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Proposal for a

COUNCIL DIRECTIVE

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

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(submitted to the Council by the Commission)

EXPLANATORY MEMORANDUM

I. General

Vinyl chloride monomer (VC) is a colourless gas which is used as a basic substance in the production of polyvinyl chloride (PVC), at present one of the plastics most commonly used for the packaging of food products. Until 1960, VC was regarded as a harmless gas with a narcotic effect. In the early sixties some scientists demonstrated that VC had harmful effects on health and caused acrosteolysis, scleroderma, and liver diseases. In 1970, it was first suspected that VC could, when inhaled, be responsible for oncogenous effects. In 1973 and 1974, the simultaneous discovery of tumours of the same type (angiosarcoma in the liver) in rats exposed to high doses of VC and in men who had worked for long periods in the PVC industry confirmed the validity of the early suspicions.

While experiments were being carried out on inhalation of VC, research was started in 1974 to determine the effects on rats of the administration of VC per os. After about a year of this research the discovery of tumours in some rats immediately prompted the Commission departments concerned to question the Scientific Committee for Foodstuffs[1], which on 27 June 1975 had delivered an opinion which included the following passage: "The aim should therefore be to take all possible steps to reduce all forms of exposure to VC ... The levels of VC in PVC and related polymers should be reduced as far as possible ... VC should not be detectable in food or potable water by an agreed method ...". At a subsequent meeting held on 13-14 November 1975, the Scientific Committee recognized the limits of sensitivity of the methods and suggested, as a temporary measure, the adoption of "a method of analysis which would be applicable generally to most foods by most control laboratories with a unit of detection of 0.050 mg/kg".

In order to study ways of applying the opinion of the Scientific Committee and of defining the method of analysis for VC, the Commission organized several meetings with representatives of the Member States' Governments and of the PVC industry, and asked for the opinion of the Advisory Committee on Foodstuffs[2], in which the various economic and social groups are represented.

Until the various series of experiments currently in hand in many countries have been completed and the results of the research allow an exact assessment to be made of the risk inherent in the use of VC in materials and articles intended to come into contact with foodstuffs, the Commission wishes, as a precautionary step, to present the appended proposal for a directive.

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[1] OJ No L 136 of 20 May 1974.

[2] OJ No L 182 of 12 August 1975.

II. Comments on the proposal for the directive

The appended draft represents a directive implementing the Directive 76/.../EEC of 22 November 1976 concerning materials and articles intended to come into contact with foodstuffs (Article 1). It proposes fixing limits for the VC content in materials and articles prepared with VC and in foodstuffs which come into contact with such materials and articles (Article 2 and Annex I).

The fixing of limits for the VC content of materials and articles as well as for the presence of VC in foodstuffs is proposed with a view to reducing to a minimum the probability of VC migration into foodstuffs, and thus offering an additional guarantee to the consumer. Furthermore, the fixing of such limits obliges industry to monitor the production of PVC materials and articles continuously and allows the State to intervene, if necessary, before the marketing of the materials and articles, or the foodstuffs with which such materials and articles are in contact. Monitoring of the VC level in foodstuffs, although essential (according to the opinion of the Scientific Committee: "there is no good correlation between the free vinyl chloride monomer concentration in PVC and the related polymers and the amount of VC migrating into food in contact with these polymers"), does not permit preventive monitoring of production and does not reduce the presence of VC in foodstuffs to an absolute minimum, since this minimum depends on the sensitivity and accuracy of the analytical methods. Finally, the fixing of a limit on VC in materials and articles is an effective and simple way of reducing to a minimum the migration of VC from materials and articles (e.g. tubes, plastic sheets, parts of apparatus used for food processing) in cases where the fixing of a VC limit in the foodstuff would be totally inadequate to protect consumer health, since such materials and articles are not marketed together with the food but are intended to come into contact only incidentally when official government inspection cannot be carried out.

The maximum value of 0.050 mg/kg for VC in foodstuffs is the minimum amount which can at present be determined with sufficient accuracy in the majority of foodstuffs by the majority of laboratories. This value is also the one currently envisaged in the laws or proposed laws already existing in the countries of the European Community. The maximum values for VC in the various types of PVC materials and articles, however, represent the minimum quanities which can now be obtained by applying the most advanced technologies. With these limits and on the basis of currently available scientific documentation, it is highly probable that the maximum quantity of VC present in foodstuffs under the most stringent conditions of preservation is well below 0.050 mg/kg.

Since further developments in the manufacturing techniques used for PVC materials and articles, in the methods of determining VC in foodstuffs and in the assessment of the hazards presented by VC are to be expected, a rapid procedure for adapting the Directive to technical progress is also provided for (Article 4).

Annex II sets out the method of analysis to be used for verifying VC levels in foodstuffs and PVC materials or articles.

III. Consultation of the European Parliament and the Economic and Social Committee

The text now proposed will constitute a "specific Directive" within the meaning of Article 3 of the Directive 76/..../EEC and therefore must be adopted under the procedure provided for in Article 100 of the Treaty - By virtue of the second paragraph of this latter Article, consultation with the European Parliament and the Economic and Social Committee is required.
Implementation of the provisions of the Directive will involve amendments to the legal provisions in all the Member States.

Proposal for a Council Directive on the approximation of the laws of the Member States relating to materials and articles containing vinyl chloride monomer and intended to come into contact with foodstuffs

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THE COUNCIL TO THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Directive 76/..../EEC of 22 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs, 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/..../EEC provides that materials and articles must not transfer to foodstuffs any constituents in quantities liable to endanger public 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 Directive 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 and whereas such effects could also occur in man;

Whereas the Scientific Committee for Foodstuffs 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";

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(1) J.O. n° L .....

Whereas further research is at present in progress on vinyl chloride monomer, but as a precaution the absorption of vinyl chloride monomer should be restricted until these results are known;

Whereas the adaptation of the Directive to technical progress is an implementing measure and whereas, 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 rules relating to materials and articles intended to come into contact with foodstuffs, a procedure should be laid down establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs set up under the Council Decision of 13 November 1969,

HAS ADOPTED THIS DIRECTIVE :

Article 1

Pursuant to Article 3 of the Directive 76/.../EEC of 22 November 1976 this Directive concerns materials and articles prepared with vinyl chloride polymers or copolymers 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. They are hereinafter called "materials and articles".

Article 2

Materials and articles shall not contain vinyl chloride monomer in quantities exceeding the limits laid down in Annex I.

Foodstuffs having come into contact with materials and articles shall not contain vinyl chloride monomer in quantities exceeding the limit laid down in Annex I.

Article 3

Compliance with the limits laid down in Annex I shall be checked by the method described in Annex II.

Article 4

Amendments to adapt the Annexes to this Directive in accordance with developments in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 10 of the Directive 76/.../EEC of 22 November 1976.

Article 5

This Directive shall not affect national provisions relating to other possible standards provided for in Article 3 of the Directive 76/.../EEC of 22 November 1976.

Article 6

1. To comply with the provisions of this Directive, the Member States shall, where necessary, amend their respective laws by 1 January 1978 and inform the Commission forthwith.

2. The laws as thus amended shall be applied with effect from 1 July 1978 both to materials and articles, and to foodstuffs with which such materials and articles have come into contact.

Article 7

This Directive is adressed to the Member States.

ANNEX I

Limits of vinyl chloride monomer in materials, articles and foodstuffs

Materials and articles:	1 mg/kg in the final product. However, in the case of materials and articles prepared with vinyl chloride copolymers and not intended for use in packaging or containing liquids for human consumption, the limit shall be 5 mg/kg.
Foodstuffs:	0.050 mg/kg.

ANNEX II

Determination of vinyl chloride (VC) monomer in materials, articles and foodstuffs

1. Principle

The presence of VC in foodstuffs, materials or articles is determined by means of gas-liquid chromatography using the "head space" method after solution or suspension of the sample in dimethylacetamide (DMA).

2. Reagents

2.1 VC, of purity greater than 99.5%.

2.2 N-N DMA, not containing any volatile impurity, with the same chromatography retention time as VC.

2.3 Any appropriate internal standard solution, such as diethyl ether in DMA.

3. Apparatus

NB. An instrument or piece of apparatus is mentioned only if it is special or made to particular specifications; usual laboratory apparatus is assumed to be available.

3.1 Gas chromatograph fitted with an automatic head-space sampler and flame ionization detectors. Alternatively, a gas chromatograph fitted for manual sample injection and equipped with a flame ionization detector may be used. It has also been found that it is satisfactory to use a specific detector in the gas chromatograph instead of a flame ionization detector, e.g., a micro-electrolytic conductivity detector of the kind described in the Journal of Chromatographic Science, Vol. 12 (March 1974), p. 152.

3.2 A potentiometer.

3.3 Sample phials or flasks fitted with a silicone or butyl rubber septum.

When using the manual technique, the taking of a sample in the head space by means of a syringe may cause the formation of a partial vacuum inside the phial or flask. Hence, for manual techniques where the phials are not pressurized before the sample is taken, the use of large phials is recommended.

3.4 Micro-syringes.

3.5 Gas-tight syringes for manual head-space sampling.

4. Procedure

4.1 Preparation of standard VC solution

NB. VC must be handled in a ventilated fume cupboard.

Weigh a suitable glass vessel accurately and place in it a quantity (e.g., 50 ml) of DMA. Reweigh. Add to the DMA a quantity of VC (e.g., 0.1 mg) in liquid or gas form, in the latter case by bubbling in or injecting. After again reweighing, calculate from the difference the quantity of VC in solution and hence the concentration of the solution obtained (standard solution). This standard solution will keep for a long time if stored in a refrigerator.

Prepare a dilute VC solution by taking an aliquot of standard solution and adding it to a predetermined quantity of DMA contained in an already tared glass phial, at the same time reducing the volume of air (head space) as much as possible. Reweigh and calculate the VC concentration by difference.

4.2 Preparation of sample

NB. Take all the necessary precautions to ensure that no VC is lost through volatilization.

Take samples of foodstuffs, materials or articles in such a way that they are representative of the product under investigation. For this purpose, in the case of non-liquid foodstuffs, homogenize the samples under investigation accurately before taking an aliquot.

4.2.1 Foodstuff sample

Weigh accurately into each of a set of three phials a suitable quantity of foodstuff under investigation. If considered necessary, add an appropriate quantity of DMA (this sometimes promotes the attainment of a state of equilibrium) and/or of the internal standard. Seal immediately and homogenize.

4.2.2 Calibration curve for the determination of VC in foodstuffs

Weigh into each of a set of not less than five phials a proportionate quantity of the same foodstuff which has never been in contact with materials or articles containing VC. If some DMA and/or some of the internal standard has been added to the foodstuff sample under section 4.2.1, add proportionate quantities to each reference sample.

Finally, add diluted standard VC solution in quantities such as give VC concentrations equal to 0.000, 0.050, 0.075, 0.100, 0.150, etc., mg/kg. Seal immediately and homogenize.

4.2.3 Sample of material and article

Weigh accurately into each of a set of three phials about 200 mg of the material or article, sampled from the product under investigation and reduced to small size. Insert a magnetic stirrer and about 2 ml of DMA containing, if considered necessary, an appropriate quantity of internal standard solution. Seal the phial, suspend it in a waterbath held at 60-70 °C and dissolve the sample by stirring the solution vigorously.

4.2.4 Calibration curve for the determination of VC in materials or articles

Place about 200 mg of a material or article of the same type as described in section 4.2.3, not containing any detectable amount of VC, in each of a set of not less than five phials. Insert a magnetic stirrer and add about 2 ml of DMA containing a suitable quantity of internal standard, if this has been used under section 4.2.3.

Dissolve the material or article by stirring. Add diluted standard VC solution in quantities such as give a range of concentrations comprising the concentration of the VC in the sample under investigation. Seal immediately and homogenize.

4.3 Gas-chromatography determination

4.3.1 Bring the sample to a state of equilibrium

Allow the samples contained in the sealed phials a sufficient time to attain a state of equilibrium before beginning the head-space sampling operation. A period of two hours at 50°C is usually sufficient for this purpose.

4.3.2 Determination

Choose a gas-chromatography column and operating conditions such that the product under investigation does not interfere with the VC or, if applicable, with the internal standard. Periodically flush the column so as to eliminate DMA peaks from the chromatogram. Measure the area (or height) of the peaks representing the VC or the internal standard, if used, and deduce the VC concentration of the sample of foodstuff, material or article under investigation from the constructed calibration curves.

4.4 Interference peaks on the chromatograms

Certain foodstuffs give rise to interference peaks. In that event, confirm that VC is actually present in the foodstuff sample, either by using a micro-electrolytic conductivity detector as mentioned in section 3.1 or by means of mass spectrometry. In this event, the fact that molecular ions with parent masses (m/e) of 62 and 64 are present in the ratio of 3:1 is regarded as confirming that VC is present. If such interference is confirmed, use a different column.