

Résumé of 2007 review for disposable peritoneal dialysis and intravenous infusion treatment products

Nordic Ecolabelling wishes to thank all parties that have commented and thereby contributed to the development of the Swan label criteria for disposable peritoneal dialysis (PD) and intravenous (IV) infusion treatment products.

A criteria proposal and a background document were sent out for public review 14 March – 16 May 2007. The proposal and the background document were written in English. The answers to the comments were discussed by a Nordic Ecolabelling working group at a meeting on 4 June 2007. The requirement numbers in this résumé refer to the numbers as they were in the proposal for review.

The working group consisted of members from the ecolabelling offices of the various Nordic countries who were appointed to develop the criteria under the leadership of the Nordic regional coordinator for paper. The discussions at this meeting formed the basis for Nordic Ecolabelling's response to the reviewers' comments. All comments and responses from the consultation process were explained in this summary. Since the criteria and background document were drafted in English and most of the comments were in English, Nordic Ecolabelling's response was written in English as well.

Nordic Ecolabelling's response to the reviewers' comments reflects the final draft criteria document, which was sent to the national environmental label boards and the Nordic Environmental Label Board for processing. Any changes made by the Nordic Environmental Label Board are explained in the background document.

In general, Nordic Ecolabelling found that hospitals and institutions had positive attitudes towards the criteria. Among them is Consorta, a leading health-care group purchasing organisation in the United States representing several thousands care sites all over the US, who welcomed the initiative and stated it would be easier for them to find PVC- and DEHP-free products.

The medical device and medicinal products industry was positive, neutral or negative, and the plastics industry and chemicals industry were negative. The ECVM (European Council of Vinyl Manufacturers), a division of Plastics Europe and the leading association representing PVC manufacturers, opposed the criteria, saying that selecting PVC-free medical devices is not a solution. The authorities were divided between positive and negative.

Based on the results from the review and fact that the market already supplies well functioning and safe alternatives to PVC products for the categories in question that are not excessively expensive, Nordic Ecolabelling concluded that the criteria can make a significant contribution to environmental and health improvements. There is a broad scientific understanding that PVC has

some aspects that are problematic for the environment and health, e.g. the generation of substantial quantities of residues after incineration that have to be landfilled and the use of DEHP, which is known to be reproductively toxic and teratogenic. DEHP is also suspected to be allergenic, according to The Karolinska Institute.

Even if there are well-recognised environmental and health problems with PVC, the material has several functional advantages that make it suitable for some applications where these advantages can not be obtained by other materials. Nordic Ecolabelling has begun ecolabelling only a limited range of medical health care products for this reason. For disposable PD and IV infusion products it is known to Nordic Ecolabelling that it is possible to find safe alternatives to these products on the market that are not made of PVC and DEHP.

The comments helped improve the criteria document. The following major changes ended up in the adopted version of the criteria:

- The requirement regarding plastic material was expanded so that all halogenated plastics are also excluded.
- The requirement regarding additives has been expanded so that
 - PBT and vPvB substances and
 - the six phthalates restricted in the EU Toys Directive are now also excluded.
- The requirement regarding labelling of plastic parts has been replaced by a compulsory text in connection with the Swan label: "Does not contain PVC".
- A new requirement has been added: that the Swan label must not reduce the visibility and readability of the CE label.
- Definitions have been corrected and checked.
- It is now explained better that the Lars B. Pedersen study is an example of one of several references in the background document and that the background document contains updated information on the environmental effects of PVC.

Nordic Ecolabelling refers to our Web sites and to the European Flower Web pages for a description of the ecolabelling concept. No further responses are given in this document to comments that ecolabelling limits competition and induces unnecessary costs, comments on the voluntary status of ecolabelling, comments that ecolabelling should not go further than the legislation does and is therefore unnecessary, comments on the scope of ecolabelling in view of fair trade, social and economic responsibility and so on.

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Summary

Total

Stakeholders	Just comments	Supporting proposal	Supporting with comments	No comments	Rejecting proposal	Total	Replies-%
Finland, 54		1	2		1	4	7
Denmark, 248	3		2	1	3	9	4
Norway, 60		3	2	3	2	10	17
Iceland, 0							
Sweden, 84	2	7	3	1	4	17	20
Total: 446	5	11	9	5	10	40	9

Finland

Stakeholders	Just comments	Supporting proposal	Supporting with comments	No comments	Rejecting proposal
1. Finnish Plastics Industries-Muoviteollisuus ry					X
2. Kuopio University Hospital			X		
3. Communal Alliance of Kyme Healthcare District			X		
4. Helsinki and Uusimaa Hospital Group		X			
Σ Finnish responses: 4		1	2		1

Denmark

Stakeholders	Just comments	Supporting proposal	Supporting with comments	No comments	Rejecting proposal
1. Indenrigs- og Sundhedsministeriet					X
2. Erhvervs- og Selskabsstyrelsens Center for Kvalitet i ErhvervsRegulering (CKR)			X		
3. Medicoindustrien	X				
4. Miljøstyrelsen					X
5. Dansk Arbejdsgiverforening DA				X	
6. Coloplast A/S	X				
7. PVC Information Council Denmark					X

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8. Nyremedicinsk afsnit Århus Universitetshospital Skejby, Regionshospital Viborg og Regionshospital Holstebro, Danmark			X		
9. Dansk Industri	X				
Σ Danish responses: 9	3		2	1	3

Norway

Stakeholders	Just comments	Supporting proposal	Supporting with comments	No comments	Rejecting proposal
1. Fylkesmanne i Oslo og Akershus				X	
2. Naturvernforbundet				X	
3. Helseforetakenes Innkjøpsservice AS (HIAS)		X			
4. Norges Kvinne- og Familieforbund		X			
5. Social- og Helsedirektoratet			X		
6. PVC Forum Norge					X
7. Apotekforeningen				X	
8. Astra Tech			X		
9. Leverandørforeningen for Helsektoren					X
10. SFT		X			
Σ Norwegian responses: 10		3	2	3	2

Sweden

Stakeholders	Just comments	Supporting proposal	Supporting with comments	No comments	Rejecting proposal
1. Karolinska Universitetssjukhuset; Upphandlingssektionen			X		
2. Arbetsmiljöverket	X				
3. Vienna Hospital Association, Environmental Department, Österrike		X			
4. Seattle Children's Hospital, USA		X			
5. Plast- & Kemiföretagen					X
6. Health Care Without Harm			X		

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7. City Hospital, Sunderland, UK		X			
8. Baxter Medical AB					X
9. Consorta, Group purchasing organisation, Illinois, USA		X			
10. Fresenius Medical Care			X		
11. Gentofte hospital, Danmark		X			
12. Swedish Medtech					X
13. Perrino Hospital, Brindisi, Italien		X			
14. Kemikalieinspektionen		X			
15. Konsumentverket				X	
16. Läkemedelsverket	X				
17. European Council of Vinyl Manufacturers (ECVM)					X
Σ Swedish responses: 17	2	7	3	1	4

General comments

Division of Neonatology, Perrino Hospital, Brindisi, Italy

We support, in its entirety, the proposal for Swan labelling of peritoneal dialysis (PD) and intravenous (IV) sets.

We are committed to reducing our use of PVC and of products containing Di (2-Ethylhexyl) Phthalate (DEHP) because of the health and environmental problems with those materials. Thus, we believe that the proposal sections prohibiting chlorinated plastics (R2) and endocrine disruptors (R3) will be of particular help to us.

It is often difficult for us to determine which products are free of PVC and DEHP. Thus, an ecolabel that identifies IV and PD sets as PVC-free and DEHP-free will make it easier for us to find such products.

Answer: Your comment has been noted.

Indenrigs- og Sundhedsministeriet/Lægemiddelstyrelsen, Denmark

Miljømærkesekretariatet har ved brev af 14. marts 2007 anmodet Indenrigs- og Sundhedsministeriet om eventuelle bemærkninger til forslag til kriterier for peritoneal dialyse (PD)- og infusions (IV)-sæt.

Indenrigs- og Sundhedsministeriet har indhentet følgende bemærkninger fra Lægemiddelstyrelsen:

"Medicinsk udstyr er omfattet af reglerne i direktiv 93/41/EEC af 14. juni 1993 om medicinsk udstyr. Heraf følger bl.a., at medicinsk udstyr, når det markedsføres, skal være forsynet med et CE-mærke, som tilkendegiver, at udstyret opfylder lovgivningens væsentlige krav til ydeevne og sikkerhed (direktivets artikel 17, stk. 1).

Endvidere følger det, at der ikke må anbringes mærker eller påtegninger på udstyret, der kan vildlede tredjemand med hensyn til betydningen af EF-mærkningen eller med hensyn til EF-mærkningens symbol (artikel 17, stk. 3).

Medicinsk udstyr kan frit markedsføres i EU, hvis det lever op til kravene i direktivet. Det følger af direktivets bilag I, at mærkningen skal indeholde de oplysninger, som er nødvendige for at brugerne kan anvende udstyret korrekt og sikkert. Ifølge direktivets artikel 4, må medlemsstater ikke hindre markedsføring af korrekt CE-mærket udstyr på deres område.

Det er ikke på nuværende tidspunkt muligt at stille krav om yderligere mærkning af medicinsk udstyr, f.eks. i form af miljømærkning.

En ekstra mærkning kan være i strid med direktivets artikel 4, som sikrer den fri markedsføring af medicinsk udstyr, som er forsynet med CE-mærkning,

fordi muligheden for en ekstra mærkning eventuelt kan signalere, at medicinsk udstyr, som "kun" er CE-mærket, ikke er af tilstrækkelig kvalitet.

I det omfang Svanemærket giver indtryk af en særlig kvalitet i produktet, vil det kunne vildlede med hensyn til den kvalitet, der tilkendes af det CE-mærke, som lovgivningen påkræver."

Indenrigs- og Sundhedsministeriet kan tilslutte sig Lægemiddelstyrelsens bemærkninger, og skal i den forbindelse henlede Deres opmærksomhed på første teksts side af "Swan labelling of Peritoneal dialysis (PD) and intravenous (IV) sets, Draft for review 14 March 2007", hvoraf det fremgår, at "The Swan label not only covers environmental issues but also quality requirements".

Answer: *Nordic Ecolabelling has modified the text at the beginning of the criteria document to specify that the quality requirements posed are entirely based on the legislation. See also the collective answer at the end of this section regarding interference with the CE label.*

Erhvervs- og Selskabsstyrelsens Center for Kvalitet i ErhvervsRegulering (CKR), Denmark

CKR har i den forbindelse følgende bemærkninger. Forslaget omhandler hvilke tekniske kriterier peritoneal dialyse- og infusions-sæt skal opfylde for at blive mærket med det Nordiske Svanemærke. Økonomiske og administrative konsekvenser Producenterne skal for at opnå Svanemærkningen betale et ansøgningsgebyr, samt et årligt gebyr for certificeringen som beregnes ud fra den årlige omsætning af produktet, som bærer Svanemærket.

Svanemærkning vil således have økonomiske konsekvenser for de virksomheder, som vælger at bruge mærkningen. Der er ligeledes administrative omkostninger forbundet med at bruge mærket. Producenter skal for at opnå Svanemærket indsende oplysningsskemaer vedrørende de tekniske kriterier for peritoneal dialyse- og infusions-sættet til Miljømærkesekretariatet.

CKR opfordrer til at lette de administrative omkostninger ved at gøre ansøgningsproceduren elektronisk tilgængelig, således at det bliver muligt at benytte digital signatur ved indsendelse af skema. Svanemærkningsordningen vil dog ikke indgå i den årlige AMVAB-opdateringen af administrative omkostninger, idet der er tale om en frivillig ordning, som ikke er en forudsætning for at være på markedet og CKR samtidigt vurderer, at under 50 % af de potentielt omfattede virksomheder vil benytte sig af ordningen. CKR har ikke yderligere bemærkninger.

Answer: *The electronic application and digital signature is something Eco-labelling Denmark is working with, and we hope it will be possible to send documents using a digital signature in the not-too-distant future.*

SFT, Norge

SFT støtter forslaget og er positive til at det stilles krav til plastmateriale, myknere og andre tilsetningsstoffer i medicinsk udstyr til peritoneal dialyse og intravenøs behandling.

Answer: *Your comment has been noted.*

Finnish Plastics Industries Federation (Muoviteollisuus Ry), Vesa Kärhä
Finnish Plastics Industries Federation rejects the proposal and wishes to highlight the following serious flaws related to the proposal:

1. The Nordic Ecolabel is now about to expand into the area of health care materials, which in Finland traditionally has been the carefully managed and regulated responsibility of the expert authorities under the Ministry of Social Affairs and Health.
2. In practice the proposal is a list that would limit the most common materials used for very critical health care products. The creators of the Swan label have emphasized many times that the intention is not to create limiting negative lists, but objective criteria, though not necessarily based on science. The actions have been totally different, only the criterion that it is not necessarily based on science has remained in place.
4. The acquirer of these products is a hospital or another institution. It is therefore the taxpayer, the patient or the insurance company that will be paying for the label, and they are not the ones that make the decision on which materials to select. Therefore there is no contact between the buyer, the payer and the end user, and once taken into use the labelling would mainly increase the costs for the treatment and reduce the product range. As a result there would be less choice at a higher cost to the persons being treated.
5. The labelling is fundamentally voluntary, but the one who needs the product the most, the patient, cannot here in practice have an impact on whether the most suitable equipment for his or her treatment selected by an expert out of a vast range has been used, or whether it's a product acquired from the narrow selection limited by the criteria of the Swan organization. The cost of the Swan label and also the removal of more inexpensive alternative materials will certainly raise the cost of the products and treatment.
6. Of greatest concern is to be at all aiming at changing the care of serious illnesses by using flimsy medical reports. Expert knowledge of patient health and medicine is lacking and the risk analysis of any potentially labelled products is almost nonexistent. There are only some references to for example potential allergic reactions and similar. What is the responsibility of the Swan labelling regarding potential injury to the patient, caused by the labelled new product, if a more functional product from a care point of view could have been found outside the labelling scheme? It is a fact, however, that the materials that the labelling excludes, have been used for the longest time, and are very well researched and known. Thanks to these materials countless peoples' lives have been saved even under very difficult circumstances.

7. The alternatives represented in the background report are on many points not in practice 1:1 – alternatives in these product groups and their use is not necessarily better or safer, not even from the point of view of producing less waste. In Finland, the legal obligation to stockpile these products for several months and their durability has among other things not been at all taken into consideration.

8. In addition to us, the review list from Finland does not include the Finnish payers of the products, the representatives for the materials which are intended to be limited, the patient organisations, or even the most important Finnish manufacturer of hospital tubing.

9. How can the Swan label and the Finnish Standards Association SFS in this country ethically even get involved in such activities as for example trying to raise funds for themselves from the care of children with cancer? That is to say, to take money for their operations from products that certainly no one buys for fun, but which are usually needed for the treatment of a very serious illness.

10. In our opinion, the preparation for labelling in this field should be abandoned, and at least the groups responsible for the labelling in Finland should totally and emphatically dismiss this.

Answer: *Nordic Ecolabelling will not give any further explanation in this document in response to comments on the general function of ecolabelling, as we stated in the last paragraph of the résumé section above (first two pages of this document).*

Items 4 and 5. The demand mechanisms and interests of buyers of single-use hospital products are not all that different from those of any other ecolabelled single-use professional products. There are many examples of ecolabelled cleaning agents, shampoo, soap and tissue paper sold to professional private and public organisations in significant numbers.

As regards the costs, see section 5 regarding the motives for choice of product group in the background document.

Item 8. The proposal was sent to a total of 54 instances in Finland for review, the first Finnish list not originally having been complete. Nordic Ecolabelling did send out to all the relevant parties for these kind of products. The review is also sent out in other Nordic countries and internationally. It is also a clear Nordic Ecolabelling policy that the review is public, so organisations that are not specifically contacted always have the opportunity to send in comments on the same terms as those contacted directly by Nordic Ecolabelling.

Medicoindustrien, Danmark

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Medicinsk udstyr, der produceres, forhandles og tages i brug i EU skal være CE-mærket i henhold til fælles EU-regler, jf. direktiv 93/42/EØF med senere ændringer. Dette indebærer, at produkter som dialyse- og IV-sæt har gennemgået en risikoanalyse, hvor fordele og ulemper ved udstyret er opvejede mod hinanden, således at udstyrets fordele overstiger de evt. ulemper, udstyret måtte medføre. Heri ligger bl.a. en risikovurdering af de anvendte materialer. Som der konstateres sikre alternativer til de ftalater, der måtte være betænkelige at anvende i medicinsk udstyr, vil der dermed naturligt ske en udfasning af det ftalatblødgjorte udstyr, idet man som fabrikant vil få sværere og sværere ved at dokumentere, at de sundhedsmæssige fordele overstiger ulemperne.

Direktivet om medicinsk udstyr er netop nu under revision, og EU-Parlamentet, Kommissionen og Rådet har ultimo marts indgået aftale om udformningen af det kommende direktiv. Man forventer, at det nye direktiv træder i kraft i 2009. Netop på området for ftalater er der indført nye bestemmelser, der indskærper vigtigheden af at have sine risikovurderinger på plads, ligesom direktivet som noget helt nyt indfører mærkningskrav for visse produkter indeholdende ftalater.

Det konsoliderede direktiv fastsætter følgende om de såkaldte CMR-stoffer (Carcinogenic, Mutagenic og toxic to Reproduction):

Bilag 1, pkt. 7.5 indeholder nu en skærpet pligt til at give CMR-stoffer opmærksomhed i den risikoanalyse, der skal udarbejdes som dokumentation for produktet. Hvilke stoffer det helt konkret vedrører, fremgår af direktiv 67/548/EØFs bilag 1, kategori 1 og 2. (Ftalaterne DEHP, DBP og BBP).

Pkt. 7.5. introducerer også en ny mærkningspligt, som gælder for udstyr (eller dele af udstyr) som administrerer eller fjerner medicin, kropsvæsker eller andre substanser til eller fra kroppen eller udstyr beregnet til transport eller opbevaring af samme væsker/substanser. Hvis sådant udstyr indeholder ftalater, jf. ovenfor nævnte direktiv, skal det mærkes på udstyret selv eller forpakningen som udstyr indeholdende ftalater. Dette betyder, at dialyse- og IV-sæt fremover vil skulle mærkes.

Endelig indeholder pkt. 7.5. en ny pligt for fabrikanten til specielt at berettiggere brugen af ftalater, hvis produktets anvendelsesområde omfatter børn, gravide kvinder og ammende kvinder. Udover at denne særlige risikovurdering skal indgå i dokumentationen, så skal man også om nødvendigt inkludere særlige forholdsregler i brugsanvisningen.

Der bliver således taget hånd om brugernes informationsbehov via reglerne om godkendelse af medicinsk udstyr, og det er derfor Medicoindustriens synspunkt, at et svanemærke på produkterne ikke vil øge gennemsigtigheden for brugere og indkøbere af produkterne, snarere tværtimod. I forvejen er alle produkter CE-mærkede, i fremtiden vil visse produkter, jf. ovenstående, blive yderligere mærket, og hvis der så også eksisterer et svanemærke på produkterne, vil der være tale om at det samme produkt er mærket med tre forskellige mærker, der overlapper hinanden. Endvidere ved vi fra de erfaringer med miljømærkerne, som man har indenfor rengøringsmidler, at der findes en del produkter, der lever op til samtlige kriterier, men som ikke er miljømærkede, fordi mærkningen indebærer betydelige omkostninger for virksomhederne. Dette forhold er egnet til at skabe uigennemsigtighed og stiller virksomheder med samme miljøvenlige produkter ulige i konkurrencen.

Endelig kan Medicoindustrien fuldt ud tilslutte os PVC-Informationsrådets holdning om, at Ecolabelling Danmark, for så vidt som man måtte fortsætte mærkningsplanerne, sørger for at kriterierne bygge på nyeste viden på området. I den forbindelse bør det erindres, at EU-Kommissionens videnskabelige komité snarligt forventes at afgive rapport om brugen af DEHP i medicinsk udstyr.

Answer: See the collective answers at the end of this section regarding:

- *interference with the CE-label*
- *revised directive on medical devices and phthalate labelling*
- *the study on plastic materials by Lars B. Pedersen*
- *the study on DEHP in medical devices from the European Scientific Committee*

Communal Alliance of Kyme Health Care District, Finland

1. It has not been handled enough environmental effects of product life cycle in the criteria proposal (appendix 1)., nor responsible business of a steady development in the criteria of producers (appendix 2).
2. After it when new combustion plants are in use it does not be more harmful for environment to destruct products including PVC-plastics as destruct other plastics products.

Appendix 1: Consideration of environmental issues of products in procurement

Raw material: By the environmental sound material

- it uses less unrenovable/renewable natural resources (ground, water, air, trees an so on)
- production of raw material use less energy
- it is consisting of recyclable material
- it is effected by less transport
- it has been used less environmental harmful chemical ib the production
- it causes less wastes, effluents e.g. environmental effects

Production: product with high quality

- is durable, serviceable, recyclable
- is easy to destruct (not hazardous waste)
- it uses less energy and other natural resources in production
- it is not used hazardous or environmental harmful chemicals
- it causes less emissions to air, water, groud
- the environmental impacts of production are not risk for polymorphism of the nature

Distribution

- not long transport travels, not empty transports
- transports by environmental sound vehicles (train, car, ship, airplane)

Trade

- responsible trade (fair trade, not children work, development countries are considered)
- small stores (less energy, volume, preservation substances, packaging material and so on
- less transports

Use

- secure and durable in use
- serviceable
- recyclable
- safe

- causes less environmental effects (use less energy, materials and produces less waste or emissions)
- not harm from noise, smell, particles

Destruction

- recyclable as goods, material
- recyclable as energy
- it is easy and secure biological decomposition on the landfills
- it does not include hazardous compounds
- it is not as hazardous waste
- it does not extra energy, chemicals, special tools for discharging or separation
- less packaging size and good working safety

Appendix 2: Consideration of treatment of environmental issues by suppliers with procurement decisions

Environmental responsibility

- fulfilment of legislative obligations
- environmental managing systems and their function
- are there significant environmental effects and how effectively they are aimed to reduce
- how environmental issues are considered by product development
- what kind of packaging materials have been used
- have hazardous wastes been treated properly
- what kind of dialogue with interest groups
- what kind of information about environmental issues
- are there requirements to suppliers for level of treatment of environmental issues

Social responsibility

- legislative working contracts are fulfilling
- fair salary for employees
- realization of equality
- not children work
- health and education of employees are considered
- working safety issues are considered
- employees have possibility to effect working processes

Economical responsibility

- positive result of company
- company does invest in the future
- company does take care of sufficiency of economical resources according to durable development of operation

Answer: See the collective answer below, at the end of this section, on how well the requirements cover the life cycle and on combustion plant technology.

Susan Heffernan, Seattle Children's Hospital, USA

I support, in its entirety, the proposal for Swan labeling of peritoneal dialysis (PD) and intravenous (IV) sets available at <http://www.svanen.nu/Eng/criteria/remissdok.asp?dok=98>.

We are committed to reducing our use of PVC and of products containing Di (2-Ethylhexyl) Phthalate (DEHP) because of the health and environmental problems with those materials. We have made some in-roads to this effort at Seattle Children's Hospital but are limited in many product areas. Thus, we believe that the proposal sections prohibiting chlorinated plastics (R2) and endocrine disruptors (R3) will be of particular help to us as communities across the world come together for the safety of not only patients in hospital and medical settings but to all and generations to come from an environmental impact.

It is often difficult for us to determine which products are free of PVC and DEHP. Thus, an ecolabel that identifies IV and PD sets as PVC-free and DEHP-free will make it easier for us to find such products.

Answer: *Your comment has been noted.*

Karolinska Universitetssjukhuset, Upphandlingssektionen, Sverige

Vi stödjer utvecklingen av kriterier för miljömärkning av rubricerade produkter.

Eftersom kriterieförslaget innehåller flera allvarliga sakfel bland annat när det gäller produktdefinitionen rekommenderar vi att dokumentet omarbetas och därefter genomgår en ny remissomgång.

Det är svårt att hantera och granska ett dokument på så många sidor när sidnumrering helt saknas.

Answer: *The missing page numbers were a mistake; normally there is page numbering. Since all the clarifications needed have been discussed with Karolinska directly, Nordic Ecolabelling doesn't see the need to send the proposal out for another review.*

Arbetsmiljöverket, Sverige

Arbetsmiljöverket har som remissinstans fått möjlighet att lämna synpunkter på ovanstående remiss. Eftersom Arbetsmiljöverkets ansvarsområde är arbetsmiljö kommenteras förslaget enbart ur denna aspekt.

De framtagna kriterierna rör framför allt den yttre miljön och i viss mån patienternas hälsa. Arbetsmiljön för de som tillverkar eller använder plastprodukterna kommenteras endast flyktigt, vilket är en brist. Miljömärkningar såsom Svanenmärkningen skulle generellt vara mer användbara om arbetsmiljöaspekter fick en större tyngd än vad som nu är fallet.

Answer: *It is correct that occupational health issues are not extensively described in the background document. But occupational health is an important issue in plastics production, as described in section 7.2.1 of the background document. The report referred to is an extensive study of, among other things, chemical exposure in the production of many different plastics.*

Nordic Ecolabelling welcomes ideas on how to impose occupational health requirements in reviews, by licensing or by other stakeholders; it will make it easier to deal with more occupational health issues in the criteria. See also our response to Coloplast further down in this section.

For the issues not yet covered, Nordic Ecolabelling will have to rely on the legislation imposed by the authorities. No products will be awarded an ecolabel if Nordic Ecolabelling knows that the relevant occupational health legislation (or any other relevant legislation) is not complied with. See also the collective answer at the end of this section regarding how well the requirements cover the life cycle.

Vienna Hospital Association, Environmental Department, Austria

We support, in its entirety, the proposal for Swan labelling of peritoneal dialysis (PD) and intravenous (IV) sets.

We are committed to reducing our use of PVC and of products containing Di (2-Ethylhexyl) Phthalate (DEHP) because of the health and environmental problems with those materials. Thus, we believe that the proposal sections prohibiting chlorinated plastics (R2) and endocrine disruptors (R3) will be of particular help to us.

It is often difficult for us to determine which products are free of PVC and DEHP. Thus, an ecolabel that identifies IV and PD sets as PVC-free and DEHP-free will make it easier for us to find such products.

Answer: *Your comment has been noted.*

Plast- & Kemiföretagen (P&K), Sverige

Sammanfattningsvis anser vi att Nordisk Miljömärkning i detta kriteriearbete inte har behandlat PVC på ett objektiva sätt. Därför strider kriteriearbetet mot ett av de grundläggande åtagandena som man har för sitt arbete och kriterierna bör avslås i sin nuvarande form.

Nordisk Miljömärkning väljer att miljömärka en mindre del i en komplex utrustning och dessutom bara med hänsyn till en miljöaspekt – avfallsmängden. Detta innebär att Nordisk Miljömärkning inte alls kan uttala sig om de Svanenmärkta produkterna kommer att leda till att det totala sättet blir bättre eller sämre ur miljösynpunkt, varken för de enskilda produkterna eller för de behandlingar där dessa produkter ingår. Vi anser att detta är högst anmärkningsvärt.

Hade Nordisk Miljömärkning valt en annan variabel att basera kriterierna på hade utfallet blivit något annat. Om t.ex. energiåtgång hade valts som enda variabel hade PVC legat bäst till. I andra sammanhang är energiåtgången annars en viktig aspekt för Nordisk Miljömärkning. Vi vill samtidigt påpeka att tabellen 7.2.2. använder en gammal siffra för energiåtgången vid tillverkning av PVC. Det miljöarbete som branschen driver har sänkt siffran till att nu vara 56 MJ/kg (se eco-profiles på www.plasticseurope.org).

Just för denna produktgrupp anser tydligen Nordisk Miljömärkning att det är helt avgörande att ett material inte skall accepteras för att det vid förbränningen bildas försurande gaser som måste neutraliseras. För en stor del av Svanens andra produktgrupper anses detta dock inte vara ett hinder för ett material. T.ex. har Svanen över 10 kriteriedokument inom pappers- och cellulosa produkter trots att papper står för ca 25 % av svavelhalten i förbränningsanläggningar för hushållsavfall och ca 12 % av klorhalten. Svanen påstår vidare att andra plaster inte har samma problem som PVC. Detta är fel eftersom det finns fler plaster som innehåller grundämnena klor (Cl), svavel (S) och kväve (N) som alla ger upphov till försurande gaser som måste neutraliseras.

Vi håller med om att det är en miljömässig nackdel att det bildas försurande gaser som måste neutraliseras, men det är en miljöaspekt bland många som måste vägas samman. I Danmark har det dessutom nyligen utvecklats en ny process som både på ett miljömässigt och ekonomiskt sätt kan ta till vara på saltet från de förbränningsrester som bildas vid avfallsförbränningsanläggningar.

Vi är även förvånade över att Svanen plötsligt är kritiska till livscykelanalyser (LCA) som metod, med motiveringen att den inte tar hänsyn till alla aspekter. Är inte LCA som metod ändå betydligt bättre än att bara välja en aspekt bland många och inte väga in produktens hela livscykel? De riskbedömningar som gjorts på tillsatserna i PVC täcker dessutom upp eventuella brister i LCA.

Ytterligare ett exempel på att Nordisk Miljömärkning har använt föråldrad information om PVC är den kategorisering som man hänvisar till som Lars Pedersen har gjort. Denna bok kom ut 1999 och baseras på ännu äldre information. En detaljerad kommentar till bokens innehåll bifogas. Mycket har hänt runt PVC under de senaste åren, både när det gäller ökad kunskap och miljöarbetet i branschen. För en uppdatering se t.ex. den nya broschyren "PVC idag och imorgon" på <http://www.pvc.se/BROSCHYRER.html>

Även när det gäller avsnittet om återvinning i bakgrundsdokumentet baseras detta på information som inte är aktuell längre. Nordisk Miljömärkning påstår att det skulle vara svårt att återvinna PVC och hänvisar till en bedömning av plasters återvinningsegenskaper som bilföretaget Opel gjorde 2000/2001. Enligt Opel gäller inte detta längre och företaget hänvisar till den senaste informationen på http://www.gm.com/company/gmability/sustainability/reports/05/800_regional/2_twenty/820.html

Att återvinningen av PVC ökar kraftigt i Europa talar för att det inte är svårt att återvinna PVC, se www.vinyl2010.org.

Answer: *It is positive that the industry has lowered the energy consumed in the production of PVC to 56 MJ/ton, and we hope production of other plastic materials can show similar improvements. As can be seen in the background document, Nordic Ecolabelling also refers to other reports with more detailed*

and recent figures. However, the picture given by the table in section 7.2.2 also takes into consideration the amount of energy recovery from incineration and thus provides a practical overview.

Even if the incineration of paper and paper products also cause emissions to air, it does not produce the same amount of problematic residues as PVC does. Other plastics and other waste may also produce residues, but not to the same extent as PVC. These issues are discussed in section 7.2.3 of the background document.

Nordic Ecolabelling is strongly in favour of using LCAs. For instance, LCAs that quantify the environmental load are of particular use in support and design point systems used in several other product groups in Nordic Ecolabelling. When using results from LCAs, however, it is important to be aware of which areas are not covered by the study and what the uncertainties are. For example, the uncertainty is greater when dealing with aspects that are difficult to quantify, such as hazardous substances.

It is positive that the PVC recycling rate is increasing in Europe. P&K says that the background document is wrong in its claim that PVC is relatively difficult to recycle. Nordic Ecolabelling cannot, however, see that the GM (Opel) Web site P&K refers to opposes such a statement or presents any new data on the matter.

The 2006 report by Schmidt that the Background document refers to confirms the still relatively low recycling rate of PVC, which is due to its content of additives that make the recycling process difficult. General recycling of used plastic materials is difficult because of the special knowledge needed to separate different plastic types and because of their contamination. This is certainly true for households, according to Schmidt, but the information Nordic Ecolabelling gathered while developing the criteria indicates that it is also true for hospitals.

See also the collective answers at the end of this section regarding:

- *how well the requirements cover the life cycle*
- *combustion plant technology*
- *the study on plastic materials by Lars B. Pedersen*

Health Care Without Harm (HCWH), Czech Republic

Health Care Without Harm is a coalition of environmental groups, hospitals and healthcare professionals associations among others whose mission is to transform the healthcare sector so that it becomes environmentally responsible without causing harm to the environment and people and without compromising patients safety or care. **One of our major campaign goals is to eliminate the use of PVC from healthcare sector.**

Résumé of review criteria for disposable peritoneal dialysis (PD) and intravenous (IV) infusion treatment products
Treated by Nordic Ecolabelling Board 13 December 2007

HCWH welcomes the proposal from Swan Ecolabelling to label medical devices on the basis of 2 major criteria:

1. the use of substances harmful to the health and environment.
2. contribution to generation of problematic waste.

We regard this tool as very progressive and perceive that such labeling will tremendously help healthcare professionals attempting to substitute PVC medical devices for safer alternatives not only in Scandinavia but also Europe- and worldwide. Right now it is often difficult for healthcare professionals to determine which products are PVC-free. Thus, this labeling will help move the market beyond Scandinavia towards safer materials. Majority of medical devices manufacturers are operating at global level and this market shift will be of significance not only to users in Europe, but also worldwide.

1. HOSPITALS ARE ALREADY PHASING OUT PVC/DEHP AND THERE IS A STRONG DEMAND FOR MORE INFORMATION ON SAFER ALTERNATIVE PRODUCTS.

HCWH works with many healthcare institutions that are responding to the growing scientific evidence and the recommendations of numerous public authorities, and substituting DEHP-softened PVC with safer DEHP-free alternatives. The Vienna Hospital and Styrian Hospital Associations in Austria, the Karolinska University Hospital and Malmo University Hospital and many other facilities in Sweden and Denmark, the Na Homolce Hospital (dialysis equipment PVC-free) and Faculty Hospital in Olomouc (the entire NICU PVC-free), the Czech Republic are among the forerunners¹. Most recently, the French clinique Champeau in Beziers committed to purchase PVC-free devices as well as Kosice-Saca hospital in Slovakia substituted IV sets for PVC-free alternatives at their NICU.

¹For more details, see HCWH factsheet at www.noharm.org/details.cfm?type=document&id=1050

Similar market shift can be seen in the United States where major healthcare providers such as Kaiser Permanente serving over 8 million people in the US, or Catholic Healthcare West awarded a sole-source contract to B. Braun for PVC-free IV bags. Healthcare purchasing groups including Broadlane and MedAssets have begun to routinely require disclosure from vendors of the chemicals (such as brominated flame retardants (BFRs), phthalates, halogenated organics, and persistent bioaccumulative toxicants (PBTs)) in their products, and have begun using this information to make purchasing decisions. This also covers PVC medical devices.

Re HCWH item 2-5: Moved to comments on the background document.

Re HCWH item 6: moved to comments on hazardousness to health and the environment (R4).

Re HCWH point 7: moved to comments on chlorinated plastics in product and packaging (R2).

Answer: *Your comment has been noted. See also specific sections.*

Social- og helsedirektoratet, Norge

Direktoratet støtter forslaget om å kunne svanemerke medisinsk engangsutstyr til peritoneal dialyse og intravenøs behandling, men med enkelte forbehold i forholdet til regelverket for medisinsk utstyr.

Forslaget til miljøkrav for svanemerking og forholdet til regelverket for medisinsk utstyr

Sosial- og helsedirektoratet er norsk ansvarlig myndighet i henhold til det europeiske regelverket knyttet til medisinsk utstyr. Alle EU-direktivene knyttet til medisinsk utstyr er implementert i forskrift av 12. desember 2005 nr. 1690 om medisinsk utstyr.

For at et medisinsk utstyr lovlig kan plasseres på markedet i EØS-området følger det av regelverket at det må CE-merkes. CE-merket er viktig både for kunder og tilsynsmyndigheter i EØS-området, da dette er produsentens erklæring på at utstyret er produsert i henhold til de felles europeiske regler. Beskyttelse av CE-merket og dets autonomi er derfor et viktig prinsipp nedfelt i regelverket og høyt på agenden i EU-fora.

I forskrift om medisinsk utstyr er dette nedfelt i § 2-4 som lyder:

"§2-4. (CE-merking)

Utstyr som fyller kravene i §2-1 og som er samsvart i overensstemmelse med en av prosedyrene angitt i kapitlene 3 til 5, skal når det markedsføres, CE-merkes av produsenten som vist i vedlegg A. Unntatt er individuelt tilpasset utstyr, utstyr til klinisk utprøving, utstyr til ytelseskontroll, samt utstyr som skal framvises etter §2-10.

CE-merket plasseres i overensstemmelse med bestemmelsene for det aktuelle utstyret i kapitlene 3 til 5, og påføres på en slik måte at det er godt synlig, varig og lett å lese.

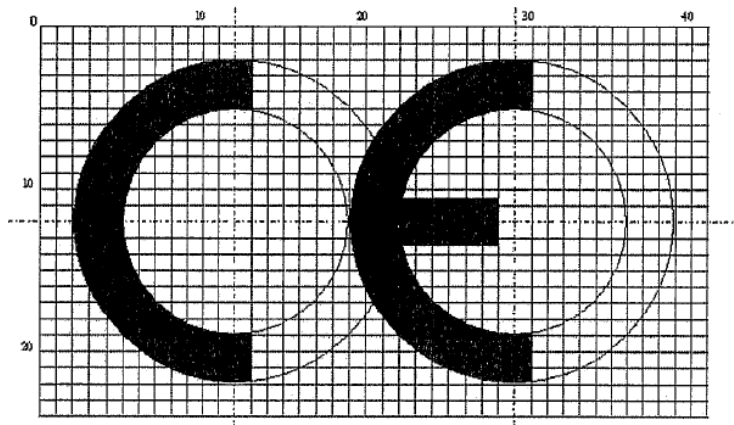
Forutsetter samsvarsprosedyren involvering av et teknisk kontrollorgan påføres det ansvarlige tekniske kontrollorgans identifikasjonsnummer sammen med CE-merket.

Det er ikke tillatt å påføre utstyret merker eller påskriften som kan virke villedende med hensyn til CE-merkingens betydning eller utforming. Annen merking kan påføres utstyret, emballasjen eller bruksanvisningen forutsatt at dette ikke gjør det vanskeligere å lese og tyde CE-merkingen.

Dersom utstyret omfattes av annet regelverk som også fastsetter krav om CE-merking, skal CE-merkingen angi at utstyret også oppfyller kravene i disse regelverkene. Dersom ett eller flere av disse regelverkene i en overgangsperiode tillater at produsenten fritt kan velge hvilke regler denne vil anvende, skal CE-merkingen angi at utstyret kun er i samsvar med kravene i det regelverk produsenten har anvendt. Dette gjøres ved at de aktuelle direktivers referansenummer, som det aktuelle regelverket er basert på, og som er offentliggjort i De Europeiske Felleskaps Tidende, oppgis i de dokumenter, veiledninger eller instruksjoner som kreves i henhold til regelverket og som følger med utstyret."

Når det gjelder den bestemte formen på CE-merket og dets størrelse fastslår forskriftens vedlegg A at:

"CE-merking for samsvar skal bestå av bokstavene « CE » og ha følgende utforming:



- *Dersom merket forminskes eller forstørres, skal proporsjonene angitt på tegningen ovenfor være de samme.*
- *De forskjellige deler av CE-merking for samsvar skal stort sett ha samme loddrette størrelse, og de skal være minst 5 mm høye. Minstestørrelsen kan fravikes for utstyr av liten størrelse."*

Hovedregelen er at medisinsk utstyr må være påført CE-merket i henhold til disse reglene for lovlig å kunne omsettes på det felles europeiske markedet.

Forskriftens § 2-4 fjerde ledd regulerer forholdet mellom CE-merket og andre merker. Andre merker som ikke virker villedende med hensyn til CE-merkingens betydning eller utforming kan settes på medisinsk utstyr. I vurderingen av hvorvidt andre merker kan tillates, legges det vekt på om merket har en annen funksjon enn CE-merke, om det kan bidra til å skape forvirring om CE-merkets betydning og om det kan redusere CE-merkets synlighet og lesbarhet.

Sosial- og helsedirektoratet mener at svanemerke bør kunne påsettes medisinsk utstyr som foreslått. Svanemerke har en annen funksjon enn CE-merket, videre er det godt kjent slik at det må antas å ikke skape forvirring om CE-merkets betydning. Sosial- og helsedirektoratet vil imidlertid oppfordre Stiftelsen Miljømerking til å ta inn i sine kriterier at svanemerke ikke må bidra til å svekke CE-merkets synlighet og lesbarhet. Dette kan særlig være aktuelt hvor det er snakk om små pakninger. I slike tilfeller bør det vurderes å ikke svanemerke utstyret, da det kan komme i konflikt med det lovpålagte CE-merket.

Når det gjelder utformingen av dokumentene "Swan labelling of Peritoneal dialysis (PD) and intravenous (IV) sets. Draft for review 14 March 2007", og "About Swan labelling of Peritoneal dialysis (PD) and intravenous (IV) sets. Draft for review 14. March 2007. Background to ecolabelling", har direktoratet en kommentar til bakgrunnsdokumentet punkt 5 hvor det står:

"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 marked unless they have been approved by the authorities."

Når det gjelder medisinsk utstyr stemmer ikke dette overens med hvordan reguleringen av området er lagt opp. Medisinsk utstyr godkjennes ikke av ansvarlige offentlige myndigheter for medisinsk utstyr, men CE-merkes egenhendig av den ansvarlige produsent. CE-merket er å tolke som produsentens erklæring om at denne har produsert utstyret i samsvar med de regler som gjelder. Sosial- og helsedirektoratet og andre ansvarlige myndigheter i EØS-området fører tilsyn i etterkant av at utstyret er markedsført. Dette avsnittet bør rettes opp for ikke å villedde leserne til å tro at CE-merket kan tolkes som at utstyret er godkjent av en offentlig myndighet.

Answer: *Nordic Ecolabelling has modified the background document so that the role of the authorities is now described correctly. Nordic Ecolabelling has added a requirement making it clear that the Swan label is not allowed to reduce the visibility and readability of the CE label (for instance on small packaging). See also the collective answer regarding interference with the CE-label at the end of this section.*

Miljøstyrelsen, Danmark

Nordisk Miljømærkning har sat udvikling af kriterier for medicotekniske plast-produkter, herunder f.eks. dialyseposer, i gang. Miljøstyrelsen gør desuden

opmærksom på, at anvendelsen af medicinsk udstyr primært hører under Indenrigs- og Sundhedsministeriet.

Miljøstyrelsen har dog følgende kommentarer:

Som udgangspunkt finder Miljøstyrelsen, at det er positivt, at der arbejdes for at opstille kriterier for en mærkningsordning af peritoneal infusions- og dialysesæt af PVC og med et indhold af ftalater for herved at fremme brugen af miljø- og sundhedsmæssige alternativer.

Det er imidlertid Miljøstyrelsens opfattelse, at det på nuværende tidspunkt er usikkert, om det er hensigtsmæssigt at indføre en svanemærkningsordning for medicinsk udstyr af PVC med ftalater. Det skyldes følgende årsager:

For det første er der her tale om en produktgruppe, som har en række særlige egenskaber, der kan være vitale for selve behandlingen, og som derfor bør afvejes i forhold til produkternes miljø og sundhedsbelastning.

For det andet har EU-Kommissionen sat et arbejde i gang og nedsat en komité, som specifik skal vurdere den sundhedsmæssige risiko ved brugen af ftalater i blandt andet medicinsk udstyr. I forlængelse heraf arbejdes der i EU-regi på at indføre en mærkningsordning for medicinsk udstyr, således at indkøbere og brugere umiddelbart kan se, om udstyret indeholder ftalater.

For det tredje er det Miljøstyrelsens opfattelse, at alternativerne til medicinsk udstyr, der indeholder ftalater, ikke er så velundersøgte. Det gælder både de sikkerhedsmæssige egenskaber for patienterne samt mulige effekter ved udløsning af stoffer til miljøet.

På grundlag af ovenstående er det således Miljøstyrelsens vurdering, at der på nuværende tidspunkt ikke er et tilstrækkeligt viden til at kunne opstille kriterier for en svanemærkning af peritoneal infusions- og dialysesæt. Miljøstyrelsen anbefaler, at dette arbejde udskydes, indtil der foreligger en udtalelse fra den videnskabelige komite samt en reaktion fra EU-Kommissionen herpå.

Hvis det senere viser sig, at der er europæisk tilslutning og tilstrækkelig viden til at indføre en svanemærkning af medicinsk udstyr, er det Miljøstyrelsens vurdering, at det videnskabelige arbejde, som EU-kommissionen allerede har sat i gang, bør inddrages i en kommende mærkningsordning. Desuden bør de kriterier, der allerede er eller ved at blive opstillet for lignende produktgrupper, inddrages. Det kunne eksempelvis være kriterier for legetøj, der indeholder ftalater.

Answer: *The considerations needed to secure the function of the treatment in question are of special importance for this kind of product, no doubt about that. That is why Nordic Ecolabelling based the function requirement on the testing by notified bodies according to a number of standards under the Medical Devices Directive or an approval from the authorities in the case of medicinal products.*

In section 7.3 of the background document, Nordic Ecolabelling refers to the European Commission BAT document for the production of polymers and the Danish EPA's own report entitled "Miljø- og sundhedsforhold for plastmateriale". These are up-to-date studies giving a detailed and scientific picture of the environmental effects of chemicals emitted into the environment during treatment of a number of different plastic types.

Regarding patient security: for patients it is important to notice that medical devices/medicinal products made of/packed in materials other than PVC must comply with the extensive European legislation in those fields.

Nordic Ecolabelling agrees that it is a good idea to include current EU scientific work and work already done by the EU and others. For this reason, a new requirement has been added that excludes the six phthalates that are restricted in the EU toys directive. Most of them were already excluded, but DIDP was not because it is not classified and not considered an endocrine disruptor.

See also the collective answers at the end of this section regarding:

- *revised directive on medical devices and phthalate labelling.*
- *the European Scientific Committee study on DEHP in medical devices.*

Coloplast A/S, Denmark

Swan labelling of Peritoneal dialysis (PD) and intravenous (iv) sets, draft 14 March 2007. Comments from Coloplast 15 May 2007. Coloplast does not manufacture peritoneal dialysis bags or intravenous sets. We can therefore only be of help giving general comments and not technical comments that are specific for those products.

General comment on plastizisers New directive from EU means that it must be stated on certain products if they contain specific phthalates.

Lay out of Draft criteria proposal Just a small practical comment: When the criteria proposal is opened at the web site, the page seems to be blank. We suggest that headers or other text parts or logos are placed higher on the page. Otherwise it can be confusing for the reader who will think something is wrong with the system.

Criterion on working environment We suggest that criteria on working environment are considered: If CMR classified materials/products are handled in the production process, there must be a) forced ventilation at the relevant work stations and machines and b) equipment for personal security If for example PUR is used as alternative to PVC, isocyanates may be handled in the production process. Some isocyanates are considered carcinogenic according to Arbejdstilsynets kræftliste. More and more production is out sourced to countries outside EU. It is important to help getting a proper working environment also in these countries. The suggested criterion will not secure a proper

working environment. In order to do that, there should also be criteria with limit values for the indoor concentrations of the compounds. But the suggested criterion can take the worst cases away. And it is easy to control whether there is ventilation and personal security equipment or not.

Answer: *Nordic Ecolabelling will take a look at the layout in order to improve readability. For the occupational health issues not yet covered, Nordic Ecolabelling will have to rely on the legislation imposed by the authorities, even if the manufacturer is outside the EU. No products can be awarded an ecolabel if Nordic Ecolabelling knows that legislation on occupational health (or any other relevant legislation) is not complied with.*

As suggested by Coloplast, Nordic Ecolabelling will consider occupational health requirements such as forced ventilation and personal security equipment if CMR substances and preparations are handled in the production of the plastic material in the future criteria.

Helsinki and Uusimaa Hospital Group, Finland

Comments: I would like to strengthen my support with the following -
The highest exposures to DEHP are considered to result from blood transfusions and hemodialysis during which DEHP may leach from PVC products into body fluids. Exposure of neonates to DEHP could be especially high.

Medical and nursing staff is not commonly aware of this because they are not familiar with plastics. Even if nurses were aware of problems with “PVC”, the problems in their opinion would not necessarily apply to “vinyl”, or any plastics which do not carry the “number in the triangle” symbol of PVC. Unfortunately, this state of art is not easily going to improve because environmental issues are non-existing in a nurse’s professional training.

Neither can health care products be expected to be marked with any symbols other than CE-symbols. However, in the env. Best Practice procurement process eco labels - or the criteria on which the label is based - are more and more often chosen for selection criteria.

Thus, eco labels are valuable tools in replacing missing education. For the end user of the product selecting of environmentally reliable product becomes obvious, less time consuming, and, consequently, more acceptable. Ecolabelling is welcome to hospital products, and PD and IV sets compose an ideal pioneer group of fitting products.

Answer: *Your comment has been noted. See also the collective answer at the end of this section regarding the revised Medical Devices Directive and phthalate labelling.*

PVC Information Council Denmark

Résumé of review criteria for disposable peritoneal dialysis (PD) and intravenous (IV) infusion treatment products
Treated by Nordic Ecolabelling Board 13 December 2007

The professional basis of the “Nordic Eco Labelling” paper on *Swan labelling of peritoneal dialyses and intravenous sets* published 14. March 2007 is primarily a Danish book that was published in 1999 by Lars Borch Pedersen with the title “Plast og miljø” (“Plastics and the Environment”). The book contains a categorisation, assessment and prioritising of plastic materials with the aim to help companies to see which materials should be chosen, if the environment is taken into consideration. It is this priority list that the “Nordic Eco Labelling” chooses to use as a main reference in its assessment of PVC and alternatives. By using this priority list “Nordic Eco Labelling” concludes that medical devices manufactured in PVC should be replaced by other plastic materials.

In this short note I will give some decisive examples to show that Lars Borch Pedersen’s book is antiquated and that the document of the “Nordic Eco Labelling” *About Swan Labelling of Pertoneal Dialysis and Intravenous Sets* thus has to be rejected as a document usable in discussions about, what kind of materials should be used in the manufacture of medical applications.

Four issues discussed

There are four properties that are traditionally discussed when PVC is on the agenda: incineration, heavy metals, working environment and phthalates. These are also the four properties that are making a central position, when Lars Borch Pedersen in his book is describing the PVC issues.

Incineration

In the book it is said that incineration of PVC means acidification of the environment. This is wrong. The implementation of the incineration directive in the EU is securing that chlorine containing waste does not mean an acidification of the environment. Smoke purification is securing that no HCL emissions are leaking off onto the environment.

In connection with incineration it is also said in the book that heavy metals in the waste is also leaking off onto the environment. Neither this is true. The heavy metals end in the neutralisation residues.

Dioxins

In the book it is said that incineration of PVC may mean building of dioxins. This is also an antiquated understanding. As a matter of fact the Danish Environmental Protection Agency stated several years ago that it is inappropriate to connect building of dioxins to incineration of PVC.

Heavy metals

The book says among other things that it is the use of heavy metals in PVC, which causes that PVC is rated very low in the categorisation of the plastic materials. To this is only to say that in Scandinavia heavy metals have not been used as a stabiliser in PVC for several years. In Denmark it was banned in 2001.

Working environment in raw material production

It is mentioned in the book that low, daily doses VCM may cause cancer, and thus it indicates that it is a problem in the working environment. This is not so. More than 20 years ago the PVC industry secured that the working environment is totally safe for the employees when it comes to VCM exposure.

Phthalates

It is stated in the book that the phthalate DEHP is carcinogenic to humans. This is not longer the position. As a matter of fact WHO has removed DEHP from the cancer list many years ago.

It is mentioned that phthalates are included in the Danish Environmental Protection Agency’s list of undesired substances. This is no longer true. The phthalates that are classified as harmful are included in the list. The most used phthalate, DINP, is for instance not any more included in the list of undesired substances.

In other words, when it comes to the discussion of the main environmental issues related to PVC Lars Borch Petersen’s book is today useless

Swan document should be rejected

When the “Nordic Eco Labelling” is choosing Lars Borch Pedersen’s book that was published almost a decade ago as a main source in its criticism of PVC, it should be a matter of course that the authors initially examined whether the description of environment and health aspects of PVC are up-to-date and still valid in 2007. This has not been done. Instead of taking a critical view on the scientific literature used the “Nordic Eco Labelling” calls Lars Borch Pedersen’s book “a good comprehensive and transparant presentation of polymers and environmental issues”. This is disturbing.

Answer: *As regards the study by Lars B. Pedersen, see the collective answer at the end of this section.*

Nyremedicinsk afsnit Århus Universitetshospital Skejby, Regionshospitalet Viborg og Regionshospitalet Holstebro, Danmark

I Region Midtjylland foretages kronisk peritonealdialysebehandling på Regionssygehus Holstebro, Regionssygehus Viborg samt Århus Universitetshospital Skejby.

Peritonealdialyseværsker og tilhørende utensilier er gennem de sidste to år for hele regionens vedkommende indkøbt gennem Amgros A/S efter følgende tildelingskriterier:

1. Bredden af det tilbudte sortiment af værsker, herunder flest mulige værsker med fysiologisk pH-værdi, er tillagt en vægtning på 20-30%.
2. Prisen for peritonealdialyseværskerne og de til behandlingen hørende utensilier er tillagt en vægtning på 30-40%.
3. Omfang, konstruktion og kvalitet af de til behandlingen hørende utensilier, herunder plasticslangesæt, er vægtet med 10-20%.
4. Emballagens udformning, herunder specielt håndterbarhed for patienterne, er tillagt en vægt på 10-20%.
5. Omfang og kvalitet af pakninger i form af kasser og sekundær emballage er tillagt en vægtning på 10-15%.

Fra et snævert medicinsk nefrologisk synspunkt kan forslaget til kriterier for mærkning af plasticutensilier til peritonealdialyse umiddelbart anbefales og accepteres.

Det foreslås derfor, at disse kriterier fremover skal indgå i en samlet vurdering af tildelingskriterium 3.

Det foreslås samtidigt, at den samlede vægtning af tildelingskriterium 3 uændret skal være 10-20%.

Den nuværende licitationsaftale gennem Amgros A/S er netop blevet forlænget med et år.

Peritonealdialyseværsker og utensilier vil derfor tidligst komme i licitation igen om ca. et år, hvor ovenstående forslag kan indarbejdes i kriterierne som anført.

Answer: *Your comment has been noted.*

Swedish Medtech

De produkter som behandlas i remissen, PD- och IV-påsar är bägge produkter som är del av läkemedel och därmed faller undre läkemedelslagstiftningen

inom EU och nationellt. Läkemedelslagstiftningen innehåller bestämmelser kring vilka krav en produkt måste uppfylla för att den ska godkännas av behörig myndighet och därefter sättas på marknaden. Det har från EU:s sida angivits att detta regelverk är tillräckligt i alla delar och därför har bland annat läkemedel undantagits från REACH. Läkemedelsprodukter ska därför inte underkastas andra certifieringar eller liknande då dessa kan stå i strid med det regelverket som finns för produkterna inom EU.

Vad gäller medicintekniska produkter så innehåller remissen en mängd hänvisningar till medicintekniska produkter. Det är viktigt att tydliggöra att läkemedel och medicintekniska produkter faller under två helt skilda regelverk där läkemedel hanteras genom myndighetsgodkännande och medicinteknik genomgår ett CE-märkningsförfarande. Det innebär att man måste hantera produkterna separat i alla frågor för att säkerställa att man möter de grundläggande regelverk som finns kring produkterna. Det finns produkter som faller under bägge regelverken, sk. kombinationsprodukter, men den absoluta majoriteten av produkterna är antingen läkemedel eller medicinteknik.

Vad gäller den aktuella remissen i sak vill Swedish Medtech invända dels mot att man i processen valt att fokusera på endast en mindre del i en hel process. En dialysprocess innehåller en maskin, förbrukningsmaterial, läkemedel och andra resurser såsom el och vatten. Till detta kommer en livscykelanalys vilken inkluderar hela produkten miljöbelastning inklusive transporter mm. Som angivits har man valt att bryta ut endast en del i processen, påsen som innehåller läkemedlet, för att fastställa kriterier för märkningen av denna. Genom att bryta ut en del av processen så ha man skapat förutsättningarna för att i praktiken generera kriterier vilka kan komma att generera mycket negativa miljökonsekvenser baserat på hela processen.

Swedish Medtech ställer sig vidare negativa till att man valt att i princip endast fokusera på materialval i den aktuella förpackningen som kriterium för märkningen. Det finns idag inga starka eller enhetliga vetenskapliga bevis som stödjer att man ska utesluta de material som angivits i remissen. Detta kombinerat med att det inte ställs krav på att ev. ersättningsmaterial uppvisar en risk-nyttoanalys som är minst lika fördelaktig som den det aktuella materialet gör, måste anses mycket uppseendeväckande. Medicintekniska produkter arbetas fram i enlighet med de bestämmelser som finns i det medicintekniska direktivet vilket inkluderar en risk-nytto analys där de risker som är kända, eller kommer till tillverkarens kännedom ska elimineras, eller om det inte är möjligt reduceras så långt som möjligt. Riskanalysen för medicintekniska produkter har varit mycket väl fungerande för att få fram produkter som är så säkra som möjligt för användare och patient samtidigt som man inte kompromissar på produktens effekt i det avsedda syftet.

Att föra in Svanenmärkning för läkemedelsprodukter är tveksamt och kanske till och med i strid mot det EU regelverk som finns på området. Vad gäller medicintekniska produkter så är det i verklig mening inte berörda i remissen eftersom produkterna inte utgör medicintekniska produkter. Det är

dock viktigt att understryka att det aldrig kan vara acceptabelt att gå in med en miljömärkning vilken kan skapa förvirring kring CE-märkning och ev annan märkning enligt det medicintekniska direktivet (här kan framförallt nämnas att det i revisionen av MDD har förts in en bestämmelse som innebär att CRM-substanser som är kända ska användas med försiktighet i medicintekniska produkter och att det finns ett märkningskrav för de produkter där sådan substanser ingår. Att införa ett Svanen märke ovanpå detta hotar att skapa osäkerhet kring märkningarna och minska värdet i den CRM-märkning som ska till.

Sammanfattningsvis uppfattar vi att denna remiss är dåligt underbyggd, att den grund som anges i vad som ligger till grund för märkning är felaktig och att märkning generellt kan vara vilseledande med tanke på den revision som skett av MDD och de märkningar som krävs av medicintekniska produkter. Den aktuella remissen hanterar inte medicintekniska produkter och detta måste tydligt anges. Om det är aktuellt att skapa kriterier för medicintekniska produkter måste denna process genomföras i samverkan men aktörer som kan regelverket och har en förståelse för vad som är möjligt och lämpligt i denna del. Swedish Medtech är branschorganisationen för de medicintekniska företagen i Sverige och besitter stor kunskap både om det regulatoriska, miljöregleringarna för medicinteknik och förutsättningarna för industri och vård att på ett bra, miljövänligt och säkert sätt förändra produkter och processer vilka används inom vården. Man får aldrig glömma att en medicinteknisk produkt värderas utifrån hela produkten, material, design, säkerhet för patient, användare och effektivitet för avsett ändamål. Här är miljödelen en mycket viktig del, men den är en del i en hel process. Detta är nödvändigt för att säkerställa tillgång till säkra och effektiva medicintekniska produkter vilka ger patienten bästa möjliga vård, och användaren bästa möjliga arbetsmiljö.

Answer: Nordic Ecolabelling has updated the definitions of the different types of products in the criteria and made the differences between the approval procedures for medicinal products and medical devices directives clearer in the background document.

Regarding comments on the general function of ecolabelling, Nordic Ecolabelling will not give any further explanation in this document, as stated in the last paragraph of the résumé section above (first two pages of this document).

The reason for selecting this particular product group is described in section 5 of the background document. The idea of ecolabelling the whole dialysis process has not yet been considered. In several cases, however, Nordic Ecolabelling has begun preparing criteria for the products and then established criteria for the whole service, e.g. cleaning agents, soaps, tissue paper and later hotels and supermarkets/grocery stores.

The scientific motives for excluding PVC are reported in section 6.2.2 of the background document. The Nordic Ecolabelling requirements with respect to the function of alternative materials are based on the Medical Devices Direc-

tive or the Medicinal Product Directive, which also, as mentioned in the comment, includes a risk/utility analysis.

See also collective answers in the end of this section regarding:

- *how well the requirements cover the life cycle.*
- *interference with the CE label.*
- *revised directive on medical devices and phthalate labelling.*

Sunderland Royal Hospital, UK

We support, in its entirety, the proposal for Swan labelling of peritoneal dialysis (PD) and intravenous (IV) sets.

We are committed to reducing our use of PVC and of products containing Di (2-Ethylhexyl) Phthalate (DEHP) because of the health and environmental problems with those materials. Thus, we believe that the proposal sections prohibiting chlorinated plastics (R2) and endocrine disruptors (R3) will be of particular help to us.

It is often difficult for us to determine which products are free of PVC and DEHP. Thus, an ecolabel that identifies IV and PD sets as PVC-free and DEHP-free will make it easier for us to find such products.

Answer: *Your comment has been noted.*

Baxter Medical AB, Sweden

We would like to express our opposition to the proposal for a SWAN ecolabelling of Peritoneal Dialysis and IntraVenous set, motivated by the following arguments:

Concerning the aspects of safety, the SWAN ecolabelling proposal, is, in this case, not supported by scientific evidence and it aims at banning de facto a material without having either the scientific evidence of its danger for the patients, nor the certainty that alternative materials present at least a similar benefit/risk ratio.

Concerning the pure environmental issues, it is worth reminding that the products at stake are covered by the Pharmaceutical legislation which has been deemed appropriate to cover environmental safety as demonstrated by the fact that medicinal products are excluded from the provisions of the REACH. The SWAN would therefore be an unjustified additional requirement.

The rationale for the choice of the product group related with this proposal is to be questioned. The initiation of the product group as a so-called "environmental pioneer" does not seem to be justified.

The proposed SWAN ecolabelling might be considered as an additional mark which could mislead on the meaning of the CE marking which could well be affixed to the medical device part of these medicinal products and as such it should be prohibited (Cfr. Art.17.3 of the MDD).

This proposal for SWAN labelling of Peritoneal Dialysis and IntraVenous set, if enforced, might have an impact on several single use medical devices.

The background Document makes references to SCENIHR opinions. SCENIHR has already given its opinion in 2002 on the lack of scientific evidence of the alleged dangers related to the use of DEHP. A second report is going to be produced in these days for public enquiry and will integrate the latest scientific evidence on the risks related to the use of DEHP, but also will give an opinion on the suitability (in terms of benefit/risk) of the so-called alternative materials. It would be wise that the promoters of the SWAN ecolabelling have full knowledge of the text of the report before suggesting an action which could well sound as though it is not based on scientifically sound data and could severely distort the market of these products without any justification.

We refuse to apply for such label, which for the time being is based exclusively on populist considerations.

Answer: *Nordic Ecolabelling will not give any further explanation in this document in response to the comments on the general function of ecolabelling, as we stated in the last paragraph of the résumé section above (first two pages of this document).*

As for the other comments, see the collective answers at the end of this section:

- *interference with the CE label.*
- *the European Scientific Committee study on DEHP in medical devices*

Consorta, Schaumburg Corporate Center, USA

Consorta is a leading healthcare resource management and group purchasing organization based in Schaumburg, Illinois whose 12 shareholders are faith-based or non-profit health systems. Consorta's membership now encompasses more than 3,280 care sites, including 530 acute care sites and over 250 extended care facilities throughout the United States.

We support, in its entirety, the proposal for Swan labeling of peritoneal dialysis (PD) and intravenous (IV) sets available at <http://www.svanen.nu/Eng/criteria/remissdok.asp?dok=98>.

Many of our customers are committed to reducing the use of PVC and of products containing Di (2-Ethylhexyl) Phthalate (DEHP) because of the health and environmental problems with those materials. Thus, we believe that the proposal sections prohibiting chlorinated plastics (R2) and endocrine disruptors (R3) will be of particular help to us.

It is often difficult for us to determine which products are free of PVC and DEHP. Thus, an ecolabel that identifies IV and PD sets as PVC-free and DEHP-free will make it easier for us to find such products.

Healthcare organizations are increasingly aware of their operations' environmental impacts, and in growing numbers are taking steps to eliminate toxic substances, reduce waste, and reduce their environmental footprints. Consorta members realized early on in these efforts that chemicals are not adequately regulated in the U.S., so the first step was to implement our own

chemicals policy to help address the challenges presented by substances such as mercury, PVC, DEHP, and BFR.

Our chemicals policy takes a multi-faceted approach, including but not limited to: seeking disclosure from suppliers and manufacturers on the extent of chemical components of their products and whether they have been adequately tested; engaging in chemicals policy debate at the national level; and providing environmentally-centric educational programs for manufacturers. We have highly successful, ongoing programs for mercury, PVC, and DEHP reduction and elimination.

Our members are concerned about these issues. They are concerned not only with patient safety issues, but with staff safety as well. We applaud your efforts and support the intent of ecolabeling.

Answer: *Your comment has been noted.*

Gentofte Hospital, Denmark

We support, in its entirety, the proposal for Swan labelling of peritoneal dialysis (PD) and intravenous (IV) sets.

We are committed to reducing our use of PVC and of products containing Di (2-Ethylhexyl) Phthalate (DEHP) because of the health and environmental problems with those materials. Thus, we believe that the proposal sections prohibiting chlorinated plastics (R2) and endocrine disruptors (R3) will be of particular help to us.

It is often difficult for us to determine which products are free of PVC and DEHP. Thus, an ecolabel that identifies IV and PD sets as PVC-free and DEHP-free will make it easier for us to find such products.

Answer: *Your comment has been noted.*

PVC Forum, Norge

Konklusjon: PVC Forum Norge anser at Nordisk Miljømerking i dette arbeidet med utkast til kriterier ikke har behandlet PVC på en objektiv måte. Av denne grunn strider arbeidet med kriteriene mot et grunnleggende prinsipp som man skal ha for denne type arbeid. Vi mener derfor at kriteriene som presenteres bør avslås i sin nåværende utforming.

BEGRUNNELSE

Den faglige basis for høringsutkastet bygger i stor grad på en dansk bok som ble publisert i 1999 av Lars Borch Pedersen med tittelen "Plast og miljø". Boken inneholder etter vårt syn foreldet informasjon om PVC og kan derfor ikke brukes som referanse i denne sammenheng. Vi viser til at mye har skjedd i PVC-bransjen de siste årene, både når det gjelder økt kunnskap og miljøarbeid. Vi vil underbygge vårt syn med eksempler nedenfor.

Det er fire forhold rundt PVC som tradisjonelt har vært i fokus: Forbrenning, tungmetaller, arbeidsmiljø og ftalater. Disse fire temaene har også en sentral posisjon i Pedersens bok når han omtaler PVC.

Forbrenning

I boken sies det at forbrenning av PVC medfører forsurening av miljøet. Dette er feil. Implementeringen av forbrenningsdirektivet i EU sikrer at klorholdig avfall ikke fører til forsurening av miljøet. Rensing av røyk sikrer at saltsyregass-utslipp ikke slipper ut i miljøet.

I forbindelse med forbrenning sies det også at tungmetaller lekker ut til miljøet. Dette er også feil – tungmetallene ender opp i det nøytraliserte restavfallet.

Det står videre i boken at forbrenning av PVC kan bety at dioksiner dannes. Dette er et foreldet syn. Det danske SFT fastslo for flere år siden at det ikke er riktig å kople dannelse av dioksiner med forbrenning av PVC.

Tungmetaller

I boken hevdes det at tungmetaller brukes i PVC – noe som fører til at PVC scorer lavt blant plastmaterialene. Til dette skal sies at i Skandinavia har ikke tungmetaller vært i bruk som stabilisator i PVC på flere år.

Arbeidsmiljø

I boken sies et at daglige doser av VCM kan medføre kreft og på denne måten indikeres at det er et problem med arbeidsmiljøet. Det er mer enn 20 år siden PVC-industrien satte i verk tiltak som sikrer at arbeidsmiljøet er helt trygt for arbeiderne når det gjelder eksponering for VCM.

Ftalater

Det hevdes i boken at ftalaten DEHP er kreftfremkallende hos mennesker. Dette er ikke lenger holdningen. WHO fjernet for flere år siden DEHP fra "kreftlisten".

ANDRE FORHOLD

PVC Forum Norge er ellers overrasket over at Svanen plutselig er kritiske til bruk av livssyklusanalyser (LCA) som metode med begrunnelse at LCA ikke tar hensyn til alle forhold. Vår oppfatning er at LCA som metode er betydelig bedre enn å bare velge ett forhold (avfallsmengden) blant mange, og ikke vekte innenfor hele produktets livssyklus.

Avslutningsvis vil vi vise til at gjenvinningen av PVC øker kraftig i Europa. Vi vil i denne sammenheng vise til www.vinyl2010.org.

Answer: *It is positive that the PVC recycling rate is increasing in Europe. Nordic Ecolabelling is strongly in favour of using LCAs. For instance, LCAs that quantify the environmental load are of particular use for support and design point systems used in several other product groups in Nordic Ecolabelling. When using results from LCAs, however, it is important to be aware of which areas are not covered by the study and what the uncertainties are. For*

instance, uncertainty is greater when dealing with aspects that are difficult to quantify, such as hazardous substances.

See also collective answer in the end of this section regarding the study on plastic materials by Lars B. Pedersen.

Astra Tech AS, Norge

Kriterier ikke behandlet objektivt nok. Boken "plast og miljø" av Lars Borch Pedersen noe foreldet.

Answer: See the collective answer at the end of this section about Pedersen's study on plastic materials.

Leverandørforeningen for Helsesektoren, Norge

Leverandørforeningen for helsesektoren forkaster forslaget. Begrunnelsen er at høringsutkastet ikke er forankret i nyeste aktuelle informasjon om PVCs kjemiske og miljømessige egenskaper og dermed baserer seg på feilaktig grunnlag.

Answer: See the collective answer at the end of this section about Pedersen's study on plastic materials.

Läkemedelsverket, Sweden

I direktiv 93/42/EEG om medisin-tekniska produkter ställs krav på CE-märkning av medisin-tekniska produkter. Andra märken får anbringas på produkterna, emballaget eller i den medföljande bruksanvisningen under förutsättning att sådana märken inte kan förväxlas med CE-märket eller att CE-märkningens synlighet eller läsbarhet inte minskas.

Tillverkare av medisin-tekniska produkter skall i den riskhantering som föregår CE-märkningen analysera och så långt möjligt eliminera de risker som patient och användare utsätts för i samband med att produkten används. Kvarstående risker skall ställas mot den visade patientnyttan innan CE-märket anbringas och produkten kan sättas ut på marknaden. LV anser att patientperspektivet är så väsentligt att det måste beaktas även vid miljömärkning av medisin-tekniska produkter. En miljömärkning får inte utformas så att patienten utsätts för onödiga risker i samband med behandling/användning. En försämrad patientnytta måste därför beaktas och ställas mot den totala miljöeffekt som aktuella produkter kan innebära.

Answer: See the collective answer at the end of this section about interference with the CE label.

European Council of Vinyl Manufacturers (ECVM), Belgium

The PVC resin producers (ECVM) would like to present some comments on the draft criteria in the document mentioned above. We would like to address two issues dealing with PVC:

1. The concerns about the incineration of PVC (p. 4) and
2. The proposal for a complete ban on “chlorinated plastics such as PVC” in the product and in the packaging (p. 7).

Instead of being based upon publicly available recent scientific findings, the statements outlined in this Nordic Swan document are based on outdated literature published almost a decade ago and describing the situation of 30 years ago.

p. 4 quotes :

"What are Swan-labelled PD and IV sets?

The Nordic health care sector uses PVC plasticised with phthalates, such as DEHP, in many disposable products. The incineration of PVC in waste incineration facilities generates large amounts of toxic residues. These residues need to be disposed of in controlled landfills. Many phthalates are problematic to health. DEHP reduces the size of testicles in laboratory animals and is classified as reproductive toxic and teratogenic.

For health care products such as peritoneal dialysis (PD) and intravenous (IV) sets there are safe and economically viable alternatives. EU legislation in the area is extensive and imposes strict requirements as to the safety of the products. Swan-labelled peritoneal dialysis and IV sets do not contain PVC or harmful plasticisers. The alternative plastic generates much less toxic residue upon waste incineration and does not require the same quantity of plasticisers."

Unquote.

Comments :

Annexed you will find a copy of the study “The Influence of PVC on the Quantity and Hazardousness of Flue Gas Residues from Incineration”, issued in April 2000 by Bertin Technologies on behalf of DG Environment of the European Commission. The study concludes that there is no need to single out PVC as a material of particular concern in incineration plants.

Regardless of the presence of PVC, incinerators have to be built in the same way, including flue gas cleaning installations and have to comply with the EU incineration directives securing that e.g. chlorine containing waste does not mean an acidification of the environment. Smoke purification is securing that no HCL emissions are leaking off onto the environment.

P. 7 quotes :

“2 Environmental and health requirements

Plastic material

*R2 Chlorinated plastics in the product and packaging
Chlorinated plastics such as PVC are not allowed in the product or in the packaging.”*

Unquote.

Comments :

Once more the Nordic Swan takes a strong anti-PVC position and would like to exclude chlorinated plastics (especially PVC) in peritoneal dialysis and intravenous sets from the ecolabelling scheme. We have serious concerns regarding these positions. The statements are ideological judgements on plastics in general and on PVC in particular, without any scientific foundation, which is unacceptable to us.

We would like to remind you that several studies by reputable independent institutes have demonstrated that PVC is a material like any other with both strong and weak points, and that there is no reason to treat PVC differently from any other material.

The "Life Cycle Assessment of PVC and of principal competing materials" issued by PE Europe on behalf of the EU Commission in June 2004 also concludes there are no grounds for discrimination. Annexed you will find the "Extended summary".

PVC (vinyl) is a critical component in hundreds of medical devices. For over 40 years, these products have been on the front lines of medicine – providing indispensable medical care and saving lives. See also the appendix on "PVC products in health care".

The main performance characteristics of PVC are:

- Clarity and transparency, allowing easy monitoring of fluids
- Flexibility (resistance to kink) and durability
- Excellent blood-preservation and compatibility with virtually all pharmaceutical products
- Sterilisability; resistance to chemical stress cracking
- Low cost and world-wide availability

No other material can match vinyl's track record of performance and safe use. Substitute materials for vinyl remain unproven in many cases, are not as cost-effective and are not easily accessible.

Selection of PVC-free medical devices is not a solution.

WHO rightfully stresses the necessity of “Balancing risks to make sound policy decisions in Health Care Waste Management”. The suggestion that PVC should be eliminated would lead to material use decisions that would risk the quality of patient care, increase costs and take the decision-making out of the hands of healthcare professionals.

We have been informed by hospital purchasers that hospitals, which have purchased PVC-free products, now again, use PVC-based products because of bad quality of the alternatives.

We offer our expertise to discuss any question that may arise from our position and we remain at your disposal for any clarification.

Answer: *Thanks for the year-2000 report on PVC and incineration (Bertin Technologies). Nordic Ecolabelling will add that to the background document. The data reported in section 7.2.3. of the background document regarding problematic residues from incineration of PVC needing to be landfilled is confirmed by the Bertin Technologies report. In Denmark and the other Nordic countries, the authorities are focusing on avoiding landfill waste.*

The LCA study of PVC and competing material is already part of the references for the background document and is also commented there.

Nordic Ecolabelling has the highest respect for the long history of PVC as a critical component in hundreds of medical devices that provide indispensable medical care and saving lives. Nordic Ecolabelling is convinced the industry will be able to maintain the high standards in medical care also with new materials with fewer problems than PVC.

Even if Nordic Ecolabelling awards the Swan label to just two kinds of products among hundreds, there will still be medical devices or medicinal products where it may not be possible to replace the PVC due to the performance characteristics needed, as mentioned above. When Nordic Ecolabelling becomes aware of safe and economically reasonable alternatives for other kinds of products than PD and IV infusion disposables, we will be able to ecolabel these alternatives as well.

Dansk Industri, Denmark

Jeg vil støtte op om PVC informationsrådets argumenter om, at der skal udarbejdes et tidssvarende dokument. Det gælder for så vidt alle dokumenter der udarbejdes, det må være en forudsætning, at det er den seneste opdaterede viden miljømærkekriterierne skal bygge på. Og hvis man som i dette tilfælde er bekendt med, at der findes ny viden, bør den selvfølgelig inddrages.

Answer: *See the collective answer below regarding the study on plastic materials by Lars B. Pedersen.*

Collective answer regarding interference with the CE label: *The Medical Devices Directive contains rules on relationships between the CE label and other labels. The rules say that other labels can be put on as long as they don't mislead with respect to the meaning or presentation of the CE label. To judge whether other labels are misleading, one must consider whether the other label has another meaning than the CE label, whether it could create confusion with respect to the meaning of the CE label and whether it could reduce the visibility and readability of the CE label.*

The role of the Nordic Swan is to focus special attention on the precautionary principle and be more proactive than the official regulations. The Nordic Swan is focused on environmental issues during the entire life cycle, which is not the case with the CE label. The function of the Swan label is therefore different from that of the CE label. The Nordic Ecolabel is a well known label in the Nordic countries. The fact that it is an environmental label from the Nordic countries ensures also that people in other countries will understand the meaning of the label because of the reputation for high environmental standards the Nordic countries enjoy.

Nordic Ecolabelling has added a requirement to make it clear that the Swan label must not reduce the visibility and readability of the CE label (for instance on small packagings).

Collective answer regarding revised directive on medical devices and phthalate labelling

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 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 disruptors are totally banned. And not only phthalates are banned but all additives that have the mentioned properties.

However, the 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 re-

quirements 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.

Collective answer regarding the study by Lars B. Pedersen

As stated in section 6.2.2 in the background document, PVC is excluded from the products in question due to problems in the waste handling and because of health related problems. These two areas are described thoroughly in the background document. Therefore the findings of the Pedersen study are far from the only reasons for excluding PVC in these products. Nordic Ecolabelling also uses other and more recent references than Pedersen, among others the industry's own Vinyl2010.org homepage.

The Pedersen study gives a practical picture of different plastics and the potential problems. Nordic Ecolabelling does not necessarily stand behind all data or rankings, but the study provides a good overview.

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

Incineration and dioxins. Nordic Ecolabelling reports in section 7.2.3 of the background document how the content of chlorine ends up in the residue that has to be landfilled. In the same section, it is reported that the amount of PVC present has a very indirect influence on dioxin formation.

Phthalates. Nordic Ecolabelling reports the updated legislative status in sections 7.2.1 and 7.3.2 of the background document as well as results from the latest risk assessments.

To avoid misunderstandings, Nordic Ecolabelling has made it clearer in the background document that also other and more recent references are used.

Collective answer regarding how well the requirements cover the life cycle

Even if several responses argue that the life cycle of these products is not covered by the requirements, many of the issues in the life cycle are covered because one requirement often deals with several issues at the same time. For instance, R4 covers health, environmental and occupational health aspects.

The issues that one would expect to be covered in the life cycle of plastics have to a great extent been covered in the literature Nordic Ecolabelling has consulted and reported in the background document.

The task for ecolabelling is to select the most relevant requirements and reject areas that are less important in order to make ecolabelling both attractive to companies and credible to consumers. The method used (the RPC concept) is described in the background document in the introduction section.

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. In 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.

Collective answer regarding the European Scientific Committee study on DEHP in medical devices

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

They therefore recommend avoiding the use of DEHP-containing medical devices and the preferential use of safer alternatives, especially for vulnerable groups such as 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 encourage manufacturers to develop new and safer DEHP-free alternatives.

Collective answer regarding combustion plant technology

It is positive that combustion plant technology has improved over the years. See, as an example, section 7.3.4 of the background document for some figures on improvements made in dioxin emissions in Norway.

Even if combustion technology is improved to the extent where new raw materials could be extracted from gas purification units, it is a long way to installing the best technology in all places where waste is incinerated.

Comments regarding the requirements in the criteria document

What are Swan-labelled disposable PD and IV products?

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige

Flera ftalater, bland annat DEHP, har visat sig ha allergena effekter. Även om dessa resultat inte har lett till någon officiell klassificering ännu kan det vara relevant att nämna redan här.

Första meningen i andra stycket är ofullständig – bör avslutas med t.ex. ... ”to PVC and phthalates”.

Om mängduppgiften för peritoneldialys gäller de nordiska länderna är mängden sannolikt överskattad. I jämförelse med de mängder som förbrukas på Karolinska per år uppskattar vi mängden ftalater till cirka 50 ton per år i Norden. Mängden PVC i dessa produkter är cirka 100 ton och total volym runt 150 ton.

***Answer:** Nordic Ecolabelling has updated the text with the information above.*

Why choose the Swan label?

Product delimitation - What can carry the Swan label?

Kuopio University Hospital, internal medicin, Finland

We suggest that it is handled in the criteria that a packaging materials and disposable products can be combusted in scattered settlement regions.

According to the dialysis and iv-products we hope that an use of single packaged instruments are reduced. It should be better to use the sets including instruments needed in operations.

***Answer:** Even if the Swan label on a medical device or medicinal product can help to improve waste handling, local and national legislation must be followed when it comes to the incineration of waste containing Swan-labelled products. This is covered in the criteria document by requirement M1.*

To help hospitals even more in their waste handling, Nordic Ecolabelling has introduced a new compulsory text in connection with the Swan logo, i.e. “Does not contain PVC”.

It could be a good idea to reduce the amount of packaging by limiting the use of singly packaged medical devices, but Nordic Ecolabelling has as yet too little information about environmental gains in the relation to the utility of the package.

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige

Innehållet i dokumentet öppnar för en större produktgruppsdefinition än bara PD och IV-set.

Det är oklart om påsar och flaskor med infusionslösningar eller nutritionslösningar ingår i produktgruppen. Det bör specificeras så att definitionen blir tydlig.

Detta material används vid PD behandling vid byte av påse. Ny påse med slang och tompåse, handdesinfektion, påsklämmor, nytt aggregatskydd.

Patienten har en kateter inopererad i bukhålan som det också står i definitionen.

Kapitlet om PD på sidan 13 är kortfattat men rätt. Vid start av hemodialys används dialys nålar, spruta 10 ml, kompresser, micropore tape, steri-strips tape, sprit för hudtvätt, handdesinfektion, handskar. Material som används till dialysapparaten är slangset, dialysator.

***Answer:** Nordic Ecolabelling has updated the definitions of the different product categories.*

How to apply

Application

Icons in the text

On-site inspection

Costs

General requirements (R1)

Chlorinated plastics in the product and packaging (R2)

Health Care Without Harm (HCWH), Czech Republic

7. CONSIDER EXCLUSION OF ALL HALOGENATED PLASTICS and HALOGENATED ORGANIC ADDITIVES

Swan Labelling Proposal: Environmental and health requirements R2-R4 Criteria

We support the exclusion of chlorinated plastics from products conforming to this standard, and we would like to suggest that Nordic Swan consider excluding products containing all

halogenated plastics or halogenated organic additives, such as those containing polytetrafluorethylene (PTFE) or brominated flame retardants.

Nordic Swan's background document on this draft standard indicates in Appendix 2 that PTFE is in Category 3, meaning it "contain[s] particularly health or environmentally hazardous substances, which are crucial for the manufacturing or for the proper-ties in use of the polymer;" and that "halogenated additives" are in Category 4, meaning they are "regarded as particularly hazardous to health and environment."

The reason these materials and additives are so problematic is that they contain halogens that can contribute to the production of halogenated dioxins if incinerated during disposal, and because the production of halogenated organic plastics and additives generally result in the release of halogenated organic byproducts that tend to be toxic, persistent, and bioaccumulative.

While halogenated plastics and additives are not now being used to substitute for PVC in these types of medical products, medical device manufacturers are constantly trying to innovate new and better-performing materials. Thus, prohibiting these halogenated organic substances now will ensure that if new, halogenated plastics or halogenated additives are later used in these products, Nordic Swan will not need to revise the standard in order to address the health and environmental concerns of these new developments.

In addition, because these materials are not now being used in PVC-free IV sets and PD sets, it should not constitute a hardship for manufacturers to qualify for the Nordic Swan label with these additional requirements.

In conclusion, the ecolabelled materials shall not contribute to the creation, use and release of harmful substances that may have serious adverse health effects on children and foetus.

Answer: *Nordic Ecolabelling has extended the requirement so that all halogenated plastics are excluded. The halogenated organic additives are mostly already covered by the R4 requirement, as they often are labelled with the R-phrases mentioned. See also answer under the R4 requirement.*

Endocrine disruption (R3)

Coloplast A/S, Denmark

R3 Endocrine disruption Additives: Is there a lower limit for the criterion? If not, we suggest a triviality limit of 0,1%. This would be similar to legislation.

Answer: *Additives are defined as something added intentionally to the plastic. Therefore there is no need for a triviality limit.*

Hazardous to health and the environment (R4)

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige

Det är tveksamt om R40 ensamt bör ingå i kravet. Klassificeringen bygger på icke fullständigt verifierade uppgifter om cancerogena effekter.

Innehållet i kravet för övrigt är bra, men kan tyvärr inte utnyttjas fullt ut för offentliga upphandlare.

Offentliga verksamheter är skyldiga att följa LOU och kan därför inte kräva svanmärkta produkter, utan bara att kraven uppfylls. Det hör till undantagen

att offentliga upphandlare har tid och kompetens att kontrollera den typen av krav som föreslås. Vi har full förståelse för att miljömärkningsorganisationerna kan granska och verifiera uppgifter som styrker om kravet är uppfyllt. Av pedagogiska skäl skulle vi ändå önska att kravet formulerades på annat vis eller kompletterades med vissa ämnen som faller för kriterierna.

Answer: R40 is in the Category 3 CMR R-phrases. Nordic Ecolabelling wants to set high standards and excludes not only CMR Category-1 and -2 substances, but also Category-3 CMR substances. In order to make that clearer, Nordic Ecolabelling has indicated in the requirement which R-phrases belong to which category.

Nordic Ecolabelling has added links to searchable databases on classified substances in order to make the requirement easier to use also for public buyers. Nordic Ecolabelling also added examples of substances not complying with the requirement.

Health Care Without Harm (HCWH), Czech Republic

6. EXCLUSION OF PBT AND vPvB SUBSTANCES/MATERIALS

Swan Labelling Proposal: Environmental and health requirements R2-R4 Criteria

The EU legislation is getting stricter on eliminating the chemicals that are toxic. The recently adopted Chemicals legislation REACH 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), vPvB (Very Persistent and Very Bioaccumulative) substances. This is the minimum requirement set up by the EU legislation for individual chemicals. Unfortunately, medical devices will not be subject to this chemicals regulation. Nordic Swan would manifest the expansion of Chemicals regulation into the exempted product groups.

Additionally, the US GBC similarly recommends concentrating on the PBT (Persistent, Bioaccumulative and Toxic) characteristics of the materials. The report *specifically suggests comprehensive approaches to issues such as bioaccumulative pollutants* screening out materials based on a suite of persistent bioaccumulative toxicants, like dioxin, halogenated flame retardants, heavy metals and perfluorocarbons.

The Nordic Swan proposes exclusion of chlorinated plastics from the criteria for the label. HCWH suggests to expand this exclusion to materials emitting the PBT and vPvB substances to be included in the R2 to R4 specifications of the Ecolabeling Draft Document so that standards are raised higher which is already the case for allergenic and environmentally hazardous substances and endocrine disruptors.

Answer: Nordic Ecolabelling has expanded the requirement to exclude also PBT and vPvB substances. Examples of PBT and vPvB are most of the brominated flame retardants.

Labelling of plastic parts and packaging (R5)

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige

Är kravet rimligt? Vi har fått signaler om att små slangar och kopplingar inte kan märkas med tillräckligt tydliga symboler. Märkning av vissa detaljer kan störa funktionen. Det är också tveksamt om det är meningsfullt med en sådan

märkning eftersom det idag saknas system för källsortering av använda produkter. Däremot är det rimligt att allt förpackningsmaterial märks enligt standarden.

Answer: *Nordic Ecolabelling has replaced the requirement with a required text in connection with the Swan label saying "Does not contain PVC".*

To ensure sterility, there may be a transparent outer packaging for the PD or IV bag. There must not be any text on the outer bag that limits readability of the text printed on the PD or IV bag.

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 or do not feature 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.

Labelling requirements can be discussed again for future versions of the criteria.

Coloplast A/S, Denmark

R5 Labelling of plastic parts It is mentioned as a target in the background document, that the criteria document should not contain too many criteria, in order to keep it simple. It can be considered to leave out the criterion on labelling of plastic parts with that argument. Normally plastic parts are marked in order to improve re-use or recycling of the plastic. It may be discussed whether the products are fit for re-use or recycling since they have been in contact with biological liquids. Labelling of plastic packaging would still be relevant.

Answer: *Nordic Ecolabelling has replaced the requirement with a required text on the Swan label saying "Does not contain PVC". See also the answer to Karolinska's response above.*

Fresenius Medical Care, Sweden

The medical or medicinal products often have components of different plastic materials. A labelling of every component is not feasible. But information about component plastics is available from the manufacturer of the products and can support the waste handling, if sorting is required.

Answer: *Nordic Ecolabelling has replaced the requirement with a required text on the Swan label saying "Does not contain PVC". See also the answer to Karolinska above.*

Helsinki and Uusimaa Hospital Group, Finland

It is very problematic that the plastics have not been labelled. Because the plastics have not been labelled it is sent the used products of plastics to landfills. If plastics will be marked as plastics not PVC can these be sent to combustion as energy waste.

In some cases producers give information on e.g. if products can be combusted or not but hospitals do not have resources to ask and control the information nor trust all information which have been achieved from far countries.

The products which are dangerous to infective are sent to destruction as dangerous waste (Ekokem in Finland). A dangerousness to infective is determined on the care places according to the dangerousness of patients. Only the small amount of dialysis and intravenous accessories are determined with use as dangerous waste to infective.

Summarized says HUS that it is very important to have the plastic markings in these products.

***Answer:** Nordic Ecolabelling has replaced the requirement with a required text on the Swan label saying "Does not contain PVC". See also the answer to Karolinska's response above.*

Recycling system (R6)

SCENIHR Recommendations (R7)

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige

Kravet kan inte anses vara entydigt då SCENIHR består av en eller flera arbetsgrupper vars resultat förändras över tiden då kriterierna kan förväntas vara giltiga.

***Answer:** The requirement has been deleted. The SCENIHR committee does not working in the same way as the committee for cosmetics issuing a recommendation that was originally the inspiration for the SCENIHR requirement. If the SCENIHR concludes things that are against the criteria, Nordic Ecolabelling will be able to include the new findings in a revised criteria document.*

Fresenius Medical Care, Sweden

This is a too general requirement because on SCENIHR website a lot of opinions and documents are published. It should be clarified between Nordic Ecolabelling and applicant, which recommendations – if any - are valid at the time of application for the products affected.

Answer: *The requirement has been deleted. The SCENIHR committee does not work in the same way as the committee for cosmetics issuing recommendation that was originally the inspiration for R7. If the SCENIHR draws conclusions that run against the criteria, Nordic Ecolabelling will be able to include the new findings in a revised criteria document.*

Safety (R8)

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige
Hänvisa tydligare till säkerhetsaspekter i medicintekniska direktivet. Det är viktigt för att kriterierna skall få önskvärd trovärdighet inom vårdsektorn.

Answer: *Nordic Ecolabelling has specified the relevant legislation in question.*

Coloplast A/S, Denmark

R8 Safety and Future criteria It is important that the products have a good function. This is seen to with criterion R8 Safety. If it is considered to include other products in the product group in future criteria it is very important to discuss function when each of the environmental criteria is set. It must be considered if a proper function can be achieved at the same time as the environmental criteria are met. For example chlorinated plastic may have some functions that can't be achieved by other plastic types. Then a criterion on the amount or share of chlorinated plastic in the product could be considered instead, for products where alternatives have not been found yet.

Answer: *Nordic Ecolabel is aware that it may be necessary to continue using PVC in some types of products. That is part of the reason why only PD and IV infusion disposables have been selected so far. As stated in section 6.1 of the background document, Nordic Ecolabelling can always consider including other products in future criteria, if there is an interest.*

Design of the Swanlabel

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige
Samma kommentar som under "What can carry the swan label". Det är oklart om påsar och flaskor med infusionslösningar eller nutritionslösningar ingår i produktgruppen.

Det bör specificeras så att det blir tydligt när texten om innehåll skall användas.

Texten under svanmärket måste kontrolleras med branchkunnig person. Lägg till produkter för nutrition om dessa skall ingå i produktgruppen.

Answer: *Nordic Ecolabelling has updated the requirement. In the new version of the criteria, products for total parenteral nutrition are not included. See also answer to Fresenius Medical Care below.*

Fresenius Medical Care, Sweden

"English: The Swan requirements do not cover the content": In case of PD solutions: "... do not cover the PD-fluid in the bags".

Additional text for PD is not needed because the term "Peritoneal Dialysis Accessories" is part of the labelling with PD-medical products of Fresenius Medical Care.

Answer: *Nordic Ecolabelling has updated the requirement, making it possible to use text already on the product if it provides the necessary information.*

Future criteria

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige

- Restmängder av produktionskemikalier kan vara av intresse att reglera.
- Antibakteriella tillsatser bör inte tillåtas om det finns någon risk att de kan trilla utanför kravet R4.
- Fler krav på förpackningsmaterial och konstruktion kan vara önskvärt.

Answer: *Process contaminants and residues are already mentioned as possible future criteria. It has been added to the background document that anti-bacterial additives should be considered when expanding the product group. Also including packaging requirements has been added as possibility for the future.*

Terms and definitions

Karolinska Universitetsjukhuset, Upphandlingssektionen, Sverige

Kapitlet om PD på sidan 13 är kortfattat men rätt. Vid start av hemodialys används dialys nålar, spruta 10 ml, kompresser, micropore tape, steri-strips tape, sprit för hudtvätt, handdesinfektion, handskar. Material som används till dialysapparaten är slangset, dialysator.

Hela listan behöver granskas och korrigeras. Under IV har en sammanblandning av olika produkttyper gjorts. Parenteral nutrition har ingenting med intravenös behandling att göra. Låt en fackman reda ut begreppen.

Answer: *Nordic Ecolabelling has updated some terms and checked that the terms are correct.*

Appendix 1 Applicant's declaration

Fresenius Medical Care, Sweden

Add: "Directives that the product has to comply to:

- (e.g. 93/42/EEC or 2001/83/EC etc.)"

Answer: Nordic Ecolabelling has added that the relevant legislation must be indicated.

Appendix 2 Manufacturer's declaration

Fresenius Medical Care, Sweden

Add: "For detailed description of product and packaging please refer to the registration dossier (Rev.xx) / the Technical File (Rev.xx) of the product" and delete the table in 1.

Answer: Nordic Ecolabelling must have a certain minimum of information so it can check the requirements. That the information can be found in a dossier by the producer is not enough to warrant awarding the label.

Appendix 3 Declaration from producer of plastic materials

Appendix 4 Requirements for plasticisers and other additives in the plastic material and for adhesives

Appendix 5 Procedures and instructions (M1-M5)

Appendix 6 Marketing of peritoneal dialysis and intravenous sets (M6)

Comments to background document

Arbetsmiljöverket, Sverige

Några specifika punkter:

- Även ur arbetsmiljösynpunkt är det positivt att inga särskilt farliga ämnen, såsom CMR-ämnen, är tillåtna i produkterna.

- Syftet att minska användningen av mjukgörare, framför allt ftalater, samt minska mängden ogynnsamt avfall är positivt men det är viktigt att beakta att ersättningsmaterialet inte medför negativa konsekvenser. Detta borde framgå tydligare.
- En möjlig ersättare till PVC-plasten som nämns i dokumentet är PUR-plast. Framställningen av denna typ av plast skulle kunna innebära risk för allvarlig ohälsa hos arbetstagarna. Exponering för diisocyanater kan leda till allvarlig luftvägsallergi och Arbetsmiljöverket har utfärdat flera regler för denna verksamhet, såsom högsta tillåtna lufthalter av diisocyanater samt krav på medicinska kontroller av berörd personal. Ur arbetsmiljösynpunkt är därför texten missvisande i sista stycket på sid 8 i dokumentet (About Swan labelling of Peritoneal Dialysis (PD) and Intravenous (IV) sets. Draft for review 14 March 2007. Background to ecolabelling). Den kanske stämmer när det gäller sjukvårdspersonal som använder plastprodukterna men inte för de som tillverkar PUR-plasten, såvida det inte rör sig om helt slutna processer.

Answer: *Nordic Ecolabelling has made it more clear that materials other than PVC will generate less residue upon incineration. The information on PUR in the background document has also been updated.*

Health Care Without Harm, Czech Republic

2. SCIENCE ON PHTHALATES TOXICITY KEEPS PILING UP

Background to Ecolabelling: Section 6.2.6 SCENIHR Opinions, pg 10(6)

There are an increasing number of studies illuminating DEHP exposures and toxicity. Most recently, the *US National Toxicology Program's Center for Evaluation of Risks to Human Reproduction (NTP CERHR)* summarized in 200-page report the latest science since 2000 and commented on its validity for evaluating DEHP risks to human reproduction. It can be downloaded from <http://cerhr.niehs.nih.gov/chemicals/dehp/dehp.html> under "Expert Panel Update Report". Similar evaluation is now expected from the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) whose task is to evaluate the DEHP toxicity in medical devices and assess the alternatives materials suitability for medical devices. The evaluation was due February 2007 but is postponed till May 2007.
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_007.pdf

3. THE NATIONAL AND EU LEGISLATION IS MOVING TOWARD MORE RESTRICTION OF DEHP-CONTAINING DEVICES

Background to Ecolabelling: Section 3 Other environmental schemes and legislation, pg 2(6)

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

Résumé of review criteria for disposable peritoneal dialysis (PD) and intravenous (IV) infusion treatment products
Treated by Nordic Ecolabelling Board 13 December 2007

The EU's own Risk Assessment and Risk Reduction Strategy on DEHP; two expert panels of the US National Toxicology Program (NTP); the US Food & Drug Administration (FDA); and the Health Canada Expert Panel have all reached the same conclusions: the animal studies of DEHP raise serious concerns because they are likely to predict human health impacts. They therefore recommend avoiding using 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 hemodialysis. The South Korean FDA requires manufacturers to label all medical devices containing PVC and DEHP with a warning about the toxicity of DEHP.

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 alternatives².

²http://www.bfarm.de/clin_042/nn_424524/DE/Medizinprodukte/riskinfo/recommend/dehp_Weichmacher_Medizinprod.html

2

Only on 29 March 2007, the EU Parliament made another step toward restricting toxic plasticisers in medical devices and adopted revised Medical Devices Directive that will require labeling medical devices containing substances that are carcinogenic, mutagenic and toxic to reproduction (CMR). Additionally, it will require certain justification from manufacturers for medical devices intended for vulnerable groups (children, pregnant and nursing mothers) on why they choose DEHP over alternative chemicals and materials³.

While these developments make the choice of phthalate-free Medical devices easier, the Nordic Swan label will provide more value by assessing other aspects of environmental performance and judging the material from the life-cycle perspective.

³ Position of the European Parliament adopted at first reading on 29 March 2007 with a view to the adoption of Directive 2007/.../EC of the European Parliament and of the Council on amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives:

“The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.

Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Directive 67/548/EEC.

If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain Phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalate.

If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements of this Section, in particular of this paragraph, within the technical documentation and within the instructions for use information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.”

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0091+0+DOC+XML+V0//EN&language=EN#BKMD-5>

4. EXPAND THE VULNERABLE GROUPS TO UNBORN FOETUS, PREGNANT AND NURSING WOMEN AND GENERALLY WOMEN OF REPRODUCTIVE AGE.

Background to ecolabelling: Section 5 Choice of product group, pg 6(6)

HCWH would recommend including pregnant women and nursing mothers and in general women of reproductive age among the vulnerable groups since the developing fetus and infant are most susceptible to the toxicity of DEHP, and many women are unaware of their pregnancy for weeks after conception.

5. LIFE-CYCLE PERSPECTIVE

Swan Labelling Proposal: Environmental and health requirements

R2 Chlorinated plastics such as PVC are not allowed in the product or in the packaging.

We are happy to see that the Nordic Swan Label will set the bar for environmentally sound products higher than what the legislation requires as minimum safety level. We therefore welcome your approach of assessing the material in the entire life-cycle. The EU Commission Life Cycle Assessment of PVC actually does not take the wider approach of assessing the effects on occupational safety and post-disposal fate of materials into account.

In this context, most recently the US Green Building Council (US GBC) Life Cycle Assessment of PVC in building materials *recognized the full scope of life cycle concerns with PVC*. The authors stated that a proper accounting of the human health impacts of PVC across its life cycle, including disposal issues and occupational exposure, found that PVC leads to the release of dangerous quantities of dioxin and other carcinogens. The report authors found that, "When we add end of life with accidental landfill fires and backyard burning, the additional risk of dioxin emissions **puts PVC consistently among the worst materials for human health impacts...**"⁴ (emphasis added). There are other numerous studies demonstrating that dioxins, furans and other carcinogens and toxic substances are formed during PVC incineration⁵. It is therefore vital for the ecolabelling to stress out the issue of dioxin emissions in air but also in solid waste residues because majority of medical waste (with PVC content) is currently incinerated.

The key argument used in the Nordic Swan (on page 8 of the Background to ecolabelling) is to reduce the risk of health-related problems which is consistent with the evaluation of material used by the US GBC.

⁴ LEED Technical and Scientific Advisory Committee – PVC Task Group. February 2007. "Assessment of the Technical Basis for a PVC Related Materials Credit for LEED". US Green Building Council. Pg 10. Available at: <http://www.usgbc.org/DisplayPage.aspx?CMSPageID=1633>

Answer: *Nordic Ecolabelling has updated the background based on the information presented.*

Coloplast A/S, Denmark

Comments to background criteria Abbreviations: Does SFS really mean law of Sweden?

6.2.2 Chlorinated plastic It seems that the literature references on amounts of residues from combustion of chlorinated plastic are building on measurements that were conducted some years ago. These may still be relevant, if the type of equipment used for flue gas cleaning and residue handling at the combustion plants are still the same as when the measurements were conducted. The organisation DAKOFA might have knowledge about that.

7.2.4 Air One would not expect air emissions of CO₂, NO_x, SO₂ and VOC to be higher from the burning of PVC than from burning of other plastics.

7.3.1 Isocyanates are described as being allergenic. Some are also considered carcinogenic according to Arbejdstilsynets kræftliste.

Answer: *Yes. SFS is the abbreviation for Svensk Författningssamling. The references regarding the amount of residues from incineration have been updated. Re the "Air" section (7.2.4), it is stated at the beginning of section 7.2*

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that the information stated is of a general nature and not only about PVC. The section on plastic (7.3.1) has been corrected.

Appendix 1 Comment from the Swedish Plastic & Chemicals Federation

This additional comment from the Swedish Plastic & Chemicals Federation (Plast & Kemiföretagen) is not included in the resumé but is here presented in its original format. The answers in the resumé cover for the most part also this comment.

Plast- & Kemiföretagen har fått ovanstående kriterieförslag på remiss. Vi anser att nuvarande kriterieförslag skall förkastas eftersom Nordisk Miljömärkning inte har behandlat PVC på ett objektivet sätt och därför har inte kriterierna tagits fram enligt de grundläggande principerna för Nordisk Miljömärkning.

Sammanfattningsvis vänder vi oss emot att:

- PVC inte behandlas på ett objektivet sätt
- att bedömningen av PVC endast beaktar en miljöaspekt – avfallsfasen
- informationen om PVC inte är uppdaterad
- att en mindre del i en komplex utrustning miljömärks

PVC behandlas inte på ett objektivet sätt

Enligt bakgrundsdocumentet togs dessa kriterier fram efter förfrågan från en tillverkare som har dessa produkter i alternativa material och som ansåg att ett Svanenmärke skulle underlätta försäljningen. Mot bakgrund av detta är det kanske inte konstigt att underlaget till kriteriedokumentet inte behandlar PVC på ett objektivet sätt utan bara lyfter fram personer och organisationer som är negativa. Däremot strider detta tillvägagångssätt mot de grundläggande principerna för Nordisk Miljömärkning.

Ett sätt att öka objektiviteten vid miljöbedömningar är att använda standardiserade livscykelanalyser. Vi anser därför att det är högst anmärkningsvärt att Nordisk Miljömärkning helt avfärdar den omfattande LCA-rapport som EU-kommissionen presenterade 2004 på PVC och de huvudsakliga alternativen. Denna rapport har samlat alla tillgängliga LCA på PVC och sedan sorterat bort de LCA som inte utgått från standarden.

Nordisk Miljömärkning påstår att kommissionens LCA-rapport har blivit hårt kritiserad och ger som exempel på detta endast en referens. Vi delar inte uppfattning att LCA-rapporten har blivit hårt kritiserad, snarare tvärt om anses den som en bra sammanfattning av tillgängliga LCA med en balanserad sammanfattning.

Det står att Rossi anser att begränsningarna ligger i att ”många LCA bara utgår ifrån mätbara data så som energi och användningen av råmaterial. För farliga kemikalier är det mer komplicerat att uttrycka olika riskscenarier och ta hänsyn till

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försiktighetsprincipen.” Detta är dock inget unikt för de LCA som kommissionens rapport innehåller utan något som är väl känt att en LCA kan behöva kombineras med riskbedömningar. I fallet PVC kan därför de riskbedömningar som gjorts på additiven komplettera LCA-rapporten. Standardiserade LCA anses ändå som den bästa objektiva metod som vi har, även om metoden inte är fulländad. Det måste ändå vara ganska självklart att LCA som metod är betydligt bättre än att som Nordisk Miljömärkning bara välja en aspekt bland många samt att inte väga in produktens hela livscykel.

Vi vill även påpeka att Mark Rossi arbetar för Healthy Building Network som uttalat arbetar mot PVC och därför är han inte en neutral person i denna fråga, se (<http://www.healthybuilding.net/pvc/resources.html>)

I kommentarerna till kommissionens LCA-rapport påstås att de flesta frågor som togs upp i grönboken fortfarande är obesvarade. Detta visar på att Nordisk Miljömärkning saknar kunskap om det miljöåtagande som den europeiska PVC-branschen har gjort som svar på frågorna i Grönboken, se www.vinyl2010.org. Om Nordisk Miljömärkning hade varit mer objektiv i sitt angreppssätt borde man ha inhämtat information från fler håll och förbättrat omvärldsanalysen i frågan. Vidare verkar det vara dålig intern kommunikation inom organisationen eftersom PVC Forum tillsammans med sina nordiska systerorganisationer har haft möten med representanter för Nordisk Miljömärkning ett antal gånger och informerat om branschens miljöarbete.

Till skillnad från kommissionens LCA-rapport anser Nordisk Miljömärkning att den miljöbedömning som Lars Pedersen gör i sin bok ”Plast & miljö” är både omfattande och transparent. Detta trots att Pedersen bara på ett kvalitativt sätt har bedömt plasterna utifrån energikonsumtion, avfallshantering och farliga ämnen vid tillverkning. Det faller på sin orimlighet att en sådan bedömning skulle vara bättre än en LCA som beaktar så många fler parametrar. Vidare är det föga intressant att göra en kvalitativ jämförelse mellan olika material. Det är väl känt i LCA-sammanhang att man skall utgå ifrån en ”funktionell enhet”. Vidare är informationen i Pedersens bok inte uppdaterad när det gäller PVC, kommentarer från PVC Informationsrådet i Danmark bifogas.

I kapitel 6.2.2 anser Nordisk Miljömärkning att eventuella risker med både PUR och PC hanteras av lagstiftningen inom området. Varför anser man inte att detta även gäller för PVC-produkterna? Vidare har man ett resonemang om att slangar i PUR är bättre eftersom risken från exponering av isocyanater är betydligt lägre därför att mängden i slangarna är mycket små. Detta resonemang visar på brist i kunskapen om riskhantering. Risken beror på exponeringen och de inneboende egenskaperna (faran). Att bara jämföra mängderna är inte relevant. Olika mjukgörare har t.ex. olika egenskaper och migrering. Detta visar igen på att Nordisk Miljömärkning inte hanterat PVC på ett objektivt sätt.

I kapitel 6.2.3 påstås att till skillnad mot PVC så innehåller andra plaster normalt få additiv. Detta stämmer inte om man avser andra additiv än mjukgörare. Det är en missuppfattning att PVC måste innehålla så mycket mer additiv. Att mjuk PVC innehåller en mer eller mindre stor del mjukgörare stämmer, men för övriga additiv stämmer det inte.

I kapitel 6.2.2 står att det inte finns restriktioner för andra plaster när det gäller avfallsförbränning. Detta stämmer inte eftersom de flesta avfallsförbränningsanläggningar har begränsningar då det gäller hur högt energiinnehåll på avfallet som man kan förbränna. Eftersom plasterna är energirika innebär det en begränsning likväl som innehållet av vissa grundämnen som klor¹ kan göra.

I kapitel 7.3.1 påstås att miljöaspekterna med medicintekniska produkter oftast associeras med ”frågan om PVC används i produkten eller inte.” Det är ett påstående som inte har motiverats. PVC Forum har under april deltagit i två mässor inom sjukvårdsområdet och vår bild är tvärtom att landstingen har börjat få en mer balanserad syn på PVC och att man idag istället allt mer fokuserar på valet av mjukgörare.

I kapitel 7.3.3 påstås att det är svårt att återvinna PVC, speciellt ”closed-loop recycling”. Detta stämmer inte vilket PVC-branschens miljöarbete, Vinyl 2010, visar. Här ser man inga tekniska hinder att t.ex. materialåtervinna styva PVC-produkter som rör och profiler tillbaka till samma produkter. Målet att återvinna 50 % av de rör respektive profiler som är tillgängliga för återvinning har nåtts, men återvinningen av dessa produkter kommer att fortsätta att öka.

Just för denna produktgrupp anser tydligen Nordisk Miljömärkning att det är helt avgörande att ett material inte skall accepteras för att det vid förbränningen bildas försurande gaser som måste neutraliseras. För en stor del av Svanens andra produktgrupper anses detta dock inte vara ett hinder för ett material. T.ex. har Svanen över 10 kriteriedokument inom pappers- och cellulosaprodukter trots att papper står för 25 % av svavelhalten i förbränningsanläggningar för hushållsavfall och 12 % av klorhalten¹. Svanen påstår vidare att andra plaster inte har samma problem som PVC. Detta är fel eftersom det finns fler plaster som innehåller grundämnena klor (Cl), svavel (S) och kväve (N) som alla ger upphov till försurande gaser som måste neutraliseras.

I bakgrundsdokumentet nämns att Health Care Without Harm arbetar med att fasa ut PVC, ftalater och kvicksilver. Vi anser att Nordisk Miljömärkning borde ha satt sig in i varför organisationen är emot PVC och om deras argument är relevanta för nordiska förhållanden (se våra kommentarer i slutet av remissvaret).

Sammanfattningsvis finns det många exempel rakt igenom hela bakgrundsdocumentet som visar på att Nordisk Miljömärkning inte har behandlat PVC på ett objektivt sätt.

Bedömningen av PVC beaktar endast en miljöaspekt – avfallsfasen

I presentationen på Svanens webbsida står under basfakta att kraven omfattar produkternas hela livscykel, från råvara till avfall, (pkt 7). I Nordisk Miljömärknings miljöfilosofi står det även tydligt att den övergripande visionen för Nordisk Miljömärkning är en **hållbar utveckling**. En hållbar utveckling innebär att skapa ett samhälle där ekonomisk utveckling, social välfärd och sammanhållning förenas med en god miljö (Enligt Hållbarhetsrådet).

I bakgrundsdocumentet står att två områden från Miljöfilosofin är speciellt relevanta för denna produktgrupp, men det finns ingen förklaring i dokumentet till hur man har kommit fram till detta. I kapitel 6.2 påstås att kraven har valts utifrån en bedömning av vilka effekter som produkten har på hälsa- och miljö under hela livscykeln samt att det även har gjorts en bedömning så att inte miljöfördelar inom ett område skapar problem i ett annat. Vi anser att dessa två grundläggande bedömningar som är helt avgörande för kriterierna självklart borde ha ingått i bakgrundsdocumentet.

Vi håller med om att det är en miljömässig nackdel att det bildas försurande gaser som måste neutraliseras, **men det är en miljöaspekt bland många som måste vägas samman**. Detta visar de LCA som gjorts på PVC och alternativa material.

I Danmark har det dessutom utvecklats en ny process som både på ett miljömässigt och ekonomiskt sätt tar till vara på saltet från de förbränningsrester som bildas vid avfallsförbränningsanläggningar. Mer information om denna process finns under kommentarerna till avsnittet om avfall (7.2.3)

Eftersom ett av kraven i kriteriedokumentet är att det skall finnas ett återvinningssystem (R6) borde det inte heller vara en avgörande fråga vad som händer vid förbränning eftersom återvinningssystemet innebär att produkterna skall materialåtervinnas. PVC är en plast som kan materialåtervinnas och den europeiska PVC-industrin har ett miljöåtagande, Vinyl 2010, som innebär att bl.a. materialåtervinningen av PVC ökar hela tiden och att ny återvinningsteknik utvecklas, se www.vinyl2010.org.

När det gäller andra miljöaspekter som energiförbrukning har PVC fördelar eftersom det är den plast som förbrukar minst energi vid tillverkningen av plastråvaran². Vid bearbetningen behöver även PVC inte värmas lika mycket som många andra plaster. PVC har även en rad goda egenskaper som bidrar till att tillverkningen av produkterna kan förenklas.

Om man talar om hållbar utveckling är även de ekonomiska aspekterna viktiga. PVC är kostnadseffektivt och kan bidra till att fler personer kan få vård för samma kostnad. Om alternativa medicintekniska produkter hade varit lika bra och kostnadseffektiva som PVC-produkterna skulle antagligen inte den tillverkare som önskat de nu remissbehandlade kriterierna ha känt behov av ett Svanenmärke för att kunna sälja sina produkter. Vid ett seminarium på Karolinska Universitetssjukhus i Stockholm (september 2005) framgick det tydligt att de största hindren för sjukhusets avveckling av PVC var de högre kostnaderna för alternativen eller att dessa inte var lika bra.

Sammanfattningsvis har inte Nordisk Miljömärkning i bakgrundsdokumentet visat att alternativen till PVC för dialys- och IV-påsar är bättre med avseende på hållbar utveckling. Inte heller har man visat att avfallsfasen skulle vara den enda relevanta miljöaspekten när det gäller materialvalet i dessa produkter och att behovet av att neutralisera HCl vid avfallsförbränning det som utesluter PVC.

Informationen om PVC är inte uppdaterad

Informationen i bakgrundsdokumentet innehåller flera exempel på föråldrad information:

- tabellen 7.2.2. använder en gammal siffra för energiåtgången vid tillverkning av PVC. Det miljöarbete som branschen driver har sänkt siffran till att nu vara 56 MJ/kg (se eco-profiles på www.plasticseurope.org).
- Opel tas som ett exempel på att PVC är svårt att återvinna. Den lista som man hänvisar till är från 2000 och den kontakt som vi tog med Opel nu visade att denna bedömning var föråldrad och inte längre gällde. Enligt Opel var bedömningen av PVC i denna lista från 2000 ett resultat av påtryckningar från miljöorganisationer i Tyskland. Som bevis för att det inte är svårt att återvinna PVC från bilsektorn kan man se på det arbete som organisationen Autovinyl har drivit sedan 1997, www.autovinyle.com.
- den kategorisering som man hänvisar till som Lars Pedersen har gjort ingår i en bok som kom ut 1999. Den baseras på ännu äldre information. Mycket har hänt runt PVC sedan dess, både när det gäller ökad kunskap och miljöarbetet i branschen. En närmare kommentar av denna bok har gjorts av PVC Informationsrådet i Danmark och bifogas detta remissvar.

Dessutom saknas det relevant information t.ex. om PVC-branschens miljöarbete, vilket har påpekats ovan.

Att en mindre del i en komplex utrustning miljömärks

Vi anser att det är högst anmärkningsvärt att Nordisk Miljömärkning väljer att miljömärka en mindre del i en komplex utrustning och dessutom bara med hänsyn till en miljöaspekt – avfallsmängden. Detta innebär att Nordisk Miljömärkning inte alls kan veta om dessa Svanenmärkta produkter kommer att leda till att det totalt sätt blir bättre eller sämre ur miljösynpunkt för de behandlingar där dessa produkter ingår.

En intressant upplysning i bakgrundsdokumentet är att EKV-verktyget arbetar med att ta fram kriterier för dialysprodukter, men att man fokuserar på hela utrustningen och val av tillsatser. Det ser ut som om Miljöstyrningsrådet har valt att arbeta utifrån ett helhetsperspektiv, vilket även Nordisk Miljömärkning borde ha gjort enligt vår uppfattning.

Kommentar till Health Care Without Harm

I bakgrundsdokumentet hänvisas till Health Care Without Harms arbete och att de arbetar med att fasa ut PVC, ftalater och kvicksilver. På deras webbsida (<http://www.noharm.org/europe/pvcDchp/contents>) anger de varför de arbetar emot PVC:

“However, the use of PVC creates a number of serious environmental and health risks. The two key health issues with PVC are:

- Dioxin, a known human carcinogen which is formed during the manufacture and incineration of PVC products.
- DEHP, a phthalate linked in animal studies to reproductive birth defects and other illnesses, which is used to soften PVC plastic and can leach from PVC medical devices into patients.”

I Europa har vi krav på avfallsförbränningsanläggningarna och det är väl accepterat att bildningen av dioxin vid förbränning i första hand är beroende av förbränningsbetingelserna och att klorlasten är av underordnad betydelse. Nordisk Miljömärkning befäster även detta i bakgrundsdokumentet under kapitel 7.2.3 ”It appears that chlorine is not the limiting factor for dioxine emissions during incineration.”

När det gäller tillverkningen av PVC är utsläppen av dioxin mycket små. I Sverige släpper Hydro Polymers anläggning i Stenungsund ut 0,024-0,025 g till vatten och 0,0010 g till luft. Det kan jämföras med utsläppen från annan materialtillverkning i Sverige³ t.ex.:

- Järn- och stålverk samt pelletsverk 5,9-8,6 g till luft (utsläpp till vatten okänt)
- Metallverk och gjuterier 5,6-10,3 g till luft (utsläpp till vatten okänt)

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- Cementindustrin 0,2-0,3 g till luft (utsläpp till vatten okänt)
- Pappers- och massaindustrin 1,2 g till luft och < 0,1 g till vatten

Eftersom utsläppen är så pass små är det inte skäl att fasa ut ett material utan man måste göra en mer noggrann analys om man vill få en bedömning över vilken produkt som är bäst ur miljösynpunkt.

Eftersom det finns möjlighet att välja olika mjukgörare i PVC är inte DEHP skäl att fasa ut PVC.

Kommentarer till EU-kommissionens LCA-rapport

Nordisk Miljömärkning påstår i kapitel 7.1 att EU-kommissionens LCA-rapport skall ses som ett försök att svara på de frågor som man presenterade i sin Grönbok om PVC. Vi anser inte att denna beskrivning är korrekt. LCA-rapporten gjordes efter uppmaning av parlamentet i kommentarer till grönboken. Man ansåg att det var en brist att inte kommissionen hade gjort en LCA av PVC-produkter och alternativa material, se (<http://www.europarl.europa.eu/sides/getDoc.do?sessionid=13D46194D0D7EF426027CDFB380270BA.node1?pubRef=-//EP//TEXT+REPORT+A5-2001-0092+0+NOT+XML+V0//EN>)

2. Regrets, however, that the Commission has not performed any lifecycle analysis of PVC products to compare them with alternative materials and calls on the Commission to ensure that the lifecycle impact on health and the environment of alternative products which are substitutes for PVC is assessed with at least the same degree of precision and openness as that of PVC;

Kommentarer till avsnitt om avfall (7.2.3)

I detta avsnitt i bakgrundsdokumentet anges att de vanligaste förbränningsanläggningarna genererar mer problematiskt avfall än den mängd PVC som förbränts. I Sverige är fördelningen på de olika teknikerna enligt uppgift från branschföreningen Avfall Sverige:

- Wet processes 15 plants
- Semi-dry processes 7 plants
- Dry processes 7 plants

Det är den våta processen som genererar minst förbränningsrester, och den är vanligast i Sverige.

I Danmark har det utvecklats en ny teknik som på ett både miljömässigt och ekonomiskt sätt tar till vara på saltet från de förbränningsrester som bildas vid avfallsförbränningsanläggningar. Den primära funktionen för HALOSEP-processen är

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att återvinna klor och minska mängden förbränningsrester som måste deponeras. Processen kan även användas för att behandla förbränningsresterna så att lakningsegenskaperna förbättras inför deponeringen.

Även metaller kan återvinnas genom HALOSEP-processen. De kostnadsbesparingar som kan göras med HALOSEP är upp till 40 %, beroende på vilken typ av reningsteknik förbränningsanläggningen använder, kostnaden för deponering och infrastruktur. Projektet har bl.a. finansierats genom PVC-industrins frivilliga åtagande Vinyl 2010.

När det gäller deponering av mjuka PVC-produkter har studier visat att mjukgörarna till största delen avgår genom att mikroorganismer äter upp dessa på ytan. Det innebär att mängden mjukgörare som avgår från produkterna inte återfinns i lakvattnet för det mesta.

Kommentarer till beskrivningen av mjukgöraranvändningen

Vi vill här påpeka att nya mjukgörare har tagits fram för sjukvårdsområdet som inte nämns. T.ex. har BASF en mjukgörare DINCH som man nu marknadsför till medicintekniska produkter och leksaker.

Vi bistår gärna med ytterligare information om detta är av intresse.

¹ "THE INFLUENCE OF PVC ON THE QUANTITY AND HAZARDOUSNESS OF FLUE GAS RESIDUES FROM INCINERATION" BERTIN 2004

² Se PlasticsEuropes eco-profiles för de mest använda plasterna på www.plasticseurope.org

³ Kartläggning av källor till oavsiktligt bildade ämnen" Rapport till regeringen 2005-03-31 RAPPORT 5462 • MARS 2005