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Price: EUR 18

⁽¹⁾ Text with EEA relevance

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EN

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⁽¹⁾ Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 550/2009**of 25 June 2009****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾, and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 26 June 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	MA	53,0
	MK	21,6
	TR	82,5
	ZZ	52,4
0707 00 05	JO	156,8
	MK	23,0
	TR	108,9
	ZZ	96,2
0709 90 70	TR	103,7
	ZZ	103,7
0805 50 10	AR	66,2
	BR	104,3
	TR	54,9
	ZA	59,9
	ZZ	71,3
0808 10 80	AR	73,6
	BR	94,4
	CL	94,9
	CN	91,3
	NZ	108,0
	US	134,0
	UY	61,5
	ZA	77,5
	ZZ	91,9
0809 10 00	TR	232,3
	US	172,2
	ZZ	202,3
0809 20 95	TR	323,9
	US	377,7
	ZZ	350,8
0809 30	TR	147,8
	US	175,8
	ZZ	161,8

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 551/2009**of 25 June 2009****amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on
detergents, in order to adapt Annexes V and VI thereto (surfactant derogation)****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents ⁽¹⁾, and in particular Article 13(1) thereof,

Whereas:

- (1) Regulation (EC) No 648/2004 ensures the free circulation of detergents, and of surfactants for detergents, on the internal market while at the same time providing, inter alia, a high level of protection to the environment by laying down requirements for the ultimate biodegradability of surfactants used in detergents.
- (2) In addition, Articles 5, 6 and 9 of the Regulation provide a mechanism by which surfactants that do not fulfil the abovementioned requirement of ultimate biodegradability may nevertheless be granted a derogation for use in specific industrial or institutional applications providing that those applications constitute a low-dispersive use and that the associated risk to the environment is small compared to the socioeconomic benefit.
- (3) The Regulation stipulates that the risk to the environment is to be assessed by means of a complementary risk assessment, described in Annex IV, carried out by the manufacturer of the surfactant and submitted to competent authority of a Member State for evaluation.
- (4) Surfactants that are granted a derogation should be listed in Annex V to the Regulation. Those that are refused a derogation should be listed in Annex VI to the Regulation.
- (5) Derogations 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 ⁽²⁾.
- (6) A request for a derogation was made for the surfactant with the IUPAC ⁽³⁾ name 'alcohols, Guerbet, C16-20, ethoxylated, n-butyl ether (7-8EO)', also known by the

trade name 'Dehypon G 2084', with the CAS ⁽⁴⁾ number 147993-59-7, for use in three industrial applications, namely: bottle washing, cleaning-in-place and metal cleaning.

- (7) The request for a derogation was evaluated by the German competent authority in accordance with the procedure described in Article 5 of the Regulation. The request was found to fulfil the three conditions required under Article 6. Firstly, the three named uses are low-dispersive applications. Secondly, the applications are specific industrial applications. Thirdly, there is no risk to the environment as the surfactant itself does not pose a risk and the metabolites are not persistent.
- (8) The three named uses were considered to be low-dispersive industrial applications in view of the total annual consumption of the surfactant and in view of the use of the surfactant exclusively in specific types of industrial installations.
- (9) The conclusion concerning lack of risk to the environment is based on the rapid achievement of a high degree of primary biodegradability of the surfactant and on the ultimate biodegradability of the surfactant metabolites. The metabolites therefore meet the same criteria as those surfactants for which the Regulation guarantees free circulation on the internal market.
- (10) The Committee for the adaptation to technical progress of legislation on the removal of technical barriers to trade in detergents decided nevertheless to limit the derogation to a period of 10 years to encourage the development of surfactants of equivalent performance which fulfil the criteria of ultimate biodegradability and which therefore would not require a derogation.
- (11) In the past, substances in the Community were allocated either an EINECS number or an ELINCS number. However, in addition, some 700 substances previously identified as polymers have been recognised as non-polymers and have been assigned NLP (No-Longer Polymer) numbers. EINECS, ELINCS and NLP numbers are now referred to collectively as 'EC numbers' and the corresponding headings in tables in Annex V and VI should be changed to reflect the new nomenclature.

⁽¹⁾ OJ L 104, 8.4.2004, p. 1.

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

⁽³⁾ International Union of Pure and Applied Chemistry.

⁽⁴⁾ Chemicals Abstracts Service.

(12) Annexes V and VI to Regulation (EC) No 648/2004 should be amended accordingly.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Detergents Committee,

1. Annex V is replaced by the text set out in Annex I to this Regulation.

2. Annex VI is replaced by the text set out in Annex II to this Regulation.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 648/2004 is amended as follows:

Article 2

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

Günter VERHEUGEN

Vice-President

ANNEX I

‘ANNEX V

LIST OF SURFACTANTS THAT HAVE OBTAINED A DEROGATION

By way of derogation granted in accordance with Articles 4-6 and in accordance with the procedure laid down in Article 12(2), the following detergent surfactants, which pass the tests stipulated in Annex II, but which fail the tests stipulated in Annex III, may be placed on the market and used subject to the limitations mentioned below.

Name in the IUPAC nomenclature	EC Number	CAS number	Limitations
Alcohols, Guerbet, C16-20, ethoxylated, n-butyl ether (7-8EO)	None (polymer)	147993-59-7	May be used for the following industrial applications until 27 June 2019: — bottle washing, — cleaning-in-place, — metal cleaning,

The “EC number” means the EINECS, ELINCS or NLP number and is the official number of the substance within the European Union.

“EINECS” means the European Inventory of Existing Commercial Chemical Substances. This inventory contains the definitive list of all substances deemed to be on the Community market on 18 September 1981. The EINECS number can be obtained from the European Inventory of Existing Commercial Chemical Substance ⁽¹⁾.

“ELINCS” means the European List of Notified Chemical Substances. The ELINCS number can be obtained from the European List of Notified Substances, as amended ⁽²⁾.

“NLP” means No-Longer Polymer. The term polymer is defined in Article 3(5) of Regulation (EC) No 1907/2006 ⁽³⁾ of the European Parliament and of the Council. The NLP number can be obtained from the list of “No-Longer Polymers”, as amended ⁽⁴⁾.

⁽¹⁾ OJ C 146 A, 15.6.1990, p. 1.

⁽²⁾ Office for Official Publications of the European Communities, 2006, ISSN 1018-5593 EUR 22543 EN.

⁽³⁾ OJ L 396, 30.12.2006, p. 1, as corrected by OJ L 136, 29.5.2007, p. 3.

⁽⁴⁾ Office for Official Publications of the European Communities, 2007, ISSN 1018-5593 EUR 20853 EN/3.’

ANNEX II

ANNEX VI

LIST OF BANNED OR RESTRICTED DETERGENT SURFACTANTS

The following detergent surfactants have been identified as not complying with the provisions of this Regulation:

Name in the IUPAC nomenclature	EC Number	CAS number	Limitations

The "EC number" means the EINECS, ELINCS or NLP number and is the official number of the substance within the European Union.'

COMMISSION REGULATION (EC) No 552/2009**of 22 June 2009****amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 131 thereof,

Whereas:

- (1) 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 ⁽²⁾ established in its Annex I restrictions for certain dangerous substances and preparations. Regulation (EC) No 1907/2006 repeals and replaces Directive 76/769/EEC with effect from 1 June 2009. Annex XVII to that Regulation replaces Annex I to Directive 76/769/EEC.
- (2) Article 67 of Regulation (EC) No 1907/2006 provides that substances, mixtures or articles may not be manufactured, placed on the market or used unless they comply with the conditions of any restrictions laid down in their regard in Annex XVII.
- (3) Directive 2006/122/EC of the European Parliament and of the Council of 12 December 2006 amending for the 30th time Council Directive 76/769/EEC (perfluorooctane sulfonates (PFOS)) ⁽³⁾ and Commission Directive 2006/139/EC of 20 December 2006 amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of arsenic compounds for the purpose of adapting its Annex I to technical progress ⁽⁴⁾ amending Annex I to Directive 76/769/EC were adopted shortly before Regulation (EC) No 1907/2006 was adopted, in December 2006, but the restrictions concerned have not yet been included in

Annex XVII to that Regulation. Therefore Annex XVII should be amended to include the restrictions corresponding to Directives 2006/122/EC and 2006/139/EC as otherwise the restrictions concerned will be repealed on 1 June 2009.

- (4) Pursuant to Article 137(3) of Regulation (EC) No 1907/2006, any amendment to the restrictions adopted under Directive 76/769/EEC from 1 June 2007 is to be incorporated in Annex XVII to that Regulation with effect from 1 June 2009.
- (5) Directive 2007/51/EC of the European Parliament and of the Council amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury ⁽⁵⁾ was adopted on 25 September 2007. Decision 1348/2008/EC of the European Parliament and Council amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of 2(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate ⁽⁶⁾ was adopted on 16 December 2008. The restrictions concerned have not yet been included in Annex XVII to that Regulation. Annex XVII should be amended to incorporate the restrictions on certain measuring devices containing mercury adopted under Directive 2007/51/EC and the restrictions on 2(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylene-diphenyl diisocyanate, cyclohexane and ammonium nitrate adopted under Decision 1348/2008/EC.
- (6) Account should be taken of the relevant provisions of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ⁽⁷⁾.
- (7) Since the provisions of Title VIII of Regulation (EC) No 1907/2006 and in particular Annex XVII are to be directly applicable from 1 June 2009, the restrictions should be clearly drafted in order to allow operators and enforcement authorities to apply them correctly. Therefore the drafting of the restrictions should be reviewed. The terminology for the different entries should be harmonised and made more coherent with the definitions contained in Regulation (EC) No 1907/2006.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ OJ L 262, 27.9.1976, p. 201.

⁽³⁾ OJ L 372, 27.12.2006, p. 32.

⁽⁴⁾ OJ L 384, 29.12.2006, p. 94.

⁽⁵⁾ OJ L 257, 3.10.2007, p. 13.

⁽⁶⁾ OJ L 348, 24.12.2008, p. 108.

⁽⁷⁾ OJ L 353, 31.12.2008, p. 1.

- (8) Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) ⁽¹⁾ requires that equipment containing PCBs and PCTs is decontaminated and disposed of as soon as possible and sets the conditions for the decontamination of equipment containing those substances. Therefore the entry in Annex XVII to Regulation (EC) 1907/2006 concerning PCTs should not include provision concerning equipment containing PCTs as that is fully regulated under Directive 96/59/EC.
- (9) The existing restrictions for the substances 2-naphthylamine, benzidine, 4-nitrobiphenyl, 4-aminobiphenyl are ambiguous as it is unclear whether the prohibition concerns only the supply to the general public or also the supply to professional users. These should be clarified. Since Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents ⁽²⁾ prohibits the production, manufacture and use at work of those substances, the restrictions in Annex XVII to Regulation (EC) No 1907/2006 relating to those substances should be consistent with Directive 98/24/EC.
- (10) The substances carbon tetrachloride and 1,1,1-trichloroethane are severely restricted under Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer ⁽³⁾. Regulation (EC) No 2037/2000 imposes for carbon tetrachloride a prohibition with exceptions, and for 1,1,1-trichloroethane a complete prohibition. Restrictions on carbon tetrachloride and 1,1,1-trichloroethane in Annex XVII to Regulation (EC) 1907/2006 are therefore superfluous and should be deleted.
- (11) Since mercury in batteries is regulated under Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators ⁽⁴⁾, the provisions on mercury in batteries currently contained in Annex XVII to Regulation (EC) No 1907/2006 are superfluous and should therefore be deleted.
- (12) Pursuant to Article 2(2) of Regulation (EC) No 1907/2006, waste is considered not to be a substance, a mixture, or an article within the meaning of Article 3 of Regulation (EC) No 1907/2006. Therefore since waste is not covered by the restrictions under that Regulation, provisions in Annex XVII thereto excluding waste are redundant and should be deleted.
- (13) Certain restrictions in Annex XVII to Regulation (EC) 1907/2006 should be modified in order to take into account the definitions of 'use' and 'placing on the market' contained in Article 3 of that Regulation.
- (14) The entry in Annex I to Directive 76/769/EEC concerning asbestos fibres included an exemption for diaphragms containing chrysotile. It should be specified that this exemption will be reviewed following receipt of reports that Member States who are making use of this exemption will have to submit. Moreover in the light of the definition of 'placing on the market' in Regulation (EC) No 1907/2006, Member States should be able to allow the placing on the market of some articles containing such fibres where the articles were already installed or in service before 1 January 2005, under specific conditions ensuring a high level of protection of human health
- (15) It should be made clear that, for substances which have been incorporated in Annex XVII to Regulation (EC) No 1907/2006 as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions do not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of the substances for export, unless the manufacture of the substances is prohibited.
- (16) Unlike Directive 76/769/EEC, Regulation (EC) No 1907/2006 defines the term 'article'. In order to cover the same items as provided for in the original restriction on Cadmium, the term 'mixtures' should be added in some of the provisions.
- (17) It should be made clear that the restrictions incorporated in Annex XVII to Regulation (EC) No 1907/2006 on the marketing of certain measuring devices containing mercury do not apply to devices already in use in the Community at the time of entry into force of the restriction.
- (18) In the entries in Annex XVII to Regulation (EC) 1907/2006 for the substances diphenylether, pentabromo derivatives and diphenylether, octabromo derivatives, it should be provided that the restrictions do not apply to articles already in use at the date from which the restriction was to apply as those substances were incorporated in articles which have a long lifecycle and are sold on the second hand market, such as aeroplanes and vehicles. Moreover, since the use of the substances in electrical and electronic equipments is regulated under Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁽⁵⁾ that equipment should not be subject to the restrictions concerned.

⁽¹⁾ OJ L 243, 24.9.1996, p. 31.

⁽²⁾ OJ L 131, 5.5.1998, p. 11.

⁽³⁾ OJ L 244, 29.9.2000, p. 1.

⁽⁴⁾ OJ L 266, 26.9.2006, p. 1.

⁽⁵⁾ OJ L 37, 13.2.2003, p. 19.

- (19) It should be made clear in the restriction on nonylphenol and nonylphenol ethoxylate that the validity of existing national authorisations for pesticides and biocidal products containing nonylphenol ethoxylate as co-formulant should not be affected, as provided for in Article 1(2) of Directive 2003/53/EC of the European Parliament and of the Council of 18 June 2003 amending for the 26th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (nonylphenol, nonylphenol ethoxylate and cement) ⁽¹⁾.
- (20) It should be made clear that the restriction incorporated in Annex XVII to Regulation (EC) No 1907/2006 concerning perfluorooctane sulfonates does not apply to products which were already in use in the Community when the restriction entered into force.

- (21) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 June 2009.

For the Commission

Günter VERHEUGEN

Vice-President

⁽¹⁾ OJ L 178, 17.7.2003, p. 24.

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

1. the title is replaced by the following:

'Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles';

2. the table setting out the designation of the substances, groups of substances and mixtures and the conditions of restriction is replaced by the following:

'For substances which have been incorporated in this Annex as a consequence of restrictions adopted in the framework of Directive 76/769/EEC (Entries 1 to 58), the restrictions shall not apply to storage, keeping, treatment, filling into containers, or transfer from one container to another of these substances for export, unless the manufacture of the substances is prohibited.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
1. Polychlorinated terphenyls (PCTs)	Shall not be placed on the market, or used: <ul style="list-style-type: none"> — as substances, — in mixtures, including waste oils, or in equipment, in concentrations greater than 50 mg/kg (0,005 % by weight).
2. Chloroethene (vinyl chloride) CAS No 75-01-4 EC No 200-831-0	Shall not be used as propellant in aerosols for any use. Aerosols dispensers containing the substance as propellant shall not be placed on the market.
3. Liquid substances or mixtures, which are regarded as dangerous according to the definitions in Council Directive 67/548/EEC and Directive 1999/45/EC.	<ol style="list-style-type: none"> 1. Shall not be used in: <ul style="list-style-type: none"> — ornamental articles, intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, — tricks and jokes, — games for one or more participants, or any article intended to be used as such, even with ornamental aspects. 2. Articles not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market if they contain a colouring agent unless required for fiscal reasons or perfume or both and if they: <ul style="list-style-type: none"> — present an aspiration hazard and are labelled with R65 or H304, and, — can be used as fuel in decorative lamps, and, — are packaged in containers of a capacity of 15 litres or less. 4. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of substances and mixtures covered by paragraph 3, where intended for use in lamps, is marked visibly, legibly and indelibly as follows: <p>"Keep lamps filled with this liquid out of the reach of children".</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>4. Tris (2,3 dibromopropyl) phosphate CAS No 126-72-7</p>	<p>1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.</p> <p>2. Articles not complying with paragraph 1 shall not be placed on the market.</p>
<p>5. Benzene CAS No 71-43-2 EC No 200-753-7</p>	<p>1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy.</p> <p>2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market.</p> <p>3. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as a substance, — as a constituent of other substances, or in mixtures, in concentrations equal to, or greater than 0,1 % by weight. <p>4. However, paragraph 3 shall not apply to:</p> <ul style="list-style-type: none"> (a) motor fuels which are covered by Directive 98/70/EC; (b) substances and mixtures for use in industrial processes not allowing for the emission of benzene in quantities in excess of those laid down in existing legislation.
<p>6. Asbestos fibres</p> <ul style="list-style-type: none"> (a) Crocidolite CAS No 12001-28-4 (b) Amosite CAS No 12172-73-5 (c) Anthophyllite CAS No 77536-67-5 (d) Actinolite CAS No 77536-66-4 (e) Tremolite CAS No 77536-68-6 (f) Chrysotile CAS No 12001-29-5 CAS No 132207-32-0 	<p>1. The manufacture, placing on the market and use of these fibres and of articles containing these fibres added intentionally is prohibited.</p> <p>However, Member States may exempt the placing on the market and use of diaphragms containing chrysotile (point (f)) for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner.</p> <p>By 1 June 2011 Member States making use of this exemption shall provide a report to the Commission on the availability of asbestos free substitutes for electrolysis installations and the efforts undertaken to develop such alternatives, on the protection of the health of workers in the installations, on the source and quantities of chrysotile, on the source and quantities of diaphragms containing chrysotile, and the envisaged date of the end of the exemption. The Commission shall make this information publicly available.</p> <p>Following receipt of those reports, the Commission shall request the Agency to prepare a dossier in accordance with Article 69 with a view to prohibit the placing on the market and use of diaphragms containing chrysotile.</p> <p>2. The use of articles containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005 shall continue to be permitted until they are disposed of or reach the end of their service life. However, Member States may, for reasons of protection of human health, restrict, prohibit or make subject to specific conditions, the use of such articles before they are disposed of or reach the end of their service life.</p> <p>Member States may allow placing on the market of articles in their entirety containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005, under specific conditions ensuring a high level of protection of human health. Member States shall communicate these national measures to the Commission by 1 June 2011. The Commission shall make this information publicly available.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	3. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, the placing on the market and use of articles containing these fibres, as permitted according to the preceding derogations, shall be permitted only if suppliers ensure before the placing on the market that articles bear a label in accordance with Appendix 7 to this Annex.
7. Tris(aziridinyl)phosphin oxide CAS No 545-55-1 EC No 208-892-5	1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
8. Polybromobiphenyls; Polybrominated biphenyls (PBB) CAS No 59536-65-1	1. Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin. 2. Articles not complying with paragraph 1 shall not be placed on the market.
9. (a) Soap bark powder (<i>Quillaja saponaria</i>) and its derivatives containing saponines CAS No 68990-67-0 EC 273-620-4 (b) Powder of the roots of <i>Helleborus viridis</i> and <i>Helleborus niger</i> (c) Powder of the roots of <i>Veratrum album</i> and <i>Veratrum nigrum</i> (d) Benzidine and/or its derivatives CAS No 92-87-5 EC No 202-199-1 (e) o-Nitrobenzaldehyde CAS No 552-89-6 EC No 209-025-3 (f) Wood powder	1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs. 2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market. 3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.
10. (a) Ammonium sulphide CAS No 12135-76-1 EC No 235-223-4 (b) Ammonium hydrogen sulphide CAS No 12124-99-1 EC No 235-184-3 (c) Ammonium polysulphide CAS No 9080-17-5 EC No 232-989-1	1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs. 2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market. 3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>11. Volatile esters of bromoacetic acids:</p> <p>(a) Methyl bromoacetate CAS No 96-32-2 EC No 202-499-2</p> <p>(b) Ethyl bromoacetate CAS No 105-36-2 EC No 203-290-9</p> <p>(c) Propyl bromoacetate CAS No 35223-80-4</p> <p>(d) Butyl bromoacetate CAS No 18991-98-5 EC No 242-729-9</p>	<p>1. Shall not be used, in jokes and hoaxes or in mixtures or articles intended to be used as such, for instance as a constituent of sneezing powder and stink bombs.</p> <p>2. Jokes and hoaxes, or mixtures or articles intended to be used as such, not complying with paragraph 1 shall not be placed on the market.</p> <p>3. However, paragraphs 1 and 2 shall not apply to stink bombs containing not more than 1,5 ml of liquid.</p>
<p>12. 2-Naphthylamine CAS No 91-59-8 EC No 202-080-4 and its salts</p> <p>13. Benzidine CAS No 92-87-5 EC No 202-199-1 and its salts</p> <p>14. 4-Nitrobiphenyl CAS No 92-93-3 Einecs EC No 202-204-7</p> <p>15. 4-Aminobiphenyl xenylamine CAS No 92-67-1 Einecs EC No 202-177-1 and its salts</p>	<p>The following shall apply to entries 12 to 15:</p> <p>Shall not be placed on the market, or used, as substances or in mixtures in concentrations greater than 0,1 % by weight.</p>
<p>16. Lead carbonates:</p> <p>(a) Neutral anhydrous carbonate (PbCO₃) CAS No 598-63-0 EC No 209-943-4</p> <p>(b) Trilead-bis(carbonate)-dihydroxide 2Pb CO₃-Pb(OH)₂ CAS No 1319-46-6 EC No 215-290-6</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint.</p> <p>However, Member States may, in accordance with the provisions of International Labour Organisation (ILO) Convention 13 on the use of white lead and sulphates of lead in paint, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors.</p>
<p>17. Lead sulphates:</p> <p>(a) PbSO₄ CAS No 7446-14-2 EC No 231-198-9</p> <p>(b) Pb_x SO₄ CAS No 15739-80-7 EC No 239-831-0</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures, where the substance or mixture is intended for use as paint.</p> <p>However, Member States may, in accordance with the provisions of ILO Convention 13 on the use of white lead and sulphates of lead in paint, permit the use on their territory of the substance or mixture for the restoration and maintenance of works of art and historic buildings and their interiors.</p>
<p>18. Mercury compounds</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use:</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>(a) to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment; <p>(b) in the preservation of wood;</p> <p>(c) in the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture;</p> <p>(d) in the treatment of industrial waters, irrespective of their use.</p>
<p>18a. Mercury</p> <p>CAS No 7439-97-6</p> <p>EC No 231-106-7</p>	<p>1. Shall not be placed on the market:</p> <p>(a) in fever thermometers;</p> <p>(b) in other measuring devices intended for sale to the general public (such as manometers, barometers, sphygmomanometers, thermometers other than fever thermometers).</p> <p>2. The restriction in paragraph 1 shall not apply to measuring devices that were in use in the Community before 3 April 2009. However Member States may restrict or prohibit the placing on the market of such measuring devices.</p> <p>3. The restriction in paragraph 1(b) shall not apply to:</p> <p>(a) measuring devices more than 50 years old on 3 October 2007;</p> <p>(b) barometers (except barometers within point (a)) until 3 October 2009.</p> <p>4. By 3 October 2009 the Commission shall carry out a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury containing sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses. On the basis of this review or as soon as new information on reliable safer alternatives for sphygmomanometers and other measuring devices containing mercury becomes available, the Commission shall, if appropriate, present a legislative proposal to extend the restrictions in paragraph 1 to sphygmomanometers and other measuring devices in healthcare and in other professional and industrial uses, so that mercury in measuring devices is phased out whenever technically and economically feasible.</p>
<p>19. Arsenic compounds</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment. <p>2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use.</p> <p>3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>4. By way of derogation from paragraph 3:</p> <p>(a) Relating to the substances and mixtures for the preservation of wood: these may only be used in industrial installations using vacuum or pressure to impregnate wood if they are solutions of inorganic compounds of the copper, chromium, arsenic (CCA) type C and if they are authorised in accordance with Article 5(1) of Directive 98/8/EC. Wood so treated shall not be placed on the market before fixation of the preservative is completed.</p> <p>(b) Wood treated with CCA solution in accordance with point (a) may be placed on the market for professional and industrial use provided that the structural integrity of the wood is required for human or livestock safety and skin contact by the general public during its service life is unlikely:</p> <ul style="list-style-type: none"> — as structural timber in public and agricultural buildings, office buildings, and industrial premises, — in bridges and bridgework, — as constructional timber in freshwater areas and brackish waters, for example jetties and bridges, — as noise barriers, — in avalanche control, — in highway safety fencing and barriers, — as debarked round conifer livestock fence posts, — in earth retaining structures, — as electric power transmission and telecommunications poles, — as underground railway sleepers. <p>(c) Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that all treated wood placed on the market is individually labelled "For professional and industrial installation and use only, contains arsenic". In addition, all wood placed on the market in packs shall also bear a label stating "Wear gloves when handling this wood. Wear a dust mask and eye protection when cutting or otherwise crafting this wood. Waste from this wood shall be treated as hazardous by an authorised undertaking".</p> <p>(d) Treated wood referred to under point (a) shall not be used:</p> <ul style="list-style-type: none"> — in residential or domestic constructions, whatever the purpose, — in any application where there is a risk of repeated skin contact, — in marine waters, — for agricultural purposes other than for livestock fence posts and structural uses in accordance with point (b), — in any application where the treated wood may come into contact with intermediate or finished products intended for human and/or animal consumption. <p>5. Wood treated with arsenic compounds that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4 may remain in place and continue to be used until it reaches the end of its service life.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>6. Wood treated with CCA type C that was in use in the Community before 30 September 2007, or that was placed on the market in accordance with paragraph 4:</p> <ul style="list-style-type: none"> — may be used or reused subject to the conditions pertaining to its use listed under points 4(b), (c) and (d), — may be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d). <p>7. Member States may allow wood treated with other types of CCA solutions that was in use in the Community before 30 September 2007:</p> <ul style="list-style-type: none"> — to be used or reused subject to the conditions pertaining to its use listed under points 4 (b), (c) and (d), — to be placed on the market subject to the conditions pertaining to its use listed under points 4(b), (c) and (d).
20. Organostannic compounds	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is acting as biocide in free association paint.</p> <p>2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture acts as biocide to prevent the fouling by micro-organisms, plants or animals of:</p> <ul style="list-style-type: none"> (a) all craft irrespective of their length intended for use in marine, coastal, estuarine and inland waterways and lakes; (b) cages, floats, nets and any other appliances or equipment used for fish or shellfish farming; (c) any totally or partly submerged appliance or equipment. <p>3. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters.</p>
<p>21. Di-μ-oxo-di-n-butylstanniohydroxyborane/Dibutyltin hydrogen borate $C_8H_{19}BO_3Sn$ (DBB)</p> <p>CAS No 75113-37-0 EC No 401-040-5</p>	<p>Shall not be placed on the market, or used, as a substance, or in mixtures in a concentration equal to, or greater than 0,1 % by weight.</p> <p>However, the first paragraph shall not apply to this substance (DBB) or mixtures containing it if these are intended solely for conversion into articles, among which this substance will no longer feature in a concentration equal to or greater than 0,1 %.</p>
<p>22. Pentachlorophenol</p> <p>CAS No 87-86-5 EC No 201-778-6 and its salts and esters</p>	<p>Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as a substance, — as a constituent in other substances, or in mixtures, in a concentration equal to or greater than 0,1 % by weight.
<p>23. Cadmium</p> <p>CAS No 7440-43-9 EC No 231-152-8 and its compounds</p>	<p>For the purpose of this entry, the codes and chapters indicated in square brackets are the codes and chapters of the tariff and statistical nomenclature of Common Customs Tariff as established by Council Regulation (EEC) No 2658/87 (*).</p> <p>1. Shall not be used to give colour to articles manufactured from the following substances and mixtures:</p> <ul style="list-style-type: none"> (a) — polyvinyl chloride (PVC) [3904 10] [3904 21] [3904 22] — polyurethane (PUR) [3909 50]

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<ul style="list-style-type: none"> — low-density polyethylene (ld PE), with the exception of low-density polyethylene used for the production of coloured masterbatch [3901 10] — cellulose acetate (CA) [3912 11] [3912 12] — cellulose acetate butyrate (CAB) [3912 11] [3912 12] — epoxy resins [3907 30] — melamine — formaldehyde (MF) resins [3909 20] — urea — formaldehyde (UF) resins [3909 10] — unsaturated polyesters (UP) [3907 91] — polyethylene terephthalate (PET) [3907 60] — polybutylene terephthalate (PBT) — transparent/general-purpose polystyrene [3903 11] [3903 19] — acrylonitrile methylmethacrylate (AMMA) — cross-linked polyethylene (VPE) — high-impact polystyrene — polypropylene (PP) [3902 10] <p>(b) paints [3208] [3209]</p> <p>However, if the paints have a high zinc content, their residual concentration of cadmium shall be as low as possible and shall in any event be less than 0,1 % by weight.</p> <p>In any case, whatever their use or intended final purpose, articles or components of articles manufactured from the substances and mixtures listed above coloured with cadmium shall not be placed on the market if their cadmium content (expressed as Cd metal) is greater than 0,01 % by weight of the plastic material.</p> <p>2. However, paragraph 1 shall not apply to articles to be coloured for safety reasons.</p> <p>3. Shall not be used to stabilise the following mixtures or articles manufactured from polymers or copolymers of vinyl chloride:</p> <ul style="list-style-type: none"> — packaging materials (bags, containers, bottles, lids) [3923 29 10], — office or school supplies [3926 10], — fittings for furniture, coachwork or the like [3926 30], — articles of apparel and clothing accessories (including gloves) [3926 20], — floor and wall coverings [3918 10], — impregnated, coated, covered or laminated textile fabrics [5903 10], — imitation leather [4202], — gramophone records, — tubes and pipes and their fittings [3917 23], — swing doors, — vehicles for road transport (interior, exterior, underbody), — coating of steel sheet used in construction or in industry, — insulation for electrical wiring.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>In any case, whatever their use or intended final purpose, the placing on the market of the above mixtures, articles or components of articles manufactured from polymers or copolymers of vinyl chloride, stabilised by substances containing cadmium is prohibited, if their cadmium content (expressed as Cd metal) exceeds 0,01 % by weight of the polymer.</p> <p>4. However, paragraph 3 shall not apply to mixtures and articles using cadmium-based stabilisers for safety reasons.</p> <p>5. For the purpose of this entry, "cadmium plating" means any deposit or coating of metallic cadmium on a metallic surface.</p> <p>Shall not be used for cadmium plating metallic articles or components of the articles used in the following sectors/applications:</p> <p>(a) equipment and machinery for:</p> <ul style="list-style-type: none"> — food production [8210] [8417 20] [8419 81] [8421 11] [8421 22] [8422] [8435] [8437] [8438] [8476 11] — agriculture [8419 31] [8424 81] [8432] [8433] [8434] [8436] — cooling and freezing [8418] — printing and book-binding [8440] [8442] [8443] <p>(b) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> — household goods [7321] [8421 12] [8450] [8509] [8516] — furniture [8465] [8466] [9401] [9402] [9403] [9404] — sanitary ware [7324] — central heating and air conditioning plant [7322] [8403] [8404] [8415] <p>In any case, whatever their use or intended final purpose, the placing on the market of cadmium-plated articles or components of such articles used in the sectors/applications listed in points (a) and (b) above and of articles manufactured in the sectors listed in point (b) above is prohibited.</p> <p>6. The provisions referred to in paragraph 5 shall also be applicable to cadmium-plated articles or components of such articles when used in the sectors/applications listed in points (a) and (b) below and to articles manufactured in the sectors listed in (b) below:</p> <p>(a) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> — paper and board [8419 32] [8439] [8441] textiles and clothing [8444] [8445] [8447] [8448] [8449] [8451] [8452] <p>(b) equipment and machinery for the production of:</p> <ul style="list-style-type: none"> — industrial handling equipment and machinery [8425] [8426] [8427] [8428] [8429] [8430] [8431] — road and agricultural vehicles [chapter 87] — rolling stock [chapter 86] — vessels [chapter 89] <p>7. However, the restrictions in paragraphs 5 and 6 shall not apply to:</p> <ul style="list-style-type: none"> — articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors whose applications require high safety standards and in safety devices in road and agricultural vehicles, rolling stock and vessels, — electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed. <p>(*) OJ L 256, 7.9.1987, p. 42.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>24. Monomethyl — tetrachlorodiphenyl methane</p> <p>Trade name: Ugilec 141</p> <p>CAS No 76253-60-6</p>	<p>1. Shall not be placed on the market, or used, as a substance or in mixtures.</p> <p>Articles containing the substance shall not be placed on the market.</p> <p>2. By way of derogation, paragraph 1 shall not apply:</p> <p>(a) in the case of plant and machinery already in service on 18 June 1994, until such plant and machinery is disposed of;</p> <p>(b) in the case of the maintenance of plant and machinery already in service within a Member State on 18 June 1994.</p> <p>For the purposes of point (a) Member States may, on grounds of human health protection and environmental protection, prohibit within their territory the use of such plant or machinery before it is disposed of.</p>
<p>25. Monomethyl-dichloro-diphenyl methane</p> <p>Trade name: Ugilec 121</p> <p>Ugilec 21</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures.</p> <p>Articles containing the substance shall not be placed on the market.</p>
<p>26. Monomethyl-dibromo-diphenyl methane bromobenzylbromotoluene, mixture of isomers</p> <p>Trade name: DBBT</p> <p>CAS No 99688-47-8</p>	<p>Shall not be placed on the market, or used, as a substance or in mixtures.</p> <p>Articles containing the substance shall not be placed on the market.</p>
<p>27. Nickel</p> <p>CAS No 7440-02-0</p> <p>EC No 231-111-4 and its compounds</p>	<p>1. Shall not be used:</p> <p>(a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/cm²/week (migration limit);</p> <p>(b) in articles intended to come into direct and prolonged contact with the skin such as:</p> <ul style="list-style-type: none"> — earrings, — necklaces, bracelets and chains, anklets, finger rings, — wrist-watch cases, watch straps and tighteners, — rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments, <p>if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week.</p> <p>(c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm²/week for a period of at least two years of normal use of the article.</p> <p>2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>28. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as carcinogen category 1A or 1B (Table 3.1) or carcinogen category 1 or 2 (Table 3.2) and listed as follows:</p> <ul style="list-style-type: none"> — Carcinogen category 1A (Table 3.1)/carcinogen category 1 (Table 3.2) listed in Appendix 1 — Carcinogen category 1B (Table 3.1)/carcinogen category 2 (Table 3.2) listed in Appendix 2 <p>29. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as germ cell mutagen category 1A or 1B (Table 3.1) or mutagen category 1 or 2 (Table 3.2) and listed as follows:</p> <ul style="list-style-type: none"> — Mutagen category 1A (Table 3.1)/mutagen category 1 (Table 3.2) listed in Appendix 3 — Mutagen category 1B (Table 3.1)/mutagen category 2 (Table 3.2) listed in Appendix 4 <p>30. Substances which appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 classified as toxic to reproduction category 1A or 1B (Table 3.1) or toxic to reproduction category 1 or 2 (Table 3.2) and listed as follows:</p> <ul style="list-style-type: none"> — Reproductive toxicant category 1A adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 1 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 5 — Reproductive toxicant category 1B adverse effects on sexual function and fertility or on development (Table 3.1) or reproductive toxicant category 2 with R60 (May impair fertility) or R61 (May cause harm to the unborn child) (Table 3.2) listed in Appendix 6 	<p>Without prejudice to the other parts of this Annex the following shall apply to entries 28 to 30:</p> <p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as substances, — as constituents of other substances, or, — in mixtures, <p>for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:</p> <ul style="list-style-type: none"> — either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, — the relevant concentration specified in Directive 1999/45/EC. <p>Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:</p> <p>“Restricted to professional users”.</p> <p>2. By way of derogation, paragraph 1 shall not apply to:</p> <ul style="list-style-type: none"> (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC; (c) the following fuels and oil products: <ul style="list-style-type: none"> — motor fuels which are covered by Directive 98/70/EC, — mineral oil products intended for use as fuel in mobile or fixed combustion plants, — fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>31. (a) Creosote; wash oil CAS No 8001-58-9 EC No 232-287-5</p> <p>(b) Creosote oil; wash oil CAS No 61789-28-4 EC No 263-047-8</p> <p>(c) Distillates (coal tar), naphthalene oils; naphthalene oil CAS No 84650-04-4 EC No 283-484-8</p> <p>(d) Creosote oil, acenaphthene fraction; wash oil CAS No 90640-84-9 EC No 283-484-8 EC No 292-605-3</p> <p>(e) Distillates (coal tar), upper; heavy anthracene oil CAS No 65996-91-0 EC No 266-026-1</p> <p>(f) Anthracene oil CAS No 90640-80-5 EC No 292-602-7</p> <p>(g) Tar acids, coal, crude; crude phenols CAS No 65996-85-2 EC No 266-019-3</p> <p>(h) Creosote, wood CAS No 8021-39-4 EC No 232-419-1</p> <p>(i) Low temperature tar oil, alkaline; extract residues (coal), low temperature coal tar alkaline CAS No 122384-78-5 EC No 310-191-5</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for the treatment of wood. Furthermore, wood so treated shall not be placed on the market.</p> <p>2. By way of derogation from paragraph 1:</p> <p>(a) The substances and mixtures may be used for wood treatment in industrial installations or by professionals covered by Community legislation on the protection of workers for in situ retreatment only if they contain:</p> <p>(i) benzo[a]pyrene at a concentration of less than 50 mg/kg (0,005 % by weight), and</p> <p>(ii) water extractable phenols at a concentration of less than 3 % by weight.</p> <p>Such substances and mixtures for use in wood treatment in industrial installations or by professionals:</p> <p>— may be placed on the market only in packaging of a capacity equal to or greater than 20 litres,</p> <p>— shall not be sold to consumers.</p> <p>Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is visibly, legibly and indelibly marked as follows:</p> <p>“For use in industrial installations or professional treatment only”.</p> <p>(b) Wood treated in industrial installations or by professionals according to subparagraph (a) which is placed on the market for the first time or retreated in situ may be used for professional and industrial use only, for example on railways, in electric power transmission and telecommunications, for fencing, for agricultural purposes (for example stakes for tree support) and in harbours and waterways.</p> <p>(c) The prohibition in paragraph 1 on the placing on the market shall not apply to wood which has been treated with substances listed in entry 31 (a) to (i) before 31 December 2002 and is placed on the second-hand market for re-use.</p> <p>3. Treated wood referred to under paragraph 2(b) and (c) shall not be used:</p> <p>— inside buildings, whatever their purpose,</p> <p>— in toys,</p> <p>— in playgrounds,</p> <p>— in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact,</p> <p>— in the manufacture of garden furniture such as picnic tables,</p> <p>— for the manufacture and use and any re-treatment of:</p> <p>— containers intended for growing purposes,</p> <p>— packaging that may come into contact with raw materials, intermediate or finished products destined for human and/or animal consumption,</p> <p>— other materials which may contaminate the articles mentioned above.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
32. Chloroform CAS No 67-66-3 EC No 200-663-8	Without prejudice to the other parts of this Annex, the following shall apply to entries 32 to 38. 1. Shall not be placed on the market, or used,
34. 1,1,2-Trichloroethane CAS No 79-00-5 EC No 201-166-9	— as substances, — as constituents of other substances, or in mixtures in concentrations equal to or greater than 0,1 % by weight,
35. 1,1,2,2-Tetrachloroethane CAS No 79-34-5 EC No 201-197-8	where the substance or mixture is intended for supply to the general public and/or is intended for diffusive applications such as in surface cleaning and cleaning of fabrics.
36. 1,1,1,2-Tetrachloroethane CAS No 630-20-6	2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures containing them in concentrations equal to or greater than 0,1 % by weight is visibly, legibly and indelibly marked as follows:
37. Pentachloroethane CAS No 76-01-7 EC No 200-925-1	“For use in industrial installations only”.
38. 1,1-Dichloroethene CAS No 75-35-4 EC No 200-864-0	By way of derogation this provision shall not apply to: (a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC; (b) cosmetic products as defined by Directive 76/768/EEC.
40. Substances meeting the criteria of flammability in Directive 67/548/EEC and classified as flammable, highly flammable or extremely flammable regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.	1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following: — metallic glitter intended mainly for decoration, — artificial snow and frost, — “whoopee” cushions, — silly string aerosols, — imitation excrement, — horns for parties, — decorative flakes and foams, — artificial cobwebs, — stink bombs. 2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with: “For professional users only”. 3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (**). 4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.
41. Hexachloroethane CAS No 67-72-1 EC No 200-666-4	Shall not be placed on the market, or used, as substance or in mixtures, where the substance or mixture is intended for the manufacturing or processing of non-ferrous metals.

(**) OJ L 147, 9.6.1975, p. 40.

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>42. Alkanes, C₁₀-C₁₃, chloro (short-chain chlorinated paraffins) (SCCPs)</p> <p>EC No 287-476-5 CAS No 85535-84-8</p>	<p>Shall not be placed on the market, or used as substances, or as constituents of other substances or in mixtures in concentrations greater than 1 % by weight, where the substance or mixture is intended for:</p> <ul style="list-style-type: none"> — metalworking, — fat liquoring of leather.
<p>43. Azocolourants and Azodyes</p>	<p>1. Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in Appendix 8, in detectable concentrations, i.e. above 30 mg/kg (0,003 % by weight) in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used, in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:</p> <ul style="list-style-type: none"> — clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping bags, — footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck, — textile or leather toys and toys which include textile or leather garments, — yarn and fabrics intended for use by the final consumer. <p>2. Furthermore, the textile and leather articles referred to in paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.</p> <p>3. Azodyes, which are contained in Appendix 9, "List of azodyes" shall not be placed on the market, or used, as substances, or in mixtures in concentrations greater than 0,1 % by weight, where the substance or the mixture is intended for colouring textile and leather articles.</p>
<p>44. Diphenylether, pentabromo derivative</p> <p>C₁₂H₅Br₅O</p>	<p>1. Shall not be placed on the market, or used,</p> <ul style="list-style-type: none"> — as a substance, — in mixtures in concentrations greater than 0,1 % by weight. <p>2. Articles shall not be placed on the market if they, or flame-retarded parts thereof, contain this substance in concentrations greater than 0,1 % by weight.</p> <p>3. By way of derogation, paragraph 2 shall not apply</p> <ul style="list-style-type: none"> — to articles that were in use in the Community before 15 August 2004, — to electrical and electronic equipment within the scope of Directive 2002/95/EC of the European Parliament and Council (**). <p>(**) OJ L 37, 13.2.2003, p. 19.</p>
<p>45. Diphenylether, octabromo derivative</p> <p>C₁₂H₂Br₈O</p>	<p>1. Shall not be placed on the market, or used:</p> <ul style="list-style-type: none"> — as a substance, — as a constituent of other substances, or in mixtures, in concentrations greater than 0,1 % by weight. <p>2. Articles shall not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations greater than 0,1 % by weight.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>3. By way of derogation, paragraph 2 shall not apply:</p> <ul style="list-style-type: none"> — to articles that were in use in the Community before 15 August 2004, — to electrical and electronic equipment within the scope of Directive 2002/95/EC.
<p>46. (a) Nonylphenol $C_6H_4(OH)C_9H_{19}$ CAS 25154-52-3 EC 246-672-0</p> <p>(b) Nonylphenol ethoxylates $(C_2H_4O)_nC_{15}H_{24}O$</p>	<p>Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:</p> <ul style="list-style-type: none"> (1) industrial and institutional cleaning except: <ul style="list-style-type: none"> — controlled closed dry cleaning systems where the washing liquid is recycled or incinerated, — cleaning systems with special treatment where the washing liquid is recycled or incinerated. (2) domestic cleaning; (3) textiles and leather processing except: <ul style="list-style-type: none"> — processing with no release into waste water, — systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin); (4) emulsifier in agricultural teat dips; (5) metal working except: <ul style="list-style-type: none"> uses in controlled closed systems where the washing liquid is recycled or incinerated; (6) manufacturing of pulp and paper; (7) cosmetic products; (8) other personal care products except: <ul style="list-style-type: none"> spermicides; (9) co-formulants in pesticides and biocides. However national authorisations for pesticides or biocidal products containing nonylphenol ethoxylates as co-formulant, granted before 17 July 2003, shall not be affected by this restriction until their date of expiry.
<p>47. Chromium VI compounds</p>	<p>1. Cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002 %) soluble chromium VI of the total dry weight of the cement.</p> <p>2. If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of cement or cement-containing mixtures is visibly, legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing mixtures are handled solely by machines and in which there is no possibility of contact with the skin.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
48. Toluene CAS No 108-88-3 EC No 203-625-9	Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.
49. Trichlorobenzene CAS No 120-82-1 EC No 204-428-0	Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight for any use except: <ul style="list-style-type: none"> — as an intermediate of synthesis, or, — as a process solvent in closed chemical applications for chlorination reactions, or, — in the manufacture of 1,3,5-triamino — 2,4,6-trinitrobenzene (TATB).
50. Polycyclic-aromatic hydrocarbons (PAH)(a) Benzo[a]pyrene (BaP) CAS No 50-32-8 (b) Benzo[e]pyrene (BeP) CAS No 192-97-2 (c) Benzo[a]anthracene (BaA) CAS No 56-55-3 (d) Chrysen (CHR) CAS No 218-01-9 (e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2 (f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3 (g) Benzo[k]fluoranthene (BkFA) CAS No 207-08-9 (h) Dibenzo[a,h]anthracene (DBAhA) CAS No 53-70-3	<p>1. From 1 January 2010, extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain:</p> <ul style="list-style-type: none"> — more than 1 mg/kg (0,0001 % by weight) BaP, or, — more than 10 mg/kg (0,001 % by weight) of the sum of all listed PAHs. <p>These limits shall be regarded as kept, if the polycyclic aromatics (PCA) extract is less than 3 % by weight as measured by the Institute of Petroleum standard IP346: 1998 (Determination of PCA in unused lubricating base oils and asphaltene free petroleum fractions — Dimethyl sulphoxide extraction refractive index method), provided that compliance with the limit values of BaP and of the listed PAHs, as well as the correlation of the measured values with the PCA extract, is controlled by the manufacturer or importer every six months or after each major operational change, whichever is earlier.</p> <p>2. Furthermore, tyres and treads for retreading manufactured after 1 January 2010 shall not be placed on the market if they contain extender oils exceeding the limits indicated in paragraph 1.</p> <p>These limits shall be regarded as kept, if the vulcanised rubber compounds do not exceed the limit of 0,35 % Bay protons as measured and calculated by ISO 21461 (Rubber vulcanised — Determination of aromaticity of oil in vulcanised rubber compounds).</p> <p>3. By way of derogation, paragraph 2 shall not apply to retreaded tyres if their tread does not contain extender oils exceeding the limits referred to in paragraph 1.</p> <p>4. For the purpose of this entry “tyres” shall mean tyres for vehicles covered by:</p> <ul style="list-style-type: none"> — Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers (****), — Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units (*****), and — Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles and repealing Council Directive 92/61/EEC (*****). <p>(****) OJ L 263, 9.10.2007, p. 1. (*****) OJ L 171, 9.7.2003, p. 1. (*****) OJ L 124, 9.5.2002, p. 1.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
<p>51. The following phthalates (or other CAS and EC numbers covering the substance):</p> <p>(a) Bis (2-ethylhexyl) phthalate (DEHP) CAS No 117-81-7 EC No 204-211-0</p> <p>(b) Dibutyl phthalate (DBP) CAS No 84-74-2 EC No 201-557-4</p> <p>(c) Benzyl butyl phthalate (BBP) CAS No 85-68-7 EC No 201-622-7</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles.</p> <p>2. Toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p>3. The Commission shall re-evaluate, by 16 January 2010, the measures provided for in relation to this entry in the light of new scientific information on such substances and their substitutes, and if justified, these measures shall be modified accordingly.</p> <p>4. For the purpose of this entry "childcare article" shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>
<p>52. The following phthalates (or other CAS- and EC numbers covering the substance):</p> <p>(a) Di-"isononyl" phthalate (DINP) CAS No 28553-12-0 and 68515-48-0 EC No 249-079-5 and 271-090-9</p> <p>(b) Di-"isodecyl" phthalate (DIDP) CAS No 26761-40-0 and 68515-49-1 EC No 247-977-1 and 271-091-4</p> <p>(c) Di-n-octyl phthalate (DNOP) CAS No 117-84-0 EC No 204-214-7</p>	<p>1. Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.</p> <p>2. Such toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.</p> <p>3. The Commission shall re-evaluate, by 16 January 2010, the measures provided for in relation to this entry in the light of new scientific information on such substances and their substitutes, and if justified, these measures shall be modified accordingly.</p> <p>4. For the purpose of this entry "childcare article" shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.</p>
<p>53. Perfluorooctane sulfonates (PFOS) C8F17SO2X (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)</p>	<p>1. Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 50 mg/kg (0,005 % by weight).</p> <p>2. Shall not be placed on the market in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or greater than 0,1 % by weight calculated with reference to the mass of structurally or microstructurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is equal to or greater than 1 µg/m² of the coated material.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the following items, nor to substances and mixtures needed to produce them:</p> <p>(a) photoresists or anti-reflective coatings for photolithography processes;</p> <p>(b) photographic coatings applied to films, papers, or printing plates;</p> <p>(c) mist suppressants for non-decorative hard chromium (VI) plating and wetting agents for use in controlled electroplating systems where the amount of PFOS released into the environment is minimised, by fully applying relevant best available techniques developed within the framework of Directive 2008/1/EC (*****);</p> <p>(d) hydraulic fluids for aviation.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>4. By way of derogation from paragraph 1, fire-fighting foams that were placed on the market before 27 December 2006 may be used until 27 June 2011.</p> <p>5. By way of derogation, paragraph 2 shall not apply to articles that were in use in the Community before 27 June 2008.</p> <p>6. Paragraphs 1 and 2 shall apply without prejudice to Regulation (EC) No 648/2004 of the European Parliament and of the Council (*****).</p> <p>7. As soon as new information on details of uses and safer alternative substances or technologies for the uses becomes available, the Commission shall review each of the derogations in paragraph 3(a) to (d) so that:</p> <p>(a) the uses of PFOS will be phased out as soon as the use of safer alternatives is technically and economically feasible;</p> <p>(b) a derogation can only be continued for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on;</p> <p>(c) releases of PFOS into the environment have been minimised, by applying best available techniques.</p> <p>8. The Commission shall keep under review the ongoing risk assessment activities and the availability of safer alternative substances or technologies related to the uses of perfluorooctanoic acid (PFOA) and related substances and propose all necessary measures to reduce identified risks, including restrictions on marketing and use, in particular when safer alternative substances or technologies, that are technically and economically feasible, are available.</p> <p>(*****) OJ L 24, 29.1.2008, p. 8. (*****) OJ L 104, 8.4.2004, p. 1.</p>
<p>54. 2-(2-methoxyethoxy)ethanol (DEGME)</p> <p>CAS No 111-77-3 EC No 203-906-6</p>	<p>Shall not be placed on the market after 27 June 2010, for supply to the general public, as a constituent of paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0,1 % by weight.</p>
<p>55. 2-(2-butoxyethoxy)ethanol (DEGBE)</p> <p>CAS No 112-34-5 EC No 203-961-6</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of spray paints or spray cleaners in aerosol dispensers in concentrations equal to or greater than 3 % by weight.</p> <p>2. Spray paints and spray cleaners in aerosol dispensers containing DEGBE and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>3. Without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that paints other than spray paints containing DEGBE in concentrations equal to or greater than 3 % by weight of that are placed on the market for supply to the general public are visibly, legibly and indelibly marked by 27 December 2010 as follows:</p> <p>“Do not use in paint spraying equipment”.</p>
<p>56. Methylenediphenyl diisocyanate (MDI)</p> <p>CAS No 26447-40-5 EC No 247-714-0</p>	<p>1. Shall not be placed on the market after 27 December 2010, as a constituent of mixtures in concentrations equal to or greater than 0,1 % by weight of MDI for supply to the general public, unless suppliers shall ensure before the placing on the market that the packaging:</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>(a) contains protective gloves which comply with the requirements of Council Directive 89/686/EEC (*****);</p> <p>(b) is marked visibly, legibly and indelibly as follows, and without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures:</p> <p>— Persons already sensitised to diisocyanates may develop allergic reactions when using this product.</p> <p>— Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product.</p> <p>— This product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used.”</p> <p>2. By way of derogation, paragraph 1(a) shall not apply to hot melt adhesives.</p> <p>(*****) OJ L 399, 30.12.1989, p. 18.</p>
<p>57. Cyclohexane</p> <p>CAS No 110-82-7</p> <p>EC No 203-806-2</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of neoprene-based contact adhesives in concentrations equal to or greater than 0,1 % by weight in package sizes greater than 350 g.</p> <p>2. Neoprene-based contact adhesives containing cyclohexane and not conforming to paragraph 1 shall not be placed on the market for supply to the general public after 27 December 2010.</p> <p>3. Without prejudice to other Community legislation concerning the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that neoprene-based contact adhesives containing cyclohexane in concentrations equal to or greater than 0,1 % by weight that are placed on the market for supply to the general public after 27 December 2010 are visibly, legibly and indelibly marked as follows:</p> <p>— This product is not to be used under conditions of poor ventilation.</p> <p>— This product is not to be used for carpet laying.”.</p>
<p>58. Ammonium nitrate (AN)</p> <p>CAS No 6484-52-2</p> <p>EC No 229-347-8</p>	<p>1. Shall not be placed on the market for the first time after 27 June 2010 as a substance, or in mixtures that contain more than 28 % by weight of nitrogen in relation to ammonium nitrate, for use as a solid fertiliser, straight or compound, unless the fertiliser complies with the technical provisions for ammonium nitrate fertilisers of high nitrogen content set out in Annex III to Regulation (EC) No 2003/2003 of the European Parliament and of the Council (*****).</p> <p>2. Shall not be placed on the market after 27 June 2010 as a substance, or in mixtures that contain 16 % or more by weight of nitrogen in relation to ammonium nitrate except for supply to:</p> <p>(a) downstream users and distributors, including natural or legal persons licensed or authorised in accordance with Council Directive 93/15/EEC (*****);</p> <p>(b) farmers for use in agricultural activities, either full time or part time and not necessarily related to the size of the land area.</p>

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
	<p>For the purposes of this subparagraph:</p> <p>(i) “farmer” shall mean a natural or legal person, or a group of natural or legal persons, whatever legal status is granted to the group and its members by national law, whose holding is situated within Community territory, as referred to in Article 299 of the Treaty, and who exercises an agricultural activity;</p> <p>(ii) “agricultural activity” shall mean the production, rearing or growing of agricultural products including harvesting, milking, breeding animals and keeping animals for farming purposes, or maintaining the land in good agricultural and environmental condition as established under Article 5 of Council Regulation (EC) No 1782/2003 (*****);</p> <p>(c) natural or legal persons engaged in professional activities such as horticulture, plant growing in greenhouses, maintenance of parks, gardens or sport pitches, forestry or other similar activities.</p> <p>3. However, for the restrictions in paragraph 2, Member States may until 1 July 2014, for socioeconomic reasons, apply a limit of up to 20 % by weight of nitrogen in relation to ammonium nitrate for substances and mixtures placed on the market within their territories. They shall inform the Commission and other Member States thereof.</p> <p>(*****) OJ L 304, 21.11.2003, p. 1. (*****) OJ L 121, 15.5.1993, p. 20. (*****) OJ L 270, 21.10.2003, p. 1.’</p>

3. in the Appendices 1 to 6, the foreword is replaced by the following:

FOREWORD

Explanations of column headings

Substances:

The name corresponds to the International Chemical Identification used for the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Whenever possible, substances are designated by their IUPAC names. Substances listed in EINECS (European Inventory of Existing Commercial Chemical Substances), ELINCS (European List of Notified Substances) or the list of “No-longer-polymers” are designated using the names in these lists. Other names, such as usual or common names, are included in some cases. Whenever possible, plant protection products and biocides are designated by their ISO names.

Entries for groups of substances:

A number of group entries are included in Part 3 of Annex VI to Regulation (EC) No 1272/2008. In these cases, the classification requirements will apply to all substances covered by the description.

In some cases, there are classification requirements for specific substances that would be covered by the group entry. In such cases a specific entry is included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 for the substance and the group entry will be annotated with the phrase “except those specified elsewhere in Annex VI to Regulation (EC) No 1272/2008”.

In some cases, individual substances may be covered by more than one group entry. In these cases, the classification of the substance reflects the classification for each of the two group entries. In cases where different classifications for the same hazard are given, the most severe classification will be applied.

Index number:

The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008. Substances are listed in the Appendix according to this index number.

EC numbers:

The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union. The EINECS number can be obtained from the European Inventory of Existing Commercial Chemical Substances (EINECS). The ELINCS number can be obtained from the European List of Notified Substances. The NLP number can be obtained from the list of "No-longer-polymers". These lists are published by the Office for Official Publications of the European Communities.

The EC number is a seven-digit system of the type XXX-XXX-X which starts at 200-001-8 (EINECS), at 400-010-9 (ELINCS) and at 500-001-0 (NLP). This number is indicated in the column entitled "EC No".

CAS number:

Chemical Abstracts Service (CAS) numbers have been defined for substances to help in their identification.

Notes:

The full text of the notes can be found in Part 1 of Annex VI to Regulation (EC) No 1272/2008.

The notes to be taken into account for the purposes of this Regulation are the following:

Note A:

Without prejudice to Article 17(2) of Regulation (EC) No 1272/2008, the name of the substance must appear on the label in the form of one of the designations given in Part 3 of Annex VI to that Regulation.

In that Part, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the supplier who places such a substance on the market is required to state on the label the correct name, due account being taken of Section 1.1.1.4 of Annex VI to Regulation (EC) No 1272/2008.

Note C:

Some organic substances may be marketed either in a specific isomeric form or as a mixture of several isomers.

Note D:

Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, supplier who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised".

Note J:

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EC No 200-753-7).

Note K:

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w 1,3-butadiene (EC No 203-450-8).

Note L:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 3 % DMSO extract as measured by IP 346.

Note M:

The classification as a carcinogen need not apply if it can be shown that the substance contains less than 0,005 % w/w benzo[a]-pyrene (EC No 200-028-5).

Note N:

The classification as a carcinogen need not apply if the full refining history is known and it can be shown that the substance from which it is produced is not a carcinogen.

Note P:

The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0,1 % w/w benzene (EC No 200-753-7).

Note R:

The classification as a carcinogen need not apply to fibres with a length weighted geometric mean diameter, less two standard errors, greater than 6µm.;

4. in Appendices 1, 2, 3, 5 and 6, in the entries, in the column headed 'notes', references to notes E, H and S are deleted;

5. in Appendix 1, the heading is replaced by 'Entry 28 — Carcinogens: category 1A (Table 3.1)/category 1 (Table 3.2)';

6. Appendix 2 shall be amended as follows:

(a) the heading is replaced by 'Entry 28 — Carcinogens: category 1B (Table 3.1)/category 2 (Table 3.2)';

(b) in the entries index Nos 024-017-00-8, 611-024-00-1, 611-029-00-9, 611-030-00-4 and 650-017-00-8, the words 'Annex I to Directive 67/548/EEC' shall be replaced by 'Annex VI to Regulation (EC) No 1272/2008';

(c) the entries with index numbers 649-062-00-6, 649-063-00-1, 649-064-00-7, 649-065-00-2, 649-066-00-8, 649-067-00-3, 649-068-00-9, 649-069-00-4, 649-070-00-X, 649-071-00-5, 649-072-00-0, 649-073-00-6, 649-074-00-1, 649-075-00-7, 649-076-00-2, 649-077-00-8, 649-078-00-3, 649-079-00-9, 649-080-00-4, 649-081-00-X, 649-082-00-5, 649-083-00-0, 649-084-00-6, 649-085-00-1, 649-086-00-7, 649-087-00-2, 649-089-00-3, 649-090-00-9, 649-091-00-4, 649-092-00-X, 649-093-00-5, 649-094-00-0, 649-095-00-6, 649-096-00-1, 649-097-00-7, 649-098-00-2, 649-099-00-8, 649-100-00-1, 649-101-00-7, 649-102-00-2, 649-103-00-8, 649-104-00-3, 649-105-00-9, 649-106-00-4, 649-107-00-X, 649-108-00-5, 649-109-00-0, 649-110-00-6, 649-111-00-1, 649-112-00-7, 649-113-00-2, 649-114-00-8, 649-115-00-3, 649-116-00-9, 649-117-00-4, 649-119-00-5, 649-120-00-0, 649-121-00-6, 649-122-00-1, 649-123-00-7, 649-124-00-2, 649-125-00-8, 649-126-00-3, 649-127-00-9, 649-128-00-4, 649-129-00-X, 649-130-00-5, 649-131-00-0, 649-132-00-6, 649-133-00-1, 649-134-00-7, 649-135-00-2, 649-136-00-8, 649-137-00-3, 649-138-00-9, 649-139-00-4, 649-140-00-X, 649-141-00-5, 649-142-00-0, 649-143-00-6, 649-144-00-1, 649-145-00-7, 649-146-00-2, 649-147-00-8, 649-148-00-3, 649-149-00-9, 649-150-00-4, 649-151-0-X, 649-152-00-5, 649-153-00-0, 649-154-00-6, 649-155-00-1, 649-156-00-7, 649-157-00-2, 649-158-00-8, 649-159-00-3, 649-160-00-9, 649-161-00-4, 649-162-00-X, 649-163-00-5, 649-164-00-0, 649-165-00-6, 649-166-00-1, 649-167-00-7, 649-168-00-2, 649-169-00-8, 649-170-00-3, 649-171-00-9, 649-172-00-4, 649-173-00-X, 649-174-00-5, 649-177-00-1, 649-178-00-7, 649-179-00-2, 649-180-00-8, 649-181-00-3, 649-182-00-9, 649-183-00-4, 649-184-00-X, 649-185-00-5, 649-186-00-0, 649-187-00-6, 649-188-00-1, 649-189-00-7, 649-190-00-2, 649-191-00-8, 649-193-00-9, 649-194-00-4, 649-195-00-X, 649-196-00-5, 649-197-00-0, 649-198-00-6, 649-199-00-1, 649-200-00-5, 649-201-00-0, 649-202-00-6, 649-203-00-1, 649-204-00-7, 649-205-00-2, 649-206-00-8, 649-207-00-3, 649-208-00-9, 649-209-00-4 and 649-210-00-X are deleted;

7. in Appendix 3, the heading is replaced by 'Entry 29 — Mutagens: category 1A (Table 3.1)/category 1 (Table 3.2)';

8. in Appendix 4, the heading is replaced by 'Entry 29 — Mutagens: category 1B (Table 3.1)/category 2 (Table 3.2)';

9. in Appendix 5, the heading is replaced by 'Entry 30 — Toxic to reproduction: category 1A (Table 3.1)/category 1 (Table 3.2)';

10. in Appendix 6, the heading is replaced by 'Entry 30 — Toxic to reproduction: category 1B (Table 3.1)/category 2 (Table 3.2)';

11. in Appendix 8, the heading is replaced by 'Entry 43 — Azocolourants — List of aromatic amines';

12. In Appendix 9, the heading is replaced by 'Entry 43 — Azocolourants — List of azodyes';

13. Appendix 10 shall be amended as follows:

(a) the heading is replaced by 'Entry 43 — Azocolourants — List of testing methods';

(b) in the footnote, the addresses of CEN and Cenelec are replaced by the following:

'CEN: Avenue Marnix 17, 1000 Brussels, Belgium, tel. +32 2550 08 11, fax +32 2550 08 19 (<http://www.cen.eu/cenorm/homepage.htm>)

Cenelec: Avenue Marnix 17, B-1000 Brussels, tel. +32 25196871, fax +32 2519 69 19 (<http://www.cenelec.eu/Cenelec/Homepage.htm>)'

COMMISSION REGULATION (EC) No 553/2009**of 25 June 2009****opening a specific invitation to tender for the resale on the Community market of maize from harvests prior to the 2007/08 marketing year, held by the Hungarian intervention agency**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products ('Single CMO Regulation') ⁽¹⁾, and in particular Article 43(f) in conjunction with Article 4 thereof,

Whereas:

- (1) Under Commission Regulation (EC) No 127/2009 of 12 February 2009 laying down the procedures and conditions for the sale of cereals held by paying agencies or intervention agencies ⁽²⁾, cereals held by intervention agencies are to be sold by tendering procedure at prices preventing market disturbance.
- (2) Commission Regulation (EC) No 712/2007 ⁽³⁾ opened standing invitations to tender for the resale on the Community market of cereals held by Member States' intervention agencies for the 2007/08 marketing year. In order to provide producers and the feed industry with supplies at competitive prices during the first months of the 2008/09 marketing year, that Regulation has been amended so as to ensure that submissions for partial tenders can be submitted until 17 December 2008.
- (3) At the start of the 2007/08 marketing year, Community intervention stocks stood at 2.46 million tonnes, 2.23 million tonnes of which were maize. During that marketing year, relatively significant sales of intervention stocks, specifically maize, took place under the tendering procedure covered by Regulation (EC) No 712/2007.
- (4) However, given the market conditions since mid-September 2008, particularly in terms of price, bids have ceased to be made by operators and on 31 October 2008, only one amount of intervention maize of approximately 16 000 tonnes remained. These

old stocks (chiefly from the 2004 and 2005 harvests) will be competing with Community maize from the abundant 2008 harvest, the selling prices of which were already below the intervention price on 31 October 2008. This stock should therefore be made available with a view to its use on the internal market.

- (5) Under Article 7(3) of Regulation (EC) No 127/2009, if the running of the common market organisation is disturbed on account in particular of difficulty during a marketing year in selling cereals at prices which comply with those given in Article 7(1) of that Regulation, sales on the Community market may be organised on the basis of specific invitations to tender under special conditions. The lengthy duration of storage of maize, from harvests prior to the 2007/08 marketing year's harvest, held by the Hungarian intervention agency and the current market price of maize in Hungary constitute a special circumstance justifying the opening of a specific invitation to tender for the sale of maize from harvests prior to that of the 2007/08 marketing year at prices potentially lower than the intervention price.
- (6) Significant price fluctuations have also been observed on the Community market. In view of these disparities, the lots awarded could not be removed by the operators to which awards are made. The security of EUR 5 per tonne provided for in the second subparagraph of Article 5(3) of Regulation (EC) No 127/2009 is not therefore sufficient to ensure this removal. In order to avoid such a situation and to ensure that the tendering procedure covered by this Regulation runs smoothly, the security should be increased in order to limit the risks.
- (7) To take account of the situation on the Community market, provision should be made for the Commission to manage this invitation to tender. Provision must also be made for an award coefficient for tenders offering the minimum selling price.
- (8) In the interests of sound management of the system, the information required by the Commission should be sent by electronic means. It is important that the notification to the Commission by the intervention agency maintains tenderers' anonymity.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 42, 13.2.2009, p. 3.

⁽³⁾ OJ L 163, 23.6.2007, p. 7.

HAS ADOPTED THIS REGULATION:

Article 1

The Hungarian intervention agency shall sell, by means of an invitation to tender across the internal market of the Community, maize from harvests prior to the 2007/08 marketing year's harvest which it holds.

Article 2

1. The sales referred to in Article 1 shall be carried out under the terms laid down by Regulation (EC) No 127/2009.

2. Notwithstanding Article 7(1) of Regulation (EC) No 127/2009, the minimum selling price may be less than the intervention price, plus a monthly increase.

3. Notwithstanding Article 5(3) of Regulation (EC) No 127/2009, the tender security is set at EUR 10 per tonne.

Article 3

1. The deadline for the submission of tenders for the first partial invitation to tender shall be 13:00 (Brussels time) on 30 June 2009.

The deadline for the submission of tenders under subsequent partial invitations to tender shall be on the following Wednesdays at 13:00 (Brussels time):

- 15 July 2009
- 5 and 26 August 2009,
- 9 and 23 September 2009,
- 14 and 28 October 2009,
- 11 and 25 November 2009,
- 2 and 16 December 2009.

2. Tenders must be lodged with the Hungarian intervention agency:

Mezőgazdasági és Vidékfejlesztési Hivatal
Soroksári út. 22-24
H-1095 Budapest
Telephone: (36) 1219 62 60
Fax: (36) 1219 89 05
E-mail: ERTEKESITES@MVH.GOV.HU
Website: www.mvh.gov.hu

Article 4

Within four hours of the expiry of the deadline for the submission of tenders laid down in Article 3(1), the intervention agency concerned shall notify the Commission of tenders received. If no tenders are received, the Member State concerned shall notify the Commission within the same time limit. If the Member State does not notify the Commission within the stipulated time limit, the Commission shall consider that no tender has been submitted in the Member State concerned.

The notifications referred to in the first subparagraph shall be sent electronically and be based on the model at Annex. The tenderers shall not be identified.

Article 5

1. In accordance with the procedure laid down in Article 195(2) of Regulation (EC) No 1234/2007, the Commission shall set the minimum maize selling price or decide not to make any award.

2. If fixing a minimum price in accordance with paragraph 1 would lead to the maximum quantity available being exceeded, an award coefficient may be fixed at the same time for the quantities offered at the minimum price in order to comply with the maximum quantity available.

Article 6

This Regulation shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

ANNEX

Notification to the Commission of tenders received under the specific invitation to tender for the resale on the internal market of maize from harvests prior to the 2007/08 marketing year's harvest, held by the Hungarian intervention agency

Model (*)

(Article 4 of Regulation (EC) No 553/2009)

1	2	3	4
Numbering of tenderers	Lot No	Quantity (t)	Tender price (EUR/tonne)
1			
2			
3			
etc.			

Indicate the total quantities offered (including rejected offers made for the same lot): ... tonnes.

(*) To be sent to DG AGRI, Unit D.2.

COMMISSION REGULATION (EC) No 554/2009**of 25 June 2009****amending Regulation (EC) No 2597/2001 as regards tariff quotas for certain wines originating in the former Yugoslav Republic of Macedonia**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 153/2002 of 21 January 2002 on certain procedures for applying the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the former Yugoslav Republic of Macedonia, of the other part, and for applying the Interim Agreement between the European Community and the former Yugoslav Republic of Macedonia ⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) The Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the former Yugoslav Republic of Macedonia, of the other part, to take account of the accession of the Republic of Bulgaria and Romania to the European Union ⁽²⁾, hereinafter 'the Protocol', has been signed on 18 February 2008. It has been approved on behalf of the European Community, the European Atomic Energy Community and the Member States by Council and Commission Decision 2008/438/EC, Euratom ⁽³⁾ and has been applied on a provisional basis from 1 January 2007.
- (2) Article 5 of the Protocol and Annex VIII thereto provide for changes to the existing tariff quotas for certain wines in containers holding more than 2 litres, originating in the former Yugoslav Republic of Macedonia with effect from 1 January 2007.

- (3) To implement the tariff quotas for wine laid down in the Protocol, it is necessary to amend Commission Regulation (EC) No 2597/2001 of 28 December 2001 opening and providing for the management of Community tariff quotas for certain wines originating in the Republic of Croatia and in the former Yugoslav Republic of Macedonia ⁽⁴⁾.
- (4) The TARIC subdivisions for certain Combined Nomenclature (CN) subheadings have been changed from 1 July 2007. The TARIC subdivisions for these CN codes in Part II of the Annex to Regulation (EC) No 2597/2001 should therefore be adjusted accordingly.
- (5) Since the Protocol applies from 1 January 2007, this Regulation should apply from the same date and enter into force immediately.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Part II of the Annex to Regulation (EC) No 2597/2001 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2007.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

László KOVÁCS

Member of the Commission

⁽¹⁾ OJ L 25, 29.1.2002, p. 16.

⁽²⁾ OJ L 99, 10.4.2008, p. 2.

⁽³⁾ OJ L 155, 13.6.2008, p. 15.

⁽⁴⁾ OJ L 345, 29.12.2001, p. 35.

ANNEX

PART II: FORMER YUGOSLAV REPUBLIC OF MACEDONIA

Order No	CN code	TARIC Subdivision	Description	Annual quota volume (in hl)	Tariff quota duty
09.1558	ex 2204 10 19	98 ⁽¹⁾	Sparkling wine, other than Champagne or Asti spumante	49 000 ⁽²⁾	Exemption
	ex 2204 10 99	98 ⁽¹⁾	Other wine of fresh grapes, in containers holding 2 litres or less		
	2204 21 10				
	ex 2204 21 79	79, 80			
	ex 2204 21 80	79, 80			
	ex 2204 21 84	59, 70			
	ex 2204 21 85	79, 80			
	ex 2204 21 94	20			
	ex 2204 21 98	20			
	ex 2204 21 99	10			
09.1559	2204 29 10		Other wine of fresh grapes, in containers holding more than 2 litres	350 000 ⁽³⁾	Exemption
	2204 29 65				
	ex 2204 29 75	10			
	2204 29 83				
	ex 2204 29 84	20			
	ex 2204 29 94	20			
	ex 2204 29 98	20			
	ex 2204 29 99	10			

⁽¹⁾ This TARIC subdivision applies from 1 July 2007.

⁽²⁾ From 1 January 2008, this quota volume is to be increased annually by 6 000 hl.

⁽³⁾ From 1 January 2008, this quota volume is to be reduced annually by 6 000 hl.'

COMMISSION REGULATION (EC) No 555/2009

of 25 June 2009

amending Regulation (EC) No 318/2007 laying down animal health conditions for imports of certain birds into the Community and the quarantine conditions thereof

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC ⁽¹⁾, and in particular the second subparagraph of Article 10(3) and the first subparagraph of Article 10(4) thereof,

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC ⁽²⁾, and in particular the fourth indent of Article 18(1),

Whereas:

- (1) Commission Regulation (EC) No 318/2007 ⁽³⁾ lays down the animal health conditions for imports of certain birds other than poultry into the Community and the quarantine conditions applicable to such birds after import.
- (2) Annex V to that Regulation sets out a list of quarantine facilities and centres approved by the competent authorities of the Member States for import of certain birds other than poultry.
- (3) Germany and the Slovak Republic have reviewed their approved quarantine facilities and centres and have sent

an updated list of those quarantine facilities and centres to the Commission. The list of approved quarantine facilities and centres set out in Annex V to Regulation (EC) No 318/2007 should therefore be amended accordingly.

- (4) Regulation (EC) No 318/2007 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex V to Regulation (EC) No 318/2007 is amended as follows:

1. in the part concerning Germany, the following entry is deleted:

DE	GERMANY	NW-2;
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2. after the part concerning Portugal, the following entry is added for the Slovak Republic:

SK	SLOVAK REPUBLIC	SK-PO-101'
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Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

⁽¹⁾ OJ L 268, 24.9.1991, p. 56.

⁽²⁾ OJ L 268, 14.9.1992, p. 54.

⁽³⁾ OJ L 84, 24.3.2007, p. 7.

COMMISSION REGULATION (EC) No 556/2009**of 25 June 2009****on the allocation of import rights for applications lodged for the period 1 July 2009 to 30 June 2010 under the tariff quota opened by Regulation (EC) No 431/2008 for frozen meat of bovine animals**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences ⁽²⁾, and in particular Article 7(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 431/2008 of 19 May 2008 opening and providing for the administration of an import tariff quota for frozen meat of bovine animals covered by CN code 0202 and products covered by

CN code 0206 29 91 ⁽³⁾ opens an import tariff quota for beef and veal products.

- (2) The applications for import rights lodged for the period 1 July 2009 to 30 June 2010 relate to quantities exceeding those available. The extent to which import rights may be allocated should therefore be determined and an allocation coefficient laid down to be applied to the quantities applied for,

HAS ADOPTED THIS REGULATION:

Article 1

The quantities for which import right applications covered by the quota with the serial number 09.4003 have been lodged for the period 1 July 2009 to 30 June 2010 under Regulation (EC) No 431/2008 shall be multiplied by an allocation coefficient of 29,943487 %.

Article 2

This Regulation shall enter into force on 26 June 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 238, 1.9.2006, p. 13.

⁽³⁾ OJ L 130, 20.5.2008, p. 3.

COMMISSION REGULATION (EC) No 557/2009**of 25 June 2009****on the allocation of import rights for applications lodged for the period 1 July 2009 to 30 June 2010 under tariff quotas opened by Regulation (EC) No 412/2008 for frozen beef intended for processing**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences ⁽²⁾ and in particular Article 7(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 412/2008 of 8 May 2008 opening and providing for the administration of an import tariff quota for frozen beef intended for processing ⁽³⁾ opened import tariff quotas for beef and veal products.

- (2) The applications for import rights lodged for the period 1 July 2009 to 30 June 2010 relate to quantities in excess of those available for rights under quota 09.4057. The extent to which import rights may be granted should therefore be determined and the allocation coefficient to be applied to the quantities requested should be laid down,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for import rights lodged for the period 1 July 2009 to 30 June 2010 under Regulation (EC) No 412/2008 shall be weighted by an allocation coefficient of 18,957513 % for rights under quota 09.4057.

Article 2

This Regulation shall enter into force on 26 June 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 238, 1.9.2006, p. 13.

⁽³⁾ OJ L 125, 9.5.2008, p. 7.

COMMISSION REGULATION (EC) No 558/2009**of 25 June 2009****amending the representative prices and additional import duties for certain products in the sugar sector fixed by Regulation (EC) No 945/2008 for the 2008/2009 marketing year**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 951/2006 of 30 June 2006 laying down detailed rules for the implementation of Council Regulation (EC) No 318/2006 as regards trade with third countries in the sugar sector ⁽²⁾, and in particular Article 36(2), second subparagraph, second sentence thereof,

Whereas:

- (1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups

for the 2008/2009 marketing year are fixed by Commission Regulation (EC) No 945/2008 ⁽³⁾. These prices and duties have been last amended by Commission Regulation (EC) No 514/2009 ⁽⁴⁾.

- (2) The data currently available to the Commission indicate that those amounts should be amended in accordance with the rules and procedures laid down in Regulation (EC) No 951/2006,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties applicable to imports of the products referred to in Article 36 of Regulation (EC) No 951/2006, as fixed by Regulation (EC) No 945/2008 for the 2008/2009, marketing year, are hereby amended as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 26 June 2009.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 178, 1.7.2006, p. 24.

⁽³⁾ OJ L 258, 26.9.2008, p. 56.

⁽⁴⁾ OJ L 155, 18.6.2009, p. 3.

ANNEX

Amended representative prices and additional import duties applicable to white sugar, raw sugar and products covered by CN code 1702 90 95 from 26 June 2009

(EUR)

CN code	Representative price per 100 kg net of the product concerned	Additional duty per 100 kg net of the product concerned
1701 11 10 ⁽¹⁾	30,00	2,29
1701 11 90 ⁽¹⁾	30,00	6,53
1701 12 10 ⁽¹⁾	30,00	2,15
1701 12 90 ⁽¹⁾	30,00	6,10
1701 91 00 ⁽²⁾	30,72	9,87
1701 99 10 ⁽²⁾	30,72	5,35
1701 99 90 ⁽²⁾	30,72	5,35
1702 90 95 ⁽³⁾	0,31	0,34

⁽¹⁾ For the standard quality defined in point III of Annex IV to Regulation (EC) No 1234/2007.⁽²⁾ For the standard quality defined in point II of Annex IV to Regulation (EC) No 1234/2007.⁽³⁾ Per 1 % sucrose content.

DIRECTIVES

DIRECTIVE 2009/49/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 June 2009

amending Council Directives 78/660/EEC and 83/349/EEC as regards certain disclosure requirements for medium-sized companies and the obligation to draw up consolidated accounts

(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 44(1) 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:

(3) The Commission's communication of 10 July 2007 on a simplified business environment for companies in the areas of company law, accounting and auditing identifies amendments that need to be made to Fourth Council Directive 78/660/EEC of 25 July 1978 on the annual accounts of certain types of companies ⁽³⁾ and Seventh Council Directive 83/349/EEC of 13 June 1983 on consolidated accounts ⁽⁴⁾. Special attention has been given to further relieving the reporting burden imposed on small and medium-sized companies.

(4) In the past, a number of changes have been made in order to enable companies falling within the scope of Directives 78/660/EEC and 83/349/EEC to use accounting methods in accordance with international financial reporting standards (IFRS). Pursuant to Regulation (EC) No 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards ⁽⁵⁾, companies the securities of which are admitted to trading on a regulated market of any Member State have to prepare their consolidated accounts in accordance with IFRS, and are consequently relieved from most of the requirements set out in Directives 78/660/EEC and 83/349/EEC. Those Directives, however, still form the basis for small and medium-sized companies' accounting in the Community.

(1) In its Presidency conclusions, the European Council of 8 and 9 March 2007 underlined that reducing administrative burdens is important for boosting the European economy, especially in view of the benefits that this could bring for small and medium-sized companies. It stressed that a strong joint effort on the part of both the European Union and the Member States is necessary in order to reduce administrative burdens.

(2) Accounting and auditing have been identified as areas in which the administrative burdens on companies within the Community can be reduced.

(5) Small and medium-sized companies are often subject to the same rules as larger companies, but their specific accounting needs have rarely been assessed. In particular, the increasing number of disclosure requirements raises concerns for such companies. Extensive reporting rules create a financial burden and can hinder efficient use of capital for productive purposes.

(6) The application of Regulation (EC) No 1606/2002 has also highlighted the need to clarify the relationship between the accounting standards required by Directive 83/349/EEC and IFRS.

⁽¹⁾ OJ C 77, 31.3.2009, p. 37.

⁽²⁾ Opinion of the European Parliament of 18 December 2008 (not yet published in the Official Journal) and Council Decision of 11 May 2009.

⁽³⁾ OJ L 222, 14.8.1978, p. 11.

⁽⁴⁾ OJ L 193, 18.7.1983, p. 1.

⁽⁵⁾ OJ L 243, 11.9.2002, p. 1.

- (7) Where formation expenses can be treated as an asset in the balance sheet, Article 34(2) of Directive 78/660/EEC requires that those expenses be explained in the notes to the accounts. Small companies can be exempted from that disclosure requirement in accordance with Article 44(2) of that Directive. In order to reduce unnecessary administrative burdens, it should also be possible to exempt medium-sized companies from that disclosure requirement.
- (8) Directive 83/349/EEC requires a parent undertaking to prepare consolidated accounts even if the only subsidiary or all of the subsidiaries as a whole are not material for the purposes of Article 16(3) of that Directive. As a consequence, those undertakings fall under Regulation (EC) No 1606/2002 and therefore have to prepare consolidated financial statements in accordance with IFRS. That requirement is considered to be burdensome where a parent undertaking has only immaterial subsidiaries. Therefore a parent undertaking should be exempted from the obligation to draw up consolidated accounts and a consolidated annual report if it has only subsidiary undertakings considered as not being material, both individually and as a whole. Although that statutory obligation should be lifted, a parent undertaking should remain able to draw up consolidated accounts and a consolidated annual report on its own initiative.
- (9) Since the objective of this Directive, namely to reduce administrative burdens relating to certain disclosure requirements imposed on medium-sized companies and the obligation to draw up consolidated accounts for certain companies within the Community, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale and effects of the action, 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 proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (10) Directives 78/660/EEC and 83/349/EEC should therefore be amended accordingly.
- (11) In accordance with point 34 of the Interinstitutional Agreement on better law-making ⁽¹⁾, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendment to Directive 78/660/EEC

In Article 45(2) of Directive 78/660/EEC, the first sentence of the second subparagraph is replaced by the following:

‘The Member States may permit the companies referred to in Article 27 to omit disclosure of the information specified in Articles 34(2) and 43(1)(8).’

Article 2

Amendment to Directive 83/349/EEC

In Article 13 of Directive 83/349/EEC the following paragraph is inserted:

‘2a. Without prejudice to Article 4(2) and Articles 5 and 6, any parent undertaking governed by the national law of a Member State which only has subsidiary undertakings which are not material for the purposes of Article 16(3), both individually and as a whole, shall be exempted from the obligation imposed in Article 1(1).’

Article 3

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 2011. They shall forthwith inform the Commission thereof.

When they are adopted by Member States, those measures shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ C 321, 31.12.2003, p. 1.

*Article 5***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 18 June 2009.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

Š. FÜLE

**DIRECTIVE 2009/54/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 18 June 2009**

on the exploitation and marketing of natural mineral waters

(Recast)

(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 procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters ⁽³⁾ has been substantially amended several times ⁽⁴⁾. Since further amendments are to be made, it should be recast in the interests of clarity.

(2) The laws of the Member States define natural mineral waters. Those laws lay down the terms on which natural mineral waters are recognised as such and govern the conditions for exploiting springs. They furthermore prescribe specific rules for marketing the waters in question.

(3) The differences between those laws hinder the free movement of natural mineral waters, creating disparate competitive situations, and consequently directly affect the functioning of the internal market.

(4) In this particular case, the elimination of these barriers may be achieved both by an obligation on each Member State to allow the marketing in its territory of the natural mineral waters recognised as such by each of the other Member States and by laying down common rules concerning in particular the microbiological requirements

to be fulfilled and the conditions in which specific names must be used for certain of the mineral waters.

(5) The primary purposes of any rules on natural mineral waters should be to protect the health of consumers, to prevent consumers from being misled and to ensure fair trading.

(6) Pending the conclusion of agreements on mutual recognition of natural mineral waters between the Community and third countries, the terms should be laid down on which, until implementation of those agreements, similar products imported from third countries may be allowed to enter the Community as natural mineral waters.

(7) Care should be taken to ensure that natural mineral waters retain at the marketing stage those characteristics which enabled them to be recognised as such. Therefore, the containers used for packaging them should have suitable closures.

(8) In respect of labelling, natural mineral waters are subject to the general rules laid down by Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽⁵⁾. Accordingly, this Directive may be limited to laying down the additions and derogations which should be made to those general rules.

(9) The inclusion of the statement of the analytical composition of a natural mineral water should be compulsory in order to ensure that consumers are informed.

(10) The measures necessary for the implementation of this Directive 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 ⁽⁶⁾.

⁽¹⁾ OJ C 162, 25.6.2008, p. 87.

⁽²⁾ Opinion of the European Parliament of 23 September 2008 (not yet published in the Official Journal) and Council Decision of 28 May 2009.

⁽³⁾ OJ L 229, 30.8.1980, p. 1.

⁽⁴⁾ See Annex IV, Part A.

⁽⁵⁾ OJ L 109, 6.5.2000, p. 29.

⁽⁶⁾ OJ L 184, 17.7.1999, p. 23.

- (11) In particular, the Commission should be empowered to adopt limits for the concentrations of constituents of natural mineral waters, any necessary provisions for the indication on the labelling of high levels of certain constituents, the conditions of use of ozone-enriched air for the treatment of natural mineral water, information on the treatments of natural mineral water, methods of analysis to determine the absence of pollution of natural mineral waters, and the sampling procedures and methods of analysis necessary for checking the microbiological characteristics of natural mineral waters. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (12) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to apply the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the adoption of amendments to this Directive necessary in order to ensure the protection of public health.
- (13) The new elements introduced into this Directive only concern the committee procedures. They therefore do not need to be transposed by the Member States.
- (14) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns waters extracted from the ground of a Member State and recognised by the responsible authority of that Member State as natural mineral waters satisfying the provisions of Annex I, Section I.
2. This Directive also concerns waters extracted from the ground of a third country, imported into the Community and recognised as natural mineral waters by the responsible authority of a Member State.

The waters referred to in the first subparagraph may be so recognised only if the responsible authority in the country of extraction has certified that they satisfy the provisions of Annex I, Section I, and that regular checks are made on the application of the provisions of Annex II, point 2.

The validity of the certification referred to in the second subparagraph may not exceed a period of five years. It shall not be necessary to repeat the recognition procedure referred to in the first subparagraph if the certification is renewed before the end of that period.

3. This Directive shall not apply to:

- (a) waters which are medicinal products within the meaning of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾;
- (b) natural mineral waters used at source for curative purposes in thermal or hydromineral establishments.

4. The grounds for granting the recognition referred to in paragraphs 1 and 2 shall be stated in due form by the responsible authority of the Member State and shall be officially published.

5. Each Member State shall inform the Commission of the cases where the recognition referred to in paragraphs 1 and 2 has been granted or withdrawn. The list of natural mineral waters so recognised shall be published in the *Official Journal of the European Union*.

Article 2

Member States shall take the measures necessary to ensure that only the waters referred to in Article 1 which comply with the provisions of this Directive may be marketed as natural mineral waters.

Article 3

Natural mineral water springs may be exploited and their waters bottled only in accordance with Annex II.

Article 4

1. Natural mineral water, in its state at source, may not be the subject of any treatment other than:

- (a) the separation of its unstable elements, such as iron and sulphur compounds, by filtration or decanting, possibly preceded by oxygenation, in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties;

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

(b) the separation of iron, manganese and sulphur compounds and arsenic from certain natural mineral waters by treatment with ozone-enriched air in so far as such treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that:

(i) the treatment complies with the conditions for use to be laid down by the Commission following consultation of the European Food Safety Authority, established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽¹⁾;

(ii) the treatment is notified to, and specifically controlled by, the competent authorities;

(c) the separation of undesirable constituents other than those specified in points (a) or (b), in so far as this treatment does not alter the composition of the water as regards the essential constituents which give it its properties, and provided that:

(i) the treatment complies with the conditions for use to be laid down by the Commission following consultation of the European Food Safety Authority;

(ii) the treatment is notified to, and specifically controlled by, the competent authorities;

(d) the total or partial elimination of free carbon dioxide by exclusively physical methods.

The measures referred to in points (b)(i) and (c)(i), designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).

The first subparagraph shall not constitute a bar to the utilisation of natural mineral waters and spring waters in the manufacture of soft drinks.

2. Natural mineral water, in its state at source, may not be the subject of any addition other than the introduction or the reintroduction of carbon dioxide under the conditions laid down in Annex I, Section III.

3. Any disinfection treatment by whatever means and, subject to paragraph 2, the addition of bacteriostatic elements or any other treatment likely to change the viable colony count of the natural mineral water, shall be prohibited.

Article 5

1. The revivable total colony count of a natural mineral water at source shall conform to its normal viable colony count and give satisfactory evidence of the protection of the source against all contamination. This total colony count shall be determined under the conditions laid down in Annex I, Section II, point 1.3.3.

After bottling, the total colony count at source may not exceed 100 per millilitre at 20 to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture and 20 per millilitre at 37 °C in 24 hours on agar-agar. The total colony count shall be measured within the 12 hours following bottling, the water being maintained at 4 °C ± 1 °C during this 12-hour period.

At source, those values must not normally exceed 20 per millilitre at 20 to 22 °C in 72 hours and 5 per millilitre at 37 °C in 24 hours respectively, on the understanding that they shall be considered as guide figures and not as maximum permitted concentrations.

2. At source and during its marketing, a natural mineral water shall be free from:

(a) parasites and pathogenic micro-organisms;

(b) *Escherichia coli* and other coliforms and faecal streptococci in any 250 ml sample examined;

(c) sporulated sulphite-reducing anaerobes in any 50 ml sample examined;

(d) *Pseudomonas aeruginosa* in any 250 ml sample examined.

3. Without prejudice to paragraphs 1 and 2 and the conditions of exploitation laid down in Annex II, at the marketing stage:

(a) the revivable total colony count of a natural mineral water may only be that resulting from the normal increase in the bacterial count which it had at source;

(b) the natural mineral water may not contain any organoleptic defects.

Article 6

Any containers used for packaging natural mineral waters shall be fitted with closures designed to avoid any possibility of adulteration or contamination.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

Article 7

1. The sales description of natural mineral waters shall be 'natural mineral water' or, in the case of an effervescent natural mineral water as defined in Annex I, Section III, as appropriate, 'naturally carbonated natural mineral water', 'natural mineral water fortified with gas from the spring' or 'carbonated natural mineral water'.

The sales description of natural mineral waters which have undergone any of the treatments referred to in point (d) of the first subparagraph of Article 4(1) shall have added to it, as appropriate, the indication 'fully de-carbonated' or 'partially de-carbonated'.

2. Labels on natural mineral waters shall also give the following mandatory information:

- (a) a statement of the analytical composition, giving its characteristic constituents;
- (b) the place where the spring is exploited and the name of the spring;
- (c) information on any treatments referred to in points (b) and (c) of the first subparagraph of Article 4(1).

3. In the absence of Community provisions on information on any treatments referred to in paragraph 2(c), Member States may maintain their national provisions.

Article 8

1. The name of a locality, hamlet or place may occur in the wording of a trade description provided that it refers to a natural mineral water the spring of which is exploited at the place indicated by that description and provided that it is not misleading as regards the place of exploitation of the spring.

2. It shall be prohibited to market natural mineral water from one and the same spring under more than one trade description.

3. When the labels or inscriptions on the containers in which the natural mineral waters are offered for sale include a trade description different from the name of the spring or the place of its exploitation, that place of exploitation or the name of the spring shall be indicated in letters at least one and a half times the height and width of the largest of the letters used for that trade description.

The first subparagraph shall apply, *mutatis mutandis* and with the same intention as regards the importance attributed to the name

of the spring or the place of its exploitation, with regard to the trade description used in advertising, in whatsoever form, relating to natural mineral waters.

Article 9

1. It shall be prohibited, both on packaging or labels and in advertising in any form whatsoever, to use indications, designations, trade marks, brand names, pictures or other signs, whether figurative or not, which:

- (a) in the case of a natural mineral water, suggest a characteristic which the water does not possess, in particular as regards its origin, the date of the authorisation to exploit it, the results of analyses or any similar references to guarantees of authenticity;
- (b) in the case of drinking water packaged in containers, which does not satisfy the provisions of Annex I, Section I, are liable to cause confusion with a natural mineral water, in particular the description 'mineral water'.

2. All indications attributing to a natural mineral water properties relating to the prevention, treatment or cure of a human illness shall be prohibited.

However, the indications listed in Annex III shall be authorised if they meet the relevant criteria laid down in that Annex or, in the absence thereof, criteria laid down in national provisions and provided that they have been drawn up on the basis of physico-chemical analyses and, where necessary, pharmacological, physiological and clinical examinations carried out according to recognised scientific methods, in accordance with Annex I, Section I, point 2.

Member States may authorise the indications 'stimulates digestion', 'may facilitate the hepato-biliary functions' or similar indications. They may also authorise the inclusion of other indications, provided that the latter do not conflict with the principles provided for in the first subparagraph and are compatible with those provided for in the second subparagraph.

3. Member States may adopt special provisions regarding indications — both on packaging or labels and in advertising — concerning the suitability of a natural mineral water for the feeding of infants. Such provisions may also concern the properties of the water which determine the use of those indications.

Member States which intend taking such measures shall inform the other Member States and the Commission of them beforehand.

4. The term 'spring water' shall be reserved for a water which is intended for human consumption in its natural state, and bottled at source, which:

- (a) satisfies the conditions of exploitation laid down in Annex II, points 2 and 3, which shall be fully applicable to spring waters;
- (b) satisfies the microbiological requirements laid down in Article 5;
- (c) satisfies the labelling requirements of Article 7(2), points (b) and (c), and Article 8;
- (d) has not undergone any treatment other than those referred to in Article 4. Other treatments may be authorised by the Commission.

The measures referred to in point (d), designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).

In addition, spring waters shall comply with the provisions of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption ⁽¹⁾.

5. In the absence of Community provisions on the treatment for spring waters referred to in point (d) of the first subparagraph of paragraph 4, Member States may maintain their national provisions on the treatments.

Article 10

Member States shall adopt the measures necessary to ensure that trade in natural mineral waters which comply with the definitions and rules laid down in this Directive cannot be impeded by the application of non-harmonised national provisions governing the properties, composition, conditions of exploitation, packaging, labelling or advertising of natural mineral waters or foodstuffs in general.

Article 11

1. Where a Member State has detailed grounds for considering that a natural mineral water does not comply with the provisions laid down in this Directive, or endangers public health, albeit freely circulating in one or more Member States, that Member State may temporarily restrict or suspend

trade in that product within its territory. It shall immediately inform the Commission and the other Member States thereof and give reasons for its decision.

2. At the request of any Member State or the Commission, the Member State which has recognised that water shall provide all relevant information concerning recognition of that water, together with the results of the regular checks.

3. The Commission shall examine as soon as possible the grounds adduced by the Member State referred to in paragraph 1 within the Standing Committee referred to in Article 14(1), and shall deliver its opinion forthwith and take appropriate measures.

4. If the Commission considers that amendments to this Directive are necessary in order to ensure the protection of public health, it shall adopt those amendments.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2). On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 14(3).

The Member State which has adopted safeguard measures may, in that event, retain them until the amendments have been adopted.

Article 12

The following measures shall be adopted by the Commission:

- (a) limits for the concentrations of constituents of natural mineral waters;
- (b) any necessary provisions for the indication on the labelling of high levels of certain constituents;
- (c) the conditions of use of ozone-enriched air referred to in point (b) of the first subparagraph of Article 4(1);
- (d) the information on the treatments referred to in Article 7(2)(c);
- (e) methods of analysis, including limits of detection, to verify the absence of pollution of natural mineral waters;

⁽¹⁾ OJ L 330, 5.12.1998, p. 32.

- (f) the sampling procedures and the methods of analysis necessary for checking the microbiological characteristics of natural mineral waters.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(2).

Article 13

Any decision likely to have an effect on public health shall be adopted by the Commission following consultation of the European Food Safety Authority.

Article 14

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 15

This Directive shall not apply to natural mineral waters intended for export to third countries.

Article 16

Directive 80/777/EEC, as amended by the acts listed in Annex IV, Part A, is hereby repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex IV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex V.

Article 17

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 18

This Directive is addressed to the Member States.

Done at Brussels, 18 June 2009.

For the European Parliament

The President

H.-G. PÖTTERING

For the Council

The President

Š. FÜLE

ANNEX I

I. DEFINITION

1. 'Natural mineral water' means microbiologically wholesome water, within the meaning of Article 5, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits.

Natural mineral water can be clearly distinguished from ordinary drinking water:

(a) by its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects;

(b) by its original purity,

both characteristics having been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution.

2. The characteristics referred to in point 1, which may give natural mineral water properties favourable to health, shall have been assessed:

(a) from the following points of view:

(i) geological and hydrological;

(ii) physical, chemical and physico-chemical;

(iii) microbiological;

(iv) if necessary, pharmacological, physiological and clinical;

(b) according to the criteria listed in Section II;

(c) according to scientific methods approved by the responsible authority.

The analyses referred to in point (a)(iv) of the first subparagraph may be optional where the water presents the compositional characteristics on the strength of which it was considered a natural mineral water in the Member State of origin prior to 17 July 1980. This is the case in particular when the water in question contains, per kg, both at source and after bottling, a minimum of 1 000 mg of total solids in solution or a minimum of 250 mg of free carbon dioxide.

3. The composition, temperature and other essential characteristics of natural mineral water shall remain stable within the limits of natural fluctuation; in particular, they shall not be affected by possible variations in the rate of flow.

Within the meaning of Article 5(1), the normal viable colony count of natural mineral water means the reasonably constant total colony count at source before any treatment, the qualitative and quantitative composition of which, as taken into account in the recognition of that water, is checked by periodic analysis.

II. REQUIREMENTS AND CRITERIA FOR APPLYING THE DEFINITION**1.1. Requirements for geological and hydrological surveys**

There shall be a requirement to supply the following particulars:

- 1.1.1. the exact site of the catchment with indication of its altitude, on a map with a scale of not more than 1:1 000;
- 1.1.2. a detailed geological report on the origin and nature of the terrain;
- 1.1.3. the stratigraphy of the hydrogeological layer;

1.1.4. a description of the catchment operations;

1.1.5. the demarcation of the area or details of other measures protecting the spring against pollution.

1.2. Requirements for physical, chemical and physico-chemical surveys

These surveys shall establish:

1.2.1. the rate of flow of the spring;

1.2.2. the temperature of the water at source and the ambient temperature;

1.2.3. the relationship between the nature of the terrain and the nature and type of minerals in the water;

1.2.4. the dry residues at 180 °C and 260 °C;

1.2.5. the electrical conductivity or resistivity, with the measurement temperature having to be specified;

1.2.6. the hydrogen ion concentration (pH);

1.2.7. the anions and cations;

1.2.8. the non-ionised elements;

1.2.9. the trace elements;

1.2.10. the radio-actinological properties at source;

1.2.11. where appropriate, the relative isotope levels of the constituent elements of water, oxygen (^{16}O — ^{18}O) and hydrogen (protium, deuterium, tritium);

1.2.12. the toxicity of certain constituent elements of the water, taking account of the limits laid down for each of them.

1.3. Criteria for microbiological analyses at source

These analyses shall include:

1.3.1. a demonstration of the absence of parasites and pathogenic micro-organisms;

1.3.2. a quantitative determination of the revivable colony count indicative of faecal contamination:

(a) absence of *Escherichia coli* and other coliforms in 250 ml at 37 °C and 44,5 °C;

(b) absence of faecal streptococci in 250 ml;

(c) absence of sporulated sulphite-reducing anaerobes in 50 ml;

(d) absence of *Pseudomonas aeruginosa* in 250 ml;

1.3.3. determination of the revivable total colony count per ml of water:

(a) at 20 to 22 °C in 72 hours on agar-agar or an agar-gelatine mixture;

(b) at 37 °C in 24 hours on agar-agar.

1.4. Requirements for clinical and pharmacological analyses

- 1.4.1. The analyses, which shall be carried out in accordance with scientifically recognised methods, shall be suited to the particular characteristics of the natural mineral water and its effects on the human organism, such as diuresis, gastric and intestinal functions, compensation for mineral deficiencies.
- 1.4.2. The establishment of the consistency and concordance of a substantial number of clinical observations may, if appropriate, take the place of the analyses referred to in point 1.4.1. Clinical analyses may, in appropriate cases, take the place of the analyses referred to in point 1.4.1 provided that the consistency and concordance of a substantial number of observations enable the same results to be obtained.

III. SUPPLEMENTARY QUALIFICATIONS RELATING TO EFFERVESCENT NATURAL MINERAL WATERS

At source or after bottling, effervescent natural mineral waters give off carbon dioxide spontaneously and in a clearly visible manner under normal conditions of temperature and pressure. They fall into three categories to which the following reserved designations respectively shall apply:

- (a) 'naturally carbonated natural mineral water' means water the carbon dioxide content of which from the spring after decanting, if any, and bottling is the same as at source, taking into account where appropriate the reintroduction of a quantity of carbon dioxide from the same water table or deposit equivalent to that released in the course of those operations and subject to the usual technical tolerances;
- (b) 'natural mineral water fortified with gas from the spring' means water the carbon dioxide content of which from the same water table or the same deposit after decanting, if any, and bottling is greater than that established at source;
- (c) 'carbonated natural mineral water' means water to which has been added carbon dioxide of an origin other than the water table or deposit from which the water comes.
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ANNEX II

CONDITIONS FOR EXPLOITATION AND MARKETING OF NATURAL MINERAL WATER

1. Exploitation of a natural mineral water spring shall be subject to permission from the responsible authority of the country where the water has been extracted, after it has been established that the water in question complies with the provisions laid down in Annex I, Section I.
2. Equipment for exploiting the water shall be so installed as to avoid any possibility of contamination and to preserve the properties, corresponding to those ascribed to it, which the water possesses at source.

To that end, in particular:

- (a) the spring or outlet shall be protected against the risks of pollution;
- (b) the catchment, pipes and reservoirs shall be of materials suitable for water and so built as to prevent any chemical, physico-chemical or microbiological alteration of the water;
- (c) the conditions of exploitation, particularly the washing and bottling equipment, shall meet hygiene requirements; in particular, the containers shall be so treated or manufactured as to avoid adverse effects on the microbiological and chemical characteristics of the natural mineral water;
- (d) the transport of natural mineral water in containers other than those authorised for distribution to the ultimate consumer shall be prohibited.

However, point (d) need not be applied to mineral waters extracted, exploited and marketed in the territory of a Member State if, in that Member State on 17 July 1980, transport of the natural mineral water in tanks from the spring to the bottling plant was authorised.

Similarly, point (d) need not be applied to spring waters extracted, exploited and marketed in the territory of a Member State if, in that Member State on 13 December 1996, transport of the spring water in tanks from the spring to the bottling plant was authorised.

3. Where it is found during exploitation that the natural mineral water is polluted and no longer presents the microbiological characteristics laid down in Article 5, the person exploiting the spring shall forthwith suspend all exploitation, particularly the bottling process, until the cause of pollution is eradicated and the water complies with the provisions of Article 5.
4. The responsible authority in the country of origin shall carry out periodic checks to see whether:
 - (a) the natural mineral water in respect of which exploitation of the spring has been authorised complies with the provisions of Annex I, Section I;
 - (b) the provisions of points 2 and 3 are being applied by the person exploiting the spring.

ANNEX III

INDICATIONS AND CRITERIA LAID DOWN IN ARTICLE 9(2)

Indications	Criteria
Low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 500 mg/l
Very low mineral content	Mineral salt content, calculated as a fixed residue, not greater than 50 mg/l
Rich in mineral salts	Mineral salt content, calculated as a fixed residue, greater than 1 500 mg/l
Contains bicarbonate	Bicarbonate content greater than 600 mg/l
Contains sulphate	Sulphate content greater than 200 mg/l
Contains chloride	Chloride content greater than 200 mg/l
Contains calcium	Calcium content greater than 150 mg/l
Contains magnesium	Magnesium content greater than 50 mg/l
Contains fluoride	Fluoride content greater than 1 mg/l
Contains iron	Bivalent iron content greater than 1 mg/l
Acidic	Free carbon dioxide content greater than 250 mg/l
Contains sodium	Sodium content greater than 200 mg/l
Suitable for the preparation of infant food	—
Suitable for a low-sodium diet	Sodium content less than 20 mg/l
May be laxative	—
May be diuretic	—

ANNEX IV

PART A

Repealed Directive with list of its successive amendments

(referred to in Article 16)

Council Directive 80/777/EEC
(OJ L 229, 30.8.1980, p. 1)

Council Directive 80/1276/EEC
(OJ L 375, 31.12.1980, p. 77).

Article 1, third indent only

Council Directive 85/7/EEC
(OJ L 2, 3.1.1985, p. 22).

Article 1, point 10 only

Point B.1.(o) of Annex I to the 1985 Act of Accession
(OJ L 302, 15.11.1985, p. 214).

Directive 96/70/EC of the European Parliament and of the Council
(OJ L 299, 23.11.1996, p. 26).

Regulation (EC) No 1882/2003 of the European Parliament
and of the Council
(OJ L 284, 31.10.2003, p. 1).

Annex III, point 4 only

PART B

Time-limits for transposition into national law

(referred to in Article 16)

Directive	Time-limit for transposition	Permission of trade in products complying with this Directive	Prohibition of trade in products not complying with this Directive
80/777/EEC	—	18 July 1982	18 July 1984
80/1276/EEC	—	—	—
85/7/EEC	—	—	—
96/70/EC	—	28 October 1997	28 October 1998 ⁽¹⁾

⁽¹⁾ However, trade in products placed on the market or labelled before the date and not conforming with this Directive may continue until stocks run out.

ANNEX V

CORRELATION TABLE

Directive 80/777/EEC	This Directive
Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)
Article 1(3), first and second indents	Article 1(3), points (a) and (b)
Article 1(4)	Article 1(4)
Article 1(5)	Article 1(5)
Article 2	Article 2
Article 3	Article 3
Article 4(1), point (a)	Article 4(1), first subparagraph, point (a)
Article 4(1), point (b), first and second indents	Article 4(1), first subparagraph, points (b)(i) and (ii)
Article 4(1), point (c), first and second indents	Article 4(1), first subparagraph, points (c)(i) and (ii)
Article 4(1), point (d)	Article 4(1), first subparagraph, point (d)
—	Article 4(1), second subparagraph
Article 4(2)	Article 4(2)
Article 4(3)	Article 4(3)
Article 4(4)	Article 4(1), third subparagraph
Article 5(1)	Article 5(1)
Article 5(2)	Article 5(2)
Article 5(3), first and second indents	Article 5(3), points (a) and (b)
Article 6	Article 6
Article 7(1)	Article 7(1)
Article 7(2)	Article 7(2)
Article 7(2a)	Article 7(3)
Article 8	Article 8
Article 9(1)	Article 9(1)
Article 9(2), points (a), (b) and (c)	Article 9(2), first, second and third subparagraphs
Article 9(3)	Article 9(3)
Article 9(4)	—
Article 9(4a), first subparagraph, first to fourth indents	Article 9(4), first subparagraph, points (a) to (d)
Article 9(4a), second subparagraph	Article 9(4), second subparagraph
Article 9(4b)	Article 9(5)
Article 10(1)	Article 10

Directive 80/777/EEC	This Directive
Article 10a	Article 11
Article 11(1), first to fourth indents	Article 12, points (a) to (d)
Article 11(2), first and second indents	Article 12, points (e) and (f)
Article 11a	Article 13
Article 12(1)	Article 14(1)
Article 12(2)	Article 14(2) and (3)
Article 12(3)	—
Article 13	—
Article 14	Article 15
Article 15	—
Article 16	—
—	Article 16
—	Article 17
Article 17	Article 18
Annex I, part I, point 1	Annex I, part I, point 1
Annex I, part I, point 2, first paragraph, points (a)(1) to (4)	Annex I, part I, point 2, first paragraph, points (a)(i) to (iv)
Annex I, part I, point 2, first paragraph, point (b)	Annex I, part I, point 2, first paragraph, point (b)
Annex I, part I, point 2, first paragraph, point (c)	Annex I, part I, point 2, first paragraph, point (c)
Annex I, part I, point 2, second paragraph	Annex I, part I, point 2, second paragraph
Annex I, part I, point 3	Annex I, part I, point 3
Annex I, part II, point 1.1	Annex I, part II, point 1.1
Annex I, part II, point 1.2	Annex I, part II, point 1.2
Annex I, part II, point 1.3	Annex I, part II, point 1.3
Annex I, part II, point 1.3.1	Annex I, part II, point 1.3.1
Annex I, part II, point 1.3.2	Annex I, part II, point 1.3.2
Annex I, part II, point 1.3.3, points (i) and (ii)	Annex I, part II, point 1.3.3, points (a) and (b)
Annex I, part II, point 1.4	Annex I, part II, point 1.4
Annex I, part III	Annex I, part III
Annex II	Annex II
Annex III	Annex III
—	Annex IV
—	Annex V

COMMISSION DIRECTIVE 2009/70/EC**of 25 June 2009****amending Council Directive 91/414/EEC to include difenacoum, didecyldimethylammonium chloride and sulphur as active substances****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 1112/2002 ⁽²⁾ and (EC) No 2229/2004 ⁽³⁾ lay down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list includes difenacoum, didecyldimethylammonium chloride and sulphur.

(2) For those active substances the effects on human health and the environment have been assessed in accordance with the provisions laid down in Regulations (EC) No 1112/2002 and (EC) No 2229/2004 for a range of uses proposed by the notifiers. Moreover, those Regulations designate the rapporteur Member States which have to submit the relevant assessment reports and recommendations to the European Food Safety Authority (EFSA) in accordance with Article 22 of Regulation (EC) No 2229/2004. For difenacoum the rapporteur Member State was Finland and all relevant information was submitted on 16 July 2007. For didecyldimethylammonium chloride the rapporteur Member State was the Netherlands and all relevant information was submitted on 28 November 2007. For sulphur the rapporteur Member State was France and all relevant information was submitted on 18 October 2007.

(3) The assessment reports have been peer reviewed by the Member States and the EFSA and presented to the

Commission on 19 December 2008 in the format of the EFSA Scientific Report for difenacoum ⁽⁴⁾, for didecyldimethylammonium chloride ⁽⁵⁾ and for sulphur ⁽⁶⁾. These reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 26 February 2009 in the format of the Commission review reports for difenacoum, and on 12 March 2009 for didecyldimethylammonium chloride and sulphur.

(4) It has appeared from the various examinations made that plant protection products containing difenacoum, didecyldimethylammonium chloride and sulphur may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review reports. It is therefore appropriate to include these active substances in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substances can be granted in accordance with the provisions of that Directive.

(5) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EEC provides that inclusion of a substance in Annex I may be subject to conditions. Therefore, for difenacoum, it is appropriate to require that the notifier submit further information on methods for the determination of residues in body fluids and on the specification of the active substance as manufactured. Moreover, for didecyldimethylammonium chloride it is appropriate to require that the notifier submit further information on the chemical specification and on the risk assessment for aquatic organisms. Finally, it is appropriate for the sulphur to require that the notifier submit further information to confirm the risk assessment for non-target organisms, in particular birds, mammals, sediment-dwelling organisms and non-target arthropods.

⁽⁴⁾ EFSA Scientific Report (2008) 218, Conclusion regarding the peer review of the pesticide risk assessment of the active substance difenacoum (finalised 19 December 2008).

⁽⁵⁾ EFSA Scientific Report (2008) 214, Conclusion regarding the peer review of the pesticide risk assessment of the active substance didecyldimethylammonium chloride (finalised 19 December 2008).

⁽⁶⁾ EFSA Scientific Report (2008) 221, Conclusion regarding the peer review of the pesticide risk assessment of the active substance sulfur (finalised 19 December 2008).

⁽¹⁾ OJ L 230, 19.8.1991, p. 1.

⁽²⁾ OJ L 168, 27.6.2002, p. 14.

⁽³⁾ OJ L 379, 24.12.2004, p. 13.

- (6) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.
- (7) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of six months after inclusion to review existing authorisations of plant protection products containing difenacoum, didcyldimethylammonium chloride and sulphur to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.
- (8) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Regulation (EEC) No 3600/92 has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.
- (9) It is therefore appropriate to amend Directive 91/414/EEC accordingly.
- (10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 30 June 2010 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 July 2010.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing difenacoum, didcyldimethylammonium chloride and sulphur as active substances by 30 June 2010.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to difenacoum, didcyldimethylammonium chloride and sulphur are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holders of the authorisations have, or have access to, dossiers satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing difenacoum, didcyldimethylammonium chloride and sulphur as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 31 December 2009 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning difenacoum, didcyldimethylammonium chloride and sulphur. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

- (a) in the case of a product containing difenacoum, didcyldimethylammonium chloride and sulphur as the only active substance, where necessary, amend or withdraw the authorisation by 30 June 2014 at the latest; or

(b) in the case of a product containing difenacoum, didecyldimethylammonium chloride and sulphur as one of several active substances, where necessary, amend or withdraw the authorisation by 30 June 2014 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 4

This Directive shall enter into force on 1 January 2010.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 25 June 2009.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common name, identification numbers	IUPAC name	Purity (%)	Entry into force	Expiration of inclusion	Specific provisions
295	Difenacoum CAS No 56073-07-5 CIPAC No 514	3-[(1RS,3RS;1RS,3SR)-3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	≥ 905 g/kg	1 January 2010	30 December 2019	<p>PART A</p> <p>Only uses as rodenticide in the form of pre-prepared baits placed in specially constructed, tamper resistant and secured bait boxes are authorised.</p> <p>The nominal concentration of the active substance in the products shall not exceed 50 mg/kg.</p> <p>Authorisations shall be limited to professional users.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on difenacoum, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 February 2009 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of birds and non-target mammals from primary and secondary poisoning. Risk mitigation measures shall be applied where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on methods for the determination of residues of difenacoum in body fluids.</p> <p>They shall ensure that the notifier provides such information to the Commission by 30 November 2011.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on the specification of the active substance as manufactured.</p> <p>They shall ensure that the notifier provides such information to the Commission by 31 December 2009.</p>
296	Didecyldimethylammonium chloride CAS: not allocated CIPAC: not allocated	Didecyldimethylammonium chloride is a mixture of alkyl-quaternary ammonium salts with typical alkyl chain lengths of C8, C10 and C12, with more than 90 % of C10	≥ 70 % (Technical concentrate)	1 January 2010	31 December 2019	<p>PART A</p> <p>Only indoor uses for ornamental plants as bactericide, fungicide, herbicide and algaecide may be authorised.</p>

No	Common name, identification numbers	IUPAC name	Purity ⁽¹⁾	Entry into force	Expiration of inclusion	Specific provisions
						<p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on didecyldimethylammonium chloride, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2009 shall be taken into account.</p> <p>In this overall assessment Member States must pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of the operator and worker safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure, — the protection of aquatic organisms. <p>Conditions of authorisation shall include risk mitigation measures, where appropriate.</p> <p>The Member States concerned shall ensure that the notifier submits to the Commission further information on the specification of the active substance as manufactured by 1 January 2010 and on the risk to aquatic organisms by 31 December 2011.</p>
297	sulphur CAS No 7704-34-9 CIPAC No 18	sulphur	≥ 990 g/kg	1 January 2010	31 December 2019	<p>PART A</p> <p>Only uses as fungicide and acaricide may be authorised.</p> <p>PART B</p> <p>For the implementation of the uniform principles of Annex VI, the conclusions of the review report on sulphur, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 12 March 2009 shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the protection of birds, mammals, aquatic organisms and non-target arthropods. Conditions of authorisation shall include risk mitigation measures, where appropriate. <p>The Member States concerned shall ensure that the notifier submit to the Commission further information to confirm the risk assessment for birds, mammals, sediment dwelling organisms and non-target arthropods. They shall ensure that the notifier at whose request sulphur has been included in this Annex provide such data to the Commission at latest by 30 June 2011.'</p>

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 22 June 2009

on a Community financial contribution towards Trust Fund 911100MTF/INT/003/EEC (TFEU 970089129) to assist the campaign against foot-and-mouth disease outside the Community

(2009/492/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾, and in particular Article 13 thereof,

Whereas:

- (1) Decision 90/424/EEC lays down the procedure governing the Community's financial contribution towards specific veterinary measures. Those measures are to include the campaign against foot-and-mouth disease. That Decision provides that any measure decided by the Community to assist the campaign against foot-and-mouth disease outside the Community, in particular with the view to protect areas at risk within the Community, may receive a Community financial contribution.
- (2) In the context of major epidemics of foot-and-mouth disease (FMD) in the late 1950s both within the Community and in neighbouring countries, the European Commission for the Control of Foot-and-Mouth Disease (EUFMD) was founded within the framework of the Food and Agriculture Organisation (FAO) of the United Nations.
- (3) In the 1960s, due to increased threats from the introduction of exotic strains of FMD into Europe, the Member Countries of the EUFMD were called to establish a Trust Fund aimed at emergency measures to

be carried out in the Balkans, the main entrance route of the disease. That fund was later divided into Trust Fund 911100MTF/003/EEC supported by those Member Countries that were at the same time Member States of the Community and Trust Fund 909700MTF/004/MUL supported by member countries of EUFMD which at that time were not or are still not Member States of the Community.

- (4) Article 4 of Council Directive 90/423/EEC ⁽²⁾ provided for the cessation of prophylactic vaccination against FMD throughout the Community in 1991.
- (5) Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease ⁽³⁾ reconfirmed the prohibition of prophylactic vaccination while extending the possibility for the use of emergency vaccination against FMD.
- (6) A number of outbreaks of FMD reported since 1992, in particular in parts of the Community adjacent to endemically infected third countries, and a major epidemic in certain Member States in 2001 necessitate a high level of disease awareness and preparedness, including international cooperation.
- (7) In addition, outbreaks and, in some cases, severe epidemics have been recorded in third countries neighbouring the Member States during recent years which are liable to threaten the health status of Community susceptible livestock.

⁽¹⁾ OJ L 224, 18.8.1990, p. 19.

⁽²⁾ OJ L 224, 18.8.1990, p. 13.

⁽³⁾ OJ L 306, 22.11.2003, p. 1.

- (8) In the light of the emergence of new virus topotypes and regional deterioration of control measures, the Community, in close cooperation with the EUFMD and by using the Trust Fund 911100MTF/003/EEC, supported emergency vaccination campaigns in Turkey and in Transcaucasia.
- (9) The Community and the United Nations signed on 29 April 2003 a Financial and Administrative Framework Agreement, which provided the enabling environment for the Agreement between the Commission of the European Communities and the Food and Agriculture Organisation of the United Nations, signed on 17 July 2003.
- (10) In accordance with Commission Decision 2005/436/EC of 13 June 2005 on Community cooperation with the Food and Agriculture Organisation with particular regard to activities carried out by the European Commission for the Control of Foot-and-Mouth Disease⁽¹⁾ the Commission concluded the 'Implementing Agreement MTF/INT/003/EEC911100 (TFEU970089129) on EC Funded Permanent Activities carried out by the FAO European Commission for the Control of Foot-and-Mouth Disease' which was signed on 1 September 2005 and operated from 1 January 2005 until 31 December 2008.
- (11) It is appropriate to renew that Implementing Agreement and fix the Community contribution to the Trust Fund 911100MTF/INT/003/EEC.
- (12) In view of the successive enlargements of the European Union of 2004 and 2007, it is appropriate that that Community contribution be fixed at a maximum level of EUR 8 000 000 for a period of four years. The budget of the Trust Fund for 2009 should be made up of the final balance of its funds on 31 December 2008 and a Community contribution to bring the amount to an equivalent in USD of EUR 2 000 000. Subsequently expenditure should be replenished by annual transfers.
- (13) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS DECIDED AS FOLLOWS:

Article 1

1. The balance of Trust Fund 911100MTF/INT/003/EEC (TFEU 970089129) (the Trust Fund) as at 31 December 2008 shall be fixed at EUR 677 855.
2. The financial contribution from the Community to the Trust Fund shall be set at a maximum of EUR 8 000 000 for a period of four years from 1 January 2009.
3. The first instalment of the amount referred to in paragraph 2 for the year 2009 shall be made up of:
 - (a) the balance referred to in paragraph 1;
 - (b) a Community contribution of the amount necessary to bring the total amount of the Trust Fund to an equivalent in USD of EUR 2 000 000.
4. Expenditure incurred by the Trust Fund during the years 2009, 2010, 2011 and 2012 shall be replenished by annual Community contributions payable in 2010, 2011, 2012 and 2013 respectively. However, the payment of those contributions shall be subject to the existence of available funds in the Community budget.
5. The annual Community contributions provided for in paragraph 4 shall be based on the financial report produced by the European Commission for the Control of Foot-and-Mouth Disease (EUFMD) to either the annual Session of the Executive Committee or the biennial General Session of EUFMD, supported by detailed documentation in accordance with the rules of the Food and Agriculture Organisation (FAO).

Article 2

1. An Implementing Agreement on the use and operation of the Trust Fund shall be concluded between the Commission and FAO for the period of four years, starting on 1 January 2009.
2. The Trust Fund shall be operated jointly by the Commission and the EUFMD in accordance with the Implementing Agreement referred to in paragraph 1.

Done at Brussels, 22 June 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

⁽¹⁾ OJ L 151, 14.6.2005, p. 26.

II *Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory*

DECISIONS

Commission

2009/492/EC:

★ Commission Decision of 22 June 2009 on a Community financial contribution towards Trust Fund 911100MTF/INT/003/EEC (TFEU 970089129) to assist the campaign against foot-and-mouth disease outside the Community	64
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