

# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(81) 5 final

Brussels, 19 January 1981

Proposal for a  
COUNCIL DIRECTIVE

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

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(submitted to the Council by the Commission)

COM(81) 5 final

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EXPLANATORY MEMORANDUM

I. INTRODUCTION

1. Under certain conditions, packaging materials used for foodstuffs are known to transfer the substances used in their manufacture to the foodstuffs themselves. Such substances, if toxic, represent a risk for the consumer. Accordingly, most of the Member States of the European Community have drawn up regulations (in the form of laws, recommendations, codes of practice) designed to avoid, or reduce to the lowest achievable level, risks connected with the use of packaging materials. Regenerated cellulose film is one of the materials used for foodstuffs packaging and, as such, is covered by specific regulations in Italy, Belgium and the Federal Republic of Germany. It is also covered by general rules in France, the Netherlands, the United Kingdom and Denmark.
  
2. Although they have the same aim, to protect the consumer, the various regulations propose different methods of achieving that protection and hence represent a technical barrier to Community trade. In its Resolution of 13 December 1973, the Council included the harmonization of laws, regulations and administrative provisions on materials and articles intended to come into contact with foodstuffs in its programme of action on the removal of technical barriers to trade and gave it priority rating.
  
3. In this context the Council adopted a Directive on 23 November 1976 relating to materials and articles intended to come into contact with foodstuffs<sup>1</sup>. This Directive laid down the general principles, criteria and procedures for drawing up specific directives relating to certain groups of materials (e.g. ceramics, plastics, paper and paperboard).

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<sup>1</sup>Directive 76/893/EEC, OJ No L 340, 9.12.1976, p. 19

Three specific directives have already been submitted to the Council. The first involves ceramic articles<sup>2</sup>, the second materials and articles containing vinyl chloride monomer<sup>3</sup> and the third plastics materials<sup>4</sup>. The present proposal for a directive is thus the fourth specific directive.

4. The Commission points out that Parliament, in its opinion on the above-mentioned framework directive, asked the Commission to submit the specific directives in question at the earliest possible juncture.
5. The Advisory Committee on Foodstuffs, which comprises industrial, consumer, agricultural, trade and worker representatives, has delivered an opinion in favour of the adoption of this proposal for a directive. The European professional organization for the producers of regenerated cellulose film (CIPCEL) has asked the Commission on several occasions to draw up a proposal for a directive in this sector. For their part, the European consumer organizations have confirmed the need to pay particular attention to materials intended to come into contact with foodstuffs where the health and safety of the consumer are concerned.

## II. COMMENTS ON THE DRAFT DIRECTIVE

1. The regulations in question on regenerated cellulose film originate from the current provisions in force in Belgium, Italy and the Federal Republic of Germany. They are based largely on the definition of an "approved list", i.e. a list of substances authorized to be used in the manufacture of regenerated cellulose film. Maximum quantities are laid down concerning the use of such substances, especially additives which are likely to "migrate", in order to limit to the technologically indispensable minimum their presence in the finished product. This reduces the risk of food contamination.

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<sup>2</sup>OJ No C 46, 27.2.1975

<sup>3</sup>Directive 78/142/EEC, OJ No L 44, 15.2.1978

<sup>4</sup>OJ No C 141, 16.6.1978

2. The drafting of the approved list required the toxicological evaluation of all substances used by European industries on the part of the Scientific Committee for Food<sup>5</sup>. This has entailed a considerable amount of work in terms of collecting scientific data, not only at European, but also at world level. The ad hoc working party of the Scientific Committee has spent two years assessing all the substances on the list proposed by the CIPCEL and which had the backing of the Member States, which were consulted in advance. It was not always possible to obtain all the data required for a serious assessment of the harmfulness of the substances, and in such cases, these substances were removed from the list with the agreement of CIPCEL and the Member States. In contrast, where it was possible to establish a daily permissible dose for substances, a comparison was made between such quantities and the estimated absorbed dose on the basis of migration data or on the basis of the assumption that all the substance present or transferable has actually migrated to the foodstuff. Given these conditions, it can be reasonably argued that observation of the present regulations more than protects the health of the consumer without putting undue strain on the European industry.
  
3. An approved list was not drawn up for dyes, since it was felt sufficient to apply the principle of non-migratability, which has to be confirmed by highly sensitive method.

Until there is a Community directive national standards currently in force regarding purity criteria will continue to apply to dyes, as to other substances included in the list.

Finally, regenerated cellulose film coated with more than 50 mg/dm<sup>2</sup> lacquer is not covered by this directive on account of the fact that it should be included in the directive on plastic materials.

<sup>5</sup>The Scientific Committee for Food is made up of highly qualified independent personalities connected with medicine, nutrition, toxicology, biology, chemistry or similar fields

<sup>6</sup>Report of the Scientific Committee for Food, Sixth series, 1978

III. CONSULTATION OF THE EUROPEAN PARLIAMENT AND OF THE ECONOMIC AND SOCIAL COMMITTEE

This proposal is for a "specific directive" within the meaning of Article 3 of Directive 76/893/EEC of 23 November 1976 and should therefore be adopted in accordance with the procedure laid down by Article 100 of the Treaty. Pursuant to the second paragraph of that Article, consultation of the European Parliament and of the Economic and Social Committee is necessary. Implementation of the provisions of a directive will, for all Member States, mean making amendments to their legal provisions.

Proposal for a Council Directive 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

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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 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<sup>1</sup> and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament,

Having regard to the Opinion of the Economic and Social Committee,

Whereas Article 2 of Directive 76/893/EEC lays down that materials and articles 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, 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 subject to specific provisions;

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

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<sup>1</sup>OJ No L 340, 9.12.1976, p. 19

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 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;

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<sup>2</sup>,

HAS ADOPTED THIS DIRECTIVE:

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<sup>2</sup>OJ No L 291, 19.11.1969, p.9.

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 which complies with the description given in Annex I and which, in the finished state, is intended to, or does, come into contact with foodstuffs, according to its purpose. It is hereinafter called "regenerated cellulose film".
3. This Directive does not apply to :
  - regenerated cellulose film which, on the side intended to come into contact with foodstuffs, has a coating exceeding 50 mg/dm<sup>2</sup>
  - synthetic casings of regenerated cellulose

Article 2

1. Only those substances or groups of substances listed in Annex II to this Directive may be used for the manufacture of regenerated cellulose film and only under the conditions laid down therein.
2. In 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), provided that there is no migration of the substance 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 direct contact with the foodstuff.

Article 4

Both sides must comply with the rules laid down in this Directive unless there is an indication of the side not intended to come into contact with the foodstuff.

Article 5

Without prejudice to the application of Article 4 of Directive 76/893/EEC, amendments to Annex II of this Directive required in order to take account of progress in scientific and technical knowledge shall be adopted, where appropriate following consultation of the Scientific Committee for Food, in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.



Article 6

This Directive shall not affect national legislation concerning:

- the purity standards of the substances listed in Annex II and of the colouring matters referred to in Article 2 (2);
- the methods of analysis.

Article 7

1. Member States shall make such amendments to their laws 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 manner that:
  - the marketing of regenerated cellulose film complying with the provisions of this Directive is authorized with effect from 1 January 1984 at the latest;
  - the marketing of regenerated cellulose film not complying with the provisions of this Directive is prohibited with effect from 1 January 1985.
2. Paragraph 1 shall not prevent Member States from prohibiting the manufacture of regenerated cellulose film not complying with the provisions of this Directive as from 1 January 1984.

Article 8

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

Description of regenerated cellulose film

Regenerated cellulose film is a thin sheet material produced by chemically dissolving a derivate of highly refined cellulose obtained from wood or cotton that have not been recycled, and subsequently regenerating the pure cellulose by chemical precipitation. To meet technical requirements, suitable additives are incorporated, either in the mass or on the surface. Regenerated cellulose film can be coated on one or both sides.

ANNEX II

List of substances authorised for the fabrication of  
regenerated cellulose film

N.B. - The percentages in the present annex are expressed in weight/weight (w/w) and are calculated in regard to anhydrous regenerated cellulose;

- The denominations of the substances or group of substances are according to the IUPAC ("International Union of Pure and Applied Chemistry") rules. Between square brackets [ ], the usual technical denominations are given.

First Part :

UNCOATED REGENERATED CELLULOSE FILM

DENOMINATIONS	RESTRICTIONS
Regenerated cellulose . . . . .	≥ 72 %
Softeners : . . . . .	≤ 27 % au total
<ul style="list-style-type: none"> <li>- Bis (2 hydroxyethyl) ether [Diethyleneglycol]</li> <li>- Ethanediol [Moncethyleneglycol]</li> </ul>	<p>The total amount of bis (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</p>
<ul style="list-style-type: none"> <li>- 1,3 Butanediol</li> <li>- Glycerol</li> <li>- 1,2 Propanediol [1,2 Propylenediol]</li> <li>- Polyethylene oxide [Polyethyleneglycol] . . . . .</li> <li>- 1,2 Polypropylene oxide [1,2 Polypropyleneglycol] . . . . .</li> </ul>	<p>Average molecular weight between 200 and 1200 Average molecular weight ≤ 400 and 1,3 propanediol content ≤ 1 % (w/w)</p>
<ul style="list-style-type: none"> <li>- Sorbitol</li> <li>- Triethylene glycol</li> <li>- Urea</li> </ul>	≤ 1 % in total
Additives : . . . . .	<p>The total quantity of individual substances or groups of substances should not exceed 2 mg/dm<sup>2</sup></p>
1st class : . . . . .	
<ul style="list-style-type: none"> <li>- Acetic acid and its NH<sub>4</sub>, Ca, Mg, K and Na salts</li> <li>- Ascorbic acid and its NH<sub>4</sub>, Ca, Mg, K and Na salts</li> <li>- Benzoic acid and sodium benzoate</li> <li>- Formic acid and its NH<sub>4</sub>, Ca, Mg, K and Na salts</li> <li>- Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also benenic acid and ricinoleic acids and the NH<sub>4</sub>, Ca, Mg, K, Na, Al, Zn salts of these acids</li> <li>- Citric, d-l lactic, maleic, l-tartaric acids and their Na, K salts</li> <li>- Sorbic acid and its NH<sub>4</sub>, Ca, Mg, K and Na salts</li> </ul>	

DENOMINATIONS	RESTRICTIONS
<ul style="list-style-type: none"><li>- 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</li><li>- Natural edible starches and flours</li><li>- Edible starches and flours modified by chemical treatment</li><li>- Amylose</li><li>- Calcium and magnesium carbonates and chloride</li><li>- 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</li><li>- 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</li><li>- Esters of sorbitol with linear fatty acids, saturated or unsaturated with an even number of carbon atoms from 8 to 20 inclusive</li><li>- Mono and/or di esters of stearic acid with ethanediol and/or bis(2-hydroxyethyl) ether and/or triethylene glycol</li><li>- Oxides and hydroxides of Aluminium, Calcium, Magnesium and Silicon and silicates and hydrated silicates of Aluminium, Calcium, Magnesium and Potassium</li><li>- Polyethylene oxide [Polyethylene glycol]</li><li>- Sodium Propionate</li></ul>	<p>(according to SCF Report of the 27th February 1976-second series - Dec. 1976)</p> <p>Average molecular weight between 1200 and 4000</p>

DENOMINATIONS	RESTRICTIONS
<u>Additives 2nd class</u> : . . . . .	$\leq 1$ mg/dm <sup>2</sup> in total and, unless otherwise indicated, the total quantity of each substance or group of substances should not exceed 0,2 mg/dm <sup>2</sup>
- Sodium alkyl (C8-C18) benzenesulphonate	
- Sodium isopropyl naphthalene sulphonate	
- Sodium alkyl (C8-C18) sulphate	
- Sodium alkyl (C8-C18) sulphonate	
- Sodium dioctylsulphosuccinate	
- Distearate of di-hydroxyethyl di-ethylene triamine mono-acetate	$\leq 0.05$ mg/dm <sup>2</sup> in total on the side in contact with foodstuffs
- Ammonium, magnesium, potassium and lauryl sulphates	
- N - N' distearoyl diaminoethane	
[NN' distearoyl ethylenediamine] and	
N - N' dipalmitoyl diaminoethane.	
[NN' dipalmitoyl ethylenediamine] and	
N - N' dioleoyl diaminoethane	
[NN' dioleoyl ethylenediamine]	
- 2-heptadecyl - 4, 4 bis (methylenestearate) oxazoline	
- Polyethylene amino stearamide ethylsulphate	$\leq 0,1$ mg/dm <sup>2</sup> in total on the side in contact with foodstuffs
<u>Additives 3rd class - Anchoring agents</u> . . . . .	$\leq 1$ mg/dm <sup>2</sup> in total
- Condensed melamine-formaldehyde, modified or unmodified : Condensation product of melamine-formaldehyde, modified with one or more of the following products : butanol, diethylene-tetramine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3-3 diaminodipropylamine, 4-4 diaminodibutylamine	Free formaldehyde content on side in contact with foodstuffs $\leq 0,5$ mg/dm <sup>2</sup> Free melamine content on side in contact with foodstuffs $\leq 0,3$ mg/dm <sup>2</sup>



Second Part :

COATED, REGENERATED CELLULOSE FILM

DENOMINATIONS	RESTRICTIONS
<u>Regenerated Cellulose</u> . . . . .	see 1st part
<u>Softeners</u> . . . . .	see 1st part
<u>Anchoring agents</u> . . . . .	see 1st part
<u>Coating</u> : . . . . .	≤ 50 mg/dm <sup>2</sup> on the side in contact with foodstuffs
Polymers : . . . . .	≤ 50 mg/dm <sup>2</sup> in total on the side in contact with foodstuffs
- Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
- Cellulose nitrate . . . . .	≤ 20 mg/dm <sup>2</sup> 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 <sub>1</sub> to C <sub>6</sub> ).	
Vinylacetate	
Alkyl C <sub>1</sub> to C <sub>4</sub> vinyl ethers	
Acrylic, crotonic, itaconic, maleic, methacrylic acids and their esters	
Butadiene	
Styrene	
Methylstyrene	
Vinylchloride . . . . .	according to the VCM directive 78/142/EEC O.J. L44, 15.2.1978, p.15
Vinylidenechloride	
Acrylonitrile	
Methacrylonitrile	
Ethylene, propylene, butylene 1 et 2	





DENOMINATIONS	RESTRICTIONS
- Butylbenzylphthalate	
- Butyl-methylcarboxybutylphthalate [Butylphthalylbutylglycolate]	
- Di-n-butyl and di-isobutyl phthalate	
- Dicyclohexyl phthalate	
- Di (2-ethyl-hexyl) phthalate	
- Di (methyl-cyclohexyl) phthalate and its isomers [Sextolphthalate]	
- 2-Ethylhexyl diphenyl phosphate . . . . .	≤ 2,5 mg/dm <sup>2</sup> on the side in contact with foodstuffs
- Glycerine mono-acetate [Monoacetine]	
- Glycerine di-acetate [Diacetine]	
- Glycerine tri-acetate [Triacetine]	
- Methyl-methylcarboxyethyl phthalate [Methylphthalylethyl-glycolate]	
- Di-butyl sebacate	
- Di(2-ethylhexyl) sebacate [Dioctylsebacate]	
- Di-n-butyl tartrate and di-iso-butyl tartrate	

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DENOMINATIONS

RESTRICTIONS

Other additives : . . . . .

≤ 6 mg/dm<sup>2</sup> in total on the side in contact with foodstuffs

(a) Additives listed in the first part : . . . . .

Same particular restrictions of the first part (parties in mg/dm<sup>2</sup> refer however to the side in contact with the foodstuffs)

(b) Specific coating additives : . . . . .

individual  
Total quantity of v substances or group of substances may not exceed 2 mg/dm<sup>2</sup> 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 oleoyl linear alcohols

- Montan waxes, comprising purified montanic (C<sub>26</sub> to C<sub>32</sub>) acids and/or their esters with ethenediol and/or 1-3 butanediol and/or their calcium and potassium salts

- Carnauba wax

- Beeswax

- Esparto wax

- Candellilla wax

- Dimethylpolysiloxane . . . . .

≤ 1 mg/dm<sup>2</sup> on the side in contact with foodstuffs

- Epoxidised soya-bean oil (oxirane content 6 - 8 %)

- Refined paraffin and microcrystalline waxes

- Pentaerythritol tetrastearate

- Mono and bis (octadecyl-di(ethyleneoxide) phosphates . . . . .

≤ 0,2 mg/dm<sup>2</sup> on the side in contact with ~~foodstuffs~~

- Aliphatic acids (C<sub>8</sub>-C<sub>20</sub>) esterified with mono or di (2 hydroxyethyl) amine

- 2- and 3- tert. butyl- 4 hydroxyanisol  
[Butylhydroxyanisol - BHA]

≤ 0,06 mg/dm<sup>2</sup> on the side in contact with foodstuffs

DENOMINATIONS	RESTRICTIONS
- 2,6-di-tert, butyl-4 methylphenol . . . . . [ Butylhydroxytoluene - BHT ]	≤ 0,06 mg/dm <sup>2</sup> on the side in contact with foodstuffs
- Di-n-octyltin-bis (2-ethylhexyl) maleate . . . . .	≤ 0,06 mg/dm <sup>2</sup> on the side in contact with foodstuffs
<u>Solvents</u> : . . . . .	Total quantity of all substances or group of substances may not exceed 0,6 mg/dm <sup>2</sup> 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 - Methyl ethyl ketone - Methylisobutyl ketone - Tetrahydrofurane - Toluene	. . . . .

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