

## COUNCIL DIRECTIVE

of 30 January 1978

on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs

(78/142/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<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<sup>(2)</sup>,

Having regard to the opinion of the Economic and Social Committee<sup>(3)</sup>,

Whereas Article 2 of Directive 76/893/EEC provides that materials and articles must not transfer any constituents to foodstuffs in quantities which could endanger human health;

Whereas Article 3 of the same Directive provides that the Council, under the procedure provided for in Article 100 of the Treaty, shall adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives); whereas these provisions may include specific limits on the migration of certain constituents into or onto foodstuffs as well as other rules to ensure compliance with Article 2 of the said Directive;

Whereas the administration of large doses of vinyl chloride monomer to experimental animals has been shown to produce harmful effects; whereas such effects could also occur in man;

Whereas the Scientific Committee for Food has given the opinion that the levels of vinyl chloride monomer in polyvinyl chloride and related polymers should be reduced as far as possible and at the same time recommended that no trace of vinyl chloride should be detectable in food or potable water by a method which can be generally applied to the majority of foodstuffs by most laboratories;

Whereas further research is at present being conducted on vinyl chloride monomer, but as a precaution the ingestion of vinyl chloride monomer should be restricted until the results are known;

Whereas the appropriate instrument for attaining this objective is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC, the general provisions of which also become applicable in this particular case;

Whereas, however, this Directive does not concern all aspects of materials and articles prepared from vinyl chloride polymers or copolymers and the Member States should therefore be authorized not to require that labels carry the particulars laid down in Article 7 of Directive 76/893/EEC, in accordance with the opinions provided for in paragraphs 4 and 5 of that Article,

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 concerns the presence of vinyl chloride monomer in, and possible migration from, materials and articles prepared with vinyl chloride polymers or copolymers, hereinafter called 'materials and articles', which in their finished state are intended to come into contact with foodstuffs, or which are in contact with foodstuffs and are intended for that purpose.

*Article 2*

1. Materials and articles must not contain vinyl chloride monomer in a quantity exceeding that laid down in Annex I.

2. Materials and articles must not pass on to foodstuffs which are in or have been brought into contact with such materials and articles any vinyl chloride detectable by the method which complies with the criteria laid down in Annex II.

<sup>(1)</sup> OJ No L 340, 9. 12. 1976, p. 19.

<sup>(2)</sup> OJ No C 118, 16. 5. 1977, p. 70.

<sup>(3)</sup> OJ No C 114, 11. 5. 1977, p. 13.

*Article 3*

The method of analysis necessary for checking compliance with Article 2 shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC and shall comply with the criteria laid down in Annex II.

*Article 4*

The Council shall review this Directive on the basis of reports from the Commission drawn up in the light of scientific and technical knowledge becoming available after adoption of the Directive and accompanied, where appropriate, by suitable proposals. The first report from the Commission shall be forwarded to the Council not later than 1 January 1979.

*Article 5*

This Directive shall not affect national provisions relating to other possible rules provided for in Article 3 of Directive 76/893/EEC or the options afforded to Member States under Article 7 (4) and (5) of that Directive.

*Article 6*

1. Member States shall bring into force the laws, regulations and administrative provisions needed in order to comply with this Directive not later than 26 November 1979. They shall forthwith inform the Commission thereof.

2. Member States may defer the introduction of Article 2 (2) and Annex II until such time as a Community method of analysis, as required by Article 3, has been adopted.

*Article 7*

This Directive is addressed to the Member States.

Done at Brussels, 30 January 1978.

*For the Council*

*The President*

P. DALSAGER

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*ANNEX I*

Maximum vinyl chloride monomer level in materials and articles

One milligram per kilogram in the final product.

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*ANNEX II*

Criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles

1. The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the 'headspace' method.
  2. For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit shall be 0.01 mg/kg.
  3. Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in certain foodstuffs is shown to be impossible for technical reasons, Member States may permit determination by simulants for these particular foodstuffs.
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