II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 25 April 1983

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

(83/229/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to Council Directive 76/893/EEC of 23 November 1976 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,

Having regard to the proposal from the Commission (2),

Having regard to the opinion of the European Parliament (3),

Having regard to the opinion of the Economic and Social Committee (4),

Whereas Article 2 of Directive 76/893/EEC lays down that materials and articles must not transfer their constituents to foodstuffs in quantites 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, a suitable instrument is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC, the general provisions of which are also applicable to the case in question;

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 will remain in force;

Whereas the establishment of a list of approved substances, accompanied by maximum percentage levels of the quantities to be used, will be sufficient in this specific case to achieve the objective laid down in Article 2 of Directive 76/893/EEC;

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

Whereas certain difficulties inherent in the interpretation of the scientific data as regards phthalates do not allow the Council to take a definitive decision at present;

Whereas fixing the procedure for the determination of possible migration in or on foodstuffs of colouring matters used in the manufacture of regenerated cellulose film is an implementing measure of a technical nature and therefore, in order to simplify and accelerate the procedure, this should be the responsibility of the Commission;

(1) OJ No L 340, 9. 12. 1976, p. 19.
(2) OJ No C 235, 15. 9. 1981, p. 3.
(3) OJ No C 149, 14. 6. 1982, p. 106.
(4) OJ No C 230, 10. 9. 1981, p. 8.

Whereas, in all cases in which the Council confers on the Commission authority to implement the rules relating to materials and articles intended to come into contact with foodstuffs, a procedure should be laid down establishing close cooperation between Member States and the Commission within the Standing Committee for Foodstuffs set up under Council Decision 69/414/EEC (1),

HAS ADOPTED THIS DIRECTIVE :

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.

2. This Directive applies 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) is a part of a finished product containing other materials and which is intended to or, in accordance with its purpose, does come into contact with foodstuffs.

3. This Directive does not apply to :

(a) regenerated cellulose film which, on the side intended to or, which in accordance with its purpose does come into contact with foodstuffs, has a coating exceeding 50 mg/dm^2 ;

(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 lown 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 method which shall be determined in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.

Article 3

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

Article 4

1. Member States shall make such amendments to their laws, regulations and administrative provisions as may be necessary in order to comply with the provisions of this Directive and shall forthwith inform the Commission thereof. The laws so amended shall be applied in such a manner that :

— the marketing of regenerated cellulose film complying with the provisions of this Directive is authorized with effect from 1 January 1985 at the latest,

— the marketing of regenerated cellulose film not complying with the provisions of this Directive is prohibited with effect from 1 January 1986.

2. However, the Member States may refuse authorization for the use of the substances listed below in the manufacture of regenerated cellulose film intended to come into contact or coming into contact, in accordance with their purpose, with foodstuffs containing fat, in so far as those substances may migrate into that fat :

— butylbenzylphthalate,

— butyl-methylcarboxybutyl-phthalate [= butylphthalyl butyl glycolate],

— di-n-butyl and di-isobutyl phthalate,

— dicyclohexyl phthalate,

— di(methyl-cyclohexyl phthalate and its isomers [= sextolphthalate],

— methyl-methylcarboxyethyl phthalate [= methyl-phthalyl ethyl glycolate].

By 1 July 1986 the Council shall, in accordance with Article 100 of the Treaty, decide on subsequent arrangements for these substances.

Article 5

This Directive is addressed to the Member States.

Done at Luxembourg, 25 April 1983.

For the Council

The President

H.-W. LAUTENSCHLAGER

(1) OJ No L 291, 19. 11. 1969, p. 9.

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 are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous regenerated cellulose film,

— the usual technical denominations are given in square brackets.

FIRST PART

UNCOATED REGENERATED CELLULOSE FILM

Denominations	Restrictions
A. **Regenerated cellulose**	≥ 72 %
B. **Additives**	
1. *Softeners*	≤ 27 % in total
— bis (2-hydroxyethyl) ether [= diethyleneglycol]	The total amount of this (2-hydroxyethyl) ether and ethanediol may not exceed 20 % and only for films to be coated afterwards, and only for packaging of non-moist foodstuffs, this means those which do not contain physically free water at the surface
— ethanediol [monoethyleneglycol]	
— 1,3-butanediol	
— glycerol	
— 1,2-propanediol [= 1,2-propylenediol]	
— polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1 200
— 1,2-polypropylene oxide [= 1,2-polypropyleneglycol]	Average molecular weight ≤ 400 and free 1,3-propanediol content ≤ 1 % (w/w)
— sorbitol	
— triethylene glycol	
— urea	
2. *Other additives*	≤ 1 % in total
First class	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm²
— 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 acid and ricinoleic acids and the NH_4, Ca, Mg, K, Na, Al, Zn salts of these acids	
— citric, d-l lactic, maleic, tartaric acids and their Na und 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	

Denominations	Restrictions
— 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 (8-14 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	
Second class	≤ 1 mg/dm² in total 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)
— sodium alkyl (C_8 to C_{18}) benzenesulphonate	
— sodium isopropyl naphthalene sulphonate	
— sodium alkyl (C_8 to C_{18}) sulphate	
— sodium alkyl (C_8 to c_{18}) sulphonate	
— sodium dioctylsuphosuccinate	
— distearate of di-hydroxyethyl di-ethylene triamine monoacetate	≤ 0,05 mg/dm² in total on the side in contact with foodstuffs
— ammonium, magnesium and potassium lauryl sulphates	
— N,N′-distearoyl diaminoethane [= N,N′-distearoyl ethylenediamine] and N,N′-dipalmitoyl diaminoethane [= N,N′-dipalmitoyl ethylenediamine] and N,N′-dioleoyl diaminoethane [= N,N′-dioleoyl ethylenediamine]	
— 2-heptadecyl — 4,4-bis (methylenestearate) oxazoline	
— polyethylene -amino stearamide ethylsulphate	≤ 0,1 mg/dm² in total on the side in contact with foodstuffs

Denominations	Restrictions
Third class — Anchoring agents	≤ 1 mg/dm² in total
— condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products :	Free formaldehyde content on side in contact with foodstuffs ≤ 0,5 mg/dm² Free melamine content on side in contact with foodstuffs ≤ 0,3 mg/dm²
butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl)amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	
— cross-linked cationic polyalkyleneamines :	In accordance with national legislation pending the adoption of Community provisions
(a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin	
(b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylene triamine 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	≤ 0,75 mg/dm² in total
— condensation product of urea-formaldehyde unmodified, or which may be modified with one or more of the following products : aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite	Free formaldehyde content on side in contact with foodstuffs ≤ 0,5 mg/dm²
Fourth class	≤ 0,01 mg/dm² in total
— products resulting from the reaction of the amines of edible oils with polyethylene oxide	
— monoethanolamine lauryl sulphate	

SECOND PART

COATED REGENERATED CELLULOSE FILM

Denominations	Restrictions
A. **Regenerated cellulose**	See first part
B. **Additives**	See first part
C. **Coating**	≤ 50 mg/dm² on the side in contact with foodstuffs
1. *Polymers*	≤ 50 mg/dm² in total on the side in contact with foodstuffs
— ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— cellulose nitrate	≤ 20 mg/dm² on the side in contact with foodstuffs; nitrogen content between 10,8 and 12,2 %
— polymers, copolymers and their mixtures made with the following monomers:	In accordance with national legislation pending the adoption of Community provisions
vinyl acetals derived from saturated aldehydes (C_1 to C_6)	
vinylacetate	
alkyl C_1 to C_4 vinylethers	
acrylic, crotonic, itaconic, maleic, methacrylic acids and their esters	
butadiene	
styrene	
methylstyrene	
vinylidenechloride	
acrylonitrile	
methacrylonitrile	
ethylene, propylene, 1- and 2- butylene	
vinylchloride	According to Directive 78/142/EEC (OJ No L 44, 15. 2. 1978, p. 15)
2. *Resins*	≤ 12,5 mg/dm² in total on the side in contact with foodstuffs to be used solely for the preparation of regenerated cellulose films with nitrocellulose or vinyl chloride and vinyl acetate copolymer base 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 acid and/or bisphenol formaldehyde and esterified with methyl, ethyl or C_2 to C_6 polyvalent alcohols or mixtures of these alcohols	

Denominations	Restrictions
— esters derived from bis (2-hydroxyethyl) ether with addition products of β-pinene and/or dipentene and/or diterpene and maleic anhydride	
— edible gelatine	
— castor oil and its products or dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acid	
— natural gum [= damar]	
— poly-β-pinene [= terpenic resins]	
— urea-formaldehyde resins (see anchoring agents)	
3. *Plasticizers*	
— acetyl tributyl citrate	≤ 12,5 mg/dm² in total on the side in contact with foodstuffs to be used solely for the preparation of regenerated cellulose films with nitrocellulose or vinyl chloride and vinyl acetate copolymer based coatings
— acetyl tri (2-ethylhexyl) citrate	
— di-isobutyl and di-n-butyladipate	
— di-n-hexyl azelate	
— butylbenzylphthalate	
— butyl-methylcarboxybutyl-phthalate [= butylphthalyl butyl glycolate]	
— di-n-butyl and di-isobutyl phthalate	
— dicyclohexyl phthalate	
— di(methylcyclohexyl) phthalate and its isomers [= sextolphthalate]	
— 2-ethylhexyl diphenyl phosphate	≤ 2,5 mg/dm² on the side in contact with foodstuffs
— glycerol monoacetate [= monoacetin]	
— glycerol diacetate [= diacetin]	
— glycerol triacetate [= triacetin]	
— methyl-methylcarboxyethyl phthalate [= methylphthalyl ethyl glycolate]	
— di-butyl sebacate	
— di(2-ethylhexyl)sebacate [= dioctylsebacate]	
— di-n-butyl tartrate and di-iso-butyl tartrate	
4. *Specific coating additives:*	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) 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 10 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleoyl 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	

Denominations	Restrictions
— dimethylpolysiloxane	≤ 1 mg/dm² 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	≤ 0,2 mg/dm² 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]	≤ 0,06 mg/dm² on the side in contact with foodstuffs
— 2,6-di-tert-butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	≤ 0,06 mg/dm² on the side in contact with foodstuffs
— di-n-octyltin-bis(2-ethylhexyl) maleate	≤ 0,06 mg/dm² on the side in contact with foodstuffs
D. **Solvents**	Total quantity of all substances may not exceed 0,6 mg/dm² on the side in contact with foodstuffs
— butyl acetate	
— ethyl acetate	
— isobutyl acetate	
— isopropyl acetate	
— propyl acetate	
— acetone	
— butyl alcohol	
— ethyl alcohol	
— isobutyl alcohol	
— isopropyl alcohol	
— propyl alcohol	
— cyclohexane	
— ethyleneglycol monobutylether	
— ethyleneglycol monobutylether acetate	
— ethyleneglycol monoethylether	
— ethyleneglycol monoethylether acetate	
— ethyleneglycol monomethylether	
— ethyleneglycol monomethylether acetate	
— methylethyl ketone	
— methylisobutyl ketone	
— tetrahydrofuran	
— toluene	