II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on the subject of additional measures concerning the official control of foodstuffs

(92/C 51/13)

COM(91) 526 final — SYN 377

(Submitted by the Commission on 10 February 1992)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas it is necessary to adopt measures with the aim of progressively establishing the internal market over the period expiring on 31 December 1992; whereas the internal market comprises an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured;

Whereas trade in foodstuffs occupies a very important place in the internal market;

Whereas it is therefore essential that the application of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (1) is uniform throughout the Member States; whereas this Directive lays down general rules on the official control of foodstuffs;

Whereas there is a need for additional rules designed to improve the control procedures in force in the Community; whereas Member States should take the necessary action to ensure that the staff of the competent authorities have sufficient technical and administrative competence;

Whereas, in order to guarantee the quality of the test data, a system of quality standards should be introduced for laboratories entrusted by the Member States with the official control of foodstuffs; whereas such a system should comply with generally accepted and standardized norms; whereas, in addition, it is essential that these laboratories use validated methods of analysis, whenever possible;

Whereas the development of trade in foodstuffs between the various Member States necessitates closer cooperation between the authorities involved in the control of foodstuffs;

Whereas general rules are required for the Commission officials specialized in the control of foodstuffs which cooperate with specific officials of the Member States in order to ensure the uniform application of legislation on foodstuffs;

Whereas provisions should be laid down under which the national authorities and the Commission must provide mutual administrative assistance with a view to ensuring proper application of the legislation on foodstuffs, in particular through preventive action and the detection of infringements or behaviour suspected of infringing the rules;

Whereas, in view of the nature of the information exchanged pursuant to this Directive, it should be covered by the requirements of commercial or professional secrecy;

Whereas the results of the implementation of the Commission's coordinated programme on the control of foodstuffs should be published,

(1) OJ No L 186, 30. 6. 1989, p. 23.

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive supplements Directive 89/397/EEC.

2. This Directive shall apply without prejudice to the provisions adopted in the context of more specific Community rules.

Article 2

This Directive:

1. ensures that the training of the food control officials is such that their technical and administrative competence is adequate;

2. provides for generally accepted quality standards for laboratories entrusted by the Member States with the official control of foodstuffs and the use of validated methods of analysis by these laboratories whenever possible;

3. introduces provisions for officials of the Commission to cooperate with the competent authorities of the Member States in carrying out controls in the field of foodstuffs;

4. lays down rules for an administrative mutual aid system between Member States;

5. provides for the circulation of annual reports on the implementation of a coordinated programme on the control of foodstuffs whithin the Community.

Article 3

Member States shall ensure that the competent authorities have a sufficient number of suitably qualified and experienced staff, notably in areas such as chemistry, (veterinary) medecine, microbiology, food hygiene, food processing and law so that the controls referred to in Article 5 of Directive 89/397/EEC can be carried out adequately.

Article 4

1. Member States shall take all measures necessary to ensure that the laboratories referred to in Article 7 of Directive 89/397/EEC comply with the general criteria for the operation of testing laboratories laid down in European standard EN 45001 supplemented by Standard Operating Procedures and the random audit of their compliance by quality assurance personnel, in accordance with the OECD principles Nos 2 and 7 of good laboratory practice [1].

2. In assessing the laboratories referred to in Article 7 of Directive 89/397/EEC Member States shall:

(a) apply the criteria laid down in European standard EN 45002; and

(b) require the use of proficiency testing schemes.

Laboratories meeting the assessment criteria shall be presumed to fulfil the criteria referred to in the first paragraph.

Laboratories which do not meet the assessment criteria shall not be considered as laboratories referred to in Article 7 of Directive 89/397/EEC.

3. Member States shall recognize bodies responsible for the assessment of laboratories as referred to in Article 7 of Directive 89/397/EEC. These bodies shall comply with the general criteria for laboratory accreditation bodies laid down in European Standard EN 45003.

Article 5

Member States shall ensure that the methods of analysis used by the laboratories referred to in Article 7 of Directive 89/397/EEC comply whenever possible with the provisions of paragraphs 1 and 2 of the Annex to Council Directive 85/591/EEC of 23 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption [2].

Article 6

1. The Commission shall designate specific officials to cooperate with the competent authorities of the Member States in the control of foodstuffs. The Commission shall ensure that such officials possess the technical expertise and appropriate experience to carry out these controls.

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[1] Section II of Annex 2 to the Decision of the Council of the Organization for Economic Cooperation and Development of 12 May 1981 concerning the mutual acceptance of data in the assessment of chemicals, C(81) 30 (final).

[2] OJ No L 372, 31. 12. 1985, p. 50.

2. The Commission may request the competent authorities of the Member States to carry out controls in conjunction with its specific officials.

3. In performing their duties, the Commission's specific officials shall have the right to carry out the operations provided for in Article 5 of Directive 89/397/EEC on the official control of foodstuffs.

For the purpose of participating in the controls referred to in paragraph 2, the Commission's specific officials shall produce written authorization specifying their identity and status.

4. A Member State in whose territory controls by the Commission's specific officials are being carried out shall give all the necessary assistance to enable them to do their work properly.

5. After the execution of each control operation as referred to in paragraph 2, the Commission shall forward a report on the work of its specific officials to the competent authorities of the Member States concerned; that communication shall record any difficulties encountered or infringements noted.

Article 7

1. The competent authorities of the Member States shall afford each other administrative assistance in all supervisory procedures in connection with legal provisions and quality standards applicable to foodstuffs and in all proceedings for infringements of the law applicable to foodstuffs.

2. On request, the competent authority concerned shall provide the requesting authority with all information enabling that authority to guarantee compliance with legal provisions and quality standards applicable to foodstuffs within its jurisdiction.

In obtaining the information requested, the authority requested to assist or the authority to which it has delegated responsibility shall proceed as if it were acting in discharge of its own responsibilities or at the request of another authority in its home country.

3. The authority requested to assist shall provide the requesting authority with all evidence and documents or certified true copies thereof which are in its possession or which it has acquired pursuant to paragraph 2 and which may assist the requesting authority in the conduct of the procedures referred to in its request.

4. The information and documents provided pursuant to paragraphs 2 and 3 shall be forwarded immediately and through the most appropriate channels in each case.

Article 8

On request, the competent authorities of the Member States shall afford the Commission with the information, evidence and documents as referred to in Article 7 (2) and (3).

Article 9

1. Information forwarded pursuant to this Directive, in whatever form, shall be confidential. Information shall be covered by professional or commercial secrecy and shall qualify for the protection conferred by the national law of the Member States which received it on information of the same type and by the corresponding provisions applying at Community level.

The information referred to in the first subparagraph may not in particular be transmitted to persons other than those who, in the Member States or Community institutions, need to know such information for the purposes of their work. Nor may it be used for the purposes other than those provided for by this Directive, unless the authority which provided it has given explicit consent, and provided that the provisions in force in the Member State where the authority which received it has its seat do not prevent such notification or utilization.

2. This Directive shall not prevent the use, in the course of court proceedings or prosecutions started subsequently for failure to comply with requirements on foodstuffs, of information obtained pursuant to this Directive.

3. The findings of the specific officials of the Commission or of the competent authorities of a Member State in the course of application of this

Directive may be invoked by the competent authorities of the other Member States or by the Commission. In such cases, they shall have no less value because of the fact that they do not come from the Member State in question.

Article 10

Once a year the Commission shall forward to the European Parliament and to the Council a report, containing the separate section on implementation of the coordinated programme, contributed by each Member State, as referred to in Article 14 (3) (3) of Directive 89/397/EEC.

Article 11

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before .... They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, these 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 12

This Directive is addressed to the Member States.