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*****I** **REPORT**

on the proposal for a European Parliament and Council directive amending for the 22nd time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (COM(1999) 577 – C5-0276/1999 – 1999/0238(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Per-Arne Arvidsson

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission)

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PROCEDURAL PAGE

By letter of 22 November 1999 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a European Parliament and Council directive amending for the 22nd time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (COM(1999) 577 - 1999/0238 (COD)).

At the sitting of 17 January 2000 the President of Parliament announced that she had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Legal Affairs and the Internal Market for its opinion (C5-0276/1999).

The Committee on the Environment, Public Health and Consumer Policy appointed Per-Arne Arvidsson rapporteur at its meeting of 26 January 2000.

It considered the Commission proposal and draft report at its meetings of 23 March, 4 and 17 April and 24 May 2000.

At the last meeting it adopted the draft legislative resolution by 46 votes to 2, with no abstentions.

The following were present for the vote: Caroline F. Jackson (chairman), Carlos Lage, Alexander de Roo and Ria G.H.C. Oomen-Ruijten (vice-chairmen), Per-Arne Arvidsson (rapporteur), Maria del Pilar Ayuso González, Hans Blokland, David Robert Bowe, Hiltrud Breyer, Dorette Corbey, Chris Davies, Avril Doyle, Jillian Evans (for Marie Anne Isler Béguin), Carlo Fatuzzo (for Roger Helmer), Jim Fitzsimons, Marialiese Flemming, Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Robert Goodwill, Koldo Gorostiaga Atxalandabaso (for Hans Kronberger), Françoise D. Grossetête, Cristina Gutiérrez Cortines, Heidi Anneli Hautala (for Patricia McKenna), Mary Honeyball (for Bernd Lange), Anneli Hulthén, Eija-Riitta Anneli Korhola, Paul A.A.J.G. Lannoye (for Inger Schörling), Peter Liese, Torben Lund, Jules Maaten, Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Mihail Papayannakis, Neil Parish (for John Bowis), Dagmar Roth-Behrendt, Guido Sacconi, Amalia Sartori (for Christa Kläß), Karin Scheele, Jonas Sjöstedt, María Sornosa Martínez, Ulrich Stockmann (for Marie-Noëlle Lienemann), Catherine Stihler, Charles Tannock (for Jorge Moreira Da Silva), Marianne L.P. Thyssen (for Horst Schnellhardt), Antonios Trakatellis, Kathleen Van Brempt (for Minerva Melpomeni Malliori) and Phillip Whitehead.

The opinion of the Committee on Legal Affairs and the Internal Market is attached.

The report was tabled on 29 May 2000.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

LEGISLATIVE PROPOSAL

Proposal for a European Parliament and Council directive amending for the 22nd time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (COM(1999) 577 – C5-0276/1999 – 1999/0238(COD))

The proposal is amended as follows:

Text proposed by the Commission ¹

Amendments by Parliament

(Amendment 1)
Recital 3

(3) The presence of phthalates in certain toys and childcare articles made of soft PVC ***and intended to be placed in the mouth***, presents risks related to general toxicity to the health of ***young*** children.

(3) The presence of phthalates in certain toys and childcare articles made of soft PVC presents risks related to general toxicity to the health of children. ***Toys and childcare articles, especially those intended for children under the age of three, which, although not intended for that purpose, can be put in the mouth, may under certain circumstances present a risk to the health of small children if they are made of, or include parts of, soft PVC.***

Justification:

Small children put all toys and childcare articles into their mouth, not only toys and childcare articles intended to be put into the mouth and not only toys and childcare articles intended for them. Therefore, the scope of the directive needs to be enlarged. Phthalates are dangerous for children regardless of their age. Toys and childcare articles must always be safe and free of toxic materials.

¹ OJ C 116, 26.4.2000, p. 14.

(Amendment 2)
Recital 5a (new)

(5a) There is a greater risk that a child will place in its mouth toys and childcare articles made of, or including parts of, soft PVC to which fragrances have been added, even though such toys and childcare articles are not intended for that purpose.

Justification:

Self-explanatory.

(Amendment 3)
Recital 7

(7) It is necessary to provide for adequate labelling for child care articles made of soft PVC or including parts made of soft PVC intended for children ***under the age of three***, which, although not intended for that purpose, can be put in the mouth. Such labelling also has to be provided for in Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys [7] for those toys, which fall within the scope of that Directive.

[7] OJ L 187, 16.7.1988, p. 1. Directive as last amended by Council Directive 93/68/EEC, OJ L 220, 30.8.1993, p. 1.

(7) It is necessary to provide for adequate labelling for child care articles made of soft PVC or including parts made of soft PVC intended for children ***of three to six years old***, which, although not intended for that purpose, can be put in the mouth ***by children under the age of three***. Such labelling also has to be provided for in Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys [7] for those toys, which fall within the scope of that Directive.

[7] OJ L 187, 16.7.1988, p. 1. Directive as last amended by Council Directive 93/68/EEC, OJ L 220, 30.8.1993, p. 1.

Justification:

Small children should be protected from putting the toys and childcare articles of their elder sisters and brothers into the mouth.

(Amendment 4)

Recital 8

(8) The Commission will review the provisions in this Directive in the light of further scientific knowledge within **four** years of adoption.

(8) The Commission will review the provisions in this Directive in the light of further scientific knowledge within **two** years of adoption. ***In doing so, it will also take account of children's exposure to phthalates from sources other than toys (particularly from floor coverings and food packaging of soft PVC and from the ambient air) and will if appropriate commission research to ascertain the values in question.***

Justification:

The rapporteur considers a shorter follow-up period to be more appropriate. When carrying out a revision on the basis of further research, it should be ascertained whether children do not also ingest excessive quantities of phthalates from sources other than toys. If appropriate, consideration should be given to reducing the use of phthalates in these soft-PVC product groups as well.

(Amendment 5)

Recital 8b (new)

(8b) The Commission will review other applications of PVC articles which may expose people to risks, for example PVC articles used in health care.

Justification:

Self-explanatory.

(Amendment 6)

Article 2

Article 2

In Annex IV of Directive 88/378/EEC the following paragraph is added:
"7. Toys, made of or including parts of soft PVC containing ***the phthalates*** listed in point XX of the Annex to Directive 76/769/EEC, which are intended for children ***under the age of three*** and which can be put

Article 2

In Annex IV of Directive 88/378/EEC the following paragraph is added:
"7. Toys, made of or including parts of soft PVC containing ***plasticisers*** listed in point XX of the Annex to Directive 76/769/EEC, which are intended for children ***of three to six years old*** and which can be put in the

in the mouth, although not intended for that purpose

The following warning shall appear in an easily legible and indelible form on the packaging for the toy.

"Warning – do not ***put in the mouth for extended periods*** as could release phthalates dangerous to child health".

The following shorter warning shall appear in an easily legible and indelible form on the toy:

"Not to be kept in the mouth".

mouth, although not intended for that purpose ***by children under the age of three***

The following warning shall appear in an easily legible and indelible form on the packaging for the toy.

"Warning - do not ***give to children under the age of three*** as could release phthalates dangerous to child health".

The following shorter warning shall appear in an easily legible and indelible form on the toy:

"Not to be kept in the mouth".

Justification:

Small children should be protected from putting the toys and child care articles of their elder sisters and brothers into the mouth.

(Amendment 7)
Annex, left column

The following point is added to Annex I to Directive 76/769/EEC:

XX Phthalates

Of the following types:

- ***di-“isononyl” phthalate (DINP)***
CAS No 28553-12-0
EINECS No 249-079-5
- ***bis(2-ethylhexyl) phthalate (DEHP)***
CAS No 117-81-7
EINECS No 204-211-0
- ***dioctyl phthalate (DNOP)***
CAS No 117-84-0
EINECS No 204-214-7
- ***di-“isodecyl” phthalate (DIDP)***
CAS No 26761-40-0
EINECS No 247-977-1
- ***benzyl butyl phthalate (BBP)***
CAS No 85-68-7
EINECS No 201-622-7
- ***dibutyl phthalate (DBP)***
CAS No 84-74-2
EINECS No 201-557-4

The following point is added to Annex I to Directive 76/769/EEC:

XX Phthalates of all kinds

Justification:

On the basis of their chemical structure it is likely that phthalates other than the six listed are likewise a danger to the health of children. The EU ought to take a lead role in applying the precautionary principle and protecting children against avoidable health hazards. On no account should strict protective measures in the interests of children, which some Member States have already adopted, be abolished again by the EU.

(Amendment 8)
ANNEX, point 3

3. The following warning shall appear in an easily legible and indelible form on the packaging for childcare articles, other than those referred to in point 1 above, made of or including parts of soft PVC containing one or more of these phthalates, and intended for children ***under the age of three*** and which can be put in the mouth:

"Warning - do not ***put in mouth for extended periods*** as could release phthalates dangerous to child health".

The following shorter warning shall appear in an easily legible and indelible form on the childcare article:

"Not to be kept in the mouth".

3. The following warning shall appear in an easily legible and indelible form on the packaging for childcare articles, other than those referred to in point 1 above, made of or including parts of soft PVC containing one or more of these phthalates, and intended for children ***of three to six years old*** and which can be put in the mouth ***by children under the age of three***:

"Warning - do not ***give to children under the age of three*** as could release phthalates dangerous to child health".

The following shorter warning shall appear in an easily legible and indelible form on the childcare article:

"Not to be kept in the mouth".

Justification:

The label should be put on all toys and childcare articles that small children might play with, although they are not intended for them.

(Amendment 9)
ANNEX, point 3a (new)

3a. Fragrances must not be added to toys or childcare articles made of, or including parts of, soft PVC containing one or more of these phthalates and which a child can place in its mouth.

Justification:

The rapporteur wants to avoid situations where children put toys or other goods into their mouths because of their pleasant smell.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending for the 22nd time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys (COM(1999) 577 – C5-0276/1999 – 1999/0238(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(1999) 577¹),
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0276/1999),
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinion of the Committee on Legal Affairs and the Internal Market (A5-0149/2000),
1. Approves the Commission proposal as amended;
 2. Asks to be consulted again should the Commission intend to amend its proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

¹ OJ C 116, 26.4.2000, p. 14.

EXPLANATORY STATEMENT

The Commission's proposal that an easily legible and conspicuous warning label be affixed to products and their packaging in the case of toys and childcare articles or parts thereof, which, although not intended for that purpose, can be placed in the mouth and are made of soft PVC containing phthalates included in the list annexed to the proposal, is unlikely to work well. It is difficult to enforce toy-labelling requirements in practice. In reality, labels that carry warnings are probably tantamount to a ban. It would therefore seem to make sense to prohibit such objects if they are designed for children under the age of three and can be placed whole or in part in the mouth.

Bringing forward the deadline for reviewing the directive provides an opportunity to assess more promptly the technology and methods to be used in any future tests for the migration of phthalates and to evaluate the potential risks posed by substitute materials.

The addition of vanilla and fruit fragrances to soft PVC containing phthalates increases the risk that children, especially small children, might put objects whole or in part into their mouths. In view of the potential risks associated with phthalates, the addition of fragrances to toys and childcare articles that children might put in their mouths should not be permitted.

Children can be very unpredictable. A toy that is intended to be used in a particular way may be used completely differently by a child. A small child may perceive a toy as a source of comfort which it wants to have with it at all times and, when tired or resting, wants to suck on. Toys and childcare articles made of soft PVC containing specified phthalates should therefore not be permitted if they are designed for children under the age of three and can be placed in the mouth.

As to the rest, your rapporteur agrees with the arguments cited by the Commission in support of its proposal.

24 May 2000

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS AND THE INTERNAL MARKET

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a European Parliament and Council directive amending for the 22nd time Directive 77/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates) and amending Council Directive 88/378/EEC on the approximation of the laws of the Member States concerning the safety of toys.

(COM(1999) 577 - C5-0276/1999 - 1999/0238(COD))

Draftsman: Arlene McCarthy

PROCEDURE

The Committee on Legal Affairs and the Internal Market appointed Arlene McCarthy draftsman at its meeting of 28 March 2000.

It considered the draft opinion at its meetings of 8/9 May 2000 and 24 May 2000.

At the latter meeting it adopted the amendments below by 20 votes to 3, with 1 abstention.

The following were present for the vote: Ana Palacio Vallelersundi, chairman; Rainer Wieland, vice-chairman; Arlene McCarthy draftsman; Luis Berenguer Fuster, Maria Berger, Willy C.E.H. De Clercq, Marcello Dell'Utri, Bert Doorn, Raina A. Mercedes Echerer, Francesco Fiori, Janelly Fourtou, Marie-Françoise Garaud, Evelyne Gebhardt, Gerhard Hager, Heidi Anneli Hautala, The Lord Inglewood, Kurt Lechner, Klaus-Heiner Lehne, Manuel Medina Ortega, Bill Miller, Angelika Niebler, Ria G.H.C. Oomen-Ruijten, Diana Paulette Wallis and Stefano Zappalà.

SHORT JUSTIFICATION

The proposal for a directive, which is based on Article 95 of the EC Treaty, contains two elements:

- a ban on the use of six phthalate plasticizers in toys and childcare articles made of PVC or including PVC parts which are intended to be mouthed by children under three;
- a labelling requirement for all other toys and childcare articles made of PVC for children under three, which could be put in the mouth to clearly indicate that the article should not be mouthed.

The ban is to be imposed within 10 days of the adoption of the directive by temporary measures taken by the Commission under Article 9 of Directive 92/59/EEC on product safety.

The Commission's independent Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) was consulted on the use of six phthalates in toys and childcare items intended to be mouthed and expressed the view that these phthalates could be used subject to the establishment of migration limits.

Negative publicity surrounding phthalates has led to a public perception that the risks involved are high. The concern of the European Parliament must be to ensure that no child under three or baby is exposed to unacceptable risks. Therefore, more research work is necessary on issues of chronic toxicity and mouthing behaviour of children in addition to the need for ongoing migration testing. Whilst phthalates have been well researched, very little is known about the toxicological effects of substitutes to replace them. Any replacements could be equally hazardous. Even toys made of traditional materials such as wood and rubber may contain substances dangerous to children's health either through natural occurrence or pollution or pesticide spraying.

In some cases, industry has stopped using phthalates in toys and childcare products and so even if a satisfactory migration test were to be developed it seems unlikely that any of those products would be reintroduced into the European market. Several Member States already ban the use of the six phthalate plasticizers. The proposal for a ban therefore formalises a ban which is already in place and respects the precautionary principle. In the interest of the integrity of the Internal Market and the establishment of common product-safety standards, while at the same time providing a common stance on public concerns on the risks associated with phthalates, it is recommended that the ban be supported.

In the case of toys and childcare articles which could be mouthed your rapporteur supports the Commission proposal for labelling. The rapporteur is of the opinion that a stringent health warning may have virtually the same effect as a ban, since industry may decide voluntarily to remove phthalates from products if they are unlikely to sell them owing to the warning labels on both the packaging and the toy. Several Member States are of the opinion that the labelling proposal goes too far. Your rapporteur is of the opinion that the ban should not be extended. A ban can only be invoked on the basis of the precautionary principle if significant evidence of risk exists. The Scientific Committee does not deem this to be the case. Your rapporteur is concerned that an extension of the ban could lead to a breach of the principle of proportionality and could lead to legal challenges by industry.

Your rapporteur believes therefore the Commission proposal would preserve the single market, restore the confidence of consumers and enable consumer choice through a partial ban and labelling. Any other legislation not supported by sound scientific data could be open to a legal challenge.

However, the labelling proposal must be accompanied by research and testing not only on replacement plasticizers but also on traditional materials which could be mouthed, i.e. an extension of the review, and in addition support should be given to the lead rapporteur's proposal to reduce from four to two years the period after which the provisions of the directive are to be reviewed. New methods for testing for the migration of phthalates should be stepped up and evaluated as soon as possible. It is also necessary to address the issue of safety of substitute plasticizers through research and testing.

AMENDMENTS

The Committee on Legal Affairs and the Internal Market calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission

Amendments by Parliament

(Amendment 1)

Recital 3

The presence of phthalates in certain toys and childcare articles made of soft PVC and intended to be placed in the mouth, presents risks related to general toxicity to the health of **young** children.

The presence of phthalates in certain toys and childcare articles made of soft PVC and intended to be placed in the mouth, presents risks related to general toxicity to the health of children.

Justification:

Phthalates are dangerous for children regardless of their age. Toys and childcare articles must always be safe and free of toxic materials.

(Amendment 2)

Recital 7

It is necessary to provide for adequate labelling for child care articles made of soft PVC or including parts made of soft PVC intended for children under the age of three, which, although not intended for that purpose, can be put in the mouth. Such labelling also has to be provided for in Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys for those toys, which fall within the scope of that Directive.

deleted

Justification:

Phthalates are dangerous to children regardless of their age. There is no need for warning

labels if phthalates are prohibited.

(Amendment 3)

Article 2

In Annex IV of Directive 88/378/EEC the following paragraph is added:

"7. Toys, made of or including parts of soft PVC containing the phthalates listed in point XX of the Annex to Directive 76/769/EEC, which ***are intended for children under the age of three and which*** can be put in the mouth, ***although not intended for that purpose.***

The following warning shall appear in an easily legible and indelible form on the packaging for the toy.

"Warning - do not put in the mouth for extended periods as could release phthalates dangerous to child health".

The following shorter warning shall appear in an easily legible and indelible form on the toy:

"Not to be kept in the mouth".

In Annex IV of Directive 88/378/EEC the following paragraph is added:

"7. Toys, made of or including parts of soft PVC containing the phthalates listed in point XX of the Annex to Directive 76/769/EEC, which can be put in the mouth ***by children.***

deleted

Justification:

Phthalates are dangerous to children regardless of their age. There is no need for warning labels if phthalates are prohibited.

(Amendment 4)

Annex, points 1 to 3

1. May not be used as substances or as constituents of preparations at concentrations of greater than 0.1% in toys and child care articles made of PVC, or including parts of PVC, ***intended to be*** put in the mouth by ***children under the age of three.***

2. Products referred to in point 1 above may not be placed on the market unless they conform to the requirements stated.

3. The following warning shall appear in an easily legible and indelible form on the

1. May not be used as substances or as constituents of preparations at concentrations of greater than 0.1% in toys and child care articles made of PVC, or including parts of PVC, ***capable of being*** put in the mouth by children.

Deleted

Deleted

packaging for childcare articles, other than those referred to in point 1 above, made of or including parts of soft PVC containing one or more of these phthalates, and intended for children under the age of three and which can be put in the mouth:
"Warning - do not put in mouth for extended periods as could release phthalates dangerous to child health".
The following shorter warning shall appear in an easily legible and indelible form on the childcare article:
"Not to be kept in the mouth".

Justification:

Phthalates are dangerous to children regardless of their age. There is no need for warning labels if phthalates are prohibited.