

Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (Text with EEA relevance) (Codified version)

COMMISSION DIRECTIVE 2007/42/EC

of 29 June 2007

relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

(Text with EEA relevance)

(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC⁽¹⁾, and in particular Article 5 thereof,

Whereas:

- (1) Commission Directive 93/10/EEC of 15 March 1993 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs⁽²⁾ has been substantially amended several times⁽³⁾. In the interests of clarity and rationality the said Directive should be codified.
- (2) The Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market. These objectives cannot be achieved by Member States individually. Furthermore, their attainment at Community level is already provided for by Regulation (EC) No 1935/2004.
- (3) In order to achieve the objective laid down in Article 3(1) of Regulation (EC) No 1935/2004 in the case of regenerated cellulose film, the suitable instrument was a specific directive within the meaning of Article 5 of that Regulation.
- (4) Synthetic casings of regenerated cellulose should be the subject of specific provisions.
- (5) The method for determining the absence of migration of colouring matters should be established at a later stage.
- (6) Until criteria of purity and methods of analysis have been drawn up, national provisions should remain in force.
- (7) The establishment of a list of approved substances, accompanied by limits to the quantities to be used, is sufficient in principle in this specific case to achieve the objective laid down in Article 3(1) of Regulation (EC) No 1935/2004.

- (8) However, the bis(2-hydroxyethyl)ether (= diethyleneglycol) and ethanediol (= monoethyleneglycol) can migrate extensively to certain foodstuffs and therefore in order to avoid this possibility, as a preventive measure, it is more appropriate to lay down definitively the maximum authorised quantity of such substances in foodstuffs which have been in contact with regenerated cellulose film.
- (9) To protect the health of the consumer, direct contact between foodstuffs and the printed surfaces of regenerated cellulose film should be avoided.
- (10) The written declaration referred to in Article 16(1) of Regulation (EC) No 1935/2004 should be provided for in the event of professional use of regenerated cellulose film for materials and articles intended to come into contact with foodstuffs, except those which are, by their nature, intended for this use.
- (11) The rules to be applied to the regenerated cellulose films should be specific to the nature of the layer in contact with the foodstuff. Accordingly, the requirements for regenerated cellulose films coated with coatings consisting of plastics should be different from those provided for regenerated cellulose films uncoated or coated with coatings derived from cellulose.
- (12) Only authorised substances should be used in the manufacture of all the types of regenerated cellulose films, including regenerated cellulose films coated with plastics.
- (13) In the case of regenerated cellulose films coated with coatings consisting of plastics, the layer in contact with foodstuffs consists of a material similar to plastic materials and articles intended to come into contact with foodstuffs. Therefore it is appropriate that the rules provided for in Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs⁽⁴⁾ apply also to such films.
- (14) In the interest of consistency of Community legislation, the verification of compliance of plastic-coated regenerated cellulose films with the migration limits set by Directive 2002/72/EC should be carried out according to the rules laid down in Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs⁽⁵⁾ and Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs⁽⁶⁾.
- (15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.
- (16) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directives set out in Annex III, Part B,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1 This Directive is a specific directive within the meaning of Article 5 of Regulation (EC) No 1935/2004.

2 This Directive shall apply to regenerated cellulose film within the meaning of the description given in Annex I which is intended to come into contact with foodstuffs or which, by virtue of its purpose, does come into such contact and which either:

- a constitutes a finished product in itself; or
- b forms part of a finished product containing other materials.

3 This Directive shall not apply to synthetic casings of regenerated cellulose.

Article 2

The regenerated cellulose films referred to in Article 1(2) shall belong to one of the following types:

- (a) uncoated regenerated cellulose film;
- (b) coated regenerated cellulose film with coating derived from cellulose; or
- (c) coated regenerated cellulose film with coating consisting of plastics.

Article 3

1 Regenerated cellulose films referred to in Article 2(a) and (b) shall be manufactured using only substances or groups of substances listed in Annex II subject to the restrictions set out therein.

2 By way of derogation from paragraph 1, substances other than those listed in Annex II may be used when these substances are employed as colouring matter (dyes and pigments) or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method.

Article 4

1 Regenerated cellulose film referred to in Article 2(c) shall be manufactured, prior to coating, using only substances or groups of substances listed in the first part of Annex II, subject to the restrictions set out therein.

2 The coating to be applied to the regenerated cellulose film referred to in paragraph 1 shall be manufactured using only substances or groups of substances listed in Annexes II to VI to Directive 2002/72/EC, subject to the restrictions set out therein.

3 Without prejudice to paragraph 1, materials and articles made of regenerated cellulose film referred to in Article 2(c) shall comply with Articles 2, 7 and 8 of Directive 2002/72/EC.

Article 5

Printed surfaces of regenerated cellulose film shall not come into contact with the foodstuffs.

Article 6

1 At the marketing stages other than the retail stages, materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16(1) of Regulation (EC) No 1935/2004.

2 Paragraph 1 shall not apply to materials and articles made of regenerated cellulose film which by their nature are clearly intended to come into contact with foodstuffs.

3 Where special conditions of use are indicated, the material or article made of regenerated cellulose film shall be labelled accordingly.

Article 7

Directive 93/10/EEC, as amended by the Directives listed in Annex III, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directives set out in Annex III, 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 IV.

Article 8

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

Article 9

This Directive is addressed to the Member States.

Done at Brussels, 29 June 2007.

For the Commission

The President

José Manuel BARROSO

ANNEX I

DESCRIPTION OF REGENERATED CELLULOSE FILM

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

ANNEX II

LIST OF SUBSTANCES AUTHORISED IN THE
MANUFACTURE OF REGENERATED CELLULOSE FILM

NB:

- The percentages in this Annex, first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.
- The usual technical denominations are given in square brackets.
- The substances used shall be of good technical quality as regards the purity criteria.

FIRST PART

Uncoated regenerated cellulose film

Denominations	Restrictions
A. Regenerated cellulose	Not less than 72 % (w/w)
B. Additives	
1. <i>Softeners</i>	Not more than 27 % (w/w) in total
— Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foodstuffs which are not moist, namely which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
— Ethanediol [= monoethyleneglycol]	
— 1,3-butanediol	
— Glycerol	
— 1,2-propanediol [= 1,2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1 200.

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—	1,2-polypropylene oxide [= 1,2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1 % (w/w) in substance.
—	Sorbitol	
—	Tetraethyleneglycol	
—	Triethyleneglycol	
—	Urea	
2.	<i>Other additives</i>	Not more than 1 % (w/w) in total.
	<i>First class</i>	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film.
—	Acetic acid and its NH ₄ , Ca, Mg, K and Na salts	
—	Ascorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
—	Benzoic acid and sodium benzoate	
—	Formic acid and its NH ₄ , Ca, Mg, K and Na salts	
—	Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH ₄ , Ca, Mg, K, Na, Al, Zn salts of these acids	
—	Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
—	Sorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
—	Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the	

	amides of behenic and ricinoleic acids	
—	Natural edible starches and flours	
—	Edible starches and flours modified by chemical treatment	
—	Amylose	
—	Calcium and magnesium carbonates and chlorides	
—	Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
—	Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
—	Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
—	Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
—	Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium	
—	Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1 200 and 4 000.
—	Sodium propionate	
<i>Second class</i>		The total quantity of the substances may not exceed 1 mg/dm ² of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed

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	0,2 mg/dm ² (or a lower limit where one is specified) of the uncoated film.
— Sodium alkyl (C ₈ -C ₁₈) benzene sulphonate	
— Sodium isopropyl naphthalene sulphonate	
— Sodium alkyl (C ₈ -C ₁₈) sulphate	
— Sodium alkyl (C ₈ -C ₁₈) sulphonate	
— Sodium dioctylsulphosuccinate	
— Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0,05 mg/dm ² of the uncoated film.
— Ammonium, magnesium and potassium lauryl sulphates	
— N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane	
— 2-heptadecyl-4,4-bis(methylene-stearate) oxazoline	
— Polyethylene-aminostearamide ethylsulphate	Not more than 0,1 mg/dm ² of the uncoated film.
<i>Third class — Anchoring agent</i>	The total quantity of substances may not exceed 1 mg/dm ² of the uncoated film.
— Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products: butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	Free formaldehyde content not greater than 0,5 mg/dm ² of the uncoated film. Free melamine content not greater than 0,3 mg/dm ² of the uncoated film.
— Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0,5 mg/dm ² of the uncoated film. Free melamine content not greater than 0,3 mg/dm ² of the uncoated film.

<p>— Cross-linked cationic polyalkyleneamines:</p> <p>(a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin;</p> <p>(b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine;</p> <p>(c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia;</p> <p>(d) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine;</p> <p>(e) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine</p>	<p>In accordance with Community directives and in their absence, with national legislation, pending the adoption of Community directives.</p>
<p>— Polyethyleneamines and polyethyleneimines</p>	<p>Not more than 0,75 mg/dm² of the uncoated film.</p>
<p>— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or of the following products: aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite</p>	<p>Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film.</p>
<p><i>Fourth class</i></p>	<p>The total quantity of substances may not exceed 0,01 mg/dm² of the uncoated film.</p>
<p>— Products resulting from the reaction of the amines of edible oils with polyethylene oxide</p>	
<p>— Monoethanolamine lauryl sulphate</p>	

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SECOND PART

Coated regenerated cellulose film

Denominations	Restrictions
A. Regenerated cellulose	See first part.
B. Additives	See first part.
C. Coating	
1. <i>Polymers</i>	The total quantity of substances may not exceed 50 mg/dm ² of the coating on the side in contact with foodstuffs.
— Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— Cellulose nitrate	Not more than 20 mg/dm ² of the coating on the side in contact with foodstuffs; nitrogen content between 10,8 % (w/w) and 12,2 % (w/w) in the cellulose nitrate.
2. <i>Resins</i>	The total quantity of substances may not exceed 12,5 mg/dm ² of the coating on the side in contact with foodstuffs and solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings.
— Casein	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C ₂ to C ₆ polyvalent alcohols, or mixtures of these alcohols	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2,2 bis (4-hydroxyphenyl) propane formaldehyde and esterified with methyl ethyl or C ₂ to C ₆ polyvalent alcohols or mixtures of these alcohols	
— Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene and/or	

	dipentene and/or diterpene and maleic anhydride	
—	Edible gelatine	
—	Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
—	Natural gum [= damar]	
—	Poly-beta-pinene [= terpenic resins]	
—	Urea-formaldehyde resins (see anchoring agents)	
3.	<i>Plasticisers</i>	The total quantity of substances may not exceed 6 mg/dm ² of the coating on the side in contact with foodstuffs.
—	Acetyl tributyl citrate	
—	Acetyl tri(2-ethylhexyl) citrate	
—	Di-isobutyl adipate	
—	Di-n-butyl adipate	
—	Di-n-hexyl azelate	
—	Dicyclohexyl phthalate	Not more than 4,0 mg/dm ² of the coating on the side in contact with foodstuffs.
—	2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed: (a) 2,4 mg/kg of the foodstuff in contact with this type of film; or (b) 0,4 mg/dm ² in the coating on the side in contact with foodstuffs.
—	Glycerol monoacetate [= monoacetin]	
—	Glycerol diacetate [= diacetin]	
—	Glycerol triacetate [= triacetin]	
—	Di-butyl sebacate	

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—	Di-n-butyl tartrate	
—	Di-isobutyl tartrate	
4.	<i>Other additives</i>	The total quantity of substances may not exceed 6 mg/dm ² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs.
4.1.	<i>Additives listed in the first part</i>	Same restrictions as in the first part (however the quantities in mg/dm ² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs).
4.2.	<i>Specific coating additives</i>	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs.
—	1-hexadecanol and 1-octadecanol	
—	Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
—	Montan waxes, comprising purified montanic (C ₂₆ to C ₃₂) acids and/or their esters with ethanediol and/or 1,3 butanediol and/or their calcium and potassium salts	
—	Carnauba wax	
—	Beeswax	
—	Esparto wax	
—	Candelilla wax	
—	Dimethylpolysiloxane	Not more than 1 mg/dm ² of the coating on the side in contact with foodstuffs.
—	Epoxidised soya-bean oil (oxirane content 6 to 8 %)	

—	Refined paraffin and microcrystalline waxes	
—	Pentaerythritol tetrastearate	
—	Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0,2 mg/dm ² of the coating on the side in contact with foodstuffs.
—	Aliphatic acids (C ₈ to C ₂₀) esterified with mono- or di-(2-hydroxyethyl)amine	
—	2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs.
—	2,6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs.
—	Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs.
5.	<i>Solvents</i>	The total quantity of substances may not exceed 0,6 mg/dm ² of the coating on the side in contact with foodstuffs.
—	Butyl acetate	
—	Ethyl acetate	
—	Isobutyl acetate	
—	Isopropyl acetate	
—	Propyl acetate	
—	Acetone	
—	1-butanol	
—	Ethanol	
—	2-butanol	
—	2-propanol	
—	1-propanol	

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—	Cyclohexane	
—	Ethyleneglycol monobutyl ether	
—	Ethyleneglycol monobutyl ether acetate	
—	Methyl ethyl ketone	
—	Methyl isobutyl ketone	
—	Tetrahydrofuran	
—	Toluene	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs.

ANNEX III

PART A

REPEALED DIRECTIVE WITH LIST OF ITS SUCCESSIVE AMENDMENTS

(referred to in Article 7)

Commission Directive 93/10/EEC	(OJ L 93, 17.4.1993, p. 27).
Commission Directive 93/111/EC	(OJ L 310, 14.12.1993, p. 41).
Commission Directive 2004/14/EC	(OJ L 27, 30.1.2004, p. 48).

PART B

LIST OF TIME-LIMITS FOR TRANSPOSITION INTO NATIONAL LAW AND APPLICATION

(referred to in Article 7)

Directive	Time-limit for transposition	Date of application
93/10/EEC	1 January 1994	1 January 1994 ^a 1 January 1994 ^b 1 January 1995 ^c
93/111/EC	—	—
2004/14/EC	29 July 2005	29 July 2005 ^d 29 January 2006 ^e

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- a** In accordance with the first indent of Article 5(1) of Directive 93/10/EEC: ‘Member States shall permit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs complying with this Directive.’
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- b** In accordance with the second indent of Article 5(1) of Directive 93/10/EEC: ‘Member States shall prohibit, as from 1 January 1994, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which complies with neither this Directive nor Directive 83/229/EEC, other than film which Directive 92/15/EEC prohibits as from 1 July 1994.’
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- c** In accordance with the third indent of Article 5(1) of Directive 93/10/EEC: ‘Member States shall prohibit, as from 1 January 1995, the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which does not comply with this Directive but did comply with Directive 83/229/EEC.’
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- d** In accordance with Article 2(1)(a) of Directive 2004/14/EC: ‘Member States shall apply those provisions in such a way as to permit the trade in and use of regenerated cellulose film which is intended to come into contact with foodstuffs complying with this Directive, from 29 July 2005.’
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- e** In accordance with Article 2(1)(b) of Directive 2004/14/EC: ‘Member States shall apply those provisions in such a way as to prohibit the manufacture and importation into the Community of regenerated cellulose film which is intended to come into contact with foodstuffs and which does not comply with the provisions of this Directive as from 29 January 2006.’
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ANNEX IV

CORRELATION TABLE

Directive 93/10/EEC	This Directive
Article 1(1) and (2)	Article 1(1) and (2)
Article 1(3), introductory wording, point (b)	Article 1(3)
Article 1a	Article 2
Article 2	Article 3
Article 2a	Article 4
Article 3	Article 5
Article 4	Article 6
Article 5	—
Article 6	—
—	Article 7
—	Article 8
Article 7	Article 9
Annex I	Annex I
Annex II	Annex II
Annex III	—
—	Annex III
—	Annex IV

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- (1) OJ L 338, 13.11.2004, p. 4.
- (2) OJ L 93, 17.4.1993, p. 27. Directive as last amended by Directive 2004/14/EC (OJ L 27, 30.1.2004, p. 48).
- (3) See Annex III, Part A.
- (4) OJ L 220, 15.8.2002, p. 18. Directive as last amended by Directive 2007/19/EC (OJ L 91, 31.3.2007, p. 17).
- (5) OJ L 297, 23.10.1982, p. 26. Directive as last amended by Commission Directive 97/48/EC (OJ L 222, 12.8.1997, p. 10).
- (6) OJ L 372, 31.12.1985, p. 14. Directive as last amended by Commission Directive 2007/19/EC.