

**COMMISSION DIRECTIVE 2004/14/EC**  
**of 29 January 2004**  
**amending Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film**  
**intended to come into contact with foodstuffs**  
 (Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European 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<sup>(1)</sup>, as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council<sup>(2)</sup>, and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) 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<sup>(3)</sup>, as amended by Directive 93/111/EC<sup>(4)</sup>, applies to regenerated cellulose film and establishes a list of authorised substances together with restrictions on their use. That Directive covers regenerated cellulose films uncoated or coated with coatings manufactured only with substances listed therein.

(2) Further to technological developments, it is necessary to authorise a new type of regenerated cellulose film with a coating consisting of plastics, which is compostable and biodegradable. This new type of regenerated cellulose film is consistent with the environmental requirements of Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste<sup>(5)</sup>, as amended by Regulation (EC) No 1882/2003. Accordingly, such authorisation is in the interest of consistency of Community legislation.

(3) The rules to be applied to the regenerated cellulose films should be specific to the nature of the layer in contact with the foodstuff. Accordingly, the requirements for regenerated cellulose films coated with coatings consisting of plastics should be different from those provided for regenerated cellulose films uncoated or coated with coatings derived from cellulose.

(4) Only authorised substances should be used in the manufacture of all the types of regenerated cellulose films, including regenerated cellulose films coated with plastics.

(5) In the case of regenerated cellulose films coated with coatings consisting of plastics, the layer in contact with foodstuffs consists of a material similar to plastic materials and articles intended to come into contact with foodstuffs. Therefore it is appropriate that the rules provided for in Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs<sup>(6)</sup> should be applicable also to such films.

(6) In the interest of consistency of Community legislation, the verification of compliance of plastic-coated regenerated cellulose films with the migration limits set by Directive 2002/72/EC should be carried out according to the rules laid down in Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>(7)</sup>, as last amended by Commission Directive 97/48/EC<sup>(8)</sup>, and Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>(9)</sup>.

(7) A number of polymers used as coatings should be deleted from the list of authorised substances set out in Directive 93/10/EEC as they are covered by the rules set out in Directive 2002/72/EC which apply to plastic-coated regenerated cellulose films.

(8) Four solvents should also be deleted from the list of authorised substances set out in Directive 93/10/EEC as new data are available showing a risk for reproduction and because they are no longer used in the manufacture of regenerated cellulose films. In addition, some plasticisers, which are no longer used, should also be deleted from that list.

<sup>(1)</sup> OJ L 40, 11.2.1989, p. 38.

<sup>(2)</sup> OJ L 284, 31.10.2003, p. 1.

<sup>(3)</sup> OJ L 93, 17.4.1993, p. 27.

<sup>(4)</sup> OJ L 310, 14.12.1993, p. 41.

<sup>(5)</sup> OJ L 365, 31.12.1994, p. 10.

<sup>(6)</sup> OJ L 220, 15.8.2002, p. 18.

<sup>(7)</sup> OJ L 297, 23.10.1982, p. 26.

<sup>(8)</sup> OJ L 222, 12.8.1997, p. 10.

<sup>(9)</sup> OJ L 372, 31.12.1985, p. 14.

- (9) In addition, the restriction on the use of 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2-ethylhexyl ester) set out in Directive 93/10/EEC should be amended to take into account the opinion of the Scientific Committee on Food of 19 March 1998.
- (10) Directive 93/10/EEC should therefore be amended accordingly.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 93/10/EEC is amended as follows:

1. In Article 1(3), point (a) is deleted.
2. The following Article 1a is inserted:  
*'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.'
3. Article 2(1) is replaced by the following:  
'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.'
4. The following Article 2a is inserted:  
*'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.

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.'

5. Annex II is amended in accordance with the Annex to this Directive.

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 July 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

Member States shall apply those provisions in such a way as to:

- (a) 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;
- (b) 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. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 29 January 2004.

*For the Commission*

David BYRNE

*Member of the Commission*

## ANNEX

The second part of Annex II to Directive 93/10/EEC is amended as follows:

1. In the third line (C. Coating) of the second column (Restrictions) of the table: 'Not more than 50 mg of coating/dm<sup>2</sup> of film on the side in contact with foodstuffs' is deleted.
2. The following polymers and their restrictions are deleted from the table:

Denominations	Restrictions
— Polymers, copolymers and their mixtures made with the following monomers: vinyl acetals derived from saturated aldehydes (C <sub>1</sub> to C <sub>6</sub> ) vinyl acetate alkyl (C <sub>1</sub> to C <sub>4</sub> ) 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	In accordance with Community directives, and, in their absence, with national legislation pending the adoption of Community directives  According to Directive 78/142/EEC (OJ L 44, 15.2.1978, p. 15)

3. For resins, the content of the column 'Restrictions' of the table is replaced by the following:

'2. Resins	The total quantity of substances may not exceed 12,5 mg/dm <sup>2</sup> 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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4. The following plasticisers and their restrictions are deleted from the table:

Denominations	Restrictions
— Butylbenzylphthalate	Not more than 2,0 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs
— Di-n-butyl phthalate	Not more than 3,0 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs
— Di(2-ethylhexyl) sebacate [= dioctylsebacate]'	

5. For the following plasticiser, the content of the column 'Restrictions' of the table is replaced by the following:

Denominations	Restrictions
— 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 <sup>2</sup> in the coating on the side in contact with foodstuffs'

6. The following solvents are deleted from the table:

Denominations	Restrictions
— Ethyleneglycol monoethyl ether — Ethyleneglycol monoethyl ether acetate — Ethyleneglycol monomethyl ether — Ethyleneglycol monomethyl ether acetate'	