

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(91) 525 final - SYN 376

Brussels, 10 January 1992

Proposal for a

COUNCIL DIRECTIVE

ON THE HYGIENE OF FOODSTUFFS

(presented by the Commission)

EXPLANATORY MEMORANDUM

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. The present draft proposal for a Directive on the hygiene of foodstuffs supplements Directive 89/397 by general rules aimed at improving the level of food hygiene in the Community and the verification of the compliance with these rules. It contains precautionary measures to be taken by the entrepreneurs of food businesses in order to ensure safe and healthy foodstuffs. Critical areas such as meat, fish and poultry are already covered by more specific Community regulations but this draft proposal relates to a framework Directive which could serve as a safety net to all foodstuffs concerning the whole chain from production to the sale, to the ultimate consumer.

Article 1 and 2

These articles contain definitions of the scope of the Directive and of certain technical terms.

Article 3

This article can be considered as the key article of the Directive. It not only obliges food business to comply with certain rules of hygiene but it explicitly states that all stages from production until the sale of foodstuffs shall be carried out in a hygienic way. It underlines the importance of the use of HACCP in all food businesses.

Article 4

This article opens the possibility, by using a standard procedure, to adopt microbiological criteria for foodstuffs such as the absence of pathogenic bacteria at levels harmful to human health.

Article 5

Apart from the legal rules which apply to all food businesses and are monitored by the competent authorities, these documents of good hygiene practices which may vary from one branch to another, are voluntary and are monitored by the food business itself. These documents need to be sufficiently specific to ensure that any entrepreneur who complies both with the regulations from the Annex and the documents of good hygiene practices, applicable in this branch, works in a hygienic way within the meaning of article 3, paragraph 1. However, by virtue of its voluntary nature, a document of good hygiene practices is not enforceable under public law and failure to comply does not automatically imply that unhygienic practices have been carried out. Nor can a document of good hygiene practices constitute a barrier to trade within the meaning of Article 30 of the EEC Treaty.

The European standardisation bodies are recommended as the right authorities to adopt these documents. The article further reflects the order of preference which these documents have.

Article 6

The European standards EN 29000 refer to the ISO 9000 series on quality and quality systems. They offer a model for quality assurance on design/development, production installation, surveying, final inspection and test and quality management. Application of the EN 29000 standards may facilitate the implementation of both general rules and the documents of good hygiene practices.

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 hygiene of foodstuffs

(92/C 24/13)

COM(91) 525 final — SYN 376

(Submitted by the Commission on 14 January 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 the free movement of foodstuffs is an essential precondition for the completion of the internal market; whereas the principle of mutual recognition on which it is based implies confidence in the standard of safety for human consumption of foodstuffs in free circulation, and in particular their standard of hygiene, throughout all stages from production and sale to the ultimate consumer;

Whereas it is essential to protect human health; whereas this protection has already been the subject of Council

Directive 89/397/EEC⁽¹⁾ on the official control of foodstuffs as well as of more specific rules in this field; whereas an important objective of such controls is food hygiene; whereas Council Directive 89/397/EEC concentrates on inspection, sampling and analysis and should be supplemented by provisions aimed at improving the level of food hygiene and increasing confidence in the standard of hygiene of foodstuffs in free circulation;

Whereas the general rules of hygiene for foodstuffs to be respected at the time of production, processing, manufacturing, packaging, storing, transportation, distribution, handling and sale to the ultimate consumer of foodstuffs should be harmonized in order to protect human health;

Whereas the use of HACCP (hazard analyses and critical control points) is recognized to identify the critical control points and their control and monitoring requirements;

Whereas microbiological criteria for certain foodstuffs should be adopted in accordance with scientifically accepted general principles, in order to protect human health;

⁽¹⁾ OJ No L 186, 30. 6. 1989, p. 23.

Whereas the use of documents on good hygiene practices within the Community based on the relevant codes of practice of the Codex Alimentarius should be recommended;

Whereas, however, as an entrepreneur is responsible for the hygiene in his food business, the use of these documents which are not part of legislation should be voluntary;

Whereas, in order to have the general rules of hygiene for foodstuffs and the documents on good hygiene practices implemented, the application of standards of the EN 29000 series should be recommended;

Whereas the respect of the general rules of hygiene for foodstuffs should be controlled in accordance with Directive 89/397/EEC by the competent authorities in the Member States, with the aim of preventing the ultimate consumer from being harmed by foodstuffs unfit for human consumption or potentially dangerous to human health;

Whereas it is necessary to ensure that only safe foodstuffs are placed on the market and appropriate powers should be granted to the competent authorities, in order to protect human health;

Whereas, however, the legitimate rights of food businesses should also be preserved;

Whereas the Commission should be aware of the competent authorities in the Member States responsible for the official control of food hygiene,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive lays down the general rules of hygiene for foodstuffs and the verification of the compliance with these rules.

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

Article 2

For the purpose of this Directive:

— 'food hygiene' means all measures necessary to ensure the safety, soundness and wholesomeness of food at all stages from its production, processing, manufacturing, packaging, storing, transportation, distribution, handling and sale to the final consumer,

— 'food business' means any undertaking carrying out production, processing, manufacturing, packaging, storing, transportation, distribution, handling and sale of foodstuffs⁽¹⁾;

— 'entrepreneur' means the owner or the operator of the food business or his representative;

Article 3

1. The production, processing, manufacturing, packaging, storing, transportation, distribution, handling and sale of foodstuffs shall be carried out in an hygienic way.

2. Food business operators shall identify any process undertaken which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed (hazard analyses and critical control points or HACCP).

3. Food businesses shall comply with the rules of hygiene for foodstuffs as listed in the Annex to this Directive.

Article 4

Microbiological criteria for foodstuffs may be adopted in accordance with the procedure laid down in Article 10 and after consulting the Scientific Committee for Foodstuffs as set up by Decision 74/234/EEC⁽²⁾, or any other procedure provided for in more specific Community rules.

Article 5

1. Member States shall recommend entrepreneurs from the various food business sectors to develop and implement documents on good hygiene practices which supplement the provisions of the Annex and are based on the Recommended International Code of Practice, General Principles of Food Hygiene⁽³⁾ and/or the relevant parts from the more specific Commodity Standards derived from it.

2. In order of preference documents on good hygiene practices shall be in the form of:

⁽¹⁾ The definition includes establishments such as hospitals, old peoples' homes, canteens etc., whether state-owned or private.

⁽²⁾ OJ No L 136, 20. 5. 1974, p. 1.

⁽³⁾ Codex Alimentarius Volume A. Recommended International Code of Practice. General Principles of Food Hygiene. Second Revision (1985). Food and Agricultural Organization of the United Nations World Health Organization, Rome 1988.

- (a) European standards adopted by a European standardization body as mentioned in List 1 of the Annex to Council Directive 83/189/EEC laying down a procedure for the provision of information in the field of technical standards and regulations⁽¹⁾;
- (b) national standards adopted by a national standardization body as mentioned in List 2 of the Annex to Directive 83/189/EEC;
- (c) professional codes of good hygiene practices.

3. Member States shall notify the Commission of the professional codes of good hygiene practices as referred to in paragraph 2 (c) adopted within their jurisdiction. They shall accompany these codes by their comments.

4. Member States and the Commission shall assess documents on good hygiene practices with a view to determining to what extent they can be presumed to comply with Article 3. In case of dispute a decision shall be taken in accordance with the procedure laid down in Article 10.

5. This Article shall apply without prejudice to Directive 83/189/EEC.

Article 6

Member States shall recommend food business entrepreneurs to apply the European Standards of the EN 29000 series in order to implement the general rules of hygiene for foodstuffs and the documents on good hygiene practices.

Article 7

The competent authorities shall carry out controls in conformity with Directive 89/397/EEC in order to ensure that the provisions of Article 3 (1) and (3) are being complied with by the food businesses. In so doing, due consideration shall be given to the documents on good hygiene practices as referred to in Article 5, where they exist.

Article 8

1. If, while carrying out the controls referred to in Article 7, the competent authorities ascertain that failure to respect these provisions might result

in risks to the wholesomeness of foodstuffs or to human health, they shall take appropriate measures, which may extend to the withdrawal and/or the destruction of the foodstuff or to the closure of the undertaking for an appropriate period of time.

2. The undertaking concerned shall be granted the right of appeal to the appropriate authorities.

Article 9

The Member States shall designate the competent authorities and shall notify these to the Commission.

Article 10

The Commission shall be assisted by the Standing Committee on Foodstuffs set up by Council Decision 69/414/EEC⁽²⁾.

The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by means of vote.

The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask for its position to be recorded in the minutes.

The Commission shall take the utmost account of the opinion delivered by the committee. It shall inform the committee of the manner in which its opinion has been taken into account.

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.

⁽¹⁾ OJ No L 109, 26. 4. 1983, p. 75.

⁽²⁾ OJ No L 291, 19. 11. 1969, p. 9.

ANNEX

I

BUILDING REQUIREMENTS

1. The building layout, design and construction of premises and equipment shall:
 - (a) permit adequate cleaning and/or disinfection;
 - (b) prevent the accumulation of dirt, the contact with toxic materials, the shedding of particles into food and, as far as practicable, the formation of condensation or mould on surfaces;
 - (c) permit good food hygiene practices, including the avoidance of cross-contamination between operations by equipment, air supply or personnel and the exclusion of external sources of contamination such as pests, insects or animals;
 - (d) provide suitable temperature conditions for the hygienic processing and storage of products.
2. All food premises must have an adequate number of wash-basins for cleaning hands and of flush lavatories connected to an effective draining system. Lavatories must not lead directly into rooms in which food is handled.
3. Wash-basins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying.
4. There must be suitable and sufficient means of ventilation in all parts of the food business premises. Mechanical air flow from a contaminated area to a clean area must be avoided. Ventilation systems must be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.
5. All sanitary conveniences within food premises shall be provided with adequate natural or mechanical extract ventilation.
6. There must be adequate natural or artificial lighting in all parts of the food business premises.

II

ROOM REQUIREMENTS

1. In areas where food is prepared, treated or processed (excluding dining areas):
 - (a) floors must be kept clean and must be made of impervious, non-absorbent, washable, and non-toxic materials; they must be maintained in a sound condition and they must be easy to clean and disinfect;
 - (b) walls must be constructed of impervious, non-absorbent, washable, non-toxic materials; their surface must be smooth and crack-free up to a height appropriate for the operations;
 - (c) ceilings must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of moulds and the shedding of particles;
 - (d) windows and other openings must be constructed to avoid the accumulation of dirt, and those which are opened to the outside environment must where necessary be fitted with insect-proof screens able to be easily removed for cleaning;
 - (e) doors must have smooth and non-absorbent surfaces;
 - (f) working surfaces must be smooth, crack-free, without joints, washable and made of non-toxic materials.

2. Where necessary, adequate provisions must be provided for the cleaning and disinfecting of work tools and equipment. These provisions must be constructed of a material resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.
3. Where appropriate, adequate provisions must be provided for any necessary washing of the food. Every sink or other such facility must have an adequate supply of hot and/or cold water as required and be kept clean.

III

EQUIPMENT REQUIREMENTS

Without prejudice to Council Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery ⁽¹⁾, all articles, fittings, equipment and accessories with which food comes into contact, or which might cause contamination in the course of a food business, shall be kept clean and:

- (a) be so constructed, be of such materials and be kept in such good order, repair and condition as to prevent, so far as is reasonably practical, any risk of contamination of the food;
- (b) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept thoroughly cleaned;
- (c) be installed in such a manner to allow adequate cleaning of the surrounding area.

IV

FOOD WASTE

1. Food waste and other refuse must not be deposited or allowed to accumulate in a food room except so far as may be unavoidable for the proper carrying on of the business.
2. Adequate provision must be made for the removal and storage of food waste and other refuse. Refuse stores must be designed and managed in such a way as to enable them to be kept clean and prevent pests from gaining access to them and avoid contamination of food, drinking water, equipment or premises.

V

WATER SUPPLY

1. There must be an adequate supply of potable water as specified in Council Directive 80/778/EEC relating to the quality of water intended for human consumption ⁽²⁾.
2. Ice used directly in contact with food must be made from water which meets the specifications referred to in Directive 80/778/EEC. It must be made, handled and stored under conditions which protect it from all contamination.
3. Steam used directly in contact with food must not contain any substance which presents a hazard to health or is likely to contaminate the product.
4. Water unfit for drinking used for the generation of steam, refrigeration, fire control and other similar purposes not relating to food must be conducted in separate systems, readily identifiable and having no connection with nor any possibility of reflux into the potable water systems.

⁽¹⁾ OJ No L 183, 29. 6. 1989, p. 9.

⁽²⁾ OJ No L 229, 30. 8. 1980, p. 11.

VI

PERSONAL HYGIENE

1. Every person, engaged in a food handling area, shall maintain a high degree of personal cleanliness.
2. No person, known or suspected to be suffering from or to be a carrier of a disease likely to be transmitted through food or while afflicted with infected wounds, skin infections, sores or with diarrhoea, shall be permitted to work in any food-handling area in any capacity in which there is any likelihood of directly or indirectly contaminating food with pathogenic micro-organisms.

VII

PRODUCTION HYGIENE

1. No raw materials or ingredients shall be accepted by a food business if they are known to be so contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances that, after normal sorting and/or preparatory or processing procedures applied by food businesses, they would still be unfit for human consumption.
2. Raw materials and ingredients stored in the establishment shall be kept in appropriate conditions designed to prevent harmful deterioration and to protect them from contamination.
3. All food shall be handled, stored, packaged and transported in such a way that it is protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

In particular, food must not be so placed as to involve any risk of cross-contamination.

4. Notwithstanding the need for more stringent requirements in certain circumstances in the interests of food safety, raw materials, ingredients, intermediate products and finished products likely to support the multiplication of pathogenic and toxigenic micro-organisms must be kept at temperatures which inhibit the growth of such micro-organisms to levels that are harmful to health except where the practicalities of handling during preparation, transport, storage, display and service of food require time-limited exemptions consistent with food safety.
5. Foodstuffs to be held or served at chilled temperatures must be cooled as quickly as possible following the final heat-processing stage, or final preparation stage if no heat process is applied, to a temperature necessary to ensure the safety of the foodstuff.
6. Inedible substances shall be adequately labelled and stored in separate and secure containers.

VIII

TRAINING

Food business operators shall ensure that food handlers are instructed/trained and supervised commensurate with their work activity.

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 hygiene of foodstuffs.

Reference Number (Répertoire)

The proposal

1. The control of foodstuffs is already the subject of Community harmonization (Dir. 89/397/EEC and others)

The present draft lays down the general rules of hygiene for foodstuffs and the verification of the compliance with these rules.

The varying situation in the Member States regarding the hygiene of foodstuffs (the absence of rules or differing rules) forms a barrier to the free circulation of foodstuffs and consequently justifies the adoption of common rules.

The impact on business

2. Who will be affected by the proposal

- which sectors of business
- which sizes of business (what is the concentration of small and medium sized firms)
- are there particular geographical areas of the Community where these businesses are found.

The regulation on food hygiene concerns all food businesses whether they are multinational or SME and equally the producers as well as the transport and business undertakings. These undertakings are found in all areas of the EEC.

3. What will business have to do to comply with the proposal.

It consists for the undertaking to identify the critical points regarding hygiene and to lay down and respect rules which will guarantee good hygiene practice.

4. What economic effects is the proposal likely to have

- on employment
- on investment and the creation of new businesses
- on the competitive position of businesses.

The adoption of these new rules should enable the quality of the food to improve both for intra-Community business and for exports outside the Community. This would consequently have a favourable impact on international competition.

5. Does the proposal contain measures to take into account of the specific situation of small and medium sized firms (reduced or different requirements etc.)

No, the measures proposed apply just as much to large undertakings as to SMEs.

Consultation

6. List the organizations which have been consulted about the proposal and outline their main views.

The Advisory Committee for Foodstuffs which includes business, industry, agriculture, consumers and trade unions was consulted on this draft. On the whole this Committee was favourable to the draft with a slight reserve from agriculture and business.

The abovementioned sector feared the introduction of new codes of good hygiene practice in the different Member States. Consequently the draft has been modified.