Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (Text with EEA relevance)

REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 31 March 2004

on detergents

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Council Directives 73/404/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to detergents[(3)], 73/405/EEC of 22 November 1973 on the approximation of the laws of the Member States relating to methods of testing the biodegradability of anionic surfactants[(4)], 82/242/EEC of 31 March 1982 on the approximation of the laws of the Member States relating to methods of testing the biodegradability of non-ionic surfactants[(5)], 82/243/EEC of 31 March 1982 amending Directive 73/405/EEC on the approximation of the laws of the Member States relating to methods of testing the biodegradability of anionic surfactants[(6)] and 86/94/EEC of 10 March 1986 amending for the second time Directive 73/404/EEC on the approximation of the laws of the Member States relating to detergents[(7)], have been significantly amended on several occasions. It is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast by bringing them all together in a single text. Commission Recommendation 89/542/EEC of 13 September 1989[(8)], as regards labelling provisions concerning detergents and cleaning products, should also be included in the single text.

(2) Since the objective of this Regulation, to ensure the internal market in detergents, cannot be sufficiently achieved by the Member States, if there is no common technical criteria throughout the Community, and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of propotionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective. A Regulation is the appropriate legal instrument as it imposes directly on manufacturers precise requirements to be implemented at the

Changes to legislation: *There are outstanding changes not yet made to Regulation (EC) No 648/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

same time and in the same manner throughout the Community; in the area of technical legislation, uniformity of application in the Member States is needed, and this can only be guaranteed by a Regulation.

(3) A new definition for detergents is needed to cover equivalent uses and be in line with developments at Member State level.

(4) It is necessary to introduce a surfactant definition, which was lacking in the existing legislation.

(5) It is important to give a clear and precise description of the relevant types of biodegradability.

(6) Measures concerning detergents should be adopted to ensure the functioning of the internal market and avoid restricting competition in the Community.

(7) As confirmed by the Commission White Paper on the strategy for a future Chemical Policy, appropriate measures concerning detergents should ensure a high level of environmental protection, especially of the aquatic environment.

(8) Detergents are already subject to certain Community provisions concerning their manufacture, proper handling, usage and labelling, in particular with reference to Commission Recommendation 89/542/EEC and Commission Recommendation 98/480/EC of 22 July 1998 concerning good environmental practice for household laundry detergents[(9)]; Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[(10)] applies to detergents.

(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[(11)], and if necessary adequate strategies to limit the risks of exposure to these substances should therefore be recommended and implemented in the framework of other Community provisions.

(10) The existing legislation on biodegradability of surfactants in detergents only covers primary biodegradability[(12)] and it is only applicable to anionic[(13)] and non-ionic[(14)] surfactants; therefore it should be replaced by new legislation, which lays the main emphasis on ultimate biodegradability and meets the important concerns related to the potential toxicity of persistent metabolites.

(11) This requires the introduction of a new set of tests based on EN ISO standards and OECD guidelines, which governs the granting of direct permission for placing detergents on the market.

(12) To provide a high level of protection of the environment, detergents not fulfilling requirements laid down by this Regulation should not be placed on the market.

***Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 648/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(13) On 25 November 1999 the Scientific Committee on Toxicity, Ecotoxicity and the Environment issued an opinion on biodegradability of surfactants in detergents and relevance of test-methods for regulatory control in this area.

(14) The existing requirements regarding primary biodegradability should be maintained on a second hierarchy level and supplemented by a complementary risk assessment, for those surfactants failing ultimate biodegradability tests; furthermore surfactants failing primary biodegradability tests should not obtain marketing authorisation by way of derogation

(15) The primary biodegradability requirements should be extended to all surfactants, in particular cationic and amphoteric, whilst allowing the possibility of applying instrumental analyses in those cases in which semi-specific analytical methods are not suitable.

(16) The determination of biodegradability test-methods and the record-keeping of lists of derogations are technical matters and should be revised taking into account technical and scientific developments as well as regulatory developments.

(17) Test-methods should produce data that give sufficient assurance of aerobic biodegradability of surfactants in detergents.

(18) Methods to test biodegradability of surfactants in detergents may produce variable results. In such cases they should be complemented by additional assessments in order to determine the risks of continued use.

(19) Provisions should also be laid down regarding the placing on the market in exceptional cases of surfactants in detergents failing ultimate biodegradability tests and this should take place on the basis of all relevant information to ensure environmental protection and on a case by case basis.

(20) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(15)].

(21) It is appropriate to recall that other horizontal legislation is applicable to detergent surfactants, in particular Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations[(16)] by which the marketing and use of dangerous substances covered by this Regulation might be banned or restricted, Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[(17)], Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC[(18)], Regulation (EEC) No 793/93, 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[(19)]; Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the

Changes to legislation: *There are outstanding changes not yet made to Regulation (EC) No 648/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

placing of biocidal products on the market[(20)]; Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances (codified version)[(21)]; Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (codified version)[(22)]; and Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[(23)].

(22) It should be the responsibility of manufacturers to refrain from marketing detergents not complying with this Regulation and to have at the disposal of the national authorities the technical files for all substances and **[**[F1]mixtures**]** covered by this Regulation; this should also apply to surfactants that have failed to pass the tests mentioned in Annex III.

(23) Manufacturers should be able to request a derogation from the Commission, which should have the possibility to grant such derogation in accordance with the procedure referred to in Article 12(2).

(24) Member States' competent authorities should be able to apply control measures to detergents on the market, but should avoid repeating tests made by the competent laboratories.

(25) The existing labelling provisions for detergents should be continued, including those in Recommendation 89/542/EEC, which are included in this Regulation in order to fulfil the objective of modernising the rules on detergents. 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 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, and Member States should be able to require that such a listing is also made available to a specific public body designated to provide this information to medical personnel.

(26) All the above points call for new legislation replacing the existing legislation; however, for a certain period, Member States can continue to apply their existing laws.

[F2](27) . . . . . .

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

(29) In order to ensure the protection of man and the environment from unforeseen risks of detergents, a safeguard clause is needed.

(30) The tests specified for the biodegradability of surfactants should be carried out in laboratories meeting an internationally recognised standard, namely EN/ISO/IEC/17025 or the principles of good laboratory practice; it would not be justified to ask for the application of this latter requirement to existing surfactants to the extent that the

***Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 648/2004 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

available tests on them had been performed before the entering into force of the above standard and still provide a comparable level of scientific quality.

(31) The issues relating to anaerobic biodegradation, the biodegradation of the main non-surfactant organic detergent ingredients, and phosphate content, which are not dealt with in this Regulation should be examined by the Commission and, where this is justified, a proposal should be presented to the European Parliament and the Council. Pending further harmonisation, the Member States may maintain or lay down national rules concerning the above issues.

(32) The five Directives and the Commission Recommendation mentioned in recital (1) which are replaced by this Regulation should be repealed,

HAVE ADOPTED THIS REGULATION:

Textual Amendments

F1 Substituted by Regulation (EC) No 1336/2008 of the European Parliament and of the Council of 16 December 2008 amending Regulation (EC) No 648/2004 in order to adapt it to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (Text with EEA relevance).

F2 Deleted by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Two.

Article 1

Objectives and scope

1 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.

2 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;

— **[**[F3]the additional labelling of detergents, including fragrance allergens;

— the information that manufacturers must hold at the disposal of the Member States' competent authorities and medical personnel;

— limitations on the content of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents.**]**

Textual Amendments

F3 Substituted by Regulation (EU) No 259/2012 of the European Parliament and of the Council of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents (Text with EEA relevance).