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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/43/EEC

of 14 June 1993

on the hygiene 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 ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾

Whereas the free movement of foodstuffs is an essential pre-condition for the completion of the internal market; whereas this principle implies confidence in the standard of safety of foodstuffs for human consumption in free circulation, and in particular their standard of hygiene, throughout all stages of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer;

Whereas the protection of human health is of paramount concern;

Whereas this protection has already been the subject of Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs ⁽³⁾ as well as of more

specific rules in this field; whereas an important objective of such controls is food hygiene; whereas 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 observed at the time of preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer must be harmonized in order to protect human health;

Whereas the use of hazard analysis, risk assessment and other management techniques to identify, control and monitor critical points is recognized;

Whereas microbiological criteria and temperature control criteria may be adopted for certain classes of foodstuffs; whereas, if adopted, they should be in accordance with scientifically accepted general principles;

Whereas Member States shall encourage and participate in the development of guides to good hygiene practice to which food businesses may refer, based, where appropriate, on the Recommended International Code of Practice, General Principles of Food Hygiene of the *Codex Alimentarius* ⁽⁴⁾;

Whereas the Commission, assisted by Member States and other interested parties, is to encourage the development

⁽¹⁾ OJ No C 174, 23. 11. 1992; and
OJ No C 150, 31. 5. 1993.

⁽²⁾ OJ No C 223, 31. 8. 1992, p. 16.

⁽³⁾ OJ No L 186, 30. 6. 1989, p. 23.

⁽⁴⁾ *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.

of guides to good hygiene practice to which food businesses may refer where necessary throughout the Community;

Whereas, however, a food business operator is responsible for the hygiene conditions in his food business; whereas this Directive does not therefore impose observance of guides to good hygiene practice, which have no legal force;

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

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

Whereas food business operators must ensure that only foodstuffs not harmful to health are placed on the market and appropriate powers should be granted to the competent authorities to protect public health; whereas, however, the legitimate rights of food businesses should be guaranteed;

Whereas the Commission should be made aware of the identity 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 procedures for verification of compliance with these rules.

2. This Directive shall apply without prejudice to the provisions adopted in the context of more specific Community food hygiene rules. Within three years of the adoption of this Directive, the Commission shall examine the relationship between the specific Community food hygiene rules and those of this Directive and, if necessary, make proposals.

Article 2

For the purposes of this Directive:

— *food hygiene*, hereinafter called 'hygiene' shall mean all measures necessary to ensure the safety and wholesomeness of foodstuffs. The measures shall cover all stages after primary production (the latter including, for example, harvesting, slaughter

and milking), during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer,

— *food business* shall mean any undertaking, whether for profit or not and whether public or private, carrying out any or all of the following: preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling or offering for sale or supply of foodstuffs,

— *wholesome food* shall mean food which is fit for human consumption as far as hygiene is concerned.

Article 3

1. The preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs shall be carried out in a hygienic way.

2. Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed on the basis of the following principles, used to develop the system of HACCP (Hazard analysis and critical control points):

— analysing the potential food hazards in a food business operation,

— identifying the points in those operations where food hazards may occur,

— deciding which of the points identified are critical to food safety — the 'critical points',

— identifying and implementing effective control and monitoring procedures at those critical points, and

— reviewing the analysis of food hazards, the critical control points and the control and monitoring procedures periodically and whenever the food business operations change.

3. Food business operators shall comply with the rules of hygiene as listed in the Annex. Derogations from certain provisions of the Annex may be granted according to the procedure laid down in Article 14.

Article 4

Without prejudice to more specific Community rules, microbiological criteria and temperature control criteria for certain classes of foodstuffs may be adopted in

accordance with the procedure laid down in Article 14 and after consulting the Scientific Committee for Food set up by Decision 74/234/EEC ⁽¹⁾.

Article 5

1. Member States shall encourage the development of guides to good hygiene practice which may be used voluntarily by food businesses as a guide to compliance with the provisions of Article 3.

2. Where the guides to good hygiene practice referred to in paragraph 1 are developed, they shall be developed as follows:

- by food business sectors and representatives of other interested parties, such as appropriate authorities and consumer groups,
- in consultation with interests substantially affected, including the competent authorities,
- where appropriate, having regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the *Codex Alimentarius*.

3. The guides referred to in paragraphs 1 and 2 may be developed under the aegis of a national standards institute referred to in list 2 of the Annex to Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations ⁽²⁾.

4. Member States shall assess the guides to good hygiene practice referred to in paragraphs 1 and 2 with a view to determining the extent to which they may be presumed to comply with Article 3.

5. Member States shall forward to the Commission those guides to good hygiene practice which they presume to comply with Article 3.

The Commission shall make these guides available to the Member States.

6. Where one or more Member States, or the Commission, consider that, for the purposes of harmonization, there may be a need for guides to good hygiene practice to be developed on a European basis (hereafter referred to as 'European guides to good hygiene practice'), the Commission shall consult Member States in the framework of the Standing Committee on

Foodstuffs in accordance with Article 14. The object of this consultation shall be to consider the case for such voluntary guides in the sectors or activities concerned, and, where such guides are considered necessary:

- to indicate the intended scope, subject matter and timetable for development of such voluntary guides, taking into account the time needed for consultation with interests substantially affected by them, and
- to refer such voluntary guides for development and/or assessment under the aegis of a European standards institute.

7. In developing the European guides to good hygiene practice referred to in paragraph 6, all necessary measures shall be taken in order to:

- ensure that such guides are developed by representatives of food business sectors and representatives of other interests substantially affected, such as, for example, the competent authorities and consumer groups,
- ensure that the contents of such guides comply with the provisions of Article 3 and, where appropriate, have regard to the Recommended International Code of Practice, General Principles of Food Hygiene of the *Codex Alimentarius*,
- ensure that the contents of such guides are practicable for the food industry sectors to which they refer throughout the Community,
- ensure that the relevant guides to good hygiene practice drawn up in accordance with paragraphs 1 to 3 are taken into account,
- ensure that all interests substantially affected by such guides, including Member States, are consulted and their comments taken into account.

8. The titles and references of European guides to good hygiene practice developed in accordance with the procedure in paragraphs 6 and 7 shall be published in the C series of the *Official Journal of the European Communities*. Member States shall ensure that such published guides are drawn to the attention of the relevant food business sectors and the appropriate authorities in their territories.

Article 6

Member States shall, if they consider it appropriate, recommend food business operators to apply the European Standards of the EN 29000 series in order to implement the general rules of hygiene and the guides to good hygiene practice.

⁽¹⁾ OJ No L 136, 20. 5. 1974, p. 1.

⁽²⁾ OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Decision 92/400/EEC (OJ No L 221, 6. 8. 1992, p. 55).

Article 7

1. Subject to the Treaty, Member States may maintain, amend or introduce national hygiene provisions that are more specific than those laid down by this Directive, provided that such provisions:

- are not less stringent than those given in the Annex,
- do not constitute a restriction, hindrance or barrier to trade in foodstuffs produced in accordance with this Directive.

2. Until detailed provisions have been laid down in accordance with Article 4, Member States may maintain, amend or introduce the relevant national provisions, subject to the Treaty.

3. Should a Member State deem it necessary, in the cases provided for in paragraphs 1 and 2, to adopt new legislation or amend existing legislation, it shall communicate to the Commission and the other Member States the measures envisaged and give the reasons justifying them. The Commission shall consult the Member States within the Standing Committee on Foodstuffs set up by Decision 69/414/EEC ⁽¹⁾ if it considers such consultation to be useful or if a Member State so requests.

The Member State may take the envisaged measures only three months after such communication and provided that it has not received an opinion to the contrary from the Commission.

In the latter event, before the expiry of the period referred to in the second subparagraph, the Commission shall initiate the procedure provided for in Article 14 in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate amendments.

Article 8

1. The competent authorities shall carry out controls in accordance with Directive 89/397/EEC in order to ensure that the provisions of Article 3 of this Directive and, where appropriate, any provisions laid down pursuant to Article 4 of this Directive are being complied with by food businesses. In doing so, due consideration shall be given to the guides to good hygiene practice referred to in Article 5 of this Directive, where they exist.

2. Inspections by competent authorities shall include a general assessment of the potential food safety hazards associated with the business. Competent authorities shall pay particular attention to critical control points identified by food businesses to assess whether the necessary monitoring and verification controls are being operated.

⁽¹⁾ OJ No L 291, 19. 11. 1969, p. 9.

Member States shall provide that all food premises are inspected at a frequency which has regard to the risk associated with the premises.

3. The competent authorities shall ensure that controls on foodstuffs imported into the Community are carried out in accordance with Directive 89/397/EEC for the purpose of ensuring that the relevant provisions of Article 3 and, where appropriate, any provisions laid down pursuant to Article 4, are being observed.

Article 9

1. If while carrying out the controls referred to in Article 8, the competent authorities ascertain that failure to comply with the provisions of Article 3 or, where appropriate, any provisions laid down pursuant to Article 4 might result in risks to the safety or wholesomeness of foodstuffs they shall take appropriate measures, which may extend to the withdrawal and/or the destruction of the foodstuff or to the closure of all or part of the undertaking for an appropriate period of time.

In determining the risk to food safety or wholesomeness regard shall be had to the nature of the food, the manner in which it is handled and packed and any process to which the food is subjected before supply to the consumer and the conditions under which it is displayed and/or stored.

2. Member States shall take the necessary measures to ensure that any natural or legal person affected by the control has a right of appeal against the measures taken by the competent authority following the control.

Article 10

1. If a hygiene problem likely to pose a serious risk to human health arises or spreads in the territory of a third country, the Commission, either on its own initiative or at the request of a Member State, shall take the following measures without delay, depending on the seriousness of the situation:

- suspend imports from all or part of the third country concerned and, where necessary, from the transit third country, and/or
- lay down special conditions for foodstuffs from all or part of the third country concerned.

2. The Commission may, in the case provided for in paragraph 1, take interim protective measures regarding the foodstuffs concerned.

3. Except in an emergency, the Commission shall consult the Member States before taking the measures referred to in paragraphs 1 and 2.

4. The Commission shall notify the Council and the Member States without delay of any decision taken pursuant to paragraphs 1 and 2.

Any Member State may refer the Commission's decision to the Council within 30 days of the notification referred to in the first subparagraph. The Council, acting by a qualified majority, may confirm, amend or revoke the decision adopted by the Commission. If the Council has not taken a decision within 30 days, the decision of the Commission is deemed to be revoked.

5. Where a Member State officially informs the Commission of the need to take safeguard measures and the Commission has not had recourse to the provisions of paragraphs 1 and 2, that Member State may take interim protective measures with regard to imports of the foodstuffs in question.

When a Member State takes interim protective measures, it shall inform the other Member States and the Commission.

Within 10 working days, the Commission shall put the matter before the Standing Committee on Foodstuffs in accordance with the procedure laid down in Article 14 with a view to the extension, amendment or abrogation of the national interim protective measures.

Article 11

1. Where a Member State, as a result of new information or of a reassessment of existing information, has good reason to suspect that application of the detailed provisions laid down pursuant to Article 4 constitutes a health risk, it may temporarily suspend or restrict application of the provisions in question in its territory. It shall inform the other Member States and the Commission thereof without delay and give reasons for its decision.

2. The Commission shall examine the reasons given by the Member State referred to in paragraph 1 as soon as possible in the Standing Committee on Foodstuffs and shall deliver its opinion and take any necessary measures in accordance with the procedure laid down in Article 14.

Article 12

Member States shall designate the competent authorities responsible for the control of hygiene and shall notify the Commission of them.

Article 13

Amendments to references to international standards, such as those of the *Codex Alimentarius*, contained in this Directive, may be adopted in accordance with the procedure laid down in Article 14.

Article 14

The Commission shall be assisted by the Standing Committee on Foodstuffs (hereinafter referred to as 'the Committee').

The representative of the Commission 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. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission.

The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.

If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 15

The Commission shall submit a report to the European Parliament and the Council, by 31 December 1998, together with any appropriate proposals, on the experience gleaned from the implementation of this Directive.

Article 16

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 months after adoption. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, the provisions 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.

Member States shall communicate to the Commission the provisions of national law which they adopted in the field governed by this Directive. The Commission shall inform the other Member States thereof.

Article 17

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1993.

For the Council

The President

J. TRØJBORG

ANNEX

Preface

1. Chapters V to X of this Annex apply throughout all stages after primary production during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the consumer.

The remaining chapters of the Annex apply as follows:

- Chapter I to all food premises except those covered by Chapter III,
 - Chapter II to all rooms where food is prepared, treated or processed except those covered by Chapter III and excluding dining areas,
 - Chapter III to those premises listed in the heading to the Chapter,
 - Chapter IV to all transportation.
2. The terms 'where appropriate' and 'where necessary' used in this Annex mean for the purposes of ensuring the safety and wholesomeness of foodstuffs.

I

General requirements for food premises (other than those specified in Chapter III)

1. Food premises must be kept clean and maintained in good repair and condition.
2. The layout, design, construction and size of food premises shall:
 - (a) permit adequate cleaning and/or disinfection;
 - (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
 - (c) permit good food hygiene practices, including protection against cross contamination between and during operations by foodstuffs, equipment, materials, water, air supply or personnel and external sources of contamination such as pests;
 - (d) provide, where necessary, suitable temperature conditions for the hygienic processing and storage of products.
3. An adequate number of washbasins must be available, suitably located and designated for cleaning hands. An adequate number of flush lavatories must be available and connected to an effective drainage system. Lavatories must not lead directly into rooms in which food is handled.
4. Washbasins for cleaning hands must be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. When necessary, the provisions for washing food must be separate from the hand-washing facility.
5. There must be suitable and sufficient means of natural or mechanical ventilation. 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.
6. All sanitary conveniences within food premises shall be provided with adequate natural or mechanical ventilation.
7. Food premises must have adequate natural and/or artificial lighting.
8. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of foodstuffs.
9. Adequate changing facilities for personnel must be provided where necessary.

II

Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in Chapter III)

1. In rooms where food is prepared, treated or processed (excluding dining areas):
 - (a) floor surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors must allow adequate surface drainage;
 - (b) wall surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary, disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (c) ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles;
 - (d) windows and other openings must be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment must where necessary be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination of foodstuffs, windows must remain closed and fixed during production;
 - (e) doors must be easy to clean and, where necessary, disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;
 - (f) surfaces (including surfaces of equipment) in contact with food must be maintained in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate.
2. Where necessary, adequate facilities must be provided for the cleaning and disinfecting of work tools and equipment. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have an adequate supply of hot and cold water.
3. When appropriate, adequate provision must be made for any necessary washing of the food. Every sink or other such facility provided for the washing of food must have an adequate supply of hot and/or cold potable water as required and be kept clean.

III

Requirements for movable and/or temporary premises (such as Marquees, market stalls, mobile sales vehicles) premises used primarily as a private dwelling house, premises used occasionally for catering purposes, and vending machines

1. Premises and vending machines shall be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contaminating foodstuffs and harbouring pests, so far as is reasonably practicable.
2. In particular and where necessary:
 - (a) appropriate facilities must be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);

- (b) surfaces in contact with food must be in a sound condition and be easy to clean and, where necessary, disinfect. This will require the use of smooth, washable, non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate;
- (c) adequate provision must be made for the cleaning and, where necessary, disinfecting of work utensils and equipment;
- (d) adequate provision must be made for the cleaning of foodstuffs;
- (e) an adequate supply of hot and/or cold potable water must be available;
- (f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) must be available;
- (g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions must be available;
- (h) foodstuffs must be so placed as to avoid, so far as is reasonably practicable, the risk of contamination.

IV

Transport

1. Conveyances and/or containers used for transporting foodstuffs must be kept clean and maintained in good repair and condition in order to protect foodstuffs from contamination and must, where necessary, be designed and constructed to permit adequate cleaning and/or disinfection.
2. Receptacles in vehicles and/or containers must not be used for transporting anything other than foodstuffs where this may result in contamination of foodstuffs.

Bulk foodstuffs in liquid, granular or powder form must be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers must be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or must be marked 'for foodstuffs only'.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there must be effective separation of products, where necessary, to protect against the risk of contamination.
4. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there must be effective cleaning between loads to avoid the risk of contamination.
5. Foodstuffs in conveyances and/or containers must be so placed and protected as to minimize the risk of contamination.
6. Where necessary, conveyances and/or containers used for transporting foodstuffs, must be capable of maintaining foodstuffs at appropriate temperatures and, where necessary, designed to allow those temperatures to be monitored.

V

Equipment requirements

All articles, fittings and equipment with which food comes into contact 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 minimize 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 and, where necessary, disinfected, sufficient for the purposes intended;
- (c) be installed in such a manner as to allow adequate cleaning of the surrounding area.

VI

Food waste

1. Food waste and other refuse must not be allowed to accumulate in food rooms except so far as is unavoidable for the proper functioning of the business.
2. Food waste and other refuse must be deposited in closable containers unless food business operators can satisfy the competent authority that other types of containers used are appropriate. These containers must be of an appropriate construction, kept in sound condition and where necessary be easy to clean and disinfect.
3. 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 to protect against access by pests and against contamination of food, drinking water, equipment or premises.

VII

Water supply

1. There must be an adequate supply of potable water as specified in Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption ⁽¹⁾. This potable water must be used whenever necessary to ensure foodstuffs are not contaminated.
2. When appropriate, ice must be made from water which meets the specifications referred to in Directive 80/778/EEC. This ice must be used whenever necessary to ensure foodstuffs are not contaminated. 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.

VIII

Personal hygiene

1. Every person working in a food handling area shall maintain a high degree of personal cleanliness and shall wear suitable, clean and, where appropriate, protective clothing.
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, for example 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.

IX

Provisions applicable to foodstuffs

1. No raw materials or ingredients shall be accepted by a food business if they are known to be, or might reasonably be expected 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 hygienically applied by food businesses, they would still be unfit for human consumption.

⁽¹⁾ OJ No L 229, 30. 8. 1980, p. 11. Directive as last amended by Directive 91/692/EEC (OJ No L 377, 31. 12. 1991, p. 48).

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 which is handled, stored, packaged, displayed and transported shall be 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 be so placed and/or protected as to minimize any risk of contamination. Adequate procedures must be in place to ensure pests are controlled.
4. Raw materials, ingredients, intermediate products and finished products likely to support the growth of pathogenic micro-organisms or the formation of toxins must be kept at temperatures which would not result in a risk to health. Consistent with food safety, limited periods outside temperature control are permitted where necessary to accommodate the practicalities of handling during preparation, transport, storage, display and service of food.
5. When foodstuffs are to be held or served at chilled temperatures they 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 which would not result in a risk to health.
6. Hazardous and/or inedible substances, including animal feedstuffs, shall be adequately labelled and stored in separate and secure containers.

X

Training

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

COUNCIL DIRECTIVE 93/44/EEC

of 14 June 1993

amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS DIRECTIVE:

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

Article 1

Directive 89/392/EEC is hereby amended as follows:

Having regard to the proposal from the Commission ⁽¹⁾,In cooperation with the European Parliament ⁽²⁾,Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas lifting persons entails specific hazards for the persons lifted; whereas those hazards are not covered by the essential health and safety requirements laid down by Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery ⁽⁴⁾;

Whereas, for the type of machinery in question, there is no reason to provide for different conformity assessment modules from those initially provided for in Directive 89/392/EEC for machinery in general;

Whereas additional essential health and safety requirements to cover the risks run by lifted persons can be laid down by means of an amendment to Directive 89/392/EEC; whereas this amendment can be used to advantage to correct certain imperfections in the said Directive;

Whereas it is also necessary to deal with safety components which are placed on the market separately and the safety function of which is declared by the manufacturer or his authorized representative established in the Community;

Whereas the dates of implementation laid down in this Directive shall not alter the dates of implementation of Directive 89/392/EEC and Directive 91/368/EEC, which amended it,

1. Article 1 shall be amended as follows:

- (a) the following subparagraph shall be added to paragraph 1:

‘It shall also apply to safety components placed on the market separately.’;

- (b) the following subparagraph shall be added to paragraph 2:

‘For the purposes of this Directive, *safety components* means a component, provided that it is not interchangeable equipment, which the manufacturer or his authorized representative established in the Community places on the market to fulfil a safety function when in use and the failure or malfunctioning of which endangers the safety or health of exposed persons.’;

- (c) paragraph 3 shall be amended as follows:

- (i) the following indent shall be deleted:

‘— lifting equipment designed and constructed for raising and/or moving persons with or without loads, except for industrial trucks with elevating operation position,’;

- (ii) the following indent:

‘— cableways for the public or private transposition of persons,’

shall be replaced by:

‘— cableways, including funicular railways, for the public or private transportation of persons,’;

- (iii) the following indents shall be added:

‘— lifts which permanently serve specific levels of buildings and constructions, having a car moving between guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal and designed for the transport of:

— persons,

⁽¹⁾ OJ No C 25, 1. 2. 1992, p. 8; and
OJ No C 252, 29. 9. 1992, p. 3.

⁽²⁾ OJ No C 241, 21. 9. 1992, p. 107; and
OJ No C 72, 15. 3. 1993, p. 70.

⁽³⁾ OJ No C 223, 31. 8. 1992, p. 60.

⁽⁴⁾ OJ No L 183, 29. 6. 1989, p. 9. Directive as amended by
Directive 91/368/EEC (OJ No L 198, 22. 7. 1991, p. 16).

- persons and goods,
- goods alone if the car is accessible, that is to say, a person may enter it without difficulty, and fitted with controls situated inside the car or within reach of a person inside,
- means of transport of persons using rack and pinion rail mounted vehicles,
- mine winding gear,
- theatre elevators,
- construction site hoists intended for lifting persons or persons and goods.;

(d) paragraph 4 shall be replaced by the following:

'4. Where, for machinery or safety components, the risks referred to in this Directive are wholly or partly covered by specific Community directives, this Directive shall not apply, or shall cease to apply, in the case of such machinery or safety components and of such risks on the implementation of these specific Directives.'

2. Article 2 shall be replaced by the following:

'Article 2

1. Member States shall take all appropriate measures to ensure that machinery or safety components covered by this Directive may be replaced on the market and put into service only if they do not endanger the health or safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for their intended purpose.

2. This Directive shall not affect Member States' entitlement to lay down, in due observance of the Treaty, such requirements as they may deem necessary to ensure that persons and in particular workers are protected when using the machinery or safety components in question, provided that this does not mean that the machinery or safety components are modified in a way not specified in the Directive.

3. At trade fairs, exhibitions, demonstrations, etc., Member States shall not prevent the showing of machinery or safety components which do not conform to the provisions of this Directive, provided that a visible sign clearly indicates that such machinery or safety components do not conform and that they are not for sale until they have been

brought into conformity by the manufacturer or his authorized representative established in the Community. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.;

3. Article 3 shall be replaced by the following:

'Article 3

Machinery and safety components covered by this Directive shall satisfy the essential health and safety requirements set out in Annex I.;

4. Article 4 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

'1. Member States shall not prohibit, restrict or impede the placing on the market and putting into service in their territory of machinery and safety components which comply with this Directive.;

(b) the following paragraph shall be added:

'3. Member States may not prohibit, restrict or impede the placing on the market of safety components as defined in Article 1 (2) where they are accompanied by an EC declaration of conformity by the manufacturer or his authorized representative established in the Community as referred to in Annex II, point C.;

5. Article 5 (1) and (2) shall be replaced by the following:

'1. Member States shall regard the following as conforming to all the provisions of this Directive, including the procedures for checking the conformity provided for in Chapter II:

- machinery bearing the CE marking and accompanied by the EC declaration of conformity referred to in Annex II.A.,
- safety components accompanied by the EC declaration of conformity referred to in Annex II.C.

In the absence of harmonized standards, Member States shall take any steps they deem necessary to bring to the attention of the parties concerned the existing national technical standards and specifications which are regarded as important or relevant to the proper implementation of the essential safety and health requirements in Annex I.

2. Where a national standard transposing a harmonized standard, the reference for which has been published in the *Official Journal of the European Communities*, covers one or more of the essential safety requirements, machinery or safety components constructed in accordance with this standard shall be presumed to comply with the relevant essential requirements.

Member States shall publish the references of national standards transposing harmonized standards.';

6. Article 7 shall be amended as follows:

- (a) paragraph 1 shall be replaced by the following:

'1. Where a Member State ascertains that

— machinery bearing the CE marking,

or

— safety components accompanied by the EC declaration of conformity,

used in accordance with their intended purpose are liable to endanger the safety of persons, and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such machinery or safety components from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof.

The Member States shall immediately inform the Commission of any such measure, indicating the reason for its decision and, in particular, whether non-conformity is due to:

- (a) failure to satisfy the essential requirements referred to in Article 3;
- (b) incorrect application of the standards referred to in Article 5 (2);
- (c) shortcomings in the standards referred to in Article 5 (2) themselves.';

- (b) paragraph 3 shall be replaced by the following:

'3. Where:

— machinery which does not comply bears the CE marking,

— a safety component which does not comply is accompanied by an EC declaration of conformity,

the competent Member State shall take appropriate action against whomsoever has

affixed the marking or drawn up the declaration and shall so inform the Commission and other Member States.';

7. Article 8 shall be amended as follows:

- (a) paragraph 1 shall be replaced by the following:

'1. The manufacturer or his authorized representative established in the Community must, in order to certify that machinery and safety components are in conformity with this Directive, draw up for all machinery or safety component manufactured an EC declaration of conformity based on the model given in Annex II, A or C as appropriate.

In addition, for machinery alone, the manufacturer or his authorized representatives established in the Community must affix to the machine the CE marking referred to in Article 10.';

- (b) the following paragraph shall be inserted:

'4a. Safety components shall be subject to the certification procedures applicable to machinery pursuant to paragraphs 2, 3 and 4. Furthermore, during EC type-examination, the notified body shall verify the suitability of the safety component for fulfilling the safety functions declared by the manufacturer.';

- (c) paragraph 6 shall be replaced by the following:

'6. Where neither the manufacturer nor his authorized representative established in the Community fulfils the obligations of the preceding paragraphs, these obligations shall fall to any person placing the machinery or safety component on the market in the Community. The same obligations shall apply to any person assembling machinery or parts thereof or safety components of various origins or constructing machinery or safety components for his own use.';

8. Article 9 (1) shall be replaced by the following:

'1. Each Member State shall notify the Commission and the other Member States of the bodies responsible for carrying out the certification procedures referred to in Article 8. The Commission shall publish a list of those bodies in the *Official Journal of the European Communities* for information and shall ensure that the list is kept up to date.';

9. Article 11 shall be replaced by the following:

'Article 11

Any decision taken pursuant to this Directive which restricts the placing on the market and putting into

service of machinery or a safety component shall state the exact grounds on which it is based. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.';

10. Annex I shall be amended as follows:

(a) the title shall be replaced by the following:

**'ESSENTIAL HEALTH AND SAFETY
REQUIREMENTS RELATING TO THE DESIGN
AND CONSTRUCTION OF MACHINERY AND
SAFETY COMPONENTS';**

(b) the following shall be added after this title:

'For the purposes of this Annex, 'machinery' means either 'machinery' or 'safety component' as defined in Article 1 (2).';

(c) the preliminary observations shall be supplemented by the following:

'3. The essential health and safety requirements have been grouped according to the hazards which they cover.

Machinery presents a series of hazards which may be indicated under more than one heading in this Annex.

The manufacturer is under an obligation to assess the hazards in order to identify all those which apply to his machine; he must then design and construct it taking account of his assessment.';

(d) in Section 1.2.4, the last paragraph concerning the emergency stop shall be replaced by the following:

'Once active operation of the emergency stop control has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.';

(e) the following sections shall be added:

'1.5.14. Risk of being trapped in a machine

Machinery must be designed, constructed or fitted with a means of preventing an exposed

person from being enclosed within it or, if that is impossible, with a means of summoning help.'

1.5.15. Risk of slipping, tripping or falling

Parts of the machinery where persons are liable to move about or stand must be designed and constructed to prevent persons slipping, tripping or falling on or off these parts.';

(f) the second paragraph of Section 1.6.2 shall be deleted;

(g) the first indent of Section 1.7.4 (a) shall be replaced by the following:

'— a repeat of the information with which the machinery is marked, except the serial number (see 1.7.3) together with any appropriate additional information to facilitate maintenance (e.g. addresses of the importer, repairers etc.);';

(h) Section 1.7.4 (b) shall be replaced by the following:

'The constructions must be drawn up in one of the Community languages by the manufacturer or his authorized representative established in the Community. On being put into service, all machinery must be accompanied by a translation of the instructions in the language or languages of the country in which the machinery is to be used and by the instructions in the original language. This translation must be done either by the manufacturer or his authorized representative established in the Community or by the person introducing the machinery into the language area in question. By way of derogation from this requirement, the maintenance instructions for use by specialized personnel employed by the manufacturer or his authorized representative established in the Community may be drawn up in only one of the Community languages understood by that personnel.';

(i) Section 1.7.4 (d) shall be replaced by the following:

'Any literature describing the machinery must not contradict the instructions as regards safety aspects. The technical documentation describing the machinery must give information regarding the airborne noise emissions referred to in (f) and, in the case of hand-held and/or hand-guided machinery, information regarding vibration as referred to in 2.2.';

- (j) the title of Section 2 shall be replaced by the following:

**'ESSENTIAL HEALTH AND SAFETY
REQUIREMENTS FOR CERTAIN CATEGORIES
OF MACHINERY';**

- (k) in Sections 2.1, 2.2 and 2.3, the following words shall be deleted:

'In addition to the essential health and safety requirements set out in 1 above;'

- (l) in Section 3, the first paragraph shall be replaced by the following:

'Machinery presenting hazards due to mobility must be designed and constructed to meet the requirements set out below.';

- (m) in Section 4, the first paragraph shall be replaced by the following:

'Machinery presenting hazards due to lifting operations — mainly hazards of load falls and collisions or hazards of tipping caused by a lifting operation — must be designed and constructed to meet the requirements set out below.';

- (n) the following paragraph shall be added to Section 4.2.3:

'Machinery serving specific levels at which operators can gain access to the load platform in order to stack or secure the load must be designed and constructed to prevent uncontrolled movement of the load platform, in particular while being loaded or unloaded.';

- (o) the title of Section 5 shall be replaced by the following:

**'ESSENTIAL HEALTH AND SAFETY
REQUIREMENTS FOR MACHINERY INTENDED
FOR UNDERGROUND WORK';**

- (p) the first paragraph of Section 5 shall be replaced by the following:

'Machinery intended for underground work must be designed and constructed to meet the requirements set out below.';

- (q) Section 6 in the Annex to this Directive shall be added;

11. Annex II shall be amended as follows:

- (a) the title of point A shall be replaced by the following:

'Contents of the EC declaration of conformity for machinery ⁽¹⁾'.

- (b) the first footnote shall be replaced by the following:

'⁽¹⁾ This declaration must be drawn up in the same language as the original instructions (see Annex I, Section 1.7.4 (b)) and must be either typewritten or handwritten in block capitals. It must be accompanied by a translation in one of the official languages of the country in which the machinery is to be used. This translation must be done in accordance with the same conditions as for the translation of the instructions.';

- (c) the following point shall be added:

'C. Contents of the EC declaration of conformity for safety components placed on the market separately ⁽¹⁾.

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or his authorized representative established in the Community ⁽²⁾,
- description of the safety component ⁽⁴⁾,
- safety function fulfilled by the safety component, if not obvious from the description,
- where appropriate, the name and address of the notified body and the number of the EC type-examination certificate,
- where appropriate, the name and address of the notified body to which the file was forwarded in accordance with the first indent of Article 8 (2) (c),
- where appropriate, the name and address of the notified body which carried out the verification referred to in the second indent of Article 8 (2) (c),
- where appropriate, a reference to the harmonized standards,
- where appropriate, the national technical standards and specifications used,
- identification of the person empowered to sign on behalf of the manufacturer, or his authorized representative established in the Community.';

(d) the following footnote 4 shall be added:

'(4) Description of the safety component (make, type, serial number, if any, etc.);'

12. Annex IV shall be amended as follows:

(a) the title shall be replaced by the following:

TYPES OF MACHINERY AND SAFETY COMPONENTS FOR WHICH THE PROCEDURE REFERRED TO IN ARTICLE 8 (2) (b) AND (c) MUST BE APPLIED;

(b) the following subtitle shall be inserted after the title:

'A. Machinery';

(c) Section 1 shall be replaced by the following:

'1. Circular saws (single or multi-blade) for working with wood and analogous materials or for working with meat and analogous materials.

1.1. Sawing machines with fixed tool during operation, having a fixed bed with manual feed of the workpiece or with a demountable power feed.

1.2. Sawing machines with fixed tool during operation, having a manually operated reciprocating saw-bench or carriage.

1.3. Sawing machines with fixed tool during operation, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading.

1.4. Sawing machines with movable tool during operation, with a mechanical feed device and manual loading and/or unloading.'

(d) Section 4 shall be replaced by the following:

'4. Band-saws with a fixed or mobile bed and band-saws with a mobile carriage, with manual loading and/or unloading, for working with wood and analogous materials or for working with meat and analogous materials.'

(e) Section 5 shall be replaced by the following:

'5. Combined machines of the types referred to in 1 to 4 and 7 for working with wood and analogous materials.'

(f) Section 7 shall be replaced by the following:

'7. Hand-fed vertical spindle moulding machines for working with wood and analogous materials.'

(g) the following shall be added to Section A:

'16. Devices for the lifting of persons involving a risk of falling from a vertical height of more than three metres.

17. Machines for the manufacture of pyrotechnics.'

(h) the following section shall be added:

'B. Safety components

1. Electro-sensitive devices designed specifically to detect persons in order to ensure their safety (non-material barriers, sensor mats, electromagnetic detectors, etc.).

2. Logic units which ensure the safety functions of bi-manual controls.

3. Automatic movable screens to protect the presses referred to in 9, 10 and 11.

4. Roll-over protection structures (ROPS).

5. Fallings-object protective structures (FOPS).'

13. the following shall be added after the title in Annex V:

'For the purposes of this Annex, 'machinery' means either 'machinery' or 'safety component' as defined in Article 1 (2).'

14. the following shall be added after the title in Annex VI:

'For the purposes of this Annex, 'machinery' means either 'machinery' or 'safety component' as defined in Article 1 (2).'

15. the following shall be added after the title in Annex VII:

'For the purposes of this Annex, 'machinery' means either 'machinery' or 'safety component' as defined in Article 1 (2).'

Article 2

1. Before 1 July 1994 Member States shall adopt and publish the laws, regulations and administrative provisions necessary in order to comply with this

Directive. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Member States shall apply these provisions with effect from 1 January 1995.

2. By way of derogation from the third subparagraph of paragraph 1, Member States shall apply the laws, regulations and administrative provisions necessary to comply with the provisions listed below as from 1 July 1994:

- Article 1 (10) excluding (a), (b) and (q),
- Article 1 (11) (a) and (b),
- Article 1 (12) (c), (d), (e) and (f).

3. However, until 31 December 1996 Member States may allow the placing on the market and putting into

service of safety components and of machinery for the lifting or moving of persons which conform with the national provisions in force in their territories as at the date of adoption of this Directive.

4. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1993.

For the Council
The President
J. TRØJBORG

ANNEX

6. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET THE PARTICULAR HAZARDS DUE TO THE LIFTING OR MOVING OF PERSONS.

Machinery presenting hazards due to the lifting or moving of persons must be designed and constructed to meet the requirements set out below.

6.1. General

6.1.1. *Definition*

For the purposes of this Chapter, "carrier" means the device by which persons are supported in order to be lifted, lowered or moved.

6.1.2. *Mechanical strength*

The working coefficients defined in heading 4 are inadequate for machinery intended for the lifting or moving of persons and must, as a general rule, be doubled. The floor of the carrier must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the maximum working load set by the manufacturer.

6.1.3. *Loading control for types of device moved by power other than human strength*

The requirements of 4.2.1.4 apply regardless of the maximum working load figure. This requirement does not apply to machinery in respect of which the manufacturer can demonstrate that there is no risk of overloading and/or overturning.

6.2. Controls

6.2.1. Where safety requirements do not impose other solutions:

The carrier must, as a general rule, be designed and constructed so that persons inside have means of controlling movements upwards and downwards and, if appropriate, of moving the carrier horizontally in relation to the machinery.

In operation, those controls must override the other devices controlling the same movement, with the exception of the emergency stop devices.

The controls for these movement must be of the maintained command type, except in the case of machinery serving specific levels.

6.2.2. If machinery for the lifting or moving of persons can be moved with the carrier in a position other than the rest position, it must be designed and constructed so that the person or persons in the carrier have the means of preventing hazards produced by the movement of the machinery.

6.2.3. Machinery for the lifting or moving of persons must be designed, constructed or equipped so that excess speeds of the carrier do not cause hazards.

6.3. Risks of persons falling from the carrier

6.3.1. If the measures referred to in 1.1.15 are not adequate, carriers must be fitted with a sufficient number of anchorage points for the number of persons possibly using the carrier, strong enough for the attachment of personal protective equipment against the danger of falling.

6.3.2. Any trapdoors in floors or ceilings or side doors must open in a direction which obviates any risk of falling should they open unexpectedly.

6.3.3. Machinery for lifting or moving must be designed and constructed to ensure that the floor of the carrier does not tilt to an extent which creates a risk of the occupants falling, including when moving.

The floor of the carrier must be slip-resistant.

6.4. Risks of the carrier falling or overturning

- 6.4.1. Machinery for the lifting or moving of persons must be designed and constructed to prevent the carrier falling or overturning.
- 6.4.2. Acceleration and braking of the carrier or carrying vehicle, under the control of the operator or triggered by a safety device and under the maximum load and speed conditions laid down by the manufacturer, must not cause any danger to exposed persons.

6.5. Markings

Where necessary to ensure safety, the carrier must bear the relevant essential information.'

COUNCIL DIRECTIVE 93/52/EEC

of 24 June 1993

amending Directive 89/556/EEC on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 thereof;

Having regard to the proposal from the Commission ⁽¹⁾,

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

Whereas Article 1 of Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species ⁽³⁾ excluded embryos derived by certain techniques from the scope of the said Directive; whereas embryos which are to be subjected to techniques which involve the penetration of the zona pellucida may be traded or imported as long as they meet the requirements of the said Directive before recourse is had to these techniques, with certain additional safeguards; whereas embryos derived by *in vitro* fertilization may also be traded or imported, with appropriate safeguards;

Whereas the additional safeguards require amendments to the Annexes, which, under Article 16 of Directive 89/556/EEC, come within the competence of the Commission;

Whereas other amendments should be made to the Directive to clarify the status of semen used for fertilization of ova and to take account of the new foot-and-mouth disease policy in the Community,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 89/556/EEC is hereby amended as follows:

1. Article 1 (2) shall be replaced by the following:

'2. This Directive shall not apply to embryos derived by transfer of nuclei.'

⁽¹⁾ OJ No C 63, 5. 3. 1993, p. 11.

⁽²⁾ OJ No C 150, 31. 5. 1993.

⁽³⁾ OJ No L 302, 19. 10. 1989, p. 1. Directive as amended by Directive 90/425/EEC (OJ No L 224, 18. 8. 1990, p. 29).

2. the following shall be added to Article 2:

'(g) "embryo production team" means an officially approved embryo collection team for *in vitro* fertilization in accordance with the conditions laid down in the relevant Annex.'

3. the first subparagraph of Article 3 (a) shall be replaced by the following:

'(a) they must have been conceived as a result of artificial insemination or *in vitro* fertilization with semen from a donor sire standing at a semen collection centre approved by the competent authority for the collection, processing and storage of semen or by semen imported in accordance with Directive 88/407/EEC (*).

(*) OJ No L 194, 22. 7. 1988, p. 10. Directive as last amended by Directive 90/425/EEC (OJ No L 224, 18. 8. 1990, p. 29).';

4. Article 4 shall be deleted;

5. the following paragraph shall be inserted in Article 5:

'2a. Approval of an embryo production team for embryos derived by *in vitro* fertilization shall be granted only where the provisions of the relevant Annex to this Directive are observed and where the embryo production team is able to satisfy the other relevant provisions of this Directive and in particular the provisions of paragraphs 1 and 2 of this Article, which shall apply *mutatis mutandis*.'

6. Article 9 (3) shall be replaced by the following:

'3. In laying down animal health provisions concerning foot-and-mouth disease in accordance with paragraph 1, it must be taken into account that:

— only frozen embryos may be imported from third countries where vaccination against foot-and-mouth disease is practised. The embryos must be stored under approved conditions for a minimum of 30 days before consignment,

— donor animals must come from a holding in which no animal has been vaccinated against foot-and-mouth disease during the 30 days prior to collection, and which is not subject to any prohibition or quarantine measures.'

7. Articles 11, 12 and 13 shall be replaced by the following:

'Article 11

The principles and rules laid down by Directive 90/675/EEC (*) shall apply, in particular as regards the organization of the checks to be carried out by Member States and the follow-up to those checks as well as the safeguard measures to be implemented.

(*) OJ No L 373, 31. 12. 1990, p. 1. Directive as last amended by Regulation (EEC) No 1601/92 (OJ No L 173, 27. 6. 1992, p. 13).'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1994. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, the provisions 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 references shall be adopted by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of domestic law they adopt in the field covered by this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 24 June 1993.

For the Council

The President

B. WESTH

COUNCIL DIRECTIVE 93/53/EEC

of 24 June 1993

introducing minimum Community measures for the control of certain fish diseases

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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 fish are listed in Annex II to the Treaty; whereas the marketing of fish constitutes an important source of revenue for the aquaculture sector;

Whereas it is necessary to establish at Community level the control measures to be taken in the event of outbreaks of disease, in order to ensure rational development of the aquaculture sector and to contribute to the protection of animal health in the Community;

Whereas it is necessary, for diseases to be covered, to refer to the lists laid down in Annex A to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products ⁽⁴⁾;

Whereas an outbreak of such diseases can quickly take on epizootic proportions, causing mortality and disturbances on a scale liable to reduce severely the profitability of aquaculture;

Whereas control measures must be taken as soon as the presence of such a disease is suspected so that immediate and effective action can be implemented as soon as its presence is confirmed;

Whereas such measures must be aimed at preventing the spread of the disease, in particular by carefully controlling movements of fish and products liable to spread the infection;

Whereas the prevention of diseases in the Community must normally be based on a non-vaccination policy;

Whereas a thorough epizootiological investigation is essential to prevent any spread of the diseases; whereas the Member States must establish special units for that purpose;

Whereas, in order to ensure an effective system of control, diagnosis of the diseases must be harmonized and carried out under the auspices of responsible laboratories, the coordination of which may be carried out by a reference laboratory designated by the Community;

Whereas, in order to ensure uniform implementation of this Directive, a Community inspection procedure should be established;

Whereas common measures for the control of the diseases form a minimum basis for maintaining a uniform standard of animal health;

Whereas Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽⁵⁾, and in particular Article 5 thereof, applies in the event of an outbreak of one of the diseases listed in Annex A to Directive 91/67/EEC;

Whereas the Commission should be entrusted with the task of adopting the necessary implementing measures; whereas, for that purpose, a procedure should be established to bring about close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive defines the minimum Community measures for the control of the fish diseases referred to in Annex A, lists I and II, to Directive 91/67/EEC.

Article 2

For the purposes of this Directive, the definitions laid down in Article 2 of Directive 91/67/EEC shall apply as necessary.

⁽¹⁾ OJ No C 172, 8. 7. 1992, p. 16.

⁽²⁾ OJ No C 150, 31. 5. 1993.

⁽³⁾ OJ No C 19, 25. 1. 1993, p. 4.

⁽⁴⁾ OJ No L 46, 19. 2. 1991, p. 1.

⁽⁵⁾ OJ No L 224, 18. 8. 1990, p. 19. Decision as last amended by Decision 92/438/EEC (OJ No L 243, 25. 8. 1992, p. 27).

In addition, the following definitions shall apply:

1. *list I diseases*: fish diseases referred to in Annex A, list I, to Directive 91/67/EEC;
2. *list II diseases*: fish diseases referred to in Annex A, list II, to Directive 91/67/EEC;
3. *fish suspected of being infected*: fish showing clinical signs or post-mortem lesions or dubious reactions in laboratory tests giving rise to reasonable suspicion of the presence of a list I or list II disease;
4. *infected fish*: fish in which the presence of a list I or list II disease has been officially confirmed as the result of a laboratory examination or, in the case of ISA, as the result of a clinical examination and a post-mortem examination;
5. *farm suspected of being infected*: farm containing fish suspected of being infected;
6. *infected farm*: farm containing infected fish; also farm which has been evacuated but not yet disinfected.

Article 3

Member States shall ensure that all farms rearing or keeping fish susceptible to list I or list II diseases:

1. are registered by the official service; this registration must be kept constantly up to date;
2. keep a record of:
 - (a) live fish, eggs and gametes entering the farm, containing all information relating to their delivery, their number or weight, their size, their source and their suppliers;
 - (b) live fish, eggs and gametes leaving the farm, containing all information relating to their dispatch, their number or weight, their size and destination;
 - (c) observed mortality.

This record, which shall be open to scrutiny by the official service whenever the latter so requests, must be regularly updated and shall be kept for four years.

Article 4

Member States shall ensure that it is compulsory for the suspected presence of any of the list I and list II diseases to be notified as soon as possible to the official service.

CHAPTER II

Control measures for list I diseases

Article 5

1. When fish on a farm are suspected of being infected with a list I disease, Member States shall ensure that the official service immediately activates official investigation arrangements to confirm or rule out the presence of the disease, including clinical examination; in particular, it must take, or have taken, the samples necessary for laboratory examination.

2. As soon as the suspected presence of the disease is notified, the official service shall have the farm placed under official surveillance and shall in particular require that:

- (a) an official census be made of all species and categories of fish and that, in respect of each of these, the number of fish already dead, infected or suspected of being infected or contaminated be recorded; the census must be kept up to date by the owner or keeper to take account of the increase in the population or new mortality observed during the period of suspected infection; the information in the census must be produced on request and may be checked at each inspection;
- (b) no fish, whether alive or dead, or eggs or gametes enter or leave the farm without the authorization of the official service;
- (c) the disposal of dead fish or their offal be carried out under the supervision of the official service;
- (d) the entry or exit of feedingstuffs, utensils, objects or other substances such as waste, liable to transmit disease be subject, if necessary, to authorization by the official service, which shall lay down the conditions required to prevent the spread of the pathogen;
- (e) the movement of persons to or from the farm be made subject to authorization by the official service;
- (f) the entry or exit of vehicles to or from the farm be made subject to authorization by the official service, which shall lay down the conditions required to prevent the spread of the pathogen;
- (g) appropriate means of disinfection be used at the entrances and exits of the farm;
- (h) an epizootic investigation be carried out in accordance with Article 8 (1);
- (i) all of the farms situated in the same water catchment area or coastal area be placed under official surveillance, and no fish, eggs or gametes leave these

farms without the authorization of the official service; in the case of extensive water catchment areas or coastal areas, the official service may decide to limit this measure to a less extensive area close to the farm suspected of being infected, if it considers that this area affords maximum guarantees for the prevention of the spread of the disease;

if necessary, the official services of neighbouring Member States or third countries must be informed of the suspected case; in that event, the official services of the Member States involved shall take appropriate action to apply the measures laid down in this Article.

Where necessary, specific measures may be taken in accordance with the procedure laid down in Article 19.

3. Until such time as the official measures laid down in paragraph 2 are enforced, the owner or keeper of any fish in which disease is suspected shall take every appropriate measure to ensure compliance with paragraph 2, except for (h) and (i) thereof.

4. The measures referred to in paragraph 2 shall not be withdrawn until the suspicion of disease has been officially ruled out.

Article 6

As soon as the presence of a list I disease has been officially confirmed, Member States shall ensure that the official service orders that, in addition to the measures listed in Article 5 (2), of the following measures be applied:

(a) in an infected farm:

- all fish must be immediately withdrawn,
- in the case of inland farms all pools must be drained for the purposes of cleaning and disinfection,
- all eggs and gametes, dead fish and fish showing clinical signs of disease shall be regarded as high-risk material and must be destroyed under the supervision of the official service, in accordance with Directive 90/667/EEC ⁽¹⁾,
- all live fish shall either be killed and destroyed under the supervision of the official service in accordance with Directive 90/667/EEC, or else, in the case of fish which have reached commercial

size and show no clinical sign of disease, be slaughtered under the supervision of the official service for marketing or processing for human consumption.

In the latter case, the official service shall ensure that the fish are immediately slaughtered and gutted, that these operations are carried out in conditions such as to prevent the spread of pathogens, that the fish waste and offal are regarded as high-risk material and are submitted to a treatment to destroy pathogens in accordance with Directive 90/667/EEC and that the used water is submitted to a treatment which inactivates any pathogens it may contain;

- after removal of the fish, eggs and gametes, ponds, equipment and any material liable to be contaminated must be cleaned and disinfected as soon as possible following the instructions established by the official service in such a way as to eliminate any risk of the agent of the disease spreading or surviving. The procedures for cleaning and disinfecting an infected farm shall be determined in accordance with the procedure laid down in Article 19,
- any substances which might be contaminated, referred to in Article 5 (2) (d), must be destroyed or treated in such a way as to ensure the destruction of any pathogen present,
- an epizootic investigation must be carried out in accordance with Article 8 (1) and the provisions of Article 8 (4) must be applied; this investigation must include the taking of samples for laboratory examination;

(b) all farms situated in the water catchment area or in the coastal zone in which the infected farm is situated shall undergo health inspections; if these inspections reveal positive cases, the measures provided for under (a) of this paragraph shall be applied;

(c) the repopulation of the farm shall be authorized by the official service following satisfactory inspection of the cleaning and disinfection operations and at the end of a period deemed adequate by the official service to ensure eradication of the pathogen, and of other possible infections in the same water catchment area;

(d) it application of the measures laid down under (a), (b), (c) and (d) of Article 5 (2) requires the cooperation of the official services of other Member States, the official services of the Member States concerned shall collaborate to ensure compliance with the measures laid down in this Article.

⁽¹⁾ Council Directive 90/667/EEC of 27 November 1990 laying down the veterinary rules for the disposal and processing of animal waste, for its placing on the market and for the prevention of pathogens in feedstuffs of animal or fish origin and amending Directive 90/425/EEC (OJ No L 363, 27. 12. 1990, p. 51). Directive as amended by Directive 92/118/EEC (OJ No L 62, 15. 3. 1992, p. 49).

Where necessary, appropriate additional measures shall be adopted in accordance with the procedure laid down in Article 19.

Article 7

Where fish from the wild and not belonging to any farm or fish in lakes, ponds or other installations intended for angling or holding ornamental fish are infected or suspected of being infected, Member States shall ensure that appropriate measures are taken. Member States shall inform the Commission and the other Member States, in the Standing Veterinary Committee, of the measures they have taken.

Article 8

1. The epizootic investigation shall deal with:
 - the likely length of time during which the disease may have existed on the farm before being notified or suspected,
 - the possible origin of the disease on the farm and the identification of other farms on which there are eggs and gametes and fish of susceptible species which may have become infected;
 - the movement of fish, eggs or gametes, vehicles or substances and persons likely to have carried the agent of the disease to or from the farms in question,
 - the possible existence of carriers of the disease, and their distribution.
2. If the epizootic investigation reveals that the disease could have been introduced from another water catchment area or another coastal area, or could have been transferred to another water catchment area or another coastal area as a result of a contact arising from the movement of fish, eggs or gametes, animals, vehicles or persons, or in any other way, the farms belonging to such water catchment areas and coastal areas shall be considered suspect and the measures laid down in Article 5 shall apply. If the presence of the disease is confirmed, the measures laid down in Article 6 shall apply.
3. If the epizootic investigation reveals that the cooperation of the official services of other Member States is required, the official services of the Member States concerned shall take all necessary measures to ensure compliance with the provisions of this Directive.
4. A crisis unit shall be established in order to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and for the purpose of carrying out the epizootic investigation.

The general rules concerning national crisis units and the Community crisis units shall be laid down by the Council, acting by a qualified majority on a proposal from the Commission.

5. The Council, acting by a qualified majority on a proposal from the Commission drawn up on the basis of the opinion of the Scientific Veterinary Committee to take account, in particular, of scientific and technological developments, shall review the provisions of this Article before 31 December 1996.

CHAPTER III

Control measures for list II diseases

Article 9

1. Where a list II disease is suspected and/or confirmed in an approved zone or on an approved farm situated in a non-approved zone, an epizootic investigation shall be carried out in accordance with Article 8. Member States wishing to regain their status defined in accordance with Directive 91/67/EEC must comply with the provisions of Annexes B and C to that Directive.
2. If the epizootic investigation reveals that the disease could have been introduced from an approved zone or from another approved farm, or could have been transferred to another approved farm as a result of the movement of fish, eggs or gametes, vehicles or persons, or in any other way, those zones or farms shall be considered suspect and the appropriate measures shall apply.
3. The official service may, however, authorize the fattening of fish to be slaughtered until they reach commercial size.

Article 10

1. Where a non-approved farm situated in a non-approved zone contains fish suspected of being infected with a list II disease, Member States shall ensure that the official service:
 - (a) immediately sets in motion official means of investigation to confirm or rule out the presence of the disease including, where necessary, the taking of samples for examination in an approved laboratory;
 - (b) carries out or causes to be carried out an official census of the infected farms, this census being regularly updated;
 - (c) places, or causes to be placed, the infected farms under official supervision, in order to ensure that, by way of derogation from Article 3 (1) (c) of Directive 91/67/EEC, the only movements authorized from

infected farms are live fish or eggs or gametes intended either for other farms infected by the same disease or for slaughter for human consumption.

2. Member States may, for a fixed period, set up under the supervision of the official service an optional or compulsory programme for the eradication of list II diseases in non-approved farms or in non-approved zones. During this period, the introduction into a zone or farm subject to such a programme of live fish, eggs or gametes from infected farms or farms of unknown health status shall be forbidden.

These programmes, which will be set up on the basis of general criteria to be determined before the date specified in Article 20 in accordance with the procedure laid down in Article 19, will be submitted to the Commission for scrutiny, and approved and where necessary amended in accordance with that same procedure.

After the period referred to in the first subparagraph, Member States which have recourse to this procedure shall inform the Commission and the other Member States, within the Standing Veterinary Committee, of the results obtained.

3. By 31 December 1996, the Commission shall submit to the Council a report, drawn up after obtaining the opinion of the Scientific Veterinary Committee, taking into account experience gained and scientific and technical developments and accompanied, where appropriate, by proposals for a review of the provision of this Article, in particular with regard to the placing on the market of infected live fish, and their eggs or gametes, intended for farming or fattening, and with regard to the carrying out of an epizootiological investigation in non-approved zones where a disease is suspected on a non-approved farm. The Council shall act by a qualified majority on any such proposals and the latter shall be put forward taking into account the conclusions of the report.

4. Any detailed rules for implementing paragraphs 1 and 2 shall be adopted by the Commission, as and when required, in accordance with the procedure laid down in Article 19.

CHAPTER IV

Final provisions

Article 11

1. Sampling and laboratory testing for the presence of list I and list II diseases shall be carried out using the methods established in accordance with Article 15 of Directive 91/67/EEC.

2. Testing for the presence of disease or pathogens shall be carried out by a laboratory approved by the official service. Laboratory testing shall, if necessary and especially on the first appearance of the disease, identify the type, sub-type or the variant of the relevant pathogen, which must be confirmed by the national reference laboratory and may be confirmed, if necessary, by the Community reference laboratory referred to in Article 13.

Article 12

1. Member States shall ensure that in each Member State a national reference laboratory is designated, with facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type, sub-type and variant of the relevant pathogen and to confirm results obtained by regional diagnostic laboratories.

2. The national laboratories designated for the diseases in question shall be responsible for coordinating diagnostic standards and methods, and for the use of reagents.

3. The national laboratories designated for the diseases in question shall be responsible for coordinating the diagnostic standards and methods laid down by each laboratory for diagnosis of the disease in question within the Member State. To this end, they:

- (a) may provide diagnostic reagents to laboratories approved by the Member State;
- (b) shall control the quality of all diagnostic reagents used in the Member State;
- (c) shall periodically arrange comparative tests;
- (d) shall hold isolates of the pathogen of the disease from cases confirmed in the Member State;
- (e) shall ensure confirmation of positive results obtained in diagnostic laboratories approved by the Member State.

4. However, by way of derogation from paragraph 1, Member States which do not have a national laboratory competent as regards the disease in question may use the services of a national laboratory with competence in the matter in another Member State.

5. The list of national reference laboratories for fish diseases is set out in Annex A.

6. The national laboratories designated for the diseases referred to shall cooperate with the Community reference laboratory referred to in Article 13.

7. The detailed rules for implementing this Article shall be adopted by the Commission under the procedure laid down in Article 19.

Article 13

1. The Community reference laboratory for fish diseases is indicated in Annex B.

2. Without prejudice to Decision 90/424/EEC, and in particular Article 28 thereof, the functions and duties of the laboratory referred to in paragraph 1 of this Article shall be those laid down in Annex C.

Article 14

1. Vaccination against list II diseases in approved zones or in approved farms situated in non-approved zones, in zones or farms which have already begun the approval procedures laid down by Directive 91/67/EEC, and against list I diseases, shall be forbidden.

2. The Council, acting by a qualified majority on a proposal from the Commission, shall by 30 June 1996, review the provisions of this Article, in particular with regard to laying down specific conditions for the use of vaccines and to take account of developments in scientific and technological research into vaccination.

Article 15

1. Each Member State shall draw up a contingency plan specifying how it will implement the measures laid down in this Directive in the event of an outbreak of a list I disease.

This plan must allow access to facilities, equipment, personnel and all other appropriate structures necessary for the rapid and efficient eradication of the outbreak.

2. The general criteria to be applied for drawing up those plans are set out in Annex D.

Member States may, however, confine themselves to the application of the criteria specific to the diseases concerned, where the general criteria have already been adopted in the context of the submission of plans relating to the application of measures for the control of another disease.

The Commission may, in accordance with the procedure laid down in Article 19, amend or supplement those criteria, taking into account the specific nature of the disease.

3. Plans drawn up in accordance with the criteria set out in Annex D shall be submitted to the Commission no later than six months after the date on which this Directive is brought into effect.

4. The Commission shall examine the plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required, in particular to ensure that they are compatible with the plans of the other Member States.

The Commission shall approve the plans, amended if necessary, in accordance with the procedure laid down in Article 19.

The plans may subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation.

Article 16

Commission experts may, in collaboration with the competent authorities, and in so far as is necessary to ensure uniform application of this Directive, make on-the-spot checks. In order to do that, they may check a representative percentage of holdings to see whether the competent authorities are checking that these holdings are fulfilling the requirements of this Directive. The Commission shall inform the Member States of the result of the checks carried out.

A Member State in whose territory a check is being carried out shall give all the necessary assistance to the experts in carrying out their duties.

The detailed rules for implementing this Article shall be determined in accordance with the procedure laid down in Article 19.

Article 17

The conditions governing the Community's financial contribution to the measures connected with the application of this Directive are laid down in Decision 90/424/EEC.

Article 18

Annexes B, C and D shall be amended, as and when required, by the Council acting by a qualified majority on a proposal from the Commission, in particular in order to take into account developments in research and in diagnostic procedures.

Annex A may be amended as and when required in accordance with the procedure laid down in Article 19.

Article 19

1. Where the procedure laid down in this Article is to be followed, the Chairman shall, without delay, refer the matter to the Standing Veterinary Committee, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission 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. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the Committee.
- (b) If the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission, save where the Council has decided against the said measures by a simple majority.

Article 20

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1994. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. However, from the date laid down in paragraph 1, Member States may, subject to the general rules of the Treaty, maintain or apply in their territory stricter provisions than those laid down by this Directive. They shall notify the Commission of any such measure.

3. Member States shall communicate to the Commission the main provisions of national law which they adopt in the field covered by this Directive.

Article 21

This Directive is addressed to the Member States.

Done at Luxembourg, 24 June 1993.

For the Council
The President
B. WESTH

ANNEX A

NATIONAL REFERENCE LABORATORIES FOR FISH DISEASES

Belgium:	Institut National de Recherches Vétérinaires Groeselenberg, 99 1180 Bruxelles.
Denmark:	Statens Veterinære Serumlaboratorium Landbrugsministeriet Hangøvej 2 8200 Aarhus N.
Germany:	Bundesforschungsanstalt für Viruskrankheiten der Tiere Anstaltsteil Insel Riems O-2201 Insel Riems.
Greece:	Εργαστήριο Ιχθυοπαθολογίας και Βιοπαθολογίας Υδροβίων Οργανισμών Κέντρο Κτηνιατρικών Ιδρυμάτων Αθηνών Ινστιτούτο Λοιμωδών και Παραστικών Νοσημάτων Νεαπόλεως 25, Αγία Παρασκευή Αττικής 153 10 Αθήνα
Spain:	Laboratorio de Sanidad y Producción Animal de Algete Madrid.
France:	Centre National d'Etudes Vétérinaires et Alimentaires Laboratoire Central de Recherches Vétérinaires 22, rue Pierre Curier BP 67 94703 Maisons-Alfort CEDEX.
Ireland:	Fisheries Research Centre Abbotstown Castleknock Dublin 15.
Italy:	Istituto Zooprofilattico Sperimentale delle Venezie Sezione Diagnostica di Basaldella di Campoformido Laboratorio di Ittiopatologia Via della Roggia 92 33030 Basaldella di Campoformido (Udine).
Luxembourg:	Institut de Recherches Vétérinaires Groeselenberg, 99 1180 Bruxelles.
Netherlands:	Centraal Diergeneeskundig Instituut Hoofdgebouw Edelhertweg 15 8219 PH Lelystad Postbus 65 8200 AB Lelystad. Centraal Diergeneeskundig Instituut Vestiging Virologie Houtribweg 39 8221 RA Lelystad Postbus 365 8200 AJ Lelystad.
Portugal:	Laboratório Nacional de Investigação Veterinária Estrada de Benefica 701 1500 Lisboa.

United Kingdom: Fish Disease Laboratory
14 Albany Road
Granby Industrial Site
Weymouth
Dorset DT4 9TU.

The Marine Laboratory
PO Box 101
Victoria Road
Aberdeen AB9 8DB.

ANNEX B

COMMUNITY REFERENCE LABORATORY FOR FISH DISEASES

Statens Veterinære Serumlaboratorium
Landbrugsministeriet
Hangøvej 2
8200 Aarhus N
Denmark.

ANNEX C

FUNCTIONS AND DUTIES OF THE COMMUNITY REFERENCE LABORATORY FOR FISH DISEASES

The functions and duties of the Community reference laboratory for list I and II diseases shall be:

1. to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing the disease concerned, specifically by:
 - (a) typing, storing and supplying strains of the pathogen of the relevant disease for serological tests and the preparation of antisera;
 - (b) supplying standard sera and other reference reagents to the national reference laboratories in order to standardize the tests and reagents used in each Member State;
 - (c) building up and retaining a collection of strains and isolates of the relevant pathogen;
 - (d) organizing periodic comparative tests of diagnostic procedures at Community level;
 - (e) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
 - (f) characterizing isolates of the pathogen of the relevant disease by the most up-to-date and appropriate methods to allow greater understanding of the epizootiology of the disease;
 - (g) keeping abreast of developments in the surveillance, epizootiology and prevention of the relevant disease throughout the world;
 - (h) retaining expertise on the relevant disease pathogen and other pertinent pathogens to enable rapid differential diagnosis;
 - (i) acquiring a thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control the relevant disease;
2. to assist actively in the diagnosis of outbreaks of the relevant disease in Member States by receiving pathogen isolates for confirmatory diagnosis, characterization and epizootic studies;
3. to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonization of diagnostic techniques throughout the Community;
4. to collaborate as regards methods of diagnosing list I diseases, with the competent laboratories in third countries where those diseases are prevalent.

ANNEX D

MINIMUM CRITERIA FOR CONTINGENCY PLANS

Contingency plans shall meet at least the following criteria:

1. the establishment of a national crisis centre which shall coordinate all control measures in the Member State concerned;
 2. a list shall be provided of local disease control centres with adequate facilities to coordinate the disease control measures at a local level;
 3. detailed information shall be given on the staff involved in control measures, their skills and their responsibilities;
 4. each local disease control centre must be able to contact rapidly persons/organizations which are directly or indirectly involved in an outbreak;
 5. equipment and materials shall be available to carry out the disease control measures properly;
 6. detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination;
 7. training programmes shall be established to maintain and develop skills in field and administrative procedures;
 8. where appropriate, diagnostic laboratories must have facilities for post-mortem examination, the necessary capacity for serology, histology, etc., and must maintain the skills for rapid diagnosis (to this end, arrangements must be made for rapid transportation of samples);
 9. provisions shall be adopted to ensure the legal powers necessary for the implementation of the contingency plans.
-

COUNCIL DIRECTIVE 93/54/EEC

of 24 June 1993

amending Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 43 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, in accordance with Article 28 of Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products ⁽⁴⁾, it is necessary to review the list of diseases set out in Annex A to the said Directive; whereas this review must take into account both the Commission report on the experience gained and the opinion of the Scientific Veterinary Committee;

Whereas, following the opinion of the Scientific Veterinary Committee, the list of diseases must be amended in order to take account of the latest epidemiological findings and of the experience gained;

Whereas the situation with regard to diseases which are exotic to the Community needs to be reviewed and whereas current epidemiological data indicate that the susceptibility of certain species to certain diseases which are endemic to the Community and the classification of those diseases in lists II or III of Annex A to Directive 91/67/EEC must be reconsidered;

Whereas it is necessary to clarify certain requirements laid down in Directive 91/67/EEC, in particular those concerning the procedure for the approval of zones and concerning the conditions governing the placing on the market of aquaculture animals not belonging to the susceptible species,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/67/EEC is hereby amended as follows:

⁽¹⁾ OJ No C 324, 10. 12. 1992, p. 16.

⁽²⁾ OJ No C 150, 31. 5. 1993.

⁽³⁾ OJ No C 129, 10. 5. 1993, p. 6.

⁽⁴⁾ OJ No L 46, 19. 2. 1991, p. 1

1. in Article 3

(a) paragraph 1 (c) shall be replaced by the following:

'(c) they must not come from a farm which is subject to a prohibition for animal health reasons and must not have been in contact with animals from such a farm, and in particular from a farm which is subject to control measures in the context of Commission Directive 93/53/EEC of 24 June 1993 introducing minimum Community measures for the control of certain fish diseases (*);

(*) OJ No L 175, 19. 7. 1993, p. 23.'

(b) the following paragraph shall be added:

'4. This Article shall apply without prejudice to the provisions of Directive 93/53/EEC with regard to the control of certain fish diseases, in particular the diseases in list I';

2. in Article 5 (1), the introductory words shall be replaced by the following:

'1. In order to obtain, for one or more of the diseases referred to in Annex A, column 1, list II, the status of approved zone, Member States shall submit to the Commission:';

3. Article 5 (2) shall be replaced by the following:

'2. The Commission shall scrutinize the information referred to in paragraph 1. The Commission shall use such information as a basis for approving zones in accordance with the procedure laid down in Article 26. If, in accordance with Annex B under I.D.5, II.D or III.D.5, the approval of a zone is withdrawn by the official service, the Commission shall revoke the decision concerning its approval. Re-approval of the zone concerned shall occur in accordance with the procedure laid down in Article 26.';

4. in Article 6 (1), the introductory words shall be replaced by the following:

'1. In order to obtain, for one or more of the diseases referred to in Annex A, column 1, list II, the status of approved farm situated in a non-approved

zone, Member States shall submit to the Commission:';

5. in Article 7 (1), the introductory words shall be replaced by the following:

'1. The placing on the market of live fish belonging to the susceptible species referred to in Annex A, column 2, list II, their eggs or gametes, shall be subject to the following additional guarantees:';

6. in Article 8 (1), the introductory words shall be replaced by the following:

'1. The placing on the market of live molluscs referred to in Annex A, column 2, list II, shall be subject to the following additional guarantees:';

7. in Article 9, the first sentence of point 1 shall be replaced by the following:

'1. Fish susceptible to the diseases referred to in Annex A, column 1, list II, must be slaughtered and eviscerated prior to dispatch.';

8. in Article 9, the first sentence of point 2 shall be replaced by the following:

'2. Live molluscs susceptible to the diseases referred to in Annex A, column 1, list II, must be delivered either for direct human consumption or to the preserving industry; they shall not be relaid unless:';

9. Article 14 shall be replaced by the following:

'Article 14

1. Without prejudice to the requirements for diseases referred to in Annex A, column 1, list III, established in accordance with Articles 12 and 13, the placing on the market of live farmed fish not belonging to the susceptible species referred to in Annex A, column 2, list II, as well as their eggs and gametes shall be subject to the following additional requirements:

- (a) where they are to be introduced into an approved zone, they must, in accordance with Article 11, be accompanied by a movement document corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from a zone of the same health status, from an approved farm in a non-approved zone or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Annex A,

column 2, list II, and is not connected with a watercourse or with coastal or estuarial waters.

However, pending the outcome of the review provided for in Article 28, Member States may, under the procedure laid down in Article 26, request a derogation from the preceding subparagraph, in particular so as to prohibit the introduction into an approved zone of fish referred to in this paragraph originating in an approved farm situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Annex A, column 2, list II, and is not connected with a watercourse or with coastal or estuarial waters. In order to ensure uniform compliance with that provision, appropriate conditions and measures shall be fixed under the same procedure. Pending those decisions, the relevant national rules shall continue to apply subject to compliance with the general provisions of the Treaty;

- (b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Annex C, they must, in accordance with Article 11, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from an approved zone, from a farm of the same health status or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Annex A, column 2, list II, and is not connected with a watercourse or with coastal or estuarial waters.

2. The requirements laid down in paragraph 1 shall apply to the placing on the market of farmed molluscs not belonging to the susceptible species referred to in Annex A, column 2, list II.

3. Without prejudice to the requirements for diseases referred to in Annex A, column 1, list III established in accordance with Articles 12 and 13, the placing on the market of wild fish, molluscs or crustaceans, their eggs or gametes, shall be subject to the following additional requirements:

- (a) where they are to be introduced into an approved zone, they must, in accordance with Article 11, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 26, certifying that they come from a zone of the same health status;
- (b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Annex C, they must, in accordance with Article 11, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in

- Article 26, certifying that they come from an approved zone;
- (c) where such animals are fished in the deep sea and are to be used for breeding in approved zones and approved farms, they must be placed in quarantine under the supervision of the official service in suitable facilities and under appropriate conditions to be determined in accordance with the procedure laid down in Article 26.
4. The requirements laid down in paragraphs 1, 2 and 3 shall not apply where practical experience and/or scientific evidence has shown that there is no passive transmission of the disease when aquaculture animals, their eggs and gametes, not belonging to the susceptible species referred to in Annex A, column 2, list II, are moved from a non-approved zone to an approved zone.
- In accordance with the procedure laid down in Article 26, the Commission shall establish the list of aquaculture animals to which the derogation referred to in the first subparagraph shall apply and, where necessary, shall amend that list in the light of scientific and technological developments. The special conditions for placing such animals on the market, including the model of the accompanying document required, shall be established and amended according to the same procedure.
5. This Article shall not apply to ornamental tropical fish kept permanently in aquariums.’;

10. the following paragraph shall be added to Article 19:
- ‘4. If by 1 January 1994 no decision has been taken with regard to the drawing up of the list referred to in paragraph 1, the requisite transitional measures may be adopted, in accordance with the procedure laid down in Article 26, for a period of three years.’;
11. the following paragraph shall be added to Article 20:
- ‘3. Pending establishment of the import conditions provided for in this Directive, Member States shall ensure that imports of aquaculture animals and products from third countries are subject to conditions at least equivalent to those applying to the production and placing on the market of Community products.’;
12. Article 24 shall be replaced by the following:
- ‘Article 24
- If an infectious or contagious disease of aquaculture animals, likely to endanger the health of livestock in a Member State breaks out or spreads in a third country or if any other animal health reason so justifies, the rules, procedures and measures laid down in Article 19 of Directive 90/675/EEC shall apply as regards aquaculture products and those laid down in Article 18 of Directive 91/496/EEC shall apply as regards aquaculture animals.’;

13. Annex A shall be replaced by the following:

‘ANNEX A

LIESTED DISEASES/PATHOGENS OF FISH, MOLLUSCS AND CRUSTACEA

1	2
Disease/pathogen	Susceptible species
LIST I	
Fish	
Infectious salmon aneamia (ISA)	Atlantic salmon (<i>Salmo salar</i>)
LIST II	
Fish	
Viral haemorrhagic septicaemia (VHS)	Salmonid species, Grayling (<i>Thymallus thymallus</i>); Whitefish (<i>Coregonus spp.</i>); Pike (<i>Esox lucius</i>); Turbot (<i>Scophthalmus maximus</i>);
Infectious haematopoietic necrosis (IHN)	Salmonid species Pike fry (<i>Esox lucius</i>)
Molluscs	
<i>Bonamia ostreae</i>	Flat oyster (<i>Ostrea edulis</i>)
<i>Marteilla refringens</i>	Flat oyster (<i>Ostrea edulis</i>)

1	2
Disease/pathogen	Susceptible species
LIST III	
Fish	
Infectious pancreatic necrosis (IPN)	To be specified in the programme referred to in Articles 12 and 13'
Spring viraemia of carp (SVC)	
Bacterial kidney disease (BKD)	
(<i>Renibacterium salmonidarum</i>)	
Furunculosis (<i>Aeromonas salmonicida</i>)	
(Enteric redmouth disease) (ERM)	
(<i>Yersinia ruckeri</i>)	
<i>Gyrodactylus salaris</i>	
Crustaceans	
Crayfish plague (<i>Aphanomyces astaci</i>)	

14. References to 'list I' of Annex A shall be deleted from Annexes B, C and D.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1994; they shall notify the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field governed by this Directive.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 24 June 1993.

For the Council
The President
B. WESTH