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

on the proposal for a directive of the European Parliament and of the Council relating to restrictions on the marketing and use of nonylphenol, nonylphenol ethoxylate and cement (twenty-sixth amendment of Council Directive 76/769/EEC)
(COM(2002) 459 – C5-0382/2002 – 2002/0206(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Paul A.A.J.G. Lannoye

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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PROCEDURAL PAGE

By letter of 16 August 2002 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a directive of the European Parliament and of the Council relating to restrictions on the marketing and use of nonylphenol, nonylphenol ethoxylate and cement (twenty-sixth amendment of Council Directive 76/769/EEC) (COM(2002) 459 – 2002/0206 (COD)).

At the sitting of 2 September 2002 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 Industry, External Trade, Research and Energy for its opinion (C5-0382/2002).

The Committee on the Environment, Public Health and Consumer Policy appointed Paul A.A.J.G. Lannoye rapporteur at its meeting of 2 October 2002.

It considered the Commission proposal and draft report at its meetings of 21 January and 19 February 2003.

At the latter meeting it adopted the draft legislative resolution by 40 votes to 2, with 1 abstention.

The following were present for the vote: Caroline F. Jackson, chairman; Mauro Nobilia, Alexander de Roo and Guido Sacconi, vice-chairmen; Paul A.A.J.G. Lannoye, rapporteur; María del Pilar Ayuso González, Emmanouil Bakopoulos (for Pernille Frahm), Hans Blokland, David Robert Bowe, Hiltrud Breyer, Giles Bryan Chichester (for John Bowis), Dorette Corbey, Anne Ferreira, Jim Fitzsimons, Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Laura González Álvarez, Robert Goodwill, Françoise Grossetête, Jutta D. Haug (for Torben Lund), Marie Anne Isler Béguin, Bernd Lange, Peter Liese, Giorgio Lisi (for Martin Callanan), Jules Maaten, Minerva Melpomeni Malliori, Erik Meijer (for Mihail Papayannakis), Emilia Franziska Müller, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Béatrice Patrie, Marit Paulsen, Fernando Pérez Royo (for Elena Valenciano Martínez-Orozco), Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Inger Schörling, Jonas Sjöstedt, María Sornosa Martínez, Catherine Stihler, Charles Tannock (for Raffaele Costa), Kathleen Van Brempt and Phillip Whitehead.

The opinion of the Committee on Industry, External Trade, Research and Energy is attached.

The report was tabled on 20 February 2003.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a directive of the European Parliament and of the Council relating to restrictions on the marketing and use of nonylphenol, nonylphenol ethoxylate and cement (twenty-sixth amendment of Council Directive 76/769/EEC) (COM(2002) 459 – 2002/0206 (COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 459¹),
 - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0382/2002),
 - 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 and the opinion of the Committee on Industry, External Trade, Research and Energy (A5-0044/2003),
1. Approves the Commission proposal as amended;
 2. Asks to the matter to be referred to it 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.

Text proposed by the Commission

Amendments by Parliament

Amendment 1
Recital –1 (new)

(-1) Nonylphenol (NP) is classified inter alia as a substance that is ‘very toxic to aquatic organisms’ and ‘may cause long-term adverse effects to the aquatic environment’ pursuant to directive 67/548/EEC. The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) confirmed the oestrogenic effect of NP as demonstrated in the risk assessment, in accordance with Regulation (EEC) 793/93. NP is classified as a

¹ Not yet published in the OJ.

'priority hazardous substance' pursuant to framework directive 2000/60/EC on water, owing to its persistence, bioaccumulation and aquatic toxicity, as well as its endocrine-disrupting potential, in line with the OSPAR list of chemicals for priority action. Article 16(6) of the water framework directive requires the cessation or phasing-out of discharges, emissions and losses of such substances.

Justification

The full picture of the properties of NP as classified in EC legislation, its endocrine-disrupting properties, as well as of the provisions applicable to it under the water framework directive and the OSPAR Convention need to be given. This is particularly relevant with regard to the presence of NPE in pesticides and biocides since they come into direct contact with the environment.

Amendment 2 Recital 2 a (new)

(2a) A recent German study of different foodstuffs commercially available in Germany found that NP is ubiquitous in food. Miscellaneous pathways of how NP could get into food are indicated. These include the use of NPE in cleaning agents or pesticides in stables, food industries and in agriculture. Certain packaging materials are indicated as another possible source. The CSTE also pointed to possible risks from the use of NPE in pesticides and confirmed that certain packaging materials could lead to the transfer of NP to food.

Justification

The findings of NP in virtually all food samples analysed by the renowned Institute of Applied Physical Chemistry, Research Centre Juelich, are an important fact to justify the extension of the scope of the restrictions of the use of NPEs to pesticides and to food packaging material. The risk assessment which forms the basis for the Commission proposal concluded with the need for restrictions on various uses, but not for the use of NPE in pesticide formulation. Importantly, while the CSTE agreed with the conclusions of the risk assessment, it did not agree with the

conclusions on the use in pesticide formulations.

Amendment 3
Recital 2 b (new)

(2b) In 2001, the OSPAR Commission recommended taking action to prevent the substitution of NP/NPE with other alkylphenols with similar properties. Butylphenol is listed as a priority substance pursuant to regulation (EEC) 793/93. Octylphenol and phenylphenol are listed amongst the twelve endocrine-disrupting substances that are given highest priority in the Commission's Communication on the implementation of the Community Strategy for Endocrine Disrupters. Alternatives to NPE such as alcohol ethoxylates, which are fully biodegradable, are already being used widely.

Justification

Various alkylphenols are under intense scrutiny owing to their hazardous properties. This should be kept in mind in order to avoid nonylphenol being replaced with them.

Amendment 4
Recital 2 c (new)

(2c) In order to protect the environment and public health, it is necessary to establish very low concentration limit values for NP and NPE in sewage sludge that is to be spread on land.

Justification

The Commission's recommendation on the risk evaluation and the risk reduction strategies recommends that 'consideration be given to the development of provisions on concentration limit values for NP and NPE when sludge is spread on land'. It seems appropriate to ensure the

follow-up of this recommendation by incorporating a request to this effect into this directive.

Amendment 5
Recital 3

(3) In order to protect the environment, it therefore appears necessary that the placing on the market and the use of NP and NPE should be ***restricted to specific uses***.

(3) In order to protect the environment ***and public health***, it therefore appears necessary that the placing on the market and the use of NP and NPE should be ***phased out in all uses which result in discharges, emissions or losses to the environment or in human exposure and that control systems should be used in order to ensure that waste water is free of phenols and derivatives***.

Justification

Wording in line with the classification of NP as a priority hazardous substance in the water framework directive, with the addition of human exposure.

Phenols have a particularly serious environmental impact and steps must be taken to ensure that waste water is free of such products. Their presence can be easily tested for using appropriate analytical determination methods, the cost of which is derisory.

Amendment 6
Recital 4

(4) Scientific studies have ***also*** shown that cement preparations containing chromium VI ***may*** cause allergic reactions ***in certain circumstances***, if there is direct and prolonged contact with the human skin.

(4) ***Chromium VI compounds are classified as carcinogenic, mutagenic and sensitising pursuant to directive 67/548/EEC***. Scientific studies have shown that cement preparations containing chromium VI cause ***a significant increase in the cancer risk for cement workers due to inhalation of cement dust, as well as allergic reactions, if there is direct and prolonged contact with the human skin. All uses of cement bear the risk of direct and prolonged contact with the human skin.***

Justification

The classification of chromium VI compounds in EC legislation needs to be given explicitly so as to take appropriate measures.

The evidence about increased cancer risk to the upper respiratory tract for cement workers needs to be mentioned. The wording by the Commission is overcautious and too conditional - the CSTEE in comparison states very clearly that 'chromium in cement induces sensitisation and causes serious allergic reactions in construction workers'.

Although the major proportion of the use of cement is largely automated, it always also involves manual activities which lead to contact with the human skin.

Amendment 7 Recital 4 a (new)

(4a) On the basis of the latest available scientific data, the Commission shall, at the latest by xx.xx.200x [two years after the date of the adoption of this Directive], submit a proposal to the Council and the Parliament for adoption of a further reduction of the limit value for chromate VI in cement and cement products.

Justification

Scientific studies have shown that allergic reactions caused by cement containing chromate VI are already to be found with exposure values of between 1.2 and 1.4 ppm. Due to this fact and to secure a high level of social and environmental protection, the Commission is obliged to take initiatives to reduce to level of chromate in cement, in no longer than 2 years after the adoption of the Directive.

Amendment 8 Recital 5 a (new)

(5a) Individual protection measures are necessary, but not sufficient to prevent skin contact with cement. Moreover, according to the hierarchy of protection provisions of directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, the

employer shall ensure as a priority that the level of exposure is reduced to as low a level as possible when substitution is impossible, and apply individual protection measures only where exposure cannot be prevented by other means.

Justification

According to EC legislation, individual protection measures are the measure of last resort.

Amendment 9
Recital 6

(6) In order to protect human health, it therefore appears necessary to restrict the placing on the market and the use of cement. ***In particular, the placing on the market and the use of cement*** or cement preparations containing more than 2 ppm chromium VI ***should be restricted in the case of manual activities where there is a risk of contact with the skin.***

(6) In order to protect human health, it therefore appears necessary to restrict the placing on the market and the use of cement or cement preparations containing more than 2 ppm chromium VI.

Justification

The suggested limitation of the restriction of certain cement to manual activities is inappropriate, as there is no definition of manual activities and no common understanding across Member States as to which activities would actually be covered. Although the major proportion of the use of cement is largely automated, it always also involves manual activities which lead to contact with the human skin.

Amendment 10
Recital 6 a (new)

(6a) Chromium VI compounds are used in various applications. Their use has already been prohibited in Directive 2000/53/EC on end-of-life vehicles and will be prohibited in Directive 2002/95/EC on the restriction of certain hazardous

substances in electrical and electronic equipment. A risk assessment of five chromium VI compounds has been ongoing since 1997. The latest draft of November 2002 showed the need for risk reductions for almost all applications, such as e.g. metal treatment. In order to protect human health and the environment, risk reduction measures should be taken by the Community without delay and a risk reduction strategy has therefore to be established immediately. Thus it seems appropriate that Council Directive 76/769/EC of 27 July 1976 be adapted so as to restrict the usage of chromium VI to closed circuits, and requests the Commission to draft a proposal in this regard at the latest by xx.xx.200x [two years after the date of adoption of this Directive].

Justification

Exposure to chromium VI can occur from various sources. While several applications have already been banned, very many of them still remain unregulated. The risk assessment has been going on for six years. Given the dangers of the substance, regulatory action is needed urgently.

Amendment 11

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, INTRODUCTORY PHRASE

Annex I, point XX (Directive 76/769/EEC)

May not be placed on the market or used as **a substance** or **constituent** of preparations in concentrations equal or higher than 0,1 % by mass **nonylphenol** or **1 % by mass nonylphenol ethoxylate** for the following purposes:

May not be placed on the market or used as **substances** or **constituents** of preparations **or articles** in concentrations equal or higher than 0,1 % by mass for the following purposes:

Justification

Although the restriction should amount to a complete ban of the use of that substance, the

threshold is not set at 0% in customary law, as this would make effective controls and enforcement difficult, given background exposure or contamination at trace level. The standard threshold for the restrictions of the use of a substance in preparations is set at 0,1%. This threshold bears no relationship to the toxicity of the substance. It is a mere administrative threshold. As there is no reason to abandon what is established customary law, the same threshold of 0,1% as used for NP should also be used for NPE.

Amendment 12

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 1
Annex I, point XX (Directive 76/769/EEC)

(1) industrial and institutional cleaning
except:

- controlled closed dry cleaning systems
where the washing liquid is recycled or
incinerated,

- cleaning systems with special treatment
where the washing liquid is recycled or
incinerated;

(1) industrial and institutional cleaning **and
washing** except:

- controlled closed dry cleaning systems
where the washing liquid is recycled or
incinerated, **so that there is no release into
the environment,**

- cleaning systems with special treatment
where the washing liquid is recycled or
incinerated, **so that there is no release into
the environment,**

Justification

Cleaning will be defined only narrowly in future legislation on detergents by reference to an ISO standard. Washing will be defined more concretely as meaning the cleaning of laundry, fabrics, dishes or kitchen utensils. In order to avoid any possible loopholes, it is suggested that both terms be used.

By analogy with the wording proposed by the Commission on textiles and leather processing (paragraph 3), the derogations should only apply to systems which are truly closed with no release into the environment.

Amendment 13

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 2
Annex I, point XX (Directive 76/769/EEC)

(2) domestic cleaning;

(2) domestic cleaning and **washing**;

Justification

Cleaning will be defined only narrowly in future legislation on detergents by reference to an ISO standard. Washing will be defined more concretely as meaning the cleaning of laundry, fabrics, dishes or kitchen utensils. In order to avoid any possible loopholes, it is suggested that both terms be used.

Amendment 14

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 3,
INDENT 1

Annex I, point XX (Directive 76/769/EEC)

- processing with no release into waste water **and where the NPE is fully bound in the polymer matrix (finishing agents, textile printing, dyestuffs),**

- processing with no release into waste water,

Justification

It is often suggested that certain chemical substances are fully bound in the polymer matrix, only to find that a certain amount does migrate, in particular if they are used as additives with no chemical link to the polymer. As NPE is normally used as an additive in polymerisation, there is no reason to believe that it will be fully bound in the polymer matrix, especially not when the products in question are subject to washing or intensive use.

Amendment 15

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUPARAGRAPH 3,
INDENT 2

Annex I, point XX (Directive 76/769/EEC)

- systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);

- systems with special treatment where the process water is pre-treated to remove the organic fraction completely **and subjected to spectrophotometric testing to ensure that it is free of phenols and derivatives thereof** prior to biological waste water treatment (degreasing of sheepskin);

Justification

Phenols have a particularly serious environmental impact and steps must be taken to ensure that

waste water is free of such products. Their presence can be easily tested for using appropriate analytical determination methods, the cost of which is derisory. This is because phenols (in this instance, of organic origin) may in some cases escape the organic fraction and dissolve completely in the water. Spectrophotometric testing can provide a cast iron guarantee that the water is free of phenols and can be afforded by all companies.

Amendment 16

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 5,
INDENT 1

Annex I, point XX (Directive 76/769/EEC)

- uses in controlled closed systems where the washing liquid is recycled or incinerated;
- uses in controlled closed systems where the washing liquid is recycled or incinerated, ***so that there is no release into the environment;***

Justification

By analogy with the wording proposed by the Commission on textiles and leather processing (paragraph 3), the derogations should only apply to systems which are truly closed with no release to the environment.

Amendment 17

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 6 A
(new)

Annex I, point XX (Directive 76/769/EEC)

(6a) as co-formulants in plant protection products pursuant to Directive 91/414/EEC; existing national authorisations of plant protection products containing NPE as a co-formulant shall be reviewed pursuant to Article 4(5) of Directive 91/414/EEC, with a view to cancelling such authorisations pursuant to Article 4(6) of that Directive, at the latest by xx.xx.200x [one year after the date of entry into force of this Directive];

Justification

NP has been classified as a priority hazardous substance in the water framework directive.

According to that directive, the discharge, emissions and losses of such substances must be stopped. Pesticides are directly released into the environment. The use of NPE in pesticides is therefore no longer tenable.

Pursuant to Commission Regulation (EC) 2076/2002, the authorisation of the use of NP as an active substance in plant protection products will have to be withdrawn by July 2003. However, no action has yet been taken on the use of NPE as co-formulants in pesticides. They should therefore be covered by this directive. There should not be any more new authorisations of NPE as a co-formulant in pesticides, and existing authorisations should be reviewed and cancelled.

Article 4(5) of Directive 91/414/EEC provides that authorisations may be reviewed at any time if there are indications that any of the requirements referred to in Article 4(1) of that Directive are no longer satisfied. Article 4(1)(v) stipulates that an authorisation may only be granted if it is established that a plant protection product has no unacceptable influence on the environment, having particular regard to its fate and distribution in the environment, and its impact on non-target species. Given the persistence, bioaccumulation and toxicity of NP (the breakdown product of NPE), and its endocrine-disrupting effect, which is particularly well documented for the non-target species of fish, it is clear that the requirements of the pesticides directive are not met by the use of NPE as a co-formulant and that any authorisations granted should therefore be cancelled.

Amendment 18

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 6 B
(new)

Annex I, point XX (Directive 76/769/EEC)

(6b) as active substances or as co-formulants in biocidal products pursuant to Directive 98/8/EC; existing national authorisations of biocidal products containing NPE as an active substance or as a co-formulant shall be reviewed pursuant to Article 6 of Directive 98/8/EC, with a view to cancelling such authorisations pursuant to Article 7 of that Directive, at the latest by xx.xx.200x [one year after the date of entry into force of this Directive];

Justification

NP has been classified as a priority hazardous substance in the water framework directive. According to that directive, the discharge, emissions and losses of such substances must be stopped. Biocides are directly released into the environment. The use of NPE in biocides is therefore no longer tenable.

While the authorisation of the use of NP as an active substance in pesticides will have to be withdrawn by July 2003, no such action has yet been taken on the use of NP in biocides, neither for its use as an active substance nor as a co-formulant. Both these uses should therefore be covered by this directive. There should not be any more new authorisations, and existing authorisations should be reviewed and cancelled.

Article 6 of Directive 98/8/EC provides that authorisations may be reviewed at any time if there are indications that any of the requirements referred to in Article 5 of that Directive are no longer satisfied. Article 5(1) stipulates that an authorisation may only be granted if it is established that a biocidal product has no unacceptable influence on the environment, having particular regard to its fate and distribution in the environment, and its impact on non-target organisms. Given the persistence, bioaccumulation and toxicity of NP (the breakdown product of NPE), and its endocrine-disrupting effect, which is particularly well documented for the non-target species of fish, it is clear that the requirements of the biocides directive are not met by NPE and that any authorisations granted should therefore be cancelled.

Amendment 19

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 7
Annex I, point XX (Directive 76/769/EEC)

(7) cosmetics including shampoos;

**(7) cosmetic products as defined in
directive 76/768/EEC;**

Justification

The wording suggested by the Commission is odd, as the definition of cosmetic products according to the cosmetics directive includes shampoos. For reasons of legal clarity, the existing definition of cosmetic products pursuant to the directive on cosmetics should be used.

Amendment 20

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 8 A
(new)
Annex I, point XX (Directive 76/769/EEC)

**(8a) Preparations for sale to the general
public;**

Justification

NPE can be found for example in preparations such as paints and inks. Given the properties of NPE/NP, and by analogy with the restrictions in points 29, 30 and 31 of Annex I of Directive 76/769/EEC on the use of substances that are carcinogenic, mutagenic or toxic to reproduction

in preparations for sale to the general public, the restriction of NP/NPE should be extended to all preparations on sale to the general public.

Amendment 21

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1, SUBPARAGRAPH 8 B
(new)
Annex I, point XX (Directive 76/769/EEC)

(8b) Food packaging and additives to food packaging;

Justification

Free NP can be found in Tris(nonylphenyl)phosphite, a stabiliser used in certain plastics used for food packaging. Given the properties of NP, such uses should be covered by the restriction.

Amendment 22

ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1 A (new)
Annex I, point XX (Directive 76/769/EEC)

(1a) The Commission shall put forward at the latest by xx.xx.200x [one year after the date of entry into force of this Directive] a proposal to amend Directive 86/278/EEC on sewage sludge with a view to establishing a concentration limit value for NP and NPE.

Justification

The Commission's recommendation on the risk evaluation and the risk reduction strategies of NP recommends that 'consideration be given to the development of provisions on concentration limit values for NP and NPE when sludge is spread on land'. It seems appropriate to ensure the follow-up of this recommendation by incorporating a request to this effect into this directive.

Amendment 23
ANNEX, POINT XX, RIGHT-HAND COLUMN, PARAGRAPH 1 B (new)
Annex I, point XX (Directive 76/769/EEC)

(1b) The Commission shall review the use of alkylphenols as possible substitutes for NPE and put forward a proposal with a view to preventing their use as substitutes for NPE at the latest by xx.xx.200x [one year after the date of entry into force of this Directive].

Justification

Various alkylphenols are under intense scrutiny owing to their hazardous properties. In 2001 the OSPAR Commission recommended taking action to prevent the substitution of NP/NPEs with other alkylphenols with similar properties. Appropriate legislative action is therefore called for.

Amendment 24
ANNEX, POINT XX CEMENT, RIGHT-HAND COLUMN, PARAGRAPH 1
Annex I, point XX Cement (Directive 76/769/EEC)

May not be placed on the market or used as a substance or constituent of preparations, if it contains more than 0,0002 % soluble chromium VI of the total dry weight of the cement, ***for manual activities, where there is a risk of contact to the skin.***

May not be placed on the market or used as a substance or constituent of preparations, if it contains more than 0,0002 % soluble chromium VI of the total dry weight of the cement.

This ban shall not apply to products manufactured using controlled, closed and totally automated processes in which the products are handled solely by machines and in which there is no risk of contact.

Justification

The suggested limitation of the restriction of certain cements to manual activities is inappropriate, as there is no definition of manual activities and no common understanding across Member States as to which activities would actually be covered. Although the major proportion of the use of cement is largely automated, it always also involves manual activities which lead to contact with the human skin.

A general restriction should apply to all cement or cement preparations containing more than 2ppm chromium VI. This is in line with existing legislation in Scandinavian countries. These countries would be forced to lower their standards if the Commission's wording were accepted.

Although most uses of cement are extensively automated, only some manufacturing processes that use closed-circuit, fully automated systems are exempt from all risk of contact with the human organism and may therefore be the subject of derogations.

Amendment 25

ANNEX, TABLE, POINT XX CEMENT, RIGHT-HAND COLUMN, PARAGRAPH 2
Annex I of directive 76/769/EEC

In addition, if ferrous sulphate is used as a reducing agent, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement preparations shall be legibly and indelibly marked with information on the packing date and storage period during which the content of soluble chromium VI is below 0,0002 % of the total dry weight of the cement.”

Ferrous sulphate should be used as a reducing agent and this at the earliest possible stage, i.e. at the point of the cement production, with a dosage as close to the maximum recommended one of 5g/kg (0,5 % by mass) for hexahydrate and 3g/kg (0,3 % by mass) for monohydrate as possible. Other reducing agents could be used if their performance and stability is greater. In addition, without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement preparations shall be legibly and indelibly marked with information on the packing date, storage conditions and storage period during which the content of soluble chromium VI is below 0,0002 % of the total dry weight of the cement.”

Justification

As concerns ferrous sulphate, it is the most common substance used for the reduction of chromium VI. It is a waste product of one of the most common procedures used to produce titanium dioxide and is available in large quantities and at a competitive price. If the dosage of ferrous sulphate is too low, then the desired chromium VI concentration cannot be guaranteed. Thus dosage should be close to the maximum recommended dosage which should not be exceeded in order to make sure that the functionality of concrete admixtures is not disturbed.

Amendment 26
ANNEX, POINT XX CEMENT, RIGHT-HAND COLUMN, PARAGRAPH 2 A (new)
Annex I, point XX Cement (Directive 76/769/EEC)

(2a) The Commission shall put forward at the latest by xx.xx.200x [one year after the date of entry into force of this Directive] a proposal with a view to restricting the uses of chromium VI that pose a risk to human health and the environment.

Justification

Exposure to chromium VI can occur from various sources. While several applications have already been banned, a great many of them still remain unregulated. The risk assessment has been going on for six years. Given the dangers of the substance, regulatory action is needed urgently.

Amendment 27
ANNEX, POINT XX CEMENT, RIGHT-HAND COLUMN, PARAGRAPH 2 A (new)
Annex I, point XX Cement (Directive 76/769/EEC)

(2a) The Commission shall put forward at the latest by xx.xx.200x [one year after the date of entry into force of this Directive] a proposal for amending Annex I of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work so as to establish a binding occupational exposure limit value for dust.

Justification

Given the evidence about increased cancer risk to the upper respiratory tract for cement workers, it is appropriate to reduce the risks by occupational exposure limit values to dust in general.

EXPLANATORY STATEMENT

The Commission proposes restricting the marketing and use of two different types of substances, nonylphenol/nonylphenoethoxylate and cement.

Nonylphenol/nonylphenoethoxylate

Nonylphenol ethoxylates (NPE) are part of the alkylphenol ethoxylate group of non-ionic surfactants. NPE degrade to short-chained NPE and nonylphenol (NP). NP and NPE are classified as very toxic to aquatic organisms. Since they are lipophilic, they bioaccumulate in aquatic species, and they accumulate in sewage sludge and sediments. They have also been shown to have endocrine-disrupting effects. NP is listed by OSPAR as a chemical for priority action and is classified as a 'priority hazardous substance' pursuant to framework directive 2000/60/EC on water. Article 16 (6) of the water framework directive requires the cessation or phasing-out of discharges, emissions and losses of such substances. Estimated use in Western Europe in 1997 was around 78 000 tonnes. In the light of these high volumes, restrictions are needed urgently. The Commission proposes to end the use of NP and NPE in 8 specific areas.

The amendments proposed by the rapporteur aim to:

- refer to the properties of the substance, its classification in EC law and additional scientific information,
- enlarge the scope of the restriction to co-formulants in pesticides and to active substances and co-formulants in biocides, as well as to preparations for sale to the general public, and food packaging,
- apply the standard concentration threshold for restrictions of 0,1% both for NP and NPE,
- tighten the wording of the derogations,
- avoid replacement with substances of the same family with similar properties,
- call for amendment of the directive on sewage sludge to establish a concentration limit value for NP and NPE in sewage sludge to be spread on land.

Cement and chromium VI

Chromium VI compounds are classified inter alia as carcinogenic, mutagenic and sensitising in EC legislation. Chromium VI in cement induces sensitisation and causes serious allergic reactions in construction workers. The allergic dermatitis caused hereby is very painful and can prevent construction workers from continuing their work in the building sector. It can also cause long illnesses in people working only periodically with mortar. Each year, several hundred new cases are recognised in the EU. This not only leads to significant suffering of the victims and their families, but also creates annual compensation costs of 36 million euro in Germany alone. However, the risk is not limited to the professional sector, but can also affect persons in the do-it-yourself sector who come into contact with cement, all the more since standard leather gloves do not lend any protection. The CSTEEL stated that chromium VI readily penetrates the skin and wet leather gloves. It is difficult, therefore, to achieve appropriate protection for workers and consumers with the help of individual protection measures.

Chromium VI can be reduced to a harmless chemical form by the addition of ferrous sulphate. According to the CSTEEL, 'the available information clearly demonstrates that reduction of chromium VI in cement to less than 2 ppm of chromium VI compounds will reduce the

prevalence of allergic eczema in workers'. In Member States where chromium VI has been reduced in cement, the number of allergic dermatitis cases resulting from exposure to cement has been dramatically reduced. During the construction of the Channel Tunnel, for which chromium-VI-containing cement was used, hundreds of British workers were diagnosed with skin dermatitis induced by chromium VI. During the construction of the bridge over the Great Belt in Denmark, for which chromium-VI-reduced cement was used, only two workers showed contact dermatitis. The Channel Tunnel works involved 5 900 British underground workers, the works on Great Belt Bridge involved 3 000 workers.

The same effectiveness cannot be claimed for personal protective measures. While there is some very limited evidence from Switzerland that personal protection measures were effective, they clearly proved ineffective in various Member States.

In Scandinavia, ferrous sulphate has been added routinely since the 80s to all cement that has elevated level of chromium VI, with very positive results. In Germany, after many years of negotiation, the cement industry agreed as of January 2000 to offer only chromate-reduced cement when sold in bags. However, the necessary reduction of chromium VI, which is in almost all cases done by the downstream formulators, is not always achieved, due to various technical problems at that level.

The Commission proposes to make the addition of ferrous sulphate mandatory for all cement for manual activities, where there is a risk of contact with skin.

The amendments proposed by the rapporteur aim to:

- refer to the properties of the substance as classified in EC law and the additional scientific information,
- enlarge the scope of the restriction to all cement and cement products containing more than 2 ppm chromium VI, in line with the legislation in place in Scandinavian countries,
- clarify that reducing agents should be added during the production of cement,
- call for legislative action to restrict the use of chromium VI in other applications.

28 January 2003

OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY

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

on the proposal for a directive of the European Parliament and of the Council relating to restrictions on the marketing and use of nonylphenol, nonylphenol ethoxylate and cement (twenty-sixth amendment of Council Directive 76/769/EEC) (COM(2002) 459 – C5-0382/2002 – 2002/0206(COD))

Draftsman: David Robert Bowe

PROCEDURE

The Committee on Industry, External Trade, Research and Energy appointed David Robert Bowe draftsman at its meeting of 12 November 2002.

It considered the draft opinion at its meetings of 3 December 2002 and 28 January 2003.

At the last meeting it adopted the following amendments unanimously.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman; Jaime Valdivielso de Cué, vice-chairman; David Robert Bowe, draftsman; Per-Arne Arvidsson (for Umberto Scapagnini), Sir Robert Atkins, Giles Bryan Chichester, Nicholas Clegg, Willy C.E.H. De Clercq, Marie-Hélène Descamps (for Marjo Matikainen-Kallström), Francesco Fiori (for Guido Bodrato), Norbert Glante, Michel Hansenne, Roger Helmer (for Bashir Khanbhai), Hans Karlsson, Werner Langen, Rolf Linkohr, Caroline Lucas, Erika Mann, Eryl Margaret McNally, Peter Michael Mombaur, Bill Newton Dunn (for Colette Flesch), Angelika Niebler, Reino Paasilinna, Paolo Pastorelli, Elly Plooij-van Gorsel, Seán Ó Neachtain, John Purvis, Alexander Radwan (for Godelieve Quisthoudt-Rowohl), Bernhard Rapkay (for Mechtild Rothe), Imelda Mary Read, María Rodríguez Ramos (for Olga Zrihen Zaari pursuant to Rule 153(2)), Christian Foldberg Rovsing, Paul Rübig, Konrad K. Schwaiger, Esko Olavi Seppänen, W.G. van Velzen, Alejo Vidal-Quadras Roca, Dominique Vlasto and Myrsini Zorba.

SHORT JUSTIFICATION

The two amendments to the directive on the marketing and use of certain dangerous substances and preparations are not linked.

The first amendment relates to nonylphenol (NP) and nonylphenol ethoxylates (NPE). A risk reduction strategy exists for both. Risk assessment concluded that aquatic, terrestrial and secondary poisoning risks were unacceptable with the most sensitive area being the aquatic environment. NP and NPE are lipophil and thus have the tendency to accumulate in living organisms. Very high volumes of NP and NPE are marketed and used, and their release into environment has to be limited as much as possible. NP and NPEs are listed by OSPAR as chemicals for priority actions. The Commission proposes to end the use of NP and NPE in 8 specifically listed areas where the risk to the environment is high and alternatives are available.

Amendments related to NP and NPEs are aimed at prohibiting the use in the restricted areas totally. Thus the mass percentage for NPEs is reduced to the same as for NP, 0,1 % by mass. This is a standard administrative threshold that should make sure that the substances are completely phased out. Two specific uses are added, firstly the use in spermicides, where a phasing out after five years is demanded. In longer term, in order to protect the environment, any potential releases of NP and NPE into the environment should be stopped. Alternatives should become available within five years. The other use that should be banned are pesticides where, the substance is spread widely into the environment, this should be prevented given the nature of the substances.

The second amendment to the directive relates to hexavalent chromium in cement and cement preparations. Chromium (Cr) VI is a highly toxic form of the metal. It can cause contact eczema which can result in the inability to work in the building sector and also causes long illnesses to people working only periodically with mortar. Hundreds of workers in the EU receive compensation for their inability to work in the building sector due to chromium eczema. But the do-it-yourself sector is in as much danger as the professional as the Scientific Committee on Toxicity, Ecotoxicity and the Environment SCTEE assumed "that chromium VI readily penetrates wet leather gloves". Consequently, a proper protection to avoid an exposure is difficult to reach.

The amendments in this area first ask the European Commission to draft another amendment to the directive regarding the use of chromium in other industries, especially leather tanning and electroplating as these can lead to environmental damage and are detrimental to human health for both workers and neighbours. Whereas the Commission wants the chromium VI content of cement only limited if it is designated for manual activities, a second amendment widens this to all activities where there is a risk of contact to the skin, this covers kneeling and also manual finishing works in otherwise automated processes. Finally, the rapporteur wants to make sure that a sufficient amount of ferrous sulphate is added and defines this as being close to the maximum recommended dosage.

AMENDMENTS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on the Environment, Public Health and Consumer, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission¹

Amendments by Parliament

Amendment 1 RECITAL 6a (new)

(6a) In order to protect human health, it also appears advisable to regulate other circumstances where there is a high risk of chromium VI getting into contact with the skin or being discharged into soil or sewage; thus it seems appropriate that Council Directive 76/769/EC of 27 July 1976 be adapted so as to restrict the usage of chromium VI to closed circuits, and requests the Commission to draft a proposal in this regard within two years from the adoption of this amendment of directive.

Justification

Contact with cement is known to be a source of chromium related health problems. The CSTEE has confirmed the adverse health effects of chromium VI in cement. This is not the case for other products. The areas where the use of chromium would need to be restricted for the protection of human health and the environment ought to be limited clearly to economic activities implying the marketing and use of chromium VI only.

Amendment 2 ANNEX, TABLE, RIGHT SIDE, PARAGRAPH 1

Annex I of directive 76/769/EEC

May not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than 0,1 % by mass nonylphenol or **1 % by mass**

May not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than

¹ Not yet published in OJ.

nonylphenol ethoxylate for the following purposes:

0,1 % by mass nonylphenol or nonylphenol ethoxylate for the following purposes:

Justification

The threshold for NP and NPE should be the same and be determined by the detection limit.

Amendment 3
ANNEX, TABLE, RIGHT SIDE, POINT 8

Annex I of directive 76/769/EEC

(8) other personal care products except:
– spermicides.

(8) other personal care products except:
– spermicides *until xx.xx.200x*
[five years after the date of entry into force];

Justification

Within five years, it should be possible to find an alternative to the use of NP and NPE in spermicides in order to stop any release of these substances into the environment.

Amendment 4
ANNEX, TABLE, POINTS [XX], RIGHT SIDE, POINT 8a (NEW)

Annex I of directive 76/769/EEC

(8a) co-formulants in pesticides;

Justification

For pesticides, the Nonylphenol Risk Reduction Strategy from 2000 concludes that there is a need for limiting the risks if the background regional PEC (predicted environmental concentration) is added to the local PEC. There are six industries defined for which this is the case, but agricultural pesticides are the only type of industry where NP or NPE are spread into

the environment. Therefore, this use should be added to the list of banned purposes.

Amendment 5
ANNEX, TABLE, POINTS [XX] CEMENT, RIGHT SIDE, PARAGRAPH 1

Annex I of directive 76/769/EEC

May not be placed on the market or used as a substance or constituent of preparations, if it contains more than 0,0002 % soluble chromium VI of the total dry weight of the cement, for **manual** activities, where there is a risk of contact to the skin.

May not be placed on the market or used as a substance or constituent of preparations, if it contains more than 0,0002 % soluble chromium VI of the total dry weight of the cement, for **all** activities, where there is a risk of contact to the skin.

Justification

Even in the mechanised use of cement or concrete, final work often has to be done by hand, fitting of links, corners, staircases etc. Research in Germany has shown that about 16% of all work with cement has to be done manually, a further reduction seems unlikely. Even for those '16%', chromium VI concentration and thus of the likelihood to develop eczema must be minimised.

Amendment 6
ANNEX, TABLE, POINTS [XX] CEMENT, RIGHT SIDE, PARAGRAPH 2

Annex I of directive 76/769/EEC

In addition, if ferrous sulphate is used as a reducing agent, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement preparations shall be legibly and indelibly marked with information on the packing date and storage period during which the content of soluble chromium VI is below 0,0002 % of the total dry weight of the cement.

Ferrous sulphate should be used as a reducing agent and this at the earliest possible stage, i.e. at the point of the cement production, with a dosage as close to the maximum recommended one of 5g/kg (0,5 % by mass) for hexahydrate and 3g/kg (0,3 % by mass) for monohydrate as possible. Other reducing agents could be used if their performance and stability is greater. In addition, without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and

preparations, the packaging of cement or cement preparations shall be legibly and indelibly marked with information on the packing date, **storage conditions** and storage period during which the content of soluble chromium VI is below 0,0002 % of the total dry weight of the cement.”

Justification

As concerns ferrous sulphate, it is the most common substance used for the reduction of chromium VI. It is a waste product of one of the most common procedures used to produce titanium dioxide and is available in large quantities and at a competitive price. If the dosage of ferrous sulphate is too low, then the desired chromium VI concentration cannot be guaranteed. Thus dosage should be close to the maximum recommended dosage which should not be exceeded in order to make sure that the functionality of concrete admixtures is not disturbed.