II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 92/15/EEC

of 11 March 1992

amending Council Directive 83/229/EEC 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

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 (2) thereof,

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 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, clearly intended for this use;

Whereas Article 4 (2) of Council Directive 83/229/EEC (2), as amended by Directive 86/388/EEC (3), enables Member States to decide whether to allow the use of phthalic esters pending scientific research to assess the risk associated with the use of such substances;

Whereas the scientific data available now make it possible to lay down thresholds below which human exposure to these substances does not involve any risk to human health; whereas, therefore, these substances should be authorized throughout the Community;

Whereas the additives authorized for use in the manufacture of coatings intended to cover regenerated cellulose film should also include the additives used in the manufacture of such film;

Whereas, on the basis of information available, the use of certain new substances may be permitted;

Whereas the Scientific Committee for Food, in accordance with Article 3 of Directive 89/109/EEC, has been consulted on the provisions liable to affect public health;

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

Directive 83/229/EEC is hereby amended as follows:

1. the following Article 3a is added:

'Article 3a

1. At the marketing stages other than the retail stage, materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs shall be accompanied by a written declaration in

(1) OJ No L 40, 11. 2. 1989, p. 38.
(2) OJ No L 123, 11. 5. 1983, p. 31.
(3) OJ No L 228, 14. 8. 1986, p. 32.

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.

(*) OJ No L 40, 11. 2. 1989, p. 38.';

2. paragraph 2 of Article 4 is deleted;

3. in the first part of Annex II, the letter B is added in the 'Denominations' column before the subtitles: '1. Softeners' and '2. Other additives';

4. in the first part of Annex II the following indent is inserted in the list 'B.1. Softeners'; 'Denominations' column, after sorbitol: '— tetraethyleneglycol';

5. (a) in the first part of Annex II the following indent is inserted after the first indent of subheading 'Third class — Anchoring agents' of heading 'B.2. Other additives', in the 'Denominations' column:

'— condensation products of melamine-urea-formaldehyde modified with tris (2-hydroxyethyl) amine';

(b) against this item and under the column 'Restrictions' the following is added:

'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';

6. (a) in the Second Part of Annex II, the letter C is added in the 'Denominations' column, before the subtitles '1. Polymes 2. Resins 3. Plasticizers';

(b) the following substances are delected from the 'Denominations' column, section 'C.3. Plasticizers':

'— butyl-methylcarboxybutyl phthalate [=butyl-phthalyl butyl glycolate]

— di-isobutyl phthalate

— di-(methylcyclohexyl) phthalate and its isomers [=sextolphthalate]

— methyl-methylcarboxyethyl phthalate [=methylphthalyl ethyl glycolate]';

(c) the following is added in the 'Restrictions' column for the substance '— butylbenzylphthalate':

'⩽ 2 mg/dm² in the coating on the side in contact with foodstuffs';

(d) the following is added in the 'Restrictions' column section 'C.3. Plasticizers' for the substance '-di-n-butyl phthalate':

'⩽ 3 mg/dm² in the coating on the side in contact with foodstuffs';

(e) the following is added in the 'Restrictions' column section 'C.3. Plasticizers' for the substance '— dicyclohexyl phthalate':

'⩽ 4 mg/dm² in the coating on the side in contact with foodstuffs';

(f) the following is inserted in the 'Denominations' and 'Restrictions' columns after Section 'C.3. Plasticizers':

'C.4. *Other additives*	⩽ 6 mg/dm² in total in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs.
C.4.1. *Additives listed in the first part*	Same restrictions as in the first part (however, the quantities in mg/dm² refer to the uncoated regerated cellulose film, inclusive of the coating on the side in contact with foodstuffs).';

(g) heading 4 'Specific coating additives', in the 'Denominations' column is replaced by 'C.4.2. Specific coating additives';

(h) against the heading 'C.4.2. Specific coating additives' the text in the column 'Restrictions' is replaced by the following:

'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) in the coating on the side in contact with foodstuffs';

(i) heading 'D. Solvents' is replaced by 'C.5. Solvents'.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 1993. They shall immediately inform the Commission thereof.

Those laws, regulations and administrative provisions shall apply as follows:

Member States shall:

— permit, by 30 June 1993, the trade and use of regenerated cellulose film complying with Directive 83/229/EEC, as amended by this Directive,

— prohibit, as from 1 July 1994, the trade and use of regenerated cellulose film which is intended to come into contact with foodstuffs and which does not conform to Directive 83/229/EEC, as amended by this Directive.

2. When Member States adopt the measures reffered to in paragraph 1, the measures 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 3

This Directive is addressed to the Member States.

Done at Brussels, 11 March 1992.

For the Commission

Martin BANGEMANN

Vice-President