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RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a directive of the European Parliament and of the Council amending for the twenty-second time Council 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 in toys and childcare articles)
(5467/1/2005 – C6-0092/2005 – 1999/0238(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Antonios Trakatellis

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)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting a directive of the European Parliament and of the Council amending for the twenty-second time Council 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 in toys and childcare articles) (5467/1/2005 – C6-0092/2005 – 1999/0238(COD))

(Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (5467/1/2005 – C6-0092/2005),
 - having regard to its position at first reading¹ on the Commission proposal to Parliament and the Council (COM(1999)0577)²,
 - having regard to Article 251(2) of the EC Treaty,
 - having regard to Rule 62 of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A6-0196/2005),
1. Approves the common position as amended;
 2. Instructs its President to forward its position to the Council and Commission.

Council common position	Amendments by Parliament
Amendment 1	
TITLE	
Directive of the European Parliament and of the Council amending for the twenty-second time Council 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 <i>in toys and childcare articles</i>)	Directive of the European Parliament and of the Council amending for the twenty-second time Council 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) <i>and amending Council Directive 88/378/EEC on the</i>

¹ OJ C 121, 24.4.2001, p. 176.

² OJ C 116, 26.4.2000, p. 14 E.

approximation of the laws of the Member States concerning the safety of toys

Justification

Reinstatement of the title of the original proposal submitted by the Commission with the aim of including the provisions relating to the safety of toys (Directive 88/378/EEC) which were removed by the Council in the common position. In order to ensure a high level of protection for children's health, it is essential to set out the relevant warnings or indications to take precautions while using toys or childcare products containing certain phthalates in plasticised material which are intended for young children and could be put in the mouths of children aged less than three, even if they are not intended for that purpose.

Amendment 2
RECITAL 3

(3) The use of certain phthalates in toys and childcare articles made of plasticised material or including parts made of plasticised material should be prohibited as the presence of certain phthalates presents or could potentially present risks related to the health of children.

(3) The use of certain phthalates in toys and childcare articles made of plasticised material or including parts made of plasticised material should be prohibited as the presence of certain phthalates presents or could potentially present risks related 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 plasticised material, or include parts made of plasticised material, which contains certain phthalates. It must be noted that phthalates may be absorbed into the body of children not only when plasticised material is put in the mouth but also if such material comes into extensive contact with the skin of a child. The risks are considered to be higher when the child is less than three years of age.***

Justification

Although the Council proposed a ban on the phthalates DEHP, DBP and BBP in concentrations of more than 0.1% in all toys and childcare articles, because they are classified, on the basis of assessment, as carcinogenic, mutagenic and reprotoxic, it exempted

the substances DINP, DIDP and DNOP in toys and childcare articles intended for children over the age of three (the assessment has not been completed, despite the fact that there are indications of harmful effects on liver and thyroid cells in experimental animals). Children under three, however, can put toys and childcare products in their mouths, even if they are not intended for that purpose, and this is a potential health threat to those children. See Amendment 1 from Parliament's first reading.

Amendment 3
RECITAL 3 A (new)

(3a) There is a greater risk that a child will place in its mouth toys and childcare articles made of plasticised material or including parts made of plasticised material to which fragrances have been added, even though such toys and childcare articles are not intended for that purpose.

Justification

Toys and childcare articles made from plasticised material or which include parts made from plasticised material to which fragrances have been added increase the tendency of small children to put them in their mouths. Reinstatement of Amendment 2 from Parliament's first reading.

Amendment 4
RECITAL 4 A (new)

(4a) Alternative plasticisers are available, such as Acetyl Tri-Butyl Citrate (ATBC) in respect of which an opinion by the SCTEE supported the view that there was no safety concern with its use as a plasticiser for PVC toys mouthed by small children.

Justification

Account should be taken of new scientific data and the new opinion of the SCTEE of 8 January 2004 which, following consultation with the Commission on ATBC, concluded that the data gaps were properly covered by the new data and that there is no safety concern with its use as a plasticiser for PVC toys mouthed by small children. See also Amendment 18 from Parliament's first reading.

Amendment 5
RECITAL 8

(8) The precautionary principle should be applied where scientific evaluation does not allow the risk to be determined with sufficient certainty in order to ensure a high level of protection of health, in particular for children.

(8) ***It is imperative that*** the precautionary principle should be applied where scientific evaluation does not, ***for the time being,*** allow the risk to be determined with sufficient certainty in order to ensure a high level of protection of health, in particular for children.

Amendment 6
RECITAL 9

(9) Children as developing organisms are particularly vulnerable to reprotoxic substances. Therefore, the exposure of children to all practically avoidable sources of emissions of these substances, especially from articles which ***are*** put into the mouth by children, should be reduced as far as possible.

(9) Children as developing organisms are particularly vulnerable to reprotoxic substances. Therefore, the exposure of children to all practically avoidable sources of emissions of these substances, ***including from articles intended for children or for childcare, and*** especially from articles which ***can be*** put into the mouth by children, should be reduced as far as possible.

Justification

New amendment modifying a new recital in the common position.

Improving of the wording. The three reprotoxic PVC softeners are to be prohibited in all toys, irrespective of whether they are put into the mouth by children or not, as articles intended for children or for childcare should not contain such substances. It is therefore more appropriate to refer firstly to articles intended for children or childcare in general with regard to the need to reduce avoidable exposure as much as possible, and then to stress the possibility of these being put into the mouth by children.

Amendment 7
RECITAL 10 A (new)

(10a) The harmful effect of DEHP, DBP and BBP on the future reproductive capacity of children under three years of age is far from being the only way in which phthalates impact on human pathology.

Amendment 8
RECITAL 11

(11) Scientific information regarding DINP, DIDP and DNOP is either lacking or conflictual, but it can not be excluded that they pose a potential risk if used in toys and childcare articles, which are by definition produced for children.

(11) Scientific information regarding DINP, DIDP and DNOP is either lacking or conflictual, but it can not be excluded that they pose a potential risk if used in toys and childcare articles, which are by definition produced for children. ***The exposure of children to practically avoidable sources of emissions of these substances, especially from articles that can be put into the mouth by them, should be reduced as far as possible. It is wise to apply the precautionary principle in this case.***

Justification

New amendment modifying a new recital in the common position.

Given the harmfulness of the substances, the high concentration with which they are to be used to soften PVC, the inevitable release of them from soft PVC, and the availability of substitutes, they represent an unnecessary risk.

Amendment 9
RECITAL 12 A (new)

(12a) The Commission will review other applications of articles made from plasticised material or including parts made from plasticised material which may expose people to risks, especially those used in healthcare.

Justification

Although the use of certain phthalates (e.g. DEHP) covers a very wide range of needs in the health sector, there is a need to review the medical appliances which are made of plasticised material or contain parts made of plasticised material and which may expose people to risks. Restrictions on the use and availability of such articles are considered necessary in cases where there are safer alternative solutions and where the restrictions do not have an adverse impact on medical treatment. Reinstatement of Amendment 5 from Parliament's first reading.

Amendment 10
RECITAL 12 B (new)

(12b) It is necessary to provide for adequate labelling for those toys and childcare articles containing DINP, DIDP or DNOP, which can be put on the market under this Directive. Such labelling also has to be provided for in Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys¹.

¹ ***OJ L 187, 16.7.1988, p. 1. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).***

Justification

While prohibiting various chemical substances in toys, Directive 88/378/EEC does not mention phthalates. The Council recognises that the exposure of children to all sources of emissions of the substances in question which are possible to avoid in practical terms should be reduced, especially those from objects which come into contact with children's mouths. Although it proposed prohibiting DEHP, DBP and BBP in all toys and childcare articles, it restricted the ban in respect of DINP, DIDP and DNOP only to toys and childcare articles intended for children under three which could come into contact with the mouth. Given that children under the age of three can put in their mouths toys and childcare articles containing DINP, DIDP and DNOP which are intended for children from three to six, it is considered necessary to adopt labelling rules. See Amendment 3 from Parliament's first reading.

Amendment 11 RECITAL 17

(17) The Commission will review the use of the phthalates listed in Annex I to Directive 76/769/EEC in other products when the risk evaluation under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances will have been concluded.

(17) The Commission will review the use of the phthalates listed in Annex I to Directive 76/769/EEC in other products when the risk evaluation under Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances will have been concluded. ***In particular, it will review exposure to phthalates from articles used in floor coverings, food packaging made of plasticised material or including parts made from plasticised material, and from the ambient air, and will, if appropriate, commission research to ascertain the values in question.***

Justification

Modified reintroduction of amendments 4 and 5 from first reading.

The review of the use of phthalates in toys and childcare articles should be distinguished from the need to review other uses of phthalates. The Commission rightly foresees a review of the use of phthalates in other products, and this should be maintained. In line with the amendments from first reading, that should address in particular, but not be limited to, certain applications that are most likely to constitute an unnecessary risk.

Amendment 12 RECITAL 17 A (new)

(17a) If a method of measuring the migration of phthalates is developed and this technique is approved by the competent scientific committee for practical use, this will provide strong grounds for the Commission to review the provisions of this Directive on the basis of the risk assessment and the opinion of the competent scientific committee.

Justification

The subject remains open of developing a reliable method to establish the migration of phthalates and of assessing the related risks on the basis of new scientific data and the opinion of the competent scientific committee. Reinstatement of amendments 11 and 24 from Parliament's first reading.

Amendment 13 ARTICLE 1, POINT 1 Article 1, paragraph 3, point (c) (Directive 76/769/EEC)

"(c) "childcare article" means any product intended to facilitate sleep, relaxation, the feeding of children or sucking on the part of children."

"(c)"childcare article" means any product intended to facilitate sleep, relaxation, ***hygiene***, the feeding of children, ***the teething process*** or sucking on the part of children."

The aim of the amendment is to ensure that the new definition of childcare articles introduced in the Council common position is slightly extended in order to cover such products as changing tables and mats that are placed on changing tables.

Amendment 14
ARTICLE 1 A (new)

The Commission, in cooperation with the Member State authorities responsible for market surveillance and enforcement for toys and childcare articles, and in consultation with the relevant organisations of producers and importers, shall monitor the use of phthalates and other substances as plasticisers in toys and childcare articles. By ... * at the latest, the Commission shall publish a report on the use of phthalates and other plasticisers in these articles. On the basis of this report, in light of the latest scientific information about the substances found, and if justified, the Commission shall present appropriate legislative proposals in accordance with Article 251 of the Treaty to limit the use of these phthalates and plasticisers in toys and childcare articles.

**** Four years after the entry into force of this Directive.***

Justification

New amendment building on the new recital 14 of the common position.

The monitoring requirements mentioned in recital 14 should also be included in the enacting terms of the directive. There are many more phthalates than the six addressed in this directive, and there are also plasticisers other than phthalates. Many of these may lead to harmful effects. To avoid the replacement of the six harmful phthalates with other harmful substances, Member States and the Commission should closely monitor the replacement of phthalates, and if necessary, the Commission should propose further legislative action.

Amendment 15
ARTICLE 1 B (new)
Annex IV (Directive 88/378/EEC)

Article 1b

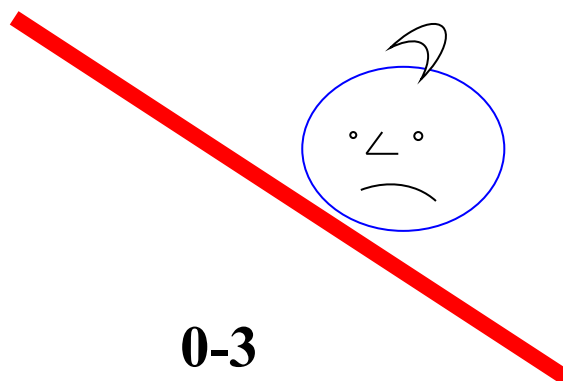
In Annex IV to Directive 88/378/EEC, the following point is added:

“7. Toys made of plasticised material or including parts made of plasticised material containing the phthalates listed in point

XXa of Annex I to Directive 76/769/EEC, which can be put on the market under that Directive.

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

"Contains phthalates - Not to be kept in the mouth"



Where the label is smaller or larger, the proportions of the above pictogram should be maintained accordingly.

Justification

Despite the ban on DEHP, DBP and BBP introduced by the Council, the question remains of protecting children's health by applying the precautionary principle in the case of DINP, DIDP and DNOP in plasticised material used in toys intended for small children and which could be put in the mouths of children under three, although not intended for that purpose. Because of the uncertainty concerning the risk assessment, there is a need to provide for the possibility of information in the form of labelling. Reinstatement of amendment 6 from Parliament's first reading. Amendment 16

ARTICLE 2

The Commission shall re-evaluate, by ... * at the latest, the measures provided for in ***Directive 76/769/EEC as amended by*** this Directive in the light of new scientific information on substances described in the Annex to this Directive and their substitutes, and if justified, ***these measures shall be modified accordingly.***

***Four** years after the entry into force of this Directive.

The Commission shall re-evaluate, by ... * at the latest, the measures provided for in this Directive in the light of new scientific information on substances described in the Annex to this Directive and their substitutes, and if justified, ***shall present appropriate legislative proposals in accordance with Article 251 of the Treaty to limit the use of these substances.***

***Three** years after the entry into force of this Directive.

Justification

Phthalates are used to plasticise a wide range of soft PVC products, which might pose similar risks as soft PVC toys. The Commission should evaluate these products to see whether further action is necessary.

The aim of the amendment, changing the four years proposed by the Council in the common position and the two years proposed by the EP to three years, is to speed up the collection of data and to ensure satisfactory time for risk evaluation, particularly in respect of the substances about which there is uncertainty, i.e. DINP, DIDP and DNOP. The amendment also seeks to approximate the positions of the two institutions with a view to the publication of the Directive. See also Amendment 8 from Parliament's first reading.

Amendment 17

ANNEX

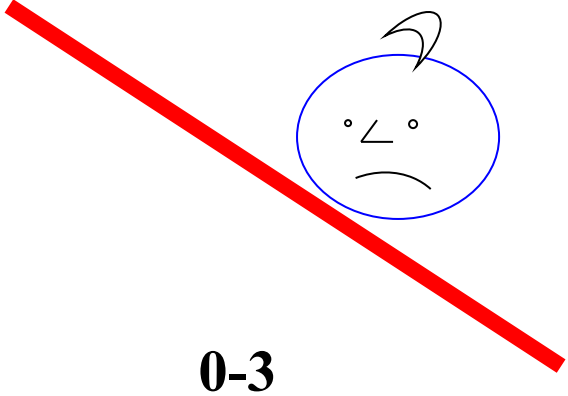
Annex I, point [XXa] (Directive 76/769/EEC)

Council common position

<p>[XXa.] The following phthalates (or other CAS- and EINECS numbers covering the substance):</p> <p>di-"isononyl" phthalate (DINP) CAS No 28553-12-0 and 68515-48-0 EINECS No 249-079-5 and 271-090-9</p> <p>di-"isodecyl" phthalate (DIDP) CAS No 26761-40-0 and 68515-49-1 EINECS No 247-977-1 and 271-091-4</p> <p>di-n-octyl phthalate (DNOP) CAS No 117-84-0 EINECS No 204-214-7</p>	<p>Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticised material, in toys and childcare articles intended for children under three years of age and which can be placed in the mouth by them.</p> <p>Such toys and childcare articles containing these phthalates in a concentration greater than the limit mentioned above shall not be placed on the market.</p>
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Amendment by Parliament

<p>[XXa.] The following phthalates (or other CAS- and EINECS numbers covering the substance):</p> <p>di-"isononyl" phthalate (DINP) CAS No 28553-12-0 and 68515-48-0 EINECS No 249-079-5 and 271-090-9</p> <p>di-"isodecyl" phthalate (DIDP) CAS No 26761-40-0 and 68515-49-1 EINECS No 247-977-1 and 271-091-4</p>	<p>Shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticised material, in parts of toys and childcare articles intended to be placed in the mouth or in toys and childcare articles which can be placed in the mouth by children.</p> <p>Such toys and childcare articles containing these phthalates in a concentration greater</p>
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<p>di-n-octyl phthalate (DNOP) CAS No 117-84-0 EINECS No 204-214-7</p>	<p>than the limit mentioned above shall not be placed on the market.</p> <p><i>Guidelines shall be drawn up by the Commission in order to facilitate the implementation of this Directive, in particular the provisions on restrictions of certain substances in toys and childcare articles insofar as they concern the condition "which can be placed in the mouth by children".</i></p> <p><i>Toys and childcare articles containing these phthalates, which can be placed on the market under this Directive, shall bear a label including the following warning and pictogram in an easily legible and indelible form:</i></p> <p><i>"Contains phthalates - Not to be kept in the mouth"</i></p>
	
	<p><i>Where the label is smaller or larger, the proportions of the above pictogram should be maintained accordingly.</i></p>
	<p><i>Fragrances may not be added to toys or childcare products made of plasticised material or including parts made of plasticised material containing one or more of these phthalates in concentrations higher than 0.1% by mass of the plasticised material, if children can put them in their mouth.</i></p>
	<p><i>Toys and childcare articles containing fragrances and these phthalates in concentrations higher than the level referred to in the previous paragraph shall</i></p>

	<i>not be placed on the market..</i>
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Justification

Reinstatement of amendments 8, 9 and 16 from Parliament's first reading.

It is not appropriate to limit the restriction of DINP, DIDP and DNOP to toys for children under three. Putting toys into the mouth is not limited to a particular age. Even if it were, an arbitrary age limit ignores the reality of families with more than one child, where younger children will want to play with the toys of their elder siblings. These substances have been found to be harmful. They are used in high concentrations in toys, they are released from them, especially when put into the mouth, and alternative toys without harmful plasticisers are available. They should therefore be prohibited in all toys that can be put into the mouth.

For all other toys, provision must be made, on the basis of the precautionary principle, for the possibility of informing, by means of labelling, parents and adults who come into contact with children, of the presence of these substances.

Fragrant toys and childcare articles made of plasticised material or which include parts made from plasticised material increase the tendency of small children to put them in their mouth and, therefore, constitute a potential risk.

EXPLANATORY STATEMENT

1. Background and remarks on procedure

On 10 November 1999, the Commission submitted to the European Parliament and the Council a proposal for a directive amending for the 22nd time Council 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))¹.

On the basis of the opinions of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), which the Commission also consulted pursuant to Article 9 of Council Directive 92/59/EEC on general product safety, the Commission decided on 7 December 1999 to prohibit the intentional use or placing on the market in quantities higher than 0.1% by weight of 6 phthalate esters, *DEHP*, *DBP*, *BBP*, *DINP*, *DIDP* and *DNO* in toys and childcare products intended to be placed in the mouth by children under three years of age². Since then and to date, the Commission has renewed this ban on a regular basis (every three months or six months).

The Economic and Social Committee delivered its opinion on the Commission's proposal on 15 February 2000³.

At its sitting of 6 July 2000, the European Parliament adopted at first reading a legislative resolution⁴, together with 12 amendments, on the Commission's proposal.

On 25 May, the Council considered the matter but was unable to reach agreement on a common position. The Council adopted a common position⁵, pursuant to Article 251(2), on 4 April 2005, after reaching a political agreement at its meeting of 24 September 2004.

Taking account of the European Parliament's amendments at first reading and the common position of the Council, the Commission published a communication for the information of Parliament on its position, pursuant to the second subparagraph of Article 251(2)⁶.

2. Assessment of the Council's common position

The common position of the Council makes significant changes to the Commission's proposal and to Parliament's first reading. In principle, the six phthalates referred to in Annex I to the proposal for a directive are no longer treated as substances in the same category and as posing the same danger to children's health.

¹ OJ C 304 E, 26.4.2000, p. 14.

² OJ L 315, 9.12.1999, p. 46.

³ OJ C 117, 26.4.2000, p. 59.

⁴ OJ C 121, 24.4.2001, p. 410.

⁵ Council document 5467/05 REV 1.

⁶ COM(2005) 143 final, 12.4.2005.

On the basis of the scientific reports and opinions of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), the Council strengthens the proposal of the Commission and of the European Parliament by imposing a total ban on the use and placing on the market of three phthalates, DEHP, DBP and BBP, in all toys and childcare articles in concentrations higher than 0.1% by mass of the plasticised material, substances which are classified on the basis of risk assessment as carcinogenic, mutagenic and reprotoxic (category 2). Phthalates are used, usually in large quantities, to increase the pliability of toys or childcare articles made from plasticised material and, therefore, the limit of 0.1% is an endeavour to protect health even against the possibility of adventitious contamination.

As regards the other three phthalates, DINP, DIDP and DNOP, because of the divergent opinions as to the danger they pose, the Council restricted the ban on their use and placing on the market as substances or as constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticised material in toys and childcare articles intended for children under three years of age and which can be placed in the mouth by them. Consequently, the ban does not apply to the substances DINP, DIDP and DNOP which are contained in toys and childcare articles intended for children over the age of three years. It should also be noted that DINP is used in toys in quantities of 35%-45%.

Furthermore, the Council's common position removes all the provisions of the proposal for a directive referring to labelling and information for the consumer, parent and individuals who come into contact with children in relation to toys and childcare articles (see amendment to Directive 88/378/EEC on toys and the provisions of Annex I concerning childcare articles). Even if labelling is not so important for the first category of the most dangerous phthalates identified, it does not mean that the same applies to labelling for the other three phthalates, DINP, DIDP and DNOP, risk assessment for which has not been concluded, although there are indications of harmful effects. Children under the age of three are likely to put toys and childcare products in their mouths which are not intended for that purpose, without parents or others being able to intervene, because they do not have the relevant information. This constitutes a potential threat to those children's health.

As regards the **success of Parliament's amendments** at first reading, it should be noted that of a total of 12 amendments, the Council did not incorporate any amendment in full or in part in the common position, while only five were accepted in principle (1, 3, 4, 6 and 8). Parliament's amendments which were not accepted in the common position of the Council were: amendment 18 concerning the use of citrates and adipates as substitutes, amendments 2 and 9 concerning the addition of fragrances in toys and childcare articles, amendment 5 concerning the extension of application to other products, amendments 11 and 24 concerning the methods of measuring the migration of phthalates, amendment 7 concerning extending the ban to all phthalates, amendments 16 and 17 rev. concerning 0.05% as the ceiling for concentration of phthalates in the plasticised material.

Although it constitutes a step in the right direction towards a general ban on certain phthalates above a particular concentration limit and, therefore, towards protecting children's health, the Council's common position does not incorporate many of Parliament's amendments, leaving some issues open.

3. Rapporteur's comments and proposals

Obviously, the protection of children's health and the building of consumer confidence call for a stringent regulatory framework to govern the manufacture and marketing of toys and childcare articles containing certain phthalates in order to reduce, as far as possible, children's exposure to substances which demonstrably give rise to or could potentially cause a health risk.

Consequently, the regulatory framework must be simple and exhaustive so that its implementation can be monitored transparently and fraud and distortion of competition can be avoided, particularly between domestic and imported products; it should also provide for the following: (a) a ban on the use of dangerous phthalates, determined on the basis of a risk assessment, (b) the adoption of rules on labelling on the basis of the precautionary principle, the main aim being to increase the awareness of and information to the parents and, in general, individuals who come into contact with children in the case of phthalates where there are indications that the substances are dangerous but they have not been banned.

Given that children may mouth toys and childcare articles containing DINP, DIDP and DNOP, it is considered that there is a need to ban the use of these substances in toys and childcare articles which can be put in the mouth. For other toys and childcare articles, it is considered that it would be useful to adopt rules on labelling, the main aim being to provide people who come into contact with children with information.

There are proposals request for the development of a method to measure the migration of phthalates, and a review of the directive on the basis of risk assessment and the opinion of the competent scientific authority. Account must also be taken of the exposure of children to risks from sources other than toys and, if appropriate, research must be commissioned to ascertain the values in question. This is also consistent with Parliament's recent resolution¹ which considers that, without prejudice to existing Community legislation and following the opinion of the Scientific Committee on Health and Environment Risks, urgent consideration is to be given to restricting the marketing and/or the use on the European market of dangerous substances, to which new-born babies, children, pregnant women, elderly persons, workers and other high-risk sections of the population are heavily exposed, as safer alternatives become available, including six products from the phthalate family (DEHP, DINP, DBP, DIDP, DNOP, BBP) in domestic products for indoor use and medical devices, except where such a restriction would have a negative impact on medical treatment.

My proposals as rapporteur are based on the above considerations, which, it should be noted provide the consumer with reliable information without subjecting the market to excessive measures and prohibitions. Furthermore, they enable consumers to be certain in their choices and provide industry with a stable legal framework within which to operate.

It is therefore proposed to reinstate the title of the original proposal submitted by the Commission together with some of Parliament's amendments in order to incorporate the provisions deleted by the Council, which relate to labelling, safety and risk assessment of

¹ P6_TA-PROV(2005)0045 on the European Environment and Health Action Plan 2004-2010 (2004/2132(INI)), report by F. Ries A6-0008/2005.

phthalates in toys and childcare products (amendments 1, 2, 4, 8, 11 and 24, 6 and 9 from Parliament's first reading).

OPINIONS OF

A) SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS¹:

- Risk Assessment Report on Benzyl Butyl Phthalate (BBP) Human Health Part” CAS No.: 85-68-7 EINECS No.: 201-622-7. Adopted by the SCHER during the 3rd plenary meeting of 28 January 2005.

B) SCIENTIFIC COMMITTEE FOR TOXICITY, ECOTOXICITY AND THE ENVIRONMENT²:

1. Opinion on "Assessment of the **bioavailability** of certain elements in toys". Adopted by the CSTEE by written procedure on 22nd June 2004.
2. Opinion on the risk assessment for acetyl tributyl citrate (ATBC) plasticizer used in children's toys. Adopted by the CSTEE during the 41th plenary meeting of 8 January 2004.
3. Opinion on the results of the Risk Assessment of: Bis(2-ethylhexyl) phthalate **dehp** human health part CAS n°.: 117-81-7 EINECS n°.: 204-211-0 Carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances Adopted by the CSTEE during the 41th plenary meeting of 8 January 2004.
4. Opinion on assessment of the European Committee for Standardisation (CEN) report on the risk assessment of **organic chemicals** in toys. Report version: final report of the work of CEN/TC 52/WG 9 - January 2003 (Contract BC/CEN/97/29.1.1). Adopted during the 40th plenary meeting on 12 November 2003
5. Opinion on the results of the Risk Assessment of Bis (2-ethylhexyl) phthalate (**DEHP**). Report version: Environment , September 2001. Opinion expressed at the 29th CSTEE plenary meeting, Brussels, 09 January 2002
6. Opinion on the results of the Risk Assessment of: 1,2-Benzenedicarboxylic acid di-C9-11-branched alkyl esters, C10-rich and di-**"isodecyl"phthalate** - CAS No.: 68515-49-1 and 26761-40-0 - EINECS No.: 271-091-4 and 247-977-1. Report version (Environment): Final report, May 2001 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances. Opinion expressed at the 27th CSTEE plenary meeting, Brussels, 30 October 2001
7. Opinion on: report on Validation of **methodologies for the release** of diisononylphthalate (**DINP**) in saliva simulant from toys (2001 EUR 19826 EN). Opinion expressed at the 25th CSTEE plenary meeting Brussels, 20 July 2001
8. Opinion on the results of the Risk Assessment of: 1,2-Benzenedicarboxylic acid di-C9-11-branched alkyl esters, C10-rich and di-**"isodecyl"phthalate** - CAS No.: 68515-49-1 and 26761-40-0 - EINECS No.: 271-091-4 and 247-977-1 - Report version (Human

¹ . http://europa.eu.int/comm/health/ph_risk/committees/04_scher/scher_opinions_en.htm

² . http://europa.eu.int/comm/health/ph_risk/committees/sct/sct_en.htm

health effects): Final report, May 2001 carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances. Opinion expressed at the 24th CSTEE plenary meeting, Brussels, 12 June 2001

9. Opinion on the results of the risk assessment Report of **DIBUTYLPHTHALATE** CAS N°: 84-74-2 EINECS N°: 201-557-4. Report version carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risk of existing substances. Opinion expressed at the 23rd CSTEE plenary meeting, Brussels, 24 April 2001
 10. Opinion on Chapters 6 and 8 (on risk issues) of the RPA ETD/99/502498 Final Report – July 2000 - The **Availability of Substitutes** for Soft PVC Containing Phthalates in Certain Toys and Childcare Articles. Opinion expressed at the 22nd CSTEE plenary meeting, Brussels, 6/7 March 2001
 11. Opinion on **validation of test methods** for phthalate migration - Opinion expressed at the 17th CSTEE plenary meeting, Brussels, 5 September 2000
 12. Opinion on the toxicological characteristics and risks of certain **citrates and adipates** used as a substitute for phthalates as **plasticisers** in certain soft PVC products. (adopted at the 11th CSTEE plenary meeting on the 28th of September 1999)
 13. Opinion on Phthalate **migration** from soft PVC toys and child-care articles - Data made available since the 16th of June 1998, opinion expressed at the 6th CSTEE plenary meeting, Brussels, 26/27 November 1998
 14. Opinion on Phthalate **migration** from soft PVC toys and child-care articles (to answer four new questions put to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the subject), opinion expressed at the 4th CSTEE plenary meeting, Brussels, 16 June 1998
 15. Phthalate **migration** from soft PVC toys and child-care articles (opinion expressed at the CSTEE third plenary meeting - Brussels, 24 April 1998)
 16. Opinion on Phthalate **migration** from soft PVC toys and child-care articles (opinion expressed on 9 February 1998).
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PROCEDURE

Title	Council common position for adopting a directive of the European Parliament and of the Council amending for the twenty-second time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provision of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles)
References	(5467/1/2005 – C6-0092/2005 – 1999/0238(COD))
Legal basis	Articles 251(2) EC
Basis in Rules of Procedure	Rule 62
Date of Parliament's first reading – P[5]	6.7.2000 T5-0334/2000
Commission proposal	COM(1999)0577] – C5-0276/1999
Amended Commission proposal	
Date receipt of common position announced in plenary	14.4.2005
Committee responsible Date announced in plenary	ENVI 14.4.2005
Rapporteur(s) Date appointed	Antonios Trakatellis 20.4.2005
Previous rapporteur(s)	Per Arne Arvidsson
Discussed in committee	24.5.2005 14.6.2005
Date adopted	14.6.2005
Result of final vote	for: 39 against: 6 abstentions: 4
Members present for the final vote	Adamos Adamou, Liam Aylward, Johannes Blokland, John Bowis, Frederika Brepoels, Hiltrud Breyer, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Karl-Heinz Florenz, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Caroline Jackson, Dan Jørgensen, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Marie-Noëlle Lienemann, Peter Liese, Jules Maaten, Linda McAvan, Roberto Musacchio, Riitta Myller, Péter Olajos, Dimitrios Papadimoulis, Vittorio Prodi, Frédérique Ries, Guido Sacconi, Carl Schlyter, Richard Seeber, Kathy Sinnott, Jonas Sjöstedt, Bogusław Sonik, María Sornosa Martínez, Antonios Trakatellis, Evangelia Tzampazi, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Anders Wijkman
Substitutes present for the final vote	Margrete Auken, Milan Gaľa, Vasco Graça Moura, Rebecca Harms, Erna Hennicot-Schoepges, Miroslav Mikolášik
Substitutes under Rule 178(2) present for the final vote	
Date tabled – A6	20.6.2005 A6-0196/2005
Comments	