Official Journal

of the European Communities

Volume 20 No L 26

31 January 1977

English Edition

Legislation

Contents

I *Acts whose publication is obligatory*

.....

II *Acts whose publication is not obligatory*

Council

77/91/EEC:

★ **Second Council Directive of 13 December 1976 on coordination of safeguards which, for the protection of the interests of members and others, are required by Member States of companies within the meaning of the second paragraph of Article 58 of the Treaty, in respect of the formation of public limited liability companies and the maintenance and alteration of their capital, with a view to making such safeguards equivalent** 1

77/92/EEC:

★ **Council Directive of 13 December 1976 on measures to facilitate the effective exercise of freedom of establishment and freedom to provide services in respect of the activities of insurance agents and brokers (ex ISIC Group 630) and, in particular, transitional measures in respect of those activities** 14

77/93/EEC:

★ Council Directive of 21 December 1976 on protective measures against the introduction into the Member States of harmful organisms of plant or plant products 20

77/94/EEC:

★ Council Directive of 21 December 1976 on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses 55

Price : £ 1·10

(Continued overleaf)

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

77/95/EEC:

* **Council Directive of 21 December 1976 on the approximation of the laws of the Member States relating to taximeters** 59

77/96/EEC:

* **Council Directive of 21 December 1976 on the examination for trichinae (trichinella spiralis) upon importation from third countries of fresh meat derived from domestic swine** 67

77/97/EEC:

* **Council Decision of 21 December 1976 on the financing by the Community of certain emergency measures in the field of animal health** 78

77/98/EEC:

* **Council Directive of 21 December 1976 amending Directives 64/432/EEC, 72/461/EEC and 72/462/EEC on health and veterinary problems** 81

77/99/EEC:

* **Council Directive of 21 December 1976 on health problems affecting intra-Community trade in meat products** 85

II

(Acts whose publication is not obligatory)

COUNCIL

SECOND COUNCIL DIRECTIVE

of 13 December 1976

on coordination of safeguards which, for the protection of the interests of members and others, are required by Member States of companies within the meaning of the second paragraph of Article 58 of the Treaty, in respect of the formation of public limited liability companies and the maintenance and alteration of their capital, with a view to making such safeguards equivalent

(77/91/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 54 (3) (g) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas the coordination provided for in Article 54 (3) (g) and in the General Programme for the abolition of restrictions on freedom of establishment, which was begun by Directive 68/151/EEC (3), is especially important in relation to public limited liability companies, because their activities predominate in the economy of the Member States and frequently extend beyond their national boundaries;

Whereas in order to ensure minimum equivalent protection for both shareholders and creditors of public limited liability companies, the coordination of national provisions relating to their formation and to the maintenance, increase or reduction of their capital is particularly important;

Whereas in the territory of the Community, the statutes or instrument of incorporation of a public limited liability company must make it possible for any interested person to acquaint himself with the basic particulars of the company, including the exact composition of its capital;

Whereas Community provisions should be adopted for maintaining the capital, which constitutes the creditors' security, in particular by prohibiting any reduction thereof by distribution to shareholders where the latter are not entitled to it and by imposing limits on the company's right to acquire its own shares;

Whereas it is necessary, having regard to the objectives of Article 54 (3) (g), that the Member States' laws relating to the increase or reduction of capital ensure that the principles of equal treatment of shareholders in the same position and of protection of creditors whose claims exist prior to the decision on reduction are observed and harmonized,

---

(1) OJ No C 114, 11. 11. 1971, p. 18.
(2) OJ No C 88, 6. 9. 1971, p. 1.
(3) OJ No L 65, 14. 3. 1968, p. 8.

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. The coordination measures prescribed by this Directive shall apply to the provisions laid down by law, regulation or administrative action in Member States relating to the following types of company:

— *in Belgium:*
la société anonyme / de naamloze vennootschap;

— *in Denmark:*
aktieselskabet;

— *in France:*
la société anonyme;

— *in Germany:*
die Aktiengesellschaft;

— *in Ireland:*
the public company limited by shares,
the public company limited by guarantee and having a share capital;

— *in Italy:*
la società per azioni;

— *in Luxembourg:*
la société anonyme;

— *in the Netherlands:*
de naamloze vennootschap;

— *in the United Kingdom:*
the public company limited by shares,
the public company limited by guarantee and having a share capital.

The name for any company of the above types shall comprise or be accompanied by a description which is distinct from the description required of other types of companies.

2. The Member States may decide not to apply this Directive to investment companies with variable capital and to cooperatives incorporated as one of the types of company listed in paragraph 1. In so far as the laws of the Member States make use of this option, they shall require such companies to include the words 'investment company with variable capital' or 'cooperative' in all documents indicated in Article 4 of Directive 68/151/EEC.

The expression 'investment company with variable capital', within the meaning of this Directive, means only those companies:

— the exclusive object of which is to invest their funds in various stocks and shares, land or other assets with the sole aim of spreading investment risks and giving their shareholders the benefit of the results of the management of their assets,

— which offer their own shares for subscription by the public, and

— the statutes of which provide that, within the limits of a minimum and maximum capital, they may at any time issue, redeem or resell their shares.

Article 2

The statutes or the instrument of incorporation of the company shall always give at least the following information:

(a) the type and name of the company;

(b) the objects of the company;

(c) — when the company has no authorized capital, the amount of the subscribed capital,

— when the company has an authorized capital, the amount thereof and also the amount of the capital subscribed at the time the company is incorporated or is authorized to commence business, and at the time of any change in the authorized capital, without prejudice to Article 2 (1) (e) of Directive 68/151/EEC;

(d) in so far as they are not legally determined, the rules governing the number of and the procedure for appointing members of the bodies responsible for representing the company with regard to third parties, administration, management, supervision or control of the company and the allocation of powers among those bodies;

(e) the duration of the company, except where this is indefinite.

Article 3

The following information at least must appear in either the statutes or the instrument of incorporation or a separate document published in accordance with the procedure laid down in the laws of each Member State in accordance with Article 3 of Directive 68/151/EEC:

(a) the registered office;

(b) the nominal value of the shares subscribed and, at least once a year, the number thereof;

(c) the number of shares subscribed without stating the nominal value, where such shares may be issued under national law;

(d) the special conditions if any limiting the transfer of shares;

(e) where there are several classes of shares, the information under (b), (c) and (d) for each class and the rights attaching to the shares of each class;

(f) whether the shares are registered or bearer, where national law provides for both types, and any provisions relating to the conversion of such shares unless the procedure is laid down by law;

(g) the amount of the subscribed capital paid up at the time the company is incorporated or is authorized to commence business;

(h) the nominal value of the shares or, where there is not nominal value, the number of shares issued for a consideration other than in cash, together with the nature of the consideration and the name of the person providing this consideration;

(i) the identity of the natural or legal persons or companies or firms by whom or in whose name the statutes or the instrument of incorporation, or where the company was not formed at the same time, the drafts of these documents, have been signed;

(j) the total amount, or at least an estimate, of all the costs payable by the company or chargeable to it by reason of its formation and, where appropriate, before the company is authorized to commence business;

(k) any special advantage granted, at the time the company is formed or up to the time it receives authorization to commence business, to anyone who has taken part in the formation of the company or in transactions leading to the grant of such authorization.

Article 4

1. Where the laws of a Member State prescribe that a company may not commence business without authorization, they shall also make provision for responsibility for liabilities incurred by or on behalf of the company during the period before such authorization is granted or refused.

2. Paragraph 1 shall not apply to liabilities under contracts concluded by the company conditionally upon its being granted authorization to commence business.

Article 5

1. Where the laws of a Member State require a company to be formed by more than one member, the fact that all the shares are held by one person or that the number of members has fallen below the legal minimum after incorporation of the company shall not lead to the automatic dissolution of the company.

2. If in the cases referred to in paragraph 1, the laws of a Member State permit the company to be wound up by order of the court, the judge having jurisdiction must be able to give the company sufficient time to regularize its position.

3. Where such a winding up order is made the company shall enter into liquidation.

Article 6

1. The laws of the Member States shall require that, in order that a company may be incorporated or obtain authorization to commence business, a minimum capital shall be subscribed the amount of which shall be not less than 25 000 European units of account.

The European unit of account shall be that defined by Commission Decision No 3289/75/ECSC [1]. The equivalent in national currency shall be calculated initially at the rate applicable on the date of adoption of this Directive.

2. If the equivalent of the European unit of account in national currency is altered so that the value of the minimum capital in national currency remains less than 22 500 European units of account for a period of one year, the Commission shall inform the Member State concerned that it must amend its legislation to comply with paragraph 1

[1] OJ No L 327, 19. 12. 1975, p. 4.

within 12 months following the expiry of that period. However, the Member State may provide that the amended legislation shall not apply to companies already in existence until 18 months after its entry into force.

3. Every five years the Council, acting on a proposal from the Commission, shall examine and, if need be, revise the amounts expressed in this Article in European units of account in the light of economic and monetary trends in the Community and of the tendency towards allowing only large and medium-sized undertakings to opt for the types of company listed in Article 1 (1).

Article 7

The subscribed capital may be formed only of assets capable of economic assessment. However, an undertaking to perform work or supply services may not form part of these assets.

Article 8

1. Shares may not be issued at a price lower than their nominal value, or, where there is no nominal value, their accountable par.

2. However, Member States may allow those who undertake to place shares in the exercise of their profession to pay less than the total price of the shares for which they subscribe in the course of this transaction.

Article 9

1. Shares issued for a consideration must be paid up at the time the company is incorporated or is authorized to commence business at not less than 25 % of their nominal value or, in the absence of a nominal value, their accountable par.

2. However, where shares are issued for a consideration other than in cash at the time the company is incorporated or is authorized to commence business, the consideration must be transferred in full within five years of that time.

Article 10

1. A report on any consideration other than in cash shall be drawn up before the company is incorporated or is authorized to commence business, by one or more independent experts appointed or approved by an administrative or judicial authority. Such experts may be natural persons as well as legal persons and companies or firms under the laws of each Member State.

2. The experts' report shall contain at least a description of each of the assets comprising the consideration as well as of the methods of valuation used and shall state whether the values arrived at by the application of these methods correspond at least to the number and nominal value or, where there is no nominal value, to the accountable par and, where appropriate, to the premium on the shares to be issued for them.

3. The expert's report shall be published in the manner laid down by the laws of each Member State, in accordance with Article 3 of Directive 68/151/EEC.

4. Member States may decide not to apply this Article where 90 % of the nominal value, or where there is no nominal value, of the accountable par, of all the shares is issued to one or more companies for a consideration other than in cash, and where the following requirements are met:

(a) with regard to the company in receipt of such consideration, the persons referred to in Article 3 (i) have agreed to dispense with the expert's report;

(b) such agreement has been published as provided for in paragraph 3;

(c) the companies furnishing such consideration have reserves which may not be distributed under the law or the statutes and which are at least equal to the nominal value or, where there is no nominal value, the accountable par of the shares issued for consideration other than in cash;

(d) the companies furnishing such consideration guarantee, up to an amount equal to that indicated in paragraph (c), the debts of the recipient company arising between the time the shares are issued for a consideration other than in cash and one year after the publication of that company's annual accounts for the financial year during which such consideration was furnished. Any transfer of these shares is prohibited within this period;

(e) the guarantee referred to in (d) has been published as provided for in paragraph 3;

(f) the companies furnishing such consideration shall place a sum equal to that indicated in (c) into a reserve which may not be distributed until three years after publication of the annual accounts of the recipient company for the financial year during which such consideration was furnished or, if necessary, until such later date as all claims relating to the guarantee referred to in (d) which are submitted during this period have been settled.

Article 11

1. If, before the expiry of a time limit laid down by national law of at least two years from the time the company is incorporated or is authorized to commence business, the company acquires any asset belonging to a person or company or firm referred to in Article 3 (i) for a consideration of not less than one-tenth of the subscribed capital, the acquisition shall be examined and details of it published in the manner provided for in Article 10 and it shall be submitted for the approval of the general meeting.

Member States may also require these provisions to be applied when the assets belong to a shareholder or to any other person.

2. Paragraph 1 shall not apply to acquisitions effected in the normal course of the company's business, to acquisitions effected at the instance or under the supervision of an administrative or judicial authority, or to stock exchange acquisitions.

Article 12

Subject to the provisions relating to the reduction of subscribed capital, the shareholders may not be released from the obligation to pay up their contributions.

Article 13

Pending coordination of national laws at a subsequent date, Member States shall adopt the measures necessary to require provision of at least the same safeguards as are laid down in Articles 2 to 12 in the event of the conversion of another type of company into a public limited liability company.

Article 14

Articles 2 to 13 shall not prejudice the provisions of Member States on competence and procedure relating to the modification of the statutes or of the instrument of incorporation.

Article 15

1. (a) Except for cases of reductions of subscribed capital, no distribution to shareholders may be made when on the closing date of the last financial year the net assets as set out in the company's annual accounts are, or following such a distribution would become, lower than the amount of the subscribed capital plus those reserves which may not be distributed under the law or the statutes.

(b) Where the uncalled part of the subscribed capital is not included in the assets shown in the balance sheet, this amount shall be deducted from the amount of subscribed capital referred to in paragraph (a).

(c) The amount of a distribution to shareholders may not exceed the amount of the profits at the end of the last financial year plus any profits brought forward and sums drawn from reserves available for this purpose, less any losses brought forward and sums placed to reserve in accordance with the law or the statutes.

(d) The expression 'distribution' used in subparagraphs (a) and (c) includes in particular the payment of dividends and of interest relating to shares.

2. When the laws of a Member State allow the payment of interim dividends, the following conditions at least shall apply:

(a) interim accounts shall be drawn up showing that the funds available for distribution are sufficient;

(b) the amount to be distributed may not exceed the total profits made since the end of the last financial year for which the annual accounts have been drawn up, plus any profits brought forward and sums drawn from reserves available for this purpose, less losses brought forward and sums to be placed to reserve pursuant to the requirements of the law or the statutes.

3. Paragraphs 1 and 2 shall not affect the provisions of the Member States as regards increases in subscribed capital by capitalization of reserves.

4. The laws of a Member State may provide for derogations from paragraph 1 (a) in the case of investment companies with fixed capital.

The expression 'investment company with fixed capital', within the meaning of this paragraph means only those companies:

— the exclusive object of which is to invest their funds in various stocks and shares, land or other assets with the sole aim of spreading investment risks and giving their shareholders the benefit of the results of the management of their assets, and

— which offer their own shares for subscription by the public.

In so far as the laws of Member States make use of this option they shall:

(a) require such companies to include the expression 'investment company' in all documents indicated in Article 4 of Directive 68/151/EEC;

(b) not permit any such company whose net assets fall below the amount specified in paragraph 1 (a) to make a distribution to shareholders when on the closing date of the last financial year the company's total assets as set out in the annual accounts are, or following such distribution would become, less than one-and-a-half times the amount of the company's total liabilities to creditors as set out in the annual accounts;

(c) require any such company which makes a distribution when its net assets fall below the amount specified in paragraph 1 (a) to include in its annual accounts a note to that effect.

Article 16

Any distribution made contrary to Article 15 must be returned by shareholders who have received it if the company proves that these shareholders knew of the irregularity of the distributions made to them, or could not in view of the circumstances have been unaware of it.

Article 17

1. In the case of a serious loss of the subscribed capital, a general meeting of shareholders must be called within the period laid down by the laws of the Member States, to consider whether the company should be wound up or any other measures taken.

2. The amount of a loss deemed to be serious within the meaning of paragraph 1 may not be set by the laws of Member States at a figure higher than half the subscribed capital.

Article 18

1. The shares of a company may not be subscribed for by the company itself.

2. If the shares of a company have been subscribed for by a person acting in his own name, but on behalf of the company, the subscriber shall be deemed to have subscribed for them for his own account.

3. The persons or companies or firms referred to in Article 3 (i) or, in cases of an increase in subscribed capital, the members of the administrative or management body shall be liable to pay for shares subscribed in contravention of this Article.

However, the laws of a Member State may provide that any such person may be released from his obligation if he proves that no fault is attributable to him personally.

Article 19

1. Where the laws of a Member State permit a company to acquire its own shares, either itself or through a person acting in his own name but on the company's behalf, they shall make such acquisitions subject to at least the following conditions:

(a) authorization shall be given by the general meeting, which shall determine the terms and conditions of such acquisitions, and in particular the maximum number of shares to be acquired, the duration of the period for which the authorization is given and which may not exceed 18 months, and, in the case of acquisition for value, the maximum and minimum consideration. Members of the administrative or management body shall be required to satisfy themselves that at the time when each authorized acquisition is effected the conditions referred to in subparagraphs (b), (c) and (d) are respected;

(b) the nominal value or, in the absence thereof, the accountable par of the acquired shares, including shares previously acquired by the company and held by it, and shares acquired by a person acting in his own name but on the company's behalf, may not exceed 10 % of the subscribed capital;

(c) the acquisitions may not have the effect of reducing the net assets below the amount mentioned in Article 15 (1) (a);

(d) only fully paid-up shares may be included in the transaction.

2. The laws of a Member State may provide for derogations from the first sentence of paragraph 1 (a) where the acquisition of a company's own shares is necessary to prevent serious and imminent harm to the company. In such a case, the next general meeting must be informed by the administrative or management body of the reasons for and nature of the acquisitions effected, of the number and nominal value or, in the absence of a nominal value, the accountable par, of the shares acquired, of the proportion of the subscribed capital which they represent, and of the consideration for these shares.

3. Member States may decide not to apply the first sentence of paragraph 1 (a) to shares acquired by either the company itself or by a person acting in his own name but on the company's behalf, for distribution to that company's employees or to the employees of an associate company. Such shares must be distributed within 12 months of their acquisition.

Article 20

1. Member States may decide not to apply Article 19 to:

(a) shares acquired in carrying out a decision to reduce capital, or in the circumstances referred to in Article 39;

(b) shares acquired as a result of a universal transfer of assets;

(c) fully paid-up shares acquired free of charge or by banks and other financial institutions as purchasing commission;

(d) shares acquired by virtue of a legal obligation or resulting from a court ruling for the protection of minority shareholders in the event, particularly, of a merger, a change in the company's object or form, transfer abroad of the registered office, or the introduction of restrictions on the transfer of shares;

(e) shares acquired from a shareholder in the event of failure to pay them up;

(f) shares acquired in order to indemnify minority shareholders in associated companies;

(g) fully paid-up shares acquired under a sale enforced by a court order for the payment of a debt owed to the company by the owner of the shares;

(h) fully paid-up shares issued by an investment company with fixed capital, as defined in the second subparagraph of Article 15 (4), and acquired at the investor's request by that company or by an associate company. Article 15 (4) (a) shall apply. These acquisitions may not have the effect of reducing the net assets below the amount of the subscribed capital plus any reserves the distribution of which is forbidden by law.

2. Shares acquired in the cases listed in paragraph 1 (b) to (g) above must, however, be disposed of within not more than three years of their acquisition unless the nominal value or, in the absence of a nominal value, the accountable par of the shares acquired, including shares which the company may have acquired through a person acting in his own name but on the company's behalf, does not exceed 10 % of the subscribed capital.

3. If the shares are not disposed of within the period laid down in paragraph 2, they must be cancelled. The laws of a Member State may make this cancellation subject to a corresponding reduction in the subscribed capital. Such a reduction must be prescribed where the acquisition of shares to be cancelled results in the net assets having fallen below the amount specified in Article 15 (1) (a).

Article 21

Shares acquired in contravention of Articles 19 and 20 shall be disposed of within one year of their acquisition. Should they not be disposed of within that period, Article 20 (3) shall apply.

Article 22

1. Where the laws of a Member State permit a company to acquire its own shares, either itself or through a person acting in his own name but on the company's behalf, they shall make the holding of these shares at all times subject to at least the following conditions:

(a) among the rights attaching to the shares, the right to vote attaching to the company's own shares shall in any event be suspended;

(b) if the shares are included among the assets shown in the balance sheet, a reserve of the same amount, unavailable for distribution, shall be included among the liabilities.

2. Where the laws of a Member State permit a company to acquire its own shares, either itself or through a person acting in his own name but on the company's behalf, they shall require the annual report to state at least:

(a) the reasons for acquisitions made during the financial year;

(b) the number and nominal value or, in the absence of a nominal value, the accountable par of the shares acquired and disposed of during the financial year and the proportion of the subscribed capital which they represent;

(c) in the case of acquisition or disposal for a value, the consideration for the shares;

(d) the number and nominal value or, in the absence of a nominal value, the accountable par of all the shares acquired and held by the company and the proportion of the subscribed capital which they represent.

Article 23

1. A company may not advance funds, nor make loans, nor provide security, with a view to the acquisition of its shares by a third party.

2. Paragraph 1 shall not apply to transactions concluded by banks and other financial institutions in the normal course of business, nor to transactions effected with a view to the acquisition of shares by or for the company's employees or the employees of an associate company. However, these transactions may not have the effect of reducing the net assets below the amount specified in Article 15 (1) (a).

3. Paragraph 1 shall not apply to transactions effected with a view to acquisition of shares as described in Article 20 (1) (h).

Article 24

1. The acceptance of the company's own shares as security, either by the company itself or through a person acting in his own name but on the company's behalf, shall be treated as an acquisition for the purposes of Articles 19, 20 (1), 22 and 23.

2. The Member States may decide not to apply paragraph 1 to transactions concluded by banks and other financial institutions in the normal course of business.

Article 25

1. Any increase in capital must be decided upon by the general meeting. Both this decision and the increase in the subscribed capital shall be published in the manner laid down by the laws of each Member State, in accordance with Article 3 of Directive 68/151/EEC.

2. Nevertheless, the statutes or instrument of incorporation or the general meeting, the decision of which must be published in accordance with the rules referred to in paragraph 1, may authorize an increase in the subscribed capital up to a maximum amount which they shall fix with due regard for any maximum amount provided for by law. Where appropriate, the increase in the subscribed capital shall be decided on within the limits of the amount fixed, by the company body empowered to do so. The power of such body in this respect shall be for a maximum period of five years and may be renewed one or more times by the general meeting, each time for a period not exceeding five years.

3. Where there are several classes of shares, the decision by the general meeting concerning the increase in capital referred to in paragraph 1 or the authorization to increase the capital referred to in paragraph 2, shall be subject to a separate vote at least for each class of shareholder whose rights are affected by the transaction.

4. This Article shall apply to the issue of all securities which are convertible into shares or which carry the right to subscribe for shares, but not to the conversion of such securities, nor to the exercise of the right to subscribe.

Article 26

Shares issued for a consideration, in the course of an increase in subscribed capital, must be paid up to at

least 25% of their nominal value or, in the absence of a nominal value, of their accountable par. Where provision is made for an issue premium, it must be paid in full.

Article 27

1. Where shares are issued for a consideration other than in cash in the course of an increase in the subscribed capital the consideration must be transferred in full within a period of five years from the decision to increase the subscribed capital.

2. The consideration referred to in paragraph 1 shall be the subject of a report drawn up before the increase in capital is made by one or more experts who are independent of the company and appointed or approved by an administrative or judicial authority. Such experts may be natural persons as well as legal persons and companies and firms under the laws of each Member State.

Article 10 (2) and (3) shall apply.

3. Member States may decide not to apply paragraph 2 in the event of an increase in subscribed capital made in order to give effect to a merger or a public offer for the purchase or exchange of shares and to pay the shareholders of the company which is being absorbed or which is the object of the public offer for the purchase or exchange of shares.

4. Member States may decide not to apply paragraph 2 if all the shares issued in the course of an increase in subscribed capital are issued for a consideration other than in cash to one or more companies, on condition that all the shareholders in the company which receive the consideration have agreed not to have an experts' report drawn up and that the requirements of Article 10 (4) (b) to (f) are met.

Article 28

Where an increase in capital is not fully subscribed, the capital will be increased by the amount of the subscriptions received only if the conditions of the issue so provide.

Article 29

1. Whenever the capital is increased by consideration in cash, the shares must be offered on a pre-emptive basis to shareholders in proportion to the capital represented by their shares.

2. The laws of a Member State:

(a) need not apply paragraph 1 above to shares which carry a limited right to participate in distributions within the meaning of Article 15 and/or in the company's assets in the event of liquidation; or

(b) may permit, where the subscribed capital of a company having several classes of shares carrying different rights with regard to voting, or participation in distributions within the meaning of Article 15 or in assets in the event of liquidation, is increased by issuing new shares in only one of these classes, the right of pre-emption of shareholders of the other classes to be exercised only after the exercise of this right by the shareholders of the class in which the new shares are being issued.

3. Any offer of subscription on a pre-emptive basis and the period within which this right must be exercised shall be published in the national gazette appointed in accordance with Directive 68/151/EEC. However, the laws of a Member State need not provide for such publication where all a company's shares are registered. In such case, all the company's shareholders must be informed in writing. The right of pre-emption must be exercised within a period which shall not be less than 14 days from the date of publication of the offer or from the date of dispatch of the letters to the shareholders.

4. The right of pre-emption may not be restricted or withdrawn by the statutes or instrument of incorporation. This may, however, be done by decision of the general meeting. The administrative or management body shall be required to present to such a meeting a written report indicating the reasons for restriction or withdrawal of the right of pre-emption, and justifying the proposed issue price. The general meeting shall act in accordance with the rules for a quorum and a majority laid down in Article 40. Its decision shall be published in the manner laid down by the laws of each Member State, in accordance with Article 3 of Directive 68/151/EEC.

5. The laws of a Member State may provide that the statutes, the instrument of incorporation or the general meeting, acting in accordance with the rules for a quorum, a majority and publication set out in paragraph 4, may give the power to restrict or

withdraw the right of pre-emption to the company body which is empowered to decide on an increase in subscribed capital within the limits of the authorized capital. This power may not be granted for a longer period than the power for which provision is made in Article 25 (2).

6. Paragraphs 1 to 5 shall apply to the issue of all securities which are convertible into shares or which carry the right to subscribe for shares, but not to the conversion of such securities, nor to the exercice of the right to subscribe.

7. The right of pre-emption is not excluded for the purposes of paragraphs 4 and 5 where, in accordance with the decision to increase the subscribed capital, shares are issued to banks or other financial institutions with a view to their being offered to shareholders of the company in accordance with paragraphs 1 and 3.

Article 30

Any reduction in the subscribed capital, except under a court order, must be subject at least to a decision of the general meeting acting in accordance with the rules for a quorum and a majority laid down in Article 40 without prejudice to Articles 36 and 37. Such decision shall be published in the manner laid down by the laws of each Member State in accordance with Article 3 of Directive 68/151/EEC.

The notice convening the meeting must specify at least the purpose of the reduction and the way in which it is to be carried out.

Article 31

Where there are several classes of shares, the decision by the general meeting concerning a reduction in the subscribed capital shall be subject to a separate vote, at least for each class of shareholders whose rights are affected by the transaction.

Article 32

1. In the event of a reduction in the subscribed capital, at least the creditors whose claims antedate the publication of the decision to make the reduction shall be entitled at least to have the right to obtain security for claims which have not fallen due by the date of that publication. The laws of a Member State shall lay down the conditions for the exercise of this right. They may not set aside such right unless the creditor has adequate safeguards, or unless the latter are not necessary in view of the assets of the company.

2. The laws of the Member States shall also stipulate at least that the reduction shall be void or that no payment may be made for the benefit of the shareholders, until the creditors have obtained satisfaction or a court has decided that their application should not be acceded to.

3. This Article shall apply where the reduction in the subscribed capital is brought about by the total or partial waiving of the payment of the balance of the shareholders' contributions.

Article 33

1. Member States need not apply Article 32 to a reduction in the subscribed capital whose purpose is to offset losses incurred or to include sums of money in a reserve provided that, following this operation, the amount of such reserve is not more than 10% of the reduced subscribed capital. Except in the event of a reduction in the subscribed capital, this reserve may not be distributed to shareholders; it may be used only for offsetting losses incurred or for increasing the subscribed capital by the capitalization of such reserve, in so far as the Member States permit such an operation.

2. In the cases referred to in paragraph 1 the laws of the Member States must at least provide for the measures necessary to ensure that the amounts deriving from the reduction of subscribed capital may not be used for making payments or distributions to shareholders or discharging shareholders from the obligation to make their contributions.

Article 34

The subscribed capital may not be reduced to an amount less than the minimum capital laid down in accordance with Article 6. However, Member States may permit such a reduction if they also provide that the decision to reduce the subscribed capital may take effect only when the subscribed capital is increased to an amount at least equal to the prescribed minimum.

Article 35

Where the laws of a Member State authorize total or partial redemption of the subscribed capital without

reduction of the latter, they shall at least require that the following conditions are observed:

(a) where the statutes or instrument of incorporation provide for redemption, the latter shall be decided on by the general meeting voting at least under the usual conditions of quorum and majority. Where the statutes or instrument of incorporation do not provide for redemption, the latter shall be decided upon by the general meeting acting at least under the conditions of quorum and majority laid down in Article 40. The decision must be published in the manner prescribed by the laws of each Member State, in accordance with Article 3 of Directive 68/151/EEC;

(b) only sums which are available for distribution within the meaning of Article 15 (1) may be used for redemption purposes;

(c) shareholders whose shares are redeemed shall retain their rights in the company, with the exception of their rights to the repayment of their investment and participation in the distribution of an initial dividend on unredeemed shares.

Article 36

1. Where the laws of a Member State may allow companies to reduce their subscribed capital by compulsory withdrawal of shares, they shall require that at least the following conditions are observed:

(a) compulsory withdrawal must be prescribed or authorized by the statutes or instrument of incorporation before subscription of the shares which are to be withdrawn are subscribed for;

(b) where the compulsory withdrawal is merely authorized by the statutes or instrument of incorporation, it shall be decided upon by the general meeting unless it has been unanimously approved by the shareholders concerned;

(c) the company body deciding on the compulsory withdrawal shall fix the terms and manner thereof, where they have not already been fixed by the statutes or instrument of incorporation;

(d) Article 32 shall apply except in the case of fully paid-up shares which are made available to the company free of charge or are withdrawn using sums available for distribution in accordance with Article 15 (1); in these cases, an amount equal to the nominal value or, in the absence thereof, to the accountable par of all the withdrawn shares must be included in a reserve. Except in the event of a reduction in the subscribed capital this reserve may not be distributed to shareholders. It can be used only for offsetting losses incurred or for increasing the subscribed capital by the capitalization of such reserve, in so far as Member States permit such an operation;

(e) the decision on compulsory withdrawal shall be published in the manner laid down by the laws of each Member State in accordance with Article 3 of Directive 68/151/EEC.

2. Articles 30 (1), 31, 33 and 40 shall not apply to the cases to which paragraph 1 refers.

Article 37

1. In the case of a reduction in the subscribed capital by the withdrawal of shares acquired by the company itself or by a person acting in his own name but on behalf of the company, the withdrawal must always be decided on by the general meeting.

2. Article 32 shall apply unless the shares are fully paid up and are acquired free of charge or using sums available for distribution in accordance with Article 15 (1); in these cases an amount equal to the nominal value or, in the absence thereof, to the accountable par of all the shares withdrawn must be included in a reserve. Except in the event of a reduction in the subscribed capital, this reserve may not be distributed to shareholders. It may be used only for offsetting losses incurred or for increasing the subscribed capital by the capitalization of such reserve, in so far as the Member States permit such an operation.

3. Articles 31, 33 and 40 shall not apply to the cases to which paragraph 1 refers.

Article 38

In the cases covered by Articles 35, 36 (1) (b) and 37 (1), when there are several classes of shares, the decision by the general meeting concerning redemption of the subscribed capital or its reduction by withdrawal of shares shall be subject to a separate vote, at least for each class of shareholders whose rights are affected by the transaction.

Article 39

Where the laws of a Member State authorize companies to issue redeemable shares, they shall require that the following conditions, at least, are complied with for the redemption of such shares:

(a) redemption must be authorized by the company's statutes or instrument of incorporation before the redeemable shares are subscribed for;

(b) the shares must be fully paid up;

(c) the terms and the manner of redemption must be laid down in the company's statutes or instrument of incorporation;

(d) redemption can be only effected by using sums available for distribution in accordance with Article 15 (1) or the proceeds of a new issue made with a view to effecting such redemption;

(e) an amount equal to the nominal value or, in the absence thereof, to the accountable par of all the redeemed shares must be included in a reserve which cannot be distributed to the shareholders, except in the event of a reduction in the subscribed capital; it may be used only for the purpose of increasing the subscribed capital by the capitalization of reserves;

(f) subparagraph (e) shall not apply to redemption using the proceeds of a new issue made with a view to effecting such redemption;

(g) where provision is made for the payment of a premium to shareholders in consequence of a redemption, the premium may be paid only from sums available for distribution in accordance with Article 15 (1), or from a reserve other than that referred to in (e) which may not be distributed to shareholders except in the event of a reduction in the subscribed capital; this reserve may be used only for the purposes of increasing the subscribed capital by the capitalization of reserves or for covering the costs referred to in Article 3 (j) or the cost of issuing shares or debentures or for the payment of a premium to holders of redeemable shares or debentures;

(h) notification of redemption shall be published in the manner laid down by the laws of each Member State in accordance with Article 3 of Directive 68/151/EEC.

Article 40

1. The laws of the Member States shall provide that the decisions referred to in Articles 29 (4) and (5), 30, 31, 35 and 38 must be taken at least by a majority of not less than two-thirds of the votes attaching to the securities or the subscribed capital represented.

2. The laws of the Member States may, however, lay down that a simple majority of the votes specified in paragraph 1 is sufficient when at least half the subscribed capital is represented.

Article 41

1. Member States may derogate from Article 9 (1), Article 19 (1) (a), first sentence, and (b) and from Articles 25, 26 and 29 to the extent that such derogations are necessary for the adoption or application of provisions designed to encourage the participation of employees, or other groups of persons defined by national law, in the capital of undertakings.

2. Member States may decide not to apply Article 19 (1) (a), first sentence, and Articles 30, 31, 36, 37, 38 and 39 to companies incorporated under a special law which issue both capital shares and workers' shares, the latter being issued to the company's employees as a body, who are represented at general meetings of shareholders by delegates having the right to vote.

Article 42

For the purposes of the implementation of this Directive, the laws of the Member States shall ensure equal treatment to all shareholders who are in the same position.

Article 43

1. Member States shall bring into force the laws, regulations and administrative provisions needed in order to comply with this Directive within two years of its notification. They shall forthwith inform the Commission thereof.

2. Member States may decide not to apply Article 3 (g), (i), (j) and (k) to companies already in existence at the date of entry into force of the provisions referred to in paragraph 1.

They may provide that the other provisions of this Directive shall not apply to such companies until 18 months after that date.

However, this time limit may be three years in the case of Articles 6 and 9 and five years in the case of unregistered companies in the United Kingdom and Ireland.

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

Article 44

This Directive is addressed to the Member States.

Done at Brussels, 13 December 1976.

For the Council

The President

M. van der STOEL

COUNCIL DIRECTIVE

of 13 December 1976

on measures to facilitate the effective exercise of freedom of establishment and freedom to provide services in respect of the activities of insurance agents and brokers (ex ISIC Group 630) and, in particular, transitional measures in respect of those activities

(77/92/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 49, 57, 66 and 235 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas, pursuant to the Treaty, all discriminatory treatment based on nationality with regard to establishment and to the provision of services is prohibited from the end of the transitional period; whereas the principle of such national treatment applies in particular to the right to join professional organizations where the professional activities of the person concerned necessarily involve the exercise of this right;

Whereas not all Member States impose conditions for the taking up and pursuit of activities of insurance agent and broker; whereas in some cases there is freedom to take up and pursue such activities but in other cases there are strict provisions making access to the profession conditional upon possession of formal evidence of qualifications;

Whereas, in view of the differences between Member States as regards the scope of activities of insurance agent and broker, it is desirable to define as clearly as possible the activities to which this Directive is to apply;

Whereas, moreover, Article 57 of the Treaty provides that, in order to make it easier for persons to take up and pursue activities as self-employed persons, Directives are to be issued for the mutual recognition of diplomas, certificates and other evidence of formal qualifications and for the coordination of the provisions laid down by law, regulation or administrative action in Member States;

Whereas, in the absence of mutual recognition of diplomas or of immediate coordination, it nevertheless appears desirable to facilitate the effective exercise of freedom of establishment and freedom to provide services for the activities in question, in particular by the adoption of transitional measures of the kind envisaged in the General Programmes (3) in order to avoid undue constraint on the nationals of Member States in which the taking up of such activities is not subject to any conditions;

Whereas, in order to prevent such difficulties arising, the object of the transitional measures should be to allow, as sufficient qualification for taking up the activities in question in host Member States which have rules governing the taking up of such activities, the fact that the activity has been pursued in the Member State whence the foreign national comes for a reasonable and sufficiently recent period of time, in cases where previous training is not required, to ensure that the person concerned possesses professional knowledge equivalent to that required of the host Member State's own nationals;

Whereas, in view of the situation in the Netherlands, where insurance brokers are, depending on their professional knowledge, divided up into several categories, an equivalent system should be provided for in respect of nationals of other Member States who wish to take up an activity in one or other of the categories concerned; whereas the most appropriate and objective criterion for this purpose is the number of employees whom the person concerned has or has had working under him;

Whereas, where the activity of agent includes the exercise of a permanent authority from one or more insurance undertakings empowering the beneficiary, in respect of certain or all transactions falling within the normal scope of the business of the undertaking

(1) OJ No C 78, 2. 8. 1971, p. 13.
(2) OJ No C 113, 9. 11. 1971, p. 6.
(3) OJ No 2, 15. 1. 1962, pp. 32/62 and 36/62.

or undertakings concerned, to enter in the name of such undertaking or undertakings into commitments binding upon it or them, the person concerned must be able to take up the activity of broker in the host Member State;

Whereas the purpose of this Directive will disappear once the coordination of conditions for the taking up and pursuit of the activities in question and the mutual recognition of diplomas, certificates and other formal qualifications have been achieved;

Whereas, in so far as in Member States the taking up or pursuit of the activities referred to in this Directive is also dependent in the case of paid employees on the possession of professional knowledge and ability, this Directive should also apply to this category of persons in order to remove an obstacle to the free movement of workers and thereby to supplement the measures adopted in Council Regulation (EEC) No 1612/68 of 15 October 1968 on freedom of movement for workers within the Community [1], as amended by Regulation (EEC) No 312/76 [2];

Whereas, for the same reason, the provisions laid down in respect of proof of good repute and proof of no previous bankruptcy should also be applicable to paid employees,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall adopt the measures defined in this Directive in respect of establishment or provision of services in their territories by natural persons and companies or firms covered by Title I of the General Programmes (hereinafter referred to as 'beneficiaries') wishing to pursue in a self-employed capacity the activities referred to in Article 2.

2. This Directive shall also apply to nationals of Member States who, as provided in Regulation (EEC) No 1612/68, wish to pursue as paid employees the activities referred to in Article 2.

Article 2

1. This Directive shall apply to the following activities falling within ex ISIC Group 630 in Annex III to the General Programme for the abolition of restrictions on freedom of establishment:

(a) professional activities of persons who, acting with complete freedom as to their choice of undertaking, bring together, with a view to the insurance or reinsurance of risks, persons seeking insurance or reinsurance and insurance or reinsurance undertakings, carry out work preparatory to the conclusion of contracts of insurance or reinsurance and, where appropriate, assist in the administration and performance of such contracts, in particular in the event of a claim;

(b) professional activities of persons instructed under one or more contracts or empowered to act in the name and on behalf of, or solely on behalf of, one or more insurance undertakings in introducing, proposing and carrying out work preparatory to the conclusion of, or in concluding, contracts of insurance, or in assisting in the administration and performance of such contracts, in particular in the event of a claim;

(c) activities of persons other than those referred to in (a) and (b) who, acting on behalf of such persons, among other things carry out introductory work, introduce insurance contracts or collect premiums, provided that no insurance commitments towards or on the part of the public are given as part of these operations.

2. This Directive shall apply in particular to activities customarily described in the Member States as follows:

(a) activities referred to in paragraph 1 (a):

— *in Belgium:*

  — Courtier d'assurance
  Verzekeringsmakelaar,

  — Courtier de réassurance
  Herverzekeringsmakelaar;

— *in Denmark:*

  — Juridiske og fysiske personer, som driver selvstændig virksomhed som formidler ved afsætning af forsikringskontrakter;

— *in Germany:*

  — Versicherungsmakler,

  — Rückversicherungsmakler;

— *in France:*

  — Courtier d'assurance,

  — Courtier d'assurance maritime,

  — Courtier de réassurance;

[1] OJ No L 257, 19. 10. 1968, p. 2.
[2] OJ No L 39, 14. 2. 1976, p. 2.

— *in Ireland:*
  — Insurance broker,
  — Reinsurance broker;
— *in Italy:*
  — Mediatore di assicurazioni,
  — Mediatore di riassicurazioni;
— *in the Netherlands:*
  — Makelaar,
  — Assurantiebezorger,
  — Erkend assurantieagent,
  — Verzekeringsagent;
— *in the United Kingdom:*
  — Insurance broker;

(b) activities referred to in paragraph 1 (b):
— *in Belgium:*
  — Agent d'assurance
    Verzekeringsagent;
— *in Denmark:*
  — Forsikringsagent;
— *in Germany:*
  — Versicherungsvertreter;
— *in France:*
  — Agent général d'assurance;
— *in Ireland:*
  — Agent;
— *in Italy:*
  — Agente di assicurazioni;
— *in Luxembourg:*
  — Agent principal d'assurance,
  — Agent d'assurance;
— *in the Netherlands:*
  — Gevolmachtigd agent,
  — Verzekeringsagent;
— *in the United Kingdom:*
  — Agent;

(c) activities referred to in paragraph 1 (c):
— *in Belgium:*
  — Sous-agent
    Sub-agent;
— *in Denmark:*
  — Underagent;
— *in Germany:*
  — Gelegenheitsvermittler,
  — Inkassant;
— *in France:*
  — Mandataire,
  — Intermédiaire,
  — Sous-agent;
— *in Ireland:*
  — Sub-agent;
— *in Italy:*
  — Subagente;
— *in Luxembourg:*
  — Sous-agent;
— *in the Netherlands:*
  — Sub-agent;
— *in the United Kingdom:*
  — Sub-agent.

Article 3

Member States in which the taking up or pursuit of any activity referred to in Article 2 is subject to the fulfilment of certain qualifying conditions shall ensure that any beneficiary who applies therefor be provided, before he establishes himself or before he begins to pursue any activity on a temporary basis, with information as to the rules governing the profession which he proposes to pursue.

Article 4

Where in a Member State the taking up or pursuit of any activity referred to in Article 2 (1) (a) and (b) is subject to possession of general, commercial or professional knowledge and ability, that Member State shall accept as sufficient evidence of such knowledge and ability the fact that one of the activities in question has been pursued in another Member State for any of the following periods:

(a) four consecutive years in an independent capacity or in a managerial capacity; or

(b) two consecutive years in an independent capacity or in a managerial capacity, where the beneficiary proves that he has worked for at least three years with one or more insurance agents or brokers or with one or more insurance undertakings; or

(c) one year in an independent capacity or in a managerial capacity, where the beneficiary proves that for the activity in question he has received previous training attested by a certificate recognized by the State or regarded by a competent professional body as fully satisfying its requirements.

Article 5

1. If a Member State makes the taking up or pursuit of any activity referred to in Article 2 (1) (a) dependent on more stringent requirements than those which it lays down in respect of the activities referred to in Article 2 (1) (b), it may in the case of the taking up or pursuit of the first-mentioned activity require this to have been pursued in another Member State in the branch of the profession referred to in Article 2 (1) (a) for:

(a) four consecutive years in an independent capacity or in a managerial capacity; or

(b) two consecutive years in an independent capacity or in a managerial capacity, where the beneficiary proves that he has worked for at least three years with one or more insurance agents or brokers or with one or more insurance undertakings; or

(c) one year in an independent capacity or in a managerial capacity, where the beneficiary proves that for the activity in question he has received previous training attested by a certificate recognized by the State or regarded by a competent professional body as fully satisfying its requirements.

An activity pursued by the beneficiary in accordance with Article 2 (1) (b), where it includes the exercise of a permanent authority from one or more insurance undertakings empowering the person concerned, in respect of certain or all transactions falling within the normal scope of the business of the undertaking or undertakings concerned, to enter in the name of such undertaking or undertakings into commitments binding upon it or them, shall be regarded as equivalent to the activity referred to in Article 2 (1) (a).

2. However, in the Netherlands, the taking up or pursuit of the activities referred to in Article 2 (1) (a) shall in addition be subject to the following conditions:

— where the beneficiary wishes to work as a 'makelaar', he must have carried on the activities concerned in a business where he was in charge of at least 10 employees,

— where the beneficiary wishes to work as an 'assurantiebezorger', he must have carried on the activities concerned in a business where he was in charge of at least five employees,

— where the beneficiary wishes to work as an 'erkend assurantieagent', he must have carried on the activities concerned in a business where he was in charge of at least two employees.

Article 6

1. Where in a Member State the taking up or pursuit of an activity referred to in Article 2 (1) (c) is dependent on the possession of general, commercial or professional knowledge and ability, that Member State shall accept as sufficient evidence of such knowledge and ability the fact that the activity in question has been pursued in another Member State for either of the following periods:

(a) two consecutive years either in an independent capacity or working with one or more insurance agents or brokers or with one or more insurance undertakings; or

(b) one year under the conditions specified under paragraph (a), where the beneficiary proves that for the activity in question he has received previous training attested by a certificate recognized by the State or regarded by a competent professional body as fully satisfying its requirements.

2. The pursuit for at least one year of one of the activities referred to in Article 2 (1) (a) or (b) and receipt of the relevant training shall be regarded as satisfying the requirements laid down in paragraph 1.

Article 7

In the cases referred to in Articles 4, 5 and 6, pursuit of the activity in question shall not have ceased more than 10 years before the date when the application provided for in Article 9 (1) is made. However, where a shorter period is laid down in a Member State for its own nationals, that period must also be applied in respect of beneficiaries.

Article 8

1. A person shall be regarded as having pursued an activity in a managerial capacity within the meaning of Articles 4 and 5 (1) where he has pursued the corresponding activity:

(a) as manager of an undertaking or manager of a branch of an undertaking; or

(b) as deputy to the manager of an undertaking or as its authorized representative, where such post involved responsibility equivalent to that of the manager represented.

2. A person shall also be regarded as having pursued an activity in a managerial capacity within the meaning of Article 4 where his duties in an insurance undertaking have involved the management of agents or the supervision of their work.

3. The work referred to in Articles 4 (b) and 5 (1) (b) must have entailed responsibility in respect of the acquisition, administration and performance of contracts of insurance.

Article 9

1. Proof that the conditions laid down in Articles 4, 5, 6 and 7 are satisfied shall be established by a certificate, issued by the competent authority or body in the Member State of origin or Member State whence the person concerned comes, which the latter shall submit in support of his application to pursue one of the activities in question in the host Member State.

2. Member States shall, within the time limit laid down in Article 13, designate the authorities and bodies competent to issue the certificate referred to in paragraph 1 and shall forthwith inform the other Member States and the Commission thereof.

3. Within the time limit laid down in Article 13 every Member State shall also inform the other Member States and the Commission of the authorities and bodies to which an application to pursue in the host Member State an activity referred to in Article 2 and the documents in support thereof are to be submitted.

Article 10

1. Where a host Member State requires of its own nationals wishing to take up or pursue any activity referred to in Article 2 proof of good repute and proof that they have not previously been declared bankrupt, or proof of either one of these, it shall accept as sufficient evidence in respect of nationals of other Member States the production of an extract from the 'judicial record' or, failing this, of an equivalent document issued by a competent judicial or administrative authority in the Member State of origin or the Member State whence the foreign national comes showing that these requirements have been met.

2. Where the Member State of origin or the Member State whence the foreign national concerned comes does not issue the document referred to in paragraph 1 it may be replaced by a declaration on oath, — or, in States where there is no provision for declaration on oath, by a solemn declaration — made by the person concerned before a competent judicial or administrative authority or, where appropriate, a notary in the Member State of origin or the Member State whence that person comes; such authority or notary shall issue a certificate attesting the authenticity of the declaration on oath or solemn declaration. The declaration in respect of no previous bankruptcy may also be made before a competent professional body in the said country.

3. Documents issued in accordance with paragraphs 1 and 2 must not be produced more than three months after their date of issue.

4. Member States shall, within the time limit laid down in Article 13, designate the authorities and bodies competent to issue the documents referred to in paragraphs 1 and 2 of this Article and shall forthwith inform the other Member States and the Commission thereof.

Within the time limit laid down in Article 13, each Member State shall also inform the other Member States and the Commission of the authorities or bodies to which the documents referred to in this Article are to be submitted in support of an application to carry on in the host Member State an activity referred to in Article 2.

5. Where in the host Member State proof of financial standing is required, that State shall regard certificates issued by banks in the Member State of origin or the Member State whence the foreign national concerned comes as equivalent to certificates issued in its own territory.

Article 11

A host Member State, where it requires its own nationals wishing to take up or pursue one of the activities referred to in Article 2 to take an oath or make a solemn declaration, and where the form of such oath or declaration cannot be used by nationals of other Member States, shall ensure that an appropriate and equivalent form of oath or declaration is offered to the persons concerned.

Article 12

This Directive shall remain applicable until the entry into force of provisions relating to the coordination of national rules concerning the taking up and pursuit of the activities in question.

Article 13

Member States shall bring into force the measures necessary to comply with this Directive within 18 months of its notification and shall forthwith inform the Commission thereof.

Article 14

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

Article 15

This Directive is addressed to the Member States.

Done at Brussels, 13 December 1976.

For the Council

The President

M. van der STOEL

COUNCIL DIRECTIVE

of 21 December 1976

on protective measures against the introduction into the Member States of harmful organisms of plants or plant products

(77/93/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas plant production is very important to the Community;

Whereas plant production yields are consistently reduced through the effects of harmful organisms;

Whereas the protection of plants against such organisms is absolutely necessary not only to avoid reduced yields but also to increase agricultural productivity;

Whereas action taken by Member States and aimed at the systematic eradication of harmful organisms within Member States would have only a limited effect if protective measures against their introduction were not applied at the same time;

Whereas the need for such measures has long been recognized; whereas they have formed the subject of many national regulations and international conventions, including the International Plant Protection Convention of 6 December 1951 concluded at the United Nations Food and Agricultural Organization, which is of world-wide interest;

Whereas this International Plant Protection Convention and the close cooperation of States in the European and Mediterranean Plant Protection Organization have, to a certain extent, already resulted in the harmonization of plant-health laws;

Whereas, independently of this international cooperation, closer harmonization of the provisions against the introduction of harmful organisms into the Member States of the Community is required;

Whereas it is necessary to make common protection arrangements against the introduction of harmful organisms from non-member countries and also to re-organize plant-health inspection in conjunction with the gradual removal of obstacles to and checks on intra-Community trade;

Whereas, in this respect, one of the most important measures consists in listing the particularly dangerous harmful organisms whose introduction into the Member States must be totally prohibited and also the harmful organisms whose introduction into the Member States when carried by certain plants or plant products must also be prohibited;

Whereas the presence of some of these harmful organisms, when plants or plant products are introduced from countries in which these organisms occur, cannot be effectively checked; whereas it is therefore necessary to make minimum provision for bans on the introduction of certain plants and plant products, or to provide for special checks to be made in the producer countries;

Whereas, due to special circumstances, certain other harmful organisms are significant in certain Member States only; whereas it is sufficient to allow these States the option to subject these harmful organisms to the Community rules on plant health;

Whereas in intra-Community trade, a plant health control currently operates for all plants, plant products and other objects not only in the consignor country but also in the country of destination; whereas it is desirable to abolish the latter controls gradually and, to that end, to render those of the

(1) OJ No 187, 9. 11. 1965, p. 2900/65.
(2) Opinion delivered 13 October 1965 (not published in the Official Journal).

consignor country compulsory and more stringent, in order to forestall as far as possible any introduction of harmful organisms into the country of destination;

Whereas, if the result of the plant-health check made in the consignor Member State is satisfactory, a phytosanitary certificate conforming to the model introduced by the International Plant Protection Convention must generally be issued;

Whereas, in order to avoid any further unnecessary checking, provision must be made for drawing up re-forwarding phytosanitary certificates under certain conditions for consignments covered by a phytosanitary certificate and coming from other Member States;

Whereas, if a plant-health check carried out in the consignor Member State constitutes a guarantee that the products are free from harmful organisms, it is possible to dispense with the systematic checks carried out in the Member State of destination;

Whereas, until confidence is established between Member States regarding the correct operation of inspection systems in the consignor Member States, systematic checks can only be dispensed with gradually;

Whereas in this respect, it would appear justified for systematic checks to continue to be allowed in the country of destination for a period of four years from the notification of this Directive, while all the other provisions of this Directive must be transposed into national laws by the end of the second year following this notification;

Whereas, on expiry of the four-year period, the plant-health checks carried out in the country of destination on fruit, vegetables and potatoes, apart from seed potatoes, will no longer be permitted, except for special reasons or, to a limited extent, apart from certain inspection formalities;

Whereas such plant-health checks must be limited to introductions of products originating in non-member countries and to cases where there is strong evidence that one of the plant-health provisions has not been observed; whereas, in all other cases, occasional checks only may be allowed;

Whereas on the other hand, it is necessary for Member States to require, with regard to introductions of products from non-member countries, checks to be carried out at least on the principal carriers of harmful organisms;

Whereas it is also necessary to make provision under certain conditions for Member States to be able to permit derogations from a certain number of provisions;

Whereas Member States must also have the right to take protective measures not laid down in this Directive, in the case of imminent danger of the introduction or spread of harmful organisms;

Whereas in this case in particular, it is appropriate for Member States to cooperate closely with the Commission within the Standing Committee on Plant Health set up by Decision 76/894/EEC [1];

Whereas the Community provisions laying down plant health measures are not in principle affected by this Directive; whereas this also applies to any plant health provisions laid down by Member States on protection against harmful organisms which generally attack plants or plant products in storage and certain other plant health measures laid down by Member States concerning both national and imported products;

Whereas the situation in the French overseas departments differs from that in the other parts of the Community owing to the conditions as regards climate, agricultural production, harmful organisms and trade patterns, taken as a whole; whereas, for the time being it is therefore not possible to apply the provisions of this Directive to the said departments until they have been suitably adjusted,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns protective measures against the introduction into the Member States from other Member States or non-member countries of organisms which are harmful to plants or plant products.

2. This Directive shall not apply to the French overseas departments.

Article 2

1. For the purposes of this Directive:

(a) plants: shall be considered to mean living plants and living parts of plants, including fresh fruit and seeds;

[1] OJ No L 340, 9. 12. 1976, p. 25.

(b) plant products: shall be considered to mean products of plant origin, unprocessed or having undergone simple preparation, in so far as these are not plants;

(c) planting: shall be considered to mean any operation for the placing of plants to ensure their subsequent growth, reproduction or propagation;

(d) harmful organisms: shall be considered to mean pests of plants or of plant products, which belong to the animal or plant kingdoms, or which are viruses, mycoplasmas or other pathogens;

(e) official statement: shall be considered to mean statement made by representatives of the official plant-protection organization or, under their responsibility, by other public servants.

2. This Directive concerns wood only in so far as it retains all or part of its natural round surface, with or without bark.

Article 3

1. Member States shall ban the introduction into their territory of the harmful organisms listed in Annex I, Part A.

2. Paragraph 1 shall not apply during the period 16 October to 30 April in the case of slight contamination of cut flowers by the harmful organisms referred to in Annex I, Part A (a) (1) and (4).

Under the procedure laid down in Article 16, Member States may be authorized on request to shorten the aforesaid period.

3. Paragraph 1 shall not apply in the case of slight contamination of fruit by the harmful organism referred to in Annex I, Part A (b) (3). However, paragraph 1 shall apply during the period 1 May to 15 September, in so far as this harmful organism is young and mobile.

4. Member States shall ban the introduction into their territory of the plants and plant products listed in Annex II, Part A, where they are contaminated by the relevant harmful organisms listed in that part of the Annex.

5. Member States may ban the introduction into their territory of the harmful organisms listed in Annex II, Part A, whether in an isolated state or occurring on objects other than the relevant ones listed in that part of the Annex.

6. The Member States listed in Annex I, Part B, and in Annex II, Part B, may ban the introduction into their territory of:

(a) the harmful organisms listed in Annex I, Part B, against their names;

(b) the plants and plant products listed in Annex II, Part B, against their names, where they are contaminated by the relevant harmful organisms listed in that part of the Annex.

7. Member States may lay down that the introduction into their territory of organisms in an isolated state other than those listed in Annexes I and II which might be considered harmful shall be prohibited or require special authorization.

Article 4

1. Member States shall ban the introduction into their territory of the plants or plant products listed in Annex III, Part A, where they originate in the relevant countries referred to in that part of the Annex.

2. Member States may:

(a) ban the introduction into their territory of the plants, plant products and other objects listed in Annex III, Part B, against their names;

(b) require of the other Member States, from which the plants or plant products listed in Annex III, Part A, other than those listed in (9) and (10) are introduced into their territory, an official certificate stating the country from which these products originate.

Article 5

1. Member States shall ban the introduction into their territory of the plants, plant products and other objects listed in Annex IV, Part A, unless the relevant special requirements indicated in that part of the Annex are met.

2. Member States may:

(a) lay down that the special requirements listed in Annex IV, Part A (1), (2), (3) or (5) shall also apply to non-member countries not referred to therein, if they do not lay down equivalent

conditions for wood originating in the relevant countries described in therein;

(b) ban the introduction into their territory of the plants listed in Annex IV, Part B, against their names unless the relevant special requirements indicated in that part of the Annex are met;

(c) require of the other Member States, from which the plant products listed in Annex IV, Part A (1), (2), (3) or (5) are introduced into their territory, an official certificate stating the country in which these products originate.

Article 6

1. Member States shall lay down, at least in respect of the introduction into another Member State of the plants, plant products and other objects listed in Annex V, that the latter and their packaging shall be meticulously examined on an official basis, either in their entirety or by representative sample, and that, if necessary, the vehicles transporting them shall also be officially examined in order to make sure:

(a) that they are not contaminated by the harmful organisms listed in Annex I, Part A;

(b) in the case of the plants and plant products listed in Annex II, Part A, that they are not contaminated by the relevant harmful organisms listed in that part of the Annex;

(c) in the case of the plants, plant products and other objects listed in Annex IV, Part A, that they comply with the relevant special requirements indicated in that part of the Annex.

2. Member States shall lay down the inspection measures referred to in paragraph 1 in order to ensure compliance with Article 3 (5), (6) and (7) or Article 5 (2), where the Member State of destination avails itself of one of the options listed in the above-mentioned Articles.

3. Member States shall lay down that the seeds referred to in Annex IV, Part A, which are to be introduced into another Member State shall be officially examined in order to make sure that they comply with the relevant special requirements listed in that part of the Annex.

Article 7

1. Where it is considered, on the basis of the examination laid down in Article 6, that the conditions therein are fulfilled, a phytosanitary certificate shall be issued in accordance with the specimen in Annex VIII, Part A, drawn up in at least one of the official languages of the Community, preferably that of the Member State of destination. For other objects, the words 'plants or plant products described' shall be replaced on the certificate by the words 'objects described'.

2. Member States shall lay down that the plants, plant products and other objects listed in Annex V may not be introduced into another Member State unless they are accompanied by a phytosanitary certificate issued in accordance with paragraph 1. The phytosanitary certificate may not be made out more than 14 days before the date on which the plants, plant products or other objects leave the consignor Member State.

3. The action to be taken by the Member States in order to implement Article 6 (3) shall be determined in accordance with the procedure laid down in Article 16 before expiry of the period referred to in Article 20 (1) (b).

Article 8

1. Unless one of the eventualities provided for in paragraph 2 arises, Member States shall lay down that the plants, plant products and other objects listed in Annex V which have been introduced into their territory from a Member State and which are to be introduced into the territory of another Member State shall be exempted from a further inspection complying with Article 6, if they are accompanied by a phytosanitary certificate from a Member State, made out in accordance with the specimen in Annex VIII, Part A.

2. Where plants, plant products or other objects from a Member State have been split up or stored or their packaging changed in a second Member State and are then introduced into a third Member State, the second Member State shall be absolved from making a new inspection complying with Article 6 if it is officially ascertained that no change in these products has occurred in its territory which would involve non-compliance with the conditions laid down in Article 6. In this case a re-forwarding phytosanitary certificate in accordance with the specimen in Annex VIII, Part B, drawn up in at least one official Community language, preferably that of the Member State of destination, shall be issued. This certificate must be attached to the phytosanitary certificate issued by the first Member State or to a certified copy of the latter certificate. This certificate may be entitled 'phytosanitary certificate for re-export'.

The re-forwarding phytosanitary certificate may not be made out more than 14 days before the date on which the plants, plant products or other objects leave the re-forwarding country.

3. Paragraphs 1 and 2 shall also apply when plants, plant products or other objects are introduced successively into several Member States. If, in that case, more than one re-forwarding certificate has been issued, the products must be accompanied by the following documents:

(a) the latest phytosanitary certificate or a certified copy thereof;

(b) the latest re-forwarding phytosanitary certificate;

(c) the re-forwarding phytosanitary certificates previous to the certificate referred to under (b) or certified copies thereof.

Article 9

1. Member States shall lay down that the plants, plant products and other objects which originate in another Member State or in a non-member country and are listed in Annex IV, Part A, except those in (1), (2), (3) (b), (4) (b), (5), (6), (35) and (36), shall not be introduced into another Member State unless accompanied by an official phytosanitary certificate in accordance with the specimen in Annex VIII, Part A, issued in the country in which they originate, or by a certified copy of that certificate, in addition to the certificates provided for in Articles 7 and 8.

2. Paragraph 1 shall also apply to the introduction of the plants and plant products listed in Annex IV, Part B, into the relevant Member States whose names are indicated against those products in that part of the Annex.

Article 10

1. Member States shall lay down that the plants listed in Annex VI introduced into their territory must be disinfected effectively against San José scale on their arrival. However they shall not require such disinfection if there is absolutely no likelihood of San José scale being propagated.

2. Under the procedure laid down in Article 16, Member States may be authorized on request to require that the plants referred to in paragraph 1 must be disinfected before entry into their territory.

Article 11

1. Member States may lay down that plants, plant products and other objects and their packaging and the vehicles transporting them be subject, at the time of their introduction into their territory from another Member State, to an inspection to ascertain compliance with the prohibitions and restrictions laid down in Articles 3, 4 and 5. Member States shall ensure that these plants, plant products and other objects, where their introduction is not prohibited under Article 3, 4 or 5, are not subjected to prohibitions or restrictions relating to plant-health measures except where:

(a) the certificates referred to in Article 4, 5, 7, 8 or 9 are not not produced;

(b) the plants, plant products or other objects are not introduced at one of the prescribed entry-points;

(c) the plants, plant products or other objects are not submitted as laid down in the regulations to an official inspection permitted in accordance with paragraph 3;

(d) these prohibitions or restrictions are laid down on the basis of Article 18.

2. They may not require any additional statement on the phytosanitary certificate.

3. With regard to fruit and vegetables and potatoes other than seed potatoes, Member States may not supplement the official check on identity and the requirements permitted under paragraph 1 by systematic official checks on compliance with the provisions adopted pursuant to Articles 3 and 5, except where:

(a) there is serious reason to believe that one of these provisions has not been complied with;

(b) the plants referred to above originate in a non-member country and the examination provided for in Article 12 (1) (a) has not already been carried out in another Member State.

In all other cases, only occasional official inspections of fruit and vegetables and potatoes other than seed potatoes shall be carried out, by sampling. They shall be deemed occasional if they are made on no more than one-third of the consignments introduced from a given Member State and are as evenly spread as possible over time and over all the products.

4. If it is ascertained at the time of introduction that part of a consignment of plants, plant products

or other objects is contaminated by harmful organisms listed in Annexes I and II, the introduction of the other part shall not be prohibited provided that it is not suspected of being contaminated and provided that there appears to be no possibility of harmful organisms having spread during the splitting up of the consignment.

5. Member States shall lay down that the phytosanitary certificates or re-forwarding phytosanitary certificates produced when the plants, plant products or other objects are introduced into their territory shall bear an entry stamp from the competent organization showing at least the name of the organization and the date of entry.

Article 12

1. Member States shall lay down, at least as regards the introduction into their territory of the plants, plant products and other objects listed in Annex V and coming from non-member countries:

(a) that these plants, plant products and other objects and their packaging shall be meticulously inspected on an official basis, either in their entirety or by representative sample, and that, if necessary, the vehicles transporting them shall also be examined by these same officials in order to make sure:

— that they are not contaminated by the harmful organisms listed in Annex I, Part A,

— in the case of the plants and plant products listed in Annex II, Part A, that they are not contaminated by the relevant harmful organisms listed in that part of the Annex,

— in the case of the plants, plant products and other objects listed in Annex IV, Part A, that they comply with the relevant special requirements indicated in that part of the Annex;

(b) that they must be accompanied by the certificates prescribed in Article 4, 5, 7, 8 or 9 and that a phytosanitary certificate may not be made out more than 14 days before the date on which the plants, plant products or other objects leave the consignor country.

2. Paragraph 1 shall apply to the cases referred to in Articles 6 (3) and 7 (3).

3. Paragraph 1 (a) shall not apply where plants, plant products or other objects are introduced into a Member State via another Member State which has already carried out the inspection provided for in paragraph 1 (a).

4. Member States may extend the application of the measures laid down in Article 8 to consignments coming from non-member countries.

Article 13

The Council acting on a proposal from the Commission, shall adopt any amendments to be made to the Annexes.

Article 14

1. Provided that there is no risk of harmful organisms spreading, the Member States may:

(a) provide for derogations generally or in individual cases:

(i) from Article 4 (1) with regard to a reduction in the period laid down in Annex III, Part A (8),

(ii) from Articles 4 (1), 10 and 12 in respect of transit through their territory and of direct traffic between two places in their territory via the territory of another country,

(iii) from Article 12, if the plants and plant products or other objects are directly dispatched from another Member State to their territory via the territory of a non-member country,

(iv) from Articles 5, 10 and 12 in the case of:

— articles involved in moving house,

— small quantities of plants or plant products, foodstuffs and animal feedingstuffs, where they are intended for use by the owner or recipient for non-industrial and non-commercial purposes or are intended for consumption during transport,

— plants from plots of land in the frontier zone of another country and worked from nearby dwellings or farms located in the frontier zone of their territory,

— plants intended for planting or for propagation in plots of land situated in their frontier zone and worked from nearby dwellings or farms situated in the frontier zone of another country;

(b) provide for derogations, in individual cases:

(i) from Articles 3 (1) and 12, during the period 1 May to 15 October, with regard to the harmful organisms referred to in Annex I, Part A (a) (1) and (4), in the case of slightly contaminated cut flowers,

(ii) from Articles 3 (1) and 12, during the period 1 November to 31 March, with regard to the harmful organisms referred to in Annex I, Part A (a) (2), in the case of slightly contaminated fruit,

(iii) from Articles 3 (1), (3) and 12, in cases of more than slight contamination of fruit by San José scale,

(iv) from Article 3 (3), second sentence, and Article 12,

(v) from Articles 3 (4) and 12, if the contamination of certain plants or plant products by certain harmful organisms is slight, in so far as these harmful organisms already exist within the Community;

(c) provide for derogations, in individual cases, and without prejudice to the procedure under paragraph 2:

(i) from Articles 3 and 4 (1) with regard to requirements referred to in Annex III, Part A (8), and from Arcticles 5 and 12 for trial or scientific purposes and for work on varietal selection,

(ii) from Article 5 (1) and the third indent of Article 12 (1) (a) with regard to the requirement referred to in Annex IV, Part A (1) and (5),

(iii) from Article 5 (1) and the third indent of Article 12 (1) (a), with regard to the requirement referred to in Annex IV, Part A (25), in respect of seed potatoes provided that an official statement is required that they originate in regions where no symptoms of contamination have been recorded with regard to the viruses listed in Annex I, Part A (e) (2), since the beginning of the last complete cycle of vegetation.

2. In the case of the derogations provided for in paragraph 1 (c), Member States shall inform the other Member States and the Commission immediately of any legislative, regulatory or administrative provisions adopted in this connection. In accordance with the procedure laid down in Article 16, and no later than six months after adoption of the said provisions, a decision may be taken on whether they should be rescinded or amended.

3. In accordance with the procedure laid down in Article 16, Member States may be authorized on request to provide for derogations from Article 4 (1) in so far as such derogations are not yet allowed under paragraph 1.

4. In the case of the derogations provided for in paragraphs 1 (b) (c) and 3, an official statement that the conditions for granting the derogation are fulfilled shall be required for each individual case.

5. Member States shall inform the Commission of the derogations which they have granted in accordance with paragraph 1 (c) or 3. The Commission shall notify the other Member States of this information each year.

In accordance with the procedure laid down in Article 16, Member States may be exempted from providing this information.

6. Member States may provide for derogations from Articles 5, 6, 7, 8 and 9 for the introduction of plants, plant products and other objects into another Member State where the latter exempts the consignor State from applying the abovementioned Articles.

Article 15

1. Where a Member State considers there is an imminent danger of the introduction or spread in its territory of harmful organisms, even those not listed in the Annexes, it may temporarily take any additional measures necessary to protect itself from that danger. It shall immediately inform the other Member States and the Commission of the measures taken and indicate the reasons for them.

2. Under the procedure laid down in Article 17, it shall be decided whether the measures taken by the Member State should be rescinded or amended. Until a decision has been taken either by the Council or by the Commission under the aforesaid procedure, the Member State may maintain the measures that it has employed.

Article 16

1. Where the procedure laid down in this Article is to be followed, the matter shall be referred without delay to the Standing Committee on Plant Health (hereinafter referred to as 'the Committee'), by its chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on these measures within a time limit set by the chairman having regard to the urgency of the matters to be examined. Opinions shall be delivered by a majority of 41 votes.

4. Where the measures are in accordance with the opinion of the Committee, the Commission shall adopt them and shall implement them forthwith. Where the measures are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall immediately submit to the Council a proposal on the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, within three months following the date on which the matter was referred to it, the Council has not adopted measures, the Commission shall adopt the proposed measures and shall implement them immediately, except where the Council has rejected the said measures by a simple majority.

Article 17

1. Where the procedure laid down in this Article is to be followed, the matter shall be referred without delay to the Standing Committee on Plant Health (hereinafter referred to as 'the Committee'), by its chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided for in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be taken. The Committee shall deliver its opinion on these measures within two days. Opinions shall be delivered by a majority of 41 votes.

4. Where the measures are in accordance with the opinion of the Committee, the Commission shall adopt them and shall implement them forthwith. Where the measures are not in accordance with the opinion of the Committee or if no opinion is delivered, the Commission shall immediately submit to the Council a proposal on the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, within 15 days following the date on which the matter was referred to it, the Council has not adopted measures, the Commission shall adopt the proposed measures and shall implement them immediately, except where the Council has rejected the said measures by a simple majority.

Article 18

1. This Directive in no way affects Community provisions on plant-health requirements for plants and plant products, except where it provides for or expressly permits stricter requirements in this respect.

2. Under the procedure laid down in Article 16, Member States may be authorized to adopt, when introducing into their territory plants or plant products, special plant-health provisions, in so far as such measures are also laid down for home-grown production.

3. For the introduction into their territory of any plants or plant products, in particular those listed in Annex VII and their packaging or the vehicles transporting them, Member States may take special plant-health measures against the harmful organisms which generally attack plants or plant products in storage.

Article 19

Council Directive 69/466/EEC of 8 December 1969 on control of San José scale [1] shall be amended as follows:

(a) In Article 7, the following paragraph 2 shall be added and the present text of that Article shall become paragraph 1:

'2. Paragraph 1 shall not apply to slightly contaminated consignments of fresh fruit.'

(b) In Article 10 (1) (a), (b) and (c), references to Article 7 shall be amended to refer to 'Article 7 (1)'.

Article 20

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply:

[1] OJ No L 323, 24. 12. 1969, p. 5.

(a) with the restrictions laid down in Article 11 (3) within a period of four years from its notification;

(b) with the other provisions of this Directive within a period of two years from its notification.

2. The Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive. The Commission shall inform the other Member States thereof.

Article 21

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1976.

For the Council

The President

A. P. L. M. M. van der STEE

ANNEX I

A. HARMFUL ORGANISMS WHOSE INTRODUCTION MUST BE PROHIBITED IN ALL MEMBER STATES

(a) **Live organisms of the animal kingdom, at all stages of their development**

1. Cacoecimorpha pronubana (Hb.),
2. Ceratitis capitata (Wied.),
3. Conotrachelus nenuphar (Herbst),
4. Epichoristodes acerbella (Walk.) Diak.,
5. Hylurgopinus rufipes Eichh.,
6. Hyphantria cunea (Drury),
7. Laspeyresia molesta (Busck),
8. Popillia japonica Newman,
9. Rhagoletis cingulata (Loew),
10. Rhagoletis fausta (Osten Sacken),
11. Rhagoletis pomonella (Walsh),
12. Scaphoideus luteolus Van Duz.,
13. Scolytus multistriatus (Marsh.),
14. Scolytus scolytus (F.),
15. Spodoptera littoralis (Boisd.),
16. Spodoptera litura (F.).

(b) **Organisms of the animal kingdom, at all stages of their development, unless it is proved that they are dead**

1. Heterodera pallida Stone,
2. Heterodera rostochiensis Woll.,
3. Quadraspidiotus perniciosus (Comst.).

(c) **Bacteria**

1. Aplanobacter populi Ridé,
2. Corynebacterium sepedonicum (Spieck. and Kotth.) Skapt. and Burkh.,
3. Erwinia amylovora (Burr.) Winsl. et al.

(d) **Cryptogamia**

1. Angiosorus solani Thirum. and O'Brien [= Thecaphora solani (Barrus)],
2. Ceratocystis fagacearum (Bretz) Hunt,
3. Ceratocystis ulmi (Buism.) C. Moreau,
4. Chrysomyxa arctostaphyli Diet.,
5. Cronartium comptoniae Arthur,
6. Cronartium fusiforme Hedgc. and Hunt ex Cumm.,
7. Cronartium quercuum (Berk.) Miyabe ex Shirai,
8. Endocronartium harknessii (J. P. Moore) Y. Hiratsuka [= Peridermium harknessii (J. P. Moore)],
9. Endothia parasitica (Murrill) P. J. and H. W. Anderson,
10. Guignardia laricina (Saw.) Yamamoto and Ito,
11. Hypoxylon pruinatum (Klotzsche) Cke.,
12. Melampsora farlowii (Arthur) Davis,

13. Melampsora medusae Thüm. [= M. albertensis Arthur],
14. Mycosphaerella populorum Thomp. (Septoria musiva Peck),
15. Ophiostoma (Ceratocystis) roboris C. Georgescu and I. Teodoru,
16. Poria weirii Murr.,
17. Synchytrium endobioticum (Schilb.) Perc.

(e) **Viruses and mycoplasmas**

1. Harmful viruses and mycoplasmas of Cydonia Mill., Fragaria (Tourn.) L., Ligustrum L., Malus Mill., Populus L., Prunus L., Pyrus L., Ribes L., Rosa L., Rubus L., Syringa L.,
2. Potato viruses and mycoplasmas (Solanum tuberosum L.):
   (a) potato spindle tuber virus,
   (b) potato yellow dwarf virus,
   (c) potato yellow vein virus,
   (d) other harmful viruses and mycoplasmas in so far as they do not exist in the Community,
3. Rose wilt,
4. Tomato bunchy top virus,
5. Tomato ring spot virus,
6. Harmful viruses and mycoplasmas of the vine (Vitis L. partim),
7. Elm phloem necrosis.

(f) **Phanerogams**

— Arceuthobium spp. (non-European species).

B. HARMFUL ORGANISMS WHOSE INTRODUCTION MAY BE PROHIBITED IN CERTAIN MEMBER STATES

(a) **Live organisms of the animal kingdom, at all stages of their development**

Species	Member State
1. Aleurocanthus woglumi Ashby	Italy
2. Anastrepha fracterculus (Wied)	Italy
3. Anastrepha ludens (Loew)	Italy
4. Bussecola fusca (Hamps.)	Italy
5. Dacus dorsalis Hendel	Italy
6. Dialeurodes citri (Ashm.)	Italy
7. Diaphorina citri (Kuway)	France, Italy
8. Gonipterus scutellatus Gyll.	Italy
9. Iridomyrmex humilis (Mayr)	France, Italy
10. Leptinotarsa decemlineata (Say)	Denmark, Ireland, United Kingdom
11. Phoracantha semipunctata (F.)	Italy
12. Pseudaulacaspis pentagona (Targ.)	France, Italy
13. Pseudococcus comstocki (Kuw.)	France, Italy
14. Toxoptera citricida (Kirk.)	France, Italy
15. Trioza erythreae Del Guercio	France, Italy

(b) **Bacteria**

Species	Member State
Xanthomonas citri (Hasse) Dowson	France, Italy

(c) **Cryptogamia**

Species	Member State
1. Cronartium ribicola J. C. Fischer	Italy
2. Diaporthe citri (Fawc.) Wolf	Italy
3. Dibotryon morbosum (Schw.) Theissen and Sydow	Italy
4. Diplodia natalensis P. Evans	Italy
5. Elsinoë fawcettii Bitanc. and Jenkins	Italy
6. Phytophthora cinnamomi Rands	Ireland
7. Scleroderris lagerbergii Gremmen	Ireland

(d) **Viruses**

Species	Member State
Viruses of citrus fruits (Citrus L.)	France, Italy

ANNEX II

A. HARMFUL ORGANISMS WHOSE INTRODUCTION MUST BE PROHIBITED IN ALL MEMBER STATES IF THEY ARE PRESENT ON CERTAIN PLANTS OR PLANT PRODUCTS

(a) Live organisms of the animal kingdom, at all stages of their development

Species	Subject of contamination
1. Anarsia lineatella Zell.	Ribes L. and Rubus L., other than fruit Cydonia Mill., Malus Mill., Prunus L., Pyrus L.
2. Diarthronomyia chrysanthemi Ahlb.	Chrysanthemums (Chrysanthemum Tourn. ex L. partim)
3. Ditylenchus destructor Thorne	Flower bulbs and potato tubers (Solanum tuberosum L.)
4. Ditylenchus dipsaci (Kühn) Filipjev	Seeds and bulbs of Allium cepa L., Allium porrum L. and Allium schoenoprasum L. for planting, flower bulbs and seeds of lucerne (Medicago sativa L.)
5. Gracilaria azaleella Brants	Azaleas (Rhododendron L. partim)
6. Lampetia equestris F.	Flower bulbs and corms
7. Phthorimaea operculella (Zell.)	Potato tubers (Solanum tuberosum L.)
8. Rhagoletis cerasi L.	Fruits of cherry trees (Prunus avium L. and Prunus cerasus L.)
9. Scolytidae (of conifers)	Wood of conifers, with bark, from countries in temperate and sub-Arctic zones other than Europe
10. Viteus vitifolii (Fitch.)	Vines (Vitis L. partim), other than fruit and seeds

(b) Bacteria

Species	Subject of contamination
1. Corynebacterium insidiosum (McCull.) Jensen	Seeds of lucerne (Medicago sativa L.)
2. Corynebacterium michiganense (E. F. Sm.) Jensen	Tomatoes (Solanum lycopersicum L.), other than fruit
3. Erwinia chrysanthemi Burkh. et al. [= Pectobacterium parthenii var. dianthicola Hellmers]	Carnations (Dianthus L.) other than cut flowers and seeds
4. Pseudomonas caryophylli (Burkh.) Starr. and Burkh.	Carnations (Dianthus L.) other than cut flowers and seeds
5. Pseudomonas gladioli Severini [= Pseudomonas marginata (McCull.) Stapp]	Gladioli corms (Gladiolus Tourn. ex L.) and freesia corms (Freesia Klatt.)
6. Pseudomonas pisi (Sackett)	Seeds of peas (Pisum sativum L.)

Species	Subject of contamination
7. Pseudomonas solanacearum (E. F. Sm.) Jensen	Potato tubers (Solanum tuberosum L.) and tomatoes (Solanum lycopersicum L.) and aubergines (Solanum melongena L.), other than fruit and seeds
8. Pseudomonas woodsii (E. F. Sm.) Stev.	Carnations (Dianthus L.) other than cut flowers and seeds
9. Xanthomonas vesicatoria (Doidge) Dows.	Tomatoes (Solanum lycopersicum L.) other than fruit

(c) **Cryptogamia**

Species	Subject of contamination
1. Atropellis spp.	Pinus L.
2. Didymella chrysanthemi (Tassi) Garibaldi and Gullino [= Mycosphaerella ligulicula Baker et al.]	Chrysanthemums (Chrysanthemum Tourn. ex L. partim)
3. Fusarium oxysporum Schlecht. f.sp. gladioli (Massey) Snyd. and Hans	Corms of freesias (Fressia Klatt), gladioli (Gladiolus Tourn. ex L.), crocuses (Crocus L.) and iris rhizomes (Iris L.)
4. Guignardia baccae (Cav.) Jacz.	Vines (Vitis L. partim) other than fruit and seeds)
5. Ovulinia azaleae Weiss	Azaleas (Rhododendron L. partim)
6. Phialophora cinerescens (Wr.) van Beyma	Carnations (Dianthus L.) other than cut flowers and seeds
7. Phytophthora fragariae Hickman	Strawberry plants (Fragaria Tourn. ex L.) other than fruit and seeds
8. Puccinia horiana P. Henn	Chrysanthemums (Chrysanthemum Tourn. ex L. partim)
9. Puccinia pelargonii-zonalis Doidge	Geraniums (Pelargonium l'Herit. partim)
10. Sclerotinia bulborum (Wakk.) Rehm	Flower corms
11. Sclerotinia convoluta Drayt.	Iris rhizomes (Iris L.)
12. Septoria gladioli Pass.	Flower bulbs and corms
13. Stromatinia gladioli (Drat) Whet.	Flower bulbs and corms
14. Uromyces spp.	Gladioli (Gladiolus Tourn. ex L.)
15. Verticillium albo-atrum Reinke and Berth	Hops (Humulus lupulus L.)

(d) **Viruses and mycoplasmas**

Species	Subject of contamination
1. Beet leaf curl virus	Beet (Beta vulgaris L.) for planting other than seeds
2. Chrysanthemum stunt virus	Chrysanthemums (Chrysanthemum Tourn. ex L. partim) other than cut flowers and seeds
3. Stolbur	Solanaceae for planting other than fruit and seeds
4. Tomato spotted wilt virus	Potato tubers (Solanum tuberosum L.)

B. HARMFUL ORGANISMS WHOSE INTRODUCTION MAY BE PROHIBITED IN CERTAIN MEMBER STATES IF PRESENT ON CERTAIN PLANTS OR PLANT PRODUCTS

(a) Live organisms of the animal kingdom, at all stages of their development

Species	Subject of contamination	Member State
1. Cephalcia alpina Klug	Larix Mill. for planting other than seeds	Ireland United Kingdom (Northern Ireland)
2. Dendroctonus micans Kugelan	Coniferous wood with bark	Ireland United Kingdom
3. Eurytoma amygdali End.	Fruit and seeds of almond (Prunus amygdalus Batsch)	Italy
4. Gilpinia hercyniae Hartig	Picea A. Dietr. for planting other than seeds	Ireland United Kingdom (Northern Ireland)
5. Helicoverpa armigera Hübner	Carnations (Dianthus L.), chrysanthemums (Chrysanthemum Tourn. ex L. partim), geraniums (Pelargonium l'Herit.) and tomatoes (Solanum lycopersicum L.) other than seeds, fruit and cut flowers	Ireland United Kingdom
6. Ips amitinus Eichh.	Coniferous wood with bark	Ireland United Kingdom
7. Ips cembrae Heer	Coniferous wood with bark	Ireland United Kingdom (Northern Ireland)
8. Ips duplicatus Sahlb.	Coniferous wood with bark	Ireland United Kingdom
9. Ips sexdentatus (Boerner)	Coniferous wood with bark	Ireland United Kingdom (Northern Ireland)
10. Ips typographus Heer	Coniferous wood with bark	Ireland United Kingdom
11. Pristiphora abietina Christ.	Picea A. Dietr. for planting other than seeds	Ireland United Kingdom (Northern Ireland)

(b) Bacteria

Species	Subject of contamination	Member State
Corynebacterium flaccumfaciens (Hedges) Dows.	Seeds of beans (Phaseolus vulgaris L. and Dolichos Jacq.) for planting	Italy

(c) **Cryptogamia**

Species	Subject of contamination	Member State
1. Ascochyta chlorospora Speg.	Almond (Prunus amygdalus Batsch)	Italy
2. Corticium salmonicolor Berk. and Br.	Citrus (Citrus L.)	Italy
3. Cryptosporiopsis curvispora (Pk) Gremmen	Apple (Malus pumila Mill.)	Italy
4. Gloeosporium limeticola Clausen	Citrus (Citrus L.)	France Italy
5. Phoma exigua var. foveata (Foister) Boerema	Seed potatoes originating in countries outside the Community	Belgium Germany France Italy Luxembourg Netherlands
6. Phoma exigua var. foveata (Foister) Boerema, where this harmful organism has caused a sizeable outbreak of potato dry rot	Potato tubers (Solanum tuberosum L.), other than seed potatoes, new potatoes and potatoes intended for immediate processing	Belgium Germany France Italy Luxembourg Netherlands
7. Urocystis cepulae Frost	Plants of Allium spp. for planting or propagation	Ireland

ANNEX III

A. PLANTS AND PLANT PRODUCTS THE INTRODUCTION OF WHICH MUST BE PROHIBITED IN ALL MEMBER STATES

Description	Country of origin
1. Plants of Abies Mill., Picea A. Dietr. and Pinus L., other than fruit and seeds	Non-European countries
2. Plants of Larix Mill., other than fruit and seeds	North American and Asian countries
3. Plants of Tsuga Carr. and Pseudotsuga Carr., other than fruit and seeds	North American countries
4. Plants of Populus L. and Quercus L., with leaves, other than fruit and seeds	Non-European countries
5. Isolated bark of conifers (Coniferae)	Countries in the temperate and sub-Arctic zones of parts of the world other than Europe
6. Isolated bark of Castanea Mill. and Quercus L.	North American countries, Romania, USSR
7. Isolated bark of Populus L.	Countries of the American continent
8. From 16 April to 30 September, plants of the genera: Acacia Tourn. ex L., Acer L., Amelanchier Med., Chaenomeles Ldl., Cotoneaster Ehrh., Crataegus L., Cydonia Mill., Euonymus L., Fagus L., Juglans L., Ligustrum L., Maclura, Malus Mill., Populus L., Prunus L., Ptelea, Pyrus L., Ribes L., Rosa L., Salix L., Sorbus L., Symphoricarpus Duham, Syringa L., Tilia L., Ulmus L., Vitis L., other than fruit, seeds and parts of plants used for decoration	All countries, unless the country of origin, when it is a Member State, and all countries through which the plants pass are free from Quadraspidiotus perniciosus, or the region of production and all regions through which the plants pass are recognized as being free from that harmful organism, according to the procedure laid down in Article 16
9. True seeds of potatoes (Solanum tuberosum L.) and other tuber-forming Solanaceae species (Solanum)	All countries
10. Isolated bark of Ulmus L.	All countries

B. PLANTS, PLANT PRODUCTS AND OTHER OBJECTS THE INTRODUCTION OF WHICH MAY BE PROHIBITED IN CERTAIN MEMBER STATES

Description	Member State
1. Citrus fruit plants (Citrus L.)	France, Italy
2. Eucalyptus plants (Eucalyptus l'Hérit.), other than fruit and seeds	Italy
3. Wood and plants of vine (Vitis L. partim) other than fruit, seeds and rootless materials for vegetative propagation	Germany

Description	Member State
4. Plants of Chaemaecyparis lawsoniana (Murr.) Parl. 'Elwoodii', Chaemaecyparis pisifera 'Boulevard', Rhododendron impeditum Balf.f. and Sm., Daboecia spp.	Ireland, United Kingdom (Northern Ireland)
5. Isolated conifer bark from temperate and sub-Arctic zones of Europe	Ireland, United Kingdom (Northern Ireland)
6. Isolated Picea A. Dietr. bark from temperate and sub-Arctic zones of Europe	United Kingdom (Great Britain)
7. Berberis spp. other than the following species and sub-species: Berberis aggregata Schn. Berberis dictyophylla Franch. Berberis koreana Palib. Berberis rubrostilla Chitt. Berberis wilsonae Hemsl. Berberis parvifolia Sprague Berberis prattii Schn. Berberis thunbergii DC. All evergreen species, except Mahoberberis Schn.	Denmark, Ireland

ANNEX IV

A. SPECIAL REQUIREMENTS WHICH MUST BE LAID DOWN BY ALL MEMBER STATES FOR THE INTRODUCTION OF PLANTS, PLANT PRODUCTS AND OTHER OBJECTS

Plants, plant products and other objects	Special requirements
1. Wood of conifers originating in countries in temperate and sub-Arctic zones of parts of the world other than Europe	The wood shall be stripped of its bark
2. Wood of Castanea and Quercus originating in North American countries	The wood shall be stripped of its bark Official statement that its water content does not exceed 20 % expressed as a percentage of the dry matter
3. Wood of Castanea and Quercus originating in Romania and the USSR	(a) Official statement that the wood originates in regions known to be free from Ophiostoma roboris or Endothia parasitica, or (b) The wood shall be stripped of its bark, and official statement that its water content does not exceed 20 % expressed as a percentage of the dry matter
4. Wood of Castanea and Quercus originating in countries other than North American countries, Romania and the USSR	(a) Official statement that the wood originates in regions known to be free from Endothia parasitica, or (b) The wood shall be stripped of its bark
5. Wood of Populus originating in countries of the American continent	The wood shall be stripped of its bark
6. Wood of Ulmus	The wood shall be stripped of its bark
7. Plants of Castanea:	
(a) originating in all countries	Official statement that no symptoms of Endothia parasitica have been observed at the place of production since the beginning of the last complete cycle of vegetation
(b) originating in North American countries, Romania and the USSR	Official statement that the plants originate in regions known to be free from Ceratocystis fagacearum and Ophiostoma roboris

Plants, plant products and other objects	Special requirements
8. Plants of Pinus, other than fruit and seeds, originating in European countries	Official statement that no symptoms of Cronartium quercuum have been observed at the place of production since the beginning of the last complete cycle of vegetation
9. Plants of Populus, other than fruit and seeds:	
(a) originating in all countries	Official statement: — that no symptoms of Mycosphaerella populorum (Septoria musiva) have been observed at the place of production since the beginning of the last complete cycle of vegetation — and that no symptoms of harmful virus or mycoplasma diseases have been observed at the place of production since the beginning of the last complete cycle of vegetation
(b) originating in countries of the American continent	Official statement that no symptoms of Hypoxylon pruinatum or Melampsora medusae have been observed at the place of production since the beginning of the last complete cycle of vegetation
10. Plants of Pseudotsuga, except fruit and seeds, originating in Asian countries	Official statement that no symptoms of Guignardia laricina have been observed at the place of production since the beginning of the last complete cycle of vegetation
11. Plants of Pseudotsuga and of Larix, except fruit and seeds, originating in countries of the American continent	Official statements that no symptoms of Melampsora medusae have been observed at the place of production since the beginning of the last complete cycle of vegetation
12. Plants of Quercus:	
(a) originating in all countries	Official statement that no symptoms of Endothia parasitica or Cronartium quercuum have been observed at the place of production since the beginning of the last complete cycle of vegetation
(b) originating in North American countries, Romania and the USSR	Official statement: — that no symptoms of Cronartium fusiforme have been observed either at the place of production or in its immediate vicinity since the beginning of the last complete cycle of vegetation — and that the plants originate in regions known to be free from Ceratocystis fagacearum and Ophiostoma roboris

Plants, plant products and other objects	Special requirements
13. Plants of Ulmus, other than fruit and seeds, originating in North American countries	Official statement that no symptoms of elm phloem necrosis have been observed either at the place of production or in its immediate vicinity since the beginning of the last complete cycle of vegetation
14. Plants of the Ulmaceae family other than fruit and seeds	Official statement that no symptoms of Ceratocystis ulmi have been observed either at the place of production or in its immediate vicinity since the beginning of the last complete cycle of vegetation
15. Plants of Crataegus, Cotoneaster, Cydonia, Malus, Pyracantha, Pyrus, Sorbus and Stranvaesia, other than fruit, seeds and parts of plants used for decoration	Official statement that no symptoms of Erwinia amylovora have been observed either at the place of production or in its immediate vicinity since the beginning of the last two cycles of vegetation and that no contamination by Erwinia amylovora has been known to occur within a radius of at least 5 km of the place of production during the same period
16. Plants of Prunus, where these do not come under 17, plants of Rubus, where these do not come under 18 and of Cydonia, Ligustrum, Malus, Pyrus, Ribes, Rosa and Syringa, for planting, other than seeds	Official statement that no symptoms of harmful virus or mycoplasma diseases have been observed in plants at the place of production since the beginning of the last complete cycle of vegetation
17. Plant of the species: Prunus amygdalus Prunus armeniaca Prunus brigantina Prunus cerasifera Prunus domestica Prunus insititia Prunus nigra Prunus persica Prunus salicina Prunus spinosa Prunus tomentosa Prunus triloba and other species of Prunus susceptible to the Sharka virus which are intended for planting, other than seeds	Official statement: (a) that no symptoms of harmful virus or mycoplasma diseases, other than the Sharka virus, have been observed in plants at the place of production since the beginning of the last complete cycle of vegetation (b) that the plants, other than those raised from seed, have been: — either officially certified under a certification scheme requiring them to be derived in a direct line from material which has been maintained under appropriate conditions and subjected to regular official virological testing for at least Sharka virus using Prunus indicators or equivalent methods and has been found free, in these tests, from those viruses — or derived in a direct line from material which is maintained under appropriate conditions and has been subjected, within the last three complete cycles of vegetation, at least once, to official virological testing

Plants, plant products and other objects	Special requirements
	for Sharka virus using Prunus indicators or equivalent methods and have been found free, in these tests, from Sharka virus (c) that no symptoms of Sharka virus have been observed in the plants or in plants of the same species in the place of production, or in its immediate vicinity since the beginning of the last three complete cycles of vegetation
18. Plants of Rubus idaeus, Rubus fructicosus and Rubus occidentalis, intended for planting, originating in North American countries, Japan and any other country where tomato ring spot virus has been known to occur	(a) Effective treatment against aphids (b) Official statement: (aa) that the plants have been: — either officially certified under a certification scheme which requires them to be derived in a direct line from material which has been maintained under appropriate conditions and subjected to regular official virological testing for at least tomato ring spot virus and has been found free, in these tests, from those viruses — or derived in a direct line from material which is maintained under appropriate conditions and has been subjected, within the last three complete cycles of vegetation, at least once, to official virological testing for tomato ring spot virus and has been found free, in these tests, from those viruses (bb) that the plants originate in a place of production free from tomato ring spot virus in the land or plants and that no symptoms of diseases caused by harmful viruses or mycoplasmas have been observed in plants at the place of production since the beginning of the last three complete cycles of vegetation
19. Plants of Rubus idaeus, Rubus fructicosus and Rubus occidentalis intended for planting, with the exception of seeds, originating in a country where raspberry leaf curl viruses have been known to occur	(a) Effective treatment against aphids (b) Official statement: (aa) that the plants have been: — either officially certified under a certification scheme which requires them to be derived in a direct line from material which has been maintained under appropriate conditions and subjected to regular official virological testing for at least raspberry leaf curl viruses and has been found free, in these tests, from those viruses

Plants, plant products and other objects	Special requirements
	— or derived in a direct line from material which is maintained under appropriate conditions and has been subjected, within the last three complete cycles of vegetation, at least once to official virological testing for raspberry leaf curl viruses and has been found free, in these tests, from those viruses (bb) that the plants originate in a place of production free from raspberry leaf curl viruses and that no symptoms of diseases caused by harmful viruses or mycoplasmas have been observed in plants at the place of production since the beginning of the last three complete cycles of vegetation
20. Plants of Vitis, other than fruits and seeds	Official statement that no symptoms of harmful virus or mycoplasma diseases have been observed in plants at the place of production since the beginning of the last complete cycle of vegetation
21. Plants of Fragaria, for planting, other than seeds, where such plants do not come under 22	Official statement: (a) that no symptoms of harmful virus or mycoplasma diseases have been observed in plants in the place of production since the beginning of the last complete cycle of vegetation (b) that no symptoms of Phytophthora fragariae have been observed at the place of production since the beginning of the last complete cycle of vegetation
22. Plants of Fragaria, for planting, other than seeds, originating in North American countries	Official statement: (a) that the plants, other than those raised from seed, have been: — either officially certified under a certification scheme which requires them to be directly derived from material which has been maintained under appropriate conditions and subjected to regular official virological testing for at least strawberry vein banding virus, strawberry witches' broom virus and strawberry latent C. virus and has been found free, in these tests, from those viruses — or directly derived from material which is maintained under appropriate conditions and has been subjected, within the last three complete cycles of vegetation, at least

Plants, plant products and other objects	Special requirements
	once to official virological testing for the viruses referred to above and has been found free, in these tests, from those viruses (b) that no symptoms of harmful virus or mycoplasma diseases have been observed in plants at the place of production since the beginning of the last four complete cycles of vegetation (c) that no symptoms of Phytophthora fragariae have been observed at the place of production since the beginning of the last complete cycle of vegetation
23. Tubers of Solanum tuberosum originating in the Community	Official statement that the Community provisions to combat Corynebacterium sepedonicum and Synchytrium endobioticum have been complied with
24. Tubers of Solanum tuberosum originating outside the Community	Official statement: — either that the tubers originate in regions known to be free from Corynebacterium sepedonicum and Synchytrium endobioticum (all races other than the common European race), and that no symptoms of Synchytrium endobioticum have been observed either at the place of production or in its immediate vicinity since the beginning of an adequate period — or that provisions recognized as equivalent to the Community provisions in accordance with the Article 16 procedure have been complied with in the country of origin
25. Tubers of Solanum tuberosum, other than new potatoes, originating in countries in the American continent and in non-member countries where potato spindle tuber virus has occurred	Suppression of the faculty of germination
26. Seed poratoes of Solanum tuberosum	Official statement that the seed potatoes originate from land known to be free from Heterodera rostochiensis and Heterodera pallida
27. Solanaceae plants for planting, other than fruit and seeds	Official statement that no symptom of Stolbur has been observed on plants at the place of production since the beginning of the last complete cycle of vegetation

Plants, plant products and other objects	Special requirements
28. Plants of Humulus lupulus, other than seed and harvested hops	Official statement that no symptoms of Verticillium albo-atrum have been observed at the place of production since the beginning of the last complete cycle of vegetation
29. Plants of Chrysanthemum, other than seeds and cut flowers	Official statement that: (a) the plants are no more than third generation stock derived from material which has been found to be free from chrysanthemum stunt virus during virological tests, or are directly derived from material of which a representative sample of at least 10 % has been found to be free from chrysanthemum stunt virus during an official inspection carried out at the time of flowering (b) the official certificate has been issued not more than 48 hours before the declared time of dispatch from the place of production (c) the plants or cuttings have come from premises: — which have been officially inspected at least monthly, during the three months prior to dispatch and on which no symptoms of Puccinia horiana have been observed during that period, and — in the immediate vicinity of which no symptoms of Puccinia horiana have been known to have occurred during the three months prior to export (d) in the case of unrooted cuttings no symptoms of Didymella chrysanthemi were observed either in the cuttings or in the plants from which the cuttings were derived, or that, in the case of rooted cuttings, no symptoms of Didymella chrysanthemi were observed either in the cuttings or in the rooting bed
30. Plants of Dianthus caryophyllus, other than cut flowers and seeds	Official statement that: — the plants have been derived in direct line from mother plants and have been found free from Erwinia chrysanthemi, Pseudomonas caryophylli, Pseudomonas woodsii and Phialophora cinerescens on officially approved tests carried out within the two previous years — no symptoms of the above harmful organisms have been observed at the place of production since the beginning of the last complete cycle of vegetation

Plants, plant products and other objects	Special requirements
31. Plants of Gladiolus	Official statement that: (a) the plants originate in a country known to be free from Uromyces spp., or (b) no symptoms of Uromyces spp. have been observed at the place of production since the beginning of the last complete cycle of vegetation
32. Bulbs of Tulipa and Narcissus	Official statement that no symptoms of Ditylenchus dipsaci have been observed at the place of production since the beginning of the last complete cycle of vegetation
33. Plants of Pelargonium X. hortorum (including P. zonale) and P.X. domesticum, other than seeds for planting, originating in countries in which tomato ring spot virus is known to occur:	
(a) where Xiphinema americanum or other vectors of tomato ring spot virus are not known to occur and	Official statement that the plants: (a) are directly derived from nurseries known to be free from tomato ring spot virus (b) or are of no more than fourth generation stock, derived from mother plants found to be free from tomato ring spot virus under an officially approved system of virological testing
(b) where Xiphinema americanum or other vectors of tomato ring spot virus are known to occur	Official statement that the plants: (a) are directly derived from nurseries known to be free from tomato ring spot virus in the soil or plants (b) are of no more than second generation stock derived from mother plants found to be free from tomato ring spot virus under an officially approved system of virological testing
34. Plants with roots, planted or for planting, grown in the open air	Official statement that the place of production is known to be free from Synchytrium endobioticum, Heterodera pallida, Heterodera rostochiensis and Corynebacterium sepedonicum
35. Plants with soil attached, originating in Japan and North American countries	Official statement that the soil has been found free from harmful organisms
36. Soil containing parts of plants or humus, originating in countries outside Europe	Official statement that the soil has been found free from harmful organisms

Plants, plant products and other objects	Special requirements
37. Plants of Beta spp. for planting, other than seeds, originating in countries where beet leaf curl virus is known to occur	Official statement: (a) that beet leaf curl virus has not been known to occur in the region of production (b) and that no symptoms of beet leaf curl virus have been observed at the place of production or in its immediate vicinity since the beginning of the last complete cycle of vegetation
38. Seeds of Medicago sativa	Official statement: — that no symptoms of Ditylenchus dipsaci have been observed at the place of production since the beginning of the last complete cycle of vegetation and that no symptoms have been revealed by laboratory tests on a representative sample, or — that fumigation has taken place prior to export
39. Seeds of Medicago sativa originating in all countries in which Corynebacterium insidiosum has occurred	Official statement that: — Corynebacterium insidiosum has not been known to occur on the farm or in the immediate vicinity since the beginning of the past 10 years — the crop was in its first or second complete cycle of vegetation from sowing when the seed was harvested — no symptoms of Corynebacterium insidiosum have been observed at the place of production, or on any Medicago sativa crop adjacent to it, during the last complete cycle of vegetation or, where appropriate, the last two cycles of vegetation — the crop has been grown on land on which no previous Medicago sativa crop has been present during the last three years prior to sowing
40. Seeds of Pisum sativum	Official statement that: — either Pseudomonas pisi has not been known to occur in the region of production, within an adequate period — or no symptoms of Pseudomonas pisi have been observed in plants at the place of production since the beginning of the last complete cycle of vegetation

Plants, plant products and other objects	Special requirements
41. Seeds of Solanum lycopersicum	Official statement that: — the seeds come from regions known to be free from tomato bunchy top virus or potato spindle tuber virus, or — no symptoms of tomato bunchy top virus or potato spindle tuber virus have been observed in plants at the place of production from where the seeds are derived since the beginning of the last complete cycle of vegetation

B. SPECIAL REQUIREMENTS WHICH MAY BE LAID DOWN BY CERTAIN MEMBER STATES FOR THE INTRODUCTION OF PLANTS AND PLANT PRODUCTS

Plants and plant products	Special requirements	Member States
1. Wood of conifers originating in countries other than those referred to in Annex IV, Part A (1)	The wood shall be stripped of its bark	Ireland United Kingdom (Northern Ireland)
2. Wood of Castanea and Quercus, complete with bark, originating in North American countries	Official statement that the wood originates in regions found to be free from Cronartium quercuum or Cronartium fusiforme	Italy
3. Wood of Picea originating in countries other than those referred to in Annex IV, Part A (1)	The wood shall be stripped of its bark	United Kingdom (Great Britain)
4. Plants of Larix excluding fruit and seeds	Official statement that the place of production is free from Cephalcia alpina	Ireland United Kingdom (Northern Ireland)
5. Plants of Picea and Pinus other than fruit and seeds	Official statement that the place of production is free from Scleroderris lagerbergii	Ireland United Kingdom (Northern Ireland)

Plants and plant products	Special requirements	Member States
6. Plants of Picea for planting, other than seeds	Official statement that the place of production is free from Gilpinia hercyniae and Pristiphora abietina	Ireland United Kingdom (Northern Ireland)
7. Plants of Ulmus and Zelkova for planting, other than fruits and seeds	Official statement that: (a) the plants are not more than one year old and are of an overall height not exceeding 30 cm, and (b) the plants are raised in a nursery in which, and in the immediate vicinity of which, no symptoms of Ceratocystis ulmi have been observed since the last two complete cycles of vegetation, and (c) the plants have been treated with appropriate insecticides to protect them against vectors of Ceratocystis ulmi	Denmark Ireland United Kingdom (Northern Ireland)
8. Plants of citrus, other than fruit and seeds	Official statement that no symptoms of virus diseases have been observed in plants at the place of production since the beginning of the last complete cycle of vegetation	France Italy
9. Tubers of Solanum	(a) Official statement that the tubers: — come from areas which have not been contaminated by Leptinotarsa decemlineata since the beginning of the last complete cycle of vegetation or in which intensive measures are taken to combat these harmful organisms — have been cleaned and packed in a suitable manner before export	Denmark Ireland United Kingdom

Plants and plant products	Special requirements	Member States
	(b) the tubers shall be transported in such a way as to avoid any contamination with Leptinotarsa decemlineata	
10. Tubers of Solanum, other than new potatoes and seed potatoes	Suppression of the faculty of germination	Ireland United Kingdom (Northern Ireland)
11. Tubers of Solanum originating in non-member countries	Official statement that the plants originate in a non-member country on the list drawn up in accordance with the procedure laid down in Article 16	Ireland United Kingdom
12. Tubers of Solanum directly derived from seed potatoes originating in a non-member country not in on the list drawn up in accordance with the procedure laid down in Article 16	Official statement that the tubers have been tested by means of sampling and have been found to be free from Corynebacterium sepedonicum	Ireland
13. Plants of Allium spp. for planting or propagation	Official statement that no symptoms of Urocystis cepulae have been observed at the place of production since the beginning of the complete cycle of vegetation	Ireland
14. From 1 April to 14 October: plants (other than seeds) of Beta, Brassica, Cichorium, Daucus and Lactuca with foliage	(a) Official statement that the plants: — have been grown under permanent structures of glass or plastic or originate in regions which are known to be free from Leptinotarsa decemlineata since the beginning of the last complete cycle of vegetation or in which intensive measures are taken to combat these harmful organisms — have been cleaned and packed in a suitable manner before export	Ireland United Kingdom

Plants and plant products	Special requirements	Member States
	(b) The plants shall be transported in such a way as to avoid any contamination with Leptinotarsa decemlineata	
15. Plants of Chrysanthemum, Dianthus and Pelargonium, other than seeds and cut flowers	Official statement: (a) that no symptoms of Epichoristodes acerbella, Spodoptera littoralis, S. litura or Helicoverpa armigera have been observed at the place of production since the beginning of the last complete cycle of vegetation, or (b) that the plants have undergone appropriate treatment to protect them from the said organisms	Denmark Germany France Ireland United Kingdom
16. Plants with roots, planted or intended for planting	Official statement that the place of production was found free of Phytophthora cinnamomi	Ireland United Kingdom (Northern Ireland)

ANNEX V

Plants, plant products and other objects which must be subjected to a plant health inspection in the country of origin or the consignor country, before being permitted to enter any of the Member States

1. Plants, planted or intended for planting, other than seeds and aquarium plants.

2. The parts of plants as shown below:

   (a) the following cut flowers and parts of plants used for decoration:

   Castanea,

   Chrysanthemum,

   Dianthus,

   Gladiolus,

   Prunus,

   Quercus,

   Rosa,

   Silax,

   Syringa,

   Vitis;

   (b) fresh fruits of:

   Citrus, other than lemons (Citrus limon (L.) Burm. and Citrus medica L.),

   Cydonia,

   Malus,

   Prunus,

   Pyrus.

3. Potato tubers (Solanum tuberosum L.).

4. The wood of:

   — Castanea, Quercus and Ulmus,

   — Conifers, originating in countries other than Europe,

   — Populus, originating in countries of the American Continent.

5. Soil:

   — containing parts of plants or humus, peat not being regarded as part of a plant or humus,

   — attached to plants or added to them.

ANNEX VI

Plants which must be disinfected

Plants of the genera Acacia, Acer, Amelanchier, Chaenomeles, Cotoneaster, Crataegus, Cydonia, Euonymus, Fagus, Juglans, Ligustrum, Maclura, Malus, Populus, Prunus, Ptelea, Pyrus, Ribes, Rosa, Salix, Sorbus, Symphoricarpus, Syringa, Tilia, Ulmus and Vitis, other than fruits, seeds and parts of plants used for decoration.

ANNEX VII

Plants and plant products to which special arrangements may be applied

1. Cereals and their derivatives.

2. Dried leguminous plants.

3. Manioc tubers and their derivatives.

4. Residues from the production of vegetable oils.

ANNEX VIII

A. MODEL

PHYTOSANITARY CERTIFICATE

No .....

PLANT PROTECTION ORGANIZATION

of: .....

to: PLANT PROTECTION ORGANIZATION(S)

of: .....

DESCRIPTION OF CONSIGNMENT

Name and address of exporter: .....

Name and address of consignee: .....

Number and description of packages: .....

Distinguishing marks: .....

Place of origin: .....

Declared means of conveyance: .....

Declared point of entry: .....

Name of produce and quantity declared: .....

Botanical name of plants: .....

This is to certify that the plants or plant products described above have been inspected and found free from quarantine pests and substantially free from other injurious pests, and that they are considered to conform with the current plant health regulations of the importing country.

DISINFESTATION AND/OR DISINFECTION TREATMENT

Date: ..... Treatment: .....

Chemical (active ingredient): .....

Duration and temperature: .....

Concentration: .....

Additional information: .....

Additional declaration: .....

Place of issue:

.....

(Stamp of organization)

Name of authorized officer:

.....

Date: .....

(Signature)

B. MODEL

PHYTOSANITARY CERTIFICATE FOR RE-EXPORT

No .....

PLANT PROTECTION ORGANIZATION

of: ..... (country of re-export)

to: PLANT PROTECTION ORGANIZATION(S)

of: ..... (country(countries) of destination)

DESCRIPTION OF CONSIGNMENT

Name and address of exporter: .....

Name and address of consignee: .....

Number and description of packages: .....

Distinguishing marks: .....

Place of origin: .....

Declared means of conveyance: .....

Declared point of entry: .....

Name of produce and quantity declared: .....

Botanical name of plants: .....

This is to certify that the plants or plant products described above were imported into ..... (country of re-export) from ..... (country of origin) covered by phytosanitary certificate No ....., original ☐ certified true copy of which is attached to this certificate; that they are packed ☐ repacked ☐ in original containers ☐ new containers; that based on the original phytosanitary certificate ☐ and additional inspection ☐ they are considered to conform with the current plant health regulations of the importing country, and that during storage in ..... (country of re-export) this consignment has not been subjected to the risk of infestation or infection.

DISINFESTATION AND/OR DISINFECTION TREATMENT

Date: ..... Treatment: .....

Chemical (active ingredient): .....

Duration and temperature: .....

Concentration: .....

Additional information: .....

Additional declaration: .....

Place of issue: Name of authorized officer:

....

Date: .....

(Stamp of organization) (Signature)

☐ Tick appropriate box.

COUNCIL DIRECTIVE

of 21 December 1976

on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses

(77/94/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas the differences between national laws relating to foodstuffs for particular nutritional uses impede their free movement, may create unequal conditions of competition and thus have a direct impact on the establishment and functioning of the common market;

Whereas the approximation of these laws is therefore necessary;

Whereas this approximation pre-supposes, in an initial stage, the preparation of a common definition, the determination of measures enabling the consumer to be protected against fraud concerning the nature of these products and the adoption of rules to be complied with in labelling the products in question;

Whereas, in a subsequent stage, the Council will have to adopt the definitions and determine the particular characteristics applicable to certain groups of these products;

Whereas the word 'dietetic' (or 'dietary') does not have the same accepted meaning in all the Member States; whereas the latter must be able to take into account the customs existing when this Directive is implemented;

Whereas the products covered by this Directive are foodstuffs the composition and preparation of which must be specially designed to meet the particular nutritional requirements of the persons for whom they are mainly intended; whereas it might be necessary, therefore, to provide for derogations to the general or specific provisions applicable to foodstuffs in order to arrive at the specific nutritional objective;

Whereas the determination of the sampling procedures and methods of analysis for verifying the additives and the composition and manufacturing specifications of the various groups of foodstuffs intended for particular nutritional uses is an implementing measure of a technical nature; whereas its adoption should be entrusted to the Commission in order to simplify and expedite the procedure;

Whereas in all the cases for which the Council confers powers on the Comission for implementing rules laid down in the fields of foodstuffs intended for human consumption, provisions should be made for a procedure for establishing close cooperation between the Member States and the Commission within the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns foodstuffs for particular nutritional uses.

2. (a) Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

(1) OJ No C 139, 28. 10. 1969, p. 39.
(2) OJ No C 10, 27. 1. 1970, p. 27.

(b) A particular nutritional use must fulfil the particular nutritional requirements:

(i) of certain categories of persons whose digestive processes or metabolism are disturbed, or

(ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from a controlled consumption of certain substances in foodstuffs, or

(iii) of infants or young children in good health.

3. The Council, in accordance with the procedure laid down in Article 100 of the Treaty, shall, by means of Directives, adopt the specific provisions applicable to certain groups of products defined in this Article (specific Directives).

Article 2

1. The nature or composition of the products referred to in Article 1 must be such that the products are appropriate for the particular nutritional use intended.

2. The products referred to in Article 1 may be characterized as 'dietetic' or 'dietary'.

However, Member States may restrict the use of these adjectives to the products defined in Article 1 (2) (b) (i) or (b) (i) and (ii).

3. In trade in foodstuffs for normal consumption and in advertisements for them, Member States shall prohibit:

(a) the use of the adjectives 'dietetic' or 'dietary', either alone or in conjunction with other words, to designate these foodstuffs;

(b) all other markings or any presentation likely to give the impression that one of the products referred to in Article 1 is involved.

4. However, in accordance with the specific Directives or, in their absence, in accordance with national provisions, it shall be possible, for foodstuffs for normal consumption which are suitable for a particular nutritional use, to indicate such suitability.

The aforesaid provisions may lay down the arrangements for indicating this suitability.

Article 3

The products referred to in Article 1 must also comply with any mandatory provisions applicable to foodstuffs for normal consumption, save as regards changes made to them to ensure their conformity with the definitions given in Article 1 and provided that these changes are permitted under the specific Directive or, in their absence, under national provisions.

Article 4

1. The label or method of labelling, the presentation and advertising of the products referred to in Article 1 must not attribute properties for the prevention, treatment or cure of human disease to such products or imply such properties.

The specific Directives or, in their absence, national provisions may provide for derogations from the first subparagraph in exceptional and clearly defined cases.

2. The specific Directives or, in their absence, national provisions shall lay down the conditions under which any reference may be made in labelling, presentation and advertising to a diet or to a category of persons for which a product referred to in Article 1 is intended.

3. Paragraph 1 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

Article 5

1. The provisions concerning the labelling of foodstuffs in general or of certain specified foodstuffs for normal consumption shall apply to the products referred to in Article 1.

2. The following particulars shall also appear on the labels of the products referred to in Article 1:

(a) the particular nutritional characteristics accompanying the description; however, in the case of the products referred to in Article 1 (2) (b) (iii), this reference may be replaced by a reference to the purpose for which they are intended;

(b) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics;

(c) the available energy value expressed in kJ and kcal and the carbohydrate, protein and fat content per 100 g or 100 ml of the product as marketed and, where appropriate, per specified quantity of the product as proposed for consumption.

If, however, the energy value is less than 50 kJ (12 kcal) per 100 g or 100 ml of the product as marketed, these particulars may be replaced either by the words 'energy value less than 50 kJ (12 kcal) per 100 g' or by the words 'energy value less than 50 kJ (12 kcal) per 100 ml';

(d) the net quantity;

(e) where appropriate, the particulars required under the specific Directives or, in their absence, under national provisions.

3. This Directive shall not affect the national laws which provide for:

— a list of ingredients, including additives,

— date-marking.

Article 6

1. The products referred to in Article 1 shall only be allowed on the retail market in prepackaged form, and the packaging shall completely cover the products.

2. Member States may, however, permit derogations from this provision for purposes of the retail trade provided that the product is accompanied by the particulars provided for in Article 5 at the time when it is put on sale.

Article 7

1. Without prejudice to Articles 3, 5 and 12, Member States shall adopt all the measures necessary to ensure that trade in the products referred to in Article 1 which comply with the definitions and rules laid down in this Directive or in the specific Directives cannot be impeded by the application of non-harmonized national provisions governing the composition, manufacturing specifications, packaging or labelling of these products in particular or of foodstuffs in general.

2. Paragraph 1 shall not apply in respect of non-harmonized provisions justified on grounds of:

— protection of public health,

— prevention of fraud, unless such provisions are liable to impede the application of the definitions and rules laid down by this Directive,

— protection of industrial and commercial property, indications of sources, designations of origin or prevention of unfair competition.

Article 8

1. The Council, acting unanimously on a proposal from the Commission, shall lay down, as far as is necessary, the purity criteria for the substances for particular nutritional uses and additives the use of which is authorized for each group of products referred to in Article 1.

2. The following shall be determined in accordance with the procedure laid down in Article 9:

(a) the sampling procedures and methods of analysis needed to verify that the purity criteria referred to in paragraph 1 are satisfied;

(b) the sampling procedures and methods of analysis needed to verify the composition and manufacturing specifications of various groups of products referred to in Article 1, including the definition of defects and defective units.

Article 9

1. Where the procedure laid down in this Article is followed, the matter shall be referred to the Standing Committee on Foodstuffs set up by the Council Decision of 13 November 1969 (hereinafter referred to as 'the Committee') by its chairman, either on his own initiative or at the request of a representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall give its opinion on that draft within a time limit set by the chairman having regard to the urgency of the matter. Opinions shall be delivered by a majority of 41 votes, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) Where the measures envisaged are in accordance with the opinion of the Committee, the Commission shall adopt them.

(b) Where 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 on the measures to be taken. The Council shall act by a qualified majority.

(c) If within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 10

Article 9 shall apply for 18 months from the date on which the matter was first referred to the Committee under Article 9 (1).

Article 11

This Directive shall not apply to products intended for export outside the Community.

Article 12

Within a period of 18 months from notification of this Directive, the Member States shall, where necessary, amend their laws to comply with this Directive and shall forthwith inform the Commission thereof. The laws thus amended shall be applied in such a way as to:

— permit, two years after notification of this Directive, trade in products complying with this Directive, without prejudice to the national provisions which shall apply in the absence of the specific Directives,

— prohibit, three years after notification of this Directive, trade in products which do not comply with this Directive.

Article 13

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1976.

For the Council

The President

A. P. L. M. M. van der STEE

COUNCIL DIRECTIVE

of 21 December 1976

on the approximation of the laws of the Member States relating to taximeters

(77/95/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas in the Member States both the construction and the methods of control of taximeters are subject to mandatory provisions which differ from one Member State to another and consequently hinder trade in such instruments; whereas it is therefore necessary to approximate these provisions;

Whereas Council Directive 71/316/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to common provisions for both measuring instruments and methods of metrological control (3), as amended by the Act of Accession (4), has laid down the EEC pattern approval and EEC initial verification procedures; whereas, in accordance with that Directive, it is necessary to lay down the technical requirements which the fabrication and operation of taximeters must satisfy in order to be freely imported, marketed and used after having undergone the requisite inspections and having been provided with the required marks and signs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive applies to time-distance meters called 'taximeters'.

Such meters are defined in 1.1 of the Annex hereto.

Article 2

Those taximeters which may bear EEC marks and signs are described in the Annex hereto.

They shall be subject to EEC pattern approval and to EEC initial verification under the conditions laid down in 1.2.2 of Annex II to Directive 71/316/EEC and under the conditions laid down in the Annex hereto.

Article 3

No Member State may refuse, prohibit or restrict the placing on the market of taximeters bearing the EEC pattern approval sign and the EEC partial initial verification mark provided for in 3.1.1.2 of Annex II to Directive 71/316/EEC.

It shall be the responsibility of the competent authorities of the Member States to ensure that the operations supplementary to EEC initial verification are carried out as provided for in 7.3 of the Annex hereto, before these instruments are put into service, if these operations are prescribed under national regulations and have not been carried out beforehand.

Article 4

1. Member States shall put into force the laws, regulations and administrative provisions necessary to comply with this Directive within 18 months of its notification, and shall forthwith inform the Commission thereof.

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1976.

For the Council

The President

A. P. L. M. M. van der STEE

(1) OJ No C 7, 12. 1. 1976, p. 38.
(2) OJ No C 35, 16. 2. 1976, p. 12.
(3) OJ No L 202, 6. 9. 1971, p. 1.
(4) OJ No L 73, 27. 3. 1972, p. 14.

ANNEX

1. TERMINOLOGY

1.1. **Time-distance meters, called 'taximeters'**

Time-distance meters, hereinafter called 'taximeters', are instruments which, according to the characteristics of the vehicle in which they are installed and the tariffs for which they have been set, calculate automatically and indicate constantly when in use the amounts to be paid by the users of public vehicles, called taxis, on the basis of the distance covered and, below a certain speed, the time for which the vehicle is occupied, exclusive of various surcharges which may be authorized by local regulations in force in the Member States.

This Annex will be adjusted in line with the provisions of Article 17 of Directive 71/316/EEC to cover taximeters containing an electronic device in the measuring sequence. Until then, electronic taximeters cannot obtain EEC pattern approval.

1.2. **Special terms**

The indication on a taximeter depends — disregarding the tariff position — on a constant 'k' of the instrument and on a characteristic coefficient 'w' of the vehicle in which the instrument is installed. This coefficient 'w' is a function of the effective circumference 'u' of the wheels of the vehicle and of the transmission ratio of the number of revolutions of the wheels to the number of revolutions of the part provided on the vehicle to connect it to the taximeter.

1.2.1. *Constant 'k' of the taximeter*

The constant 'k' of a taximeter is a characteristic quantity that indicates the type and number of signals that the instrument must receive in order to give correctly an indication corresponding to a given distance travelled.

This constant 'k' is expressed:

(a) in revolutions per indicated kilometre (rev/km), or

(b) in pulses per indicated kilometre (pulse/km),

depending on whether the information relating to the distance travelled by the vehicle is fed into the taximeter in the form of a number of revolutions of its main shaft (drive shaft at point of entry to the instrument) or in the form of electrical signals.

1.2.2. *Characteristic coefficient 'w' of the vehicle*

The characteristic coefficient 'w' of a vehicle is a quantity indicating the type and number of signals intended for driving the taximeter, and displayed at the appropriate part provided for this purpose on the vehicle, corresponding to a given distance travelled.

This coefficient 'w' is expressed:

(a) in revolutions per kilometre travelled (rev/km), or

(b) in pulses per kilometre travelled (pulse/km),

depending on whether the information relating to the distance travelled by the vehicle is in the form of the number of revolutions of the part driving the taximeter or in the form of electrical signals.

This coefficient varies in relation to several factors, in particular tyre wear and tyre pressure, the load carried by the vehicle and the conditions in which the journey is made. It must be determined under the standard test conditions for the vehicle (1.2.7).

1.2.3. *Effective circumference 'u' of the wheels*

The effective circumference 'u' of the wheel of the vehicle which drives the taximeter directly or indirectly is the distance travelled by the vehicle during one complete revolution

of this wheel. When two wheels drive the taximeter jointly, the effective circumference is the mean of the effective circumferences of each of the two wheels, expressed in millimetres.

The effective circumference 'u' is correlated with the characteristic coefficient 'w' of the vehicle (1.2.2), and consequently this circumference, if it is necessary to identify it, must also be determined under the conditions described in 1.2.7.

1.2.4. *Adapting device*

The purpose of the adapting device is to adjust the characteristic coefficient 'w' of the vehicle to the constant 'k' of the taximeter.

1.2.5. *Range of permissible errors*

The range of the permissible errors mentioned in Section 5 depends solely on the instrument itself (instrumental errors). The true values (Section 5) used for the determination of errors are calculated from the constant 'k' of the taximeter and the tariffs for which the meter has been set.

The range of persmissible errors determines the maximum deviation between the highest and the lowest of the indications.

1.2.6. *Changeover speed*

The changeover speed is the speed at which the drive of the indicating device of the taximeter changes over from time to distance travelled or vice versa.

It is obtained by dividing the 'time' tariff by the 'distance' tariff.

1.2.7. *Standard test conditions for the vehicle* (for determining its characteristic coefficient)

The 'standard test conditions for the vehicle' are obtained when:

(a) the tyres fitted to the wheel or wheels driving the taximeter are of a type which has the same effective circumference 'u' as that of the wheels which were used to determine characteristic coefficient 'w'.

They must be in good condition and be inflated to the correct pressure;

(b) the load carried by the vehicle is approximately 150 kg. (This corresponds by convention to the weight of two adult persons, including the driver.);

(c) the vehicle is moving under its own power, on flat and level ground, in a straight line, at a speed of 40 ± 5 km/h.

If the tests are carried out under different conditions, e.g. at different weights, different speeds, or at walking speed, using bench tests, etc., the results will be corrected by the conversion coefficients required to convert their value to that which would have been obtained under the 'standard test conditions' specified above.

2. UNITS OF MEASUREMENT

The following units of measurement only are authorized for the indications provided or displayed by taximeters:

— the metre or kilometre, for distance. However, until expiry of the transitional period during which the use of the imperial units of measurement shown in Chapters C and D of the Annex to Council Directive 71/354/EEC of 18 October 1971 relating to units of measurement [1], as last amended by Directive 76/770/EEC [2], is authorized

[1] OJ No L 243, 29. 10. 1971, p. 29.
[2] OJ No L 262, 27. 9. 1976, p. 204.

within the Community, distances may be expressed in yards or miles in the United Kingdom or Ireland if those countries so desire,

— the second, minute, or hour, for time.

The fare must be expressed in the legal monetary units of the country where the vehicle is registered.

3. TECHNICAL CHARACTERISTICS

3.1. Measuring device and calculating device

3.1.1. The taximeter must be constructed in such a way that it calculates and indicates the fare solely on the basis of:

(a) the distance travelled (distance-based drive) when the vehicle is moving at a speed greater than the changeover speed;

(b) the time (time-based drive) when the vehicle is moving at a speed below the changeover speed or has stopped.

3.1.2. The distance-based drive must be effected by the wheels, but reversing the vehicle must not result in a reduction in the fare or distance indicated.

The time-based drive must be effected by a timekeeping movement which can be activated only by operating the control device of the taximeter.

If the mechanical timekeeping movement is hand-wound, it must function for at least eight hours without rewinding, or for two hours if there is a winding system connected with each manual action which precedes the starting of the taximeter.

If the mechanical timekeeping movement is electrically wound, the process must be automatic.

The electrical timekeeping movement must be ready to function at all times.

3.1.3. With distance-based drive for each of the tariffs, the first change of indication must take place after an initial distance, determined according to the tariff regulations in each Member State, has been covered. The subsequent changes on the indicator must correspond to equal distance intervals.

With time-based drive for each of the tariffs, the first change of indication must take place after an initial time lapse determined according to the tariff regulations in each Member State. The subsequent changes on the indicator must correspond to equal time intervals.

Without any change in the drive base, the ratio between the initial distance and the subsequent distance intervals must be the same as that between the initial time and the subsequent time intervals, whichever tariff is used.

3.1.4. The adapting device must be so constructed that access cannot be gained to other parts of the taximeter by opening the housing.

3.1.5. The taximeter must be so designed that any modifications to the calculating device that are necessary to comply with tariff changes imposed by the tariff regulations in each Member State can be easily effected.

When the instrument is equipped to deal with a wider range of tariffs than is currently in force, the taximeters must, in all the supernumerary positions, calculate and indicate a fare based on one of the tariffs authorized by the tariff regulations in each Member State.

3.2. Control device

3.2.1. It must not be possible to set the mechanism of the taximeter in motion until it has been activated by the control device set in one of the following authorized positions:

3.2.2. *'FOR HIRE' position*

In the 'FOR HIRE' position:

(a) there must be no indication of a fare to be paid, or this indication must be equal to zero. This indication may however be equal to the initial charge in those Member States where such indication is in use at the time of adoption of this Directive;

(b) neither the distance-based drive nor the time-based drive must actuate the device indicating the fare to be paid;

(c) the device indicating possible supplements (3.3.7) must be blank or bear the indication 'zero'.

3.2.3. *Other positions*

The control device must be so designed that, starting from the 'FOR HIRE' position, the taximeter can be set successively in the following operating positions:

(a) in the various operating positions at any of the existing tariffs in ascending order of magnitude or in any other order authorized by the tariff regulations in each Member State; in these positions, the time-based drive, the distance-based drive and supplement indicator, if any, must be engaged;

(b) in a 'STOPPED' position showing the final amount to be paid exclusive of any supplement. In this position, the time-based drive must be disengaged and the distance-based drive must be engaged at the tariff authorized by the relevant regulations in each Member State.

3.2.4. *Operation of the control device*

Operation of the control device is subject to the following restrictions:

(a) starting from an operating position at any tariff, it must not be possible to return the taximeter to the 'FOR HIRE' position without passing through the 'STOPPED' position. However, transition from one tariff to another must still be possible;

(b) starting from the 'STOPPED' position, it must not be possible to return the taximeter to the operating position at any tariff without passing through the 'FOR HIRE' position;

(c) the taximeter must be so designed that changing from one tariff to another by passing through the 'FOR HIRE' position is possible only if the conditions specified for this position on the control device (3.2.2) are fully complied with while it passes through this position;

(d) it must be impossible to operate the control device in such a way that the taximeter can assume other positions than those specified above.

3.2.5. *Special provisions*

Independently of the requirements set out above, the succession of different tariffs may also be effected automatically as a function of a given distance travelled or of a time during which the vehicle was occupied, as specified by the tariff regulations in each Member State.

3.3. **Indicating device**

3.3.1. The dial of the taximeter must be so constructed that the indications of interest to the passenger can be easily read either by day or by night.

3.3.2. The fare to be paid, excluding possible supplements, must be evident from simply reading an indication in aligned figures of 10 mm minimum height.

When the instrument has been started from the 'FOR HIRE' position by operation of the control device, a fixed amount corresponding to the initial charge must be shown on the indicating device.

Thereafter, the fare indication must change discontinuously by successive increments of a constant monetary value.

3.3.3. The taximeter must be provided with a device which constantly indicates the engaged operating position on the dial in conformity with the national requirements.

3.3.4. The taximeter must be designed to enable a repeater control device to indicate on the outside of the vehicle the operating position or the tariff in use.

This repeater device must in no case disturb the correct operation of the instrument or enable access to be gained to the mechanism or to the drive of the taximeter.

3.3.5. If the mandatory indications are not presented in the form of luminous figures or letters, the taximeter must have incorporated in it a device to illuminate these indications which does not dazzle but is strong enough to ensure easy reading.

It must be possible to replace the light source of this device without opening the sealed parts of the instrument.

3.3.6. It must be possible to provide the taximeter with totalizers specified or authorized by national regulations, such as recorders indicating:

(a) the total distance travelled by the vehicle;

(b) the total distance travelled when hired;

(c) the total number of 'hirings';

(d) the number of registered incremental fare units.

These recorders must correctly fulfil the function for which they are intended. They must show the information in aligned figures of a minimum apparent height of 4 mm.

3.3.7. It must be possible to provide the taximeter with a supplement indicator conforming to national regulations, which is independent of the fare indicator, and which automatically returns to zero in the 'FOR HIRE' position.

These supplements must be indicated by means of aligned figures of a minimum apparent height of 8 mm and must not exceed the height of the figures showing the fare.

3.4. **Optional supplementary devices**

A taximeter may in addition be fitted with supplementary devices such as:

(a) recording devices of interest to the vehicle owner;

(b) card or tape-printing devices indicating the fares to be paid.

The presence of such devices and their operation must not affect the correct operation of the taximeter itself.

3.5. **Construction**

3.5.1. Taximeters must be strongly and soundly constructed.

Their essential components must be made of materials guaranteeing adequate strength and stability.

3.5.2. The housing of the taximeter itself and that of any adapting device not incorporated in the housing of the taximeter, as well as the sleeves of the transmission members, must be so constructed that the essential components of the mechanism cannot be reached from the outside and are protected against dust and moisture.

Access to the components permitting adjustment without damaging the guarantee seals must be impossible (Section 6.).

4. MARKINGS

4.1. **General markings and identification**

Each taximeter must bear on the dial or on a sealed plate the following markings, easily visible and legible under normal conditions of installation:

(a) the manufacturer's name and address or mark;

(b) the type designation of the instrument, its number and year of manufacture;

(c) the EEC pattern approval sign;

(d) its constant 'k'; (given to a relative accuracy of not less than 0·2 %).

Each taximeter must be provided with spaces for the following:

(a) additional information, if appropriate, relating to the instrument or the vehicle in conformity with the requirements of the national regulations;

(b) apart from the EEC partial initial verification mark, the other marks provided for under national regulations.

4.2. Special markings

4.2.1. The meaning of the values indicated must be displayed clearly, legibly and unambiguously, near the windows of all indicating devices.

4.2.2. The name or symbol of the monetary unit must be displayed next to the indication of the fare for the journey and the indication of the supplements to be paid.

5. RANGE OF PERMISSIBLE ERRORS

For the test bench inspection of a time-distance meter which is ready for installation and has been fitted with its accessories, the (conventional) true value of the quantities measured shall be that resulting from the 'k' value displayed on the instrument and the tariff(s) for which the instrument has been set.

The true value of these quantities must be contained between the highest and the lowest of the permitted indications.

5.1. With distance-based drive, the range of permissible errors for a given distance travelled must not exceed:

(a) for the initial distance (3.1.3): 2 % of the true value; however, for initial distances of less than 1 000 metres, a range of 20 metres is acceptable;

(b) for subsequent distances: 2 % of the true value.

5.2. With time-based drive, the range of permissible errors for a given time must not exceed:

(a) for the initial time (3.1.3): 3 % of the true value; however, for initial times of less than 10 minutes, a range of 18 seconds is acceptable.

(b) for subsequent times: 3 % of the true value.

5.3. National regulations shall specify whether the whole measuring system (taximeter + vehicle) must be adjusted in such a way that the limits of the range of permissible errors are symmetric or asymmetric in relation to the zero error; for distance-based drive this is the error which relates to the actual distance travelled by the vehicle.

6. SEALING

6.1. The following taximeter components must be so constructed that it is possible to seal them with a seal mark:

(a) the housing in which the internal mechanism of the taximeter is enclosed;

(b) the housing of the adapting device;

(c) the protective covers of the mechanical or electrical devices which link the entry point on the taximeter with the corresponding component provided on the vehicle to connect it to the instrument, including the detachable parts of the adapting device;

(d) when the timekeeping mechanisms are electrically wound and the taximeter control device is electrically driven: the electrical cable connections;

(e) any plates for the mandatory markings or for the verification marks;

(f) the electrical cable connections of the repeater device, if fitted, referred to in 3.3.4.

6.2. Any such seals must be so affixed that all access to the protected components and connections is impossible without damaging a seal mark.

6.3. The EEC pattern approval certificate shall specify where the seals are to be placed and, whenever necessary, the nature and form of the sealing devices.

7. EEC INITIAL VERIFICATION

7.1. If complete EEC verification is required, the initial verification of a taximeter shall be carried out in several stages.

7.2. First stage: the taximeter shall receive the EEC partial initial verification mark when:

(a) its pattern has received EEC pattern approval;

(b) the instrument conforms to the approved pattern and bears the markings required by 4.1;

(c) the range of these errors complies with the requirements of 5.1 and 5.2.

7.3. Subsequent stages: these shall be the responsibility of the authorities in the country where the taximeter is to be used.

They include:

— prior to installation on the vehicle:

(a) checking of the adjustment of the instrument in accordance with 5.3;

(b) checking of the tariff adjustment in accordance with national regulations.

— after installation on the vehicle:

checking of the measuring system thus constructed.

COUNCIL DIRECTIVE

of 21 December 1976

on the examination for trichinae (trichinella spiralis) upon importation from third countries of fresh meat derived from domestic swine

(77/96/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries [1], as last amended by Directive 75/379/EEC [2], and in particular Article 21 thereof,

Having regard to the proposal from the Commission,

Whereas in Directive 72/462/EEC the Council provided in Article 21 for the laying down of the method and procedures required for detecting the presence of trichinae in fresh pigmeat;

Whereas the application of Directive 72/462/EEC will not have the desired effects as long as disparities exist between the Member States as to the guarantees required in respect of the detection of trichinae upon importation of fresh meat from third countries; whereas it is therefore necessary to lay down Community arrangements in this field;

Whereas, in order to protect consumer health, it is necessary that fresh pigmeat be systematically subjected to an examination using methods recognized as effective, in order to eliminate meat containing trichinae;

Whereas when the examination is carried out in the exporting third country, it must be carried out in slaughterhouses which comply with certain conditions and which contain, in particular, a screening laboratory provided with suitable equipment;

Whereas in order to be able to distinguish the meat samples examined from those not examined it is necessary to provide for the affixing of a special mark to meat which has been examined with a negative result;

Whereas there should be a procedure establishing close and effective cooperation between the Commission and the Member States for assessing the advisability of permitting establishments in the third countries to carry out this examination or to work on the meat examined; whereas there should also be a procedure for bringing the technical provisions relating in particular to the examination methods, the requirements concerning the screening laboratories and the procedure for marking examined meat into line with technical progress and with experience acquired;

Whereas the Member States should be allowed to admit fresh meat which has not been screened for trichinae in the exporting third country, provided that this meat, undergoes treatment by freezing, which ensures that any trichinae which may be present are rendered harmless, either in the exporting third country, or in the Member State for which the meat is intended; whereas this treatment must nevertheless be carried out according to certain well defined procedures and establishments fulfilling certain conditions,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The definitions used in this Directive are those contained in Directive 72/462/EEC.

Moreover:

(a) 'fresh meat' means fresh meat of domestic swine;

(b) 'examination' refers to the examination to detect the presence of trichinae in fresh meat.

Article 2

1. In order to be admitted to intra-Community trade, fresh meat originating in third countries which contains skeletal muscles (striated muscles) shall be

[1] OJ No L 302, 31. 12. 1972, p. 28.
[2] OJ No L 172, 3. 7. 1975, p. 17.

examined under the supervision and responsibility of an official veterinarian.

2. The examination shall be carried out in accordance with one of the methods provided for in Annex I, on the whole carcase or, failing this, on each half carcase, quarter carcase or piece to be imported into the Community.

3. The examination shall take place in a slaughterhouse approved in the exporting country in accordance with Article 4 of Directive 72/462/EEC and authorized to carry out this examination in accordance with Article 4 of this Directive.

4. The examination shall take place before the health marking provided for in Chapter X of Annex B to Directive 72/462/EEC.

5. If it is not possible to carry out the examination in the exporting country, the Member State for which the fresh meat is intended may authorize its importation provided that the examination is carried out within its territory at the time of the public health inspection provided for in Article 24 (2) of Directive 72/462/EEC, at an inspection post within the meaning of Article 27 (1) (b) of that Directive.

6. (a) If the outcome of the examination is negative, the fresh meat shall be marked immediately after the examination, in accordance with Annex III.

(b) In the case of ink stamping, use shall be made of a colorant within the meaning of Article 17 (3) of Directive 72/462/EEC.

Article 3

1. By way of derogation from Article 2, the Member State for which it is intended may authorize the exemption from examination of fresh meat from certain third countries or parts of such countries, provided it is frozen in accordance with the provisions of Annex IV.

2. This treatment shall be carried out in an establishment situated in the exporting third country, and described in Article 4 (1).

Freezing in the exporting third country must be the subject of certification by the official veterinarian on the health certificate accompanying the meat, as referred to in Article 22 (3) of Directive 72/462/EEC.

3. If the treatment has not been carried out in the exporting third country, it must be carried out at an inspection post as described in Article 2 (5).

Freezing in a Member State must be the subject of certification by the official veterinarian on the certificates accompanying the meat, as referred to in Article 25 of Directive 72/462/EEC.

Article 4

1. The authorization for a slaughterhouse to carry out the examination and of a cutting plant to cut up or bone meat which has undergone such examination, or the authorization for an establishment to carry out the freezing treatment referred to in Article 3, shall be decided on in accordance with the procedure laid down in Article 9. In addition to the requirements of Article 4 of Directive 72/462/EEC, account shall be taken of the guarantees given in respect of compliance with this Directive and, in the case of slaughterhouses, of:

(a) the presence of the rooms and apparatus necessary for carrying out the examination;

(b) the qualifications of the personnel responsible for carrying out the examination.

Authorization shall be granted to a slaughterhouse and cutting plant only where the competent authorities of the third country concerned have officially recognized that the slaughterhouse and cutting plant are in a position to satisfy the conditions laid down in Article 5 and in Annex III; also, in the case of a slaughterhouse, that it has a laboratory which complies with the conditions laid down in Annex II, Chapter I, and which is in a position to satisfy the requirements of the other chapters of Annex II and those of Annex I.

Authorization shall be granted to an establishment to carry out the freezing treatment only if the competent authorities of the third country concerned have officially recognized that the establishment is in a position to satisfy the conditions laid down in Annex IV.

2. On the list(s) referred to in Article 4 (4) of Directive 72/462/EEC, a special indication shall be inserted against the names of the establishments which have been granted an authorization within the meaning of paragraph 1.

Article 5

1. In slaughterhouses which have been granted an authorization in accordance with Article 4, swine the meat of which is intended for the Community must be slaughtered in different rooms or in the absence thereof at different times from swine the meat of which is not intended for the Community, unless the meat of such swine is examined in accordance with the same procedure.

2. The cutting and boning of meat which has undergone an examination with negative results and is intended for the Community must be carried out in cutting plants, in accordance with Article 4.

In these cutting plants, the cutting and boning of such meat must be carried out in different rooms or in the absence thereof, at different times from meat which is not intended for the Community, unless the meat is examined in accordance with the same procedure.

Article 6

The inspections in third countries provided for in Article 5 of Directive 72/462/EEC must also verify whether the present Directive is being applied.

Article 7

The Member States shall draw up and communicate to the Commission the list of the inspection posts referred to in Article 2 (5) at which:

— the examination,

— the freezing referred to in Article 3,

may be carried out.

They shall ensure that these posts have the equipment necessary for carrying out the operations in question.

Article 8

Acting on a proposal from the Commission, the Council shall decide before 1 January 1979 on any additions to be made to the methods laid down in Annex I.

Article 9

1. Where the procedure laid down in this Article is followed, the matter shall without delay be referred by the chairman, either on his own initiative or at the request of a Member State, to the Standing Veterinary Committee (hereinafter referred to as 'the Committee') set up by the Council Decision of 15 October 1968.

2. Within the Committee the votes of the Member States shall be weighted as laid down in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measure to be adopted. The Committee shall deliver its opinion on these measures within a time limit set by the chairman having regard to the urgency of the questions under examination. Opinions shall be delivered by a majority of 41 votes.

4. The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee. Where 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 on the measures to be taken.

The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within three months of the date on which the matter is referred to it, the Commission shall adopt the proposed measures and shall implement them immediately save where the Council has decided against such measures by a simple majority.

Article 10

Article 9 shall apply until 21 June 1981.

Article 11

The Member States shall bring into force on 1 January 1979 at the latest the laws, regulations and administrative provisions needed for compliance with this Directive. They shall forthwith inform the Commission thereof.

Article 12

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1976.

For the Council

The President

A. P. L. M. M. van der STEE

ANNEX I

METHODS OF EXAMINATION FOR TRICHINAE

I. TRICHINOSCOPIC EXAMINATION

(a) **Apparatus**

An incandescent lamp trichinoscope with 50 × and 80 to 100 × magnification.

A pressure glass consisting of two glass plates — one of which is divided into equal fields — small curved scissors, small forceps, a knife for cutting specimens, small numbered containers for storing the specimens separately, a dropping pipette, a glass of acetic acid and a glass of potassium hydroxide solution for brightening any calcifications or softening dried meat.

(b) **Taking of specimens**

In the case of whole carcases, at least one specimen of the size of a hazelnut is to be taken from both diaphragm pillars at the transition of the sinewy part.

If there is only one diaphragm pillar, one specimen the size of two hazelnuts is to be taken. In the absence of both diaphragm pillars, two specimens approximately the size of a hazelnut are to be taken from the rib part or the breastbone part of the diaphragm or, as the case may be, from the lingual muscle or the jaw muscle or from the abdominal muscles.

For pieces of meat, from each piece take three samples of skeletal muscle, containing little fat, if possible the size of a hazelnut, and taken from different points, where possible near to bones or tendons.

(c) **Method**

If both diaphragm pillars are present the trichinae inspector must cut, from each of the above specimens taken from a whole carcase, seven pieces the size of an oat-kernel making 14 in all; if only one diaphragm pillar is present, 14 pieces, from different places and if possible from the transition to the sinewy part; he must then compress them between the glass plates in such a way that normal print can be clearly read through the slide preparation. If the flesh of the specimens to be examined is dry and old, the preparations must be softened in a mixture of one part potassium hydroxide solution to about two parts water for 10 to 20 minutes before pressing.

If, in the case of whole carcases, specimens have to be taken from the rib part or the breastbone part of the diaphragm, the lingual muscle or jaw muscle or the abdominal muscles, then 14 pieces the size of an oat-kernal are to be cut from each specimen, i.e. a total of 28.

From each of the samples taken from pieces of meat, the trichinae inspector must cut four pieces the size of an oat-kernal, making 12 pieces in all.

The trichinoscopic examination must be carried out in such a manner that each preparation is scanned slowly and carefully. If the trichinoscopic examination reveals suspect areas, the nature of which cannot be definitely ascertained even with the most powerful magnification of the trichinoscope, these must be checked by microscope.

The microscopic examination should be carried out in such a manner that each preparation is scanned slowly and carefully at a magnification of 30 to 40 ×.

In the case of an uncertain result, the examination must be continued on a further number of specimens and slide preparations, if necessary with the aid of higher magnifications, until the information required is obtained. The trichinoscopic examination must be carried out for at least three minutes.

The trichinoscopic examination must be carried out for at least six minutes in the case of substitute specimens taken from the rib part or breastbone part of the diaphragm pillars, the lingual muscle or the jaw muscle or the abdominal muscles.

The minimum time fixed for the examination does not include the time necessary for sample-taking and for making the preparations.

As a general rule, the trichinoscopic examiner should not inspect more than 840 pieces a day, though by way of exception he may inspect up to 1 050.

II. THE ARTIFICIAL DIGESTION METHOD

(a) Apparatus and material

— knife for taking samples,

— small numbered containers, with closures, for storing samples, if necessary until repetition of the examinations,

— incubator,

— 2 to 3 litre glass funnel with stand, a connecting hose in rubber, clamps for fastening the connecting hose,

— a plastic sieve (approximately 18 cm in diameter, and approximately 1 mm mesh),

— gauze,

— a small tapering tube with a sealed end,

— a glass block dish,

— a meat mincer,

— a stereo-microscope,

— digestive liquid made up as follows:

10 g of pepsin (1 200 u/g), 5 ml HCl (at least 37 %) made up to a litre with tap water.

(b) Taking of specimens

1. In the case of whole carcases a sample of at least 20 g to be taken from a diaphragm pillar at the transition to the sinewy part. In the absence of diaphragm pillars a specimen of at least 20 g to be taken from the rib part or the breastbone part of the diaphragm or from the lingual muscle or the jaw muscle or the abdominal muscles.

2. For pieces of meat, a sample of at least 20 g of skeletal muscle to be taken, containing little fat and where possible near to bones or tendons.

(c) Method

For the examination of a collective specimen from 10 pigs, a 10 g specimen shall be prepared from each individual 20 g sample. The remaining 10 g shall be kept for additional single-specimen examination should this be necessary.

10 specimens, each weighing 10 g, shall be combined into a collective specimen; it shall be minced in a meat mincer (with 2 mm perforations) and placed loosely in a sieve lined with a layer of gauze. The sieve shall then be placed in a funnel connected by a length of rubber hose to a small tapered tube with a sealed end; the funnel shall be filled from the edge with digestive liquid until the matter for analysis is completely covered. The proportion of matter for analysis to digestive liquid must be approximately 1:20 to 1:30.

After 18 to 20 hours of incubation at 37 to 39 °C, the small tapered tube shall be disconnected and removed. After carefully drawing off the supernatant liquid, the sediment present in the tip of the tube is to be carefully rinsed in a dish. Then to be examined for the presence of trichinae with a stereo-microscope at 20 to 40 × magnification.

In the case of a positive or doubtful result from the examination of a collective specimen, the remaining single specimens to be examined individually after addition of a further 20 g from each pig, or in the case of pieces of meat, the addition of 20 g taken from each piece, according to (b) above.

III. METHOD USING THE ARTIFICIAL DIGESTION OF COLLECTIVE SAMPLES

(a) **Apparatus and reagents**

— knife and tweezers for collecting specimens,

— meat mincer with 2 to 3 mm diameter perforations,

— a 3 ml Erlenmeyer flask with a rubber or cotton-wool plug,

— a conical separation funnel of 2 000 ml capacity,

— an ordinary A-base stand of approximately 28 cm length with an 80 cm stem,

— a ring, diameter approximately 10 to 11 cm which can be fixed to the stand,

— a clamp with a flat vice (23 × 40 mm) which can be attached to the stand by means of a double coupling,

— an Endecott sieve number 80 (mesh fineness 177) with an external diameter of 11 cm fitted with brass or stainless steel mesh,

— a plastic funnel with an internal diameter of not less than 12 cm,

— an ordinary dissection microscope (magnification 40 ×) fitted with its ordinary lamp, or a standard binocular microscope (magnification 40 ×),

— a trichinoscope with horizontal table for the compressor,

— when using the trichinoscope: a larvae counting basin of the same outer shape as the compressor with a volume of approximately 60 to 65 cc. The larvae counting basin may be described as follows:

The shape of the basin consists of a 23 cm long glass plate being of the same thickness as that of a single plate in a common compressor. The width, however, is slightly less, e.g. 4·5 cm in order to provide for the fixation of a glass plate, 2 mm thick, 1·8 cm high, and 17·5 cm long, on both of the long sides of the bottom plate.

The basin is closed at the ends by two glass plates fixed directly onto the bottom plate, and which are 5 cm long, 1 cm high, and 2 mm thick. The height of the basin, measured from inside, will thus be about 1 cm.

The plates are glued together with ordinary glass adhesive. Approximately 2·8 cm of the bottom plate is left free at both ends for protection purposes, and for easy handling of the filled basin.

The volume of the basin is approximately 60 to 65 cc in total,

— when using the microscope a number of 9 cm diameter Petri dishes are needed,

— a speedmarker for marking out in the bottom of the Petri dish the 1 cm square examination areas,

— a number of 10 litre bins to be used when applying formol treatment to the apparatus, and for the remaining digestive juice in the case of positive results,

— concentrated (37 %) hydrochloric acid,

— 30 000 units per gram of 'Merck' powdered pepsin, or pepsin with known strength from another firm,

— one or two trays which can hold 100 samples or approximately 2 g of meat.

(b) **Collection of specimens**

1. In the case of whole carcases a specimen to be taken of approximately 2 g from a pillar of the diaphragm at the transition to the sinewy part. In the absence of diaphragm pillars a specimen of the same size to be taken from the rib part or the breastbone part of the diaphragm, from the lingual muscle or the jaw muscle or the abdominal muscles.

2. For cuts of meat, a sample of approximately 2 g of skeletal muscle to be taken, containing little fat and where possible near to bones or tendons.

(c) **Method**

Approximately 1 g of sample shall be taken from each of the 100 individual samples from the pigs. The pooled sample is put once through the mincer.

The minced meat shall be placed in the 3 litre Erlenmeyer flask together with 7 g of pepsin, approximately 2 litres of tap water heated to about 37 to 40 °C, and 25 ml of concentrated hydrochloric acid. The mixture shall be shaken to dissolve the pepsin.

The pH of the solution will be about 1·5 to 2.

— For digestion the Erlenmeyer flask shall be incubated at 37 °C for approximately four hours. The flask shall be regularly shaken during the time of incubation, e.g. once or twice every hour.

— The digested solution shall be filtered through the sieve into the conical 2 litre separation funnel and left undisturbed on the stand for at least one hour.

— A total volume of approximately 45 cc shall be run out of the funnel and divided between three Petri dishes, the bottoms of which shall be marked out in 1 cm squares, with 15 ml in each dish.

— Each Petri dish shall be minutely examined for larval trichinae under the microscope (around 40 × magnification).

— Where larvae counting basins are employed, the 45 cc shall be distributed between two larvae counting basins and examined under the trichinoscope.

The larvae appear as identifable organisms in the deposit, and often, when the water is lukewarm, rolling and unrolling movements of the 'spiral' may be observed.

If an insufficiently transparent sediment forms, it shall be clarified by rinsing. The final sample of 45 ml is poured into a test tube and allowed to settle for 15 minutes. The supernatant liquid shall then be carefully removed by suction and the sediment placed into suspension in about 45 ml of tap water.

After a further settling period of 15 minutes, the supernatant liquid shall again be carefully removed by suction and the sediment carefully rinsed in about 20 ml of tap water in a Petri dish, and examined.

In the case of a positive or doubtful result from analysis of a collective specimen, the remaining single specimens to be analyzed individually after addition of a further 20 g from each pig, or, in the case of pieces of meat, the addition of 20 g taken from each piece, in accordance with (b) above.

ANNEX II

CHAPTER I

CONDITIONS FOR THE AUTHORIZATION OF TRICHINAE (TRICHINELLA SPIRALIS) LABORATORIES

1. Trichinae laboratories must be situated next to the swine slaughterhouses and, if the establishment does not already possess such facilities to fulfil the other requirements of the Directive on third countries, have at least the following facilities available:

   (a) a lockable room adequately equipped for the preparation of specimens; its walls must be smooth and must be lined with a washable light-coloured covering or paint up to a height of 2 m. A preparation room must be provided for each method of examination used;

   (b) an adequately equipped lockable examination room for trichinoscopy and microscopy;

   (c) equipment providing adequate ventilation and, if necessary, air conditioning equipment which ensures that the room temperature does not exceed + 25 °C;

   (d) adequate natural or artificial lighting which does not alter colours; direct sunlight must be avoided;

(e) in the preparation room, adequate equipment for cleaning and disinfecting hands;

(f) equipment for darkening the examination room;

(g) possibly, refrigerators in which to store meat samples;

(h) a washroom for cleansing and disinfecting examination equipment (e.g. containers for samples, compressors, knives and scissors), with:

— a waterproof floor-covering which is rot-proof and easy to clean and disinfect,

— smooth walls which, up to a height of at least 2 m, are lined by a washable, and light-coloured covering or paint;

(i) changing rooms, wash basins and rest rooms and flush lavatories;

(j) wash basins with hot and cold running water, provided with cleansing and disinfecting materials and disposable towels;

(k) watertight corrosion-resistant containers, with hermetically sealed lids, for collecting the samples after examination, and so designed as to prevent unauthorized removal of the contents;

(l) adequate supplies of hot and cold drinking water;

(m) equipment for removing waste water which fulfils the conditions for the authorization of slaughterhouses;

(n) proper equipment for protection against pests (insects, rodents, etc.).

CHAPTER II

REQUIREMENTS APPLICABLE TO STAFF, PREMISES, EQUIPMENT AND INSTRUMENTS IN TRICHINAE LABORATORIES

2. Absolute cleanliness is required at all times of laboratory staff, premises, equipment and instruments:

(a) staff must wear clean working clothes and wash their hands several times during working hours and after each break;

(b) no animal may enter trichinae laboratories;

(c) equipment and instruments used must be kept clean and in good repair. They must be carefully cleansed and disinfected several times during and at the end of the day's work.

3. Drinking water must be used for all purposes.

4. As regards health, staff taking meat samples for examination must comply with the rules in Annex B, Chapter IV (11) and (12) of Directive 72/462/EEC.

5. The meat samples required for examination must be taken immediately after slaughter and examined without delay in the trichinae laboratory of the slaughterhouse.

These examinations are forbidden away from the slaughterhouse in which the animals were slaughtered.

6. To avoid fatigue and its consequences, inspection staff should be given short breaks during the working day.

CHAPTER III

REQUIREMENTS IN RESPECT OF TRICHINOSCOPES

The construction and design of trichinoscopes must meet the following minimum criteria:

1. Simple operation.

2. High light intensity:
   - accurate results must be obtainable even in a room which is not completely dark,
   - a projector bulb of 100 W (12 V) must be used as the light source.

3. Adequate magnification:
   - normal working magnification: 50 ×,
   - 80 to 100 × magnification for more precise assessment of objects not clearly identifiable under normal working magnification.

4. Resolving power:
   - a clear sharp picture of well-defined colour must be obtainable at each magnification.

5. Switch mechanism:
   - each change of magnification must be accompanied by automatic adjustment of the brightness of the image.

6. Increase of contrast:
   - the condensor must be provided with an iris diaphragm enabling the contrast to be increased for the closer inspection of difficult cases,
   - the iris diaphragm must be easy to operate (e.g. control lever on the platform of the trichinoscope).

7. Easy focusing:
   - rapid focusing by means of an adjusting ring,
   - precise focusing by means of a control lever.

8. Voltage regulation:
   - so that brightness may be adjusted as required.

9. One-way movement of the compressor:
   - an automatic blocking mechanism must ensure that the compressor moves in only one direction, to prevent unintentional displacement.

10. Free view of the projector screen.

11. Projector screen:
   - at least 54 cm in diameter,
   - high reflecting capability,
   - durable,
   - can be dismantled,
   - easy to clean.

ANNEX III

MARKING OF MEAT WHICH HAS BEEN EXAMINED FOR TRICHINAE

1. Marking of the meat must be carried out under the responsibility of the official veterinarian. For this purpose, he shall keep and maintain:

   — the instruments intended for marking which he may hand over to the assistant staff only at the time of marking and for the length of time required for this purpose,

   — the tags mentioned in paragraph 5. These tags shall be given to the assistant staff at the time when they must be used and in the required number.

2. The mark must be round with a diameter of 2·5 cm. The following information must appear on the mark in perfectly legible characters:

   — towards the centre the capital letter 'T' with arms 1 cm long and 0·2 cm wide,

   — under the letter 'T' one of the following sets of initials: CEE, EEG, EWG, EØF or EEC. The letters must be 0·4 cm high.

3. Carcases must be marked in ink or hot-branded on the inside of the thighs, in accordance with paragraph 2.

4. Heads must be marked in ink or hot-branded, with a mark meeting the requirements of paragraph 2.

   With the exception of cuts exempt from health marking by virtue of Annex B, Chapter X (43) of Council Directive 72/462/EEC, those taken in cutting plants from carcases marked in accordance with the rules must, where they bear no stamp, be marked in accordance with paragraph 2 before the health mark is affixed.

   The label provided for in the second subparagraph of the abovementioned paragraph 43 must comply with the conditions of paragraph 6 below.

5. Marking may also be effected by means of a round tag. This tag, to be affixed to each piece or to each carcase must not be reusable, must be made of strong materials and must meet all hygiene requirements. The following information must appear on the stamp seals in perfectly legible characters:

   — towards the centre the capital letter 'T',

   — under the letter 'T' one of the following sets of initials: CEE, EEG, EWG, EØF or EEC. The letters must be 0·2 cm high.

6. The label provided for in Annex B, Chapter X (44) of the Directive mentioned in paragraph 4 above must, in addition to the health mark, bear a clearly legible mark identical to that provided for in paragraph 2.

ANNEX IV

THE FREEZING OF MEAT

1. Meat brought in already frozen must be kept in this condition.

2. The technical equipment and energy supply of the refrigerating room, must be such as to ensure that the temperature referred to under paragraph 6 is reached very rapidly and maintained in all parts of the room and of the meat.

3. Insulated packaging should be removed before freezing, except for meat which has already reached throughout the temperature referred to under paragraph 6 when it is brought into the refrigeration room.

4. Consignments in the refrigeration room must be kept separately and under lock.

5. The date and time when each consignment is brought into the refrigeration room must be recorded.

6. The temperature in the refrigeration room must be at least — 25 °C. It should be measured with calibrated thermo-electric instruments and continuously recorded. It may not be measured directly in the cold air flow. The instruments must be kept under lock. The charts must include the relevant numbers from the meat inspection register on importation and the date and time of the commencement and completion of freezing, and must be retained for one year after compilation.

7. Meat with a diameter or thickness of up to 25 cm must be frozen for at least 240 consecutive hours, and meat with a diameter or thickness of between 25 and 50 cm must be frozen for at least 480 consecutive hours. This freezing process may not be applied to meat which has a larger diameter or is thicker. The freezing time shall be calculated from the point when the temperature referred to in paragraph 6 is reached in the freezing room.

COUNCIL DECISION

of 21 December 1976

on the financing by the Community of certain emergency measures in the field of animal health

(77/97/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas it has been recognized that everything possible must be done to accelerate the harmonization of national provisions relating to animal health and to find suitable means of achieving this end, particularly as regards the Community's financial responsibility;

Whereas such responsibility should at first relate only to the risk of outbreaks of exotic diseases occurring within the territory of the Community and should involve measures to be carried out both within and outside the Community; whereas the outbreak of such diseases in a Member State may constitute a serious danger for the Community as a whole;

Whereas the manner in which responsibility is to be assumed should be defined in each particular case as it arises, under a flexible and rapid Community procedure in which the Commission cooperates closely with the Member States,

HAS ADOPTED THIS DECISION:

Article 1

1. Where an outbreak of cattle plague, exotic foot and mouth disease, contagious pleuro-pneumonia, African swine fever, blue tongue disease or contagious vesiculate stomatitis occurs in the territory of a Member State, such State may receive financial assistance from the Community for the purpose of eradicating the disease, provided that the measures which are applied forthwith include the isolation of the farm in question from the moment when an outbreak is suspected and, as soon as the disease is officially confirmed:

— the slaughter and destruction of animals of susceptible species which are afflicted or infected or suspected of being so,

— the destruction of contaminated feedingstuffs,

— the disinfection of the farm,

— the establishment of buffer zones,

— the application of measures to prevent the spread of infection,

— the fixing of a minimum period during which the farm may not be restocked following slaughter.

The Member State concerned shall forthwith inform the Commission and the other Member States of the measures applied and the results obtained. The Standing Veterinary Committee (hereinafter referred to as 'the Committee') set up by the Council Decision of 15 October 1968 (3) shall meet as soon as possible to examine the situation. The decision to grant Community financial assistance shall be taken in accordance with the procedure laid down in Article 5.

2. If, in the light of the development of the situation in the Community, it should prove advisable to continue the action provided for in the second subparagraph of paragraph 1, a further decision shall be taken in accordance with the same procedure. This decision may be made conditional upon the adaptation of the measures adopted by the Member State pursuant to paragraph 1, or the application of such measures other than those specified above, as may be considered necessary for the achievement of the aim in view.

(1) OJ No C 5, 8. 1. 1975, p. 19.
(2) OJ No C 47, 27. 2. 1975, p. 34.
(3) OJ No L 255, 18. 10. 1968, p. 23.

3. The Community's financial contribution, which may be divided into several instalments, may cover:

— up to 50 % of the expenses incurred by the Member State in compensating owners for the slaughter and destruction of the animals, and the disinfecting of the farm,

— where vaccination has been ordered in accordance with paragraph 2, 100 % of the cost of the vaccine and up to 50 % of the expenses incurred in carrying out vaccination.

The contribution shall be calculated on the basis of documentary evidence submitted by the Member State concerned.

4. The list of diseases set out in paragraph 1 may, for the purposes of this Decision, be altered by the Council on a proposal from the Commission. This list may only extend to diseases which are exotic for the Community.

Article 2

1. If a Member State is directly threatened by an outbreak in the territory of an adjacent third country or Member State of one of the contagious diseases referred to in Article 1 (1), such Member State may, if it considers special measures necessary for its protection, in particular the creation of a buffer zone of vaccinated animals, obtain financial assistance from the Community on condition that the creation of this zone has been approved in accordance with the procedure laid down in Article 5.

2. The Member State concerned shall to this end inform the Commission and the other Member States of its intentions without delay. The Committee shall meet as soon as possible to examine the situation.

The decision to grant Community financial assistance, which may relate only to the cost of purchasing vaccine and of carrying out vaccination, shall be taken in accordance with the procedure laid down in Article 5. The grant of such assistance may be made conditional on the application of such special measures as may be considered necessary for the achievement of the aim in view.

3. The Community's financial contribution, which may be split up into several instalments, may cover up to 100 % of the cost of the vaccine and up to 50 % of the cost of carrying out vaccination.

Article 3

The Community may decide to build up stocks of biological products (vaccines, appropriate virus strains, diagnosis serums) to combat the contagious diseases referred to in Article 1 (1).

Such action and the relevant implementing rules, particularly as regards the choice, production, transport and use of such stocks, shall be determined in accordance with the procedure laid down in Article 5.

Article 4

1. If the outbreak in a third country of a contagious disease as referred to in Article 1 (1) is likely to present a danger to the Community, it may help combat the disease by supplying vaccine or by financing the purchase thereof.

2. Such Community intervention, the implementing rules and the conditions to which it may be made subject shall be determined in accordance with procedure laid down in Article 5.

3. Such financial contribution by the Community may not exceed 25 % of the appropriations shown in the budget in any given year for all the measures provided for in this Decision.

Article 5

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The representative of the Commission shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 41 votes.

The Commission shall adopt the measures and put them immediately into effect where they are in accordance with the opinion of the Committee. Where the measures are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

If, within 15 days of the proposal being submitted to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and put them immediately into effect, unless the Council has decided by a simple majority against the said measures.

Article 6

An amount of 2 500 000 units of account shall be allocated in 1977 for the financing of actions resulting from this Decision. The appropriations required for the implementation of the measures provided for in this Decision shall be fixed each year as part of the budget.

Article 7

Article 5 shall apply until 22 June 1981.

Article 8

The Council shall, in the light of experience gained, examine the amendments to be made to this Decision on the basis of the report to be submitted to it by the Commission before 31 December 1980.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 21 December 1976.

For the Council

The President

A. P. L. M. M. van der STEE

COUNCIL DIRECTIVE

of 21 December 1976

amending Directives 64/432/EEC, 72/461/EEC and 72/462/EEC on health and veterinary problems

(77/98/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

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

Whereas, on the occasion of the enlargement of the Community, Denmark, Ireland and the United Kingdom were authorized, by way of derogation from the existing Community Regulations, to retain to some extent their national rules relating to veterinary matters;

Whereas the special arrangements applying to these three Member States were incorporated into the provisions of Articles 104 and 105 of the Act of Accession (3); whereas similar provisions, which were the logical extension of the original provisions have been introduced in Council Acts subsequently adopted; whereas Article 13 of Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat (4) and Article 33 of Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (5) were adopted to this end, the two aforementioned Directives having been last amended by Directive 75/379/EEC (6);

Whereas Article 106 of the Act of Accession and the other abovementioned provisions laid down that the Commission should submit to the Council, by 1 July 1976 at the latest, a report, and in so far as is necessary appropriate proposals, with a view to finding a solution to the problem of these derogations;

Whereas the solutions adopted must not be such as to compromise the health standard already attained and must ensure, as far as possible, the free movement of animals and meat;

Whereas, as far as fresh beef and veal is concerned, the risk of spreading disease is undeniably less than is involved in trade in live animals; whereas, in addition, the conditions governing trade in meat under existing Directives are such that further special guarantees are unneccessary;

Whereas, as far as live animals are concerned, a system common to all the Member States should gradually be introduced, making a distinction between the various types of animals according to the danger they represent and taking into account the need to expand trade on the basis of existing patterns; whereas appropriate amendments should be made to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (7), as last amended by Directive 75/379/EEC;

Whereas it must be possible for imports into certain Member States from third countries to remain subject to arrangements which are at least as strict as those currently applied in those Member States;

Whereas the Community Regulations relating, in particular, to foot-and-mouth disease and swine fever should make it possible to find a common and complete solution for all these problems;

Whereas it would be justified to make provision for a special transitional period for Ireland and the United

(1) OJ No C 6, 10. 1. 1977, p. 141.
(2) Opinion delivered on 27 October 1976 (not yet published in the Official Journal).
(3) OJ No L 73, 27. 3. 1972, p. 14.
(4) OJ No L 302, 31. 12. 1972, p. 24.
(5) OJ No L 302, 31. 12. 1972, p. 28.
(6) OJ No L 172, 3. 7. 1975, p. 17.
(7) OJ No 121, 29. 7. 1964, p. 1977/64.

Kingdom in respect of Northern Ireland, which would enable the said countries to effect the amendments necessitated by the implementation of Community Regulations;

Whereas it seems appropriate, in the light of experience acquired, to extend the use of a rapid and effective procedure for making technical changes to certain provisions or for establishing rules of implementation,

HAS ADOPTED THIS DIRECTIVE:

Article 1

From 1 January 1977, the text of Article 13 of Directive 72/461/EEC shall be replaced by the following:

'*Article 13*

Until 31 December 1982, Ireland and the United Kingdom in respect of Northern Ireland, shall be authorized to retain for imports of fresh meat, their national rules relating to protection against foot-and-mouth disease while complying with the general provisions of the Treaty.

Until 31 December 1977, Denmark, Ireland and the United Kingdom shall be authorized to retain, for imports of fresh meat, their national rules relating to protection against swine fever, while complying with the general provisions of the Treaty.'

Article 2

The following Article 4a, shall be inserted into Directive 64/432/EEC:

'*Article 4a*

Until 31 December 1982, with regard to imports from other Member States of bovine animals for breeding, store and slaughter, Ireland and the United Kingdom in respect of Northern Ireland shall be authorized to retain their national rules relating to protection against foot-and-mouth disease while complying with the general provisions of the Treaty.

The Council, acting unanimously on a proposal from the Commission to be submitted before 1 July 1977, shall adopt before 1 January 1978 any amendments to be made to Annexes A, B and C to Directive 64/432/EEC or any other measures, including provisions, relating to traditional trade between Ireland and the United Kingdom.'

Article 3

From 1 January 1978, the following Article 4b shall be inserted into Directive 64/432/EEC:

'*Article 4b*

Without prejudice to Article 4a, Member States which have been free of foot-and-mouth disease for more than two years, which do not practice routine vaccination and which, by way of derogation from the requirements of this Directive do not allow in their territory animals vaccinated against the said disease for a period to be determined in accordance with the procedure laid down in Article 12, may, until 31 December 1982 and while complying with general rules of the Treaty, impose the following conditions upon the introduction into their territory of animals for breeding, store and slaughter:

A. when such animals come from a Member State which has been free from foot-and-mouth disease for at least two years:

(1) does not practise vaccination against foot-and-mouth disease and does not allow animals vaccinated against the said disease on its territory, the animals must fulfil the requirements of this Directive, with the exception of the provisions relating to the compulsory vaccination against foot-and-mouth disease;

(2) practises vaccination against foot-and-mouth disease and allows animals vaccinated against the said disease on its territory, the animals shall be subject to the requirements of this Directive, with the exception of the provisions relating to vaccination against foot-and-mouth disease, which shall be replaced by the following guarantees:

— bovine animals must have undergone a foot-and-mouth virus test involving scraping of the larynx and the pharynx (known as "probang test") and have shown a negative result,

— bovine animals and swine must have undergone a serological test for the detection of foot-and-mouth antibodies and have shown a negative result,

— bovine animals and swine must have been kept in isolation for 14 days in the exporting country either at the holding of origin or in a quarantine station and under the supervision of an official veterinarian,

on the understanding that:

(i) no animal on the holding of origin or in the quarantine station (where required) shall have been vaccinated against foot-and-mouth disease for a period of 21 days prior to export and no animal other than those to be exported shall have been brought into the holding and quarantine station during that period;

(ii) when the tests required in application of this Article are carried out on the holding, the animals to be exported must be segregated from other animals until they are exported.

The animals shall also be subject to 21 days of quarantine in the importing country;

B. when such animals come from a Member State which has not been free of foot-and-mouth disease for at least two years:

(1) does not practise vaccination against foot-and-mouth disease and does not allow animals vaccinated against the said disease on its territory, the animals shall be subject to the requirements of this Directive, with the exception of the provisions relating to vaccination against foot-and-mouth disease, which shall be replaced by the following guarantees:

— bovine animals must have undergone a foot-and-mouth virus test involving scraping of the larynx and the pharynx (known as "probang test") and have shown a negative result,

— bovine animals and swine must have undergone a serological test for the detection of foot-and-mouth antibodies and have shown a negative result,

— bovine animals and swine must have been kept in isolation for 14 days in a quarantine station in the exporting country and under the supervision of an official veterinarian,

on the understanding that:

(i) no animal on the holding of origin or in the quarantine station (where required) shall have been vaccinated against foot-and-mouth disease for a period of 30 days prior to export and no animal other than those to be exported shall have been brought into the holding and the quarantine station during that period;

(ii) when the tests required in application of this Article are carried out on the holding, the animals to be exported must be segregated from other animals until they are exported.

The animals shall also be subject to 21 days of quarantine in the country of destination;

(2) practises vaccination against foot-and-mouth disease and allows animals vaccinated against the said disease on its territory, the animals shall be subject to the requirements laid down in B (1) and any additional requirements which may be adopted in accordance with the procedure laid down in Articles 12 or 13.

The procedure under Article 12 shall be used to determine the detailed rules for the application of this Article, in particular to which of the categories mentioned in the first subparagraphs of A or B Member States belong and also the rules for acceding to the said categories.'

Article 4

Subparagraph (b) of Article 7 (1) (A) of Directive 64/432/EEC shall be deleted.

In Article 7 (1) (C) of Directive 64/432/EEC, the date '31 December 1977' shall be replaced by '31 December 1979'.

Article 5

From 1 January 1978, Article 8 (2) of Directive 72/462/EEC shall be completed as follows:

'For breeding and store animals the requirements of this paragraph may vary from one Member State to another in order to take account of the special provisions which Member States enjoy in the framework of intra-Community trade.'

Article 6

From 1 January 1978, the text of Article 33 of Directive 72/462/EEC shall be replaced by the following:

'*Article 33*

When applying Articles 8 and 16, the conditions laid down in accordance with the procedure of Article 29 for imports effected by certain Member States must be at least as strict as those which the same Member States apply in the framework of intra-Community trade.'

Article 7

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive:

(a) not later than 1 January 1977 as regards the provisions of Article 1;

(b) not later than 1 January 1978 as regards all the other provisions.

They shall forthwith inform the Commission thereof.

Article 8

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1976.

For the Council

The President

A. P. L. M. M. van der STEE

COUNCIL DIRECTIVE

of 21 December 1976

on health problems affecting intra-Community trade in meat products

(77/99/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 43 and 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Whereas, since the establishment of the common organization of the markets, meat products may move freely within the Community; whereas, however, intra-Community trade in these products is curbed by the existence of different health requirements in this sector in the various Member States; whereas, in order to remove such disparities, it is necessary to substitute common provisions for these national requirements;

Whereas, in order to guarantee the quality of the products in question from the health point of view, it is necessary to use, in their manufacture, only that fresh meat obtained in accordance with the Community standards laid down in Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (2), as last amended by Directive 75/379/EEC (3), Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (4), as last amended by Directive 75/379/EEC, and also Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries (5), as last amended by Directive 75/379/EEC; whereas meat products must be manufactured, stored and trasnported in conditions offering every guarantee as regards health; whereas the need for manufacturing and processing establishments to obtain approval is likely to facilitate supervision of compliance with these conditions; whereas provision should be made for a procedure intended to settle any disputes which may arise between Member States as to the justification of the approval of a manufacturing establishment;

Whereas, moreover, Community control arrangements should be introduced to ensure that the standards laid down in this Directive are applied uniformly in all Member States; whereas provision should be made for the procedure for such controls to be determined according to a Community procedure within the Standing Veterinary Committee set up by the Council Decision of 15 October 1968 (6);

Whereas provision should be made for the possibility of derogating from certain provisions of this Directive in respect of certain meat products which contain other foodstuffs and which contain a minimal percentage of meat; whereas these derogations should be made according to a Community procedure within the Standing Veterinary Committee;

Whereas, as regards intra-Community trade, the issue of a health certificate drafted by the competent authority is considered to be the best way of assuring the competent authorities of the country of destination that a consignment of meat products complies with this Directive; whereas this certificate must accompany the consignment of these products to the place of destination;

Whereas Member States must have the right to prohibit the introduction into their territory of meat products from another Member State which prove unfit for human consumption or do not comply with Community health provisions;

Whereas, in such cases, the consignor should, at his own request or upon request of his representative, be allowed to have the meat products returned to him unless there are health reasons to the contrary;

(1) OJ No C 114, 11. 11. 1971, p. 40.
(2) OJ No 121, 29. 7. 1964, p. 2012/64.
(3) OJ No L 172, 3. 7. 1975, p. 17.
(4) OJ No L 55, 8. 3. 1971, p. 23.
(5) OJ No L 302, 31. 12. 1972, p. 28.
(6) OJ No L 255, 18. 10. 1968, p. 23.

Whereas, in case of prohibition or restriction, the reasons therefor should be made known to the consignor or his representative and also, in certain cases, to the competent authorities of the exporting country;

Whereas, in the event of a dispute between himself and the authorities of the Member State of destination as to the justification for prohibition or restriction, the consignor should be enabled to obtain the opinion of an expert;

Whereas, in order to facilitate the implementation of the proposed measures, a procedure should be provided for close cooperation betwen the Member States and the Commission in the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down health requirements for meat products intended for intra-Community trade.

Article 2

1. For the purposes of this Directive, the following definitions shall apply:

(a) meat products: products prepared wholly or partly from meat which has undergone treatment to ensure a certain degree of preservation.

However, meat which has only undergone chilling or freezing shall not be regarded as a meat product.

The following are not covered by this Directive:

(i) meat extracts, meat consommé and stock, meat sauces and similar products not containing fragments of meat;

(ii) whole, broken or crushed bones, meat peptones, animal gelatin, meat powder, pork-rind powder, blood plasma, dried blood, dried blood plasma, cellular proteins, bone extracts and similar products;

(iii) fats melted down from animal tissues;

(iv) stomachs, bladders and intestines, cleaned and bleached, salted or dried;

(b) meat: meat as defined in:

— Article 1 of Directive 64/433/EEC,

— Article 1 of Directive 71/118/EEC,

— Article 2 of Directive 72/462/EEC;

(c) fresh meat: fresh meat as defined in Article 1 of Directives 64/433/EEC and 71/118/EEC and Article 2 of Directive 72/462/EEC;

(d) treatment: the treatment of fresh meat, whether or not combined with other foodstuffs, by heating, salting or drying, or a combination or these processes;

(e) complete treatment: treatment the effects of which are sufficient to guarantee the subsequent wholesomeness of the product at normal ambient temperature;

(f) incomplete treatment: treatment which does not meet the requirements laid down for complete treatment in Annex A, Chapter V (27);

(g) heating: use of dry or damp heat;

(h) salting: use of salt (NaCl);

(i) drying: natural or artificial reduction of the water content;

(j) exporting country: the Member State from which meat products are sent to another Member State;

(k) country of destination: the Member State to which meat products are sent from another Member State;

(l) consignment: a quantity of a meat product which is covered by the same health certificate;

(m) wrapping: the protection of meat products by the use of an initial wrapping or initial container in direct contact with the product concerned as well as the initial wrapper or initial container itself;

(n) packaging: the placing of a wrapped or unwrapped meat product or products in a second container, as well as the container itself.

2. Pending the adoption, following submission of a proposal in accordance with Article 9 (2), of provisions regarding meat which is treated by a process other than heating, salting or drying or which has undergone treatment which does not meet the requirements of Annex A, Chapter V (26), such meat shall be subject to the Directives referred to in paragraph 1 (b).

Article 3

1. Each Member State shall ensure that only meat products complying with the following general

conditions are sent from its territory to the territory of another Member State:

(1) they must have been prepared in an establishment approved and inspected in accordance with Article 6;

(2) they must have been prepared, stored and transported in accordance with Annex A;

(3) they must have been prepared from:

(a) fresh meat as defined in Article 2 (1) (c). This fresh meat may originate:

(i) in accordance with Directive 64/433/EEC, in the Member State in which the preparation is carried out or in any other Member State,

(ii) in accordance with Directive 72/462/EEC, in a third country, being imported either directly or by another Member State,

(iii) in accordance with Article 15 of Directive 71/118/EEC, in a third country, in so far as:

— products obtained from this meat fulfil the requirements of this Directive,

— the health marking laid down in Annex A, Chapter VII, is not carried out on these products,

— intra-Community trade in these products remains subject to the national provisions of each Member State;

(b) a meat product, provided that it meets the requirements of this Directive;

(4) they must have been prepared by heating, salting or drying, which processes may be combined with smoking or maturing, possibly under specific microclimatic conditions, and associated, in particular, with certain curing agents within the meaning of Article 12. They may also be associated with other foodstuffs and condiments;

(5) they must have been prepared from fresh meat handled in accordance with Annex A, Chapter III;

(6) they must, in accordance with Annex A, Chapter IV, have undergone an inspection carried out by the competent authority; such inspections may be carried out, in purely routine tasks and in accordance with rules to be defined where necessary under the procedure provided for in Article 18, with the help of aissistants specially trained for the purpose;

(7) they must meet the standards laid down in Annex A, Chapter V;

(8) they must have been wrapped and packaged in accordance with Annex A, Chapter VI, where wrapping and packaging are necessary;

(9) they must bear a health marking in accordance with Annex A, Chapter VII;

(10) they must, in accordance with Annex A, Chapter VIII, be accompanied by a health certificate during transport to the country of destination;

(11) they must be stored and transported to the country of destination under satisfactory health conditions in accordance with Annex A, Chapter IX.

2. Meat products may not have been subjected to ionizing radiation, unless this is justified on medical grounds and unless such procedure is clearly indicated on the product and on the health certificate.

Article 4

1. Meat products which have undergone complete treatment in accordance with Annex A, Chapter V (27), may be stored and transported at normal ambient temperatures.

Products which have been subjected to natural fermentation and maturing for a long period shall be regarded as having undergone complete treatment until the Council, acting, unanimously on a proposal by the Commission, shall have amended the limits given in Annex A, Chapter V (27) (b).

2. For inspection purposes, the producer must ensure that the packaging of meat products which have undergone incomplete treatment bears a clear and legible indication of the temperature at which the products must be transported and stored and the period during which preservation may thus be assured.

3. If necessary, in accordance with the procedure laid down in Article 18, a derogation may be made from paragraph 2 in respect of certain meat products which do not comply with the standards laid down in Annex A, Chapter V (27), subject to certain conditions which shall be verified by the competent authority.

Article 5

Articles 3 and 4 shall not apply to meat products which are imported with the authorization of the

country of destination for uses other than human consumption; in this case, the country of destination shall ensure that these products are used only for the purposes for which they were dispatched to that country.

Article 6

1. Each Member State shall draw up a list of the establishments approved by it and having a veterinary approval number. It shall send this list to the other Member States and to the Commission.

The Commission shall draw up a list of these approved establishments and shall have it published in the *Official Journal of the European Communities*.

Without prejudice to Article 8, a Member State shall not approve an establishment unless compliance with this Directive is assured.

The Member State shall withdraw approval if the conditions for approval are no longer fulfilled.

If a check has been made in accordance with Article 7, the Member State concerned shall take account of the conclusions resulting therefrom.

The other Member States and the Commission shall be informed of the withdrawal of approval.

2. Inspection and supervision of approved establishments shall be carried out under the responsibility of the competent authority which may be assisted in purely technical tasks by personnel specially trained for the purpose.

The detailed rules governing this assistance shall be determined in accordance with the procedure provided for in Article 18.

3. If a Member State considers that the conditions for approval are not or are no longer complied with by an establishment in another Member State, it shall so inform the Commission and the competent central authority of the latter Member State.

4. In the case referred to in paragraph 3, the Commission shall forthwith initiate the procedure laid down in Article 7.

If justified by the conclusions of the inspection report, the Member States may be authorized, in accordance with the procedure laid down in Article 19, to refuse entry to their territory of meat products from the establishment in question.

This authorization may be withdrawn in accordance with the same procedure laid down in Article 19, if such action is justified by the findings of a further expert inspection carried out in accordance with Article 7.

Article 7

Experts of the Member States and of the Commission shall carry out regular inspections of the approved establishments to ensure that the latter in fact apply this Directive, and in particular Annex A, Chapters I and II.

They shall provide the Commission with a report on the results of the inspections carried out.

The Member State in whose territory an inspection is carried out shall give the experts all the necessary help in performing their task.

The experts of the Member States who carry out the inspections shall be designated by the Commission acting upon a proposal from the Member States. They must be nationals of a Member State other than that in which the inspection is carried out and, in the case provided for in Article 6 (3) and (4), other than that of the Member States involved in the dispute.

Inspections shall be carried out on behalf of the Community, which shall bear the cost involved.

The frequency and the detailed rules for these inspections shall be determined in accordance with the procedure laid down in Article 18.

Article 8

1. By way of derogation from the conditions stipulated in Article 3, it may be decided, in accordance with the procedure laid down in Article 18, that some provisions of this Directive shall not apply to certain products which contain other foodstuffs and only a small percentage of meat or meat product.

These exceptions shall relate only to:

(a) the conditions for approval of establishments as laid down in Annex A, Chapter I;

(b) the inspection requirements described in Annex A, Chapters IV and V;

(c) the requirements for a health marking and health certificate as laid down in paragraphs 9 and 10 of Article 3 (1).

When considering whether to allow exception such as those provided for under this Article, both the nature and the composition of the product shall be taken into account.

Notwithstanding the provisions of this Article, the Member States shall ensure that all meat products intended for intra-Community trade are wholesome products prepared from fresh meat or meat products within the meaning of this Directive.

2. The first subparagraph of paragraph 1 shall be implemented for the first time before the date of implementation of this Directive.

Article 9

1. The Council, acting on a proposal from the Commission, shall determine for the first time, before the implementation of this Directive, the provisions applying to fresh meat which has been minced, ground or similarly broken down into small pieces, with the addition of other foodstuffs and condiments.

Pending the entry into force of the provisions thus adopted, this meat shall remain subject to national laws.

2. The Commission shall submit to the Council, before the date of implementation of this Directive, a proposal dealing with the case of products not having undergone treatment and thus not fulfilling the requirements laid down Annex A, Chapter V (26).

Article 10

The methods required in order to check compliance with the standards laid down in Annex A, Chapter V (26) and (27) and the tolerances to be permitted for these standards, shall be established six months before the date of implementation of this Directive in accordance with the procedure laid down in Article 18.

These methods, standards and tolerances may, if necessary, be altered or updated using the same procedure.

Article 11

1. Without prejudice to the powers resulting from Articles 6 and 7, a Member State on whose territory it has been established in the course of a health inspection that:

(a) the meat products imported from another Member State are unfit for human consumption, shall prohibit the marketing of such products within its territory;

(b) Article 3 has not been complied with, may impose such a prohibition.

2. Decisions taken pursuant to paragraph 1 must, at the request of the consignor or his representative, authorize the reconsignment of the meat products, in so far as there are no objections thereto on health grounds. In any event, precautions shall be taken to prevent improper use of these products.

If reconsignment is not possible the products must be destroyed on the territory of the Member State in which the inspection is carried out.

By way of derogation from this provision and at the request of the consignee or his representative, the Member State carrying out the animal health and public health inspections may authorize their entry for use other than for human consumption, to the extent that there is no danger for humans or for animals. These meat products may not leave the territory of that Member State, which must check their destintaion.

These decisions must be communicated to the consignor or his representative together with the reasons for such decisions. These reasoned decisions must, on request, be communicated forthwith in writing, with an indication of the channels of appeal provided for under the current legislation and of their forms and the time limits within which they are open.

3. Where such decisions are based on the establishment of the presence of a contagious disease, deterioration dangerous to human health or a serious infringement of this Directive, they shall also be communicated forthwith, together with the reasons for these decisions, to the competent central authority of the exporting country and to the Commission.

Article 12

Without prejudice to current Community rules on additives authorized for use in foodstuffs, the use of additives in meat products and the detailed rules governing such use shall continue to be subject to national laws until the entry into force of Community provisions on the matter.

Article 13

The Council, acting unanimously on a proposal from the Commission, shall, before 31 December 1978, determine the temperatures to be observed during cutting and initial wrapping as provided for in Annex A, Chapter II (9), and without prejudice to the provisions laid down in Annex A, Chapter III (20).

Article 14

1. The Council, acting on a proposal from the Commission, shall take a unanimous decision on

Community rules relating to the methods of detecting trichinae and also to the cases where such detection is unnecessary.

2. Pending the entry into force of such rules, the Member States' legislation on the detection of trichinae in meat products containing pigmeat shall remain applicable.

3. Pigmeat recognized as trichinous must not be used in the manufacture of meat products intended for intra-Community trade.

Article 15

1. This Directive shall not affect the channels of appeal open under the current legislation in Member States against the decisions of the competent authorities provided for in this Directive.

2. Each Member State shall grant consignors of meat products, the movement of which is prohibited pursuant to Article 11 (1), the right to obtain the opinion of an expert. Each Member State shall ensure that, before the competent authorities take any other measures such as destroying the meat, the experts have an opportunity of determining whether the conditions of Article 11 (1) have been fulfilled.

The expert must be a national of a Member State other than the exporting country or country of destination.

Acting on a proposal from the Member States, the Commission shall draw up a panel list of the experts who may be instructed to formulate such opinions. After consulting the Member States, it shall lay down general rules which are to be applied, in particular as regards the procedure for formulating these opinions.

Article 16

Until the entry into force of Community provisions on problems of animal health affecting intra-Community trade in meat products, national rules shall continue to apply in this field.

Article 17

Pending the implementation of Community provisions concerning imports of meat products from third countries, Member States shall apply to such imports provisions which are at least equivalent to those resulting from this Directive.

Article 18

1. Where the procedure laid down in this Article is to be used, the matter shall be referred without delay to the Standing Veterinary Committee (hereinafter referred to as 'the Committee'), set up by the Council Decision of 15 October 1968, by the chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The Commission representative shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on the measures within a period to be determined by the chairman in keeping with the urgency of the question submitted for examination. Opinions shall be delivered by a majority of 41 votes.

4. The Commission shall adopt the measures and shall implement them immediately, where they are in accordance with the opinion of the Committee. Where they 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 on the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within three months from the date on which the proposal was submitted to it, the Commission shall adopt the proposed measures and apply them immediately save where the Council has decided against them by a simple majority.

Article 19

1. Where the procedure laid down in this Article is to be used, the matter shall be referred without delay to the Committee by the chairman, either on his own initiative or at the request of a Member State.

2. Within the Committee, the votes of the Member States shall be weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. The Commission representative shall submit a draft of the measures to be adopted. The Committee shall deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 41 votes.

4. The Commission shall adopt the measures and shall apply them immediately where they are in

accordance with the opinion of the Committee. Where they 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 on the measures to be adopted. The Council shall adopt the measures by a qualified majority.

If the Council has not adopted any measures within 15 days from the date on which the proposal was submitted to it, the Commission shall adopt the proposed measures and shall apply them immediately save where the Council has decided against them by a simple majority.

Article 20

Acting on a Commission proposal to be submitted before 1 July 1977, the Council shall adopt before 31 December 1977 the provisions determining who shall be empowered to carry out the supervision and inspections provided for in paragraph 6 of Article 3 (1) and of Articles 4 (3) and 6 (2) and in Annex A, Chapters II, IV, V, VII and VIII.

Article 21

Articles 18 and 19 shall be applicable until 21 June 1981.

Article 22

The Member States shall bring into force the laws, regulations and administrative provisions necessary for them to comply with this Directive on 1 July 1979.

However, in the case of those Member States not requiring annual medical check-ups on the date of adoption of this Directive, pursuant to existing veterinary laws, the medical check-up provided for in Annex A, Chapter II (17), shall be obligatory only from 15 February 1980, unless the Council, acting on a proposal by the Commission, decides before 31 December 1979 to postpone that date in the light of the report which the Commission will submit to it.

Article 23

This Directive is addressed to the Member States.

Done at Brussels, 21 December 1976.

For the Council

The President

A. P. L. M. M. van der STEE

ANNEX A

CHAPTER I

CONDITIONS FOR THE APPROVAL OF ESTABLISHMENTS MANUFACTURING MEAT PRODUCTS

1. Establishments must, throughout the period for which the approval is valid, comprise at least:

   (a) suitable rooms large enough for the separate storage:

      (i) under refrigeration:

         — of fresh meat within the meaning of Article 2 (1) (c),

         — of meat other than that referred to in Article 2 (1) (c);

      (ii) at ambient temperature or, where appropriate, under refrigeration:

         — of meat products fulfilling the requirements of the Directive,

         — of other products prepared wholly or partly from meat;

   (b) facilities enabling the veterinary inspection and supervision operations prescribed by the Directive to be carried out efficiently at any time;

(c) in the vicinity of the work rooms, an adequately equipped lockable room for the exclusive use of the competent authority;

(d) suitable rooms sufficiently large for the preparation of meat products;

(e) a lockable room for the storage of certain ingredients such as condiments;

(f) an installation enabling an adequate supply, under pressure, of potable water only; however, an installation supplying non-potable water shall be authorized in exceptional cases for steam production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes.

Non-potable water pipes must be easily distinguishable from those used for potable water and may not pass through rooms where fresh meat or meat products are worked or stored.

However, for five years from the date of implementation of the Directive, exceptional authorization may be given for non-potable water pipes to pass through rooms containing meat and meat products in establishments carrying on their activities before adoption of the Directive, provided that there are no outlets on the sections of the pipes which pass through the aforesaid rooms;

(g) an installation providing an adequate supply of hot potable water under pressure;

(h) a waste water disposal system which meets hygiene requirements;

(i) an adequate number of changing rooms, wash basins, showers and flush lavatories. The latter shall not open directly on to the work rooms. The wash basins must have hot and cold running water or water premixed to a suitable temperature (from a premixing tap), materials for cleaning and disinfecting the hands and disposable hand towels; the wash basins must be near the lavatories and must not have hand-operated taps;

(j) facilities meeting hygiene requirements for:

— handling fresh meat and meat products,

— storing the containers used for these products in such a way that neither the fresh meat or meat product nor the containers come into direct contact with the ground;

(k) proper equipment for protection against pests such as insects and rodents;

(l) a room for final packaging and for dispatch;

(m) special air- and water-tight non-corrodible containers, with lids and fasteners to prevent access by unauthorized persons, for fresh meat, meat products or trimmings thereof not intended for human consumption, or a lockable room for such meat, meat products or trimmings if they are in sufficiently large quantities to necessitate this or if they are not removed or destroyed at the end of each working day;

(n) a room for the storage of cleaning and maintenance tools and products;

(o) a room for cleaning both maintenance and cleaning equipment.

2. Depending on the type of product involved the establishment must have:

(a) a cutting room;

(b) a room:

— for cooking; equipment for heat treatment must be fitted with a recording thermometer or telethermometer,

— for retorting; the retorts must be fitted with a recording thermometer or telethermometer, and a direct-reading control thermometer;

(c) a room for the rendering down of fats;

(d) a room for smoking;

(e) a room for drying and maturing;

(f) a room for desalting, soaking or otherwise treating natural guts;

(g) a curing room, if necessary with air-conditioning facilities enabling a temperature not exceeding + 10 °C to be maintained;

(h) a room, if necessary with air-conditioning facilities, for slicing or cutting and for the wrapping of meat products intended for sale in pre-packed form;

(i) a storeroom for empty cans and a device for conveying such cans hygienically to the work room;

(j) an apparatus enabling cans to be thoroughly cleaned immediately before filling;

(k) an apparatus for washing cans in potable water after they are hermetically sealed and before retorting;

(l) facilities for the incubation of samples of meat products in hermetically sealed containers.

However, provided that the equipment used can have no deleterious effect on the fresh meat and meat products, the same room may be used for the operations to be carried out in the separate rooms referred to in (b), (c), (d) and (e).

3. The rooms referred to in 1 (a) and 2 (b) to (i) must have:

— waterproof flooring which is easy to clean and disinfect, rotproof and laid in such a way as to facilitate the draining of water,

— smooth walls with light-coloured washable coating or paint up to a height of at least 2 m and with rounded angles and corners.

4. The rooms referred to in 1 (d) and 2 (a) must comprise:

— waterproof flooring which is easy to clean and disinfect, rotproof, and laid in such a way as to facilitate the draining of water; the water must be channelled under cover towards drains fitted with traps and gratings,

— smooth walls with light-coloured washable coating or paint up to storage height and at least up to 2 m and with rounded angles and corners.

5. Rooms where work on fresh meat and meat products is undertaken must have at least:

— adequate ventilation and if necessary, good extraction of steam,

— adequate natural or artificial lighting which does not distort colours;

— equipment, which must be as near as possible to the work stations, for cleaning and disinfecting hands and working materials. Taps may not be hand-operable. For washing hands, these facilities must have hot and cold running water or water premixed to a suitable temperature (from a premixing tap), cleaning and disinfecting products and disposable hand towels. For cleaning tools, the temperature of the water must be not less than + 82 °C,

— instruments and working equipment such as cutting tables, tables with detachable cutting surfaces, containers, conveyor belts and saws, of non-corrodible material, not liable to taint meat and easy to clean and disinfect. The use of wood in particular is forbidden.

CHAPTER II

HYGIENE REQUIREMENTS FOR STAFF, ROOMS, EQUIPMENT AND INSTRUMENTS IN ESTABLISHMENTS

6. The highest possible standard of cleanliness shall be required of staff, rooms, equipment and instruments.

   (a) All persons entering rooms in which work on fresh meat and meat products is undertaken must, in particular, wear clean, light-coloured and easy-to-wash working clothes and headgear with, where necessary, a neck shield. Staff engaged in manufacture shall wash and disinfect their hands several times during each working day, each time they resume work, and when their hands have been soiled. Smoking shall be forbidden in work rooms and storerooms.

   (b) No animals shall be allowed inside the establishment. Rodents, insects and any other vermin must be systematically destroyed.

   (c) Equipment and instruments used in manufacture must be carefully cleaned and disinfected several times during each working day, at the end of the day's work and before being used again, if they have been contaminated.

   However, continuous production machines should only be cleaned when work has been finished or in cases where contamination is suspected.

7. Rooms, instruments and working equipment must be used only for the preparation of meat products.

   However, they may be used for the preparation of other foodstuffs either simultaneously or at different times following authorization by the competent authority, provided that all appropriate measures are taken to prevent contamination or adverse changes in the products covered by this Directive.

8. Fresh meat and meat products, their ingredients and containers shall not:

   — come into direct contact with the ground,

   — be deposited or handled under conditions which might contaminate them.

   Care must be taken to ensure that there is no contact between raw materials and finished products.

9. While they are in use, the rooms referred to in 2 (g) and (h) must be kept at a temperature not exceeding + 10 °C.

10. The temperature laid down in 9 may be disregarded if the competent authority agrees and if it considers it permissible to do so in order to fulfil technical conditions of preparation.

11. Cans and similar containers must be thoroughly cleaned immediately before filling by means of the cleaning apparatus referred to in 2 (j).

12. If necessary, cans and similar containers must be washed in potable water, after they are hermetically sealed and before retorting, by means of the apparatus referred to in 2 (k).

13. Products for maintenance and cleaning must be kept in rooms provided for this purpose.

14. The use of detergents, disinfectants and pesticides must not affect the wholesomeness of the fresh meat or meat products.

15. Potable water must be used for all purposes including in the retorts. However, non-potable water may in exceptional cases be used in closed circuit for steam production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes.

16. Persons who may contaminate fresh meat and meat products shall be prohibited from working on or handling them, in particular, persons:

(a) suffering from or suspected of suffering from typhoid fever, paratyphoid A and B, infectious enteritis (salmonellosis), dysentery, infective hepatitis, scarlet fever, or who are carriers of these diseases;

(b) suffering from or suspected of suffering from infectious tuberculosis;

(c) suffering from or suspected of suffering from an infectious skin disease;

(d) exercising at the same time an activity which might cause microbial contamination of the fresh meat or meat products;

(e) wearing a bandage on the hands, other than a waterproof dressing protecting a non-infected wound.

17. A medical certificate shall be required from every person working on fresh meat or meat products. It shall attest that there is no impediment to such employment; it shall be renewed annually and each time the competent authority so requests; it shall be kept at the disposal of the latter.

CHAPTER III

REQUIREMENTS FOR FRESH MEAT TO BE USED FOR THE MANUFACTURE OF MEAT PRODUCTS

18. Fresh meat which comes from a slaughterhouse, cutting establishment, cold store or another processing establishment in the same country as the establishment concerned must be transported to it under satisfactory sanitary conditions in accordance with the provisions of the Council Directives referred to in Article 2 (1) (b) except those on sealing.

19. Meat which does not comply with the conditions of Article 2 (1) (c) may be held in approved establishments only if stored in separate places; it must be used in other places or at other times than meat which does comply with these conditions. The competent authority must at all times have free access to cold stores and to all work rooms in order to verify strict observance of these provisions.

20. As soon as it arrives at the establishment and until it is used, fresh meat intended for the manufacture of meat products must be stored in a room where it is kept at a constant internal temperature of not more than + 7 °C; however, for offal the temperature shall be not more than + 3 °C and for poultrymeat not more than + 4 °C.

CHAPTER IV

SUPERVISION OF PRODUCTION

21. Establishments shall be subject to supervision by a competent authority who must be given due notice before work on meat products intended for intra-Community trade is undertaken.

22. Constant supervision by the competent authority shall include the following:

— inspection of the entry and exit register for fresh meat and meat products,

— sanitary inspection of fresh meat intended for the manufacture of meat products for intra-Community trade and, in the case referred to in paragraph 3 (b) of Article 3 (1), of meat products,

— inspection of meat products on dispatch from the establishment;

— filling in and issuing the health certificate provided for in 34,

— verification of the cleanliness of the premises, facilities and instruments and of staff hygiene as provided for in Chapter II,

— taking of any samples required for laboratory tests,

— any supervision measures considered necessary by the competent authority to ensure compliance with this Directive.

The results of such tests shall be recorded in a register.

23. In the manufacture of meat products in hermetically sealed containers the competent authority must ensure that:

— the producer samples the daily output, at intervals determined in advance, to ensure the efficacy of the sealing,

— the producer uses control markers to check that the containers have in fact undergone suitable heat treatment,

— products in hermetically sealed containers are removed from the heating equipment at a sufficiently high temperature to ensure rapid evaporation of humidity and are not touched by hand until completely dry.

24. The results of the various processing controls and tests carried out by the producer must be kept for presentation on request to the competent authority.

CHAPTER V

CHECK ON THE EFFECTIVENESS OF TREATMENTS

25. The competent authority must check the effectiveness of the treatment of meat products, if necessary by taking samples, to ensure that:

— the products have undergone treatment as defined in Article 2 (1) (d),

— the treatment may be considered as complete within the meaning of Article 2 (1) (e) or incomplete in accordance with Article 2 (1) (f).

26. A product has been treated within the meaning of Article 2 (1) (d) when either the a_w value is less than 0·97 or the cut surface shows that the product no longer has the characteristics of fresh meat.

27. A product has undergone complete treatment:

(a) if it has undergone heat treatment in a hermetically sealed container, when the Fo value exceeds or equals 3·00 or, in Member States in which this value is not customarily applied when the check on the treatment has been carried out by means of a seven-day incubation test at 37 °C or a 10-day test at 35 °C;

(b) if it has undergone a treatment other than that referred to in (a), when:

(i) the a_w value does not exceed 0·95 and the pH does not exceed 5·2,

(ii) or the a_w value does not exceed 0·91,

(iii) or the pH value is less than 4·5.

If the conditions referred to in (a) and (b) are not fulfilled in the treatment, the product shall be regarded as having undergone incomplete treatment.

CHAPTER VI

WRAPPING AND PACKAGING OF MEAT PRODUCTS

28. Wrapping and packaging must take place under satisfactory hygienic conditions in rooms intended for this purpose.

29. Wrapping and packaging must comply with all rules of hygiene, including the following:

— it must not be such as to alter the organoleptic characteristics of the meat products,

— it must not be capable of transmitting to the meat products substances harmful to human health,

— it must be strong enough to protect the meat products adequately.

30. Wrappings may not be re-used for meat products, with the exception of certain special types of earthenware which may be re-used after cleaning and disinfecting.

CHAPTER VII

HEALTH MARKING

31. Meat products must be marked. This marking must be carried out under the responsibility of the competent authority during or immediately after manufacture in an easily visible place. The mark must be legible, indelible and its characters easily distinguishable.

32. However:

(a) where the meat product is individually wrapped and packaged, it shall suffice for the health mark to be put on the packaging;

(b) where the meat products are to be dispatched in a second container the mark must also be put on that second container;

(c) the health marking may also consist of an irremovable disc of resistant material complying fully with hygiene requirements and bearing the information specified in 33 (a).

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

— above:

the initial(s) of the exporting country in capitals, i.e. B — D — DK — F — IRL — I — L — NL — UK, followed by the approval number of the establishment;

— below:

one of the following sets of initials: CEE — EEG — EWG — EEC — EØF.

(b) The health mark may be applied to the product, wrapping or packaging by inking or branding, or it may be printed on or applied to a label. The mark must be destroyed when the package is opened. Non-destruction of this mark may be tolerated only when the package is destroyed on being opened.

CHAPTER VIII

HEALTH CERTIFICATE

34. The original copy of the health certificate which must accompany meat products during their transportation to the country of destination must be issued by the competent authority at the time of loading.

It must correspond in form and content to the model in Annex B. It must be written at least in the language(s) of the country of destination and must be supplemented by the particulars specified. It must be drawn up on a single sheet of paper.

CHAPTER IX

STORAGE AND TRANSPORT

35. Meat products intended for intra-Community trade must be stored in the premises referred to in 1 (a).

36. Meat products for which certain storage temperatures are indicated in accordance with Article 4 must be maintained at these temperatures.

37. Meat products must be dispatched in such a way that they are adequately protected during transportation from anything which may de detrimental to them or contaminate them, taking into account the length of the journey, the means of transport and the weather conditions.

38. Meat products must be transported in vehicles equipped to enable them to be transported when necessary under refrigeration, the temperatures indicated in accordance with Article 4 not being exceeded.

ANNEX B

HEALTH CERTIFICATE FOR MEAT PRODUCTS (1) INTENDED FOR CONSIGNMENT TO A MEMBER STATE OF THE EEC

No (2) .....

Exporting country: .....

Ministry: .....

Department concerned: .....

Ref. (2): .....

I. Identification of meat products

Products manufactured with meat from: .....
(Animal species)

Nature of products (3): .....

Nature of packaging: .....

Number of individual items or of packages: .....

Storage and transport temperature (4): .....

Storage life (4): .....

Net weight: .....

II. Meat products from

Address(es) and veterinary approval number(s) of approved processing establishment(s): ...

.....

.....

III. Destination of meat products

The meat products will be sent from: .....
(Place of loading)

to: .....
(Country of destination)

by the following means of transport (5): .....

Name and address of consignor: .....

.....

Name and address of consignee: .....

.....

IV. **Health attestation**

I, the undersigned, certify that:

(a) the meat products described above were manufactured from fresh meat or meat products under conditions that comply with the standards laid down in Directive 77/99/EEC (6):

(b) the said meat products, their wrappings or packaging, bear a mark proving that they have all come from approved establishments (6):

(c) the fresh pigmeat used in the manufacture of the meat products has/has not been (6) subjected to a trichinae detection test;

(d) the transport vehicles and equipment and the loading conditions of this consignment comply with the hygiene requirements laid down in Directive 77/99/EEC.

Done at ..... on .....

(Signature)

Stamp

(Name in capital letters)

---

(1) Under Article 2 of Directive 77/99/EEC.
(2) Optional.
(3) Possible indication of ionizing radiation for medical reasons.
(4) Where an indication is given in accordance with Article 4 of Directive 77/99/EEC.
(5) Indicate the registration number (railway, wagons and trucks); the flight number (aircraft) or the name (ship).
(6) Delete as appropriate.