Basic information

1999/0238(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC) **Subject** 4.60.04.02 Consumer security 4.60.08 Safety of products and services, product liability	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	TRAKATELLIS Antonios (PPE-DE)	20/04/2005

Former committee responsible	Former rapporteur	Appointed
ENVI Environment, Climate and Food Safety		
ENVI Environment, Public Health, Consumer Policy	ARVIDSSON Per-Arne (PPE-DE)	26/01/2000

Former committee for opinion	Former rapporteur for opinion	Appointed
JURI Legal Affairs and Internal Market	MCCARTHY Arlene (PSE)	28/03/2000

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2389	2001-11-26
Competitiveness (Internal Market, Industry, Research and Space)	2605	2004-09-24
Competitiveness (Internal Market, Industry, Research and Space)	2289	2000-09-28
Competitiveness (Internal Market, Industry, Research and Space)	2265	2000-05-25
Agriculture and Fisheries	2692	2005-11-22

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	

Key events

Date	Event	Reference	Summary
10/11/1999	Legislative proposal published	COM(1999)0577	Summary
17/01/2000	Committee referral announced in Parliament, 1st reading		
24/05/2000	Vote in committee, 1st reading		Summary
24/05/2000	Committee report tabled for plenary, 1st reading	A5-0149/2000	
25/05/2000	Debate in Council		Summary
05/07/2000	Debate in Parliament		
06/07/2000	Decision by Parliament, 1st reading	T5-0334/2000	Summary
28/09/2000	Debate in Council		
26/11/2001	Debate in Council		
04/04/2005	Council position published	05467/1/2005	Summary
14/04/2005	Committee referral announced in Parliament, 2nd reading		
14/06/2005	Vote in committee, 2nd reading		Summary
20/06/2005	Committee recommendation tabled for plenary, 2nd reading	A6-0196/2005	
04/07/2005	Debate in Parliament		
05/07/2005	Decision by Parliament, 2nd reading	T6-0266/2005	Summary
05/07/2005	Results of vote in Parliament		
22/11/2005	Act approved by Council, 2nd reading		
14/12/2005	Final act signed		
14/12/2005	End of procedure in Parliament		
27/12/2005	Final act published in Official Journal		

Technical information

Procedure reference	1999/0238(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/30495 ENVI/6/27554

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee report tabled for plenary, 1st reading/single reading		A5-0149/2000 OJ C 067 01.03.2001, p. 0010	24/05/2000	
Text adopted by Parliament, 1st reading/single reading		T5-0334/2000 OJ C 121 24.04.2001, p. 0176-0410	06/07/2000	Summary
Amendments tabled in committee		PE359.891	01/06/2005	
Amendments tabled in committee		PE359.998	08/06/2005	
Committee recommendation tabled for plenary, 2nd reading		A6-0196/2005	20/06/2005	
Text adopted by Parliament, 2nd reading		T6-0266/2005 OJ C 157 06.07.2006, p. 0018-0057 E	05/07/2005	Summary

Council of the EU

Document type	Reference	Date	Summary
Council position	05467/1/2005 OJ C 144 14.06.2005, p. 0024-0029 E	04/04/2005	Summary
Council statement on its position	01182/2005	05/04/2005	
Draft final act	03645/1/2005	14/12/2005	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(1999)0577  OJ C 116 26.04.2000, p. 0014 E	10/11/1999	Summary
Commission communication on Council's position	COM(2005)0143 	12/04/2005	Summary
Commission response to text adopted in plenary	SP(2005)2923	14/07/2005	
Commission opinion on Parliament's position at 2nd reading	COM(2005)0434 	16/09/2005	Summary

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0243/2000 OJ C 117 26.04.2000, p. 0059	01/03/2000	

Additional information

Source	Document	Date

European Commission	EUR-Lex	

Final act	
Directive 2005/0084 OJ L 344 27.12.2005, p. 0040-0043	Summary

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 16/09/2005 - Commission opinion on Parliament's position at 2nd reading

The Commission states that it accepts in full all four amendments adopted by the European Parliament.

They are the result of a compromise package agreed between the Parliament and the Council with a view to the adoption of the Directive in second reading. The amendments are in line with the objectives of the Commission’s proposal and maintain the balance of interests achieved in the common position.

The amendments to the Common Position mainly refer to the extension of the restriction of the three phthalates DINP, DIDP and DNOP to all toys that can be placed in the mouth by children. In addition, the definition of childcare articles was extended to include the word "hygiene", and the Commission was asked to also review other applications, notably medical devices.

The conclusion of the compromise package has been facilitated by two declarations which the Commission made during the July 2005 Plenary session. (Please see the summary of 05/07/2005.)

Accordingly, the Commission amends its proposal as set out above.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 24/09/2004

The Council unanimously reached political agreement on a draft Directive that amends Directive 76/769/EEC in order to restrict the use of certain phthalates in toys and childcare articles.

Phthalates are substances which are used as softeners in plastic materials. Some of them have been identified as reprotoxic. On the basis of the text agreed by the Council, toys and childcare articles will be forbidden and cannot be placed on the market if DEHP, DBP or BBP3 occur in concentrations exceeding 0,1% of the plasticised part of the item. This also applies for toys and childcare articles, the plasticised parts of which contain DINP, DIDP and DNOP4 in concentrations exceeding the same limit, if those articles are intended for children under three years and can be placed in the mouth.

The provisions will be subject to a review, in the light of new scientific information on these substances and their substitutes, no later than four years after the Directive has entered into force.

The Council took note of a written statement by the Commission on the implementation of certain provisions of the draft Directive and of an oral statement by the Danish delegation on its general position in relation to this legislative proposal.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 25/05/2000

On the basis of a progress report presented by the Presidency, the Council held an exchange of views on a proposal for a 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 Directive 88/378/EEC on the approximation of laws of the Member States concerning the safety of toys. In view of continued divergencies between delegations, the Council invited the Permanent Representatives Committee to pursue work on this dossier with a view to enabling the Council to reach an agreement, in light of the forthcoming Opinion of the European Parliament, on this proposal.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 12/04/2005 - Commission communication on Council's position

The Commission supports the common position because it is founded on the precautionary measures needed to protect children having regard also to considerable scientific uncertainty as to whether certain phthalates can present a risk to them. In addition, the Commission supports the common position provisions for the review of scientific developments on phthalates and their potential substitutes after 4 years.

Lastly, the Commission made a declaration at the Competitive Council Meeting on 24 September 2004 announcing its intention to prepare a guidance document in order to facilitate the implementation of the Directive. This document will address in particular the provisions on restrictions of certain substances in toys and childcare articles intended for children under three years of age insofar as they concern the condition "which can be placed in the mouth by them" as specified in the annex to the Directive.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 05/07/2005 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Antonios **TRAKATELLIS** (EPP-ED, EL) and voted in favour of a permanent ban on six phthalates in toys and childcare articles. The plenary approved the compromise reached by the rapporteur with the Council just after the vote that took place on 14/06/2005 in the Environment Committee.

DINP, DIDP and DNOP shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticised material, intoys and childcare articles which can be placed in the mouth by children.The ban applies irrespective of the age for which the toys and articles are made.

In addition a new definition of childcare articles includes any product intended to facilitate hygiene.

A new recital states that 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 medical devices.

Finally, there are two Statements annexed to the resolution. One concerns the fact that the Commission, in consultation with Member States' experts responsible for the management of Directive 76/769/EEC and stakeholders, will prepare a guidance document in order to facilitate the implementation of the Directive. The document will address in particular the provisions on restrictions of certain substances in toys and childcare articles intended for children insofar as they concern the condition "which can be placed in the mouth" as specified in the annex to the Directive. The aspects related to "accessible" plasticised material and "handheld" toys will be examined.

The second statement confirms the Commission's intention to address the issue of fragrances in toys in the framework of the revision of Council Directive 88/378/EEC on the safety of toys. This will identify exactly what should be understood as fragrances, consider the appropriate measures to deal with the risks identified and ensure consistency with the other legislative provisions of the said Directive.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 06/07/2000 - Text adopted by Parliament, 1st reading/single reading

The European Parliament, in its first reading, adopted a resolution (Per-Arne ARVIDSSON, EPP/ED, Sweden) on phthalates and toy safety. The main amendments to the Commission's proposal were as follows: - in the case of toys that contain phthalates and are intended for children between the ages of three and six, but which younger children could place in their mouths, warnings must be placed on the packaging and on the toy itself. -the prohibition applies to all phthalates and not the six in the Commission's proposal. -the ban is extended to all toys, not just toys intended for children under three, and not only toys that are designed to be placed in the mouth. Toys which can be placed in the mouth by children may have concentrations no greater than 0.5%, rather than 1% envisaged by the original proposal. -fragrances may not be added to toys containing phthalates which a child can place in its mouth.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 10/11/1999 - Legislative proposal

PURPOSE: To harmonise provisions relating to phthalates in toys and child care articles in order to ensure a high level of health protection, notably of young children.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: The purpose of the proposed Directive is to harmonise provisions on phthalates is toys and child care articles in order to ensure a high level of health protection for young children under the age of three. The proposed Directive is being presented on the back of research conducted in Denmark and Spain, which indicates that unsafe levels of phthalates are migrating from certain soft PVC child care articles. The Commission's preferred route of action is to initiate an outright ban on the use of certain phthalates in PVC toys and child care articles put in the mouth by small children under the age of three. An additional provision would ensure that soft PVC toys intended for children under the age of three, which could be put in the mouth, should carry a label alerting carers that children should not put those toys in their mouths. To enact the ban the Commission is proposing to amend, for the twenty second time, Directive 76/769/EEC relating to restriction on the marketing and use of certain dangerous substances and preparations (phthalates). At the same time it is proposing an amendment to Council Directive 88/378/EEC concerning the safety of toys. The phthalates concerned are DINP and DEHP. It should be noted that a ban was chosen over an above testing methods given that tests for detecting the migration of phthalates are incomplete and are therefore not sufficiently good enough for regulatory purposes.

As the adoption and implementation of the proposed ban on phthalates will take a certain period of time, the Commission is proposing to simultaneously agree to Council Decision, Article 9 of the Directive on Product Safety, which requires the Member States to take temporary measures to implement the prohibition within less than 10 days.

Given that most of the Member States have already notified their intention to introduce (in the framework of Commission Recommendation 98/485/EC) national bans on the use of phthalates in toys, the costs are considered minimal. In addition, industry has adapted to the situation and in a majority of Member States, most of the products in question no longer contain phthalates.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 14/12/2005 - Final act

PURPOSE: to ban the use of phthalates in toys and childcare articles.

LEGISLATIVE ACT: Directive 2005/84 of the European Parliament and of the Council amending for the 22nd time Council Directive 76/769 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).

CONTENT: The scope of Directive 76/769 has been extended to include the use of phthalates in toys and "childcare articles" (meaning any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children). In doing so the Community has effectively banned and restricted the use of phthalates in toys and childcare articles. The Commission will re-evaluate the situation by 16 January 2010 at the latest. By 16 July 2006, the Member States must adopt and publish the laws, regulation and administrative provisions necessary to comply with this Directive. The measures must apply from 16 January 2007.

ENTRY INTO FORCE: 16 January 2006.

Child health protection: phthalates, dangerous substances, safety of toys (amend. Directives 76/769/EEC, 88/378/EEC)

1999/0238(COD) - 04/04/2005 - Council position

The Council's common position represents a fresh start after several years of stalemate and therefore does not address each of the amendments proposed by the European Parliament during the first reading.

The Council wishes to move forward in the same direction as the European Parliament, by significantly broadening the scope of the ban, replacing labelling with an outright ban. The Council believes that this will greatly assist towards adopting a permanent ban, subject to a continuous review, leading to an even broader ban, should new scientific evidence arise after its entry into force.

More specifically, as far as the group of phthalates is concerned which have been classified as CMR (carcinogen, mutagen, reprotoxic) substances, the proposal goes further than the amendments of the European Parliament by banning their use in toys regardless of the age-group.

For the other group of phthalates, the common position follows the proposed amendments. A review clause, as suggested by the European Parliament, has been included in the proposal.

The amendments relating to the labelling of toys and childcare articles and the banning of fragrances have not been taken into account, because bearing in mind the risk assessment results and the wider scope of the proposed limitations as compared to the ones initially proposed these measures were not considered proportional.

Moreover, the Council has introduced new modifications as follows:

- the introduction of the obligation for the Commission to review these measures within four years from their entry into force;

- compliance with the guidelines on drafting legislative texts, and to add the obligation for Member States to notify the transposition measures to the Commission;

- in the Annex, the scope of the ban has been clarified, by extending it, for DEHP, DBP and BBP to all toys and childcare articles; for DINP, DIDP and DNOP, the ban will cover toys and childcare articles intended for children under three years of age and which can be placed in the mouth by them. In both cases, it has been clarified that the concentration limit of 0,1 % of the mass applies to the plasticised material mass, so that in case of items which include both plasticised material and other components, it

remains applicable in full to the plasticised part only.