EUROPEAN PARLIAMENT

1999 *2004*

Session document

FINAL
A5-0181/2002

24 May 2002

***I
REPORT

on the proposal for a European Parliament and Council directive amending, for the twenty-fifth 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 (substances classified as carcinogens, mutagens or substances toxic to reproduction – c/m/r)
(COM(2002) 70 – C5-0063/2002 – 2002/0040(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Inger Schörling

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.

CONTENTS

Page

PROCEDURAL PAGE 4

DRAFT LEGISLATIVE RESOLUTION.....5

EXPLANATORY STATEMENT 8

PROCEDURAL PAGE

By letter of 12 February 2002 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 twenty-fifth 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 (substances classified as carcinogens, mutagens or substances toxic to reproduction – c/m/r) (COM(2002) 70 - 2002/0040(COD)).

At the sitting of 27 February 2002 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible (C5-0063/2002).

The Committee on the Environment, Public Health and Consumer Policy had appointed Inger Schörling rapporteur at its meeting of 20 February 2002.

It considered the Commission proposal and draft report at its meetings of 23 April 2002 and 23 May 2002.

At the latter meeting it adopted the draft legislative resolution by 43 votes to 0, with 1 abstention.

The following were present for the vote: Caroline F. Jackson, chairman; Alexander de Roo and Anneli Hulthén, vice-chairmen; Inger Schörling, rapporteur; María del Pilar Ayuso González, Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Hans Udo Bullmann (for Catherine Stihler, pursuant to Rule 153(2)), Philip Bushill-Matthews (for Per-Arne Arvidsson), Rosa M. Díez González (for María Sornosa Martínez, pursuant to Rule 153(2)), Avril Doyle, Jillian Evans (for Marie Anne Isler Béguin...), Francesco Fiori (for Raffaele Costa, pursuant to Rule 153(2)), Karl-Heinz Florenz, Robert Goodwill, Cristina Gutiérrez Cortines, Jutta D. Haug (for Rosemarie Müller), Heidi Anneli Hautala (for Patricia McKenna), Hedwig Keppelhoff-Wiechert (for Marialiese Flemming), Christa Klaß, Bernd Lange, Peter Liese, Torben Lund, Jorge Moreira da Silva, Eluned Morgan (for Elena Valenciano Martínez-Orozco), Emilia Franziska Müller, Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Neil Parish (for Françoise Grossetête), Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Guido Sacconi, Giacomo Santini (for Eija-Riitta Anneli Korhola), Karin Scheele, Horst Schnellhardt, Jonas Sjöstedt, Robert William Sturdy (for Martin Callanan), Astrid Thors, Antonios Trakatellis and Kathleen Van Brempt.

The report was tabled on 24 May 2002.

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

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending, for the twenty-fifth 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 (substances classified as carcinogens, mutagens or substances toxic to reproduction – c/m/r) (COM(2002) 70 – C5-0063/2002 – 2002/0040(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 70[1]),

– having regard to Article 251(2) of the EC Treaty and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0063/2002),

– 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 (A5-181/2002),

1. Approves the Commission proposal as amended;

2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Recital 3 a (new)	
	(3a) The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, after being consulted by the Commission, has stated that substances classified according to Council Directive 67/548/EEC as carcinogens category 1 or 2 (except substances only carcinogenic by inhalation), mutagens category 1 and 2, or toxic to reproduction category 1 or 2 and

[1] OJ C not yet published.

substances with similar potentials, must not be intentionally added to cosmetic products.

Justification

The Scientific Committee's opinion of 25 September 2001 needs to be referred to.

Amendment 2
Recital 3 b (new)

(3b) To improve health protection and consumer safety against the use of preparations containing substances classified as carcinogenic, mutagenic or toxic to reproduction, the derogation for cosmetic products from the ban of the sale to the general public of such preparations should be deleted.

Justification

Directive 76/769/EEC excludes cosmetic products from the ban of the sale to the general public of substances and preparations classified as CMR. This derogation was introduced to allow specific rules for cosmetics. This would make sense insofar as one may want to envisage special and stricter rules on cosmetics, given the very direct, repeated and prolonged exposure of consumers to such products. However, the opposite is true - CMR substances are not fully restricted in current legislation on cosmetics. The derogation for cosmetic products in Directive 76/769/EEC has the absurd effect that while the use of CMR substances is rightly banned from all preparations, such as e.g. paints and shoe polish, they may continue to be used in preparations such as cosmetic products.This derogation needs to be deleted in line with the latest opinion of the Scientific Committee.

Amendment 3
Article 1

Annex I to directive 76/769/EEC is hereby amended as follows:

1. In the column entitled "Conditions of restriction", the following is deleted from points 29, 30 and 31: "(b) cosmetic products as defined by Directive 76/768/EEC"

The substances listed in the Annex to this Directive shall be added to those substances listed in the appendix concerning points 29,

2. The substances listed in the Annex to this Directive shall be added to those substances listed in the appendix

30 and 31 of Annex I to Directive 76/769/EEC. The substances listed in the Annex to this Directive in point 1(c) shall be deleted from list 2 of point 29 of Annex Annex I to Directive 76/769/EEC.	concerning points 29, 30 and 31 of Annex I to Directive 76/769/EEC. The substances listed in the Annex to this Directive in point 1(c) shall be deleted from list 2 of point 29 of Annex Annex I to Directive 76/769/EEC.

Justification

Directive 76/769/EEC excludes cosmetic products from the ban of the sale to the general public of substances and preparations classified as CMR. This derogation was introduced to allow specific rules for cosmetics. This would make sense insofar as one may want to envisage special and stricter rules on cosmetics, given the very direct, repeated and prolonged exposure of consumers to such products. However, the opposite is true - CMR substances are not fully restricted in current legislation on cosmetics. The derogation for cosmetic products in Directive 76/769/EEC has the absurd effect that while the use of CMR substances is rightly banned from all preparations, such as e.g. paints and shoe polish, they may continue to be used in preparations such as cosmetic products. This derogation needs to be deleted in line with the latest opinion of the Scientific Committee.

Amendment 4
Draft legislative resolution

Paragraph 2 a (new)

	1a. Asks the Commission to make publically available a consolidated list of Annex I of Directive 76/769/EEC, as well as of Annexes I of Directive 67/548/EEC and Directive 99/45/EC, and to update this consolidation after each modification of these directives.

Justification

The transparency of current chemicals legislation is seriously hampered by a lack of publically available Annexes in consolidated form of the relevant directives.

EXPLANATORY STATEMENT

This proposal for a directive seeks to amend for the twenty-fifth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations. It proposes to add a list of substances classified as category 1 or 2 carcinogens, mutagens or substances toxic to reproduction (c/m/r) to Annex I of Directive 76/769/EEC. Inclusion in the Annex stipulates that these substances, or preparations containing them, may not be placed on the market for sale to the general public. The proposal covers a total of 44 substances.

The Commission justified its proposal by stating that "*Due to the fact that use of chemicals by consumers cannot be controlled, safety can only be ensured by prohibiting use by consumers of c/m/r substances and preparations*".

This raises the question of whether "*substances and preparations*" cover all relevant uses by consumers of c/m/r substances. Substances are defined as individual compounds, and preparations are defined as mixtures or solutions of compounds. This does not cover articles, such as e.g. toys or flooring. While there is currently no definition of what is an article, the Working Group on Substances in Products that was set up for the revision of the EU chemicals policy agreed on the following definition in January 2002: "An article is a manmade object which during manufacturing has been given a special shape, surface or form which determine its function to a greater degreee that does its chemical composition".

The European Environment Agency and the UN Environment Programme found that consumer goods can be one of the main route of exposure to chemicals. All published risk assessments of existing c/m/r substances pursuant to current chemicals legislation found a need for limiting the risk when there was use in consumer products. The scientific committee on cosmetics stated that c/m/r substances in category 1 and 2 should not be added to cosmetic products.

Given that consumers get in direct contact with articles, safety can only be ensured if the use of these substances is also prohibited in articles. This is fully in line with the justification of the Commission for its proposal.

The problem is best illustrated by one of the substances now proposed for addition to the Annex: bis(2-ethylhexyl)phthalate (DEHP). DEHP has been classified toxic to reproduction category 2. In 1997, annual use of DEHP in Western Europe was close to 500,000 tonnes. DEHP is the main plasticiser used in PVC, and it is almost exclusively used as a PVC plasticiser (97%). The remaining 3% are used in non-polymer applications, such as inter alia adhesives and sealants or printing inks. While the use of DEHP in the non-polymer applications would be covered in this proposal - the applications qualify as "preparations" - the use of DEHP in flexible PVC would not be covered, as this concerns "articles".

Flexible PVC is used in many different articles such as toys and child-care articles, flooring, cables, hoses, leather imitation textiles. The typical concentration of DEHP in soft PVC is around 30%. It is well known and undisputed that DEHP leaches out of PVC during use, as it is not chemically bound to the PVC polymer. Around 78% of the PVC uses are estimated to be indoor applications. Safer alternatives to soft PVC, which replace the need for the PVC softener DEHP, are available for all applications.

It is absurd that the ban of the sale to the general public of DEHP should only apply to the substance itself and to preparations that contain it, but not to everyday articles containing it, although articles represent the large majority of the uses of DEHP. Consumers get in touch with these articles, and DEHP is used in high concentrations in them.

It is also suggested by the rapporteur that the European Parliament should help to illustrate why the sale to the general public of c/m/r substances should not only apply to substances and preparations, but also to articles, if safety of consumers is to be ensured. On 5 February, the European Parliament adopted a recital in first reading on the analogous 23rd amendment to this directive to address this lacuna. It called on the Commission to "submit a proposal by the end of 2002 to prohibit the use of such substances in products for use by the general public". This suggestion was not endorsed by the committee.

Your rapporteur suggested to improve the wording of the recital adopted in the context of the first reading on the 23rd amendment to the Directive and to add this request to the Annex of the Directive to give it more strength.