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COUNCIL DIRECTIVE

of 20 December 1985

concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption

(85/591/EEC)

(OJ L 372, 31.12.1985, p. 50)

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COUNCIL DIRECTIVE

of 20 December 1985

concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption

(85/591/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 the proposal from the Commission ([1]),

Having regard to the opinion of the European Parliament ([2]),

Having regard to the opinion of the Economic and Social Committee ([3]),

Whereas the production, manufacture, marketing and use of foodstuffs intended for human consumption are of considerable importance in the European Economic Community;

Whereas the methods of sampling and analysis used for this purpose can have direct repercussions on the establishment and functioning of the common market; whereas they should, therefore, be harmonized;

Whereas the laying down of these methods of sampling and analysis constitutes a measure of a purely scientific and technical nature; whereas a rapid procedure for developing, improving and supplementing such methods is necessary; whereas, in order to facilitate the adoption of such measures, a procedure should be introduced for close cooperation between the Member States and the Commission within the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Where it is necessary to introduce Community methods of sampling or analysis for the purpose of determining the composition, conditions of manufacture, packaging or labelling of a foodstuff, such methods shall be adopted by the Commission or by the Council as appropriate in accordance with the procedure laid down in Article 4.

2. Paragraph 1 shall be without prejudice to any specific provisions currently in force or hereafter adopted in the context of special Community rules.

3. For the purposes of determining whether it is necessary to introduce the measures provided for in paragraph 1, the following criteria in particular will be taken into consideration:

(a) the need to ensure that Community law is uniformly applied;

(b) the existence of barriers to intra-Community trade;

(c) the permanent or recurrent nature of the criteria referred to in (a) or (b).

Article 2

1. The Directives provided for in Article 1 shall take account of the state of scientific and technical knowledge, in particular of proven methods of sampling and analysis.

([1]) OJ No C 53, 24. 2. 1984, p. 9.
([2]) OJ No C 46, 18. 2. 1985, p. 95.
([3]) OJ No C 44, 15. 2. 1985, p. 1.

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2. Such Directives shall specify appropriate time limits for Member States to implement them.

3. The introduction of the measures provided for in Article 1 (1) shall not preclude Member States from using other tested and scientifically valid methods provided that this does not hinder the free movement of products recognized as complying with the rules by virtue of Community methods. However, in the event of differences in the interpretation of results, those obtained by the use of Community methods shall be determinant.

4. The methods of analysis introduced shall comply with the criteria set out in the Annex.

5. Without prejudice to Article 3, the necesaary amendments to existing Directives in so far as appropriate in view of the advanced state of scientific and technological knowledge may, at the request of a Member State, be adopted by means of the procedure provided for in Article 4.

Article 3

1. Where a Member State has detailed evidence that a measure adopted in accordance with Article 1 is inappropriate in a particular case for technical reasons or because it is insufficiently conclusive for the examination of an important health question, that Member State may temporarily suspend the measure in question in its territory but only for that particular case. It shall immediately inform the other Member States and the Commission thereof and give reasons for its decision.

2. The Commission shall examine as soon as possible the evidence given by the Member State and then consult the Member States within the Standing Committee for Foodstuffs referred to in Article 4, after which it shall deliver its opinion forthwith and take the appropriate measures.

3. If the Commission considers that amendments to the measure adopted in accordance with Article 1 are necessary in order to resolve the difficulties mentioned in paragraph 1, it shall initiate the procedure laid down in Article 4. The member State which has suspended the Community measure may, in that event, continue to do so until the amendments enter into force.

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Article 4

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002 ([1]), hereinafter referred to as 'the Committee'.

2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC ([2]) shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

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Article 5

Member States shall, within a period of two years following notification thereof ([3]), bring into force by law, regulation or administrative

([1]) OJ L 31, 1.2.2002, p. 1.
([2]) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).
([3]) This Directive was notified to the Member States on 23 December 1985.

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action any provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

Article 6

This Directive is addressed to the Member States.

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ANNEX

1. Methods of analysis which are to be considered for adoption under the provisions of the Directive shall be examined with respect to the following criteria:

   (i) specificity,

   (ii) accuracy,

   (iii) precision; repeatability intra-laboratory (within laboratory) and reproducibility interlaboratory (within and between laboratories) variabilities,

   (iv) limit of detection,

   (v) sensitivity,

   (vi) practicability and applicability,

   (vii) other criteria which may be selected as required.

2. The precision values referred to in 1 (iii) shall be obtained from a collaborative trial which has been conducted in accordance with an internationally recognized protocol on collaborative trials (e.g. International Organization of Standarization 'Precision of Test Methods' (ISO 5725/1981)). The repeatability and reproducibility values shall be expressed in an internationally recognized form (e.g. the 95 % confidence intervals as defined by ISO 5725/1981). The results from the collaborative trial shall be published or freely available.

3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

4. Methods of analysis adopted under this Directive should be edited in the standard layout for methods of analysis recommended by the International Organization for Standardization.