management Council (EKU). January 2006. http://www.eku.nu/criterion/criterionGroup.asp?group=17 (medicinal products), http://www.eku.nu/criterion/criterionGroup.asp?group=18 (medical devices and disposables), and http://www.eku.nu/criterion/criterion.asp?critId=105 (disposables for peritoneal dialysis, criteria and background document).
European Commission. (2000). *Green Paper – Environmental issues of PVC*. Brussels. 26.7.2000 COM (2000) 469 final.
European Commission DG ENV. (2000). *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption - preparation of a candidate list of substances as a basis for priority setting*. Final report. BKH Consulting Engineers, Delft, The Netherlands, in association with TNO Nutrition and Food Research, Zeist, The Netherlands. 10 November 2000. http://ec.europa.eu/environment/docum/01262_en.htm
European Commission. (2002). *Opinion on Medical Devices Containing DEHP Plasticised PVC; Neonates and Other Groups Possibly at Risk from DEHP Toxicity*. European Commission. Health & Consumer Protection Directorate-General. http://www.dehp-facts.com/upload/documents/document46.pdf
European Commission. (2004). *Life Cycle Assessment of PVC and of principal competing materials*. Commissioned by the European Commission. July 2004.
European Commission (2006). *Integrated Pollution Prevention and Control. Reference Document on Best Available Techniques in the Production of Polymers*. Directorate General JRC (Joint Research Center). Institute for Prospective Technological Studies, Seville, Spain. www.eippcb.jrc.es. October 2006.
Frost & Sullivan. (1996). http://www.frost.com/prod/servlet/frost-home.pag (accessed January 2007).
Gambro. (1999). Renal Care Products. http://www.gambro.com/operation/d_prod.html (accessed January 2007).
Health Care Without Harm (HCWH). (2007). http://www.noharm.org
Jacquinot, B, Hjelmar, O. and Vehlow, J. (2000). The influence of PVC on the quantity and hazardousness of flue gas residues from incineration. Final Report, Bertin Technologies. April 2000.
Kleis, H. and Dalager, S. (2004). 100 years of waste incineration in Denmark. Babcock & Wilcox Vølund and Rambøll.
Laeversuch, Robert D. (1999). Speciality Polyolefins Challenges PVC in Medical Fluid Systems, *Modern Plastics International*, July: 92-96.
Lindskog, B.I. and Zetterberg, B.L. (1975). *Medicinsk Terminologi*. Aktebolaget Nordiska Bokhandlens Förlag. Stockholm. ISBN 91 516 0022 6.
Miljø- og Energiministeriet (1999). *Strategi for PVC-området – Statusredegørelse og fremtidige initiativer*. June 1999.
Miljøstyrelsen. (2003). *Status for phtalater*. Miljøstyrelsen i Danmark.

Miljøstyrelsen. (2004). Listen over uønskede stoffer 2004. Orientering fra Miljøstyrelsen nr. 8, 2004. Miljøstyrelsen i Danmark.
Møller, S, Larsen, J, Jelnes, J.E, Førgemann, H, Mørck Ottosen, L. and Egtoft Knudsen, F. (1996). *Environmental Aspects of PVC*. Second edition. Environmental Protection Agency, Denmark. Environmental project nr. 313, 1996.
Nordic Council of Ministers. (2004*). Survey of Special Waste Fractions in the Nordic Countries: Legislation, Logistics, Quantities, Treatment and Disposal*. TemaNord 2005:530. June 2004.
Nordic Ecolabelling. (2005). PVC-Notat till NMN fra SLM.
Nordic Ecolabelling. (2007). "Resumé of review criteria for disposable peritoneal dialysis (PD) and intravenous (IV) infusion treatment products." Nordic Ecolabelling Board, 18-20 October 2007.
Nordisk Miljømærkning. (2000). *Miljøfilosofi*. Nordisk Miljømærkning. 16 June 2000.
Nordiska Ministerrådet. (1995). "Nordic guidelines on Life-Cycle Assessment". Nordiska Minsterrådet (miljö).
Nordiska Ministerrådet. (2001). Nordiska Minsterrådets beslut om mål och principer för Nordisk Miljömärkning av 19 juni 2001.
Opel. (2000). Environmental Report 2000/2001. www.**opel**.com/corporate/download/**environment**al_report.pdf (accessed January 2007).
Plastindustrien i Danmark. (1999). *En verden i plast*. Plastens abz. 1999.
Pedersen, L.B. (1999). *Plast og Miljø*. Teknisk Forlag.
Rossi, M. (2004). Reaching the Limits of Quantitative Life Cycle Assessment". Clean Production Action (www.cleanproductionaction.org). Commissioned by the European Commission and authored by a consortium led by PE Europe GmbH. June 2004.
SCENHIR. (2006). Request for an opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk. SCENIHR Scientific Committee on emerging and newly identified health risks. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_007.pdf
Schmidt, A. (2006). Miljø– og sundhedsforhold for plastmaterialer. Force Technology for Miljøstyrelsen i Danmark. Miljøprojekt nr. 1103.
SETAC. (1993). "Guidelines for Life-Cycle Assessment: A 'Code and Practice'". Society of Environmental Toxicology and Chemistry (SETAC). From the SETAC workshop held at Sesiembre, Portugal. Edition 1.
Tukker, A. (1999). "Life Cycle Impact Assessment – Some Remarks". Life Cycle Impact Assessment of SETAC-Europe (Second Working Group – WIA-2).
US NTP CERHR. (2007). US National Toxicology Program Center for Evaluation of Risks to Human Reproduction. http://cerhr.niehs.nih.gov/chemicals/dehp/dehp.html, under "Expert Panel Update Report".
Vang Sparsø, F. and Fischer Jensen, T. (2007). "In vivo og in vitro hyrdolyse og omsætning af alternativ blødgører". *Dansk Kemi*, 88, no. 1, 2007.
Vesterberg A, Hedenmark M. and Vass, A-M. (2005). "PVC in medical devices: An inventory of PVC and phthalates containing devices used in health care". Karolinska hospital, Solna, Sweden. Final report. http://www.noharm.org/details.cfm?type=document&id=1118
Vinyl2010. (2004). Press release from Vinyl2010, 3 June 2004. http://www.vinyl2010.org/images/stories/food/03062004.pdf (accessed February 2007).

Appendix 1 Description of kidney treatment

Peritoneal Dialysis and Haemodialysis (Mark Rossi 2000)

Peritoneal dialysis and haemodialysis are the two treatments available for patients with kidney disease who do not receive a kidney transplant. The primary difference between the two treatments is how waste products are separated from the blood: in peritoneal dialysis the body's peritoneum separates waste products from the blood, whereas in haemodialysis a machine does the separating. Some patients are not candidates for peritoneal dialysis because it requires some residual renal function: patients with end-stage renal disease and very little to no renal function require haemodialysis.

The primary components of peritoneal dialysis are the dialysis solution (dialysate) and its container, fill and drain lines, catheter, and drainage bag. In peritoneal dialysis the patient introduces dialysate into the body through the fill line and a surgically implanted catheter. The peritoneum removes waste products from the blood and discharges them into a drain line that connects to a drainage bag. The two primary peritoneal dialysis techniques are continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD). In CAPD the patient introduces dialysate into the peritoneum four times per day. In CCPD the patient connects the catheter to a machine which cycles solution in and out of the peritoneum while the patient sleeps.

The primary components of haemodialysis are the haemodialysis machine, blood lines (tubing that carries blood from and to the body), anticoagulants, and dialysate. In haemodialysis a machine pumps blood out of the patient through blood lines, mixes it with dialysis solution and anticoagulants (primarily heparin to keep the blood from clotting), runs it through a dialyser, and returns cleansed blood to the patient. A "dialyser" is an artificial kidney: it separates waste products and excess water from the blood. Patients usually receive three two-to-six-hour treatments per week at a dialysis centre.

Peritoneal dialysis is much less disruptive than haemodialysis because a patient does not travel to a dialysis centre three or more times per week. But peritoneal dialysis requires some renal function and does increase the risk of peritonitis, an infection of the peritoneum.

Appendix 2 Categorisation of common plastic polymers

The following table categorises common plastic polymer materials (Lars Pedersen 1999). The study presented by Pedersen paints a practical picture of different plastics and the potential problems. It does not necessary mean that Nordic Ecolabelling stands behind all data or rankings (see discussion in section 7.1 above).

Category	Description	Material
1	The substances added or generated in the production, use or disposal phase do not require any special precautions or result in significant health or environmental impact. The energy consumption during manufacturing of the raw material and in further processing is relatively low, whereas the energy generated by incineration (heat of combustion) of the polymer material is high.	Polypropylene – PP
		Polyethylene – PE
		Cellulose acetate – CA
		Poly (isobutylene) – PIB
		Ethylene vinyl acetate – EVA
2	The polymer materials in this category contain substances hazardous to health or the environment and crucial in manufacturing or for the properties desired in the polymer. According to law, the substances added or generated in the production, use or disposal phases may not require any special end-of pipe treatment or special protective equipment but could have health or environmental impacts. The polymer materials, which fulfil the first criterion in Category 1 but require a great deal of energy to manufacture or which generate relatively low levels of energy upon incineration, are also listed in Category 2.	Polyamide – PA or Nylon
		Styrene ethylene butylene styrene co-block polymer – SEBS
		Styrene-isoprene block polymer
		Polymethyl methacrylate – PMMA
		Polyethylene terephthalate – PET
		Polyacetal or polyoxymethylene– POM
		Aminoplast – MF, UF
		Phenolformaldehyde – PF
		Polystyrene – PS
		Styrene co-polymer and ter-polymer – SAN and ABS
		Silicone

Category	Description	Material
3	The polymer materials in this category contain substances particularly hazardous to health or the environment and crucial in manufacturing or for the properties desired in the polymer. The substances added or generated in the production, use or disposal phase may require special end-of-pipe precautions or protective equipment and may result in significant health or environmental impacts. It should be noted that where the necessary end-of-pipe precautions and protective equipment are adequately installed during manufacturing, the impact on health and environment can be made to be negligible.	Latex/natural rubber (cis-polyisoprene) – NR
		Polytetrafluorethylene – PTFE
		Polyvinyl chloride – PVC (hard)
		Polyvinyl chloride not plasticised with DEHP – PVC (soft)
		Thermoplastic polyurethane – TPU
		Polyurethane foam – PUR foam
		Polysulphone – PSU
		Polycarbonate – PC
		Epoxy – EP
4	The polymer materials in this category are regarded particularly hazardous to health and environment. This category includes polymer materials that would otherwise be in Category 1, 2 or 3 but contain additives considered hazardous to health and the environment.	Polyvinyl chloride plasticised with DEHP – PVC(soft)
		Halogenated additives
		Additives with heavy metals
		Fire retardants based on bisphenols or diphenyl
		Plasticisers based on DEHP
		Other additives with the ability to act as endocrine disrupters