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I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 3094/95

of 22 December 1995

on aid to shipbuilding

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 92 (3) (e), 94, and 113 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 Council Directive 90/684/EEC of 21 December 1990 on aid to shipbuilding ⁽⁴⁾ expires on 31 December 1995;

Whereas, within the framework of the Organization for Economic Cooperation and Development (OECD), an Agreement has been concluded between the European Community and certain third countries respecting normal competitive conditions in the commercial shipbuilding and repair industry ⁽⁵⁾;

Whereas the current rules of the Directive will need to be prolonged *ad interim* if the OECD Agreement does not enter into force by 1 January 1996;

Whereas that Agreement should enter into force on 1 January 1996, after all parties to the Agreement have deposited their instruments of ratification, acceptance or approval;

Whereas the Agreement provides for the elimination of all direct shipbuilding aids except social aids and authorized aids to research and development within the limit of certain ceilings;

Whereas indirect measures of support to shipbuilding in the form of credit facilities and loan guarantees for shipowners are permitted by the aforesaid Agreement provided they are in conformity with the OECD Understanding on Export Credits for Ships;

Whereas the OECD Agreement respecting normal competitive conditions in the commercial shipbuilding and repair industry and the Community legislation deriving therefrom are a matter of signal importance;

Whereas the Commission's powers under Articles 85, 86, 92 and 93 of the Treaty enable it to act in the event of anticompetitive measures or practices and whereas actions initiated by the Commission in connection with such measures and practices by shipyards would form an integral part of the annual report to be submitted to the Member States;

Whereas the abovementioned Agreement can be reviewed three years after it enters into force,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL

Article 1

For the purposes of this Regulation:

⁽¹⁾ OJ No C 304, 15. 11. 1995, p. 21.

⁽²⁾ OJ No C 339, 18. 12. 1995.

⁽³⁾ Opinion delivered on 23 November 1995 (not yet published in the Official Journal).

⁽⁴⁾ OJ No L 380, 31. 12. 1990, p. 27. Directive as last amended by Directive 94/73/EC (OJ No L 351, 31. 12. 1994, p. 10).

⁽⁵⁾ OJ No C 375, 30. 12. 1994, p. 3.

(a) 'shipbuilding' shall mean the building, in the Community, of self-propelled seagoing commercial vessels, namely:

- vessels of not less than 100 gt used for the transportation of passengers and/or goods;
- vessels of not less than 100 gt for the performance of a specialized service (for example dredgers and ice-breakers, excluding floating docks and mobile offshore units);
- tugs of not less than 365 kW;
- fishing vessels of not less than 100 gt for export outside the Community; and
- unfinished shells of the abovementioned vessels that are afloat and mobile.

Military vessels and modifications made or features added to other vessels exclusively for military purposes shall be excluded, provided that any measures or practices applied in respect of such vessels, modifications or features are not disguised actions taken in favour of commercial shipbuilding inconsistent with this Regulation;

(b) 'ship repair' shall mean the repair or reconditioning in the Community of self-propelled seagoing commercial vessels, as defined in (a);

(c) 'ship conversion' shall mean, subject to the provisions of Article 5, the conversion, in the Community, of self-propelled seagoing commercial vessels, as defined in (a), on condition that conversion operations entail radical alterations to the cargo plan, the shell, the propulsion system or the passenger reception infrastructure;

(d) 'self-propelled seagoing vessel' shall mean a vessel that, by means of its permanent propulsion and steering, has all the characteristics of self-navigability on the high seas;

(e) 'OECD Agreement' shall mean the Agreement respecting normal competitive conditions in the commercial shipbuilding and repair industry;

(f) 'aid' shall mean State aid within the meaning of Articles 92 and 93 of the Treaty. This shall include not only aid granted by the State itself but also that granted by regional or local authorities or other public bodies and any aid elements contained in financing measures taken directly or indirectly by Member States in respect of shipbuilding, conversion or repair undertakings which cannot be regarded as a genuine provision of risk capital according to standard investment practice in a market economy;

(g) 'related entity' shall mean any natural or legal person who:

- (i) owns or controls a shipbuilder; or

- (ii) is owned or controlled by a shipbuilder, directly or indirectly, whether through stock ownership or otherwise. Control shall be presumed to arise once a person or a shipbuilder owns or controls an interest of more than 25 % in the other.

Article 2

1. Aid granted specifically, whether directly or indirectly, for shipbuilding, conversion and repair, as defined under this Regulation, financed by Member States or their regional or local authorities or through State resources in any form whatsoever may be considered compatible with the common market only if it complies with the provisions of this Regulation. This applies not only to undertakings engaged in such activities but also to related entities.

2. No aid granted pursuant to this Regulation may be conditional upon discriminatory practices against products originating in other Member States.

CHAPTER II

COMPATIBLE MEASURES

Article 3

Social assistance

1. Aid to cover the cost of measures for the exclusive benefit of workers who lose retirement benefits or who are made redundant or otherwise separated permanently from employment in the respective shipbuilding, conversion or repair enterprise, when such assistance is related to the discontinuance or curtailment of shipyard activities, bankruptcy, or changes in activities other than shipbuilding, conversion or repair may be considered compatible with the common market.

2. The costs eligible for the aid referred to in this Article are, in particular:

- payments to workers made redundant or retired before legal retirement age,
- the costs of counselling services to workers made or to be made redundant or retired before legal retirement age, including payments made by shipyards to facilitate the creation of small enterprises which are independent of the shipyards in question and whose activities are not principally shipbuilding, conversion or repairs,
- payments to workers for vocational retraining.

*Article 4***Research and development aid**

1. Public aid for research and development to the shipbuilding, conversion and repair industry may be considered compatible with the common market where this public assistance relates to:

- (i) fundamental research;
- (ii) basic industrial research, provided that the aid intensity is limited to 50 % of eligible costs;
- (iii) applied research, provided that the aid intensity is limited to 35 % of eligible costs;
- (iv) development, provided that the aid intensity is limited to 25 % of eligible costs.

2. The maximum permissible aid intensity for research and development carried out by small and medium-sized enterprises⁽¹⁾ shall be 20 points higher than the percentages specified in paragraph 1 (ii), (iii) and (iv).

3. For the purposes of this Article, the following definitions shall apply to research and development aid:

- (a) eligible costs shall be only those relating to:
 - (i) the costs of instruments, material, land and buildings to the extent that they are used for specific research and development projects;
 - (ii) the costs of researchers, technicians and other staff to the extent that they are engaged in the specific research and development projects;
 - (iii) consultancy and equivalent services including research bought, technical knowledge, patents, etc.;
 - (iv) overhead costs (infrastructure and support services) to the extent that they are related to the research and development projects, on condition that they do not exceed 45 % of the total costs of the project for basic industrial research, 20 % for applied research and 10 % for development;
- (b) 'fundamental research' shall mean research activities independently conducted by higher education or

research establishments for the enlargement of general scientific and technical knowledge, not linked to industrial or commercial objectives;

- (c) 'basic industrial research' shall mean original theoretical and experimental work whose objective is to achieve better understanding of the laws of science and engineering in general and which might apply to an industrial sector or to the activities of a particular undertaking;
- (d) 'applied research' shall mean investigation or experimental work on the basis of the results of basic research with a view to facilitating the attainment of specific practical objectives such as the creation of new products, production processes or services. It normally ends with the creation of a first prototype and does not include efforts whose principal aim is the design, development or testing of products or services to be considered for sale;
- (e) 'development' shall mean the systematic use of scientific and technical knowledge in the design, development, testing or evaluation of new products, production processes or services or in the improvement of an existing product or service to meet specific performance requirements and objectives. This stage normally includes pre-production models such as pilot and demonstration projects but does not include industrial application and commercial exploitation;
- (f) aid for research and development specifically provided to the shipbuilding, conversion or repair industry shall include, but not be limited to, the following:
 - (i) research and development projects carried out by the shipbuilding, conversion or repair industry or by research institutes controlled or financed by that industry;
 - (ii) research and development projects carried out by the shipping industry or by research institutes controlled or financed by that industry where these projects are directly related to the shipbuilding, conversion or repair industry;
 - (iii) research and development projects carried out by universities, public and/or independent private research institutes and other industrial sectors in collaboration with the shipbuilding, conversion or repair industry;

⁽¹⁾ For the purposes of this Regulation 'small and medium-sized enterprises' shall mean enterprises which employ fewer than 300 employees, the yearly turnover of which does not exceed ECU 20 million, and the capital of which is not more than 25 % owned by a large company.

- (iv) research and development projects carried out by universities, public and/or independent private research institutes and other industrial sectors, when, at the time the project is carried out, it can reasonably be expected that the results will be of substantial specific importance for the shipbuilding, conversion or repair industry.

4. Information on the results of research and development shall be published promptly, at least once a year.

Article 5

Indirect aid

1. Aid for shipbuilding and ship conversion, excluding repair, granted to shipowners or third parties in the form of State loans and guarantees may be considered compatible with the common market if it complies with the OECD Understanding on Export Credits for Ships ⁽¹⁾ or with any agreement amending or replacing that Understanding.

2. Aid for shipbuilding and ship conversion granted for genuine reasons as development assistance to a developing country may be deemed compatible with the common market if it complies with the relevant terms of the OECD Understanding or with any agreement amending or replacing that Understanding, as referred to in paragraph 1.

3. Aid granted by a Member State to its shipowners or to third parties in that State for the building or conversion of ships may not distort or threaten to distort competition between shipyards in that Member State and shipyards in other Member States in the placing of orders.

4. For the purpose of this Article, 'ship conversion' shall mean the conversion, in the Community, of self-propelled seagoing commercial vessels, as defined in Article 1 (a), of not less than 1 000 g t on condition that conversion operations entail radical alterations to the cargo plan, the shell, the propulsion system or the passenger reception infrastructure.

Article 6

Spain, Portugal, Belgium

Reconstruction aid granted in Spain, Portugal and Belgium in the form of investment assistance and any assistance for social measures not covered under Article 3 and paid after 1 January 1996 may be considered

compatible with the common market. This aid must be subject to individual notification and prior approval by the Commission by 31 December 1996 at the latest and be subject to the following maximum limits and payments deadlines:

	<i>Amount of aid</i>	<i>Payment deadline</i>
Spain:	Pta 10 billion	31 December 1998
Portugal:	Esc 5,2 billion	31 December 1998
Belgium:	Bfrs 1 320 million	31 December 1997

Article 7

Other measures

1. In exceptional cases, and subject to Article 92 of the Treaty, other aids may be deemed compatible with the Common market. If the Commission considers that this is the case, it shall be empowered, after consulting the special committee set up under Article 113 of the Treaty, to request a derogation from the Parties Group pursuant to Article 5 (5) of the OECD Agreement.

2. For research and development projects related to safety and the environment, and subject to compliance with the conditions set out in Article 92 of the Treaty, a higher aid intensity than provided for in Article 4 (1) (ii), (iii) and (iv) may be deemed compatible with the common market. If the Commission considers that this is the case, it shall be empowered to request the Parties Group to approve the project pursuant to Annex I B 3 (2) to the OECD Agreement.

3. Where aid granted pursuant to this Regulation is the subject of Dispute Panel Proceedings under Article 8 of the OECD Agreement or, in the case of export credits, the subject of consultation mechanisms as laid down in the OECD Understanding on Export credits for Ships, the Community position shall be adopted by the Commission after consultation of the special Committee set up under Article 113 of the Treaty.

CHAPTER III

MONITORING PROCEDURE

Article 8

1. Aid to shipbuilding and repair undertakings covered by this Regulation shall be subject to, in addition to the provisions of Article 93 of the Treaty, the special notification rules provided for in paragraph 2.

⁽¹⁾ OJ No C 375, 30. 12. 1994, p. 38.

2. The following shall be notified to the Commission in advance by the Member States and authorized by the Commission before they are put into effect:

- (a) any aid scheme - new or existing - or any amendment of an existing scheme covered by this Regulation;
- (b) any decision to apply a generally applicable aid scheme, including generally applicable regional aid schemes, to the undertakings covered by this Regulation in order to verify compatibility with Article 92 of the Treaty;
- (c) any individual application of aid schemes in the case referred to in Article 5 (2) or when specifically provided for by the Commission in its approval of the aid scheme concerned.
- (c) completion reports on each shipbuilding and conversion contract signed before the entry into force of this Regulation by the end of the month following the month of completion, in accordance with the annexed Schedule 2;
- (d) yearly reports, to be provided by 1 March of the year following the year subject to the report, giving details of the total amount of aid granted to each individual national shipyard during the previous calendar year, in accordance with the annexed Schedule 3;
- (e) in the case of shipyards able to build merchant ships over 5 000 gt, yearly reports to be provided not later than two months after the annual general meeting has approved the shipyard's yearly report, giving publicly available information on capacity developments and on the structure of ownership, in accordance with the annexed Schedule 4.

Article 9

1. To enable the Commission to monitor application of the aid rules contained in Chapter II, Member States shall supply it with:

- (a) monthly reports on officially supported credit facilities granted for each shipbuilding and conversion contract by the end of the month following the month of signing of each contract, in accordance with the annexed Schedule 1;
- (b) where Member States have schemes providing for official guarantees and insurance for ships, reports to be submitted by 1 April of the year following the year under review, including the results of the schemes, claims paid, income from premiums and fees, income from recoveries and any other appropriate information requested by the Commission;

2. On the basis of the information communicated to it in accordance with Article 8 and paragraph 1 of this Article, the Commission shall draw up an annual overall report to serve as a basis for discussion with national experts.

Article 10

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Communities*.

It shall apply as from the date of entry into force of the OECD Agreement ⁽¹⁾.

Should the said Agreement not enter into force on 1 January 1996, the relevant provisions of Directive 90/684/EEC shall apply until the Agreement enters into force and until 1 October 1996 at the latest.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 22 December 1995.

For the Council

The President

L. ATIENZA SERNA

⁽¹⁾ The date of entry into force of the OECD Agreement will be published in the *Official Journal of the European Communities* by the General Secretariat of the Council.

ANNEX

Schedule 1

EUROPEAN COMMUNITY

**REPORT ON AID TO SHIPOWNERS AND OTHER THIRD PARTIES FOR THE NEW BUILDING
OR CONVERSION OF SHIPS**

1. Name and nationality of enterprise receiving aid
2. Contract price
3. Credit granted
 - Form (e.g., export credit, home credit, etc.):
 - Volume:
 - Repayment period:
 - Frequency of payments:
 - Interest rate:
4. Guarantees granted
 - Volume:
 - Premium paid:
 - Duration:
 - Other terms and conditions:
5. Month of aid granting:
6. New building or conversion contract (please specify which)
 - Ship type and yard No:
 - Deadweight (DWT):
 - Gross tonnage (GT):
 - Compensated gross tonnage (CGT):
 - Performing yard: — Country:
 - Name:
 - Completion/delivery date

Contact for enquiries: Date:

Position held: Signature:

EUROPEAN COMMUNITY

REPORT OF MERCHANT SHIP COMPLETIONS

Section 1: Contract details

1. New building/conversion			
2. Company	3. Yard	4. Yard No	
5. Registered owner			
6. Holding owner			
7. Vessel's country of registration			
8. Date contract signed	9. Completion/delivery date		

Section 3: Financial arrangements

	Currency	Ecu (Prevailing rate)	% of Contract price
14. Contract price			
15. Estimated contract loss (if any)			
16. Contract-related aid:			
A. Granted to yard: (a) grants (b) credit facilities (c) specific fiscal concession (d) other support			
B. Granted to customer or ultimate owners: (a) grants (b) credit facilities (c) fiscal concessions (d) other aid			

Section 2: Ship details

10. Type of vessels (by OECD category)
11. Deadweight (DWT)
12. Gross tonnage (GT)
13. Compensated gross tonnage (CGT)

Contact for enquiries: Date:

Position held: Signature:

Schedule 3

EUROPEAN COMMUNITY

REPORT OF EMPLOYEES' OR ENTERPRISE' FINANCIAL SUPPORT

Name of enterprise:

	Eligible costs (including for (1) details of numbers of workers involved)	Aid received		Legal basis (including date of approval by Commission)
		Form	Amount	
1. Social aid: (a) Redundancy payments (b) Early-retirement payments (c) Reconversion payments (d) Vocational retraining				
2. Research and development aid (a) Fundamental research (b) Basic industrial research (c) Applied research (d) Development				
3. General aid schemes (please specify nature of support)				

Contact for enquiries: Date:

Position held: Signature:

Schedule 4

REPORT ON YARDS ABLE TO BUILD MERCHANT SHIPS OF OVER 5 000 GT

1. Name of the company (.....)
 2. Total available capacity (.....) (CGT)
 3. Data on the dock/berth

Dock or berth	Maximum size of ships (GT)
(.....)	(.....)
(.....)	(.....)
(.....)	(.....)
 4. Description of any plans for future capacity expansion or reduction
 5. Structure of ownership (capital structure, share of direct and indirect public ownership)
 6. Financial statements (balance sheet, profit and loss statement, including, if available, separate accounts covering the shipbuilding activities of holding)
 7. Transfer of public resources (including debt guarantees, bond infusions, etc.)
 8. Exemptions from financial or other obligations (including tax privileges, etc.)
 9. Capital contribution (including equity infusions, withdrawal of capital dividend, loans and their refunding, etc.)
 10. Debt write-off
 11. Transfer of losses
-

COUNCIL DIRECTIVE 95/68/EC

of 22 December 1995

amending Directive 77/99/EEC on health problems affecting the production and marketing of meat products and certain other products of animal origin

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 77/99/EEC⁽¹⁾ and in particular Article 19 thereof,

Having regard to the proposal from the Commission,

Whereas certain aspects of the Annexes to Directive 77/99/EEC should be adapted in order to take account of technological progress in the meat processing sector and in order to bring technical requirements into line with current practice;

Whereas it is therefore necessary to amend the requirements relating to the general conditions for approval of establishments, the general conditions of hygiene applicable to premises, equipment and tools, the special conditions of hygiene for establishments preparing meat products, the requirements for the wrapping, packaging, labelling, health marking, storage and transport of meat products and those relating to the special conditions for prepared meat meals and for rendered fats;

Whereas, until such time as measures have been taken to simplify existing texts, it is necessary to adopt provisional measures to avoid the application of several health marks to meat products containing other products of animal origin;

Whereas the amendments made by the Council to Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat⁽²⁾ including small cold stores and Council Directive 88/657/EEC of 14 December 1988 laying down the requirements for the production of, and trade in, minced meat, meat in pieces of less than 100 grams and meat preparations and amending Directives 64/533/EEC,

71/118/EEC and 72/462/EEC⁽³⁾ require subsequent adjustments to Directive 77/99/EEC; whereas, pending such proposals, measures should be adopted to adjust the Annexes to Directive 77/99/EEC to technological progress,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annexes to Directive 77/99/EEC are hereby amended as follows:

1. in Annex A, Chapter I, point 2 (e) shall be replaced by the following:
'(e) adequate ventilation and, where necessary, good steam and water-vapour extraction facilities in order to eliminate as far as possible condensation on surfaces such as walls and ceilings or roof linings;'
2. in Annex A, Chapter I, the following shall be added to point 8:
'for disinfecting equipment and utensils, water of a temperature of not less than 82° C, or other disinfection methods approved by the competent authority, must be used;'
3. in Annex A, Chapter I, the following shall be added to point 12:
'where the competent authority is not required to be present at all times, a lockable device of sufficient capacity for storage of equipment and materials is sufficient;'
4. in Annex A, Chapter I, point 15 shall be replaced by the following:
'15. adequate facilities for cleaning and disinfecting means of transport; unless, with the agreement of the competent authority, facilities not situated in the establishment may be used;'
5. in Annex A, Chapter I, the following point 16 shall be added:

⁽¹⁾ OJ No L 26, 31. 1. 1977, p. 85. Directive as last amended by the 1994 Act of Accession.

⁽²⁾ OJ No 121, 29. 7. 1964, p. 2012/64. Directive as last amended by Directive 95/23/EC (OJ No L 243, 11. 10. 1995, p. 7).

⁽³⁾ OJ No L 382, 31. 12. 1988, p. 3. Directive as last amended by the 1994 Act of Accession.

- '16. where the treatment applied requires the absence of water for manufacture of the products, certain requirements of this Chapter, in particular those laid down in points 2 (a) and (g), may be adjusted. Should recourse be had to such a derogation, cleaning and disinfecting processes which do not make use of water may, with the authorization of the competent authority, be applied in the parts of the establishment concerned.';
6. in Annex A, Chapter II A, the last sentence of point 1 shall be replaced by the following:
- 'Cleaning and disinfecting must be performed with a frequency and by means of processes which are in line with the principles set out in Article 7 of the Directive.';
7. in Annex A, Chapter II A, point 5 shall be replaced by the following:
- '5. Detergents, disinfectants and similar substances must be used in accordance with the manufacturers' instructions in such a way that they do not have adverse effects on the machinery, equipment, raw materials and products. Their use must be followed by thorough rinsing of such instruments and working equipment with potable water except where the directions for use of such substances render such rinsing unnecessary.
- Products for maintenance and cleaning must be kept in the room or facility provided for in Chapter I (14) of this Annex.';
8. (concerns only the German text) in Annex A, Chapter II B, the second subparagraph of point 2 shall read:
- '... bearbeitet und behandelt';
9. in Annex B, Chapter III, point 3 shall be replaced by the following:
- '3. The presence of products of animal origin, other than meat as defined in Article 2 (d) of the Directive contained in the meat products, is authorized only if these products comply with the requirements laid down in the relevant Community legislation.';
10. in Annex B, Chapter V, the third indent of point 4 shall be replaced by the following:
- for packaging not intended for the final consumer, the date of preparation or a code which can be interpreted by the recipient and by the competent authority allowing the identification of that date.';
11. in Annex B, Chapter VI shall be replaced by the following:
- 'CHAPTER VI
- HEALTH MARK
1. Meat products must carry a health mark. Marking must be carried out during or immediately after manufacture in the establishment or wrapping centre, in an easily visible place in legible and indelible characters which are easy to distinguish. The health mark may be applied directly to the product or to its wrapping if the meat product is individually wrapped, or to a label affixed to the wrapping, in accordance with point 4 (b). However, where a meat product is wrapped and packaged individually, a health mark applied to the packaging is sufficient.
2. Where meat products carrying a health mark in accordance with point 1 are then packaged, the health mark must also be applied to the packaging.
3. By way of derogation from points 1 and 2, the health marking of meat products is not necessary:
- (a) where the health mark, in compliance with point 4, is applied to the external surface of each sales unit containing them;
- (b) where, for meat products in consignments intended for further processing or wrapping in an approved establishment:
- the said consignments bear the health mark of the approved establishment consigning them in a visible place on the external surface, together with a clear indication of the intended destination,
- the recipient establishment maintains a record of the quantities, type and origin of meat products received in accordance with this point and stores that record for the period laid down in the fourth indent of the second subparagraph of Article 7 (1) of the Directive. However, meat products in large packagings which are intended for immediate sale without

further processing or wrapping must bear a health mark in compliance with point 1, 2 or 3 (a);

(c) where, for meat products which are not wrapped or packaged but sold in bulk by the manufacturer directly to a retailer:

- the health mark, in compliance with point 1, is applied to the container carrying them,
- the manufacturer maintains a record of the quantities and type of the meat products consigned in accordance with this point and of the name of the recipient and stores that record for the period laid down in the fourth indent of the second subparagraph of Article 7 (1) of the Directive.

4. (a) The health mark must give the following particulars within an oval surround:

(i) either:

- above: the initial letter or letters of the consigning country in printed capitals, i.e. B — DK — D — EL — E — F — IRL — I — L — NL — AT — P — FI — S — UK, followed by the approval number of the establishment or, the rewrapping centre, in accordance with Decision 94/837/EC, if necessary accompanied by a code number stating the type of product for which the establishment is approved,
- below: one of the following sets of initials: CEE — EØF — EWG — EOK — ETY — EC — EEG;

(ii) or:

- above: the name of the consigning country in capitals,
- in the centre: the approval number of the establishment or the rewrapping centre, in accordance with Decision 94/837/EC, if necessary accompanied by a code number stating the type of product for which the establishment is approved,
- below: one of the following sets of initials: CEE — EØF — EWG — EOK — ETY — EEC — EEG;

(b) the health mark may be applied directly to the product by authorized means or be pre-printed on its wrapping or packaging, or to a label affixed to the product, its wrapping or packaging. Where it is applied to the

wrapping, the stamp must be destroyed when the wrapping is opened. Failure to destroy the stamp can be tolerated only where the wrapping is destroyed by opening it. In the case of products in hermetically sealed containers, the stamp must be applied indelibly on either the lid or the can;

(c) the health mark may also consist of an irremovable plate of resistant material, complying with all the hygiene requirements and containing all the information listed in point (a).

5. Where a meat product contains other foodstuffs of animal origin such as fishery products, dairy products or egg products, only one health mark must be applied.;

12. in Annex B, Chapter VII, point 1 shall be replaced by the following:

‘1. Meat products must be stored in the rooms provided for in Annex B, Chapter I, point 1(a).

However, meat products may also be stored outside the rooms provided for in that point on the following conditions:

(a) meat products which cannot be kept at ambient temperatures may be stored in cold storage plant as referred to in Article 3 (A) (8) of the Directive or in cold storage plant approved in accordance with the other relevant Directives;

(b) meat products which can be kept at ambient temperatures may be stored in stores of solid construction, easy to clean and disinfect, and approved by the competent authority.;

13. in Annex B, Chapter VII, the following shall be added:

‘5. The commercial document referred to in Article 3 A (9) (b) (i) of the Directive must accompany meat products during the first stage of marketing.

For transport and marketing at subsequent stages, the products must be accompanied by a

commercial document bearing the approval number of the consigning establishment identifying the competent authority responsible for control';

— microbiological examination of the contents and the containers in the establishment's laboratory or in another approved laboratory;

14. in Annex B, Chapter VIII, point B shall be replaced by the following:

'B. The operator or manager of an establishment manufacturing meat products in hermetically sealed containers must also check by sampling that:

- (1) a heat treatment is applied to meat products intended for storing at ambient temperature which is capable of destroying or inactivating pathogenic germs and the spores of pathogenic micro-organisms. A register of manufacturing parameters such as duration of heating, temperature, filling, size of containers, etc. must be kept.

The heat treatment apparatus must be fitted with control devices making it possible to check that containers have undergone effective heat treatment;

- (2) the material used for the containers meets Community requirements relating to materials intended to come into contact with foodstuffs;

- (3) checks on the daily output are carried out at intervals determined in advance, to ensure the efficacy of the sealing. To this end, suitable equipment must be available for examining perpendicular sections and the seams of the sealed containers;

- (4) additional checks by sampling are carried out by the manufacturer to ensure that:

- (a) sterilized products have undergone effective treatment, by means of:

— incubation tests. Incubation must be performed at a least 37° C for seven days or at at least 35° C for 10 days, or any other time/temperature combination recognized as equivalent by the competent authority,

- (b) pasteurized products in hermetically sealed containers satisfy criteria recognized by the competent authority,

- (5) the necessary checks are carried out to ensure that the cooling water contains a residual level of chlorine after use. Member States may, however, grant a derogation from this requirement if the water fulfils the requirements of Directive 80/778/EEC.;

15. in Annex B, Chapter IX, point 2 (a) shall be replaced by the following:

- '2. (a) The meat product contained in the prepared meal must, as soon as it has been cooked:

- (i) either be mixed with the other ingredients as soon as practically possible; in that event the time during which the temperature of the meat products is between 10° C and 60° C must be kept to a maximum of two hours;

- (ii) or be refrigerated to 10° C or less before being mixed with the other ingredients.

Where other preparation methods are applied, these must be approved by the competent authority, which shall inform the Commission accordingly.;

16. in Annex C, Chapter II A, point 2 (a) shall be replaced by the following:

- '(a) a cold store, unless the raw materials are collected and rendered within the time limits laid down in B (3) (b) and B (3) (c);;

17. in Annex C, Chapter II B, the words 'for the production of raw materials' shall be deleted in point 7;

18. in Annex C, Chapter II B, point 8 shall be replaced by the following:

- '8. Rendered animal fat, depending on type, must meet the following standards:

	Bovines			Pigs			Other animal fat	
	Edible tallow		Tallow for refining	Edible pig fat		Lard and other pork fat for refining	Edible	For refining
	Premier jus ⁽¹⁾	Other		Lard ⁽²⁾	Other fat			
FFA (m/m % oleic acid) maximum Maximum peroxide	0,75 4 meq/kg	1,25 4 meq/kg	3,0 6 meq/kg	0,75 4 meq/kg	1,25 6 meq/kg	2,0 6 meq/kg	1,25 4 meq/kg	3,0 10 meq/kg
Moisture and impurities	max 0,5 %							
Odour, taste, colour	normal							

⁽¹⁾ Rendered animal fat obtained by the low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.

⁽²⁾ Melted fat obtained from rendering the adipose tissues of swine.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 October 1996. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, 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 reference shall be laid down by Member States.

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

Article 3

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1995.

For the Council

The President

L. ATIENZA SERNA

COUNCIL DIRECTIVE 95/69/EC

of 22 December 1995

laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European 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⁾,

1. Whereas Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽⁴⁾, lays down the minimum conditions to be met by manufacturers of certain additives, premixtures and compound feedingstuffs containing such additives;
2. Whereas these rules restrict the manufacture or use of certain categories of additives, premixtures and compound feedingstuffs containing such additives and premixtures to those manufacturers who are included on a national list;
3. Whereas individuals holding goods covered by this Directive for the sole purposes of their trade promotion or their transport are not regarded as being intermediaries as defined in this Directive;
4. Whereas with the operation of the internal market in mind, some optional provisions which still allow the Member States to derogate from the Community provisions applying to the sector in question should be abolished and the criteria for approving or registering manufacturers or intermediaries should be specified so as to avoid distortions of competition caused by the Member

States' different ways of applying and interpreting pre-existing approval conditions and to forestall any potentially adverse effects on animals, humans or the environment, given the risks inherent in using certain additives;

5. Whereas, to forestall certain particularly undesirable substances occurring in feedingstuffs, Council Directive 74/63/EEC of 17 December 1973 on undesirable substances and products in animal nutrition ⁽⁵⁾, aims to limit their presence in raw materials to an acceptable level; whereas these rules also restrict the use of those raw materials to those persons who have the necessary qualifications, facilities and equipment for the dilution operations which ensure that the maximum levels laid down in the Directive as regards the various types of compound feedingstuffs are complied with;
6. Whereas establishments producing certain substances listed in Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ⁽⁶⁾, should also be subject to approval, as should intermediaries;
7. Whereas, with a view to ensuring the quality of the product and preventing the occurrence of residues of certain additives in animal products or of high levels of certain undesirable substances which might result from defective manufacture, all manufacturers of additives, premixtures, compound feedingstuffs and certain products covered by Directive 82/471/EEC, and intermediaries should be approved or registered on the basis of standard, specific criteria;
8. Whereas the level of requirements for the exercise of activities laid down in this Directive must be in proportion to the risks involved in the manufacture or use by establishments of additives and premixtures listed in Directive 70/524/EEC,

⁽¹⁾ OJ No C 348, 28. 12. 1983, p. 18.

⁽²⁾ OJ No C 91, 28. 3. 1994, p. 296.

⁽³⁾ OJ No C 148, 30. 5. 1994, p. 21.

⁽⁴⁾ OJ No L 270, 14. 12. 1970, p. 1. Directive as last amended by Commission Directive 95/37/EC (OJ No L 172 an 22. 7. 1995, p. 21).

⁽⁵⁾ OJ No L 38, 11. 2. 1974, p. 31. Directive as last amended by Commission Directive 94/16/EC (OJ No L 104, 23. 4. 1994, p. 32).

⁽⁶⁾ OJ No L 213, 21. 7. 1982, p. 8. Directive as last amended by Commission Directive 95/33/EC (OJ No L 167, 18. 7. 1995, p. 17).

products covered by Directive 82/471/EEC or raw materials containing undesirable substances or products listed in Directive 74/63/EEC;

9. Whereas establishments which intend to manufacture or use products deemed sensitive under the Directive must receive prior approval on the basis of very strict conditions that should safeguard animals, humans and the environment, whereas, however, in exceptional cases Member States may decide not to approve a specific category of establishment, provided such measures do not hinder the free movement of agricultural products in the territory of the Member States; whereas, conversely, for establishments using less sensitive products, mere registration based on an undertaking by the establishment to comply with a number of conditions will suffice; whereas this distinction must also apply to intermediaries which wrap, package, store or put into circulation additives, premixtures of additives or products covered by Directive 82/471/EEC;
10. Whereas, on grounds of equal treatment, the fundamental principles of these new rules must apply both to establishments which put products into circulation and to manufacturers/stock farmers who manufacture feedingstuffs solely for the requirements of their own farms, without any distinction; whereas, nonetheless, some relief should be allowed the latter on account of the particular circumstances in which they exercise their activity;
11. Whereas provision should be made for amending or withdrawing approval if an establishment changes or ceases its activities or if it no longer fulfils one of the essential conditions applicable to its activity; whereas the same rules should apply, *mutatis mutandis*, to registration;
12. Whereas Member States may be entitled to levy fees for granting approval; whereas the levels of such fees should subsequently be harmonized in order to obviate distortion of competition; whereas such harmonization will fall within the general framework of future Community rules on fees or charges to be levied in the animal feed sector;
13. Whereas it is necessary to give the Commission the task of adopting detailed rules for the application of this Directive, including the conditions for approval and registration of establishments in third countries;
14. Whereas, should the Council confer on the Commission responsibility for implementing the rules laid down on the conditions and arrangements for approving and registering the establishments in question, provision should be made for close cooperation between the Member States and the Commission within the Standing Committee for Feedingstuffs established by Decision 70/372/EEC ⁽¹⁾;
15. Whereas to ensure greater transparency the conditions and arrangements relating to the approval and registration of establishments in the animal feed sector should be brought together in a single text; whereas this entails adapting existing legislation;
16. Whereas the requirement for manufacturers to be approved or registered will make it possible for Member States to check on manufacturers and intervene, if necessary, where substances are being used illegally, in particular where prohibited substances such as hormones or beta-agonists are in use; whereas Member States have a duty to check beforehand that establishments requiring approval actually meet the minimum conditions which the Directive lays down for exercise of the relevant activity; whereas national supervisory authorities must also ensure subsequently, by means of appropriate checks, that approved or registered establishments and intermediaries are indeed complying with the conditions imposed upon them; whereas these provisions must apply without prejudice to Community rules governing the organization of official checks on animal feed;
17. Whereas it is necessary to adopt these measures at Community level in order better to achieve the objectives of guaranteeing the quality and safety of feedingstuffs,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

1. This Directive lays down the conditions and arrangements applicable to certain categories of establishments and intermediaries in the animal feed

⁽¹⁾ OJ No L 170, 3. 8. 1970, p. 1.

sector to allow them to exercise the activities described in Articles 2 and 7 and Articles 3 and 8 respectively.

2. This Directive shall apply without prejudice to the Community provisions concerning the organization of official checks on animal feed.

3. For the purposes of this Directive:

(a) 'putting into circulation' means holding products for the purposes of sale, including offering for sale, or for the purposes of any other form of transfer, whether or not free of charge, to third parties, and the sale and other forms of transfer themselves;

(b) 'establishment' means any unit producing or manufacturing additives, premixtures prepared from additives, compound feedingstuffs or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Annex to this Directive;

(c) 'intermediary' means any person other than the manufacturer or the person producing for the exclusive requirements of his holding, compound feedingstuffs, who holds additives, premixtures prepared from additives, or one of the products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Annex to this Directive at an intermediate stage between production and use.

4. The definitions laid down in Community legislation on animal feed shall apply where necessary.

minimum conditions laid down in Chapter I.2 (b) of the said Annex;

(c) manufacturing compound feedingstuffs containing premixtures prepared from additives referred to in Chapter I.3 (a) of the Annex, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.3 (b) of the Annex;

(d) manufacturing compound feedingstuffs, with a view to putting them into circulation, from raw materials referred to in Article 3a (2) of Directive 74/63/EEC which contain high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter I.4 of the Annex to this Directive;

(e) producing, for the exclusive requirements of its holding, compound feedingstuffs containing premixtures which include additives referred to in Chapter I.3 (a) of the Annex must meet the minimum conditions laid down in Chapter I.3 (b) of the Annex, with the exception of the requirements set out in point 7;

(f) producing, for the exclusive requirements of its holding, compound feedingstuffs which contain raw materials referred to in Article 3a (2) of Directive 74/63/EEC containing high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter I.4 of the Annex to this Directive, with the exception of the requirements set out in point 7.

CHAPTER II

APPROVAL OF ESTABLISHMENTS AND INTERMEDIARIES

Article 2

Approval of establishments

1. An establishment wishing to exercise one or more of the activities referred to in paragraph 2 must receive approval for each of its activities. A Member State may decide not to approve establishments referred to in paragraph 2 (f).

2. To be approved by the competent authorities an establishment:

(a) manufacturing additives or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Annex to this Directive with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.1 (b) of the said Annex 1;

(b) manufacturing premixtures prepared from additives referred to in Chapter I.2 (a) of the Annex, with a view to putting them into circulation, must meet the

3. Approval shall be:

— withdrawn if an establishment ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,

— amended if the establishment has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Article 3

Approval of intermediaries

1. Where additives, products covered by Directive 82/471/EEC or premixtures of additives referred to in Chapters I.1 (a) and I.2 (a) of the Annex respectively are put into circulation, intermediaries must be approved.

The provisions laid down in point 7 of Chapter I.1 8 (b) or Chapter I.2 (b) of the Annex shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives, premixtures of additives or products covered by Directive 82/471/EEC.

2. Approval shall be:

- withdrawn if an intermediary ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time;
- amended if the intermediary has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Article 4

Approval procedure for establishments and intermediaries

1. To obtain approval, establishments referred to in Article 2 and intermediaries referred to in Article 3 which intend to exercise for the first time one or more of the activities referred to in Article 2 and 3 shall, as from 1 April 1998 submit an application to the competent authority of the Member State in which their facilities are located.

Member States shall ensure that a decision is taken on applications for approval mentioned in the first subparagraph within six months of their submission.

2. Establishments and intermediaries which, on 1 April 1998, were exercising one or more of the activities referred to in Articles 2 and 3 respectively, may continue their activities until a decision has been taken on their application for approval, on condition that they submit the application before 1 September 1998.

Member States shall act on applications for approval from the establishments and intermediaries referred to in the first paragraph before 1 April 2001.

Article 5

Register of approved establishments and intermediaries

1. For each activity, the competent authority shall enter the establishments and intermediaries it has approved in accordance with Articles 2 and 3 in a register under an individual approval number which identifies them, once it has established by means of on-the-spot verification that they satisfy the conditions laid down by this Directive.

In respect of intermediaries who act solely as dealers without ever holding the product in their facilities, Member States need not carry out on-the-spot verification of compliance with the conditions under point 7 of Chapters I.1 (b) or I.2 (b) of the Annex, providing that those intermediaries lodge with the competent authority a declaration to the effect that they meet the requirements laid down under point 6.2 in the Annex for the exercise of their activity.

2. Member States shall update the entries of establishments and intermediaries in the register in accordance with the decisions referred to in Article 2 (3) and Article 3 (2) to withdraw or amend approval.

Article 6

Publication and communication of the list of approved establishments and intermediaries

1. Each Member State shall publish a list of the establishments and intermediaries approved in accordance with Articles 2 and 3 for the first time in November 2001, and then each year, by 30 November at the latest, the list of amendments made during the year; every five years, it shall publish a consolidated list.

2. Before 31 December each year, Member States shall send the Commission the list referred to in paragraph 1.

Before 31 December each year, Member States shall send the other Member States a list of the establishments referred to in Article 2 (2) (a) and (b) and of the intermediaries approved in accordance with Article 3 (1).

Upon request, Member States shall send the other Member States all or part of the list of establishments referred to in Article 2 (2) (c) to (f).

CHAPTER III

REGISTRATION OF ESTABLISHMENTS AND INTERMEDIARIES

Article 7

Registration of establishments

1. An establishment wishing to exercise one or more of the activities referred to in paragraph 2 must be registered by a Member State for each activity in accordance with this Directive.

2. In order to be registered by the competent authorities an establishment:

- (a) manufacturing additives for which a prescribed maximum level is set and which are not included in Chapter I.1 (a) of the Annex, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II (c) of the Annex;
- (b) manufacturing premixtures containing additives referred to in Chapter II (a) of the Annex, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II (c) of the Annex;
- (c) manufacturing compound feedingstuffs containing premixtures of additives referred to in Chapter II (b) of the Annex or additives referred to in Chapter II (a)

of the Annex with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II (c) of the Annex;

(d) manufacturing, for the exclusive requirements of its holding, compound feedingstuffs containing premixtures of additives referred to in Chapter II (b) of the Annex or containing additives referred to in Chapter II (a) of the Annex, must meet the minimum conditions laid down in Chapter II (c) of the Annex.

3. Approved establishments exercising the corresponding activities referred to in Article 2 (2) (a), (b), (c) and (e) shall be regarded as satisfying *de facto* the conditions laid down in paragraph 2 (a), (b), (c) and (d).

4. Registration shall be:

- withdrawn if an establishment ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,
- amended if the establishment declares that it is engaged in activities which are additional to those for which it was first registered or which replace them.

Article 8

Registration of intermediaries

1. Where additives for which a prescribed maximum level is set other than those referred to in Chapter I.1 (a) of the Annex or premixtures of additives referred to in Chapter II (a) of the Annex are put into circulation, intermediaries must be registered.

The provisions laid down in point 7 of Chapter II (c) of the Annex shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives or premixtures of additives.

2. Intermediaries approved in accordance with Article 3 shall be regarded as meeting *de facto* the conditions laid down in paragraph 1.

3. Registration shall be:

- withdrawn if an intermediary ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,
- amended if the intermediary has declared that it is engaged in activities which are additional to those for which it was first registered or which replace them.

Article 9

Registration procedure for establishments and intermediaries

1. In order to be registered, the establishments referred to in Article 7 (2) and the intermediaries referred to in Article 8 (1) shall, as from 1 April 1998, submit a declaration to the competent authority of the Member State in which they intend to exercise their activities.

2. Establishments and intermediaries which, on 1 April 1998, were exercising one or more of the activities referred to in Articles 7 and 8 respectively, may continue their activities on condition that they submitted the declaration referred to in paragraph 1 by 1 September 1998.

Article 10

List of registered establishments and intermediaries

1. For each activity, the competent authority shall enter the establishments and intermediaries which it has registered in accordance with Articles 7 and 8 on a list under an individual registration number which identifies them.

2. Member States shall update the entries of establishments and intermediaries on the list in accordance with the decisions referred to in Articles 7 (4) and 8 (3) to withdraw or amend registration.

Article 11

Communication of the list of registered establishments and intermediaries

1. Before 31 December each year, Member States shall send the Commission the list of establishments and intermediaries registered during the year in accordance with Articles 7 and 8 and, every five years, they shall send a consolidated list.

2. Upon request, Member States shall send to the other Member States all or part of the lists referred to in paragraph 1.

CHAPTER IV

COMMON PROVISIONS

Article 12

Simplified procedure

Where an establishment manufacturing an additive is already authorized to manufacture the same active substance as a veterinary medicinal product within the meaning of Article 24 of Directive 81/851/EEC ⁽¹⁾,

⁽¹⁾ OJ No L 317, 6. 11. 1981, p. 16. Directive as last amended by Commission Directive 93/40/EEC (OJ No L 214, 24. 8. 1993, p. 31).

Member States shall not be obliged to verify that the conditions laid down in Article 2 (2) (a) and contained in Chapter I.1 (b) of the Annex to this Directive have been fulfilled, with the exception of the requirements set out in points 4, 5, 6.2 and 7.

Article 13

Checks

Member States shall ensure, by means of appropriate checks carried out in establishments and at the premises of intermediaries which they have approved or registered, that the requirements imposed by this Directive are met.

Article 14

Fees

The Council, acting by a qualified majority on a proposal from the Commission, shall, before 1 April 1998, adopt the amounts of the fees to be charged for the approval of establishments and their intermediaries.

Article 15

Detailed arrangements, amendment of the Annex and imports from non-member countries

The following shall be adopted in accordance with the procedure laid down in Article 16:

- (a) before 1 April 1998, practical arrangements for the approval pursuant to Article 2 and registration pursuant to Article 7 of establishments located in a non-member country and putting additives, premixtures, products covered by Directive 82/471/EEC as referred to in Chapter 1.1 (a) of the Annex to this Directive or feedingstuffs into circulation within the Community, so that safeguards are provided equivalent to those supplied by establishments located in the Community.

These arrangements shall comprise:

- establishment and updating of a list of non-member countries able to provide safeguards equivalent to those offered by the Member States in respect of their own establishments and able to perform the checks referred to in Article 13,
- establishment and updating of a list of establishments which have been found by the non-member countries on the list referred to in the first indent to fulfil the conditions laid down in this Directive,
- the possibility that experts from the Commission and the Member States may carry out on-the-spot checks if necessary. Such checks shall be performed on behalf of the Community, which will bear the relevant expenses;

- (b) measures for implementing this Directive, in particular the form of the register and approval numbers;

- (c) the amendments to be made to the Annexes.

Article 16

Standing Committee for Feedingstuffs

The Commission shall be assisted by the Standing Committee for Feedingstuffs established by Decision 70/372/EEC, 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, 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.

CHAPTER V

ADAPTATION OF LEGISLATION

Article 17

Amendment of Directive 70/524/EEC

Article 13 (1) of Directive 70/524/EEC shall be replaced by the following:

'Article 13

1. Member States shall require that additives covered by this Directive, premixtures prepared from these additives with a view to their being incorporated in compound feedingstuffs and compound feedingstuffs containing these premixtures may be put into circulation or used only by the establishments or intermediaries which meet the conditions laid down, as appropriate, in Council Directive 95/69/EC of 22

December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (*).

(*) OJ No L 332, 30. 12. 1995, p. 15.'

Article 18

Amendment of Directive 74/63/EEC

Point (a) of Article 3a (2) of Directive 74/63/EEC shall be replaced by the following:

'(a) it is intended for use by establishments which meet the conditions of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (*).

(*) OJ No L 332, 30. 12. 1995, p. 15.'

Article 19

Amendment of Directive 79/373/EEC

In Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs ⁽¹⁾, the following subparagraph shall be added to Article 5 (1):

'(k) the approval number allocated to the establishment in accordance with Article 5 of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector (*).

(*) OJ No L 332, 30. 12. 1995, p. 15.'

Article 20

Amendment of Directive 82/471/EEC

Directive 82/471/EEC is hereby amended as follows:

(1) The following paragraph shall be added to Article 3:

'3. Member States shall require that products referred to in Chapter I.1 (a) of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries

operating in the animal feed sector (*) may be put into circulation only by establishments or intermediaries which meet the conditions laid down in Article 2 or Article 3 of that Directive, as appropriate.

(*) OJ No L 332, 30. 12. 1995, p. 15.'

(2) In the Annex, for the products referred to in Chapter I.1 (a) of this Directive, in column 7 ('special provisions'), the terms 'approval number' shall be added as a final indent to the details to be given on the packaging of the product, on the container or on a label affixed thereto.

CHAPTER VI

FINAL PROVISIONS

Article 21

1. Member States shall adopt, not later than 1 April 1998 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof. The measures adopted shall be applicable as from 1 April 1998.

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 reference shall be laid down by the Member States.

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

Article 22

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Artikel 23

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1995.

For the Council

The President

L. ATIENZA SERNA

⁽¹⁾ OJ No L 86, 6. 4. 1979, p. 30. Directive as last amended by Directive 93/74/EEC (OJ No L 237, 22. 9. 1993, p. 23).

ANNEX

CHAPTER I

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in Articles 2 and 3 (subject to approval)

CHAPTER I.1. (a)

Additives and products covered by Directive 82/471/EEC ('products') and referred to in Article 2 (2) (a) and Article 3 (1) of this Directive

Additives

— Antibiotics:	all additives in the group
— Coccidiostats and other medicinal substances:	all additives in the group
— Growth promoters:	all additives in the group
— Vitamins, provitamins and chemically well-defined substances having a similar effect:	all additives in the group
— Trace elements:	all additives in the group
— Enzymes:	all additives in the group
— Micro-organisms:	all additives in the group
— Carotenoids and xanthophylls:	all additives in the group
— Substances with antioxidant effects:	only those with a fixed maximum content

Products covered by Directive 82/471/EEC

— Proteins obtained from micro-organisms belonging to the group of bacteria, yeasts, algae, lower fungi:	all products in the group (except for sub-group 1.2.1)
— Co-products of the manufacture of amino acids by fermentation:	all products in the group
— Amino acids and their salts:	all products in the group
— Hydroxy analogues of amino acids:	all products in the group

CHAPTER I.1. (b)

Minimum conditions which must be fulfilled by establishments referred to in Article 2 (2) (a) and intermediaries referred to in Article 3 (1) ('products' referred to in Chapter I.1(a))

1. *Facilities and equipment*

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the 'products' concerned. The lay-out, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for production of the products.

2. *Personnel*

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the 'products' concerned. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities of the supervisory staff must be drawn up and made

available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the 'products' concerned.

3. *Production*

A qualified person responsible for production must be designated.

The manufacturer must ensure that the different stages of production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.

Technical or organizational measures must be taken to avoid cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.

4. *Quality control*

A qualified person responsible for quality control must be designated.

The manufacturer must have access to a quality control laboratory having adequate staff and equipment to guarantee and check, before the release of the 'products' concerned with a view to putting them into circulation, that they comply with the specifications defined by the manufacturer and are in conformity with the provisions laid down in Directive 70/524/EEC or Directive 82/741/EEC. The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and the destination in the event of non-compliance — of raw materials, active substances, carrier substances and 'products'.

Samples of the active substance and of each batch of 'product' put into circulation or of each specific portion of production in the case of continuous production must be taken in sufficient quantity by a procedure pre-established by the manufacturer and be retained in order to ensure traceability. The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities at least until the guarantee date of the finished product.

5. *Storage*

Raw materials, active substances, carrier substances, 'products' which meet the specifications — and those which do not — must be stored in suitable containers in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

They must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances. Additives must be packaged and labelled in particular in compliance with the provisions laid down in Directive 70/524/EEC. Products covered by Directive 82/471/EEC must be labelled in compliance with the provisions of that Directive.

6. *Documentation*

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of 'product' put into circulation and to establish responsibility if complaints arise.

6.2. Register

The manufacturer must record the following information in order to ensure traceability:

(a) *register of additives:*

- the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture, and the names and addresses of the intermediaries or manufacturers to whom the additives have been delivered,

- indication of the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture;

(b) *register of products covered by Directive 82/471/EEC:*

- the nature of the products and the quantity produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,
- the names and addresses of the intermediaries or users (manufacturers or stock breeders) to whom these products have been delivered, together with an indication of the nature and quantity of the products delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture.

7. *Intermediaries referred to in Article 3 (1)*

Where the manufacturer delivers additives to a person other than a manufacturer or products referred to in Directive 82/471/EEC to a person other than a user (manufacturer or stock breeder), that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5, 6.2 and 8 and, in the case of wrapping, by those referred to in point 3.

8. *Complaints and product recall*

The manufacturer or any intermediary putting a product into circulation under his own name must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.2. (a)

Additives referred to in Article 2 (2) (b) and Article 3 (1)

- | | |
|---|----------------------------|
| — Antibiotics: | all additives in the group |
| — Coccidiostats and other medicinal substances: | all additives in the group |
| — Growth promoters: | all additives in the group |
| — Vitamins, provitamins and chemically well-defined substances having a similar effect: | A and D |
| — Trace elements: | Cu and Se |

CHAPTER I.2. (b)

Minimum conditions which must be fulfilled by establishments referred to in Article 2 (2) (b) and intermediaries referred to in Article 3 (1) (premixtures of additives referred to in Chapter I.2 (a))

1. *Facilities and equipment*

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the premixtures concerned. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for operations which are essential for the quality of the products must undergo appropriate and regular checks in accordance with the written procedures pre-established by the manufacturer.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. *Personnel*

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the premixtures concerned. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the premixtures concerned.

3. *Production*

A qualified person responsible for production must be designated.

The manufacturer must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as in corporation of the additive in the premixture, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the premixtures concerned in accordance with the provisions of Directive 70/524/EEC.

Technical or organizational measures must be taken to avoid cross-contamination and errors.

4. *Quality control*

A qualified person responsible for quality control must be designated.

The manufacturer must have access to a quality control laboratory having adequate staff and equipment to guarantee and check that the premixtures concerned comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content, homogeneity and stability of the additives in the premixture, and as low a level of cross-contamination as possible. The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for carrier substances, additives and premixtures ('products').

Samples of each batch of premixture put into circulation must be taken in sufficient quantity by a procedure pre-established by the manufacturer and be retained in order to ensure traceability. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities at least until the guarantee date of the premixture.

5. *Storage*

'Products' which meet the specifications — and those which do not — must be stored in suitable containers or in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The 'products' must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products and with medicinal substances. Premixtures must be wrapped and labelled in accordance with the provisions of Directive 70/524/EEC.

6. *Documentation*

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. These sets of documents must be kept in such a way as to make it possible to trace the manufacturing history of each premixture batch put into circulation and to establish responsibility if complaints arise.

6.2. Register of premixtures

The manufacturer must record the following information in order to ensure traceability:

- the names and addresses of manufacturers of additives or of intermediaries, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,
- the date of manufacture of the premixture, the batch number where appropriate,
- the names and addresses of the intermediaries or manufacturers of compound feedingstuffs to whom the premixture is delivered, the delivery date, the nature and quantity of the premixture is delivered, and the batch number where appropriate.

7. *Intermediaries referred to in Article 3 (1)*

Where the manufacturer delivers premixtures to a person other than a manufacturer of compound feedingstuffs, that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5, 6.2 and 8 and, in the case of wrapping, by those referred to in point 3.

8. *Complaints and product recall*

The manufacturer or any intermediary putting a product into circulation under his own name must implement a system for registering and processing complaints. Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.3. (a)

Additives referred to in Article 2 (2) (c) and (e)

- | | |
|---|----------------------------|
| — Antibiotics: | all additives in the group |
| — Coccidiostats and other medicinal substances: | all additives in the group |
| — Growth promoters: | all additives in the group |

CHAPTER I.3. (b)

Minimum conditions which must be fulfilled by establishments referred to in Article 2 (2) (c) and (e) (compound feedingstuffs containing premixtures of additives referred to in Chapter I.3 (a))

1. *Facilities and equipment*

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of compound feedingstuffs containing premixtures. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid, as far as possible, contamination, cross-contamination and any adverse effects generally on the quality of the products.

Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with the written procedures pre-established by the manufacturer, or possibly, in the case of manufacture solely for the manufacturer's own needs, pre-established by a qualified outside person acting at the request and under the responsibility of the manufacturer. Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. *Personnel*

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of compound feedingstuffs containing premixtures. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up — if appropriate in the case of manufacture solely for the manufacturer's own needs — and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the compound feedingstuffs containing premixtures.

3. *Production*

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as incorporation of the premixture in the feedingstuff, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the compound feedingstuffs in accordance with the provisions of Directive 79/373/EEC.

Technical or organizational measures shall be taken to avoid cross-contamination and errors as far as possible.

4. *Quality control*

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must have at his disposal a quality control laboratory having adequate staff and equipment to guarantee and check that the compound feedingstuffs containing premixtures comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content and homogeneity of the additives concerned in the compound feedingstuffs, and as low a level as possible of cross-contamination, as well as, in the case of feedingstuffs to be put into circulation, the contents as regards analytical constituents (Directive 79/373/EEC). The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for raw materials, premixtures and compound feedingstuffs 'products'.

Samples must be taken in sufficient quantity by a procedure pre-established by the manufacturer on the basis of each batch of compound feedingstuffs or each specific portion of production in the case of continuous manufacture, and be retained in order to ensure traceability where it is put into circulation, or on a regular basis in the case of manufacture solely for the manufacturer's own needs. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities for an appropriate period.

5. *Storage*

'Products' which meet the specifications — and those which do not — must be stored in suitable containers in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The 'products' must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products and with medicinal substances or medicinal feedingstuffs, or with raw materials containing high levels of undesirable substances and products, or with additives. Compound feedingstuffs intended to be put into circulation must comply with the provisions of Directive 79/373/EEC.

6. *Documentation*

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each batch produced and, where it is put into circulation, to establish responsibility if complaints arise.

6.2. Register of compound feedingstuffs

The manufacturer must record the following information in order to ensure traceability:

- the names and addresses of premixture manufacturers or intermediaries, with the batch number if appropriate, the nature and quantity of the premixture used,
- the nature and quantity of feedingstuffs manufactured, together with the date of manufacture.

7. *Complaints and product recall*

The manufacturer must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.4

Minimum conditions which must be fulfilled by establishments referred to in Article 2 (2) (d) and (e) (compound feedingstuffs from raw materials which contain high levels of undesirable substances and products ('raw materials concerned'))

1. *Facilities and equipment*

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of compound feedingstuffs from the 'raw materials concerned'. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, as far as possible, contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer, or possibly, in the case of manufacture solely for the manufacturer's own needs, pre-established by a qualified outside person acting at the request and under the responsibility of the manufacturer.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. *Personnel*

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of compound feedingstuffs from the 'raw materials concerned'. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must — if appropriate in the case of manufacture solely for the manufacturer's own needs — be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of compound feedingstuffs from the 'raw materials concerned'.

3. *Production*

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacture must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as incorporation in the feedingstuff of the 'raw material concerned', chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the compound feedingstuffs in accordance with the provisions of Directive 79/373/EEC.

Technical or organizational measures shall be taken to avoid cross-contamination and errors as far as possible.

4. *Quality control*

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must have at his disposal a quality control laboratory having adequate staff and equipment to guarantee and check that the compound feedingstuffs concerned comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content and homogeneity of the undesirable substances and products concerned in the compound feedingstuff, and as low a level as possible of cross-contamination as well as compliance with the maximum levels of undesirable substances and products as laid down in Directive 74/63/EEC and, in the case of feedingstuffs to be put into circulation, contents as regards analytical constituents (Directive 79/373/EEC). The use of an outside laboratory is permitted.

A quality control plan shall be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for raw materials, including those with high levels of undesirable substances and products, and compound feedingstuffs.

Samples must be taken sufficient quantity by a procedure pre-established by the manufacturer on the basis of each of compound feedingstuffs or each specific portion of production in the case of continuous manufacture, and be retained in order to ensure traceability where it is put into circulation, or on a regular basis in the case of manufacture solely for the manufacturer's own needs. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities for a period appropriate to the use to which the feedingstuffs are put.

5. *Storage*

Raw materials, notably those containing high levels of undesirable substances and products and compound feedingstuffs which meet the specifications — and those which do not — must be stored in suitable containers or in places designed, adapted and maintained in order to ensure good storage conditions.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The products must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances or medicinal feedingstuffs, or with additives or premixtures of additives. Compound feedingstuffs intended to be put into circulation must comply with the provisions of Directive 79/373/EEC.

6. *Documentation*

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must in particular keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each batch produced and, where it is put into circulation, to establish responsibility if complaints arise.

6.2. Register of compound feedingstuffs

The manufacturer must record the following information in order to ensure traceability:

- the names and addresses of suppliers of raw materials containing high level of undesirable substances and products, and
- the nature and level of undesirable substances and products, the delivery date and the nature and quantity of the products manufactured, plus the date of manufacture.

7. *Complaints and product recall*

The manufacturer must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER II

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in Articles 7 and 8 (subject to registration)

CHAPTER II (a)

Additives referred to in Article 7 (2) (b), (c) and (d) and in Article 8 (1)

- | | |
|---|--|
| — Vitamins, provitamins and chemically well-defined substances having a similar action: | all additives in the group except for vitamins A and D |
| — Trace elements: | all additives in the group except for Cu and Se |
| — Carotenoids and xanthophylls: | all additives in the group |
| — Enzymes: | all additives in the group |
| — Micro-organisms: | all additives in the group |
| — Substances with antioxidant effects: | only those with a fixed maximum content |

CHAPTER II (b)

Additives referred to in Article 7 (2) (c) and (d)

- | | |
|---|---|
| — Vitamins, provitamins and chemically well-defined substances having a similar action: | all additives in the group |
| — Trace elements: | all additives in the group |
| — Carotenoids and xanthophylls: | all additives in the group |
| — Enzymes: | all additives in the group |
| — Micro-organisms: | all additives in the group |
| — Substances with antioxidant effect: | only those with a fixed maximum content |

CHAPTER II (c)

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in Article 7 (2) (a) and (b) and Article 8 (1), (additives for which a prescribed maximum level is set and which are not referred to in Chapter I.1 (a), premixtures of additives referred to in Chapter II (a)) and establishments referred to in Article 7 (2) (c) and (d), (compound feedingstuffs containing premixtures of additives referred to in Chapter II (b) or additives referred to in Chapter II (a)).

1. *Facilities and equipment*

Facilities and technical equipment must be located, designed, constructed and maintained to suit the manufacture of the additives, premixtures of additives and compound feedingstuffs containing additives or premixtures of additives concerned ('products concerned').

2. Personnel

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the 'products concerned'.

3. Production

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must ensure that the different stages of production are carried out in such a way as to obtain the desired quality of the 'products concerned' in accordance with the provisions of Directive 70/524/EEC or Directive 79/373/EEC.

4. Quality control

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must draw up and implement a quality control plan to guarantee and check that the 'products in question' comply with the specifications defined by the manufacturer and that they comply, as appropriate, with the provisions of Directive 70/524/EEC or Directive 79/373/EEC.

In order to ensure traceability, samples must be taken and kept, where appropriate, from each batch of the product or from each specific portion of production in the case of continuous or regular manufacture. They must be kept at the disposal of the competent authorities for a period appropriate to the use to which the feedingstuffs are put.

5. Storage

Raw materials, active substances, carrier substances, premixtures and compound feedingstuffs must be stored in places designed, adapted and maintained in order to ensure good storage conditions.

The products must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances or medicinal feedingstuffs. Products to be put into circulation must be wrapped, where appropriate, and labelled in accordance with the provisions of Directive 70/524/EEC or Directive 79/373/EEC, as appropriate.

6. Register

The manufacturer must record the following information in order to ensure traceability:

(a) *for additives:*

- the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,
- the names and addresses of the intermediaries or users (manufacturers or stock breeders) to whom the additives have been delivered, with an indication of the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture.

(b) *for premixtures:*

- the names and addresses of the additive manufacturers or intermediaries, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,
- the date of manufacture of the premixture, the number of the batch where appropriate,
- the names and addresses of the intermediaries or manufacturers to whom the premixtures have been delivered and the nature and quantity of the premixture delivered, and the number of the batch, where appropriate;

(c) *for compound feedingstuffs containing premixtures or additives:*

- the names and addresses of the premixture manufacturers or intermediaries, with the batch number where appropriate, the nature and quantity of the premixture used,

- the names and addresses of the additive manufacturers or intermediaries, the nature and quantity of the additive used and the number of the batch or of the specific portion of production in the event of continuous manufacture,
- the nature and quantity of the feedingstuffs manufactured, with the date of manufacture.

7. *Intermediaries referred to in Article 8 (1)*

Where the manufacturer delivers additives to a person other than a manufacturer or stock breeder, or premixtures to a person other than a manufacturer, that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5 and 6.2 and, in the case of wrapping, by those laid down in point 3.

COUNCIL DIRECTIVE 95/70/EC

of 22 December 1995

introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European 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 molluscs are listed in Annex II to the Treaty; whereas the marketing of molluscs constitutes an important source of revenue for the aquaculture sector;

Whereas the mollusc diseases referred to in Annex A, list II, 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 ⁽³⁾, have a very serious effect on the shellfish industry; whereas other diseases having a similar effect occur in third countries, whereas a list of such diseases should be drawn up and the Commission should be given the ability to adjust that list in the light of developments in the animal-health field;

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

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

Whereas Member States should report to the Commission and the other Member States all cases of abnormal mortality observed in bivalve molluscs;

Whereas, in such an event, measures must be taken aimed at preventing the spread of the disease, in particular with regard to the removal of live bivalve molluscs from the farms or zones concerned;

Whereas a thorough epidemiological investigation is essential to determine the origin of the disease and to prevent further spread;

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 ensured 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 diseases form a minimum basis for maintaining a uniform standard of animal health;

Whereas the Commission should be entrusted with the task of adopting the necessary implementing measures,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive establishes minimum Community measures for the control of the diseases affecting bivalve molluscs referred to in this Directive.

Article 2

1. For the purposes of this Directive, the definitions laid down in Article 2 of Directive 91/67/EEC and Article 2 of Directive 91/492/EEC ⁽⁴⁾ shall apply as necessary.

2. In addition, 'observed abnormal mortality' shall mean sudden mortality affecting approximately 15 % of stocks and occurring over a short period between two inspections (confirmed within 15 days). In hatchery a mortality shall be considered abnormal when the farmer cannot obtain larvae during a period which included successive spawns from different broodstocks. In nursery

⁽¹⁾ OJ No C 285, 13. 10. 1994, p. 9.

⁽²⁾ OJ No C 109, 1. 5. 1995, p. 2.

⁽³⁾ OJ No L 46, 19. 2. 1991, p. 1. Directive as last amended by Directive 95/22/EC (OJ No L 243, 11. 10. 1995, p. 1).

⁽⁴⁾ Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs (OJ No L 268, 24. 9. 1991, p. 1). Directive as amended by the 1994 Act of Accession.

a mortality shall be considered abnormal when a sudden sizeable mortality occurs in a short time on a number of tubes.

Article 3

Member States shall ensure that all farms rearing bivalve molluscs:

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

This record, which shall be open to scrutiny by the official service at all times, on demand, shall be updated regularly and kept for four years.

Article 4

1. Member States shall ensure that a monitoring and sampling programme is applied in bivalve mollusc farms, farming areas and harvested natural beds in order to observe whether there is an abnormal mortality and keep track of the health situation of stocks.

In addition, the official service may apply the above programme to purification centres and storage tanks which discharge water into the sea.

If, during application of this programme, any abnormal mortality is observed, or if the official service has information giving it reason to suspect the presence of diseases, the following measures shall be taken:

- a list shall be drawn up of the sites where the diseases referred to in Annex A, list II to Directive 91/67/EEC are present, provided that such diseases are not the subject of a programme approved pursuant to the aforementioned Directive,
- a list shall be drawn up of the sites at which abnormal mortality has been observed as a result of the presence of the diseases referred to in Annex D, or on which the official service has information giving it reason to suspect the presence of diseases,
- monitoring of the evolution and geographical spread of the diseases referred to in the first and second indents.

2. The detailed rules for implementing this Article, and *inter alia* the rules to be applied for establishing the programme referred to in paragraph 1, particularly as regards the frequency and timetable of monitoring, procedures for taking samples (statistically representative volume) and methods of diagnosis, shall be adopted in accordance with the procedure provided for in Article 10.

Article 5

1. Member States shall ensure that the suspected presence of any diseases referred to in Article 4 and any abnormal mortality rate observed in bivalve molluscs in farms, in farming areas or in harvested natural beds or in purification centres or storage tanks which discharge water into the sea is notified as soon as possible to the official service by the shellfish-farmers or any other person who has made such observations.

2. In the case referred to in paragraph 1, the official service in the Member States shall ensure that:

- (a) samples are taken for examination in an approved laboratory;
- (b) pending the result of the examination referred to in (a), no molluscs leave the affected farm, farming area or harvested natural beds or purification centres or storage tanks which discharge water into the sea for relaying or reimmersion in another farm or in the aquatic environment, unless authorized by the official service.

3. If the examination referred to in paragraph 2 (a) fails to demonstrate the presence of a pathogen, the restrictions referred to in paragraph 2 (b) shall be lifted.

4. If the examination referred to in paragraph 2 shows the presence of a pathogen causing the observed abnormal mortality capable of being the cause of that mortality, or of a pathogen of one of the diseases referred to in Article 4, an epizootic investigation must be carried out by the official service in order to determine the possible means of contamination and to investigate whether molluscs have left the farm, the farming area or the harvested natural beds for relaying or reimmersion elsewhere during the period preceding observation of the abnormal mortality.

If the epizootic investigation shows that the disease has been introduced into one or more farms, farming areas or harvested natural beds as a result *inter alia* of molluscs being moved, the provisions of paragraph 2 shall apply.

However, by way of derogation from Article 3 (1) (c) of Directive 91/67/EEC, the official service may, within its

territory, authorize the movement of live bivalve molluscs to other farms, farming areas or harvested natural beds which are infected with the same disease.

If necessary, further appropriate measures may be decided on in accordance with the procedure in Article 10.

5. The official service shall ensure that the Commission and the other Member States are immediately informed, in accordance with the current Community procedures, of any cases of abnormal mortality rates observed involving a pathogen, of any measures taken to analyse and control the situation and of the cause of the mortality.

Article 6

1. Sampling and laboratory testing for the determination of the cause of abnormal mortality of bivalve molluscs shall be carried out using the methods established in accordance with the procedure laid down in Article 10.

2. Member States shall ensure that in each Member State a national reference laboratory is designated, with facilities and expert personnel enabling it to carry out the testing referred to in paragraph 1.

3. By way of derogation from paragraph 2, Member States which do not have a national laboratory competent in the matter may use the services of a national laboratory with competence in the matter in another Member State.

4. The list of national reference laboratories for diseases of bivalve molluscs is set out in Annex C.

5. National reference laboratories shall cooperate with the Community reference laboratory referred to in Article 7.

Article 7

1. The Community reference laboratory for diseases of bivalve molluscs is indicated in Annex A.

2. Without prejudice to Decision 90/424/EEC of 26 June 1990⁽¹⁾ on expenditure in the veterinary field and in particular Article 28 thereof, the functions and duties of the laboratory referred to in paragraph 1 shall be those laid down in Annex B.

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19. Decision last amended by Decision 94/370/EC (OJ No L 168, 2. 7. 1994, p. 31).

Article 8

1. Commission experts may, to the extent necessary to ensure uniform application of this Directive, carry out on-the-spot checks. In so doing, they may carry out random, non-discriminatory checks to ensure that the competent authority is monitoring compliance with the requirements of this Directive.

The Commission shall inform the Member States of the results of these checks.

2. The checks referred to in paragraph 1 shall be carried out in collaboration with the competent authority.

3. The Member State in whose territory the inspections are carried out shall provide the experts with any assistance they require to accomplish their task.

4. Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 10.

Article 9

Annex A shall be amended as necessary by the Council, acting by a qualified majority on a proposal from the Commission.

Annexes B, C and D may be amended as necessary in accordance with the procedure laid down in Article 10.

Article 10

1. Where the procedure laid down in this Article is to be followed, matters shall be referred without delay to the Standing Veterinary Committee, (hereinafter referred to as 'the Committee'), set up by decision 68/361/EEC⁽²⁾, by its Chairman, either on his own initiative or at the request 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 the 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.

⁽²⁾ OJ No L 255, 18. 10. 1968, p. 23.

- (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 11

By 31 December 1999 at the latest, the Commission shall submit a report to the Council which has been drawn up, if necessary after consulting the Scientific and veterinary Committee, taking account of experience acquired in applying this Directive and of technical and scientific developments, accompanied where appropriate by any proposals for amendments.

The Council shall act by a qualified majority on any such proposals.

Article 12

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 June 1997. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, 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 reference shall be laid down by 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 for their production 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 governed by this Directive.

Article 13

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Article 14

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1995.

For the Council

The President

L. ATIENZA SERNA

ANNEX A

COMMUNITY REFERENCE LABORATORY FOR DISEASES OF BIVALVE MOLLUSCS

IFREMER
Boîte Postale 133
17390 La Tremblade
France

ANNEX B

FUNCTIONS AND DUTIES OF THE COMMUNITY REFERENCE LABORATORY FOR DISEASES OF BIVALVE MOLLUSCS

The function and duties of the Community reference laboratory shall be:

1. to coordinate, in consultation with the Commission, the methods employed in Member States for diagnosing diseases of bivalve molluscs, specifically by:
 - (a) building up and retaining a collection of histological slides, strains or isolates of the relevant pathogens and making these available to approved laboratories in the Member States;
 - (b) organizing periodic comparative tests of diagnostic procedures at Community level;
 - (c) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
 - (d) characterizing isolates of pathogens by the most up-to-date and appropriate methods to allow greater understanding of the epizootiology of the disease;
 - (e) keeping abreast of developments in the surveillance, epizootiology and prevention of the relevant diseases throughout the world;
 - (f) retaining expertise on relevant disease pathogens to enable rapid differential diagnosis;
2. to assist actively in the diagnosis of disease outbreaks 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 exotic diseases, with the competent laboratories in third countries where those diseases are prevalent.

ANNEX C

NATIONAL REFERENCE LABORATORIES FOR DISEASES OF BIVALVE MOLLUSCS

Germany: Bundesforschungsanstalt für Viruskrankheiten der Tiere
Anstaltsteil Insel Riems
D-0-2201 Insel Riems
Germany

Spain: Instituto de investigaciones marinas del C.S.I.C.
C/Eduardo Cabello, No 6
36208 Vigo (Pontevedra)
Spain

France: IFREMER
Boîte postale 133
17390 La Tremblade
France

Greece: Κέντρο Κτηνιατρικών Ιδρυμάτων Θεσσαλονίκης
Ινστιτούτο Λοιμωδών και Παραστικών Νοσημάτων
Τμήμα Παθολογίας Υδροβίων Οργανισμών
26^{ης} Οκτωβρίου 80
54627 Θεσσαλονίκη
Greece

Ireland: Fisheries Research Centre
Abbotstown
Castleknock
Dublin 15
Ireland

Italy: Istituto zooprofilattico sperimentale delle Venezie
Sezione diagnostica di Basaldella di Campofornido
Laboratorio di Ittiopatologia
Via della Roggia, 92
33030 Basaldella di Campofornido (UD)
Italy

Netherlands: Rijksinstituut voor visserijonderzoek (RIVO-DLO)
Haringkade 1
Postbus 68
1970 AB IJmuiden
Netherlands

United Kingdom: Fish Diseases Laboratory
The Nothe
Weymouth
Dorset DT4 8UB
United Kingdom

The Marine Laboratory
PO box 101
Victoria Road
Aberdeen AB9 8DB
United Kingdom

ANNEX D

Diseases	Pathogens	Sensitive species
Haplosporidiosis	<i>Haplosporidium nelsoni</i> <i>Haplosporidium costale</i>	<i>Crassostrea virginica</i> <i>Crassostrea virginica</i>
Perkinosis	<i>Perkinsus marinus</i> <i>Perkinsus olseni</i>	<i>Crassostrea virginica</i> <i>Haliotis rubra</i> <i>H. Laevigata</i>
Mikrokytosis	<i>Mikrokytos mackini</i> <i>Mikrokytos roughleyi</i>	<i>Crassostrea gigas</i> <i>O. edulis</i> <i>O. puelchana</i> <i>O. denselomellosa</i> <i>Tiostrea chilensis</i> <i>Saccostrea commercialis</i>
Iridovirosis	Oyster velar virus	<i>Crassostrea gigas</i>
Marteiliosis	<i>Marteilia sidneyi</i>	<i>Saccostrea commercialis</i>

COUNCIL DIRECTIVE 95/71/EC

of 22 December 1995

amending the Annex to Directive 91/493/EEC laying down the health conditions for the production and the placing on the market of fishery products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products ⁽¹⁾ and in particular Article 13 thereof,

Having regard to the proposal from the Commission,

Whereas Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products obtained on board certain vessels in accordance with Article 3 (1) (a) (i) of Directive 91/493/EEC ⁽²⁾ provides that freezer vessels shall be entered in a list kept regularly up to date by the competent authority;

Whereas fishery products obtained on board freezer vessels which meet the hygiene requirements laid down in Directive 92/48/EEC should be permitted to be placed on the market on the same identification terms as fishery products frozen in establishments on land; whereas the Annex to Directive 91/493/EEC should therefore be amended accordingly;

Whereas certain problems of application reported by the Member States call for the clarification of certain technical aspects of Directive 91/493/EEC, to enable the provisions to be uniformly applied in the Community, especially in connection with the identification of fishery products marketed,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 91/493/EEC is hereby amended as follows:

(1) Chapter I (II) (5) shall be replaced by the following:

⁽¹⁾ OJ No L 268, 24. 9. 1991, p. 15. Directive as amended by the 1994 Act of Accession.

⁽²⁾ OJ No L 187, 7. 7. 1992, p. 41.

'5. On-board processing of fishery products must be carried out under the conditions of hygiene laid down in Section II, points 2 and 3, Section IV and Section V of Chapter IV of this Annex.'

(2) The second sentence of Chapter IV (I) (3) shall be replaced by the following:

'Fillets and slices must not remain on work tables any longer than is necessary for their preparation and must be protected from contamination by appropriate packaging.'

(3) Chapter IV (IV), point 1 shall be replaced by the following:

'Fresh, frozen and thawed products used for processing must comply with the requirements set out in I, II or III of this Chapter.'

(4) The first sentence of Chapter IV (IV) (4) (d) shall be replaced by the following:

'(d) samples must be taken of production each day at predetermined intervals to ensure the efficacy of sealing or of any other method of hermetic closure.'

(5) In Chapter IV (V) (3) (c) the verb 'destroy' shall be replaced by the verb 'kill'.

(6) The first sentence of the second paragraph of Chapter V (II) (3) (A) (b) shall be replaced by the following:

'These limits apply only to fish species of the following families: *scombridae*, *clupeidae*, *engraulidae* and *coryphaenidae*.'

(7) Chapter VII shall be replaced by the following:

CHAPTER VII

IDENTIFICATION

Without prejudice to the provisions of Directive 79/112/EEC, it must be possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means either of labelling or of the accompanying documents.

For that purpose, the following information must appear on the packaging or, in the case of a non-packaged product, in the accompanying documents:

- the country of dispatch, which may be written out in full or shown as an abbreviation, using capital letters, i.e. for the Member States of the Community, one of the following:
B — DK — D — EL — E — F — IRL — I — L — NL — P — UK — AT — FI — SE,
- identification of the establishment or factory vessel by its official approval number or, in the case of marketing from a freezer vessel covered by point 7 of Annex II to Directive 92/48/EEC, the identification number of the vessel, or, in the case of separate registering of auction or wholesale markets as laid down in the third subparagraph of Article 7 (1) of this Directive, the registration number of the auction or wholesale market,
- one of the following abbreviations: CE — EC — EG — EK — EF — EY.

All the letters and figures must be fully legible and grouped together on the packaging in a place where they are visible from the outside without any need to open the said packaging.

Article 2

1. The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 1997. They shall notify the Commission thereof. However, products

prepared before the date on which this Directive is brought into effect shall not be covered by the provisions of Chapter VII of Directive 91/493/EEC as amended by this Directive.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such references 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 text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1995.

For the Council

The President

L. ATIENZA SERNA