Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision 2002/0216(COD) procedure) Regulation	Procedure completed
Detergents Amended by 2007/0213(COD) Amended by 2010/0298(COD)	
Subject 3.40.01 Chemical industry, fertilizers, plastics 3.70.04 Water control and management, pollution of waterways, water pollution 4.60.02 Consumer information, advertising, labelling	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health, Consumer Policy		02/10/2002
		UEN NOBILIA Mauro	
	Former committee responsible		
	ENVI Environment, Public Health, Consumer Policy		02/10/2002
		UEN NOBILIA Mauro	
	Former committee for opinion		
	JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
	ITRE Industry, External Trade, Research, Energy		12/11/2002
		PPE-DE PURVIS John	
Council of the European Union	Council configuration	Meeting	Date
	Competitiveness (Internal Market, Industry, Research and Space)	2570	11/03/2004
	Economic and Financial Affairs ECOFIN	2537	04/11/2003
	Competitiveness (Internal Market, Industry, Research and Space)	<u>2510</u>	19/05/2003
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs		

Key events			
04/09/2002	Legislative proposal published	COM(2002)0485	Summary
	Committee referral announced in		

05/09/2002	Parliament, 1st reading		
25/03/2003	Vote in committee, 1st reading		Summary
25/03/2003	Committee report tabled for plenary, 1st reading	<u>A5-0105/2003</u>	
10/04/2003	Debate in Parliament	F	
10/04/2003	Decision by Parliament, 1st reading	<u>T5-0184/2003</u>	Summary
05/06/2003	Modified legislative proposal published	COM(2003)0306	Summary
04/11/2003	Council position published	10595/3/2003	Summary
06/11/2003	Committee referral announced in Parliament, 2nd reading		
02/12/2003	Vote in committee, 2nd reading		Summary
02/12/2003	Committee recommendation tabled for plenary, 2nd reading	<u>A5-0455/2003</u>	
13/01/2004	Debate in Parliament	-	
14/01/2004	Decision by Parliament, 2nd reading	<u>T5-0017/2004</u>	Summary
11/03/2004	Act approved by Council, 2nd reading		
31/03/2004	Final act signed		
31/03/2004	End of procedure in Parliament		
08/04/2004	Final act published in Official Journal		

Technical information	
Procedure reference	2002/0216(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by <u>2007/0213(COD)</u>
	Amended by <u>2010/0298(COD)</u>
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/19453

Documentation gateway				
Document attached to the procedure	COM(2002)0287	10/06/2002	EC	Summary
Legislative proposal	COM(2002)0485	04/09/2002	EC	Summary
Economic and Social Committee: opinion, report	CES0282/2003 OJ C 095 23.04.2003, p. 0024-0026	26/02/2003	ESC	
Committee report tabled for plenary, 1st reading/single reading	<u>A5-0105/2003</u>	25/03/2003	EP	

Text adopted by Parliament, 1st reading/single reading	T5-0184/2003 OJ C 064 12.03.2004, p. 0392-0540 E	10/04/2003	EP	Summary
Modified legislative proposal	COM(2003)0306	05/06/2003	EC	Summary
Council position	10595/3/2003 OJ C 305 16.12.2003, p. 0011-0051 E	04/11/2003	CSL	Summary
Council statement on its position	13271/2003	04/11/2003	CSL	
Commission communication on Council's position	SEC(2003)1051	06/11/2003	EC	Summary
Committee recommendation tabled for plenary, 2nd reading	A5-0455/2003	02/12/2003	EP	
Text adopted by Parliament, 2nd reading	T5-0017/2004 OJ C 092 16.04.2004, p. 0126-0252 E	14/01/2004	EP	Summary
Commission opinion on Parliament's position at 2nd reading	COM(2004)0138	26/02/2004	EC	Summary
Follow-up document	COM(2007)0234	04/05/2007	EC	Summary
Follow-up document	COM(2009)0208	04/05/2009	EC	Summary
Follow-up document	COM(2009)0230	26/05/2009	EC	Summary
Follow-up document	COM(2015)0229	29/05/2015	EC	Summary

Additional	information	
Auditional	IIIIOIIIIalioii	

European Commission EUR-Lex

Final act

Regulation 2004/648

OJ L 104 08.04.2004, p. 0001-0035 Summary

Final legislative act with provisions for delegated acts

Detergents

This document comprises of the report from the Commission on the results reached for the period 1996-2000 by the implementation of Commission Recommendation 98/480/EC of 22 July 1998 concerning good environmental practice for household laundry detergents. As regards the implementation of Commission Recommendation 98/480/EC of 22 July 1998 concerning good environmental protection, the Recommendation recommends for the first time at Community level "Environmental Agreements" as a tool for industry to implement the actions envisaged in the Recommendation. AISE (the official body that represents the soap, detergents and maintenance products industry within Europe) committed itself to undertake initiatives in order to achieve these targets. For this purpose AISE developed a Code of Good Environmental Practice for the Household Laundry Detergents for implementation in eighteen countries: the fifteen EU Member States plus Iceland, Norway and Switzerland. Implementation of the Code started in Denmark and Sweden in autumn 1997 as a pilot project. Following the positive results obtained in this pilot project, and the endorsement by the European Commission in the form of a Recommendation in July 1998, implementation in the other participating countries started in mid-1998/early 1999 and has continued since. Commitments and targets in the AISE Code are based on risk assessment and life cycle analysis. Under the Code, manufacturers agree to provide consumers with relevant usage instructions to guide them on how to do their laundry in an environmentally responsible manner. It should be noted that Member States agreed to contribute to the implementation of this Commission Recommendation and that all stakeholders showed interest in the achievement of the targets set in the above Recommendation, and particularly: - the use of lower washing temperatures to decrease energy consumption and thus decrease CO2 emissions; - a decrease of the consumption of detergents and their packaging to lower the general environmental impact of detergents; - a decrease of the poorly biodegradable ingredients in detergents (PBO's), to reduce the effects of detergents on the environment. As stipulated in Article 7 of the Recommendation, AISE has provided for an independent organisation to collect and process statistics. PricewaterhouseCoopers (PwC) was selected to monitor progress towards targets for consumption, packaging and PBOs every two years, and in addition to report on the energy consumption in the final report in 2002. The 1996-1998 figures for the three targets mentioned above, at both European and National levels, were presented in a first intermediate report by PwC with a summary of the main trends from 1996 to 1998. PwC has now prepared a second report covering the period 1999-2000. The main conclusions of these Organisations for the reporting period 1996-1998 were that for the four targets which were to be considered in the intermediate evaluation, two of them were fully achieved: the reduction of the PBOs and the information to consumers, but that the 1996-1998 data suggested that much remained to be done to reduce consumption of detergents and of packaging. PwC report that for the period 1999-2000 the number of companies committed to the code has increased from 154 to 179, despite a number of mergers in the industry. Data on the consumption of detergents, packaging and PBOs is presented and compared with the data for the period 1996-1998. ?

Detergents

PURPOSE: to present a proposal for a Regulation on detergents. CONTENT: this proposed regulation establishes rules designed to achieve the free movement of detergents in the internal market while, at the same time, ensuring a high degree of protection for the environment. It lays down rules for: - the biodegradability of surfactants in detergents, and - the labelling of detergents. This proposal modernises the existing detergent directives, regarding the biodegradability of surfactants and the protection of the environment. The proposed new biodegradability tests ensure a higher level of environmental protection and at the same time are applicable to all types of surfactants in detergents. Furthermore, the requirements specified in Commission Recommendation 89/542, on labelling of detergents and cleaning products, and specific information to consumers related to the presence in detergents of fragrance substances are made binding for the products covered by this Regulation. The main points in the proposed legislation are: - a new definition for detergents to cover equivalent uses and be in line with developments in Member States; - the introduction of a definition for surfactants; - a clear and precise definition of the relevant types of biodegradability. The existing legislation on biodegradability of surfactants in detergents only covers primary biodegradability and it is only applicable to anionic and non-anionic surfactants. It needs to be replaced by new legislation, which lays the main emphasis on ultimate biodegradability and meets concerns related to the potential toxicity of persistent metabolites. The existing requirements regarding primary biodegradability are to be maintained on a second hierarchy level for those surfactants failing the ultimate biodegradability tests. Surfactants failing primary biodegradability tests cannot obtain marketing authorisation by way of derogation. The primary biodegradability requirements are extended to all surfactants, in particular cationic and amphoteric, whilst allowing for the possibility of applying instrumental analyses in those cases in which semi-specific analytical methods are not suitable. There are provisions to place on the market in exceptional cases surfactants failing the ultimate biodegradability test. Detergents not fulfilling requirements laid down by this Regulation will not be placed on the market. Specific labelling is introduced to inform consumers about fragrance substances and preservation agents that are present in detergents. Manufacturers of detergents remain responsible for not placing on the market detergent preparations containing non-complying surfactants and for ensuring that all the required technical documentation is available.?

Detergents

The committee adopted the report by Mauro NOBILIA (UEN, I) amending the proposal under the codecision procedure (1st reading). The amendments sought to tighten up the proposal, including stricter conditions on derogations from biodegradability rules and clearer labelling for consumers. The Commission was also urged to table a new legislative proposal with a view to phasing out phosphates, or restricting them to specific applications, three years after the regulation takes effect. In addition, the committee called for new proposals on testing for anaerobic biodegradation and the biodegradation of the product as a whole, these being the two elements of testing neglected by the Commission in its current proposal. The committee insisted that there must be only two conditions for granting a marketing derogation. Firstly, the detergents must be intended for specific industrial or institutional use, provided the volume of sales and use throughout the whole of EU territory is below that which would pose a threat to the environment and health. Secondly, an essential need for the detergent's use must have been shown, in particular in view of food safety or hygiene standards, and no safer alternatives must be available. The committee also specified that, if derogations are granted, industry should be able to demonstrate that safer alternatives are being developed and the need for a derogation should be reviewed after 5 years. On labelling, the committee adopted an amendment which would group the list of other substances together into categories that are better known than the individual components, thus making them easier for consumers to recognise. It argued that an excess of cryptic information on labels can lead to confusion, thus negating the original point of including it. It also wanted products covered by a derogation to be suitably labelled.?

Detergents

The Parliament amended and tightened up the draft regulation from the Commission on detergents by including stricter conditions on derogations from biodegradability rules and clearer labelling for consumers. MEPs also took a stand on the question of phosphates by urging the Commission to table a new legislative proposal with a view to phasing out phosphates, or restricting them to specific applications, three years after the regulation takes effect. In addition, Parliament called for new proposals on testing for anaerobic biodegradation and the biodegradation of the product as a whole, these being the two elements of testing neglected by the Commission in its current proposal. On labelling, Parliament adopted an amendment which would group the list of other substances together into categories that are better known than the individual components, thus making them easier for consumers to recognise. Parliament supported the reporter's, Mauro NOBILIA's (UEN, I), view that an excess of cryptic information on labels can lead to confusion, thus negating the original point of including it. It should also be noted that an amendment was adopted stating that if a detergent product carries any claim to be 'green' and not the European Eco-label, then it must clearly indicate which of the European Eco-label criteria it does not fulfil. This must be indicated on the packaging next to and in same letter size as the 'green' claim.?

Detergents

The Commission has adopted the amended proposal adapting the original proposal for a Regulation on Detergents following Parliament's first reading of the text. The text has been adopted where appropriate in the interest of clarity. A number of detailed improvements on matters of substance, in line with the Commission's original proposal, have also been made. Five Parliamentary proposals have been accepted in their entirety. Those accepted in part or subject to reformulation relate to: - Complementary risk assessment; - The definition of industrial and institutional detergents; - Forwarding information on detergents to medical staff and the definition of medical personnel; - In cases of "specific analytical methods", the Commission has reformulated the text to include high performance liquid chromatography (HPLC) and/or gas

chromatography (GC). This applies to surfactants methods MBAS, BiAS and DBAS. - Additional consumer information on two different categories of detergent, namely heavy-duty detergents and detergents for delicate fabrics. - The definition of a surfactant in terms of an extended list of properties instead of including the intention of the manufacturer. - The criteria for derogations remaining subject to the co-decision procedure - Clarifications concerning the implementation of the provisions. The Commission did not accept thirty-eight amendments.?

Detergents

The Council adopted the common position, by a qualified majority, the Portuguese delegation voting against. The Council accepted 5 amendments as they were accepted by the European Parliament and 12 were accepted in principle. All the other amendments have been rejected. The common position amends the Commission's proposal and intends to reply to the following demands: The Common Position modifies the Commission Proposal by attempting to cater for the following requirements: - better definition of the parties intervening in the authorisation or derogation process; - clarification of the scope (inter alia by defining the boundaries with respect to biocidal products); - need to inform and to protect consumers; - providing clearer guidelines for approved laboratories and for testing methods. The Council has introduced new elements in the common position compared with the Commission proposal. - Objectives and scope : this article has been modified, strengthening the importance of biodegradability for surfactants and underlining the importance of the information, contained in the technical file, that manufacturers must hold at the disposal of the Member States. It has also been stressed that, besides the environment, one of the objectives is to protect the human health. - Definitions : new definitions were added for "medical personnel" and for "industrial and institutional detergent" (as requested by the Parliament). - The placing on the market: the distinction between detergents and surfactants, on the one hand, and biocidal products, on the other hand, has been included. - Limitations on biodegradability of surfactants: the link between aerobic biodegradation of surfactants and limitations as regard placing on the market has been clarified. - Granting of derogations: Derogations are now subject to fees, a tiered approach for tests has been introduced and various deadlines have been added to this Article. -Refusal of derogation: Refusal of derogation will henceforth be decided by the Commission assisted by the Committee set up by Art. 12. Also, deadlines have been introduced together with the obligation to publish a list of surfactant not complying with this Regulation. - Testing of surfactants: Testing requirements have been clarified. - Duties of the Member States: criteria for appointing approved laboratories have been modified, by introducing a reference to the norm EN ISO/IEC 17025 and to good laboratory practices. - Information to be provided by manufacturers: this Article has been modified by slightly rewording it and by introducing the notion of a public body which, in a Member State, may circulate the information received to medical personnel. - Control measures: this Article has been slightly reworded for clarity and the obligation for the Commission to verify false positive results has been introduced. - Labelling: amendments to this Article were made to better identify the party responsible for placing on the market the detergent and to allow for national provisions forbiddingdisplaying on the package of liquid products symbols (e.g. fruits) which might lead the consumer into error as to the use of the product (essentially to protect children). -Committee procedure: the text was changed to the standard legal text for this type of legislative Articles. - Adaptation of the annexes: Minor drafting changes were made to this Article, also stressing inter alia that all amendments to rules on solvent-based detergents will be made by Committee procedure (Art. 12). - Free movement clause : a legal clarification as to when products complying with this Regulation may be prevented from being placed on the market was introduced. - Legislation to be replaced and sanctions for non-compliance: minor legal redrafting changes were made to both Articles. - Annex I: Standards for accreditation: References to good laboratory practices (GLP) and to animal protection were added. - Annex II: (Testing methods): It was specified that in certain cases high performance liquid cromatography (HPLC) or gas cromatography (GC) should be used. - Annex III: (Biodegradability tests): Footnotes were renumbered. - Annex IV: A tiered approach for the technical file was introduced, the relation between failing a test and refusing a derogation was reworded and the header of a section dedicated to biodegradability tests was reworded. Some footnotes were renumbered. - Annex VII : Annex VII was deleted. - Annex VIII : (Labelling and ingredient datasheet): An amendments was made to include salts of some compounds previously already listed. The prescription to list allergenic fragrances if superior to a 0,01% concentration was introduced. Consumer information as to the expected number of loads which may be washed with a package content and the standard dose recommended for a specific type of wash was added.?

Detergents

The Commission supports the Council Common Position because it largely follows the lines of the amended proposal. It also includes the 2 following statements: 1) Fragrance Allergens: the Commission recognises the importance of the incidence of allergy amongst consumers. It is therefore necessary to take all necessary measures to ensure that detergents are appropriately labelled so that consumers who know that they are allergic, can avoid specific ingredients. Thus, the Commission will ask the Scientific Committee on Cosmetics and Non-Food Products to continue - and where possible accelerate - its work on establishing individual risk based limits for fragrance allergens, with special reference to detergents. It is the aim of the Commission to have such limits established and adopted by Comitology closely after the entry into force of the Detergents Regulation. 2) Publication of Standards: the Commission recognises that some of the standardised test methods are rather old and in need of updating. In addition, some of them are national standards and are therefore only available in their original language. It is desirable to remedy this situation by establishing European Standards that would replace the national ones and would be available in the languages of the CEN system. The Commission will therefore ask CEN to review the existing national standards and to adopt, where possible, equivalent European Standards. As soon as these are available, the Commission will propose to integrate them into the Regulation by Comitology.?

Detergents

The committee adopted the report by Mauro NOBILIA (UEN, I) amending the Council's common position under the 2nd reading of the codecision procedure: - the new legislation should be re-assessed after three years and reviewed after five years in the light of separate legislation in the pipeline on the biodegradability of surfactants, a key ingredient of detergents; - a new article should be inserted providing for a "sunset clause", as in financial services legislation, whereby subsequent implementing rules for this legislation which are adopted by an advisory committee would expire after eight years unless they are renewed by EU lawmakers; - in order to achieve the objectives, in particular the objective of ensuring a high degree of protection of human health, the regulation should also lay down rules on restrictions other than those on grounds of biodegradability; - any derogation granted should be reviewed after 5 years and the applicant should provide information to demonstrate that he is developing alternatives which will fulfil the requirements for "ultimate aerobic biodegradation"; - the list of substances to

be labelled should be shortened and grouped together in order to make them easier for consumers to recognise; - not just enzymes and disinfectants but also preservatives, perfumes and optical brighteners should be labelled; - a complete list of substances added to the detergent should be published on the internet and made available via a freephone or supplied in writing on demand and within a reasonable period. In order to make this information easily understandable, the Commission should establish, one year after the regulation comes into force, a common ingredients nomenclature for detergents. In addition, the website address, telephone number and postal address of the information service should be indicated on the primary packaging; - if a product carries any claim to be "green" but not the European Eco-label, it should clearly indicate which of the European Eco-label criteria it does not fulfil; - national rules on detergents should remain valid as long as there is no EU legislation to the contrary.?

Detergents

The European Parliament adopted a resolution based on the report drafted by Mauro NOBILIA (UEN, I). Following the meeting of the Environment committee, (please see the summary of 02/12/03.), the Council and the Parliament held negotiations, which led to a "provisional compromise" adopted by the plenary: - with regard to metabolites, if further information is sought, stepwise testing strategies should be employed to ensure maximum use of in vitro and other non-animal test methods; the article headed "refusal of derogation" has been amended to "conditions for granting a derogation". Such conditions include consideration of the following criteria: use in low-dispersive applications, rather than in wide-dispersive applications; use in specific industrial and/or institutional applications only; and, the risk to the environment or to health posed by the volume of sales and the pattern of use throughout the EU is small compared to the socio-economic benefits, including food safety and hygiene standards; - the Commission may review a derogation as soon as information comes to light which would justify a significant revision of the technical file that was included in the application for derogation; - pending further harmonisation, Member States may maintain or lay down national rules concerning the use of phosphates in detergents. In committee, MEPs had asked for national standards on detergents to remain valid for as long as there is no contradictory European legislation. According to the provisional compromise, this rule would apply only to the use of phosphates in detergents; - by following the compromise, Parliament rejected an agreement from the Greens, which proposed the banning of phosphates or restrictions on their use. However, they voted to insist that the Commission should present a proposal to ban or restrict phosphates within three years. This is why the compromise is only "provisional" - the Council is proposing a five year period. Some Members expect the Council to agree to three years without recourse to conciliation, but the question remains open for the time being; - five years after the date of publication of the Regulation, the Commission will carry out a review of its application, paying particular regard to the biodegradability of surfactants, and where justified, present legislative proposals relating to anaerobic biodegradation, and the biodegradation of main nonsurfactant organic detergent ingredients; - in committee, Members had asked for an exhaustive list of all additives to be made public on the Internet, and according to the preference of the company, by telephone or in writing. The compromise proposes instead that "manufacturers shall make available on a website the ingredient datasheet mentioned above except for the following information: weight percentage ranges, constituents of perfumes and essential oils, constituents of colouring agents. This obligation shall not apply to industrial or institutional detergents containing surfactants, or to surfactants for industrial or institutional detergents, for which a technical data sheet or safety data sheet is available; - as requested by the Environment Committee, not only enzymes and disinfectants, but also perfumes and optical brighteners will be labelled. On the other hand, preservatives will not now belabelled. Three other proposals made by the Environment Committee were left out of the compromise and were therefore rejected by the plenary session: - the obligation to explain the areas of non-compliance with European ECOLabel standards when a product is labelled as 'Green' despite not meeting all the ECOLabel conditions; - the shortening and regrouping of the list of substances to be labelled; - the request to apply a sunset clause, according to which the standards adopted by a consultative committee would expire after 8 years if they were not renewed by the legislature.?

Detergents

The European Commission accepted the eight amendments adopted by the European Parliament and has adopted its proposal accordingly.?

Detergents

PURPOSE: to establish rules designed to achieve the free movement of detergents in the internal market while, at the same time, ensuring a high degree of protection for the environment.

LEGISLATIVE ACT: Regulation 648/2004/EC of the European Parliament and of the Council on detergents.

CONTENT: the Council approved the amendments adopted by the European Parliament at second reading.

This Regulation establishes rules designed to achieve the free movement of detergents and surfactants for detergents in the internal market while, at the same time, ensuring a high degree of protection of the environment and human health. For this purpose, this Regulation harmonises the following rules for the placing on the market of detergents and of surfactants for detergents:

- the biodegradability of surfactants in detergents;
- restrictions or bans on surfactants on grounds of biodegradability;
- the additional labelling of detergents, including fragrance allergens; and
- the information that manufacturers must hold at the disposal of the Member States competent authorities and medical personnel.

The Regulation seeks to achieve these objectives by modernising the directives that lay down rules for the biodegradability of surfactants used in detergents and by incorporating and expanding labelling rules contained in Commission recommendation 89/542/EEC. Modernisation is provided by new biodegradability tests which will provide an enhanced level of protection to the aquatic compartment. In addition, the scope of the tests is extended to all classes of surfactant thereby including the 10% of surfactants that escape current legislation.

As regards the labelling, labelling rules are extended to include fragrance ingredients that could cause allergies, and manufacturers are obliged to disclose a full list of ingredients to medical practitioners treating patients suffering from allergies.

By 8 April 2007, the Commission shall evaluate, submit a report on and, where justified, present a legislative proposal on the use of phosphates with a view to their gradual phase-out or restriction to specific applications.

By 8 April 2009, the Commission shall carry out a review of the application of this Regulation, paying particular regard to the biodegradability of surfactants, and shall evaluate, submit a report on, and, where justified, present legislative proposals relating to:

- anaerobic biodegradation,
- the biodegradation of main non-surfactant organic detergent ingredients.

No later than 8 October 2005, Member States shall adopt appropriate legal or administrative measures in order to deal with any infringement of this Regulation and dissuasive, effective and proportionate sanctions for any such infringement.

ENTRY INTO FORCE: 08/10/2005.

Detergents

The Commission presented a report concerning the use of phosphates, pursuant to Article 16 of Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents.

Phosphates are one of the most commonly-used and abundant ingredients in domestic and industrial detergents. The annual consumption of phosphate containing detergents in the EU-25 is about 1.8 million tonnes, a value equivalent to a phosphorous content of about 110,000 tonnes. 90-95% of these are consumed in domestic laundry and dishwashing detergents.

The Commission has taken a significant number of steps to establish the knowledge base needed to evaluate the impact of the use of phosphates in detergents on eutrophication, as required by Regulation 648/2004.

Building on the results of an earlier study on the impact of phosphates contained in detergents on eutrophication by WRc in 2002, and on opinions of the Commission?s Scientific Committee in March and November 2003, two further studies were carried out to fill the data gaps identified in the Committee?s opinions. The results of those two further studies were discussed with delegates from Member States and industry at a meeting of the Detergents Working Group in November 2006, and have then also been submitted to the Commission?s Scientific Committee for an opinion, which is currently still pending.

According to reports submitted in the context of the WFD, eutrophication remains one of the most important threats to fresh and marine waters. Significant improvements in understanding have been achieved over the past years. However, in April 2007 the state of knowledge concerning eutrophication is still developing rapidly, and extensive additional data on water quality assessment throughout the EU is expected shortly through the inter-calibration exercise of the Water Framework Directive.

A decision on whether restrictions on phosphates in detergents are justified at EU level will be taken once sufficient evidence has been acquired and various policy options have been assessed in consultation with the Detergents Working Group. In particular, justification for harmonised measures should await the outcome of the opinion of the Commission?s Scientific Committee on the already completed studies. The Commission will initiate an impact assessment in 2007 with the aim of concluding it in 2008, if possible, depending on the forthcoming Scientific Committee opinion and the extent of the open issues identified. The Commission will present a legislative proposal without delay once a decision is taken that restrictions are justified.

Pending a decision, the Commission recalls that Member States may proceed with measures to replace phosphate-based detergents where this can be justified on environmental grounds (e.g. on the basis of the WFD). Member States wishing to introduce "technical regulations" falling under Directive 98/34/EC will have to notify the Commission and justify that these measures are in accordance with the requirements of the Directive

Detergents

This report presents the results of the Commission's review on the biodegradation of the main non-surfactant organic ingredients in detergents pursuant to Regulation (EC) No 648/2004 on detergents.

When the Detergents Regulation was adopted in 2004, the criterion of ultimate biodegradability was considered to be an effective and proportionate way of ensuring that detergent surfactants do not pose a risk to the environment. Biodegradability was used as a proxy for environmental toxicity because insufficient direct data on the environmental toxicity of surfactants was available at that time. However, in the meantime, and in preparation for REACH, much effort has gone into carrying out targeted risk assessments on detergent ingredients. The Commission has therefore been able to go further than required by the Regulation and has been able to evaluate not only the biodegradability, but also the risk posed by those substances.

A study conducted for the Commission in 2006 reviewed the biodegradability and ecotoxicity of the main non-surfactant organic detergent ingredients. No risk to the environment has been identified for any of the non-surfactant organic detergent ingredients. Although risk cannot be definitely excluded for a few of those substances, as information on them is incomplete, the amount of additional data needed for a complete risk assessment is now relatively small. It is, therefore, not considered appropriate to propose legislation to impose a requirement of ultimate biodegradability on the non-surfactant organic ingredients. In fact, many of the non-surfactant organic ingredients for which data is complete are not ultimately biodegradable, but are neither toxic to human health nor to the environment. Applying a surrogate risk indicator such as ultimate biodegradability to the non-surfactant organic ingredients would therefore ban a number of them where it is known that they do not pose risks. It would therefore be more proportionate, as well as more scientifically robust, to complete instead the risk assessments on the few outstanding substances.

Uncertainties remain concerning the environmental fate of: (a) polycarboxylates and phosphonates, both of which are used in considerable tonnages in household detergent formulations and (b) Ethylendiammine tetra acetate (EDTA) and its salts (mainly used in I&I detergents),

triethanolamine, FWA-5 and paraffins for which existing data are not yet sufficient to exclude the possibility of environmental risk.

The information requirements of the REACH registration dossiers will ensure that for most of these substances, comprehensive data on hazard properties and possible risks to human health or the environment will be submitted by industry to the European Chemical Agency (ECHA). In fact, for substances manufactured or imported in quantities of 1 000 tonnes or more per year registrations are due by December 2010 and chemical safety reports as part of the registration dossiers will need to demonstrate the safe use throughout their life cycle.

Therefore, the REACH registration information should be sufficient to decide whether restrictions on the above-mentioned detergent organic ingredients are needed on grounds of environmental risk, and if so, the restriction procedure of REACH would be the most appropriate instrument to impose such restrictions. Concerning polycarboxylates, for which according to REACH only the monomers need to be registered, a revised HERA risk assessment is foreseen in the near future which should clarify the remaining uncertainties with regard to potential environmental risks. The revised report will by submitted in April 2009. Furthermore EDTA will be also reviewed by the Commission by 2011 in view of a possible identification as a priority substance under the Water Framework Directive.

Consequently, the Commission does not intend to propose legislation concerning the biodegradability of non-surfactant organic ingredients. The concept of using biodegradability as an acceptance criterion for detergent ingredients has become redundant in light of comprehensive risk assessment data on the environmental toxicity of the substances.

Detergents

Pursuant to Regulation (EC) No 648/2004 on detergents, the Commission presents its report on anaerobic biodegradation. This report concerns the anaerobic biodegradation of detergent surfactants with a focus on linear alkylbenzene sulphonate (LAS) which is a widely-used surfactant that is reported to be poorly biodegradable under anaerobic conditions. The report covers the properties of LAS obtained from the scientific literature, risk assessment reports on the risks associated with the use of LAS in detergents, and a review of anaerobic testing methodology.

Although no reports have been received from Member States of any environmental concerns due to surfactants since the introduction of the Detergents Regulation, it has been noted that some surfactants do accumulate in sewage sludge where they remain until the sludge is disposed of, for example as a fertiliser in agriculture, where re-exposure to aerobic conditions allows aerobic biodegradation to proceed to completion.

The environmental fate and behaviour and the toxicity of surfactants must be considered for evaluating the effectiveness of the existing legislation in managing the overall risk. The Commission approached this task in two stages: first to establish the existing knowledge base and identify gaps, second, to fill those gaps. The first stage was completed in 2005; the second has taken from 2006 to 2009.

The report notes that the Commission has taken a number of steps to establish a knowledge base sufficient to review the anaerobic biodegradation of surfactants. The results of a study conducted in 2003 on anaerobic biodegradation together with the findings of risk assessment studies of major surfactants which were conducted by Industry in 2007 on a voluntary basis and the outcome of their evaluation by SCHER, were discussed with delegates from Member States and industry associations.

Following a systematic evaluation of the risks from the presence of non-degradable surfactants in various anaerobic compartments, it was concluded that, in contrast to the adverse effects observed in the absence of aerobic degradation, the lack of anaerobic degradation does not seem to be correlated with any apparent risk for these environmental compartments. It can therefore be concluded that anaerobic biodegradability should not be used as an additional pass/fail criterion for the environmental acceptability of surfactants such as LAS which are readily biodegradable under aerobic conditions.

Concerning the recently produced data on the terrestrial toxicity of LAS leading to an increased PNECsoil (which reduces the PEC/PNEC ratio and thereby diminishes the predicted environmental risk from LAS in anaerobic sludge and soil) this should be better substantiated as requested by SCHER in its opinion of 2008.

The remaining concerns therefore focus on the possible environmental toxicity of surfactants, rather than on their biodegradability. At present, however, there is no evidence that would justify legislative measures at EU level, such as regulatory limit values for LAS in sludge.

The information requirements of the REACH registration dossiers will ensure that comprehensive data on the health and environmental effects of detergents ingredients - including surfactants such as LAS - will be submitted by industry to the European Chemical Agency (ECHA). In fact, for substances manufactured or imported in quantities of 1 000 tonnes or more per year registrations are due by December 2010 and chemical safety reports as part of the registration dossiers will need to demonstrate the safe use throughout their life cycle. The REACH registration information should therefore be sufficient to decide whether restrictions on certain surfactants in detergents formulations are needed on environmental grounds in addition to those already imposed by the Detergents Regulation. If so, the restriction procedure of REACH would be the most appropriate instrument to impose such restrictions.

Detergents

In accordance with Regulation (EC) No 648/2004 on detergents, the Commission presents a report on the use of phosphorus in consumer automatic dishwasher detergents (CADD). It sets out its analysis of the impacts on the environment and health, on industry and on consumers of CADD with phosphorus levels above and below the limit value of 0.3 grams, taking into account matters such as the costs for producers, the availability of alternative substances to phosphates, the comparative cleaning efficiency of the detergents complying with this restriction and the impact on waste water treatment practices and efficiency. The Commission is required to state whether the limit value should be modified. The report is based on the CADD study carried out by the Commission. The limit value of 0.3 g will become effective from 1 January 2017.

The report recalls that phosphate in the form of Sodium Tri-Poly-Phosphate (STPP) is the most commonly used compound of modern domestic and industrial detergents due to its cleaning enhancing properties and the fact that it is cost-effective

Alternatives to phosphate: technical feasibility for phosphates-free automatic dishwashing detergent is confirmed by the CADD study which observes that a large number of patents have been placed on substitution approaches since 2012 for replacing phosphates. Moreover

consumer associations from various Member States have performed tests comparing performance of phosphates-free and phosphates containing CADD. Overall, phosphates-free CADD and phosphates-containing CADD perform similarly as regards their cleaning efficiency.

Market: many manufacturers already offer phosphate-free CADD in some Member States of the EU. The prices of CADD seem to be based mostly on performance and do not depend on the presence of STPP seeing as both types of CADD are sold within approximately the same price range. With a complete switch to phosphates-free CADD, the majority of the stakeholders expect prices for the alternative substances to further decline, in turn lowering phosphate-free CADD prices.

Analysis of impacts: approximately 78% of the 35 stakeholders who responded to the questionnaire survey said that it is possible to meet the requirement of limiting phosphorus content in CADD to 0.3 grams per dosage as of 2017 and 69% even found the limit desirable. No stakeholders claimed that the requirements were not possible to comply with.

Environmental impacts: the Commission recalls that a total ban of phosphate in detergent would be the most effective policy option for reducing the risk of phosphorus related eutrophication of surface water throughout the EU. While completely eliminating phosphorus in CADD would decrease the eutrophication risk even further, this is technically not feasible. However, the limit of 0.3% grams per standard dosage already reduces the amount of phosphorus in CADD by more than 75% on average. The report finds that only three alternatives (sodium gluconate; L-aspartic-N,N-diacetic acid, sodium salts and B-alaninediacetic acid) appeared to have data gaps. According to the CADD study, all the other alternatives that were assessed do not pose an unacceptable environmental risk based on current scientific knowledge.

With regard to wastewater, the Commission recalls that the <u>Urban Waste Water Directive</u> requires Member States to include removal of phosphorus in the wastewater treatment in sensitive areas under certain conditions. The CADD study estimates that phosphorus from CADD made up about 10% of the phosphorus load in wastewater treatment in the EU in 2013. A limitation on phosphorus use in CADD to 0.3 grams per wash would lead to the conclusion that phosphorus coming from CADD would eventually account for ca. 1.6% of the total phosphorus load in wastewater in the EU in 2017.

Health impacts: a few data gaps exist relating to the health effects of certain alternatives. Data are lacking for the three substances cited above. Based on current scientific knowledge, the study concludes that for the remaining alternatives to STPP there is no significant risk to human health.

Conclusion: the Commission finds no evidence that a revision is required of the limit value for phosphorus in CADD of 0.3 grams/standard dosage which will become applicable as of 1 January 2017. In order to strengthen the hazard and risk assessment of the alternatives, the Commission encourages all manufacturers to generate further toxicity test data and assess all relevant scientific information once they are made available in the context of REACH and to share with the Commission any relevant risks that they could identify from a particular alternative substance to phosphates in CADD.