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II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 10 December 1990

laying down the principles governing the organization of veterinary checks on products entering the Community from third countries

(90/675/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 ⁽¹⁾,

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

Having regard to the opinion of the Economic and Social Committee.

Whereas the animal products or products of animal origin and plant products subject to checks intended to prevent the spread of contagious or infectious animal diseases are listed in Annex II to the Treaty;

Whereas laying down principles at Community level on the organization of veterinary checks on products coming from third countries helps to safeguard supplies and ensure market stability while also harmonizing the measures necessary to ensure the protection of animal and public health;

Whereas Article 19 of Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽³⁾ and Article 23 of Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the

completion of the internal market ⁽⁴⁾ provide, in particular, that the Council must lay down, before 31 December 1990, the general principles applicable to checks on imports from third countries of products covered by the said Directives;

Whereas each consignment of products from third countries must be subjected to documentary and identity checks upon entry to the Community;

Whereas principles valid throughout the Community should be fixed concerning the organization and follow-up of physical checks to be carried out by the competent veterinary authorities;

Whereas provision must be made for safeguard arrangements; whereas, in this context, the Commission must be able to act, particularly by visiting the places concerned and adopting measures appropriate to the circumstances;

Whereas, if the checking system is to function smoothly there must be an approval procedure and border inspection posts must be inspected and there should be exchanges of officials empowered to carry out checks on products coming from third countries;

Whereas the laying down of common principles at Community level is all the more necessary given that with the completion of the internal market in prospect, internal border controls are to be abolished;

Whereas the provision of certain transitional measures of limited duration appears to be necessary in order to facilitate the move over to the new checking arrangements instituted by this Directive;

⁽¹⁾ OJ No C 252, 6. 10. 1990, p. 10.

⁽²⁾ Opinion delivered on 23 November 1990 (not yet published in the Official Journal).

⁽³⁾ OJ No L 395, 30. 12. 1989, p. 13.

⁽⁴⁾ OJ No L 224, 18. 8. 1990, p. 29.

Whereas the task of adopting measures for the application of this Directive should be entrusted to the Commission,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Veterinary checks in respect of products from third countries entering the Community shall be carried out by the Member States in accordance with this Directive.

2. This Directive shall be without prejudice to the continued application of national veterinary requirements in respect of products, trade in which has not been the subject of Community harmonization or to the requirements resulting from Community rules where such requirements have not yet been completely harmonized at Community level.

Article 2

1. For the purposes of this Directive, the definitions contained in Article 2 of Directive 89/662/EEC and in Directive 90/425/EEC shall apply as necessary.

2. In addition:

- (a) 'products' means the animal products or products of animal origin referred to in Directives 89/662/EEC and 90/425/EEC, or, in the circumstances described in Article 18:
 - fresh fish landed immediately from fishing vessels,
 - certain plant products,
 - by-products of animal origin not covered by Annex II to the Treaty;
- (b) 'documentary check' means verification of the veterinary certificates or documents accompanying a product;
- (c) 'identity check' means verification, by visual inspection only, for consistency between the documents or certificates and the products and for the presence of the stamps and marks which must appear on the products in accordance with Community rules or in the case of products trade in which has not been harmonized at Community level, in accordance with the national legislation relevant to the various cases provided for by this Directive;
- (d) 'physical check' means a check of the product itself, possibly including sampling and laboratory testing;
- (e) 'importer' means any national or legal person who presents products for importation into the Community;
- (f) 'consignment' means a quantity of products of the same type, covered by the same veterinary certificate or document, conveyed by the same means of transport and coming from the same third country or part of such country;

- (g) 'border inspection post' means any inspection post located in the vicinity of the external border of one of the territories referred to in Annex I, designated and approved in accordance with Article 9;
- (h) 'competent authority' means the central authority of a Member State, empowered to carry out veterinary or zootechnical checks, or any authority to which it has delegated such powers.

CHAPTER I

ORGANIZATION AND EFFECTS OF CHECKS

Article 3

The Member States shall ensure that the customs authorities do not authorize entry for home use into one of the territories referred to in Annex I unless — without prejudice to the special provisions to be adopted in accordance with Article 17 — proof has been supplied that:

- (i) in the form of the certificate for which Article 10 (1) provides, that the veterinary checks have been carried out on the products in question in accordance with Articles 4, 5, 6 and 8 to the satisfaction of the competent authority;
- (ii) that the veterinary checks have been paid for, and that where relevant a deposit covering any costs provided for in Article 16 (3) has been lodged. If necessary, detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 24.

Article 4

1. Each consignment of products from a third country shall be subjected to a documentary and identity check, irrespective of the customs destination of the products, in order to verify:

- their origin,
- their subsequent destination, particularly in the case of non-harmonized products,
- that the particulars they contain afford the guarantees required by Community rules or, where products are concerned for which trade has not been harmonized at Community level, the guarantees required under national rules referred to in the various cases covered by this Directive.

2. These documentary and identity checks shall be carried out:

- (i) on entry into one of the territories referred to in Annex I at one of the border inspection posts or at any other

border crossing point a list of which — and regular updates — are to be notified by the Member States to the Commission, which shall arrange for their publication in the *Official Journal of the European Communities*;

- (ii) by the veterinary staff of the border inspection post or — in the case of passage through a crossing point referred to in (i), by the competent authority.

Where the products undergo the documentary and identity checks at such a crossing point, they must be dispatched without delay under customs supervision to the nearest border inspection post to undergo the checks provided for in Article 8.

3. Entry into one of the territories defined in Annex I shall be prohibited where these checks show that:

- (a) these products come from a territory or part of a territory of a third country which does not meet the following conditions:

- (i) in the case of products rules governing the import of which have been harmonized:

- they shall be entered on a list drawn up in accordance with Community rules, and Directive 72/462/EEC ⁽¹⁾ in particular, as last amended by Directive 90/425/EEC,
- imports are not prohibited pursuant to a Community decision;

- (ii) in the absence of harmonized rules, in particular rules on animal health, they do not comply with the requirements provided for in the national rules applicable to the various cases covered by this Directive;

- (b) the veterinary certificate or document accompanying the products does not meet the conditions set pursuant to Community rules or, where rules have not been harmonized, the requirements provided for in the national rules applicable to the various cases covered by this Directive.

4. The Member States shall ensure that importers are obliged to give prior notice to the veterinary staff of the border inspection post where the products are to be submitted specifying the amount, nature and estimated time of arrival of the products.

5. Where:

- products are intended for a Member State or an area having specific requirements,
- samples have been taken but the results are not known when the means of transport leaves the border inspection post,

- imports authorized for specific cases,

are involved, information from the competent authority of the place of destination must be given:

- for products covered by Directive 90/425/EEC by means of the computerized system provided for in Article 20 of the said Directive,
- for the other products, in accordance with Article 7(1) of Directive 89/662/EEC.

6. The detailed rules for applying paragraphs 1 to 5 shall be adopted in accordance with the procedure laid down in Article 24.

7. All expenditure incurred by the application of this Article shall be chargeable to the consignor, the consignee or their agent, without reimbursement by the Member State.

Article 5

1. For the purpose of admission to a free zone or free warehouse, as defined in Article 1 (4) (a) and (b) of Regulation (EEC) No 2504/88 ⁽²⁾ the competent authority shall ensure that products undergo a documentary check and verification by simple visual inspection that the documents or certificates tally with the products and, if necessary, where there are grounds for suspicion, an identity check and a physical check. Products leaving a free zone or free warehouse to be entered for home use in one of the territories referred to in Annex I will have to undergo the checks provided for in this Directive.

2. The detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 24.

Article 6

1. At the time of admission to the warehouse, the competent authority shall carry out an identity check on products to be stored under the 'customs warehousing procedure' as defined in Regulation (EEC) No 2503/88 ⁽³⁾ or the 'temporary storage of goods procedure' as defined in Regulation (EEC) No 4151/88 ⁽⁴⁾ in a warehouse designated by the competent authority on the basis of guidelines to be determined under the procedure laid down in Article 24.

In addition, the competent authority shall perform the appropriate veterinary checks at the warehouse in accordance with paragraph 5.

2. The Member States shall draw up a list of the warehouses referred to in paragraph 1, specifying the type of veterinary check made on entry and exit of the products

⁽²⁾ OJ No L 225, 15. 8. 1988, p. 8.

⁽³⁾ OJ No L 225, 15. 8. 1988, p. 1.

⁽⁴⁾ OJ No L 367, 31. 12. 1988, p. 1.

⁽¹⁾ OJ No L 302, 31. 12. 1972, p. 28.

referred to in Article 2. They shall forward the list, and any subsequent updates to the Commission.

The Commission shall publish the list of these warehouses and any subsequent updates in the *Official Journal of the European Communities*.

3. Products stored in a warehouse designated by a Member State which are to enter free circulation in the territories referred to in Annex I must be kept under customs supervision and before entering free circulation they must undergo the checks provided for in Article 8, or in the case of products trade in which has not been harmonized at Community level to the checks set out in Article 11.

Where a consignment is split, the products leaving the warehouse must be accompanied:

- by the certificate provided for in Article 10 (1), second indent drawn up by an official veterinarian on the basis of the certificates accompanying the consignments of products during storage and must specify the origin of the products,
- in accordance with Article 11 (4) (b) second indent by the copy of the original certificates.

4. The cost of the veterinary checks provided for in this Article shall be borne by the operator seeking customs warehousing or temporary storage.

These costs, including a deposit to cover the costs incurred as a result of any recourse to the possibilities provided for in Article 16 (3), must be paid before the products enter the warehouse.

5. Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 24.

Article 7

1. Without prejudice to measures adopted pursuant to Article 19, Member States need not apply the requirements of Article 4 (3) to products which do not satisfy either the requirements of Community rules or, in the case of products trade in which has not been the subject of Community harmonization, the relevant national rules and which are intended to be stored in a free zone provided that:

- there is a correspondence between the products or consignments and the accompanying documents,
- the products in question are subsequently forwarded to a third country under the conditions laid down in Article 12,

- the products in question are stored in such a way as to be clearly separated from products intended to be admitted for home use to the territories referred to in Annex I.

2. Any detailed rules for implementing this Article shall be adopted in accordance with the procedure laid down in Article 24.

Article 8

Products for which the veterinary requirements governing trade have been harmonized at Community level and which have been presented at one of the points of entry to the territory defined in Annex I must meet the following requirements:

1. If

- (a) the point of entry is a border inspection post, the products must undergo without delay the checks provided for in Article 4 (1) and in point 2 below:
- (b) the point of entry is a crossing point of the kind referred to in Article 4 (2), or if the products come from a warehouse in accordance with Article 6 (3), they must be transferred without delay under customs supervision to the nearest border inspection post where the official veterinarian must:
 - ensure that the checks provided for in Article 4 (1) have been satisfactorily performed,
 - carry out the checks provided for in point 2.

2. The official veterinarian must:

- (a) carry out a physical check on each consignment, on the basis of a representative sample of the consignment in order to ensure that the products are still in a fit state to be used for the purpose specified in the accompanying certificate or document;
- (b) perform the laboratory tests which have to be carried out on-the-spot;
- (c) take official samples to be examined for residues or pathogens and have them analysed as soon as possible.

The official veterinarian may be assisted in certain of these tasks by qualified staff with special training, working under his direction.

3. The detailed rules for carrying out the checks provided for in points 1 and 2 shall be laid down by the Commission under the procedure provided for in Article 24.

At the request of a Member State, accompanied by the requisite substantiating information, or acting on its own initiative, the Commission may follow the same procedure and determine that checks are to be less frequent, under certain conditions and in the light in particular of the results of previous checks, with respect to certain third countries or third country establishments offering satisfactory guarantees as regards checks at the point of origin.

The Commission will take into account the following criteria for granting derogations of this nature:

- (a) the guarantees offered by the third country in question with respect to compliance with Community requirements, particularly those laid down in Directives 72/462/EEC and 90/426/EEC ⁽¹⁾;
 - (b) the health situation of animals in the third country concerned;
 - (c) information on the general health situation in the country;
 - (d) nature of the measures to monitor and to combat disease applied by the third country;
 - (e) structures and powers of the veterinary service;
 - (f) compliance with the minimum standards laid down by Community law in regard to production hygiene;
 - (g) rules on the authorization of certain substances and compliance with the requirements set out in Article 7 of Directive 86/469/EEC ⁽²⁾;
 - (h) outcome of the Community inspection visits;
 - (i) outcome of the import controls carried out.
4. However, by way of derogation from point 2, for products entering a port or airport in one of the territories referred to in Annex I, the checks may be carried out in the port or airport of destination, provided that such port or airport has a border inspection post of the kind referred to in Article 2 and the products are transported by sea or air as the case may be.

Article 9

1. The border inspection posts must satisfy the requirements of this Article.

2. Border inspection posts must be:

- (i) located in the vicinity of the point of entry into one of the territories referred to in Annex I;
- (ii) designated and approved in accordance with paragraph 3;
- (iii) placed under the authority of an official veterinarian, who shall be effectively responsible for the checks. The official veterinarian may be assisted by specially trained auxiliary staff.

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 42.

⁽²⁾ OJ No L 275, 26. 9. 1986, p. 36.

3. Before 31 March 1991, and once border posts have been shortlisted by national authorities, acting in conjunction with the Commission departments which will verify their compliance with the minimum requirements set out in Annex II, the Member States shall submit to the Commission the list of border inspection posts that will carry out veterinary checks on products and provide the following information:

- (a) nature of the border inspection post:
 - port,
 - airport,
 - road checkpoint,
 - rail checkpoint;
- (b) nature of the products which could be checked at the border inspection post in question given the equipment and veterinary staff available, possibly mentioning any products that cannot be checked at those border inspection posts;
- (c) staff allocated to veterinary checks:
 - number of official veterinarians with at least one official veterinarian on duty at all times that the border inspection post is open,
 - number of specially qualified auxiliary staff or assistants;
- (d) description of the equipment and premises available given the various checks to be carried out for the following operations:
 - documentary check,
 - physical check,
 - sampling,
 - laboratory for carrying out on the spot the general tests laid down in Article 8 (2) (b),
 - laboratory available for specific tests ordered by the official veterinarian;
- (e) capacity of the available premises and cold stores for storing the products pending the test results;
- (f) nature of the equipment allowing a rapid exchange of information, particularly with other border inspection posts;
- (g) procedure for handling disputes with third countries;
- (h) volume of trade (types and quantities of products passing through this border inspection post).

4. Acting in conjunction with the competent national authorities, the Commission shall inspect the border inspection posts designated in accordance with paragraph 3 with a view to ensuring that there is uniform application of the rules on veterinary checks and that the various border inspection posts in fact possess the necessary infrastructures and meet the minimum requirements laid down in Annex II.

No later than 31 December 1991, the Commission shall submit to the Standing Veterinary Committee a report on the outcome of this inspection together with proposals taking into account the conclusions of the report with a view to establishing a Community list of border inspection posts approved in accordance with the procedure laid down in Article 24.

This report shall cover any problems encountered by certain Member States if the shortlisting referred to in the first subparagraph of paragraph 3 were to result in a large number of border inspection posts being excluded at 1 January 1992.

In accordance with the procedure laid down in Article 23, a period of up to three years may be granted to enable the border inspection posts of the Member States referred to in the previous subparagraph to comply with the requirements of this Directive and in particular those concerning equipment and infrastructure.

The Commission shall publish the list of border inspection posts, and any subsequent updates, in the *Official Journal of the European Communities*.

5. The Commission shall adopt any detailed rules required for implementing this Article in accordance with the procedure laid down in Article 24.

Article 10

1. Where products, trade in which has been harmonized at Community level, are not to be entered for home use in the territory of the Member State which carried out the checks referred to in Article 8, point 2, the official veterinarian responsible for the border inspection post shall:

- provide the person concerned with a copy or, if the consignment of goods is split, several authenticated copies of the original certificates relating to the goods; the period of the certificates' validity will be set in accordance with the procedure laid down in Article 24 and will depend on the nature of the product concerned,
- issue a certificate which matches the model to be devised by the Commission in accordance with the procedure laid down in Article 24 attesting that the checks referred to in Article 8, point 2, have been carried out to the satisfaction of the official veterinarian, and specifying the nature of the samples that have been taken and the results of any laboratory tests,
- keep the original certificate or certificates accompanying the goods.

2. Detailed rules for the application of paragraph 1 particularly those concerning products imported for specific purposes shall be adopted in accordance with the procedure laid down in Article 24.

3. Trade in the products referred to in Directive 89/662/EEC and allowed into the territories referred to in Annex I of this Directive shall be conducted in accordance with the rules laid down in the said Directive, in particular in Chapter II thereof.

Article 11

1. This Article shall apply in respect of the products referred to in Article 2, where the rules governing trade in which have not yet been harmonized at Community level, and which, after entering one of the territories referred to in Annex I are to be re-dispatched to another Member State which authorizes the entry of such products into its territory.

2. Each consignment of products must undergo the checks provided for in Article 4 (1) and:

- (a) must either undergo the veterinary checks laid down in Article 8 at the border inspection post situated in the territory of the Member State where the products are introduced, to verify in particular whether the products concerned comply with the rules of the Member State of destination;
- (b) or, where a prior bilateral agreement has been reached between the Member State in the territory of which the point of entry to one of the territories referred to in Annex I is located and the Member State of destination, possibly together with the Member State or States of transit, on the arrangements for carrying out the checks, must be sent under customs supervision to the place of destination where veterinary checks must be carried out.

Member States shall inform the Commission and the other Member States meeting the Standing Veterinary Committee of the system adopted pursuant to this paragraph.

3. In the case referred to in paragraph 2 (a), Article 10 shall apply.

4. In the cases referred to in paragraph 2 (b):

- (a) the documentary and identity checks and the physical check must be carried out at a border inspection post situated in the territory of the Member State of destination;
- (b) the competent authorities carrying out the documentary check and the identity check must:
 - give the official veterinarian at the inspection post of the place of destination notice of the passage of the products, and of their probable date of arrival, in the context of the programme for developing the computerization of veterinary procedures in respect of imports (Shift project),
 - specify the fact of passage on the copy or, if the consignment of products is split, copies of the original certificates,
 - keep the original certificate or certificates relating to the products.

Where special conditions so warrant and where a Member State so requests, with due substantiation, the physical check may be carried out in a place other than one referred to in point (a).

Such a place shall be determined in accordance with the procedure laid down in Article 24.

5. In the cases provided for in paragraph 4, the products shall be transported under the Community transit system (external procedure) as defined in Regulation (EEC) No 2726/90 ⁽¹⁾ in vehicles or containers sealed by the competent authority.

Trade in the products admitted after being checked in accordance with this Article shall be subject to the rules laid down in Directive 89/662/EEC.

6. If the physical check referred to in this Article shows that the product cannot be entered for home use, Article 16 shall apply.

7. Any detailed rules necessary for the application of this Article shall be adopted in accordance with the procedure laid down in Article 24.

Article 12

1. The Member States shall authorize the transport of products from one third country to another third country provided that:

- (a) the party concerned supplies proof that the first third country to which products are being sent, after transit through one of the territories referred to in Annex I, undertakes under no circumstances to reject or to send back products the importation or transit of which it has authorized;
- (b) such transport has been previously authorized by the official veterinarian of the border inspection post of the Member State in the territory of which the checks provided for in Article 4 (1) are carried out;
- (c) in the case of passage through one of the territories referred to in Annex I such transport is carried out, without the goods being unloaded, under the supervision of the competent authorities in vehicles or containers sealed by the competent authorities; the only handling authorized during transport shall be that carried out at the point of entry into or exit from one of the territories referred to in Annex I.

2. All expenditure incurred pursuant to this Article shall be chargeable to the consignor, the consignee or their representative without compensation by the Member State.

3. Detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 24.

Article 13

1. The competent veterinary service shall carry out an identity check and, where appropriate and without prejudice to Article 15, a physical check on products for which the customs destination is other than as provided for in Articles 5, 6, 10, 11 and 12.

⁽¹⁾ OJ No L 262, 26. 9. 1990, p. 1.

2. Detailed rules for the application of this Article shall be adopted, where necessary, in accordance with the procedure laid down in Article 24.

Article 14

1. Apart from Article 15, this Chapter shall not apply to products which:

- (i) form part of travellers' personal luggage and are intended for their personal consumption insofar as the quantity does not exceed a quantity to be defined in accordance with paragraph 3 and provided that the products come from a third country or part of a third country appearing on the list adopted in accordance with Community rules and from which importation is not prohibited;
- (ii) are sent as small packages to private persons, provided that the products are not being imported by way of trade, insofar as the quantity sent does not exceed a quantity to be defined in accordance with paragraph 3 and provided that the products come from a third country or part of a third country appearing on a list drawn up in accordance with Community rules and from which importation is not prohibited;
- (iii) are intended for consumption by the crew and passengers on board means of transport operating internationally, provided that they come from a third country or part of a third country or from an establishment imports from which are not prohibited under Community rules.

Where such products or their kitchen waste are unloaded, they must be destroyed. It is not, however, necessary to destroy products when they are transferred, directly or after being placed provisionally under customs supervision, from one means of transport to another;

- (iv) where quantities not exceeding a figure to be fixed in accordance with paragraph 3 are involved, have undergone heat treatment in a hermetically sealed container to a Fo value of 3,00 or more and:
 - (a) form part of travellers' personal luggage and are intended for their personal consumption;
 - (b) are sent as small packages to private persons, provided that the products are not being imported by way of trade.

2. Paragraph 1 shall not affect the rules applicable to fresh meat and meat products in accordance with Article 1 (2) of Directive 72/462/EEC.

3. In accordance with the procedure laid down in Article 24, the Commission shall set the weight limits for the different products liable to be covered by the derogations referred to in paragraph 1.

Article 15

Without prejudice to the provisions of this Chapter, the official veterinarian or the competent authority shall, where it is suspected that veterinary legislation has not been complied with or there is doubt as to the identity of a product, carry out any veterinary checks it deems appropriate.

Article 16

1. Where the checks referred to in this Directive show the competent authority that the product does not satisfy the requirements laid down in the Community rules or national rules in matters which have not yet been harmonized at Community level, or where such checks reveal an irregularity, the competent authority, in consultation with the importer or his representative, shall decide either:

- (a) to re-dispatch, within a time limit to be set by the competent national authority, the consignment outside the territories referred in Annex I where veterinary inspection and health requirements so allow.

In this case, the official veterinarian of the border post must:

- inform the other border inspection posts, in accordance with paragraph 5 that the consignment has been rejected, indicating the infringements observed;
- under arrangements to be defined by the Commission in accordance with the procedure provided for in Article 24, cancel the veterinary certificate or document accompanying the rejected consignments;
- at intervals to be determined by the Commission, supply information via the competent central authority, as to the nature and frequency of the infringements observed;

- (b) to destroy the consignment in the territory of the Member State where the checks were carried out if re-dispatch is impossible.

2. Without prejudice to the options provided in Article 24 (5) third subparagraph of Directive 72/462/EEC and in Article 8 (1) (b) first indent of Directive 90/425/EEC, derogations from paragraph 1 of this Article may be made in accordance with the procedure laid down in Article 24, in particular to permit the use of products for purposes other than human consumption. In the context of such derogations and in accordance with the same procedure, conditions shall be adopted with regard to the use of the products concerned.

3. The importer or his representative shall be liable for the costs incurred in the process of re-dispatching or destroying the consignment or using the product for other purposes.

4. Detailed rules for the application of this Article shall be adopted, where necessary, in accordance with the procedure laid down in Article 24.

5. Provisions concerning the communication of information to the Member States will be adopted in the context of the programme for developing the computerization of veterinary procedures in respect of imports (Shift project).

6. The competent authorities shall, where appropriate, communicate to the Commission and the other Member States any information at their disposal in accordance with Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters ⁽¹⁾.

Article 17

The Commission, in accordance with the procedure laid down in Article 24, shall on the basis of the plans referred to in the second paragraph, adopt the rules applicable to imports into certain parts of the territories referred to in Annex I, to take account of the natural constraints specific to these territories in particular their remoteness from the mainland part of Community territory.

To that end, by 1 July 1991 at the latest, the French Republic and the Hellenic Republic will submit a plan to the Commission setting out, in the particular case of the French Overseas Departments and of certain islands and groups of islands, the nature of the checks to be carried out on imports into these regions of products originating in third countries, taking into account the natural geographical constraints specific to these territories.

These plans must specify the checks carried out to prevent products introduced into these territories being re-dispatched under any circumstances to other parts of Community territory.

Article 18

1. The Commission, in accordance with the procedure laid down in Article 24, shall draw up a list of plant products covered by Article 2 (2) (a) second indent which, in particular on account of their subsequent destination, may give rise to the risk of spreading infectious or contagious animal diseases and on that account are to be subjected to the veterinary checks laid down by this Directive, and in particular those provided for in Article 4, in order to verify the origin and planned destination of such plant products.

The following shall be adopted in accordance with the same procedure:

- the animal health conditions which third countries must comply with and the guarantees which must be offered, in particular the nature of any processing to be required in the light of their animal health situation,
- a list of the third countries which, in the light of these guarantees, may be authorized to export to the Community the plant products referred to in the first paragraph,

⁽¹⁾ OJ No L 351, 2. 12. 1989, p. 34.

— any specific inspection procedures, in particular with reference to sampling which may be applied to these products, especially in the case of imports in bulk.

2. Pending the adoption of Community rules applicable to imports of these products, the Commission may, in accordance with the procedure laid down in Article 24, extend to by-products of animal origin not covered by Annex II to the Treaty the veterinary inspection rules laid down by this Directive by fixing where appropriate certain specific criteria which must be complied with when veterinary checks on these products are being carried out.

3. Fresh fish immediately landed from a vessel flying a third country flag must — before entering for home use in the territory defined in Annex I — undergo the checks laid down in respect of fish immediately landed by vessels flying the flag of a Member State.

4. In accordance with the procedure laid down in Article 24, derogations may be granted from the provisions of Article 9 and, as regards the staff responsible for carrying out the checks, those of Article 8 (2) for ports where fish is landed.

CHAPTER II

Safeguard provisions

Article 19

1. If, in the territory of a third country, a disease referred to in Directive 82/894/EEC ⁽¹⁾, a zoonosis or other disease or phenomenon liable to present a serious threat to animal or public health, or if any other serious animal health or public health reason so warrants in particular in the light of the findings of its veterinary experts, the Commission may, acting on its own initiative or at the request of a Member State, adopt one of the following measures without delay and depending on the gravity of the situation:

- suspend imports coming from part or all of the third country concerned, and where appropriate from the transit third country,
- set special conditions in respect of imports coming from part or all of the third country concerned.

2. If one of the checks provided for in this Directive indicates that a consignment of products is likely to constitute a danger for animal or human health, the competent veterinary authority shall immediately take the following measures:

- it shall seize and destroy the consignment,
- it shall immediately inform the other border inspection posts and the Commission of the findings and of the origin of the products, in accordance with Article 16 (5).

3. In the case provided for in paragraph 1, the Commission may take provisional protective measures in respect of products covered by Article 12.

4. Representatives of the Commission may make an immediate visit to the third country concerned.

5. As regards products the rules on imports of which have not yet been harmonized, and in the case where a Member State informs the Commission officially of the need to take safeguard measures and the Commission has not invoked the provisions of paragraphs 1 and 3 or made a referral to the Standing Veterinary Committee in accordance with paragraph 6, that Member State may take interim protective measures in respect of the products in question.

Where a Member State takes provisional protective measures in respect of a third country or third country establishment under the terms of this paragraph, it shall inform the other Member States and the Commission in accordance with Article 16 (5).

6. Without delay the Commission shall review the situation within the Standing Veterinary Committee. It may adopt the necessary decisions in accordance with the procedure laid down in Article 23, including those relating to intra-Community movements of products and to transit.

7. Decisions to modify, repeal or extend measures decided on by virtue of paragraphs 1, 2, 3 and 6 shall be taken in accordance with the procedure laid down in Article 23.

8. Detailed rules for the application of this Chapter shall be adopted, where necessary, in accordance with the procedure laid down in Article 24.

CHAPTER III

Inspection

Article 20

1. Veterinary experts from the Commission may, in conjunction with the competent national authorities and to the extent that uniform application of the requirements of this Directive renders necessary, verify that the border inspection posts approved in accordance with Article 9 satisfy the criteria listed in Annex II.

2. Veterinary experts from the Commission may, in conjunction with the competent authorities, make on-the-spot checks.

⁽¹⁾ OJ No L 378, 31. 12. 1982, p. 58.

3. A Member State in whose territory an inspection is made shall provide the veterinary experts from the Commission with any assistance they may require in the performance of their tasks.

4. The Commission shall inform the Member States of the outcome of the checks.

5. Where the Commission deems that the outcome of checks so justifies, it shall review the situation within the Standing Veterinary Committee. It may adopt the necessary decisions in accordance with the procedure laid down in Article 23.

6. The Commission shall monitor developments; in the light of such developments and in accordance with the procedure laid down in Article 23, it may amend or repeal the decisions referred to in paragraph 5.

7. Detailed rules for the application of this Article shall be adopted, where necessary, in accordance with the procedure laid down in Article 24.

Article 21

1. Where, on the basis of the checks carried out at the point where the products are marketed, a competent authority of a Member State considers that this Directive is not being complied with at a border inspection post, a crossing point referred to in Article 4 (2) (i), a free port or free zone referred to in Article 5 or a free warehouse referred to in Article 6 of another Member State, it shall contact the competent central authority of that Member State without delay.

The latter shall take all the necessary measures and inform the competent authority of the first Member State of the nature of the checks made, the decisions taken and the reasons for such decisions.

If the competent authority of the first Member State believes the measures are insufficient it shall examine, with the competent authority of the Member State in question, the ways and means in which the situation could be remedied, where necessary by visiting the Member State in question.

Where the checks referred to in the first subparagraph show repeated non-compliance with this Directive, the competent authority of the Member State of destination shall inform the Commission and the competent authorities of the other Member States.

The Commission may, at the request of the competent authority of the Member State of destination or on its own initiative, and taking account of the type of infringements complained of:

- send an inspection team to the Member State in question in conjunction with the competent national authorities,
- request the competent authority to step up the checks carried out at the border inspection post, crossing point, free port, free zone or free warehouse in question.

Pending the Commission's findings, the Member State attached must, at the request of the Member State of destination, step up checks at the border inspection post, crossing point, free port, free zone or free warehouse concerned.

The Member State of destination may, for its part, intensify checks on products coming from these sources.

At the request of one of the two Member States concerned — where the irregularities are conformed by the inspection referred to in the first indent of the fourth subparagraph — the Commission must, in accordance with the procedure laid down in Article 23, take the appropriate measures. These measures must be confirmed or reviewed as soon as possible in accordance with the same procedure.

2. Rights of appeal existing under the laws in force in the Member States against decisions by the competent authorities shall not be affected by this Directive.

Decisions taken by the competent authority and the reasons for such decisions shall be notified to the operator concerned by such decisions or his representative.

If the operator concerned or his representative so requests, the said decisions and reasons shall be forwarded to him in writing with details of the rights of appeal which are available to him under the law in force in the Member State performing the checks of the procedure and time limits applicable.

3. The detailed rules for the application of this Article shall be adopted in accordance with the procedure laid down in Article 24.

Article 22

1. Each Member State shall draw up a programme for the exchange of officials empowered to carry out the checks on products coming from third countries.

2. The Commission and the Member States shall coordinate the programmes referred to in paragraph 1 within the Standing Veterinary Committee.

3. Member States shall take all the measures necessary to allow implementation of the programmes resulting from the coordination referred to in paragraph 2.

4. Each year, in the Standing Veterinary Committee, the implementation of programmes shall be reviewed on the basis of reports drawn up by the Member States.

5. Member States shall take into account the experience gained in order to improve and develop the programme of exchanges.

6. A financial contribution from the Community may be granted in order to promote the efficient development of exchange programmes. Detailed rules for the Community's financial contribution and the estimated amount to be

charged to the Community budget are laid down in Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁾.

7. Detailed rules for the application of paragraphs 1, 4 and 5 shall be adopted where necessary, in accordance with the procedure laid down in Article 24.

CHAPTER IV

General provisions

Article 23

Where reference is made to the procedure provided for in this Article, the Standing Veterinary Committee set up by Decision 68/361/EEC ⁽²⁾ shall take decisions in accordance with the rules established in Article 17 of Directive 89/662/EEC.

Article 24

Where reference is made to the procedure defined in this Article, the Standing Veterinary Committee shall take decisions in accordance with the rules established in Article 18 of Directive 89/662/EEC.

Article 25

Annex II to this Directive may be supplemented in accordance with the procedure laid down in Article 24.

Article 26

This Directive shall be without prejudice to obligations arising from customs rules.

Article 27

Article 23 of Directive 72/462/EEC is hereby deleted.

Pending the decisions provided for in Article 4 (6), the acts taken pursuant to Article 23 of Directive 72/462/EEC shall continue to apply.

Article 28

Article 6 (1) of Directive 89/662/EEC is hereby replaced by the following:

'1. Member States shall ensure that, during the checks carried out at the places where products from a third country may be brought into the territories, defined in Annex I to Directive 90/675/EEC (*) such as ports,

airports and border inspection posts with third countries, the following measures are taken:

- (a) a documentary check is made on the products' origin;
- (b) products originating in the Community are subject to the rules on checks provided for in Article 5;
- (c) products from third countries are subject to the rules laid down in Directive 90/675/EEC.

(*) OJ No L 373, 31. 12. 1990, p. 1.'

Article 29

Article 7 of Directive 90/425/EEC is hereby replaced by the following:

'Article 7

1. Member States shall ensure that during the checks carried out at the places where animals and products referred to in Article 1 from a third country may be brought into the territories referred to in Annex I to Directive 90/675/EEC (*), such as ports, airports and border inspection posts with third countries, the following measures are taken:

- (a) certificates or documents accompanying the animals and products are checked;
- (b) the products from third countries shall be subject to the rules laid down by Directive 90/675/EEC;
- (c) where animals are imported from third countries, they must be sent, under customs supervision, to border inspection posts in order that veterinary checks may be carried out.

The animals referred to in Annex A may not be given customs clearance unless those checks have shown that they comply with Community rules;

- (d) Community animals and products shall be subject to the control rules laid down in Article 5.

2. The animals must be brought directly into Community territory via one of the border inspection posts of the Member State which intends to import them and be inspected there in accordance with paragraph 1 (b).

Member States which make imports from third countries on the basis of national animal health rules shall inform the Commission and the other Member States, in particular Member States of transit, of the existence of such imports and of the requirements to which they subject such imports.

Member States of destination shall prohibit animals from being sent on from their territory unless they have remained there for the periods laid down in the specific

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19.

⁽²⁾ OJ No L 255, 18. 10. 1968, p. 23.

Community rules unless they are bound, without transit, for another Member State using the same option.

However, pending the adoption of Community rules, those animals may be brought into the territory of a Member State other than that referred to in the second subparagraph following prior agreement given by that other Member State in a general manner and, where appropriate, by a Member State of transit on the arrangements for control. Member States shall inform the Commission and the other Member States in the framework of the Standing Veterinary Committee when they are making use of this derogation and of the control arrangements agreed upon.

3. However, from 1 January 1993 and by way of derogation from paragraph 1, all animals and products transported by regular, direct means of transport linking two geographical points of the Community shall be subject to the control rules laid down in Article 5.

(*) OJ No L 373, 31. 12. 1990, p. 1.

Article 30

Acting in accordance with the procedure laid down in Article 24, the Commission may adopt for three years the transitional measures necessary to facilitate the move over to the new checking arrangements provided for in this Directive.

Article 31

Member States may make use of the Community financial assistance provided for in Article 38 of Directive 90/424/EEC for the implementation of this Directive.

Article 32

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1991 at the latest. They shall forthwith inform the Commission thereof.

Detailed rules for applying this Directive and in particular those of Article 8 (3) shall be adopted and the Shift system brought into force not later than 31 December 1991.

Should the date referred to in the preceding subparagraph not be met, the transitional measures provided for in Article 30 shall be taken on that date.

2. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 33

This Directive is addressed to the Member States.

Done at Brussels, 10 December 1990.

For the Council
The President
V. SACCOMANDI

ANNEX I

1. The territory of the Kingdom of Belgium.
 2. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland.
 3. The territory of the Federal Republic of Germany.
 4. The territory of the Kingdom of Spain, with the exception of the Canary Islands, Ceuta and Melilla.
 5. The territory of the Hellenic Republic.
 6. The territory of the French Republic.
 7. The territory of Ireland.
 8. The territory of the Italian Republic.
 9. The territory of the Grand Duchy of Luxembourg.
 10. The territory of the Kingdom of the Netherlands in Europe.
 11. The territory of the Portuguese Republic.
 12. The territory of the United Kingdom of Great Britain and Northern Ireland.
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ANNEX II

In order to obtain Community approval, border inspection posts must have:

- the staff necessary to check the documents (public health and animal health certificates or any other document laid down by Community legislation) accompanying the products,
 - sufficient numbers, in relation to the quantity of products dealt with by the border inspection post, of veterinary and auxiliary staff specially trained to carry out checks that products correspond to the accompanying documents and systematic physical checks of each product consignment,
 - sufficient staff to take and process random samples of product consignments presented at a given border inspection post,
 - sufficiently large premises at the disposal of the staff responsible for carrying out veterinary checks,
 - appropriate premises and facilities for taking and processing the samples for the routine checks laid down in Community rules (microbiological standards),
 - the services of a specialized laboratory situated near the border inspection post and able to carry out special tests on the samples taken at that post,
 - premises and cold stores permitting the storage of part-consignments taken for testing and products whose release for free circulation has not been authorized by the veterinary officer responsible for the border inspection post,
 - appropriate equipment permitting the rapid exchange of information, in particular with other border inspection posts (from 1 January 1993, through the computerized system provided for in Article 20 of Directive 90/425/EEC or the Shift project).
-

COUNCIL DIRECTIVE

of 13 December 1990

amending Directive 81/851/EEC on the approximation of the laws of the Member States
relating to veterinary medicinal products

(90/676/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Article 23 (2) of Council Directive 81/851/EEC ⁽⁴⁾ provides that the Commission should submit to the Council a proposal containing appropriate measures leading towards the elimination of any remaining barriers to trade or to the free movement of veterinary medicinal products not later than four years after the implementation of the abovementioned Directive;

Whereas the Directives on the approximation of laws relating to veterinary medicinal products must be adapted to scientific progress and improved to take account of the experience acquired since their adoption;

Whereas it is necessary from the point of view of public health and the free movement of veterinary medicinal products for the competent authorities to have at their disposal all useful information on authorized veterinary medicinal products in the form of approved summaries of the characteristics of products;

Whereas the approximation of laws brought about in this connection must enable a veterinary medicinal product, manufactured and placed on the market in one Member State on the basis of harmonized provisions, to be allowed into the other Member States, taking due consideration of the initial authorization, save in exceptional cases submitted for an opinion to the Committee for Veterinary Medicinal Products set up by Directive 81/851/EEC;

Whereas the system for package inserts accompanying veterinary medicinal products should be improved;

Whereas it is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to

obtaining authorization for a veterinary medicinal product which is essentially similar to an innovative product, while ensuring that innovative firms are not placed at a disadvantage; whereas, however, there are reasons of public policy for not repeating tests carried out on animals without overriding cause;

Whereas the guarantees of the quality of veterinary medicinal products manufactured within the Community should be maintained by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the products;

Whereas the Commission should be empowered to define in detail principles of good manufacturing practice for veterinary medicinal products in close cooperation with the Committee for Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector established by Article 2b of Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products ⁽⁵⁾, as amended by Directive 87/20/EEC ⁽⁶⁾;

Whereas measures should be taken to improve the provision of information for third countries about the conditions of use of veterinary medicinal products within the Member States and the Community;

Whereas measures should also be taken to ensure that distributors of veterinary medicinal products are authorized by Member States and maintain adequate records,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 81/851/EEC is hereby amended as follows:

1. Article 1 (5) is replaced by the following:

'5. Member States shall take all measures necessary to ensure that only persons empowered under their national legislation in force possess or have under their control veterinary medicinal products or substances which may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.

⁽¹⁾ OJ No C 61, 10. 3. 1989, p. 11 and OJ No C 131, 30. 5. 1990, p. 16.

⁽²⁾ OJ No C 96, 17. 4. 1990, p. 104 and Decision of 21 November 1990 (not yet published in the Official Journal).

⁽³⁾ OJ No C 201, 7. 8. 1989, p. 1.

⁽⁴⁾ OJ No L 317, 6. 11. 1981, p. 1.

⁽⁵⁾ OJ No L 317, 6. 11. 1981, p. 16.

⁽⁶⁾ OJ No L 15, 17. 1. 1987, p. 34.

Member States shall maintain a register of producers and dealers permitted to be in possession of active substances which may be used in the manufacture of veterinary medicinal products having the properties referred to in the first subparagraph. Such persons must maintain detailed records of all dealings in substances which may be used in the manufacture of veterinary medicinal products and keep these records available for inspection by the competent authorities for a period of at least three years.

Any amendments to be made to the list of substances referred to in the first subparagraph shall be adopted in accordance with the procedure referred to in Article 2c of Directive 81/852/EEC (*) as amended by Directive 87/20/EEC (**).

(*) OJ No L 317, 6. 11. 1981, p. 16.

(**) OJ No L 15, 17. 1. 1987, p. 34.

2. The following subparagraph is added to Article 2 (1):

'This Directive shall apply to veterinary medicinal products used in order to produce active or passive immunity or to diagnose the state of immunity, in accordance with the provisions of Directive 90/676/EEC (***) which widens the scope of this Directive.

(***) OJ No L 373, 31. 12. 1990, p. 15.'

3. The second and fourth indents of Article 2 (2) are deleted.
4. Article 4 is replaced by the following:

'Article 4

1. No veterinary medicinal product may be placed on the market in a Member State unless authorization has previously been granted by the competent authority of that Member State.

However, where the health situation so requires, a Member State may authorize the placing on the market or administration to animals of veterinary medicinal products which have been authorized by another Member State in accordance with this Directive.

In the event of a serious disease epidemic the States may provisionally allow the use of immunological veterinary medicinal products without an authorization for placing on the market, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.

2. A Member State shall not authorize the placing on the market of a veterinary medicinal product intended for administration to food-producing animals whose flesh or products are intended for human consumption, unless:

- (a) the active substance or substances capable of pharmacological action contained in the veterinary medicinal product were authorized for use in other veterinary medicinal products in the Member State

concerned on the date of entry into force of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the fixing of maximum levels of residues of veterinary medicinal products in foodstuffs of animal origin (*);

- (b) the active substance or substances capable of pharmacological action is or are mentioned in Annex I, II or III to the aforementioned Regulation.

3. No veterinary medicinal product may be administered to animals unless the authorization referred to above has been issued, except for the tests of veterinary medicinal products referred to in point 10 of Article 5 which have been accepted by the competent national authorities, following notification or authorization, in accordance with the national rules in force.

The Member States shall permit the placing on the market of foodstuffs obtained from animals treated during these tests only if they are satisfied that the foodstuffs do not contain residues which may present a risk for human health.

Without prejudice to stricter Community or national rules relating to dispensing veterinary medicinal products and to protect human and animal health, a prescription shall be required for dispensing to the public the following veterinary medicinal products;

- (a) those products subject to official restrictions on supply or use, such as:
- the restrictions resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances,
 - the restrictions on the use of veterinary medicinal products resulting from Community law;
- (b) those products in respect of which special precautions must be taken by the veterinarian in order to avoid any unnecessary risk to:
- the target species,
 - the person administering the products to the animal,
 - the consumer of foodstuffs obtained from the treated animal,
 - the environment;
- (c) those products intended for treatments or pathological processes which require a precise prior diagnosis or the use of which may cause effects which impede or interfere with subsequent diagnostic or therapeutic measures;
- (d) magistral formulae intended for animals.

In addition, a prescription shall be required for new veterinary medicinal products containing an active ingredient which has been authorized for use in a

veterinary medicinal product for less than five years unless, having regard to the information and particulars provided by the applicant, or experience acquired in the practical use of the product, the competent authorities are satisfied that none of the criteria referred to in (a) to (d) of the third subparagraph apply.

4. However, where there exists no authorized medicinal product for a condition, Member States may exceptionally, in particular in order to avoid causing unacceptable suffering to the animals concerned, permit the administration by a veterinarian or under his/her direct personal responsibility to an animal or to a small number of animals on a particular holding (*):

- (a) of a veterinary medicinal product authorized in the Member State concerned for use in another animal species, or for another condition in the same species; or
- (b) if there is no product such as referred to in point (a), of a medicinal product authorized for use in the Member State concerned in human beings in accordance with Directive 65/65/EEC of 26 January 1965; or
- (c) if there is no product such as referred to in point (b) and within the limits of the law of the Member State concerned, of a veterinary medicinal product prepared extemporaneously by a person authorized to do so under national legislation in accordance with the terms of a veterinary prescription,

provided that the medicinal product, where administered to animals whose flesh or products are intended for human consumption, contains only substances to be found in a veterinary medicinal product authorized for such animals in the Member State concerned and that in the case of food-producing animals the veterinarian responsible specifies an appropriate withdrawal period to ensure that food produced from the treated animals does not contain residues harmful to consumers.

Unless the product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than:

- 7 days: eggs,
- 7 days: milk,
- 28 days: meat from poultry and mammals including fat and offal,
- 500 degree days: meat from fish.

The veterinarian shall keep adequate records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products prescribed, the dosages administered, the duration of treatment and the withdrawal periods recommended, and make these records available for inspection by the competent authorities for a period of at least three years. This requirement may be extended by the Member States to animals whose flesh or products are not intended for human consumption.

5. Notwithstanding paragraph 3, Member States shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of ready-made veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorized for use in the Member State in which the services are provided (host Member State), providing that the following conditions are satisfied:

- (a) the authorization to place the product on the market provided for in paragraph 1 has been issued by the competent authorities of the Member State in which the veterinarian is established;
- (b) the veterinary medicinal products are transported by the veterinarian in the original manufacturer's packaging;
- (c) the veterinary medicinal products intended for administration to food-producing animals have the same qualitative and quantitative composition in terms of active principles as the medicinal products authorized in accordance with paragraph 1 in the host Member State;
- (d) a veterinarian providing services in another Member State shall acquaint himself with the good veterinary practices applied in that Member State. He shall ensure that the withdrawal period specified on the labelling of the veterinary medicinal product concerned is complied with, unless he could reasonably be expected to know that a longer withdrawal period should be specified to comply with these good veterinary practices;
- (e) the veterinarian shall not furnish any veterinary medicinal product to the owner or keeper of the animals treated in the host Member State unless this is permissible on the basis of the rules of the host Member State; in this case he shall, however, supply only in relation to animals under his care and only the minimum quantities of veterinary medicinal product necessary to complete the treatment of animals concerned on that occasion;
- (f) the veterinarian shall be required to keep detailed records of the animals treated, the diagnosis, the veterinary medicinal products administered, the dosage administered, the duration of treatment and the withdrawal period applied. These records shall be available for inspection by the competent authorities of the host State for a period of at least three years;
- (g) the overall range and quantity of veterinary medicinal products carried by the veterinarian shall not exceed that generally required for the daily needs of good veterinary practice.

(*) OJ No L 224, 18. 8. 1990, p. 1.

(**) The phrase "an animal or a small number of animals on a particular holding" also covers pets, and should be interpreted more flexibly for minor or exotic animal species which do not produce food.

5. Article 5 is replaced by the following:

'Article 5

For the purpose of obtaining the authorization for placing a product on the market provided for in Article 4, the person responsible for placing the product on the market shall lodge an application with the competent authority of the Member State.

The following particulars and documents shall accompany such application:

1. name or business name and permanent address or registered place of business of the person responsible for placing the product on the market and, if different, of the manufacturer or manufacturers involved and of the sites of manufacture;
2. name of the veterinary medicinal product (brand name, non-proprietary name, with or without a trademark, or name of the manufacturer or scientific name or formula, with or without a trademark, or the name of the manufacturer);
3. qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, using the usual terminology but not empirical chemical formula and giving the international non-proprietary name recommended by the World Health Organization, where such a name exists;
4. description of the method of preparation;
5. therapeutic indications, contra-indications and side-effects;
6. dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;
7. if applicable, explanations of the precautionary and safety measures to be taken when the product is stored, when it is administered to animals and when waste therefrom is disposed of, together with an indication of any potential risks the medicinal product might pose to the environment and the health of humans, animals or plants;
8. indication of the withdrawal period necessary between the last administration of the veterinary medicinal product to animals under normal conditions of use and the production of foodstuffs from such animals in order to ensure that such foodstuffs do not contain residues in quantities in excess of the maximum limits laid down. Where necessary, the applicant shall propose and justify a tolerance level for residues which may be accepted in foodstuffs without risk for the consumer, together with routine analysis methods which could be used by the competent authorities to trace residues;

9. description of the control testing methods employed by the manufacturer (qualitative and quantitative analysis of the constituents and the finished product, specific tests, e.g. sterility tests, test for the presence of pyrogens, for the presence of heavy metals, stability tests, biological and toxicity tests, tests on intermediate products);

10. results of:

- physico-chemical, biological or microbiological tests,
- toxicological and pharmacological tests,
- clinical trials.

However, and without prejudice to the law relating to the protection of industrial and commercial property:

- (a) the applicant shall not be required to provide the results of toxicological and pharmacological tests and clinical trials if he can demonstrate:

- (i) either that the veterinary medicinal product is essentially similar to a medicinal product authorized in the Member State concerned by the application and that the person responsible for placing the original veterinary medicinal product on the market has agreed that the toxicological, pharmacological or clinical references contained in the file on the original veterinary medicinal product may be used for the purpose of examining the application in question;
- (ii) or by detailed references to the scientific literature presented in accordance with the second paragraph of Article 1 of Directive 81/852/EEC, as amended by Directive 87/20/EEC, that the constituent or constituents of the veterinary medicinal product have a well-established medicinal use, with recognized efficacy and an acceptable level of safety;
- (iii) or that the veterinary medicinal product is essentially similar to a product which has been authorized within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products appearing on the list in Part A of the Annex to Directive 87/22/EEC (*) or of a medicinal product appearing on the list in Part B of the Annex to that Directive for which the procedure laid down in Article 2 of that Directive has been followed. Furthermore, a Member State may also extend this period to 10 years by a single

Decision covering all the products marketed in its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the abovementioned six-year period beyond the date of expiry of a patent protecting the original product;

(b) in the case of new veterinary medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of toxicological and pharmacological tests and of clinical trials relating to that combination must be provided, but it shall not be necessary to provide references relating to each individual constituent;

11. a summary in accordance with Article 5a of the product characteristics, one or more specimens or mock-ups of the sales presentation of the veterinary medicinal product together with the package insert referred to in Article 48 (1);
12. a document showing that the manufacturer is authorized in his own country to produce veterinary medicinal products;
13. any authorization to place the relevant veterinary medicinal product on the market which may have been obtained in another Member State or in a third country, together with a list of those countries to which an application for authorization to place the product on the market has been made and explanation of the reasons for which the Member State or third country has refused to grant authorization for the veterinary medicinal product concerned;
14. in the case of medicinal products containing new active ingredients which are not mentioned in Annex I, II or III to Regulation (EEC) No 2377/90, a copy of the documents submitted to the Commission in accordance with Annex V to the Regulation.

(*) OJ No L 15, 17. 1. 1987, p. 38.

6. The following Article is inserted:

'Article 5a

The summary of the product characteristics referred to in point 11 of point 2 of the second paragraph of Article 5 shall contain the following information:

1. name of the veterinary medicinal product;
2. qualitative and quantitative composition in terms of the active ingredients and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product; the international non-proprietary names recommended by the World Health Organization shall be used, where such names exist, or failing this, the usual non-proprietary name or chemical description;
3. pharmaceutical form;

4. pharmacological properties and, in so far as this information is useful for therapeutic purposes, pharmacokinetic particulars;

5. clinical particulars:

- 5.0 target species,
- 5.1 indications for use, specifying the target species,
- 5.2 contra-indications,
- 5.3 undesirable effects (frequency and seriousness),
- 5.4 special precautions for use,
- 5.5 use during pregnancy and lactation,
- 5.6 interaction with other medicaments and other forms of interaction,
- 5.7 posology and method of administration,
- 5.8 overdose (symptoms, emergency procedures, antidotes) (if necessary),
- 5.9 special warnings for each target species,
- 5.10 withdrawal periods,
- 5.11 special precautions to be taken by the person administering the product to animals;

6. pharmaceutical particulars:

- 6.1 incompatibilities (major),
- 6.2 shelf life, when necessary after reconstitution of the product or when the container is opened for the first time,
- 6.3 special precautions for storage,
- 6.4 nature and contents of container,
- 6.5 name or style and permanent address or registered place of business of the holder of the authorization to place the product on the market,
- 6.6 special precautions for the disposal of unused product or waste materials, if any.

7. The following Article is inserted:

'Article 5b

When the authorization to place the product on the market, referred to in Article 4 (1), is issued, the person responsible for placing that product on the market shall be informed, by the competent authorities of the Member States concerned, of the summary of the product characteristics as approved by them. The competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the authorization to place the product on the market is issued or subsequently.'

8. The last sentence of Article 7 is replaced by the following:

'The experts' detailed reports shall form part of the documentation which the applicant shall lodge with the competent authorities. A brief curriculum vitae of the expert shall be appended to each report.'

9. Article 9 (2) is replaced by the following:

'2. may submit the medicinal product, its active principles and if necessary intermediate products or other constituent materials for testing by a State laboratory or by a laboratory designated for that purpose, in order to ensure that the testing methods employed by the manufacturer and described in the application documents, in accordance with point 9 of the second paragraph of Article 5, are satisfactory.'

10. In Article 9, the following point is added:

'4. may require the applicant to submit substances in the quantities necessary to verify the analytical detection method proposed by the applicant in accordance with point 8 of the second paragraph of Article 5 and to put it into effect as part of routine checks to reveal the presence of residues of the veterinary medicinal products concerned'.

11. Article 14 is replaced by the following:

'Article 14

1. After an authorization has been issued, the person responsible for placing the product on the market must, in respect of the control methods provided for in point 9 of the second paragraph of Article 5, take account of technical and scientific progress and introduce any changes that may be required to enable the veterinary medicinal product to be checked by means of generally accepted scientific methods. These changes must be approved by the competent authorities of the Member States concerned.

Upon request from the competent authorities, the person responsible for placing the product on the market shall also review the analytical detection methods provided for in point 8 of the second paragraph of Article 5 and propose any changes which may be necessary to take account of scientific and technical progress.

2. The person responsible for placing the product on the market shall forthwith inform the competent authorities of any new information which might entail the amendment of the particulars and documents referred to in Article 5 or the approved summary of the product characteristics referred to in Article 5b. In particular, he shall forthwith inform the competent authorities of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is marketed and of any serious unexpected reaction occurring in the animals concerned or human beings.

3. The person responsible for placing the product on the market shall be required to maintain records of all undesirable effects observed in animals or human beings. The records so established shall be kept for at least five years and shall be made available to the competent authorities upon request.

4. The person responsible for placing the product on the market shall immediately inform the competent authorities, with a view to authorization, of any alteration he proposes to make to the particulars and documents referred to in Article 5.'

12. Article 15 is replaced by the following:

'Article 15

Authorization shall be valid for five years and shall be renewable for five year periods, on application by the holder at least three months before the date of expiry.

However, veterinary medicinal products which contain active substances included in Annex III to Regulation (EEC) No 2377/90 shall be authorized only for the period for which a provisional tolerance has been established and authorization may be extended if the provisional tolerance is renewed.'

13. Chapter IV of Directive 81/851/EEC is replaced by the following:

'CHAPTER IV

Committee for Veterinary Medicinal Products

Article 16

1. In order to facilitate the adoption of a common position by the Member States with regard to decisions on the issue of authorizations to place products on the market and to promote thereby the free movement of veterinary medicinal products, a Committee for Veterinary Medicinal Products, hereinafter referred to as 'the Committee' and composed of representatives of the Member States and of the Commission, is hereby set up.

2. The Committee's task shall be to examine, at the request of a Member State or the Commission and in accordance with Articles 17 to 22, questions concerning the application of Articles 11, 36 and 49.

3. The Committee shall draw up its own rules of procedure, which shall be published by the Commission.

The rules of procedure shall provide for, in particular:

- the publication of the names and qualifications of the members of the Committee;
- appropriate safeguards to ensure that the members of the Committee discharge their responsibilities with complete impartiality.

The Commission shall maintain available for public inspection at its offices a register of all interests relating

to the pharmaceutical industry held by members of the Committee and persons taking part in its discussions.

Article 17

1. In order to make it easier to obtain an authorization to place a product on the market in at least two other Member States taking into due consideration an authorization issued in one Member State in accordance with Article 4, the holder of the latter authorization may submit an application to the competent authorities of the Member States concerned together with the information and documents referred to in Articles 5, 5a and 5b.

He shall testify to its identity with the dossier accepted by the first Member State, specifying any additions it may contain, and shall certify that all the dossiers filed as part of this procedure are identical.

2. The holder of the authorization to place a product on the market shall notify the Committee of the application, inform it of the Member States concerned and send it a copy of the authorization. He shall also inform the Member State which granted him the initial authorization and notify it of any additions to the original dossier; that State may require the applicant to provide it with all the particulars and documents necessary to enable it to check the identity of the dossiers filed with the dossier on which it took its decision.

3. The holder of the authorization to place a product on the market shall notify the dates on which the dossiers were sent to the Member States concerned; the latter shall immediately send an acknowledgement of receipt of the dossier to the Committee and to the person responsible for placing the product on the market. As soon as the Committee has noted that all the Member States concerned are in possession of the dossier, it shall forthwith inform all the Member States and the applicant of the date on which the last Member State concerned received the dossier. The Member States concerned shall either grant the authorization valid for their markets within a period of 120 days of the aforementioned date, taking into due consideration the authorization issued in accordance with paragraph 1, or put forward a reasoned objection.

Article 18

1. Where a Member State considers that it is unable to grant an authorization to place a product on the market, it shall forward to the Committee and to the person responsible for placing the veterinary medicinal product on the market its reasoned objection in accordance with Article 11, within the time limits stipulated in Article 17 (3).

2. Upon the expiry of this period, the matter shall be referred to the Committee and the procedure referred to in Articles 21 and 22 shall be applied.

3. On receipt of the reasoned objection referred to in paragraph 1, the person responsible for placing the product on the market shall immediately send the Committee a copy of the particulars and documents referred to in Article 17 (1).

Article 19

Where several applications submitted in accordance with Articles 5 and 5a have been made for authorization to place a particular veterinary medicinal product on the market, and one or more Member States have granted an authorization while one or more of the other Member States have refused it, one of the Member States concerned or the Commission or the person responsible for placing the product on the market may refer the matter to the Committee for application of the procedure provided for in Articles 21 and 22. The Member States will be informed each time this procedure is invoked.

The same shall apply where one or more Member States have suspended or revoked an authorization to place a product on the market while one or more Member States have not done so.

In both cases, the person responsible for placing the veterinary medicinal product on the market shall be informed of any decision of the Committee to apply the procedure provided for in Article 22.

Article 20

The competent authorities of Member States may, in specific cases where the interests of the Community are involved, refer the matter to the Committee before reaching a decision on a request for authorization to place a product on the market or on the suspension or revocation of an authorization.

Article 21

1. The competent authorities shall draw up an assessment report and comments on the dossier as regards the result of the analytical and toxico-pharmacological tests on, and clinical trials of, any veterinary medicinal products containing a new active substance which are the subject of a request for authorization to place the products on the market in the Member States concerned for the first time.

2. As soon as the notification referred to in Article 17 is received, the competent authorities shall immediately communicate to the Member States concerned an assessment report, accompanied by a summary of the dossier relating to an particular veterinary medicinal product. This report shall also be communicated to the Committee where a matter is referred to the Committee pursuant to Article 18.

The assessment report shall also be forwarded to the other Member States concerned and to the Committee as soon as a matter is referred to the Committee under the procedure laid down in Article 19. Any assessment report so forwarded shall remain confidential.

The competent authorities shall bring the assessment report up to date as soon as it is in possession of information which is of importance for the evaluation of the balance between effectiveness and risk.

Article 22

1. Where reference is made to the procedure described in this Article, the Committee shall consider the matter concerned and issue a reasoned opinion within 60 days of the date on which the matter was referred to it.

In the case referred to in Article 18, the person responsible for placing the product on the market may, at his request, provide an oral or written explanation and provide additional information before the Committee issues its opinion. The Committee may extend the time limit referred to in the preceding paragraph to give the applicant time to provide an oral or written explanation.

In the case referred to in Article 19, the person responsible for placing the product on the market may be asked to provide an oral or written explanation.

2. The Committee's opinion shall concern the grounds for the objection provided for in Article 18 (1) and the grounds on which the authorization to place the product on the market has been refused, suspended or withdrawn in the cases described in Article 19.

The Committee shall immediately inform the Member States concerned and the person responsible for placing the product on the market of its opinion or of the opinions of its members where the latter differ.

3. The Member State or States concerned shall decide on the action to be taken further to the Committee's opinion within 60 days of the notification referred to in paragraph 2. They shall immediately inform the Committee of their decision.

Article 23

The Commission shall report to the Council every two years on the operation of the procedure laid down in this Chapter.'

14. Article 24 (1) is replaced by the following:

'1. Member States shall take all appropriate measures to ensure that the manufacture of veterinary medicinal products is subject to the holding of an authorization. This manufacturing authorization shall likewise be required for veterinary medicinal products intended for export.'

15. The following is added to Article 24 (3):

'Member States shall take all appropriate measures to ensure that veterinary medicinal products brought into

their territory from a third country and destined for another Member State are accompanied by a copy of the authorization referred to in paragraph 1.'

16. The following Article is inserted:

'Article 24a

At the request of the manufacturer of veterinary medicinal products, the exporter thereof or the authorities of an importing third country, Member States shall certify that such manufacturer is in possession of the authorization referred to in Article 24. When issuing such certificates, Member States shall comply with the following conditions:

1. Member States shall have regard to the prevailing administrative arrangements of the World Health Organization;
2. for veterinary medicinal products intended for export which are already authorized in their territory, they shall supply the summary of the product characteristics as approved in accordance with Article 5b or, in the absence thereof, an equivalent document.

Where the manufacturer is not in possession of an authorization to place the product on the market, he shall provide the authorities responsible for establishing the certificate referred to in the first paragraph with a declaration explaining why such authorization is not available.'

17. In Article 27, the following is added:

- '(f) comply with the principles and the guidelines of good manufacturing practice for medicinal products laid down by Community law;
- (g) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with the laws of the countries of destination. The following information at least shall be recorded in respect of each transaction, whether or not it is made for payment:
 - date,
 - name of the veterinary medicinal product,
 - quantity supplied,
 - name and address of the recipient,
 - batch number.

These records shall be available for inspection by the competent authorities for a period of at least three years.'

18. The following Article is inserted:

'Article 27a

The principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in Article 27 (f) shall be adopted in the form of a Directive

addressed to the Member States in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC, taking account of the specific nature of the veterinary medicinal product. Detailed guidelines shall be published by the Commission and revised as appropriate to take account of scientific and technical progress.'

19. Article 34 is hereby amended as follows:

(a) The first paragraph is replaced by the following:

'The competent authority of the Member State concerned shall ensure by means of repeated inspection that the legal requirements relating to veterinary medicinal products are complied with.'

(b) The following paragraph is added:

'The officials representing the competent authority shall report after each of the inspections mentioned in the first paragraph on whether the manufacturer complies with the principles and guidelines of good manufacturing practice referred to in Article 27a. The inspected manufacturer shall be informed of the content of such reports.'

20. The following Article is added:

'Article 38a

Member States shall take appropriate measures to encourage veterinarians and other professionals concerned to report to the competent authorities any undesirable effect of veterinary medicinal products.'

21. Article 39 is replaced by the following:

'Article 39

Member States shall take all measures necessary to ensure that the competent authorities concerned communicate the appropriate information to each other, in particular regarding compliance with the requirements adopted for authorization as referred to in Article 24 (1), or for authorization to place products on the market, for the purpose of verifying compliance with the provisions of Chapter VIII.

Upon reasoned request, Member States shall forthwith communicate the reports referred to in the third paragraph of Article 34 to the competent authorities of another Member State. If, after considering the reports, the Member State receiving the reports considers that it cannot accept the conclusions reached by the competent authority of the Member State in which the report was established, it shall inform the competent authorities concerned of its reasons and may request further information. The Member States concerned shall attempt to reach agreement. If necessary, in the event of serious differences of opinion, one of the Member States concerned shall inform the Commission.'

22. Article 42 is replaced by the following:

'Article 42

1. Each Member State shall take all appropriate measures to ensure that the Committee is informed immediately of decisions granting marketing authorization and of all decisions refusing or withdrawing marketing authorization, cancelling a decision refusing or withdrawing marketing authorization, prohibiting supply or withdrawing a product from the market, together with the reasons on which such decisions are based.

2. The person responsible for placing a veterinary medicinal product on the market shall be obliged to notify the Member States forthwith of any action taken by him to suspend the marketing of a product or to withdraw a product from the market, together with the reasons for such action if it concerns the effectiveness of the veterinary medicinal product or the protection of public health. Member States shall ensure that this information is brought to the attention of the Committee.

3. Member States shall ensure that appropriate information about actions taken pursuant to paragraphs 1 and 2 which may affect the protection of health in third countries is forthwith brought to the attention of the relevant international organizations, with a copy to the Committee.'

23. The first paragraph to Article 43 is hereby amended as follows:

(a) Points 1 and 2 are replaced by the following:

'1. Name of the veterinary medicinal product, which may be a brand name or a non-proprietary name accompanied by a trade mark or the name of the manufacturer, or a scientific name or formula, with or without a trade mark, or the name of the manufacturer.

Where the special name of a medicinal product containing only one active ingredient is a brand name, this name must be accompanied in legible characters by the international non-proprietary name recommended by the World Health Organization, where such name exists, or where no such name exists, by the usual non-proprietary name.

2. A statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a particular volume or weight, using the international non-proprietary names recommended by the World Health Organization, where such names exist or, where no such names exist, the usual non-proprietary names.'

(b) Points 7 and 8 are replaced by the following:

'7. The withdrawal period, even if nil, in the case of veterinary medicinal products administered to food-producing animals.

8. Expiry date, in plain language.'

(c) The following point is inserted:

'9a. Special precautions for disposal of unused product or waste material, if any.'

24. In Article 48, the first paragraph is replaced by the following:

'The inclusion of a package insert in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this Article can be conveyed on the container and the external packaging. Member States shall take all appropriate measures to ensure that the insert relates solely to the veterinary medicinal product with which it is included. The insert shall be in the official language or languages of the Member State in which the medicinal product is marketed.'

25. The second paragraph of Article 48 is hereby amended as follows:

(a) Point (e) is replaced by the following:

'(e) the withdrawal period, even if this is nil, in the case of veterinary medicinal products administered to food-producing animals;'

(b) The following point is added:

'(h) special precautions for the disposal of unused product or waste materials, if any.'

26. The final paragraph of Article 48 is deleted.

27. The following Chapter VIII is inserted:

'CHAPTER VIIIa

Distribution of veterinary medicinal products

Article 50a

1. Member States shall take all appropriate measures to ensure that wholesale dealing in veterinary medicinal products is subject to the holding of an authorization and to ensure that the time taken for the procedure for granting this authorization does not exceed 90 days from the date on which the competent authority receives the application.

For the purposes of this Directive, wholesale dealing shall include the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:

- the supply by a manufacturer of veterinary medicinal products manufactured by himself,
- retail supplies of veterinary medicinal products by persons permitted to carry out such supplies in accordance with Article 50b.

Member States may also exclude supplies of small quantities of veterinary medicinal products from one retailer to another.

2. In order to obtain the authorization referred to in paragraph 1, the applicant shall have at his disposal technically competent staff and suitable and sufficient premises complying with the requirements laid down in the Member State concerned as regards the storage and handling of products.

3. The holder of the authorization referred to in paragraph 1 shall be required to keep detailed records. The following minimum information shall be recorded in respect of each incoming or outgoing transaction:

- (a) date;
- (b) precise identity of the veterinary medicinal product;
- (c) manufacturer's batch number, expiry date;
- (d) quantity received or supplied;
- (e) name and address of the supplier or recipient.

At least once a year a detailed audit shall be carried out to compare incoming and outgoing supplies with supplies currently held in stock, any discrepancies being recorded.

These records shall be available for inspection by the competent authorities for a period of at least three years.

4. Member States shall take all appropriate measures to ensure that wholesalers supply veterinary medicinal products only to persons permitted to carry out retail activities in accordance with Article 50b, or to other persons who are lawfully permitted to receive veterinary medicinal products from wholesalers.

Article 50b

1. Member States shall take all appropriate measures to ensure that the retail supply of veterinary medicinal products is conducted only by persons who are permitted to carry out such operations by the legislation of the Member State concerned.

2. Any person permitted under the preceding paragraph to sell veterinary medicinal products shall be required to keep detailed records. The following information shall be recorded in respect of each incoming or outgoing transaction:

- (a) date;
- (b) precise identity of the veterinary medicinal product;
- (c) manufacturer's batch number;

- (d) quantity received or supplied;
- (e) name and address of the supplier or recipient;
- (f) where relevant, name and address of the prescribing veterinarian and a copy of the prescription.

At least once a year a detailed audit shall be carried out, and incoming and outgoing products shall be reconciled with products currently held in stock, any discrepancies being recorded.

These records shall be available for inspection by the competent authorities for a period of three years.

3. Member States may limit the scope of the record-keeping requirements referred to in paragraph 2. However, these requirements shall always be applied in case of veterinary medicinal products intended for administration to animals whose flesh or products are intended for human consumption and which are available only on veterinary prescription or in respect of which a withdrawal period must be observed.

4. Not later than 1 January 1992, Member States shall communicate to the Commission a list of the veterinary medicinal products which are available without prescription. After having taken note of the communication from the Member States, the Commission shall examine whether suitable measures should be proposed for drawing up a Community list of such products.

Article 50c

Member States shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products containing the substances set out in Article 1 (5); Member States may extend the scope of this obligation to other medicinal veterinary products.

In particular, Member States may require the maintenance of a record giving at least the following information:

- (a) date;
- (b) identity of the veterinary medicinal product;

- (c) quantity;
- (d) name and address of the supplier of the medicinal product;
- (e) identification of the animals treated.'

Article 2

1. Member States shall take the necessary measures to comply with this Directive not later than 1 January 1992. They shall forthwith inform the Commission thereof.

2. By way of derogation from paragraph 1, Member States shall take the necessary measures to comply with Article 27 (f) and the third paragraph of Article 34 not later than two years after notification of the Directive referred to in Article 27a.

3. Where Member States adopt the provisions referred to in paragraphs 1 and 2, such provisions shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

4. Request for authorization to place products on the market lodged from the date set out in paragraph 1 must comply with the provisions of this Directive.

5. Within four years of the date set out in paragraph 1, Article 1 shall, where relevant, be progressively extended to existing veterinary medicinal products.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 13 December 1990.

For the Council
The President
P. ROMITA

COUNCIL DIRECTIVE

of 13 December 1990

extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products

(90/677/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In cooperation with the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas disparities in the provisions laid down by law, regulation or administrative action by Member States may hinder trade in immunological veterinary medicinal products within the Community;

Whereas the essential aim of any rules governing the production, distribution or use of veterinary medicinal products must be to ensure a high level of protection of public health;

Whereas the provisions of Directive 81/851/EEC ⁽⁴⁾ as last amended by Directive 90/676/EEC ⁽⁵⁾, although appropriate, are not adequate for veterinary medicinal products used in order to produce active immunity, to diagnose the state of immunity or to produce passive immunity (immunological veterinary medicinal products);

Whereas in accordance with Article 5 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national provisions relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology ⁽⁶⁾, the Commission is required to submit proposals to harmonize the conditions for authorizing the manufacture and placing on the market of immunological veterinary medicinal products;

Whereas, before an authorization to market an immunological veterinary medicinal product can be granted, the manufacturer must demonstrate his ability to attain batch-to-batch consistency;

Whereas the competent authorities should also be empowered to prohibit the use of an immunological veterinary medicinal product when the immunological responses of the treated animal will interfere with a national or Community programme for the diagnosis, eradication or control of animal disease;

Whereas changes will be required to the requirements for the testing of veterinary medicinal products laid down in Annex I to Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products ⁽⁷⁾, as amended by Directive 87/20/EEC ⁽⁸⁾, to take account of the special nature of immunological veterinary medicinal products; whereas the Commission should be empowered to adopt the necessary changes in close cooperation with the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, thus ensuring greater quality, safety and effectiveness,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Subject to the provisions of this Directive, Directive 81/851/EEC shall apply to immunological veterinary medicinal products.

2. For the purposes of this Directive 'immunological veterinary medicinal product' means a veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity.

3. This Directive and Directive 81/851/EEC shall not apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality.

4. Member States may provide that this Directive does not apply to non-activated immunological veterinary medicinal products of the type referred to in paragraph 3.

⁽¹⁾ OJ No C 61, 10. 3. 1989, p. 20 and OJ No C 131, 30. 5. 1990, p. 20.

⁽²⁾ OJ No C 96, 17. 4. 1990, p. 111 and Decision of 21 November 1990 (not yet published in the Official Journal).

⁽³⁾ OJ No C 201, 7. 8. 1989, p. 1.

⁽⁴⁾ OJ No L 317, 6. 11. 1981, p. 1.

⁽⁵⁾ See page 15 of this Official Journal.

⁽⁶⁾ OJ No L 15, 17. 1. 1987, p. 38.

⁽⁷⁾ OJ No L 317, 6. 11. 1981, p. 16.

⁽⁸⁾ OJ No L 15, 17. 1. 1987, p. 34.

Article 2

1. The quantitative particulars of an immunological veterinary medicinal product shall be expressed by mass or by international units or by units of biological activity or by the number of germs or by specific protein content where possible, as appropriate to the product concerned.

2. In respect of immunological veterinary medicinal products, in Directive 81/851/EEC the expression 'qualitative and quantitative composition of the constituents' shall include particulars relating to biological activity or to protein content and the expression 'qualitative and quantitative composition' shall include the composition of the product expressed in terms of the biological activity or of protein content.

3. In any document established in accordance with Directive 81/851/EEC in which the name of an immunological veterinary medicinal product is expressed, the full common or scientific name of the active constituents shall also be included at least once.

Article 3

1. Member States shall take all appropriate measures to ensure that the manufacturing processes used in the manufacture of immunological veterinary medicinal products are completely validated and batch-to-batch consistency is ensured, in accordance with Article 34 of Directive 81/851/EEC.

2. For the purpose of implementing Article 35 of Directive 81/851/EEC, Member States may require persons responsible for placing immunological veterinary medicinal products on the market to submit to the competent authorities copies of all the control reports signed by the qualified person in accordance with Article 30 of Directive 81/851/EEC.

The person responsible for placing immunological veterinary medicinal products on the market shall ensure that an adequate number of representative samples of each batch of finished products is held in stock at least up to the expiry date, and provide samples promptly to the competent authorities on request.

3. Where it considers it necessary, a Member State may require persons responsible for placing immunological veterinary medicinal products on the market to submit samples from the batches of the bulk and/or finished product for examination by a State laboratory or an approved laboratory before entry in free circulation. In the case of a batch manufactured in another Member State, examined by the competent authority of another Member State and declared to be in conformity with national specifications, such a control may be carried out only after the control reports of the batch in question have been examined, after the Commission has been informed, and where the difference in veterinary conditions between the two Member States concerned justifies it. Except where the Commission has been informed that a longer period is necessary to complete the analyses, Member States shall ensure that any such

examination is completed within 60 days of receipt of the samples. The person responsible for placing the product on the market shall be notified of the results of the examination within the same time limit. Before 1 January 1992, the Member States shall notify the Commission of the immunological veterinary medicinal products subject to compulsory official control before being placed on the market.

Article 4

In the absence of specific Community legislation concerning the use of immunological veterinary medicinal products for the eradication or control of animal disease, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

- (a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal disease, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals;
- (b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.

The competent authorities of the Member States shall inform the Commission of all instances in which the provisions of this Article are applied.

Article 5

The amendments which need to be made to the testing requirements for veterinary medicinal products set out in the Annex to Directive 81/852/EEC to take account of the extension of the scope of Directive 81/851/EEC to cover immunological veterinary medicinal products shall be adopted in accordance with the procedure laid down in Article 2c of Directive 81/852/EEC.

Article 6

1. Member States shall take the necessary measures to comply with this Directive not later than 1 January 1992. They shall forthwith inform the Commission thereof.

In the event of the amendments referred to in Article 5 not being adopted by 1 January 1991, the date indicated in the first subparagraph shall be put back to one year after the date of adoption of those amendments.

2. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive

or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

3. Requests for marketing authorization for products covered by this Directive lodged after the date indicated in paragraph 1 must comply with the provisions of this Directive.

4. Within five years of the date indicated in the first subparagraph of paragraph 1, this Directive shall apply to existing immunological veterinary medicinal products.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 13 December 1990.

For the Council
The President
P. ROMITA

COUNCIL DECISION

of 13 December 1990

recognizing certain parts of the territory of the Community as being either officially swine fever free or swine fever free

(90/678/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine ⁽¹⁾, as last amended by Directive 90/425/EEC ⁽²⁾, and in particular Article 4b (1) (c) thereof,

Having regard to Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat ⁽³⁾, as last amended by Directive 89/662/EEC ⁽⁴⁾, and in particular Article 13a (2) thereof,

Having regard to the proposal from the Commission,

Whereas Decision 88/303/EEC ⁽⁵⁾, as last amended by Decision 90/63/EEC ⁽⁶⁾, recognizes certain parts of the territory of Belgium, Germany, France, Greece, the Netherlands and Spain as being officially swine fever free and certain parts of Belgium, Germany, France and Italy as being swine fever free;

Whereas by Commission Decisions 89/420/EEC ⁽⁷⁾, 89/473/EEC ⁽⁸⁾, 90/251/EEC ⁽⁹⁾ Spain, the Netherlands and Greece were recognized respectively as officially swine fever free Member States within the context of disease eradication in accordance with the provisions of Article 2 (2), 3 (2) and 7 of Directive 80/1095/EEC ⁽¹⁰⁾, as last amended by Directive 87/487/EEC ⁽¹¹⁾; whereas those Member States comply since that date with the criteria for an

officially swine fever free Member State as defined in Article 2 (q) of Directive 64/432/EEC;

Whereas in a certain part of the territory of Germany swine fever has not been detected for more than one year, vaccination against swine fever has not been authorized for at least the preceding 12 months and the holdings contain no pigs which have been vaccinated against swine fever during the previous 12 months; consequently, this part of the territory fulfils the requirements for being recognized as officially swine fever free for the purpose of intra-Community trade;

Whereas within the framework of an eradication plan the Commission, by Decision 90/614/EEC ⁽¹²⁾, has recognized certain regions in Germany as being officially swine fever free;

Whereas in certain parts of the territory of Germany, Belgium, France and Italy swine fever has not been detected for more than one year; whereas, consequently, these parts of the territory fulfil the requirements for being recognized as swine fever free for the purpose of intra-Community trade in fresh meat,

HAS ADOPTED THIS DECISION:

Article 1

The parts of the territory of the Community described in Annex I shall be recognized as being officially swine fever free in accordance with Article 4b (1) (c) of Directive 64/432/EEC.

Article 2

The parts of the territory of the Community described in Annex II shall be recognized as being swine fever free in accordance with Article 13a (2) of Directive 72/461/EEC.

⁽¹⁾ OJ No 121, 29. 7. 1964, p. 1977/64.

⁽²⁾ OJ No L 224, 18. 8. 1990, p. 29.

⁽³⁾ OJ No L 302, 31. 12. 1972, p. 24.

⁽⁴⁾ OJ No L 395, 30. 12. 1989, p. 12.

⁽⁵⁾ OJ No L 132, 28. 5. 1988, p. 76.

⁽⁶⁾ OJ No L 43, 17. 2. 1990, p. 32.

⁽⁷⁾ OJ No L 192, 7. 7. 1989, p. 39.

⁽⁸⁾ OJ No L 233, 10. 8. 1989, p. 34.

⁽⁹⁾ OJ No L 143, 6. 6. 1990, p. 10.

⁽¹⁰⁾ OJ No L 325, 1. 12. 1980, p. 1.

⁽¹¹⁾ OJ No L 280, 3. 10. 1987, p. 24.

⁽¹²⁾ OJ No L 328, 28. 11. 1990, p. 23.

Article 3

Done at Brussels, 13 December 1990.

Decision 88/303/EEC is hereby repealed.

Article 4

This Decision is addressed to the Member States.

For the Council

The President

P. ROMITA

ANNEX I

Parts of the territory of the Community which are recognized as being officially swine fever free

CHAPTER 1

Germany

Bundesländer:

- Schleswig-Holstein,
- Hamburg,
- Bremen,
- Saarland.

Regierungsbezirke:

- Braunschweig, Hannover, Weser-Ems and Lüneburg within Bundesland Lower Saxony,
- Detmold, Arnsberg, Cologne, Münster and Düsseldorf within Bundesland North-Rhine Westphalia,
- Koblenz, Rheinhessen-Pfalz and Trier within Bundesland Rhine Palatinate,
- Stuttgart, Karlsruhe, Freiburg and Tübingen within Bundesland Baden-Württemberg,
- Niederbayern, Oberfranken, Oberpfalz, Unterfranken, Mittelfranken und Oberbayern within Bundesland Bavaria.

CHAPTER 2

France

Departments:

- Eure and Seine-Maritime within the Haute-Normandie region,
- Calvados, Manche and Orne within the Basse-Normandie region,
- Côtes d'Armor, Finistère, Ile-et-Vilaine and Morbihan within the region of Brittany,
- Loire Atlantique, Maine et Loire, Mayenne, Sarthe and Vendée within the region of Pays de Loire,
- Charente, Charente-Maritime, Deux-Sèvres and Vienne within the Poitou-Charentes region,
- Dordogne, Gironde, Landes, Lot-et-Garonne and Pyrénées-Atlantiques within the Aquitaine region,
- Ariège, Aveyron, Haut-Garonne, Gers, Lot, Hautes-Pyrénées, Tarn and Tarn-et-Garonne within the Midi-Pyrénées region,
- Aude, Gard, Hérault, Lozère, Pyrénées-Orientales within Languedoc,
- Nord and Pas-de-Calais within Nord-Pas-de-Calais,
- Meurthe-et-Moselle, Meuse, Moselle and Vosges within the region of Lorraine,
- Cher, Indre, Indre-et-Loire, Loir-et-Cher, Loiret and Eure-et-Loire within the Centre region,
- Côte d'or, Nièvre, Saône-et-Loire and Yonne within the region of Burgundy,
- Allier, Cantal, Haute-Loire and Puy-de-Dôme within the region of Auvergne,
- Doubs, Jura, Haute-Saône, territoire de Belfort within the region of Franche-Comté,
- Corrèze, Creuse, Haute-Vienne within the Limousin region,
- Aisne, Oise, Somme within the region of Picardie,
- Alpes-de-Haute Provence, Hautes-Alpes, Alpes-Maritimes, Bouches-du-Rhône, Var, Vaucluse within the region of Provence-Alpes-Côtes d'Azur,
- Ain, Ardèche, Drôme, Isère, Rhône, Savoie, Haute-Savoie within the region of Rhône-Alpes,
- Aube, Marne, Haute Marne and Ardennes within the region of Champagne-Ardenne,
- Haut-Rhin and Bas-Rhin within the region of Alsace,
- Ville-de-Paris, Seine-et-Marne, Yvelines, Essonne, Hauts-de-Seine, Seine-Saint-Denis, Val-de-Marne and Val d'Oise within the Ile-de-France region.

CHAPTER 3

Belgium

The provinces:

- Brabant,
 - Hainaut,
 - Liège,
 - Limbourg,
 - Luxembourg,
 - Namur,
 - West Flanders,
 - East Flanders.
-

ANNEX II

Parts of the territory of the Community which are recognized as being swine fever free

CHAPTER 1

Germany

Land: Berlin

Regierungsbezirke:

- Chemnitz, Cottbus, Darmstadt, Dresden, Erfurt, Frankfurt, Gera, Giessen, Halle, Kassel, Leipzig, Magdeburg, Neubrandenburg, Potsdam, Rostock, Schwaben, Schwerin and Suhl.

CHAPTER 2

Belgium

The province of Antwerp.

CHAPTER 3

France

Departments:

- Haute Corse and Corse du Sud within the region of Corsica.

CHAPTER 4

Italy

The provinces:

- Alessandria, Asti, Cuneo, Novara, Torino and Vercelli (Piemonte region),
- Valle d'Aosta,
- Bergamo, Brescia, Como, Cremona, Mantova, Milan, Pavia, Sondrio and Varese (Lombardy region),
- Bolzano and Trento (Trentino Alto Adige region),
- Belluno, Padua, Rovigo, Treviso, Venezia, Verona and Vicenza (Veneto region),
- Gorizia, Pordenone, Trieste and Udine (region of Friuli-Venezia Giulia),
- Genova, Imperia, La Spezia and Savona (region of Liguria),
- Bologna, Ferrara, Forlì, Modena, Parma, Piacenza, Ravenna and Reggio Emilia (Emilia Romagna region),
- Perugia and Terni (Umbria region),
- Ancona, Ascoli Piceno, Macerata and Pesaro (Marche region),
- Frosinone, Latina, Rieti, Rome and Viterbo (Lazio region),
- Chieti, L'Aquila, Pescara and Teramo (Abruzzi region),
- Campobasso and Isernia (Molise region),
- Avellino, Benevento, Caserta, Naples and Salerno (Campania region),
- Bari, Brindisi, Foggia, Lecce and Taranto (Puglie region),
- Matera and Potenza (Basilicata region),
- Cantazaro, Cosenza and Reggio Calabria (Calabria region),
- Arezzo, Florence, Lucca, Pistoia and Massa Carrara (Toscana region),
- Agrigento, Caltanissetta, Catania, Enna, Messina, Palermo, Ragusa, Siracusa and Trapani (Sicily region).