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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

(OJ L 93, 17.4.1993, p. 27)

Amended by:

	Official Journal		
	No	page	date
► <u>M1</u> Commission Directive 93/111/EC of 10 December 1993	L 310	41	14.12.1993
► <u>M2</u> Commission Directive 2004/14/EC of 29 January 2004	L 27	48	30.1.2004



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;

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

⁽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.

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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:

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- (b) synthetic casings of regenerated cellulose.

▼M2*Article 1a*

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.

▼B*Article 2***▼M2**

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

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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.

▼M2*Article 2a*

1. Regenerated cellulose film referred to in Article 1a(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.

▼M2

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

▼B*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,

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— 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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— 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.

▼B*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.

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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. <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, i.e. which do not contain water which is physically free at the surface. The total amount of bis(2 hydroxyethyl)ether and etha- nediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
— Ethanediol [= monoethyle- neglycol]	
— 1,3-butanediol	
— Glycerol	
— 1,2-propanediol [= 1,2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1 200
— 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
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	
— 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	

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Denominations	Restrictions
— 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	

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Denominations	Restrictions
<p>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>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>Not more than 0,05 mg/dm² of the uncoated film</p> <p>Not more than 0,1 mg/dm² of the uncoated film</p>
<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, triethylene-tetramine, tetraethylene-pentamine, tri-(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine — Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine 	<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>

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Denominations	Restrictions
<ul style="list-style-type: none"> — Cross-linked cationic polyalkyleneamines: <ul style="list-style-type: none"> (a) polyamide-epichlorhydrin resin based on diaminopropylmethamine 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 diaminopropylmethamine 	<p>In accordance with Community directives and in their absence, with national legislation, pending the adoption of Community directives</p>
<ul style="list-style-type: none"> — Polyethyleneamines and polyethyleneimines 	<p>Not more than 0,75 mg/dm² of the uncoated film</p>
<ul style="list-style-type: none"> — Condensation product of urea-formaldehyde unmodified, or which may be modified with one or of the following products: <ul style="list-style-type: none"> aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite 	<p>Free formaldehyde content not greater than 0,5 mg/dm² of the uncoated film</p>
<p>Fourth class</p>	<p>The total quantity of substances may not exceed 0,01 mg/dm² of the uncoated film</p>
<ul style="list-style-type: none"> — Products resulting from the reaction of the amines of edible oils with polyethylene oxide 	
<ul style="list-style-type: none"> — Monoethanolamine lauryl sulphate 	

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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	► <u>M2</u> ◀
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
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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
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— 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 beta-pinene 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	

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Denominations	Restrictions
(see anchoring agents)	
3. <i>Plasticizers</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	
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— Dicyclohexyl phthalate	Not more than 4,0 mg/dm ² of the coating on the side in contact with foodstuffs
▼M2	
— 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
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— Glycerol monoacetate [= monoacetin]	
— Glycerol diacetate [= diacetin]	
— Glycerol triacetate [= triacetin]	
— Di-butyl sebacate	
▼M2	
▼B	
— 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	

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Denominations	Restrictions
— 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
— Epoxidized soya-bean oil (oxirane content 6 to 8 %)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyl-diethyleneoxide)-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	
— Cyclohexane	

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| — Ethyleneglycol mono-methyl ether | |
| — Ethyleneglycol mono-methyl ether acetate | |
| — Methyl ethyl ketone | |

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Denominations	Restrictions
— Methyl isobutyl ketone — Tetrahydrofuran — Toluene	Not more than 0,06 mg/dm ² of the coating on the side in contact with foodstuffs.

▼B*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