

II

(Acts whose publication is not obligatory)

COMMISSION

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs⁽¹⁾, and in particular Article 3 thereof,

After consulting the Scientific Committee for Food,

Whereas the number and nature of the changes that have had to be made and should now be made to Council Directive 83/229/EEC of 25 April 1993 on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs⁽²⁾, as last amended by Commission Directive 92/15/EEC⁽³⁾, indicate the need for the said Directive to be replaced;

Whereas the Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market; whereas these objectives cannot be achieved by Member States individually; whereas, furthermore, their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas Article 2 of Directive 89/109/EEC lays down that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities

which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs;

Whereas, in order to achieve this objective in the case of regenerated cellulose film, the suitable instrument is a specific directive within the meaning of Article 3 of Directive 89/109/EEC;

Whereas synthetic casings of regenerated cellulose should be the subject of specific provisions;

Whereas the method for determining the absence of migration of colouring matters should be established at a later stage;

Whereas, until criteria of purity and methods of analysis have been drawn up, national provisions should remain in force;

Whereas 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 2 of Directive 89/109/EEC;

Whereas, 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 authorized quantity of such substances in foodstuffs which have been in contact with regenerated cellulose film;

Whereas, to protect the health of the consumer, direct contact between foodstuffs and the printed surfaces of regenerated cellulose film should be avoided;

⁽¹⁾ OJ No L 40, 11. 2. 1989, p. 38.

⁽²⁾ OJ No L 123, 11. 5. 1983, p. 31.

⁽³⁾ OJ No L 102, 16. 4. 1992, p. 44.

Whereas the written declaration referred to in Article 6 (5) of Directive 89/109/EEC 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;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific directive within the meaning of Article 3 of Directive 89/109/EEC.

2. This Directive shall apply to regenerated cellulose film within the meaning of the description given in Annex I which either:

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

and which is intended to come into contact with foodstuffs or which, by virtue of its purpose, does come into such contact.

3. This Directive does not apply to:

- (a) regenerated cellulose film which, on the side intended to come into contact with foodstuffs or which, by virtue of its purpose does come into such contact, has a coating exceeding 50 mg/dm²;
- (b) synthetic casings of regenerated cellulose.

Article 2

1. Only those substances or groups of substances listed in Annex II may be used for the manufacture of regenerated cellulose film and only under the conditions laid down 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 3

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

Article 4

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 6 (5) of Directive 89/109/EEC.

2. Paragraph 1 does 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 5

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 January 1994. They shall immediately inform the Commission thereof.

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,
- 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,
- 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.

2. When Member States adopt the measures referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 6

1. Directive 83/229/EEC is hereby repealed as from 1 January 1994.

2. References to Directive 83/229/EEC shall be construed as references to this Directive and should be read in accordance with the correlation table appearing in Annex III.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 15 March 1993.

For the Commission

Martin BANGEMANN

Member of the Commission

*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 AUTHORIZED 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. Softeners	Not more than 27 % (w/w) in total
<ul style="list-style-type: none"> — Bis (2-hydroxyethyl) ether [= diethyleneglycol] — Ethanediol [= monoethyleneglycol] 	Only for films intended to be coated and then used for foodstuffs which are not moist, i.e. 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.
— 1,3-butanediol	
— Glycerol	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1 % (w/w) in substance
— 1,2-propanediol [= 1,2 propyleneglycol]	Average molecular weight between 250 and 1 200
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1 % (w/w) in substance
— 1,2-polypropylene oxide [= 1,2 polypropyleneglycol]	Average molecular weight between 250 and 1 200
— Sorbitol	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1 % (w/w) in substance
— Tetraethyleneglycol	Average molecular weight between 250 and 1 200
— Triethyleneglycol	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1 % (w/w) in substance
— Urea	Average molecular weight between 250 and 1 200
2. Other additives	Not more than 1 % (w/w) in total
First class	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	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film
— Ascorbic acid and its NH ₄ , Ca, Mg, K and Na salts	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film
— Benzoic acid and sodium benzoate	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film
— Formic acid and its NH ₄ , Ca, Mg, K and Na salts	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film
— 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	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film
— Citric, d and l lactic, maleic, l-tartaric acids and their Na and K salts	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film
— Sorbic acid and its NH ₄ , Ca, Mg, K and Na salts	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film

Denominations	Restrictions
<ul style="list-style-type: none"> — 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] — Sodium propionate 	<p data-bbox="791 1256 1272 1310">Average molecular weight between 1 200 and 4 000</p>
<p data-bbox="232 1378 381 1410">Second class</p> <ul style="list-style-type: none"> — Sodium alkyl (C₈ to C₁₈) benzene sulphonate — Sodium isopropyl naphthalene sulphonate — Sodium alkyl (C₈-C₁₈) sulphate — Sodium alkyl (C₈-C₁₈) sulphonate — Sodium dioctylsulphosuccinate — Distearate of dihydroxyethyl diethylene triamine monoacetate — 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 	<p data-bbox="791 1378 1272 1537">The total quantity of the substances may not exceed 1 mg/dm² of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0,2 mg/dm² (or a lower limit where one is specified) of the uncoated film</p> <p data-bbox="791 1771 1272 1803">Not more than 0,05 mg/dm² of the uncoated film</p> <p data-bbox="791 2072 1272 2104">Not more than 0,1 mg/dm² of the uncoated film</p>

Denominations	Restrictions
<p>Third class — Anchoring agent</p> <ul style="list-style-type: none"> — 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 — Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine — Cross-linked cationic polyalkyleneamines : <ul style="list-style-type: none"> (a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin (b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine (c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia (d) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine (e) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine — Polyethyleneamines and polyethyleneimines — 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>The total quantity of substances may not exceed 1 mg/dm² of the uncoated film</p> <p>Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film</p> <p>Free melamine content not greater than 0,3 mg/dm² of the uncoated film</p> <p>Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film.</p> <p>Free melamine content not greater than 0,3 mg/dm² of the uncoated film</p> <p>In accordance with Community directives and in their absence, with national legislation, pending the adoption of Community directives</p> <p>Not more than 0,75 mg/dm² of the uncoated film</p> <p>Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film</p>
<p>Fourth class</p> <ul style="list-style-type: none"> — Products resulting from the reaction of the amines of edible oils with polyethylene oxide — Monoethanolamine lauryl sulphate 	<p>The total quantity of substances may not exceed 0,01 mg/dm² of the uncoated film</p>

SECOND PART

COATED REGENERATED CELLULOSE FILM

Denominations	Restrictions
A. Regenerated cellulose	See first part
B. Additives	See first part
C. Coating	Not more than 50 mg of coating/dm ² of film on the side in contact with foodstuffs
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
— Polymers, copolymers and their mixtures made with the following monomers:	In accordance with Community directives, and, in their absence, with national legislation pending the adoption of Community directives
vinyl acetals derived from saturated aldehydes (C ₁ to C ₆)	
vinyl acetate	
alkyl (C ₁ to C ₄) vinyl ethers	
acrylic, crotonic, itaconic, maleic, methacrylic acids and their esters	
butadiene	
styrene	
methylstyrene	
vinylidene chloride	
acrylonitrile	
methacrylonitrile	
ethylene, propylene, 1- and 2-butylene	
vinyl chloride	According to Directive 78/142/EEC (OJ No L 44, 15. 2. 1978, p. 15)
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 or vinyl chloride and vinyl acetate copolymer 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	

Denominations	Restrictions
<ul style="list-style-type: none"> — 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) 	
<p>3. <i>Plasticizers</i></p>	<p>The total quantity of substances may not exceed 6 mg/dm² of the coating on the side in contact with foodstuffs</p>
<ul style="list-style-type: none"> — Acetyl tributyl citrate — Acetyl tri(2-ethylhexyl) citrate — Di-isobutyl adipate — Di-n-butyl adipate — Di-n-hexyl azelate — Butylbenzylphthalate — Di-n-butyl phthalate — Dicyclohexyl phthalate — 2-ethylhexyl diphenyl phosphate — Glycerol monoacetate [= monoacetin] — Glycerol diacetate [= diacetin] — Glycerol triacetate [= triacetin] — Di-butyl sebacate — Di(2-ethylhexyl) sebacate [= dioctylsebacate] — Di-n-butyl tartrate — Di-isobutyl tartrate 	<p>Not more than 2,0 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 3,0 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 4,0 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 2,5 mg/dm² of the coating on the side in contact with foodstuffs</p>
<p>4. <i>Other additives</i></p>	<p>The total quantity of substances may not exceed 6 mg/dm² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs</p>
<p>4.1. <i>Additives listed in the first part</i></p>	<p>Same restrictions as in the first part (however the quantities in mg/dm² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs)</p>
<p>4.2. <i>Specific coating additives:</i></p>	<p>The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm² (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs</p>
<ul style="list-style-type: none"> — 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 (C₂₆ to C₃₂) acids and/or their esters with ethanediol and/or 1,3 butanediol and/or their calcium and potassium salts 	

Denominations	Restrictions
<ul style="list-style-type: none"> — Carnauba wax — Beeswax — Esparto wax — Candelilla wax — Dimethylpolysiloxane — Epoxidized soya-bean oil (oxirane content 6 to 8 %) — Refined paraffin and microcrystalline waxes — Pentaerythritol tetrastearate — Mono and bis(octadecyldiethyleneoxide)-phosphates — Aliphatic acids (C₈ to C₂₀) esterified with mono- or di-(2-hydroxyethyl)amine — 2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA] — 2,6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT] — Di-n-octyltin-bis(2-ethylhexyl) maleate 	<p>Not more than 1 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 0,2 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs</p>
<p>5. <i>Solvents</i></p> <ul style="list-style-type: none"> — Butyl acetate — Ethyl acetate — Isobutyl acetate — Isopropyl acetate — Propyl acetate — Acetone — 1-butanol — Ethanol — 2-butanol — 2-propanol — 1-propanol — Cyclohexane — Ethyleneglycol monobutyl ether — Ethyleneglycol monobutyl ether acetate — Ethyleneglycol monoethyl ether — Ethyleneglycol monoethyl ether acetate — Ethyleneglycol monomethyl ether — Ethyleneglycol monomethyl ether acetate — Methyl ethyl ketone — Methyl isobutyl ketone — Tetrahydrofuran — Toluene 	<p>The total quantity of substances may not exceed 0,6 mg/dm² of the coating on the side in contact with foodstuffs</p> <p>Not more than 0,06 mg/dm² of the coating on the side in contact with foodstuffs.</p>

*ANNEX III***CORRELATION TABLE**

Directive 83/229/EEC	Present Directive
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article —	Article 4
Article 4 (1)	Article 5
Article 4 (2)	Article —
Article —	Article 6
Article 5	Article 7