

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	

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	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.

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<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	

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	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 %)	

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—	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