COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 6 February 1992

Proposal for a

COUNCIL DIRECTIVE

ON THE SUBJECT OF ADDITIONAL MEASURES CONCERNING

THE OFFICIAL CONTROL OF FOODSTUFFS

(presented by the Commission)

EXPLANATORY NOTE

Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs, which deals with the general principles of food control, allows for the adoption of more specific provisions. Article 13 of that Directive, which was introduced at the request of the European Parliament, suggests provisions in the field of the basic and further training of food inspectors, quality standards for official food control laboratories, a Community inspection service and the exchange of information on inspections at Community level. Article 13 requests the Commission to report to the European Parliament and to the Council about the possibility of establishing such provisions and in its document (90) 392 final of 13 September 1980, the Commission complied with that request. The document, which was generally well received by the Member States, made it clear that further provisions in this field are an essential precondition for an unrestricted trade in foodstuffs between the Member States. The Directive proposed herewith is largely a consequence of that document.

Articles 1 and 2

These articles define the scope of the Directive.

Article 3

Widely differing methods are used in the Member States for the official control of foodstuffs. Not only do considerable differences occur between a central approach on the one hand, and a local approach on the other, but in one country the emphasis may be placed on the advisory role of the food inspector, whereas in another he or she is clearly seen as having a policing role.

In point of fact, the professional function of a food inspector in the Community has not been defined. In some Member States the term "food inspector" applies to the academically trained and in others that is not the position.

Although there is no point in drawing up Community requirements for the training of food inspectors, as long as the national inspection systems diverge so sharply and the function is not clearly defined, it is nevertheless desirable to allocate areas in which personnel responsible for official inspection must have received certain minimum training. This includes such areas as (veterinary) medicine, chemistry, microbiology, food processing, food hygiene, law, etc.

Article 4

In order to avoid barriers to trade and unnecessary duplication of laboratory tests, mutual recognition of the laboratory results obtained by the inspection bodies should be regarded as an essential precondition for unrestricted trade in foodstuffs between Member States. Given that these laboratory results serve not only as the basis for criminal proceedings within a Member State but also - under the rapid alert system - as the basis for Community measures, steps should be taken in the interests both of human health and of legal security to introduce mandatory requirements in the field of reliability and accuracy. This means that, in those laboratories entrusted by the competent authorities of the Member States with the control of foodstuffs, a system of quality standards should be introduced, so that the quality of the test data can be guaranteed.

The European Standard EN 45,000 series provides a satisfactory model for the repetitive work of these laboratories but it should be supplemented by some provisions of the OECD principles of good laboratory practice in order to have a random check on the compliance of non repetitive laboratory work with Standard Operating Procedures.

Article 5

It is essential that for mutual recognition of laboratory results the working methods of analysis, whenever possible, are fully validated, i.e. methods which have been subjected to a full collaborative trial.

Guidelines on criteria for the validation are given in the Annex of Council Directive 85/591/EEC.
The first section of that Annex states that methods of analysis shall be examined with respect to specificity, limit of detection, sensitivity, accuracy and so on.

Provision 1 (iii) of this Annex specifies parameters such as repeatability and reproduceability values. Information on these can be obtained by carrying out a full collaborative trial.

Article 6

There are a number of arguments in favour of designating a number of Community officials, who are entitled to exercise control acts in the Member States. As has been recognized in other parts of the food sector including fisheries, fresh meat, fruits and vegetables and wine, these officials may have a beneficial influence on the quality and hygiene of products and production.

They are expected to :

- help to coordinate the uniform application of Community law and,
- to assist in resolving Member States problems emanating from the free movement of foodstuffs in the Community.

Furthermore they may help Member States in providing greater uniformity in their control procedures and to promote optimal use of the Commission's Rapid Alert System.
This will provide for a more effective system of dealing with calamities and emergencies in relation to foodstuffs.

Articles 7 and 8

In July 1988 the European Parliament adopted the Stauffenberg report (Document A2-248/87) on judicial and administrative assistance between authorities and courts of the Member States in respect of legal provisions and quality standards applicable to foodstuffs. When debated in Parliament the report was welcomed by the Commission, who undertook to consider the needs for increased judicial and administrative assistance. The present article 7 reflects the report's view on administrative assistance in all supervisory standards in connection with legal provisions and quality standards and all proceedings for infringements of the law, applicable to foodstuffs.
Article 8 involves, on request, the Commission in this exchange of information.

Article 10

In order to improve confidence in food products coming from other Member States this article foresees in the publication of the results of the Commission's coordinated control programme.

Article 11

The deadlines laid down in this article take account of the legislative procedures which must be completed in the various Member States.

PROPOSAL FOR A COUNCIL DIRECTIVE
ON THE SUBJECT OF ADDITIONAL MEASURES CONCERNING
THE OFFICIAL CONTROL OF FOODSTUFFS

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(1) on the official control of foodstuffs 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;

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(1) OJ nr L 186 of 30.06.1989, p. 23

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;

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive supplements Council 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 Council 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 Council 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 n° 2 and 7 of good laboratory practice.(2)

2. In assessing the laboratories referred to in article 7 of Council 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 Council Directive 89/397/EEC.

3. Member States shall recognize bodies responsible for the assessment of laboratories as referred to in article 7 of Council 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 Council Directive 89/397/EEC comply whenever possible with the provisions of paragraph 1 and 2 of the annex of Council Directive 85/591/EEC(3) of 23 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption.

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(2) section II of Annex 2 of the Decision of the Council of the Organisation for Economic Cooperation and Development of 12 May 1981 concerning the mutual acceptance of data in the assessment of chemicals, C (81)30 (final).

(3) OJ nr L 372 of 31.12.1985, p. 50

Article 6

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

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 Council 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 authorisation 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 paragraphs 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 States 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 seperate section on implementation of the coordinated programme, contributed by each Member State, as referred to in article 14 paragraph 3 sub-paragraph 3 of Council 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.

Impact assessment form

The impact of the proposal on business with special reference to small and medium sized enterprises (SMEs)

Title of the proposal

Draft proposal for a Council Directive on the subject of additional measures concerning the official control of foodstuffs.

Reference Number (Répertoire)

The proposal

This proposal which aims at improving the official control of foodstuffs, introduces provisions applicable to the national food inspection services and not to the food businesses themselves.
Therefore the propsosal has no direct impact on the SMEs.

FINANCIAL STATEMENT

SECTION 1: FINANCIAL IMPLICATIONS

1. **Title of operation**

   Community inspection service

2. **Budget headings involved**

- A 11: Staff in active employment

- B8-530: Completing the internal market - Support expenditure

3. **Legal basis**

- Article 100a of the Treaty

4. **Description of operation**

4.1 Officials responsible for Community inspection, as envisaged by Directive 89/397/EEC on the official control of foodstuffs, must in general assume "auditing" tasks, which will involve assistance, on the one hand, in ensuring that Community law is being correctly applied and, on the other, in resolving problems between Member States caused by the free movement of foodstuffs in the Community.

4.2 Duration: indefinite

4.3 Target population

Directly involved: bodies responsible for the control of foodstuffs in the Member States

Indirectly involved: economic operators in the food sector

5. **Classification of expenditure or revenue**

5.1 Non-compulsory
5.2 Non-differentiated, the expenditure involved being chiefly expenditure on staff
5.3 Revenue: nil

6. **Type of expenditure or revenue**

6.4 On regular or outside staff
6.5 No
6.6 No

7. **Financial impact on appropriations for operations (Part B of the budget)**

7.1 In accordance with the scales applied by the Commission to outside staff and to the purchase of data-processing equipment.

7.2 Up to 100% if it proves impossible to recruit regular staff.

7.3 1992, with the recruitment of five external persons:
3 A auxiliaries
1 B auxiliary
1 C auxiliary

Commitment appropriations = payment appropriations

284 550 = 284 550

8. **What anti-fraud measures are planned in the proposal for the operation?**

Not applicable

Section 2: Administrative expenditure (Part A of the budget)

1. **Will the proposed operation involve an increase in the number of Commission staff?**

Yes 15 A officials
2 B officials
3 C officials

This assessment of required staff is based on the following considerations. In order to ensure the success of the audits of national inspection arrangements two officials are needed: one from the Member State which is the subject of the audit, and who therefore has basic knowledge of the authorities of his country, and the other from a different Member State, to ensure total impartiality. Where the mission involves the settlement of a dispute between Member States, three officials will be needed: two with a good knowledge of the systems of the Member States concerned and a third to act as impartial mediator.

The missions themselves will last two weeks, though it may take two months to prepare and draw up the report.

Similar working methods are already being used by the Commission's other inspection services, which employ between 15 and 20 inspectors.

These officials will be recruited gradually. Five are to be recruited in 1992, five in 1993 and five in 1994.

The required staff are to be found either by internal redeployment or under the annual budget procedure.

2. **Indicate the amount of staff and administrative expenditure involved in the proposed operation. Explain the method of calculation.**

Where regular staff are involved, the costs are assessed by DG IX.

Where outside staff are involved, the Commission's current scales have been used.

Section 3: Elements of cost-effectiveness analysis

1. **Objectives and coherence with financial programming**

1.1 Completion of the internal market in the food sector will be effective only when the national inspections are considered equivalent in each Member State and are recognized as such by all the Member States. Even though the Member States remain responsible for the control of foodstuffs, the Commission has a key role to play in this area, e.g. by checking that the inspections are performed to a high standard and putting the authorities responsible for control in the various Member States in contact with each other, and possibly acting as mediator in cases of dispute.

1.2 Yes

1.3 The principal objective falls within the overall objective of completing the internal market and more generally within the framework of ensuring the uniform application of Community law.

2. **Grounds for the operation**

Similar objectives could be attained by setting up a "Food Agency", though this approach has been rejected, since the proliferation of such bodies is politically undesirable. Moreover, even though it is hard to put an exact figure on the cost of setting up a new agency, it would undoubtedly be greater than that of recruiting 15 officials.

Lastly, in view of the auditing duties to be entrusted to these officials, it is better for them to be completely independent of the Member States.

Moreover, similar arrangements exist in other food sectors, such as fisheries, fresh meat, etc.

3. **Monitoring and evaluation of the operation**

3.1 - Number of audit reports
- Number of settlements of disputes between Member States

3.2 A work programme will be finalized at the beginning of each year. This will then be evaluated and set down in a report. The report will be used to draw up the following year's work programme.

3.3 The chief causes of uncertainty are, firstly, whether it will actually be possible to recruit the necessary staff and, secondly, the extent to which the national bodies responsible for the control of foodstuffs will cooperate.

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