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REPORT

on the proposal for a European Parliament and Council regulation on detergents
(COM(2002) 485 – C5-0404/2002 – 2002/0216(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Mauro Nobilia

CODE1AM

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

By letter of 4 September 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 regulation on detergents (COM(2002) 485 – 2002/0216 (COD)).

At the sitting of 5 September 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 and the Committee on Industry, External Trade, Research and energy for its opinion (C5-0404/2002).

The Committee on the Environment, Public Health and Consumer Policy appointed Mauro Nobilia rapporteur at its meeting of 2 October 2002.

It considered the Commission proposal and draft report at its meetings of 19 February 2003 and 25 March 2003.

At the latter meeting it adopted the draft legislative resolution by 38 votes to 7, with no abstentions.

The following were present for the vote: Caroline F. Jackson (chairman); Mauro Nobilia (vice-chairman and rapporteur); Alexander de Roo and Guido Sacconi (vice-chairmen); Hans Blokland, David Robert Bowe, John Bowis, Hiltrud Breyer, Philip Bushill-Matthews (for María del Pilar Ayuso González), Martin Callanan, Dorette Corbey, Chris Davies, Avril Doyle, Jillian Evans (for Marie Anne Isler Béguin), Anne Ferreira, Christel Fiebiger (for Pernille Frahm), Karl-Heinz Florenz, Cristina García-Orcoyen Tormo, Robert Goodwill, Françoise Grossetête, Christa Klaß, Bernd Lange, Peter Liese, Giorgio Lisi (for Raffaele Costa), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Pietro-Paolo Mennea (for Marialiese Flemming), Jorge Moreira da Silva, Emilia Franziska Müller, Rosemarie Müller, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Neil Parish (for Cristina Gutiérrez Cortines), Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Jonas Sjöstedt, Renate Sommer (for Eija-Riitta Anneli Korhola), María Sornosa Martínez, Bart Staes (for Patricia McKenna), Catherine Stihler, Robert William Sturdy (for Giuseppe Nisticò), Nicole Thomas-Mauro, Antonios Trakatellis and Kathleen Van Brempt.

The opinion of the Committee on Industry, External Trade, Research and Energy is attached; the Committee on Legal Affairs and the Internal Market decided on 8 October 2002 not to deliver an opinion.

The report was tabled on 26 March 2003.

DRAFT LEGISLATIVE RESOLUTION

European Parliament legislative resolution on the proposal for a European Parliament and Council regulation on detergents (COM(2002) 485 – C5-0404/2002 – 2002/0216(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 485[1]),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0404/2002),

– 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 (A5-0105/2003),

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) As set out in Article 174 of the Treaty, the Community's environment policies shall contribute to pursuit of the objectives of preserving, protecting and improving the quality of the environment through, inter alia, encouraging the prudent and rational utilisation of natural resources, and shall be based on the precautionary principle and on the principles that preventive action shall be taken and environmental damage, as a priority, rectified at source, and that the polluter shall pay the costs of such

[1] OJ not yet published

rectification;

Justification

It is important to remind those who will be entrusted with ensuring that this legislation is effective of the general context in which it has been enacted and the general principles of Community environmental law.

Amendment 2
Recital 9

(9) Ditallow-dimethyl-ammonium-chloride (DTDMAC) and Nonylphenol (including ethoxylates derivatives-APEs) are priority substances undergoing at Community level Risk Assessment activities, in accordance with Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, and ***if necessary*** adequate strategies to limit the risks of exposure to these substances will be recommended and implemented in the framework of other relevant EC instruments;	(9) Ditallow-dimethyl-ammonium-chloride (DTDMAC) and Nonylphenol (including ethoxylates derivatives-APEs) are priority substances undergoing at Community level Risk Assessment activities, in accordance with Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, and adequate strategies to limit the risks of exposure to these substances will ***therefore*** be recommended and implemented in the framework of other relevant EC instruments;

Justification

Ditallow-dimethyl-ammonium-chloride (DTDMAC) and nonylphenol ethoxylate are highly toxic substances whose biodegradability is limited. The international scientific community has recommended that a ban be placed on the use of such substances, which are anyway no longer used in the production of detergents (see Article 7(1a)).

Amendment 3
Recital 14

(14) The existing requirements regarding primary biodegradability are to be maintained on a second hierarchy level for those surfactants failing "ultimate biodegradability" tests; furthermore surfactants failing primary biodegradability tests cannot obtain marketing authorisation by way of derogation;	(14) The existing requirements regarding primary biodegradability ***and the complementary risk assessment*** are to be maintained on a second hierarchy level for those surfactants failing "ultimate biodegradability" tests; furthermore surfactants failing primary biodegradability tests cannot obtain marketing authorisation by way of derogation;

Justification

Surfactants that fail the test provided for in Annex III but pass those in Annex II should undergo a complementary risk assessment.

Amendment 4
Recital 18

(18) Test-methods to test biodegradability of surfactants in detergents may produce variable results ***and may*** need to be complemented by additional assessments in order to determine the risks of continued use;	(18) Test-methods to test biodegradability of surfactants in detergents may produce variable results***. In such cases they*** need to be complemented by additional assessments in order to determine the risks of continued use;

Justification

It is important to emphasise the need for comprehensive testing. Where tests produce variable results, further tests must be carried out.

Amendment 5
Recital 21 a (new)

	(21a) Detergents must not be harmful under normal or foreseeable conditions of use. Given the special risks that the substances classified as carcinogenic, mutagenic or toxic for reproduction - category 1, 2 and 3, pursuant to Directive 67/548/EEC - may entail for human health, their use in detergents should be prohibited. As an exception, a substance classified in category 3 may be used in detergents if the substance has been evaluated by the SCCNFP and found acceptable for use in detergents;

Justification

This approach would be in keeping with the stated principles underlying Community law and with previous legislation such as that governing cosmetics.

Amendment 6
Recital 23

(23) Manufacturers ***should be able to***	(23) Manufacturers ***may*** request a

request a derogation and the Commission ***should have the possibility to*** grant ***such derogation*** in accordance with the Committee procedure of this Regulation;

derogation which the Commission ***may*** grant ***if the conditions set out in Article 6 are met and*** in accordance with the Committee procedure of this Regulation;

Justification

The Commission must ensure that the conditions set out in this regulation are met before granting a derogation.

Amendment 7
Recital 24

(24) Members State competent authorities ***should be able to*** apply control measures to detergents on the market, but should avoid repeating tests made by the competent laboratories;

(24) Members State competent authorities ***may*** apply control measures to detergents on the market, but should avoid repeating tests made by the competent laboratories ***and must ensure in particular that animal tests are not repeated***;

Justification

Under Directive 86/609/EEC, animal experiments must not be carried out if the result sought is available by a method not entailing the use of an animal. Thus, duplication of animal tests should not happen. The principle of repeat tests being 'avoided' is unsatisfactory: repeat animal testing must be ended, and Member State competent authorities should ensure that this is the case.

Amendment 8
Recital 25

(25) Labelling provisions should be continued, including those in Recommendation 89/542/EEC, for the labelling of detergents and cleaning products, which is included in order to fulfil the objective of modernising the rules on detergent products. Specific labelling is introduced to inform consumers about fragrance substances and preservation agents that are present in detergents. ***Health care professionals*** should be able

(25) Labelling provisions should be continued, including those in Recommendation 89/542/EEC, for the labelling of detergents and cleaning products, which is included in order to fulfil the objective of modernising the rules on detergent products. Specific labelling is introduced to inform consumers about fragrance substances and preservation agents that are present in detergents. ***Medical personnel*** should be able to obtain

to obtain from the manufacturer upon request a full listing of all ingredients of a detergent to assist them investigate whether a causal link exists between the development of an allergic response and exposure to a particular chemical substance;	from the manufacturer upon request a full listing of all ingredients of a detergent to assist them investigate whether a causal link exists between the development of an allergic response and exposure to a particular chemical substance;

Justification

With a view to maintaining commercial secrecy and enabling access to be gained to the full list of ingredients contained in a detergent, the concept of 'health care professional' requires clarification and should be restricted to persons authorised to practise as doctors, making diagnoses and prescribing courses of treatment, since such persons are bound by professional secrecy rules.

Amendment 9
Recital 27

(27) The technical Annexes to this Regulation are to be adapted by Committee procedure;	(27) The technical ***parts of the*** Annexes to this Regulation are to be adapted by Committee procedure;

Justification

Amendment in line with amendment 29, which refers adaptation of Annexes IA and VIII to the legislative process.

Amendment 10
Recital 28

(28) Detergents complying with this Regulation should be allowed to be placed on the market without prejudice to other relevant Community provisions;	(28) Detergents complying with this Regulation should be allowed to be placed on the market without prejudice to other relevant ***national or*** Community provisions;

Justification

The Regulation should not affect national provisions with regard to aspects concerning detergents that are not covered by this Regulation.

Amendment 11
Recital 31

(31) The issues relating to anaerobic biodegradation, the biodegradation of the main non-surfactant organic detergent	(31) The issues relating to anaerobic biodegradation, the biodegradation of the main non-surfactant organic detergent

ingredients, and phosphate content should be ***reviewed by the Commission*** and, where this is justified, a proposal should be presented to the European Parliament and the Council;	ingredients, and phosphate content should be ***evaluated*** and, where this is justified, a ***legislative*** proposal should be presented to the European Parliament and the Council ***at the latest by xx.xx.200x (three years after the entry into force of this Regulation). The review of phosphate content should include the evaluation of a gradual phase-out or a restriction to specific applications;***

Justification

Anaerobic biodegradation, the biodegradation of the main non-surfactant detergent ingredients and phosphates should be subject to specific regulation, in addition to the rules covering detergents. The studies which the Commission is having carried out in this area are nearing completion, whence the request that a proposal regulating such issues be drawn up in the near future.

The use of phosphates in detergents and/or surfactants for detergents should be specifically addressed.

Amendment 12
Recital 31 a (new)

	(31a) In accordance with its White Paper entitled 'Strategy for a Future Chemicals Policy', the Commission should promote research into the development and validation of non-animal alternative test methods at Community and national level and promote the competitiveness of the chemical industry to encourage innovation and in particular the development of safer chemicals;

Justification

Parliament's resolution on the White Paper: Strategy for a future Chemicals Policy, requests that 'more resources be provided immediately to accelerate the development and validation of further scientifically reliable, recognised and standardised alternative tests to replace animal tests in the implementation of the new system'. Use of the term 'non-animal alternative tests' emphasises the need for animal-based toxicity tests to be fully replaced by non-animal alternatives rather than for the number of animals used merely to be 'reduced'. Where research funding and expertise are needed to develop and validate new 'alternative tests', those methods that replace animal tests should be prioritised above those that simply reduce animal use.

Amendment 13
Recital 31 b (new)

(31b) In accordance with the provisions of Directive 86/609/EEC, it is important to ensure that conventional test methods are replaced first and foremost by validated alternative methods that do not involve the use of animals or, should no such methods exist, by methods intended significantly to reduce the number of animals used or methods that enable the suffering caused to animals to be significantly reduced;

Justification

In accordance with Directive 86/609/EEC the Member States should promote the spread of alternative test methods which do not involve the use of animals. The Council's definition of 'alternative method' includes methods which reduce the number of animals used or reduce the suffering of those that are used.

Amendment 14
Recital 31 b (new)

(31b) The long-term aim of replacing all animal-based toxicity testing must be actively pursued, and the Commission should set out a targeted timeframe for such replacement;

Justification

The seventh amendment to the Cosmetics Directive states that the Commission should establish deadlines for the prohibition of the marketing of cosmetics or cosmetic ingredients tested on animals, and the prohibition of each test currently carried out using animals. This sense of an organised 'phase-out' of animal-based toxicity testing for human health effects must be extended to eco-toxicological endpoints.

Amendment 15
Article 1, paragraph 2

2. For this purpose, this Regulation lays down rules for:	2. For this purpose, this Regulation lays down rules for:
- the biodegradability of surfactants in detergents ***and***	- the biodegradability of surfactants in detergents***,***

- the labelling of detergents**.**	- the labelling of detergents ***and***
	- restrictions of the use of certain substances or preparations in detergents.

Justification

In order to achieve the objectives, the regulation also needs to lay down rules on restrictions.

Amendment 16
Article 2, paragraph 1

1. "Detergent" means any substance or preparation containing soaps or other surfactants intended ***for water-based*** washing processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and used for household, and/or institutional and/or industrial purposes. Other products to be considered as covered within the meaning of this definition are listed in Annex I.A;	1. "Detergent" means any substance or preparation containing soaps or other surfactants intended ***to be dissolved or dispersed in water or in other liquids for*** washing processes***, except for substances and preparations covered by Directive 98/8/EC on biocidal products[1]***. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and used for household, and/or institutional and/or industrial purposes. Other products to be considered as covered within the meaning of this definition are listed in Annex I.A;
	_____
	[1] OJ L 123, 24.4.1998.

Justification

The new wording of this paragraph is clearer.

Amendment 17
Article 2, paragraph 2

2. "Washing" means the cleaning of laundry, fabrics, dishes ***or*** kitchen utensils;	2. "Washing" means the cleaning of laundry, fabrics, dishes***,*** kitchen utensils***, floors, windows or sanitary facilities***;

Justification

More comprehensive definition.

Amendment 18
Article 2, paragraph 3a (new)

3a. "Industrial and institutional use" means washing and cleaning outside the domestic sphere, carried out by specialised personnel using specific products;

Justification

Detergents are also used outside the domestic sphere, in the industrial and institutional sectors.

Amendment 19
Article 2, paragraph 6

6. "Surfactant" means any organic substance and/or preparation used in detergents which is intentionally added to achieve cleaning, rinsing, fabric softening and/or any other purpose due to its surface-active properties, and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of forming micelles;	6. "Surfactant" means any organic substance and/or preparation used in detergents which is intentionally added to achieve cleaning, rinsing, fabric softening and/or any other purpose due to its surface-active properties, and which consists of one or more hydrophilic and one or more hydrophobic groups of such a nature and size that it is capable of ***reducing the surface tension of water,*** forming ***spreading or adsorption monolayers at the water-air interface and forming emulsions and/or microemulsions and*** micelles, ***and of adsorption at water-solid interfaces***;

Justification

A more comprehensive definition of what surfactants do is required.

Amendment 20
Article 4, paragraph -1 (new)

-1. Substances and preparations, the use of which is prohibited in detergents, are listed in Annex VII.

Justification

A clear reference to the Annex which lists the restrictions is needed.

Amendment 21
Article 4, paragraph 1

1. If a detergent contains surfactants for which the level of "ultimate aerobic biodegradation" is less than that stipulated in Annex III, manufacturers of detergents containing surfactants, and/or of surfactants for detergents may ask for derogation. Requests for derogation shall be made in accordance with the provisions of Articles 5 and 9.	1. If a detergent contains surfactants for which the level of "ultimate aerobic biodegradation" is less than that stipulated in Annex III, manufacturers of detergents containing surfactants, and/or of surfactants for detergents may ask for derogation. Requests for derogation shall be made ***and granted*** in accordance with the provisions of Articles 5***, 6*** and 9.

Justification

With a view to making the text more comprehensive, a reference to the article covering the granting of derogations is included.

Amendment 22
Article 5

1. The request by a manufacturer for derogation shall be made by sending an application to the competent authorities of the Member State concerned, referred to in Article 8(1), and to the Commission, providing evidence relating to the criteria mentioned under Article 6(1).	1. The request by a manufacturer for derogation shall be made by sending an application to the competent authorities of the Member State concerned, referred to in Article 8(1), and to the Commission, providing evidence relating to the criteria mentioned under Article 6(1).
2. Applications shall include a technical file supplying all the information and justifications necessary for evaluating the safety aspects related to the specific use of surfactants in detergents failing to comply with the biodegradability limits, as set out in ***Annexes II and*** III.	2. Applications shall include a technical file supplying all the information and justifications necessary for evaluating the safety aspects related to the specific use of surfactants in detergents failing to comply with the biodegradability limits, as set out in ***Annex*** III.
In addition to the results of tests stipulated in Annex III, the technical file shall include results of tests, as stipulated in Annexes II and IV.	In addition to the results of tests stipulated in Annex III, the technical file shall include results of tests, as stipulated in Annexes II and IV.
	2 bis The tests laid down in Annex IV(4) shall be carried out on the basis of a graded risk assessment (tiered approach). Within twelve months of the date upon which this Regulation comes into force the Commission shall lay down an appropriate technical guideline in accordance with the procedure referred to in Article 12.
3. The competent authorities of the Member States, receiving applications for derogation according to paragraphs 1 and 2 above, shall examine the requests, evaluate their compliance with the conditions for derogation and inform the Commission about the results without delay.	3. The competent authorities of the Member States, receiving applications for derogation according to paragraphs 1 and 2 above, shall examine the requests, evaluate their compliance with the conditions for derogation and inform the Commission about the results without delay.
If the competent authority of the Member State deems it necessary, for the evaluation of the risk which may be caused by a substance and/or a preparation, it ***may*** ask for further information, verification and/or confirmatory tests concerning these substances and/or preparations or their transformation products, of which they have	If the competent authority of the Member State deems it necessary, for the evaluation of the risk which may be caused by a substance and/or a preparation, it ***shall*** ask for further information, verification and/or confirmatory tests concerning these substances and/or preparations or their transformation products, of which they have

been notified or have received information under this Regulation.	been notified or have received information under this Regulation. ***If the necessary information is not provided by a timeline to be clearly specified, the application is considered incomplete and thus invalid.*** ***If further information on metabolites is sought, stepwise testing strategies should be employed to ensure maximum use of in-vitro and other non-animal test methods.***
4. The Commission may grant derogation in accordance with the procedure set out in Article 12(2). If necessary before granting derogation the Commission ***may*** evaluate further the matters indicated in paragraph 3 above.	4. ***On the basis of the evaluation done by the Member States, the*** Commission may grant derogation in accordance with the procedure set out in Article 12(2). If necessary before granting derogation the Commission ***shall*** evaluate further the matters indicated in paragraph 3 above.
5. Such derogations may allow, limit or severely restrict the placing on the market and the use of surfactants in detergents, depending on the results of the complementary risk assessment, as defined in Annex IV of this Regulation. They may include a phase-out period for placing on the market and the use of surfactants in detergents.	5. Such derogations may allow, limit or severely restrict the placing on the market and the use of surfactants in detergents, depending on the results of the complementary risk assessment, as defined in Annex IV of this Regulation. They may include a phase-out period for placing on the market and the use of surfactants in detergents. ***A derogation must be reviewed after 5 years and the applicant must provide information that he is developing alternatives, which will fulfil the demands to the "ultimate aerobic biodegradation".***
6. The Commission shall publish the list of surfactants that have obtained derogation, with the corresponding conditions or limitations of use, as provided in Annex V.	6. The Commission shall publish the list of surfactants that have obtained derogation, with the corresponding conditions or limitations of use, as provided in Annex V.

Justification

Article 4 paragraph 2 of the Commission proposal stipulates that surfactants not passing the level of primary biodegradability as laid down in Annex II shall not be granted a derogation. Such surfactants can therefore not qualify for an application for derogation.

In accordance with customary risk-assessment procedure the tests laid down in Annex IV(4) should be carried out on the basis of a graded risk assessment appropriate to the actual level of risk.

In this connection see, inter alia, Directive 93/67/EEC laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC and Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93.

In line with the European Parliament resolution on the White Paper: Strategy for a future Chemicals Policy; toxicity testing should progress from the conventional 'tick box' approach towards tailor-made testing, utilising non-animal stepwise strategies where possible.

Where substances or preparations constitute a potential risk, the competent national authorities and the Commission must carry out further checks and 'additional' assessments.

Derogations can be problematic for the purposes of environment and public health protection. If derogations are granted, industry should be able to demonstrate that safer alternatives are being developed and the necessity for a derogation should be subsequently reviewed.

Amendment 23
Article 6, heading and paragraph 1

Refusal of derogation	***Conditions for granting a*** derogation
1. Where the Commission intends to ***refuse to*** grant a derogation it may do so on the basis of the following criteria:	1. Where the Commission intends to grant a derogation it may do so on the basis of the following criteria***, provided that such a course of action is justified on the basis of the further checks carried out pursuant to Article 5(3)***;
– ***use in high volumes;***	– ***only specific*** industrial or institutional ***use, provided that the volume of sales and use throughout whole EU territory is below that which would pose a threat to the environment and health, and***
– ***use in wide-dispersive applications, such as use by the general public, rather than in low-dispersive applications, such as specialized*** industrial ***and/***or institutional ***cleaning;***	– ***an essential need for its use has been shown, in particular in view of food safety or hygiene standards, and no safer alternatives are available.***
– ***socio-economic benefits do not outweigh the impact on human health and the environment.***	

Or. en

Justification

The original wording of Article 6, covering refusals to grant a derogation, in fact laid down the conditions for obtaining a derogation, thus generating confusion as to the applicable

rules. It would therefore be clearer to use the heading 'Conditions governing the granting of derogation'.

Derogations should be allowed only on the basis of a complementary risk assessment in which specialist applications and particular user benefits should be measured against environmental impact.

Amendment 24
Article 6, paragraph 2

2. As long as the Commission has not decided on a request for derogation, the use of the surfactant in question may be maintained, provided the manufacturer can show that the surfactant was already in use on the Community market at the date of entry into force of this Regulation and that the request for derogation was made within two years from that date. If the Commission refuses to grant a derogation for a surfactant, it ***may*** set a transitional period during which the use of the surfactant in question shall be phased-out. This transitional period shall not exceed two years.	2. As long as the Commission has not decided on a request for derogation, the use of the surfactant in question may be maintained, provided the manufacturer can show that the surfactant was already in use on the Community market at the date of entry into force of this Regulation and that the request for derogation was made within two years from that date. If the Commission refuses to grant a derogation for a surfactant, it ***shall*** set a transitional period during which the use of the surfactant in question shall be phased-out. This transitional period shall not exceed two years.

Justification

A phase-out, to be meaningful, requires a clear objective in time.

Amendment 25
Article 7, paragraph 1 a (new)

	1a. The use of the following substances shall be banned unless it is recognised as safe by the competent scientific committee and the results of the tests referred to in Annexes II, III and IV are satisfactory:
	- ditallow-dimethyl-ammonium-chloride (DTDMAC);
	- alkylphenol (including ethoxylates derivatives-APEs).

Justification

These two substances are highly toxic, and their biodegradability is limited. The international scientific community has recommended that a ban be placed on the use of such substances,

which are anyway no longer used in the production of detergents

Amendment 26
Article 9, paragraph 2

2. Whenever substances and preparations covered by this Regulation are placed on the market, the manufacturer shall be responsible for the ***correct*** performance of the relevant tests mentioned above. He shall also have available - documentation on the testing carried out to demonstrate compliance with the Regulation, and to show that he is allowed to benefit from the property rights concerning the test results, other than for those test results already in the public domain.	2. Whenever substances and preparations covered by this Regulation are placed on the market, the manufacturer shall be responsible for the performance of the relevant tests mentioned above. He shall also have available - documentation on the testing carried out to demonstrate compliance with the Regulation, and to show that he is allowed to benefit from the property rights concerning the test results, other than for those test results already in the public domain.

Justification

This amendment is intended to relieve the manufacturer of the obligation to check that the tests have been performed correctly. In addition to the fact that the manufacturer may lack the necessary competence or instruments, the only laboratories authorised to carry out the required tests are those selected by the Member States, on the basis of specific conditions, and approved by the Commission.

Amendment 27
Article 9, paragraph 3

3. Manufacturers placing on the market the preparations covered by this Regulation shall, ***upon request***, make available without delay and free of charge, ***to any health care professional***, a datasheet listing all ingredients as stipulated in *Annex* VIII.C.	3. Manufacturers placing on the market the preparations covered by this Regulation shall make available without delay and free of charge to ***the authorities appointed by the Member States pursuant to Article 8(1)*** a datasheet listing all ingredients as stipulated in *Annex* VIII.C. ***The manufacturer or the authority shall, upon request, make that datasheet available without delay and free of charge to medical staff bound by professional secrecy.***

Or. en

Justification

As a matter of principle the competent authorities must be in possession of the datasheet so that, in an emergency, medical practitioners can apply to them too.

The term 'health care professional' should be restricted to medical practitioners.

On competitive grounds the publishing of information concerning the formulation of a product is a highly sensitive issue and such information should be released only to medical practitioners bound by the duty of confidentiality.

Amendment 28

Article 11, paragraph 2, letter (ca) (new)

(ca) Products covered by an Article 5 derogation must be suitably labelled.

Justification

Derogations are necessary in some areas. However, products must be clearly identifiable as being covered by such a derogation, since the user must know what kind of a product he is buying.

Amendment 29
Article 13

Adaptation of the annexes	**Adaptation of the annexes**
The amendments necessary for adapting Annexes I, II, III, IV, V, VI, VII***, VIII*** and IX shall be adopted in accordance with the procedure laid down in Article 12(2), and shall, wherever possible, use European Standards.	The amendments necessary for adapting Annexes I***B***, II, III, IV, V, VI, VII and IX ***to technical progress*** shall be adopted in accordance with the procedure laid down in Article 12(2), and shall, wherever possible, use European Standards.

Justification

Some of the provisions contained in the annexes form an essential part of the legislation and are not merely implementing measures. Any amendments to them must therefore be made under the normal legislative procedure. This applies in particular to Annex IA, which supplements the definitions given in Article 2, and Annex VIII, which lays down the provisions applying to labelling and the information to be provided to health care operators. Furthermore, the implementing powers which the legislative authorities delegate to the

committee must be specifically restricted to the adoption of the measures required to adapt provisions to technical progress.

Amendment 30
Article 13a (new)

Article 13 a
Sunset Clause
Without prejudice to the implementing measures already adopted, on the expiry of an eight-year period following the entry into force of the Regulation, the application of its provisions requiring the adoption of technical rules and decisions in accordance with the procedure referred to in Article 13 by the Committee referred to in Article 12 (2) shall be suspended. On a proposal from the Commission, the European Parliament and the Council may renew the provisions concerned in accordance with the procedure laid down in Article 251 of the Treaty and, to that end, they shall review them prior to the expiry of the period referred to above;

Justification

This is the so-called sunset clause from the European Parliament resolution on the implementation of financial services legislation adopted on 5.2.2002. Originally meant for the field of financial services legislation, it can be adapted to the field of environmental legislation. With a view to consolidating democratic scrutiny of implementing powers and bringing them into line with a changing economic and technical environment, the legislator must be able to revise the scope of the powers conferred on the Commission by specifying the period during which they may be exercised. As the situation changes faster in the field of financial services than in the field of detergents and environmental standards, the period of four years has been extended to eight years.

Amendment 31
Article 14, paragraph 1 a (new)

Without prejudice to the provisions of the Treaty establishing the European Community, with particular reference to

Articles 28 and 30 thereof, paragraph 1 shall be without prejudice to national legislation governing the use of phosphates in detergents in the absence of Community harmonisation measures adopted by the European Parliament and the Council.

Justification

Where Member States have adopted more restrictive national laws, they should not be forced to amend them.

Amendment 32
Article 15 a (new)

By xx.xx.200x (3 years after the date of entry into force of this regulation) at the latest, the Commission shall have evaluated, submitted a report and, where this is justified, presented to the European Parliament and Council a legislative proposal to regulate the issues relating to:

- anaerobic biodegradation

- the biodegradation of main non-surfactant organic detergent ingredients

- the use of phosphates with a view to the gradual phase-out or a restriction to specific applications.

Or. en

Justification

Anaerobic biodegradation, the biodegradation of the main non-surfactant detergent ingredients and phosphates should be subject to specific regulation, in addition to the rules covering detergents. The studies which the Commission is having carried out in this area are nearing completion, whence the request that a proposal regulating such issues be drawn up in the near future.

The use of phosphates in detergents and/or surfactants for detergents should be specifically addressed.

Amendment by Erik Meijer

Amendment 33
Article 15 a (new)

By xx.xx.200x [12 months after entry into force of this regulation] at the latest, the Commission shall submit a proposal seeking to regulate:

- Methods and analyses of ecotoxicological tests on all detergent substances and/or preparations and their metabolites.

Or. en

Justification

It vital to provide future criteria for ecotoxicological impact of detergents and their metabolites. In the proposal this is only undertaken as a part of the risk assessment, which is insufficient as those substances and preparations that pass biodegradability tests may still have ecotoxic properties. A minimum requirement should be that they are not persistent, bio-accumulative, very toxic, carcinogenic, mutagenic or reprotoxic. The same tests and hurdles as are used for the classification of hazardous substances can be used (Directive 67/548/EEC).

Amendment 34
ANNEX II, Point A

A. **Analytical Methods for Anionic Surfactants**	A. **Analytical Methods for Anionic Surfactants**
The determination of anionic surfactants in the tests shall be done by the Methylene Blue Active Substance (MBAS) analysis according to the criteria established in Annex IX.2.	The determination of anionic surfactants in the tests shall be done by the Methylene Blue Active Substance (MBAS) analysis according to the criteria established in Annex IX.2.
For those anionic surfactants not reacting to the above-mentioned MBAS method, ***or if it seems more appropriate for reasons of efficiency or precision (this must be justified)*** appropriate instrumental analyses ***specific for the surfactant under study*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national	For those anionic surfactants not reacting to the above-mentioned MBAS method, appropriate ***specific*** instrumental analyses ***such as HPLC (high performance liquid chromatography) and gas chromatography (GC)*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national authorities of the

authorities of the Member States upon request.	Member States upon request.

Justification

HPLC and GC are two analytical methods recommended by the scientific community which could be included in the proposal for a regulation. They are not excessively expensive and may be used for the analysis of all surfactants.

Amendment 35
ANNEX II, Point B

B. **Analytical Methods for Non-ionic Surfactants**	B. **Analytical Methods for Non-ionic Surfactants**
The determination of non-ionic surfactants in the tests shall be done by the Bismuth Active Substance (BiAS) method, according to the analytical procedure established in Annex IX.3.	The determination of non-ionic surfactants in the tests shall be done by the Bismuth Active Substance (BiAS) method, according to the analytical procedure established in Annex IX.3.
For those non-ionic surfactants not reacting to the above-mentioned BiAS method, ***or if it seems more appropriate for reasons of efficiency or precision (this must be justified)*** appropriate instrumental analyses ***specific for the surfactant under study*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national authorities of the Member States upon request.	For those non-ionic surfactants not reacting to the above-mentioned BiAS method, or if it seems more appropriate for reasons of efficiency or precision (this must be justified) appropriate instrumental analyses ***such as HPLC (high performance liquid chromatography) and gas chromatography (GC)*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national authorities of the Member States upon request.

Justification

HPLC and GC are two analytical methods recommended by the scientific community which could be included in the proposal for a regulation. They are not excessively expensive and may be used for the analysis of all surfactants.

Amendment 36
ANNEX II, Point C

C. **Analytical Methods for Cationic Surfactants**	C. **Analytical Methods for Cationic Surfactants**
The determination of cationic surfactants in the tests shall be done by the Disulfine Blue Active Substance (DBAS) analysis according to the following DBAS procedures:	The determination of cationic surfactants in the tests shall be done by the Disulfine Blue Active Substance (DBAS) analysis according to the following DBAS procedures:
The method in use in the Federal Republic of Germany, (1989) DIN 38 409 – Ausgabe: 1989-07.	The method in use in the Federal Republic of Germany, (1989) DIN 38 409 – Ausgabe: 1989-07.
For those cationic surfactants not reacting to the above-mentioned test method, ***or if it seems more appropriate for reasons of efficiency or precision (this must be justified)*** appropriate instrumental analyses specific ***for the surfactant under study*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national authorities of the Member States upon request.	For those cationic surfactants not reacting to the above-mentioned test method, appropriate ***specific*** instrumental analyses ***such as HPLC (high performance liquid chromatography) and gas chromatography (GC)*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent national authorities of the Member States upon request.

Justification

HPLC and GC are two analytical methods recommended by the scientific community which could be included in the proposal for a regulation. They are not excessively expensive and may be used for the analysis of all surfactants.

Amendment 37
ANNEX II, Point D

D. **Analytical Methods for Amphoteric Surfactants**	D. **Analytical Methods for Amphoteric Surfactants**
The determination of amphoteric surfactants in the tests shall be done by analysis following the procedures listed below:	The determination of amphoteric surfactants in the tests shall be done by analysis following the procedures listed below:
1. *If cationics absent:*	1. *If cationics absent:*
The method in use in the Federal Republic	The method in use in the Federal Republic

of Germany, (1989) DIN 38 409-Teil 20.	of Germany, (1989) DIN 38 409-Teil 20.
2. *Otherwise:*	2. *Otherwise:*
Orange II method (Boiteux, 1984).	Orange II method (Boiteux, 1984).
For those amphoteric surfactants not reacting to the above-mentioned tests, ***or if it seems more appropriate for reasons of efficiency or precision (this must be justified)*** appropriate instrumental analyses ***specific for the surfactant under study*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent authorities of the Member States upon request.	For those amphoteric surfactants not reacting to the above-mentioned tests, appropriate ***specific*** instrumental analyses ***such as HPLC (high performance liquid chromatography) and gas chromatography (GC)*** are to be applied. Samples of the pure surfactant of interest shall be provided by the manufacturer to the competent authorities of the Member States upon request.

Justification

HPLC and GC are two analytical methods recommended by the scientific community which could be included in the proposal for a regulation. They are not excessively expensive and may be used for the analysis of all surfactants.

Amendment 38
ANNEX IV, paragraph 2

The complementary risk assessment run in the scope of this Regulation***, in case it is likely that recalcitrant metabolites are produced,*** shall be considered in the context of assessments made on the basis of Directive 93/67/EEC and Regulation (EEC) No 793/93. ***This is to be assessed case by case and in particular on the basis of the results of the tests referred to in part 3 of this Annex.***	The complementary risk assessment run in the scope of this Regulation shall be considered in the context of assessments made on the basis of Directive 93/67/EEC and Regulation (EEC) No 793/93.

Justification

Annex IV introduces the concept of 'complementary risk assessment for surfactants in detergents', particularly in the aquatic environmental compartment. However, the original wording raises doubts about whether complementary risk assessments for surfactants that have failed the ultimate biodegradeability tests are compulsory. Surfactants that fail the

Annex III tests but pass the Annex II tests should undergo complementary risk assessment.

This additional test will provide the information required to establish why the ultimate biodegradeability tests were failed and whether the substance should be allowed to be placed on the market.

Amendment 39
ANNEX IV, Point 3, paragraph 1 (new)

3.1 (new) Information shall be provided on contents of chemicals that are very persistent and/or very bio-accumulative chemicals and /or persistent, bio-accumulative, toxic and/or chemicals with endocrine-disrupting properties and /or contain any chemicals that have these properties;

Or. en

Justification

Self-explanatory.

Amendment 40
ANNEX VII, heading and paragraph 1

List of banned or restricted detergent surfactants in implementation of other Community legislation	List of banned or restricted detergent surfactants***, including*** in implementation of other Community legislation
The following list of detergent surfactants incorporates surfactants covered by this Regulation and banned or restricted by other Community legislation, in particular Directive 76/769/EEC:	The following list of detergent surfactants incorporates substances and preparations covered by this Regulation and banned or restricted by other Community legislation, in particular Directive 76/769/EEC:
	- Substances and preparations listed in points 29, 30 and 31 of Annex I of Directive 76/769/EEC,
	- Substances classified as carcinogenic, mutagenic or toxic to reproduction category 3 pursuant to Directive 67/548/EEC;

Justification

Substances that are banned or restricted by this Regulation or other applicable Community legislation should be listed.

Amendment 41
ANNEX VIII, Point A, paragraph 2

The following weight percentage ranges:	The following weight percentage ranges:
- less than 5 %,	- less than 5 %,
- 5 % or over but less than 15 %,	- 5 % or over but less than 15 %,
- 15 % or over but less than 30 %,	- 15 % or over but less than 30 %,
- 30 % and more,	- 30 % and more,
shall be used to indicate the content of the constituents listed below where they are added in a concentration above 0,2 weight %:	shall be used to indicate the content of the constituents listed below where they are added in a concentration above 0,2 weight %:
- phosphates,	***- total surfactants,***
- phosphonates,	***- other chelating agents,***
- anionic surfactants,	***- oxidants,***
- cationic surfactants,	***- fabric softening ingredients,***
- amphoteric surfactants,	***- dirt redepositing inhibitors,***
- non-ionic surfactants,	***- oxidant activators,***
- oxygen-based bleaching agents,	***- colour protectors,***
- chlorine-based bleaching agents,	***- other solvents,***
- EDTA,	***- other hardness sequestering agents,***
- nitrilotriacetic acid,	
- phenols and halogenated phenols,	
- paradichlorobenzene,	
- aromatic hydrocarbons,	
- aliphatic hydrocarbons,	
- halogenated hydrocarbons,	
- soap,	
- zeolites,	
- polycarboxylates.	
	shall be used to indicate the content of the constituents listed below, if added, irrespective of their concentration:
	- EDTA,
	- phosphates,

- phenols.

Justification

Consumers are now more aware and more capable of making both 'commercial' and 'political' choices. However, an excess of, in some cases, cryptic information on labels can lead to confusion, thus negating the original point of its inclusion.

The new wording provides for information being supplied on substances in respect of which greater caution should be exercised and which should thus be included on the label irrespective of concentration in the detergent, whilst remaining within the specified weight percentage limits (so as to ensure more comprehensive information and higher safety levels). Furthermore, grouping the list of other substances together into categories that are better known than the individual components, makes them easier for consumers to recognise.

Amendment 42
ANNEX VIII, Point A, paragraph 3

For other constituents, if added, neither the above percentage ranges nor the concentration threshold of 0,2 % shall be applied. The following classes of constituent, if added, shall be listed irrespective of their concentration:	For other constituents, if added, neither the above percentage ranges nor the concentration threshold of 0,2 % shall be applied. The following classes of constituent, if added, shall be listed irrespective of their concentration:
- enzymes,	- enzymes,
- disinfectants.	- disinfectants,
	- preservatives,
	- perfumes,
	- optical bleaches.

Justification

As part of the necessary revision and updating process, three further categories are added to the list, namely preservatives, optical bleaches and perfumes, which must be included on labels irrespective of their concentration, so as to raise safety levels and provide more comprehensive information.

Amendment 43
ANNEX VIII, Point A, paragraph 5

If added, fragrances that appear on the list of allergenic perfume ingredients, first established by the Scientific Committee on Cosmetics and Non Food Products in its opinion SCCNFP/0017/98, shall be listed using the nomenclature established by that Committee***, irrespective of their concentration***.	If added, fragrances that appear on the list of allergenic perfume ingredients, first established by the Scientific Committee on Cosmetics and Non Food Products in its opinion SCCNFP/0017/98, shall be listed using the nomenclature established by that Committee. ***The Scientific Committee on Cosmetics and Non-Food Products shall give an opinion, within 18 months of the adoption of this regulation, on whether, based on scientific knowledge, a concentration limit shall be established for listing those fragrances. On the basis of that opinion, the Commission shall put forward, if necessary, a proposal establishing a concentration limit.***

Justification

The inclusion of information on allergenic perfume ingredients should be linked to the existence of a specific risk, as is the case in legislation on hazardous substances, in which information is provided on a substance if a specific risk threshold laid down by a scientific committee is exceeded. The same principle should be applied here. The Scientific Committee is therefore asked to express an opinion on the matter.

Amendment 44
ANNEX VIII, Point A, paragraph 6 a (new)

	A full list of the substances added to the detergent shall be made readily accessible to consumers and shall be published by the manufacturer on appropriate web sites, made available by a toll-free telephone number, and supplied in writing on demand and within a reasonable period. To this end, the Commission shall adopt a common ingredients nomenclature for detergents no later than 1 year after the entry into force of this Regulation. ***The web site address, telephone number, and postal address of the information***

	service shall be indicated on the primary packaging

Justification

In order to ensure respect for the consumer's right to appropriate information without overcrowding the label with information, a full list of ingredients should be made available elsewhere. In order to make this information easily understandable, the Commission should establish a common nomenclature for detergents to facilitate common usage of terms throughout the European Union.

Amendment 45
ANNEX VIII, Point B, paragraph 1, indent 2

- ***The*** number of standard washing machine loads of 'normally soiled' fabrics that can be washed with the contents of the package using water of medium hardness, corresponding to 2,5 millimoles $CaCO_3$/l.	- ***For normal detergents, the*** number of standard washing machine loads of 'normally soiled' fabrics***, and, for detergents for delicate fabrics, the number of standard washing machine loads of lightly soiled fabrics,*** that can be washed with the contents of the package using water of medium hardness, corresponding to 2,5 millimoles $CaCO_3$/l.

Justification

Producers must tell consumers how to use their detergents so as to obtain the best possible washing performance with the least possible environmental impact. A distinction should therefore be made between detergents for delicate fabrics, to which 'lightly soiled' conditions apply, and other detergents, to which 'normally soiled' conditions apply. This distinction is necessary in order to show the number of washing machine loads that a given quantity of each type of detergent will allow.

EXPLANATORY STATEMENT

1. Introduction

Since 1973 a large number of directives, recommendations and decisions covering detergents and their components have been adopted with a view *inter alia* to establishing minimum limits and techniques for measuring the biodegradeability of surfactants in detergents.

The existing body of provisions does not, however, cover all types of surfactant currently added to detergents. It therefore fails to ensure both an appropriate degree of environmental protection and the free movements within the internal market of detergents and their main components, namely surfactants.

The Commission's stated aim is to remove barriers to the free movement of the detergents and surfactants coming under the proposed regulation which, with a view to enhancing environmental and consumer protection takes over, updates and consolidates part of the existing provisions in this area.

The proposal seeks *inter alia* to:

- increase the number of surfactant categories covered by biodegradeability testing requirements (from two to four);
- introduce a new method for measuring biodegradeability;
- harmonise the system of biodegradeability tests and complementary risk assessments;
- introduce implicitly the principle of authorisation for the marketing of surfactants and, explicitly, a conditional derogation scheme,
- establish a binding labelling system.

The rapporteur would first like to make the general remark that, although the proposed regulation is rather pretentiously claimed to be a 'single text' on detergents, it reads more like a directive on surfactants. This is not simply because it focuses almost exclusively on the latter, but also because its structure is somewhat arbitrary. Furthermore, the proposal makes a large number of references to previous provisions, while failing to tackle various important issues in this area (pending the officialisation of the studies on phosphates and the completion of those on anaerobic biodegradation and the biodegradation of the other organic components of detergents).

The main issues covered by the amendments tabled are set out below.

2. Biodegradeability

As was mentioned above, new rules relating to tests on the biodegradeability of surfactants have been introduced.

The existing method involves the conducting of *primary biodegradeability* tests, the results of which are deemed satisfactory when they show a minimum level of 80% biodegradation of the surfactant over a period of four to six weeks. It should be pointed out that this test basically demonstrates the separation of the hydrophobic part of the surfactant from the hydrophilic part (loss of foaming effect), but not the degradation of each of the two parts.

The new method proposed, which involves the use of *ultimate biodegradeability* tests, is to apply not just to anionic and non-ionic surfactants, as was the case under the existing provisions, but also to cationic and amphoteric surfactants, which had not previously been subject to testing requirements. The results of such tests are deemed satisfactory when they show a minimum level of 60% biodegradation of the surfactant over a 28-day period.

The apparent lowering of the *aerobic biodegradeability* threshold is justified by the different method of analysis used, which, unlike its predecessor, is intended to check, in the presence of carbon dioxide, water, salts and biomass, the total (100%) biodegradation (mineralisation) of the surfactant. This new methodology was, furthermore, approved by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) at its twelfth plenary meeting on 25 November 1999.

The problem therefore is neither the aerobic biodegradeability thresholds for surfactants nor the test system to be used, but the absence of a test methodology for the *anaerobic biodegradeability* of surfactants and the *biodegradeability of the product as a whole* (in other words of every non-surfactant organic ingredient of the detergent), which is postponed to some future date, as is the drafting of provisions thereon.

It therefore appeared appropriate to set a deadline within which the Commission must submit the necessary proposals.

3. Granting of derogations, and conditions

The proposed regulation makes it compulsory to conduct *ultimate biodegradeability* tests on all surfactants in detergents. The findings of preliminary studies have shown that no more than 3% of the surfactants currently available on the market are likely to fail this test.

The Commission stipulates that, as a precondition for the granting of a marketing derogation, surfactants that fail the *ultimate biodegradeability* test must pass *primary biodegradation* tests and undergo a *complementary risk assessment.*

However, the other conditions set for the granting of such derogations are not laid down in a clear manner, even by way of an example. The Commission merely lays down general criteria for the refusal of derogation, leaving the final assessment to a committee (Article 12).

Without undermining the assessment procedure conducted by this committee, the rapporteur considers that Article 6 should be reworded in positive terms by changing the heading '*Refusal of derogation'* to *'Conditions governing the granting of derogation'.*

It should also be noted that the condition providing for the option of refusing a derogation in cases where '*socio-economic benefits do not outweigh the impact on human health and the environment*' has been deleted from the original wording, since it was open to a very wide range of interpretations.

4. Manufacturers' duties

The rapporteur considers two amendments to be necessary here:

- the first, to the provisions on the responsibility of manufacturers for the correct performance of the relevant tests (Article 9(2));
- the second, to those covering the making available to health care professionals of the information contained in the datasheet listing all ingredients of the detergent (Article 9(3)).

The first amendment seeks to relieve the manufacturer of the obligation to check that the tests have been performed correctly. This is because, in addition to the fact that the manufacturer may lack the necessary competence or instruments, the only laboratories authorised to carry out the required tests are those selected by the Member States, on the basis of specific conditions, and approved by the Commission

As regards the second amendment it should be said that 'health care operator' does not appear the right term to describe a professional person capable of handling the information gathered in a proper manner and at the same time ensuring the necessary degree of confidentiality. The term *'health care professional'* has therefore been changed to *'medical personnel'*.

5. Labelling

Careful thought needs to be given to the aims and usefulness of the information contained on labels, so as to ensure that the following requirements are met:
- the need to respect the consumer's lawful right to information; and
- the need to ensure that the label itself is clear.

Consumers are now unquestionably more aware and more capable of making both 'commercial' and 'political' choices than was previously the case. However, an excess of in some cases cryptic information on labels can lead to confusion, thus negating the original point of its inclusion.

A practical example of this is provided by the label appearing on a product widely available on the market, which contains the following list:

Mica, Talc, Titanium dioxide, Dimeticone,Octyl, Methoxycinnamate, Silica, Trimethylsiloxysilicate, Nylon - 12, Methicone, Cholesteryl stearate, Dioctyl succinate, Octyl hidroxystearate, Methylparaben, Propxlparaben, Sodium dehydroacetate, Aqua, Tocopherol,[+/- CI 77491, CI 77492, CI 77499].

Were the manufacturer to change the quantities of the ingredients in the formula for a given detergent, millions of packets of detergent would need to be recycled, given that an average factory in Europe produces approximately 40 tonnes per hour.

For the above reasons, the rapporteur has amended the provisions on labelling in order to simplify the contents and bring the provisions into line with existing legislation on cosmetics and hazardous substances and on disinfectants.

The amendments tabled seek:
- to group the substances together into categories (which are better-known than the individual

substances) and provide other information on the product which is more useful to consumers such as contains perfume and/or contains preservatives;
- in Annex VIII, to change the breakdown of substances whose presence must be indicated irrespective of concentration and those that must be indicated when they exceed the threshold laid down. This is necessary not least because of the heterogeneity and anachronistic listing of the components which must be indicated, which is the same as that in Recommendation 89/542/EEC, which is now 14 years old.

6. Adaptation of annexes

The amendment seeks to improve the division of competences between Parliament, the Commission and the Council and the manner in which information is managed.

7. Conclusions

The above provides an overview of the main amendments tabled by the rapporteur. It should be added, however, that the amendments as a whole are intended to make the provisions set out in the Commission proposal clearer and more useable.

20 March 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 European Parliament and Council regulation on Detergents (COM(2002) 485 – C5-0404/2002 – 2002/0216(COD))

Draftsman: John Purvis

PROCEDURE

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

It considered the draft opinion at its meetings of 23 January, 20 February and 20 March 2003.

At the last meeting it adopted the following amendments by 15 votes to 2, with no abstention.

The following were present for the vote: Carlos Westendorp y Cabeza chairman; John Purvis draftsman; Sir Robert Atkins, Luis Berenguer Fuster, Dorette Corbey (for Mechtild Rothe), Colette Flesch, Norbert Glante, Michel Hansenne, Roger Helmer (for Giles Bryan Chichester), Hans Karlsson, Bashir Khanbhai, Caroline Lucas, Erika Mann, Eryl Margaret McNally, Paolo Pastorelli, Esko Olavi Seppänen and Alejo Vidal-Quadras Roca.

SHORT JUSTIFICATION

This regulation will completely overhaul and modernise legislation concerning detergents. The objective is to facilitate the free movement of detergent products in the Internal Market. Biodegradability tests will be applicable to all types of surfactants, not only to two types as at present.

The draft Regulation will be an advance for detergent producers and consumers. There are however some shortcomings. The Commission proposal covers all types of detergents, independent of their production volume and their use. But there are big differences between a laundry product, made by an international player in thousands of tons for a mass consumer market, where alternatives are abundant, and a specialised product which is used (for example) to clean dairy equipment and is produced by an SME in small quantities for a limited market.

For the first group, it should be no problem to follow the provisions of the draft. Large companies can implement the process of testing all ingredients and apply for derogations if needed. If derogations are not granted, alternative substances are generally available. But, in the case of specialised industrial and professional products, the situation is more complicated. Many of these products are made by SMEs. They operate in niche markets with very specific requirements, such as degreasing in the metal industry or cleansing machinery in the food processing industry. Alternative substances are not only unavailable, but also alternative processes, such as super heat treatment for sterilising, are more environmentally detrimental than using specialised detergents.

That is why, for these products, different approval procedures should apply in order to make a derogation easier to obtain and more legally certain. Two amendments are proposed in this respect.

A further amendment introduces a sunset clause, first introduced in the financial services area, which will require a review of the proposed Comitology procedure after 8 years.

The last amendment concerns fragrances. No limit has been set by the Commission in its draft, whereas in other pieces of legislation there are always concentration limits set for the labelling of fragrances. There is a 10 ppm standard for leave-on products (e.g. face cream), a 100 ppm standard for rinse-off cosmetics (e.g. shampoo), proposed in the cosmetics directive 2003/.../EC1, and a 1000 ppm standard in the draft dangerous substances directive 1999/45/EC2. Thus, a standard of 500 ppm for products such as laundry detergents is proposed. These products are neither put on the skin to be left on nor are they used like shampoos, but are rinsed out of clothes before these are worn. The draftsman considers this level a reasonable compromise in such circumstances.

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[1] This directive is currently being amended. The third reading in the European Parliament will soon take place, Report Roth-Behrendt, A5-001/2003

[2] OJ L 200, 30/7/1999, p. 1.

AMENDMENTS

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

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1

Article 2, point 10 a (new)

	10. a "Specialised industrial and institutional product" means a product used in specific professional conditions in medicine, agriculture and industry where either human health and hygiene are at risk or industrial production processes require a high standard of cleanliness; such products are not available retail.

Justification

In certain areas, very specific products, "specialised industrial and institutional products", are used. Examples are the cleansing of dairy processing equipment, cleaning reusable containers, removing engine grease, sterilising operating theatres, etc. For these applications, alternatives are either not available or much more expensive or very energy-intensive and thus less environmentally friendly than detergents. These specific products are often produced in small quantities by SMEs and there is no retail consumer marketing.

Amendment 2
Article 2, point 10 b (new)

	10. b "Consumer product" means all other products not covered by 10. a.

[1] Not yet published in OJ.

Justification

This covers products that are produced in large quantities, are used by general consumers and can be bought retail.

Amendment 3
Article 4, paragraph 1a (new)

1. a In the case of specialised industrial and institutional products, requests for derogation shall be made in accordance with the provisions of Articles 5a and 9 if the following conditions are fulfilled:
- the product is not available retail,

- it is designated only for industrial and institutional use.

Justification

For the above products, a derogation should be easier to obtain. This is intended to help specialised SMEs whose products operate in very specific areas or extreme conditions where alternatives to these detergents are not available or are environmentally unsound. Only industrial and professional products should be eligible for this derogation, while products which are used by the general public and are available retail should not fall under this rule. This will ensure that only niche products and SMEs can use this rule.

Amendment 4
Article 5, Title

Granting of derogation	Granting of derogation ***for consumer products***

Justification

This amendment is necessary to distinguish the procedure of granting derogations for mass market consumer products, which will be more difficult and where derogation is not automatically granted, from the procedure for specialised industrial and professional

products, often produced by SMEs and in small quantities.

Amendment 5
Article 5 a (new)

Article 5a

Granting of derogation for specialised industrial and institutional products

1. The request by a manufacturer for derogation shall be made by sending an application to the competent authorities of the Member State concerned, referred to in Article 8(1), and to the Commission, providing evidence relating to the criteria mentioned under Article 4 (1 a) and Article 6 (1). The specific use of the product must be described in detail.

2. Applications shall include a technical file supplying all the information and justifications necessary for evaluating the safety aspects related to the specific use of surfactants in detergents failing to comply with the biodegradability limits, as set out in Annexes II and III.

In addition to the results of tests stipulated in Annex III, the technical file shall include results of tests, as stipulated in Annexes II and IV.

The appropriate tests from Annex IV, which will allow a tiered risk assessment, will be defined in a technical guidance document.

3. The competent authorities of the Member States, receiving applications for derogation according to paragraphs 1 and 2 above, shall examine the requests, evaluate their compliance with the conditions for derogation and inform the Commission about the results without delay.

If the competent authority of the Member State deems it necessary for the evaluation of the risk, which may be caused by a substance and/or a preparation, it may ask for further information, verification and/or confirmatory tests concerning these substances and/or preparations or their

transformation products, of which they have been notified or have received information under this Regulation.
4. The Commission will grant a derogation in accordance with the procedure set out in Article 12(2) if
- the conditions of Article 4 (1a) are fulfilled,
- Article 6 (1) does not apply,
- there are no environmentally sound alternatives for the specific use readily available.
If necessary, before granting the derogation, the Commission may evaluate further the matters indicated in paragraph 3 above.
5. Such derogations may allow, limit or severely restrict the placing on the market and the use of surfactants in detergents, depending on the results of the complementary risk assessment as defined in Annex IV of this Regulation and the availability of alternatives in the specific area of use. They may include a phase-out period for placing on the market and the use of surfactants in detergents.
6. The Commission shall publish the list of surfactants that have obtained derogation, with the corresponding conditions or limitations of use, as provided in Annex V.

Justification

For specialised industrial and institutional products which are produced in small quantities for very specific applications it should be possible to obtain derogations even if the biodegradability limits are not fulfilled and by a tiered risk assessment procedure which reduces the cost of obtaining such derogations.

Amendment 6

Article 11, paragraph 2, letter (ca) (new)

(ca) Products covered by an Article 5 derogation must be suitably labelled.

Justification

Derogations are necessary in some areas. However, products must be clearly identifiable as being covered by such a derogation since the user must know what kind of a product he is buying.

Amendment 7
Article 15a (new)

Article 15 a
Sunset Clause
Without prejudice to the implementing measures already adopted, on the expiry of an eight-year period following the entry into force of the Directive, the application of its provisions requiring the adoption of technical rules and decisions in accordance with the procedure referred to in Article 13 by the Committee referred to in Article 12 (2) shall be suspended. On a proposal from the Commission, the European Parliament and the Council may renew the provisions concerned in accordance with the procedure laid down in Article 251 of the Treaty and, to that end, they shall review them prior to the expiry of the period referred to above;

Justification

This is the so-called sunset clause from the European Parliament resolution on the implementation of financial services legislation adopted on 5.2.2002. Originally meant for the field of financial services legislation, it can be adapted to the field of environmental legislation. With a view to consolidating democratic scrutiny of implementing powers and bringing them into line with a changing economic and technical environment, the legislator must be able to revise the scope of the powers conferred on the Commission by specifying the period during which they may be exercised. As the situation changes faster in the field of financial services than in the field of detergents and environmental standards, the period of four years has been extended to eight years.

Amendment 8

Annex VIII, part B, paragraph 1, indent 2 a (new)

- Different dosage indications shall be allowed on packaging where the water is not of medium hardness.

Justification

The calcium carbonate content of water of medium hardness is given as 2.5 mmol/l CaCO3. According to the SI system of classification this is what is known as hard water. The proposal for a regulation stipulates that the number of washing cycles should be calculated in accordance with the dosage for such hard water.

In those countries and areas where soft water predominates, the dosage of detergent needed in the water can be less than half that for hard water. For this reason the packaging of detergents should allow dosage indications advising consumers to use less detergent in soft water, e.g. semi-hard water which according to the SI classification has a calcium carbonate content of between 0.882 and 1.764 mmol/l.