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Legislation

Contents

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

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

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 14 June 1988

amending Directive 64/432/EEC as regards enzootic bovine leukosis and repealing Directive 80/1102/EEC

(88/406/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 (3),

Whereas one of the tasks of the Community in the veterinary field is to improve the state of health of livestock, and thus to make stock-breeding more profitable;

Whereas there is a need to protect the Community against enzootic bovine leukosis; whereas the Community, by Directives 77/391/EEC (4) and 78/52/EEC (5), and by Decision 87/58/EEC (6) has already taken measures to eradicate this disease;

Whereas such measures must contribute to the abolition of barriers to trade in live animals between Member States, which are due to differences in health situations;

Whereas to that end measures for protection against enzootic bovine leukosis were introduced until 31 December 1987, by Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (7), as last amended by Regulation (EEC) No 3805/87 (8);

Whereas such measures should be extended, whilst recognizing new methods of detection of enzootic bovine leukosis;

Whereas, at the end of a transitional period, special rules laid down by the current arrangements for countries which applied national programmes for the combat of this disease, should be cancelled;

Whereas rules should be laid down for the qualification of herds with regard to enzootic bovine leukosis;

Whereas Member States must, in order to qualify their herd, implement a programme such that their herds undergo one of the tests for detecting leukosis laid down in Annex G to Directive 64/432/EEC;

Whereas, with the exception of animals for slaughter of less than 30 months, animals intended for intra-Community trade must come from a tested herd and have undergone an individual test,

HAS ADOPTED THIS DIRECTIVE:

Article 1

As from 1 July 1988, Directive 64/432/EEC is hereby amended as follows:

(1) OJ No C 5, 9. 1. 1988, p. 5.
(2) OJ No C 49, 22. 2. 1988, p. 164.
(3) OJ No C 80, 28. 3. 1988, p. 34.
(4) OJ No L 145, 13. 6. 1977, p. 44.
(5) OJ No L 15, 19. 1. 1978, p. 34.
(6) OJ No L 24, 27. 1. 1987, p. 51.
(7) OJ No 121, 29. 7. 1964, p. 1977/64.
(8) OJ No L 357, 19. 12. 1987, p. 1.

1. the following is added to Article 2:

'(s) 'Enzootic bovine leukosis free herd' means: a herd in which:

(i) there is no evidence, either clinical or as a result of tests carried out in accordance with Annex G, of any case of enzootic bovine leukosis nor has any such case been confirmed in the previous two years;

(ii) the animals over 24 months of age have, during the previous 12 months reacted negatively to two tests carried out in accordance with Annex G, at intervals of at least four months or, in the case of a herd which has already satisfied that requirement, have reacted negatively to a single test carried out in accordance with that Annex;

(iii) from the date of the first inspection, there are only animals born in the herd, or which have come from an enzootic bovine leukosis free herd.';

2. the following is added to Article 3 (2):

'(j) in the case of pure-bred breeding bovine animals, as defined in Article 1 of Directive 77/504/EEC, which are intended solely for reproductive purposes and are highly valuable, come from a herd:

(i) in which no facts have been brought to the notice of the official veterinarian which would lead him to conclude that a case of enzootic bovine leukosis has occurred within the preceding two years;

(ii) the owner of which has declared that he has no knowledge of such facts and has further declared in writing that the animal or animals intended for intra-Community trade have either been born and reared in the said herd or have remained an integral part of it for the previous 12 months.';

3. the following is added to Article 3 (3):

'(d) come from a herd in which there has been no evidence of enzootic bovine leukosis during the preceding two years and, if they are more than 12 months of age, have reacted negatively to an individual test carried out in accordance with Annex G during the 30 days before they are loaded.

However, this test will not be required in the case of male bovine animals and bullocks less than 30 months of age intended for meat production, provided that such animals are identified by a special mark when they are loaded and that the Member State takes all measures to prevent contamination of indigenous herds.';

4. the following is added to Article 7 (1):

'G. Female bovine animals less than 30 months of age intended for meat production which, by way of derogation from Article 3 (3) (d), have not been subjected to an individual test. Such animals must bear a special mark. The Member State of destination shall take all measures to prevent contamination of indigenous herds.';

5. the following is added to Article 8 (2):

'With particular regard to enzootic bovine leukosis and in the case of the animals referred to in Article 3 (2) (j). Member States are authorized to require in addition, subject to compliance with the general provisions of the Treaty, that all members of the herd from which the animals come and more than 24 months of age at the date of the test have in the previous 12 months reacted negatively to a test carried out in accordance with Annex G. However, such guarantees shall not be required upon the introduction of animals from a Member State which, in accordance with the procedure laid down in Article 12, is recognized as providing adequate guarantees as regards enzootic bovine leukosis.';

6. the following Article is inserted:

'Article 8a

1. Member States which since 1980 have been applying a compulsory national programme for the eradication of enzootic bovine leukosis may make the introduction into their territory of bovine animals for breeding or production intended for combining with bovine herds not suspected of having leukosis, conditional upon the production of a certificate issued on the day of loading by a competent official veterinarian and drawn up, as a minimum requirement, in the language or languages of the country of destination, certifying:

(a) that the veterinarian has no knowledge of facts which would lead him to conclude that a case of enzootic bovine leukosis has occurred within the three preceding years in the herd from which they come, and that the owner of this herd has declared that he has no knowledge of such facts and that he has further declared, in writing, that the animal or animals intended for intra-Community trade have been born and reared in the said herd or have remained an integral part of it for the previous 12 months;

(b) that during the previous 12 months all the bovine animals over 24 months of age on the date of the test and forming part of the herd from which they come have reacted negatively to a test carried out in accordance with Annex G.

2. In accordance with the procedure laid down in Article 12, Member States other than those referred to in

paragraph 1 may be authorized to apply the same requirements for their territory or, in the case of the United Kingdom, for Northern Ireland, if a plan for the eradication of enzootic bovine leukosis is being implemented therein pursuant to Decision 87/58/EEC, or if it can be proved that on the date on which the matter is referred to the Standing Veterinary Committee they have been applying therein for at least two years a minimum eradication programme including the following minimum requirements:

— all tumours in the organs and the lymphatic system of bovines must be notified and must be examined histologically by a veterinary laboratory which is directly supervised by a laboratory mentioned in Annex G,

— all cattle in herds which have had contagious contact with an animal found to be suffering from leukotic tumours shall be subjected to a test for enzootic bovine leukosis carried out in accordance with the requirements of Annex G and in a laboratory directly supervised by a laboratory mentioned in that Annex,

— in a herd in which an animal is found to be afflicted with a leukotic tumour and the diagnosis of enzootic bovine leukosis has been confirmed, infected animals may be removed only for slaughter under the supervision of the veterinary authorities. The herd should remain under official supervision until such time as it has shown a negative reaction to at least two tests carried out at at least four-monthly intervals on all the cattle over 24 months of age and in accordance with the requirements of Annex G in a laboratory directly supervised by a laboratory mentioned in Annex G.

The additional conditions to which this extension to each Member State or part thereof concerned may be subject may be specified in the decision provided for in the first subparagraph.';

7. the following is added at the end of (a) of Annex E:

'— enzootic bovine leukosis.';

8. Annex F, Model I:

(a) V:

(aa) the following is added after (d):

'(e) — for the previous 12 months (5) or, if less than 12 months of age, since birth, they have been kept in a herd in which, during the preceding three years (5) to the knowledge of the undersigned and as declared by their owner, no cases of enzootic bovine leukosis have been diagnosed (2) (12),

— they come from a herd in which there has been no evidence of enzootic bovine leukosis during the preceding three years (2),

— on the date of their examination, all the animals more than 24 months old had within the previous 12 months (5) undergone (2) (12) a test (13) the result of which proved negative,

— within the prescribed 30 days (5), they have given a negative reaction (2) (5) (11) to an individual test (13) for enzootic bovine leukosis,

— they are intended for fattening (2) (11);'

(bb) (e) to (i) become (f) to (j) respectively;

(b) the following are added after footnote (10):

'(11) This exception is permitted only in the case of male animals less than 30 months of age intended for fattening and provided that the animals are marked in a different manner and undergo a special check in the country of destination.

(12) This is unnecessary except in the case of pure-bred breeding animals intended solely for reproductive purposes and which are highly valuable.

(13) The individual test was carried out in accordance with Annex G to Directive 64/432/EEC.';

9. Annex G annexed to this Directive is added.

Article 2

As from 1 July 1990, Directive 64/432/EEC is hereby amended as follows:

1. Article 3 (2) (j) is deleted;

2. Article 3 (3) (d) is replaced by the following and (e) to (f) are added:

'(d) come from an enzootic bovine leukosis free herd within the meaning of Article 2 (s);

(e) in addition to the condition under (d) where they are over 12 months of age, have reacted negatively to an individual test carried out in accordance with Annex G during the 30 days before they were loaded;

(f) not be subject to the requirements of (d) and (e) if they are under 30 months of age and intended for meat production, if they:

(i) come from a herd in which no case of enzootic bovine leukosis has been notified and confirmed within the previous 2 years;

(ii) they are identified by a special mark when they are loaded and they remain under supervision until they are slaughtered;

provided that the Member State of destination takes all the measures necessary to prevent contamination of indigenous herds.';

3. Article 7 (1) G is deleted;

4. Article 8 (2), the last subparagraph is deleted;

5. Article 8a is deleted;

6. in Model I of Annex F:

— V (e) is replaced by the following:

'(e) — the previous 12 months (5) or, if less than 12 months of age (5), since birth, they have been kept in an enzootic bovine leukosis free herd (2) (11),

— within the prescribed 30 days (5) they have given a negative reaction to an individual test (12) for the detection of enzootic bovine leukosis (2) (11),

— they are intended for fattening (11).';

— footnote (11) is replaced by the following:

'(11) This exception is permitted only in the case of bovine animals less than 30 months of age intended for fattening, and provided that the animals:

— come from a herd in which no case of enzootic bovine leukosis has been notified and confirmed during the preceding two years,

— are marked in a different manner and undergo a special check in the country of destination.';

— footnote (12) is deleted,

— footnote (13) becomes footnote (12).

Article 3

1. In order to qualify their herds as enzootic bovine leukosis free, Member States shall implement a programme, such that their herds undergo one of the tests referred to in Annex G to Directive 64/432/EEC.

2. Member States shall notify the Commission at least once a year of the progress of their programmes, and the results obtained.

Article 4

The Council, acting on a proposal from the Commission, shall, before 1 January 1990, lay down the criteria permitting a Member State or part of the territory of a Member State to be recognized as being free from enzootic bovine leukosis and the conditions to be implemented to guarantee the maintenance of such status, as well as the rules applicable to trade from enzootic bovine leukosis free regions or Member States.

Article 5

Member States shall bring into force the necessary provision to comply with the requirements of:

— Articles 1 and 3 not later than 1 July 1988,

— Article 2 not later than 1 July 1990.

They shall forthwith inform the Commission thereof.

Article 6

Directive 80/1102/EEC (1) is hereby repealed.

Article 7

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1988.

For the Council

The President

I. KIECHLE

(1) OJ No L 325, 1. 12. 1980, p. 18.

ANNEX

'ANNEX G

TESTS FOR ENZOOTIC BOVINE LEUKOSIS

Tests for enzootic bovine leukosis shall be carried out by the immuno-diffusion test under the conditions described in points A and B below or by the enzyme-linked immunosorbent assay (Elisa) under the conditions described in point C below. The immuno-diffusion method may only be used for individual tests.

If test results are the subject of a duly-substantiated challenge, an additional check shall be carried out by means of the immuno-diffusion test.

A. Agar gel immuno-diffusion test for enzootic bovine leukosis

1. The antigen to be used in the test must contain bovine leukosis virus glycoproteins. The antigen must be standardized against a standard serum (El serum) supplied by the State Veterinary Serum Laboratory, Copenhagen.

2. The official institutes indicated below must be made responsible for calibrating the standard working antigen of the laboratory against the official EEC standard serum (El serum) provided by the State Veterinary Serum Laboratory, Copenhagen.

(a)	Germany:	Bundesforschungsanstalt für Viruskrankheiten der Tiere, Tübingen
(b)	Belgium:	Institut national de recherches vétérinaires, Bruxelles
(c)	France:	Laboratoire national de pathologie bovine, Lyon
(d)	Grand Duchy of Luxembourg:	—
(e)	Italy:	Istituto Zooprofilattico Sperimentale, Perugia
(f)	Netherlands:	Centraal Diergeneeskundig Instituut, Afdeling Rotterdam
(g)	Denmark:	Statens Veterinære Serum Laboratorium, Copenhagen
(h)	Ireland:	Veterinary Research Laboratory, Abbotstown, Dublin
(i)	United Kingdom:	
	1. Great Britain:	The Central Veterinary Laboratory, Weybridge, England
	2. Northern Ireland:	The Veterinary Research Laboratory, Stormont, Belfast
(j)	Spain:	Laboratorio de Sanidad y Produccion Animal de Barcelona
(k)	Portugal:	Laboratório Nácional de Investigação Veterinária, Lisboa

3. The standard antigens used in the laboratory must be submitted at least once a year to the EEC reference laboratories listed in paragraph 2 above for testing against the official EEC standard serum. Apart from this standardization the antigen in use can be calibrated in accordance with B.

4. The reagents for the test shall consist of:

   (a) antigen: the antigen must contain specific glycoproteins of enzootic bovine leukosis virus which has been standardized against the official EEC serum;

   (b) the test serum;

   (c) known positive control serum;

   (d) Agar gel,

   0,8 % agar,

   8,5 % NaCl,

   0,05 M Tris-buffer pH 7,2,

   15 ml of this agar must be introduced into a petri dish of 85 mm diameter, resulting in a depth of 2,6 mm of agar.

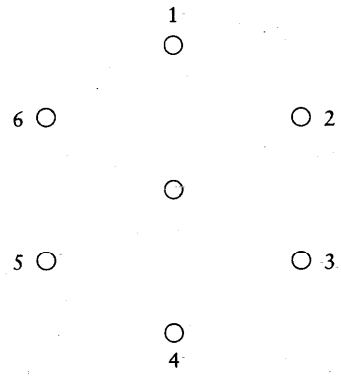
5. A test pattern of seven moisture-free wells be cut in the agar to the bottom of the plate; the pattern must consist of one central well and six wells in a circle around it.

   Diameter of central well: 4 mm

   Diameter of peripheral wells: 6 mm

   Distance between central and peripheral wells: 3 mm

6. The central well must be filled with the standard antigen. The peripheral wells 1 and 4 (see diagram below) are filled with the known positive serum, the wells 2, 3, 5 and 6 with the test sera. The wells must be filled until the meniscus disappears.



7. This results in the following quantities being obtained:

antigen:	32 µl;
control serum:	73 µl;
test serum:	73 µl.

8. Incubation must be for 72 hours at room temperature (20 to 27 °C) in a closed humid chamber.

9. The test may be read at 24 and 48 hours but a final result may not be obtained before 72 hours:

   (a) a test serum is positive if it forms a specific precipitin line with the BLV antigen and forms a complete line of identity with the control serum;

   (b) a test serum is negative if it does not form a specific precipitin line with the BLV antigen and if it does not bend the line of the control serum;

   (c) the reaction cannot be considered conclusive if it:

      (i) bends the line of the control serum towards the BLV antigen well without forming a visible precipitin line with the antigen;

      or

      (ii) if it cannot be read either as negative or as positive.

   In inconclusive reactions the test may be repeated and concentrated serum utilized.

B. Method for antigen standardization

Solutions and materials required:

1. 40 ml of 1,6 % agarose in 0,05 % M Tris/HCl buffer, pH 7,2 with 8,5 % NaCl.
2. 15 ml of a bovine leukosis serum, having antibody only to bovine leukosis virus glycoproteins, diluted 1:10 in 0,05 M Tris/HCl buffer, pH 7,2 with 8,5 % NaCl.
3. 15 ml of a bovine leukosis serum, having antibody only to bovine leukosis virus glycoproteins, diluted 1:5 in 0,05 M Tris/HCl buffer, pH 7,2 with 8,5 % NaCl.
4. Four plastic petri dishes with a diameter of 85 mm.
5. A punch with a diameter of 4 to 6 mm.
6. A reference antigen.
7. The antigen which is to be standardized.
8. A water bath (56 °C).

Procedure:

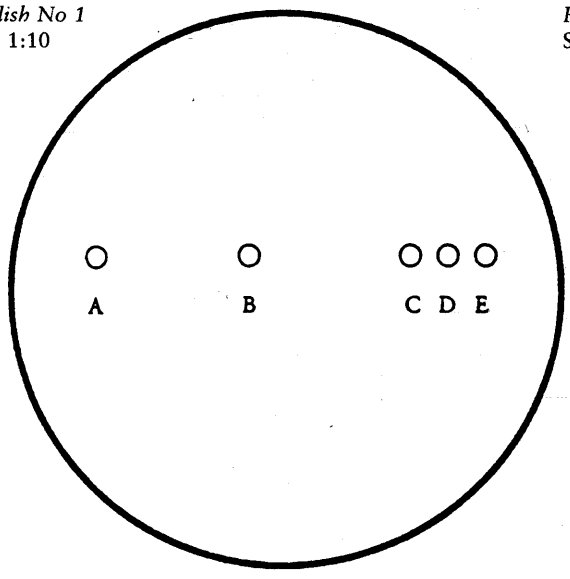
Dissolve the agarose (1,6 %) in the Tris/HCl buffer by carefully heating to 100 °C. Place in 56 °C water bath for approximately one hour. Also, place the bovine leukosis serum dilutions in 56 °C water bath.

Now, mix 15 ml of the 56 °C agarose solution with the 15 ml bovine leukosis serum (1:10), quickly shake and pour 15 ml into each of two petri dishes.

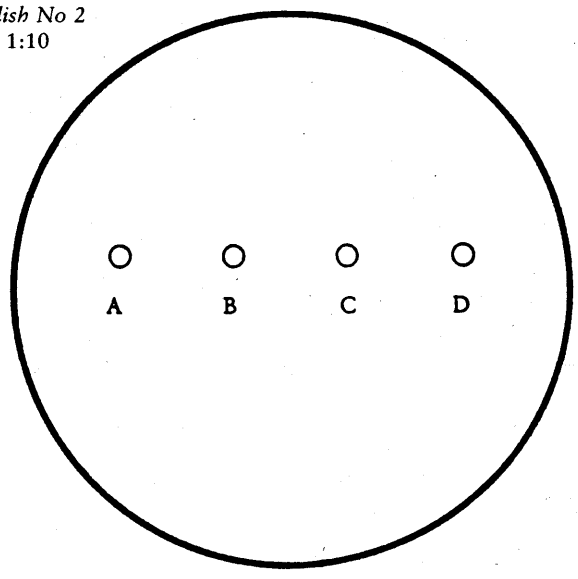
Repeat this procedure with the bovine leukosis serum diluted 1:5.

When the agarose has hardened, holes are made in it as follows:

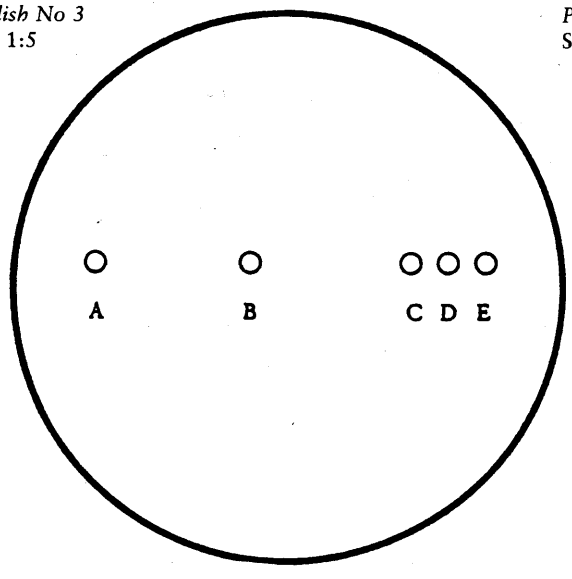
Petri dish No 1
Serum 1:10



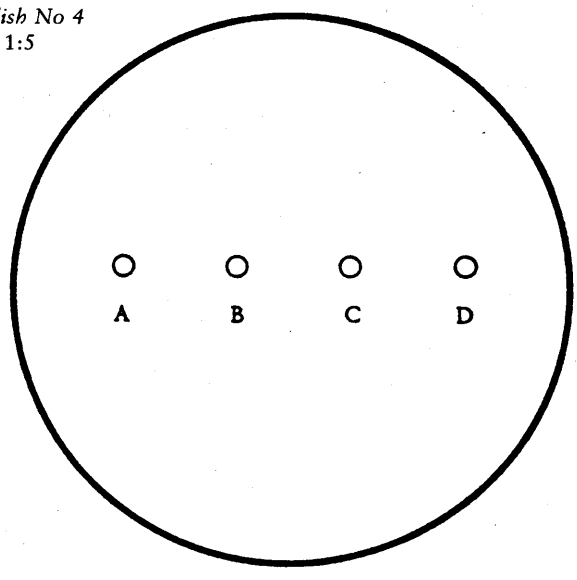
Petri dish No 2
Serum 1:10



Petri dish No 3
Serum 1:5



Petri dish No 4
Serum 1:5



Addition of antigen:

I. Petri dishes 1 and 3

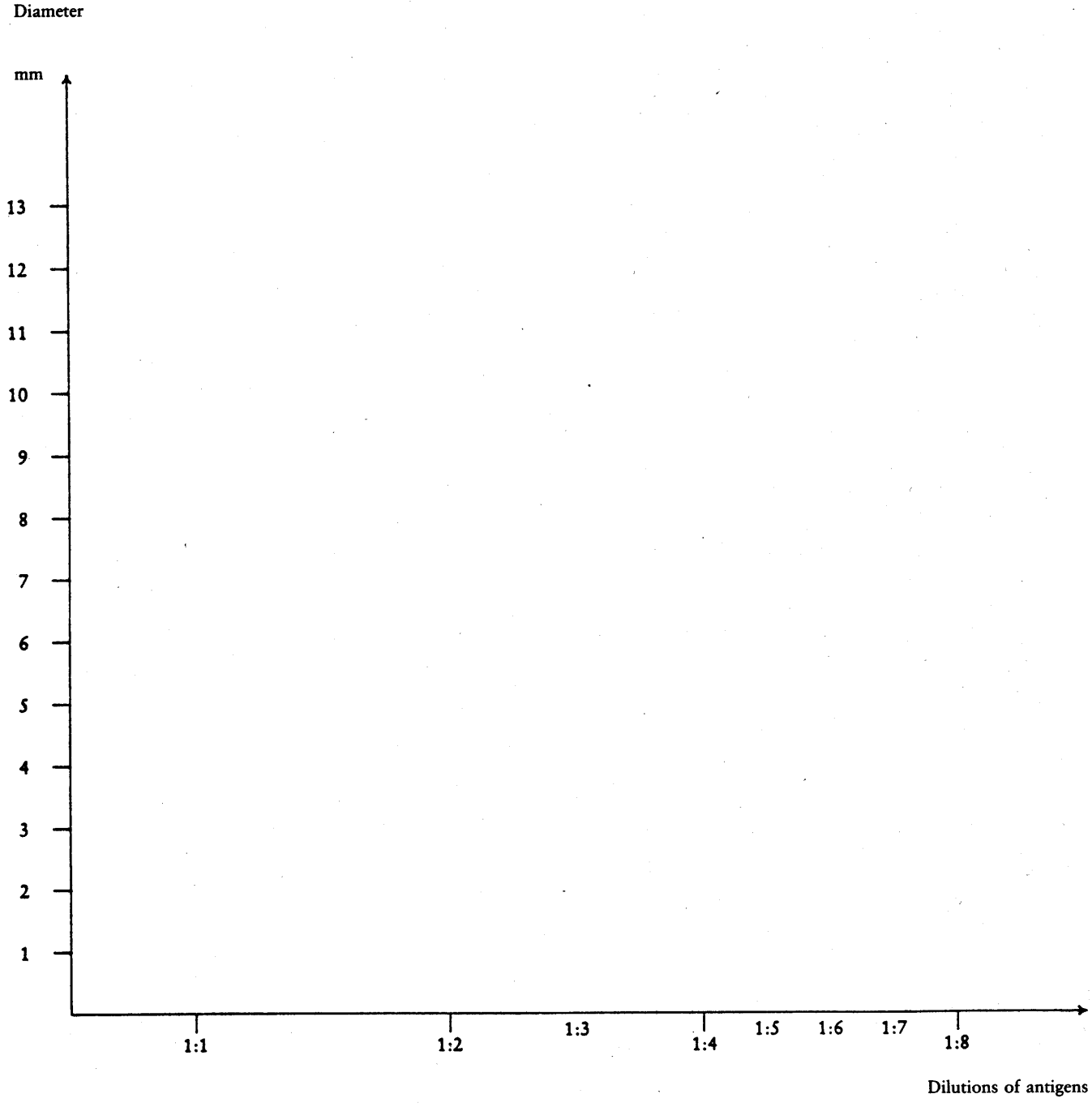
well A = undiluted reference antigen,
well B = 1:2 diluted reference antigen,
wells C and E = reference antigen,
well D = undiluted antigen to be tested.

II. Petri dishes 2 and 4

well A = undiluted test antigen,
well B = 1:2 diluted test antigen,
well C = 1:4 diluted test antigen,
well D = 1:8 diluted test antigen.

Additional instructions:

1. The experiment shall be carried out with two serum dilutions (1:5 and 1:10) in order to achieve optimal precipitation.
2. If the precipitation diameter is too small with both dilutions, then the serum must be further diluted.
3. If the precipitation diameter in both dilutions is too large and faint, then a lower serum must be chosen.
4. The final concentration of the agarose must be 0,8 %; that of the sera 5 % and 10 % respectively.
5. Plot the measured diameters in the following coordinate system. The dilution of the antigen to be tested with the same diameter as the reference antigen is the working dilution.



C. **Enzyme-linked immunosorbent assay (Elisa) for enzootic bovine leukosis**

1. For the Elisa method, the materials and reagents to be used are as follows:

   (a) solid phase microplates, cuvettes or any other solid phase;

   (b) the antigen is fixed to the solid phase with or without the aid of polyclonal or monoclonal catching antibodies. If antigen is coated directly to the solid phase all test samples giving positive reactions have to be retested against control antigen. The control antigen should be identical to the antigen except for the BLV antigens. If catching antibodies are coated to the solid phase the antibodies must not react to other antigens other than BLV antigens;

   (c) the bilogical fluid to be tested (serum or milk);

   (d) a positive and negative control;

   (e) conjugate — an antibovine immunoglobulin biotinylated or enzyme conjugated or an anti-BLV immunoglobulin biotinylated or enzyme conjugated;

   (f) avidin — enzyme for assays using biotynilated immunoglobulin preparations;

   (g) a substrate adapted to the enzyme used;

   (h) a stopping solution;

   (i) buffered solutions for the dilution of the test samples for preparations of the reagents and for washing;

   (j) a reading system with appropriate filters corresponding to the substrate used.

2. *Standardization and sensitivity of test*

   The sensitivity of the Elisa assay must be of such a level that E4 serum is scored positive when diluted 10 times (serum samples) or 250 times (milk samples) more than the dilution obtained of individual samples when these are included in pools.

   In assays where samples (serum and milk) are tested individually E4 serum diluted 1 to 10 (in negative serum) or 1 to 250 (in negative milk) must be scored positive when tested in the same assay dilution as used for the individual test samples.

   The E4 serum will be supplied by the National Veterinary Laboratory, Copenhagen.

3. *Conditions for use of the Elisa test*

   The Elisa method may be used on a sample of milk taken from the milk collected from a farm with at least 30 % of dairy cows in milk on condition that the sample comes from the milk produced by less than 50 cows, and from a whey concentration if collected from between 20 and 50 cows maximum, and that, if the milk collected comes from more than 50 cows, the number of samples is increased proportionally.

   The Elisa method may also be used on a blood sample taken from a maximum of 50 animals.

   If use is made of one of these abovementioned possibilities, measures must be taken to ensure that the samples taken can be identified with the animals from which the milk or sera examined were taken.

   If one of the samples scores positive, the herd must remain under official supervision until a negative result has been recorded for at least two individual tests carried out, at a minimum interval of four months, on all cattle aged more than six months, in accordance with the abovementioned provisions and in a laboratory that is directly supervised by a laboratory mentioned in point A.'

COUNCIL DIRECTIVE

of 14 June 1988

laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species

(88/407/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 (3),

Whereas provisions relating to animal health problems in intra-Community trade in bovine animals and swine appear in Directive 64/432/EEC (4), as last amended by Regulation (EEC) No 3768/85 (5); whereas in addition, Directive 72/462/EEC (6), as last amended by Regulation (EEC) No 3768/85 contains provisions relating to veterinary inspection problems upon importation of bovine animals and swine from third countries;

Whereas the abovementioned provisions have ensured, with regard to intra-Community trade and imports into the Community of bovine animals and swine from third countries, that the country of provenance guarantees that animal health criteria have been fulfilled so that the risk of animal disease spreading has been virtually eliminated; whereas there is nevertheless a certain risk of the spread of such disease in the case of trade in semen;

Whereas in the context of the Community policy of harmonizing national animal health provisions governing intra-Community trade in animals and animal products, it is now necessary to create a harmonized system for intra-Community trade and imports into the Community of semen of bovine animals;

Whereas, in the context of intra-Community trade in semen, the Member State where the semen is collected should be under an obligation to ensure that such semen has been collected and processed at approved and supervised semen collection centres, has been obtained from animals whose health status is such as to ensure that the risk of spread of animal disease is eliminated, has been collected, processed, stored and transported in accordance with rules which preserve its health status and is accompanied during transport to the country of destination by an animal health certificate in order to ensure that this obligation has been fulfilled;

Whereas the difference in the policies pursued within the Community with regard to vaccination against certain diseases justifies the maintenance of derogations, limited in time, authorizing the requirement by the Member States, in respect of certain diseases, of additional protection against those diseases;

Whereas for imports of semen into the Community from third countries a list of third countries should be drawn up taking into account animal health criteria; whereas without prejudice to such a list the Member States should authorize importation of semen only from semen collection centres which reach certain standards and which are officially supervised; whereas, in addition, in respect of countries on that list, specific animal health conditions should be laid down according to circumstances; whereas, in order to verify compliance with these standards, on-the-spot checks may be carried out;

Whereas a procedure should be provided for the purpose of settling any disputes which arise between Member States as to whether approval of a collection centre is justified;

Whereas the Member States may refuse a consignment of semen where it has been established that it does not comply with the provisions of this Directive; whereas it must be possible to return such semen if this is not contrary to considerations of animal health and if the consignor or his representative so requests; whereas the consignor or his representative should be allowed to know the reasons for a prohibition or restriction and to obtain the opinion of an expert;

Whereas in order to prevent the transmission of certain contagious diseases, import controls should be carried out when a consignment of semen arrives on the territory of the Community, except in the case of external transit;

(1) OJ No C 267, 6. 10. 1983, p. 5.
(2) OJ No C 342, 19. 12. 1983, p. 11.
(3) OJ No C 140, 28. 5. 1984, p. 6.
(4) OJ No 121, 29. 7. 1964, p. 1977/64.
(5) OJ No L 362, 31. 12. 1985, p. 8.
(6) OJ No L 302, 31. 12. 1972, p. 28.

Whereas after such control, in the case of internal transit, the measures to be taken by Member States must be defined;

Whereas a Member State should be permitted to take emergency measures in the event of an outbreak of a contagious disease in another Member State or in a third country; whereas the dangers associated with such diseases and the protective measures they necessitate should be assessed in the same way throughout the Community; whereas to that end, an emergency Community procedure under which the necessary measures must be taken should be instituted within the Standing Veterinary Committee;

Whereas the Commission should be entrusted with taking certain measures for implementing this Directive; whereas to that end, a procedure should be established for close and effective cooperation between the Commission and the Member States within the Standing Veterinary Committee;

Whereas this Directive does not affect trade in semen produced before the date on which the Member States must comply with it.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

General provisions

Article 1

This Directive lays down the animal health conditions applicable to intra-Community trade in and imports from third countries of deep-frozen semen of domestic animals of the bovine species.

Article 2

For the purposes of this Directive, the definitions contained in Article 2 of Directive 64/432/EEC and Article 2 of Directive 72/462/EEC shall apply as necessary.

Moreover:

(a) 'semen' means the prepared or diluted ejaculate of a domestic animal of the bovine species;

(b) 'semen collection centre' means an officially approved and supervised establishment situated in the territory of a Member State or third country, in which semen is produced for use in artificial insemination;

(c) 'official veterinarian' means the veterinarian designated by the competent central authority of a Member State or a third country;

(d) 'centre veterinarian' means the veterinarian responsible for day-to-day compliance in the centre with the requirements laid down in this Directive;

(e) 'consignment' means a quantity of semen covered by a single certificate;

(f) 'country of collection' means the Member State or third country in which semen is collected and from which it is sent to a Member State;

(g) 'approved laboratory' means a laboratory situated in the territory of a Member State or third country designated by the competent veterinary authority to carry out the tests laid down in this Directive;

(h) 'collection' means a quantity of semen taken from a donor at any time.

CHAPTER II

Intra-Community trade

Article 3

Each Member State shall ensure that only semen meeting the following general conditions is sent from its territory to the territory of another Member State;

(a) it must have been collected and processed, for the purpose of artificial insemination, in a semen collection centre approved from the point of view of animal health for the purposes of intra-Community trade in accordance with Article 5 (1);

(b) it must have been collected from domestic animals of the bovine species whose health status complies with Annex B;

(c) it must have been collected, processed, stored and transported in accordance with Annexes A and C;

(d) it must be accompanied, during transport to the country of destination, by an animal health certificate complying with Article 6 (1).

Article 4

1. Without prejudice to paragraph 2, Member States shall, until 31 December 1992 authorize the admission of semen from bulls giving a negative reaction to the serum neutralization test or the Elisa test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis or showing a positive result after vaccination in accordance with this Directive.

Member States may, until 31 December 1992, authorize the admission of semen of bulls giving a positive reaction to the serum neutralization test or the Elisa test for infectious bovine rhino-tracheitis/infectious pustular vulvo-vaginitis and not having been vaccinated in accordance with this Directive.

In that case, each consignment must pass an examination by inoculation into a live animal and/or a virus isolation test.

This requirement shall not apply in respect of the semen of animals which, prior to their first vaccination at the insemination centre, reacted negatively to the tests referred to in the first paragraph.

These examinations can, by bilateral agreement, be carried out either in the country of collection or in the country of destination.

Before 1 January 1992, the Council shall review this paragraph on the basis of a Commission report accompanied, if appropriate, by proposals.

2. Member States in which all centres contain only animals giving a negative reaction to the serum neutralization test or the Elisa test may refuse admission to their territory of semen from centres which do not have that status.

In accordance with the procedure referred to in Article 19, it may be decided to extend the above provisions to part of the territory of a Member State if all the centres of that part of the territory contain only animals giving a negative reaction to the serum neutralization test or the Elisa test.

3. Without prejudice to other Community provisions, Member States which do not practise vaccination against foot-and-mouth disease may not oppose the admission of semen from animals vaccinated in accordance with this Directive.

In that event, up to 10 % of the semen from each collection intended for trade (with a minimum of five straws) may be subjected to a virus isolation test for foot-and-mouth in a laboratory in the Member States of destination or in a laboratory specified by that Member State. If the result is positive, admission of the semen may be refused.

Article 5

1. The Member State on whose territory the semen collection centre is situated shall ensure that the approval provided for in Article 3 (a) is granted only where the provisions of Annex A are observed and where the semen collection centre is able to satisfy the other provisions of this Directive.

The Member State shall also ensure that the official veterinarian supervises the observance of those provisions and shall withdraw approval when one or more of the provisions is no longer observed.

2. All approved semen collection centres shall be registered, each centre being given a veterinary registration number. Each Member State shall send a list of semen collection centres and their veterinary registration numbers to the other Member States and to the Commission and shall notify them of any withdrawal of approval.

When a Member State considers that the provisions governing approval are not, or are no longer, observed in a semen collection centre in another Member State, it shall inform the competent authority of the State. The latter shall then take all necessary measures and notify the competent authority of the other Member State of the decisions taken and the reasons for them.

If that other Member State fears that the necessary measures have not been taken or are inadequate, it shall so inform the Commission, which shall seek the opinion of one or more veterinary experts. In the light of that opinion, Member States may be authorized, in accordance with the procedure laid down in Article 19, to prohibit temporarily the admission of semen coming from the centre in question.

Such authorization may be withdrawn in accordance with the procedure laid down in Article 19 in the light of a fresh opinion delivered by one or more veterinary experts.

The veterinary experts must be nationals of a Member State other than those involved in the dispute.

The general rules for applying this Article shall be adopted in accordance with the procedure laid down in Article 18.

Article 6

1. Member States shall make the admission of semen conditional upon submission of an animal health certificate drawn up by an official veterinarian of the Member State of collection in accordance with Annex D.

This certificate must:

(a) be drawn up in at least one of the official languages of the Member State of collection and one of those of the Member State of destination;

(b) accompany the consignment to its destination in its original form;

(c) be drawn up on a single sheet of paper;

(d) be made out to a single consignee.

2. (a) The Member State of destination may prohibit the admission of consignments if a documentary check reveals that Article 3 has not been observed.

(b) The Member State of destination may take the necessary measures, including storage in quarantine, in order to obtain definite proof in cases where semen is suspected of being infected or contaminated by pathogenic organisms.

(c) Decisions taken under (a) or (b) must, at the request of the consignor or his representative, authorize the return of the semen, provided this is not contrary to considerations of animal health.

3. If the admission of semen has been prohibited on any of the grounds set out in paragraph 2 (a) and (b) and the Member State of collection does not within 30 days authorize the return of the semen, the competent veterinary authority of the Member State of destination may order it to be destroyed.

4. The decisions taken by the competent veterinary authority under paragraphs 2 and 3 must be communicated to the consignor or his representative, together with the reasons therefor.

Article 7

1. Avenues of appeal provided for in current legislation in the Member States against decisions taken pursuant to this Directive by the competent authority shall not be affected by this Directive.

These reasoned decisions must, on request, be communicated to the consignor or his representative forthwith in writing, with an indication of what avenues of appeal against them are provided for in current legislation and of the form and time limits in which proceedings must be initiated. The decisions must also be communicated to the competent veterinary authority of the Member State of collection or provenance.

2. Each Member State shall grant to consignors in respect of whose consignments of semen such measures as are provided for in Article 6 (2) have been taken, the right to obtain, before other measures are taken by the competent authority, the opinion of a veterinary expert to determine whether Article 6 (2) has been complied with.

The veterinary expert must be a national of a Member State other than the Member State of collection or of destination.

The Commission shall, on a proposal from the Member States, draw up a list of veterinary experts who may be instructed to formulate such opinions. The general rules for applying this Article, and in particular the procedure to be followed in formulating these opinions, shall be adopted in accordance with the procedure laid down in Article 18.

CHAPTER III

Imports from third countries

Article 8

1. A Member State may authorize importation of semen only from those third countries which appear on a list drawn up in accordance with the procedure laid down in Article 19.

That list may be supplemented or amended in accordance with the procedure laid down in Article 18.

2. In deciding whether a third country may appear on the list referred to in paragraph 1, particular account shall be taken of:

(a) the state of health of the livestock, other domestic animals and wildlife in the third country, with particular reference to exotic animal diseases, and of the environmental health situation in that country, which might endanger animal health in the Member States;

(b) the regularity and rapidity of the information supplied by the third country concerning the existence of contagious animal diseases in its territory, in particular those diseases mentioned in lists A and B of the International Office of Epizootic Diseases;

(c) that country's rules on animal disease prevention and control;

(d) the structure of the veterinary services in the country and their powers;

(e) the organization and implementation of measures to prevent and control contagious animal diseases; and

(f) the guarantees which the third country can give with regard to compliance with this Directive.

3. The list referred to in paragraph 1 and all amendments thereto shall be published in the *Official Journal of the European Communities*.

Article 9

1. In accordance with the procedure laid down in Article 19, a list shall be drawn up of semen collection centres from which Member States may authorize the importation of semen originating in third countries. The list may be amended or supplemented according to the same procedure.

2. In deciding whether a semen collection centre in a third country may appear on the list referred to in paragraph 1, particular account shall be taken of the veterinary supervision of semen production systems in the third country, the powers of the veterinary services and the supervision to which semen collection centres are subject.

3. A semen collection centre may appear on the list provided for in paragraph 1 only if:

(a) it is situated in one of the countries on the list referred to in Article 8 (1);

(b) it fulfils the requirements of Chapters I and II of Annex A;

(c) it has been officially approved for exports to the Community by the veterinary services of the third country concerned;

(d) it is under the supervision of a centre veterinarian of the third country concerned; and

(e) it is subject to regular inspection by an official veterinarian of the third country concerned at least twice a year.

Article 10

1. Semen must come from animals which, immediately prior to collection of their semen, have remained for at least six months in the territory of a third country on the list drawn up in accordance with Article 8 (1).

2. Without prejudice to Article 8 (1) and paragraph 1 of this Article, the Member States shall not authorize the importation of semen from a third country on the list unless the semen complies with the animal health requirements adopted, in accordance with the procedure laid down in Article 18, for imports of semen from that country.

In adopting the requirements referred to in the preceding subparagraph, consideration shall be given to:

(a) the health situation in the area surrounding the semen collection centre, with particular reference to the diseases appearing on list A of the International Office of Epizootic Diseases;

(b) the state of health of the herd in the semen collection centre, including testing requirements;

(c) the state of health of the donor animal and testing requirements;

(d) testing requirements in relation to semen.

3. The reference basis for fixing animal health conditions in accordance with paragraph 2 for bovine tuberculosis and brucellosis shall be the standards laid down in Annex A to Directive 64/432/EEC. It may be decided, in accordance with the procedure laid down in Article 18, on a case-by-case basis, to waive these conditions where the third country concerned provides similar animal health guarantees; in that case, animal health conditions at least equivalent to those in Annex A to that Directive shall be laid down in accordance with the same procedure in order to permit the entry of such animals into semen collection centres.

4. Article 4 shall apply *mutatis mutandis*.

Article 11

1. Member States shall authorize the importation of semen only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection.

This certificate must:

(a) be drawn up in at least one of the official languages of the Member State of destination and one of those of the Member State where the import control provided for in Article 12 is carried out;

(b) accompany the semen in the original;

(c) be drawn up on a single sheet of paper;

(d) be made out to a single consignee.

2. The certificate must correspond to a specimen drawn up in accordance with the procedure laid down in Article 19.

Article 12

1. Member States shall ensure that each consignment of semen entering the customs territory of the Community is subjected to control before being released for free circulation or placed under a customs procedure and shall prohibit the introduction of such semen into the Community if the import control made on arrival reveals that:

— the semen does not come from the territory of a third country on the list drawn up in accordance with Article 8 (1),

— the semen does not come from a semen collection centre on the list provided for in Article 9 (1),

— the semen comes from the territory of a third country from which imports are prohibited in accordance with Article 15 (2),

— the animal health certificate which accompanies the semen is not in conformity with the conditions laid down in Article 11 and fixed pursuant thereto.

This paragraph shall not apply to consignments of semen which arrive in the customs territory of the Community and are placed under a customs transit procedure for consignment to a destination situated outside the said territory.

However, it shall be applicable where customs transit is waived during transport throught the territory of the Community.

2. The Member State of destination may take the necessary measures, including storage in quarantine, in order to obtain definite proof in cases where semen is suspected of being contaminated by pathogenic organisms.

3. If the introduction of semen has been prohibited on any of the grounds set out in paragraphs 1 and 2 and the exporting third country does not within 30 days authorize the return of the semen, the competent veterinary authority of the Member State of destination may order it to be destroyed.

Article 13

Each consignment of semen authorized for introduction into the Community by a Member State on the basis of the control referred to in Article 12 (1) must, when sent to the territory of another Member State, be accompanied by the original certificate or an authenticated copy thereof, suitably endorsed, in either case, by the competent authority which was responsible for the examination carried out in accordance with Article 12.

Article 14

If it is decided to take destruction measures pursuant to Article 12 (3), any costs incurred shall be chargeable to the consignor, the consignee or their agent, without compensation by the State.

CHAPTER IV

Safeguard and control measures

Article 15

1. A Member State may take the following measures if there is a danger of an animal disease spreading as a result of the introduction of semen into its territory from another Member State:

(a) in the event of an outbreak of an epizootic disease in the other Member State, it may temporarily prohibit or restrict the introduction of semen from the areas of that Member State where the disease has occurred;

(b) if an epizootic disease becomes widespread, or if there is an outbreak of a further contagious animal disease of a serious nature, it may temporarily prohibit or restrict the introduction of semen from the whole of the territory of that Member State.

Each Member State shall immediately inform the other Member States and the Commission of the outbreak on its territory of any disease covered by the first subparagraph and of the measures which it has taken to control that disease. It shall also notify them immediately of the disappearance of the disease.

2. Without prejudice to Article 8, 9 and 10, if in a third country a contagious animal disease which can be carried by semen and is liable to endanger the health of the livestock in a Member State breaks out or spreads or if any other reason connected with animal health so justifies, the Member State of destination concerned shall prohibit the importation of that semen, whether imported directly or indirectly through another Member State, either from the whole of the third country or from part of its territory.

3. Measures taken by the Member States on the basis of paragraphs 1 and 2 and the repeal of such measures must be communicated immediately to the other Member States and the Commission together with the reasons for such measures.

In accordance with the procedure laid down in Article 18, it may be decided that those measures must be amended, in particular in order to coordinate them with measures adopted by the other Member States, or that they must be repealed.

4. If the situation envisaged in paragraphs 1 and 2 arises and if it is necessary that other Member States also apply the measures taken under those paragraphs, amended where necessary in accordance with paragraph 3, appropriate steps shall be taken in accordance with the procedure laid down in Article 18.

5. Resumption of importation from the third country concerned shall be authorized in accordance with the procedure laid down in Article 18.

Article 16

1. Veterinary experts from the Commission may, in cooperation with the competent authorities of the Member States and third countries, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of this Directive.

The country of collection within whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the country of collection concerned of the results of the investigation.

The country of collection concerned shall take any measures which may prove necessary to take account of the results of the investigation. If the country of collection does not take those measures, the Commission may, after the situation has been examined by the Standing Veterinary Committee, have recourse to the provisions of the fourth subparagraph of Article 5 (2) and 9 (1).

2. The general provisions for implementing this Article, especially as regards the frequency and method of carrying out the checks referred to in the first subparagraph of paragraph 1, shall be laid down in accordance with the procedure set out in Article 19.

CHAPTER V

Final provisions

Article 17

Amendments to the Annexes to this Directive, in particular to adapt them to advances in technology, shall be decided by the Council acting by a qualified majority on a proposal from the Commission.

Article 18

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

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

3. The representative of the Commission shall submit a draft of the measures to be adopted. The committee shall deliver its opinion on such measures within two days. Opinions shall be delivered by a majority of 54 votes.

4. The Commission shall adopt the measures and apply them immediately where they are in accordance with the committee's opinion. Where they are not in accordance with the committee's opinion or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, on the expiry of three months from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided against the said measures by a simple majority.

Article 19

1. Where the procedure laid down in this Article is to be followed, matters shall without delay be referred to the committee by the chairman, either on his own initiative or at the request of a Member State.

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

3. The representative of the Commission shall submit to the committee a draft of the measures to be adopted. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by a majority of 54 votes.

4. The Commission shall adopt the measures and apply them immediately where they are in accordance with the committee's opinion. Where they are not in accordance with the committee's opinion, or in the absence of any opinion, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall adopt the measures by a qualified majority.

If, on the expiry of 15 days from the date on which the matter was referred to it, the Council has not adopted any measures, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided against the said measures by a simple majority.

Article 20

1. This Directive shall not be applicable to semen collected and processed in a Member State before 1 January 1990.

2. Until the date of entry into force of the decisions adopted pursuant to Articles 8, 9 and 10, the Member States shall not apply to imports of semen from third countries more favourable conditions than those resulting from application of Chapter II.

Article 21

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1990 at the latest. They shall forthwith inform the Commission thereof.

Article 22

This Directive is addressed to the Member States.

Done at Luxembourg, 14 June 1988.

For the Council

The President

I. KIECHLE

ANNEX A

CHAPTER I

CONDITIONS FOR THE APPROVAL OF SEMEN COLLECTION CENTRES

Semen collection centres must:

(a) be placed under the permanent supervision of a centre veterinarian;

(b) have a least

(i) animal housing including isolation facilities;

(ii) semen collection facilities including a separate room for the cleaning and disinfection or sterilization of equipment;

(iii) a semen processing room which need not necessarily be on the same site;

(iv) a semen storage room which need not necessarily be on the same site;

(c) be so constructed or isolated that contact with livestock outside is prevented;

(d) be so constructed that the animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected;

(e) have isolation accommodation which shall have no direct communication with the normal animal accomodation;

(f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

CHAPTER II

CONDITIONS RELATING TO THE SUPERVISION OF SEMEN COLLECTION CENTRES

The collection centres must:

(a) be so supervised that they contain only animals of the species whose semen is to be collected. Other domestic animals which are strictly necessary for the normal operation of the collection centre may nonetheless also be admitted, provided that they present no risk of infection to those species whose semen is to be collected and they fulfil the conditions laid down by the centre veterinarian;

(b) be so supervised that a record is kept of all bovine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record of all checks for diseases and all vaccinations carried out, giving also information from the disease/health file of each animal;

(c) be regularly inspected by an official veterinarian, at least twice a year, at which time standing checks on the conditions of approval and supervision shall be carried out;

(d) be so supervised that the entry of unauthorized persons is prevented. Furthermore, authorized visitors must be required to comply with the conditions laid down by the centre veterinarian;

(e) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

(f) be so supervised that:

(i) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen. However, semen not collected in an approved centre may be processed in approved collection centres provided that:

— such semen is produced from bovine animals which fulfil the conditions laid down in Chapter I. 1 (d) (i), (ii), (iii) and (v) of Annex B,

— processing is carried out with separate equipment or at a different time from semen intended for intra-Community trade, the equipment in the latter case being cleaned and sterilized after use,

— such semen may not be the subject of intra-Community trade and cannot at any time come into contact with or be stored with semen intended for intra-Community trade,

— such semen is identifiable by a marking different from that provided for in point (vii);

(ii) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under conditions of the strictest hygiene;

(iii) all implements which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilized prior to use;

(iv) products of animal origin used in the processing of semen — including additives or a diluent — are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

(v) storage flasks and transport flasks are properly disinfected or sterilized before the commencement of each filling operation;

(vi) the cryogenic agent used has not been previously used for other products of animal origin;

(vii) each individual dose of semen is clearly marked in such a way that the date of collection of the semen and the breed and identification of the donor animal, as well as the name of the centre, possibly in code, can be readily established; the characteristics and form of this marking will be established in accordance with the procedure laid down in Article 19.

ANNEX B

CHAPTER I

CONDITIONS APPLYING TO THE MOVEMENT OF ANIMALS INTO APPROVED SEMEN COLLECTION CENTRES

1. All bovine animals admitted to a semen collection centre must:

   (a) have been subjected to a period of isolation of at least 30 days in accommodation specifically approved for the purpose by the competent authority of the Member State, and where only other cloven-hoofed animals having at least the same health status are present;

   (b) prior to their stay in the isolation accommodation described in (a) have belonged to herds:

      (i) which are officially tuberculosis free;

      (ii) which are officially brucellosis free or brucellosis free.

      The animals may not previously have been kept in other herds of a lower status;

   (c) have come from a herd free of enzootic bovine leukosis or have been produced by a cow which has been subjected to a serological test for enzootic bovine leukosis with a negative result, not more than 30 days before the animal's admission to the centre.

      If this requirement cannot be fulfilled, the semen may not be the subject of trade until the donor has reached the age of two years and has been tested in accordance with Chapter II. 1 (iii) with a negative result;

   (d) before the period of isolation specified in (a), and within the previous 30 days, have been subjected to the following tests with negative results:

      (i) an intradermal tuberculin test carried out in accordance with the procedure laid down in Annex B to Directive 64/432/EEC;

      (ii) a serum agglutination test carried out in accordance with the procedure laid down in Annex C to Directive 64/432/EEC and showing a brucella count lower than 30 IU of agglutination per millilitre and in the case of brucellosis free herds a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units);

      (iii) a serological test for enzootic bovine leukosis carried out in accordance with the procedure laid down in Annex G to Directive 64/432/EEC;

      (iv) a serum neutralization test or an Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis;

      (v) a virus isolation test (fluorescent antibody test or immunoperoxidase test) for bovine viral diarrhoea. In the case of an animal less than six months of age the test must be deferred until that age is reached.

      The competent authority may give authorization for the tests referred to in (d) to be carried out in the isolation accommodation, provided that the results are known before the commencement of the 30-day isolation period laid down in (e);

   (e) during the period of isolation of at least 30 days specified in (a), have been subjected to the following tests with negative results:

      (i) a serum agglutination test complying with the procedure laid down in Annex C to Directive 64/432/EEC and showing a brucella count lower than 30 IU of agglutination per millilitre and a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units) in the case of animals coming from brucellosis free herds;

      (ii) either an immunofluorescent antibody test or a culture test for campylobacter foetus infection on a sample of preputial material or artificial vaginal washings; in the case of female animals a vaginal mucus agglutination test shall be carried out;

      (iii) a microscopic examination and culture test for trichomonas foetus on a sample of vaginal washings or preputial washings; in the case of female animals a vaginal mucus agglutination test shall be carried out;

      (iv) a serum neutralization test or an Elisa test for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis;

      and have treatment against leptospirosis comprising two injections of streptomycin at an interval of 14 days (25 mg per kilogram of live body weight).

If any of the above tests should prove positive, the animal must be removed forthwith from the isolation accommodation. In the case of group isolation, the competent authority must take all necessary measures to re-establish the eligibility of the remaining animals for entry into the collection centre in accordance with this Annex.

2. All tests must be carried out in a laboratory approved by the Member State.

3. Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All movements, both in and out, must be recorded.

4. No animal admitted to the semen collection centre may show any clinical sign of disease on the day of admission. All animals must, without prejudice to paragraph 5, have come from isolation accommodation as referred to in paragraph 1 (a) which, on the day of consignment, officially fulfils the following conditions:

   (a) is situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease for at least 30 days;

   (b) has for at least three months been free from foot-and-mouth disease and brucellosis;

   (c) has for at least 30 days been free from those bovine diseases which are compulsorily notifiable in accordance with Annex E to Directive 64/432/EEC.

5. Provided that the conditions laid down in paragraph 4 are satisfied and the routine tests referred to in Chapter II have been carried out during the previous 12 months, animals may be transferred from one approved semen collection centre to another of equal health status without isolation or testing if transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been disinfected before use. If the movement from one semen collection centre to another takes place between Member States it must take place in accordance with Directive 64/432/EEC.

CHAPTER II

ROUTINE TESTS AND TREATMENT WHICH MUST BE APPLIED TO ALL BOVINE ANIMALS IN AN APPROVED SEMEN COLLECTION CENTRE

1. All bovine animals kept at an approved semen collection centre mut be subjected at least once a year to the following tests and treatment:

   (i) an intradermal tuberculin test for tuberculosis, carried out in accordance with the procedure laid down in Annex B to Directive 64/432/EEC, with a negative result;

   (ii) a serum agglutination test for brucellosis, carried out in accordance with the procedure laid down in Annex C to Directive 64/432/EEC, giving a count lower than 30 IU of agglutination per millilitre;

   (iii) a serological test for enzootic bovine leukosis, carried out in accordance with the procedure laid down in Annex G to Directive 64/432/EEC, with a negative result;

   (iv) for infectious bovine rhinotracheitis/infectious pustular vulvo-vaginitis, a serum neutralization test or an Elisa test with a negative result. However, until 31 December 1992, vaccination against these diseases may be practised on sero-negative bulls, either with one dose of a temperature-sensitive live vaccine administered intranasally or two doses of an inactivated vaccine separated by an interval of not less than three weeks and not more than four weeks; the vaccination must be repeated subsequently at intervals of not more than six months;

   (v) either an immunofluorescent antibody test or a culture test for campylobacter foetus infection on a sample of preputial material or artificial vaginal washings; in the case of female animals a vaginal mucus agglutination test must be carried out.

2. All tests must be carried out in a laboratory approved by the Member State.

3. If any of the above tests should prove positive, the animal must be isolated and the semen collected from it since the last negative test may not be the subject of intra-Community trade.

   Semen collected from all other animals at the centre since the date when the positive test was carried out shall be held in separate storage and may not be the subject of intra-Community trade until the health status of the centre has been re-established.

ANNEX C

CONDITIONS WHICH SEMEN COLLECTED AT APPROVED CENTRES MUST SATISFY FOR THE PURPOSES OF INTRA-COMMUNITY TRADE

1. Semen must be obtained from animals which:

   (a) show no clinical signs of disease on the day the semen is collected;

   (b) (i) have not been vaccinated against foot-and-mouth disease; or

   (ii) come from a centre where all the animals have been fully protected against types A, O and C;

   — and are thus either animals which, before entering the centre, were not previously vaccinated against foot-and-mouth disease and must, therefore, have received two doses of inactivated virus vaccine approved and controlled by the competent authority of the exporting Member State at an interval of not less than six weeks and not more than eight months,

   — or animals which, before entering the centre, were vaccinated on at least three occasions at intervals of not more than one year.

   When vaccination is practised, all animals must receive repeat vaccinations at intervals of not more than 12 months;

   (c) have not been vaccinated against foot-and-mouth disease within 30 days immediately prior to collection;

   (d) have been kept at an approved semen collection centre for a continuous period of at least 30 days immediately prior to collection of the semen;

   (e) are not allowed to serve naturally;

   (f) are kept in semen collection centres which have been free from foot-and-mouth disease for at least three months prior to collection of the semen and 30 days after collection, and are situated in the centre of an area of 10 kilometres radius in which for at least 30 days there has been no case of foot-and-mouth disease;

   (g) have been kept in semen collection centres which, during the period commencing 30 days prior to collection and ending 30 days after collection of the semen, have been free from those bovine diseases which are compulsorily notifiable in accordance with Annex E to Directive 64/432/EEC.

2. Antibiotics as listed below must be added to produce these concentrations in the final diluted semen:

   not less than: 500 IU per ml streptomycin,
   500 IU per ml penicillin,
   150 µg per ml lincomycin,
   300 µg per ml spectinomycin.

   An alternative combination of antibiotics with an equivalent effect against campylobacters, leptospires and mycoplasmas may be used.

   Immediately after their addition the diluted semen must be kept at a temperature of at least 5 °C for a period of not less than 45 minutes.

3. Semen for intra-Community trade must:

   (i) be stored in approved conditions for a minimum period of 30 days prior to dispatch;

   (ii) be transported to the Member State of destination in flasks which have been cleaned and disinfected or sterilized before use and which have been sealed prior to dispatch from the approved storage facilities.

ANNEX D

ANIMAL HEALTH CERTIFICATE

No: .....

Country of collection: .....

Competent authority: .....

Competent local authority: .....

I. **Identification of semen:**

.....

Number of doses	Date(s) of collection	Identification of donor animal	Breed	Date of birth

II. **Origin of semen:**

Address of semen collection centre(s): .....

.....

.....

Approval number of semen collection centre(s): .....

.....

III. **Destination of semen:**

The semen will be sent from: .....
(place of loading)

to: .....
(country and place of destination)

by: .....
(means of transport)

Name and address of consignor: .....

.....

.....

Name and address of consignee: .....

.....

.....

IV. **I, the undersigned official veterinarian, certify that:**

1. the semen described above was collected, processed and stored under conditions which comply with the standards laid down in Directive 88/407/EEC;

2. the semen described above was sent to the place of loading in a sealed container under conditions which comply with Directive 88/407/EEC.

Done at ..... on .....

.....
(Signature)

.....
(Name in block letters)

Seal

COUNCIL DECISION

of 15 June 1988

on the levels of the fees to be charged for health inspections and controls of fresh meat pursuant to Directive 85/73/EEC

(88/408/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 85/73/EEC of 29 January 1985 on the financing of health inspections and controls of fresh meat and poultrymeat [1], and in particular Article 2 (1) thereof,

Having regard to the proposal from the Commission,

Whereas Directive 85/73/EEC laid down harmonized rules for the financing of health inspections and controls introduced by Community law; whereas in particular that Directive requires fees to be collected for such inspections and controls; whereas the standard fee levels should be fixed at Community level;

Whereas, however, without prejudice to the second indent of Article 1 (1) or the second subparagraph of Article 2 (1) of Directive 85/73/EEC, the levels should be set, in an initial stage, only for the fees to be collected in respect of meat from the animals mentioned in Article 1 (2) of the abovementioned Directive, and slaughtered on Community territory, it being understood that Articles 23 and 26 of Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries [2], as last amended by Directive 87/64/EEC [3], whereby the costs are chargeable to the parties concerned, remain applicable to imports from third countries;

Whereas Article 12 of Council Directive 85/358/EEC of 16 July 1985 supplementing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action [4] requires that the fees also take account of expenses entailed by the controls referred to in that provision;

Whereas Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues [5] makes provision for controls to be carried out to this end; whereas the level of the fees to be fixed should also take account of the costs incurred by such controls;

Whereas it is possible that slaughtering, cutting and storage operations may take place in separate plants; whereas, as a result in such cases, not all the health inspections and controls to be covered by the fees under Directives 64/433/EEC [6], 71/118/EEC [7], 85/358/EEC and 86/469/EEC, are consequently carried out in the slaughterhouse; whereas, in accordance with the first subparagraph of Article 2 (1) of Directive 85/73/EEC these exceptional cases should be covered by providing for fees to be charged in proportion to the different health controls and inspections to be carried out;

Whereas the principle should be adopted that the fees are charged to the person who has the slaughtering, cutting or storage operations carried out; whereas, as a general rule, all the fees are therefore collected at the slaughterhouse; whereas, however, exceptional cases should be covered in the light of the abovementioned principle;

Whereas the rate should be fixed for converting into national currency the amount of the fee expressed in ECU, provision being made for the review of that amount if necessary,

HAS ADOPTED THIS DECISION:

Article 1

This Decision fixes the levels of the fees to be collected by the Member States for health inspections and controls of fresh meat as provided for in Directives 64/433/EEC, 71/118/EEC, 85/358/EEC and Articles 3 and 7 of Directive 86/469/EEC and the rules for implementing Directive 85/73/EEC.

Article 2

1. The fees referred to in Article 1 shall be fixed at the following standard levels:

(a) *beef and veal:*

— adult bovine animals: 4,5 ECU/animal,

— young bovine animals: 2,5 ECU/animal;

(1) OJ No L 32, 5. 2. 1985, p. 14.
(2) OJ No L 302, 31. 12. 1972, p. 28.
(3) OJ No L 34, 5. 2. 1987, p. 52.
(4) OJ No L 191, 23. 7. 1985, p. 46.
(5) OJ No L 275, 26. 9. 1986, p. 36.
(6) OJ No 121, 29. 7. 1964, p. 2012/64.
(7) OJ No L 55, 8. 3. 1971, p. 23.

(b) *Solipeds/equidae:*

4,4 ECU/animal;

(c) *pigs:*

1,30 ECU/animal;

(d) *sheepmeat and goatmeat:* animals of a carcase weight:

(i) of less than 12 kilograms: 0,175 ECU/animal;

(ii) of between 12 and 18 kilograms: 0,35 ECU/animal;

(iii) of more than 18 kilograms: 0,5 ECU/animal.

2. Until the review provided for in Article 10, Member States where salary costs, the structures of establishments, and the ratio between veterinarians and inspectors differ from those of the Community average adopted for the calculation of the standard amounts laid down in paragraph 1 may depart from them through increases or reductions up or down to the real figure for inspection costs.

Member States shall have recourse to the exemptions laid down in the first paragraph on the basis of the principles set out in the Annex.

In no case shall the application of the exemptions provided for in the first paragraph lead to reductions of more than 55 % up to and including 31 December 1992 or, as from 1 January 1993, 50 % of the average levels set out in paragraph 1.

3. Pending the review of the inspection rules laid down by Directive 71/118/EEC and until 31 December 1992 at the latest, the minimum amount to be collected for inspecting fresh poultrymeat shall be fixed at a standard rate at the following levels:

— for broilers, other young poultry for fattening weighing less than two kilograms and for cast hens: 0,01 ECU/animal,

— other young poultry for fattening of a carcase weight of more than two kilograms: 0,02 ECU/animal,

— other heavy adult poultry weighing more then five kilograms: 0,04 ECU/animal.

Paragraph 2 shall apply *mutatis mutandis*.

4. Until 31 December 1992 the share of the fees for:

(i) administrative costs shall be fixed at a standard rate of 0,725 ECU per tonne. This amount may be deducted when the operator of the establishment is the natural or legal person referred to in Article 6 (1) and when he pays the administrative costs;

(ii) examination for the presence of residues may not be lower than 1,35 ECU/tonne.

5. Until 31 December 1992, Member States may, on the basis of the figures laid down in Article 2, collect amounts expressed in ECU/tonne, taking as the basis for conversion the national average weight of slaughtered carcases expressed on an annual basis.

Article 3

1. The part of the fees covering the controls and inspections connected with the cutting operations referred to in Article 3 (1) B of Directive 64/433/EEC and Article 3 (1) B (b) of Directive 71/118/EEC shall be fixed at a standard rate of 3 ECU/tonne of unboned meat intended for cutting.

2. The amount referred to in paragraph 1 shall be added to the amounts referred to in Article 2 (1).

3. The provisions of Article 2 (2) and (5) shall apply *mutatis mutandis*.

4. Where the cutting operations are carried out in the establishment where the meat is obtained, the amounts laid down in paragraph 1 may be reduced by up to 50 %.

Article 4

Member States shall collect an amount corresponding to the actual expenditure necessary for entry and exit controls or inspections of the meat being stored, pursuant to Article 3 (1) D of Directive 64/433/EEC and Article 3 (1) B (c) of Directive 71/118/EEC.

Article 5

1. The amount referred to in Article 2 shall replace all other health inspection charges or fees levied by the national, regional or local authorities of the Member States for the inspection and control of fresh meat referred to in Article 1 and the certification thereof. However, until 31 December 1992, Member States shall be authorized to collect registration costs for slaughterhouses approved in accordance with Article 8 of Directive 64/433/EEC.

2. When so requested by the Commission and in the situation referred to in Article 2 (2), Member States must be able to justify the method of calculation, in particular the salary costs.

As part of the checks laid down in Article 9 of Directive 64/433/EEC, the Commission may, in particular by checking compliance with the requirements of Chapters V, VI and VII, by random spot checks, verify whether the granting of the exemptions laid down in Article 2 (2) of this Decision does not compromise the effective application of the rules laid down by the said Directive.

Article 6

1. Fees shall be payable by the natural or legal person who has the slaughtering, cutting or storage operations carried out.

2. The full amount of the fees, including the amounts provided for in Articles 2 and 3, shall in principle be collected at the slaughterhouse. However, in the event of the conditions laid down in Article 3 (4) and Article 4 not being fulfilled, the amounts provided for in Articles 2 and 3 shall be collected in the cases concerned at the slaughterhouse, cutting plant and cold store, as appropriate.

Article 7

The application in the Member States or in the case of individual establishments, particularly in the event of recourse to the exemptions provided for in Article 2 (2), of the rules for calculation adopted by this Decision shall be verified when the checks provided for in Article 9 of Directive 64/433/EEC are carried out.

Article 8

The minimum amount per tonne to be collected in respect of meat imported from third countries shall be decided on by the Council, acting by a qualified majority on a Commission proposal, following the establishment of Community inspection for frontier posts as provided for in Article 27 of Directive 72/462/EEC.

The decisions referred to in the first paragraph must be adopted before 1 October 1989.

Article 9

The rate of conversion into national currency of the amounts in ECU specified in this Decision shall be that published annually on the first working day of the month of September in the C Series of the *Official Journal of the European Communities*.

Article 10

1. The Council, acting by a qualified majority on a proposal from the Commission, may annually review the share of the fees covering the search for residues in order to take account of experience acquired in implementing the plans referred to in Article 4 of Directive 86/469/EEC.

2. Before 1 April 1989, the Commission shall submit to the Council a report on the possible devolution of certain inspection tasks to auxiliary inspectors who are not veterinarians, on the tasks to be entrusted to these auxiliary inspectors, the qualifications of such auxiliary inspectors and the average proportion of veterinarian inspectors to non-veterinarian inspectors required for the satisfactory inspection of meat.

The Council will act by a qualified majority, before 1 October 1989, on Commission proposals based on this report.

Before that date and using the same procedure, the Council will adopt new rules for ante-mortem and post-mortem health inspection of fresh poultrymeat.

3. To take account of experience acquired, the Commission shall, before 1 January 1992, submit to the Council a report accompanied, if necessary, by appropriate proposals for the adjustment of the cost of health inspections and controls in the Community.

The Council, acting by a qualified majority on these proposals, shall fix — before 1 April 1992 in accordance with the same procedure — the levels of fees to be collected with effect from 1 January 1993.

Article 11

Member States shall implement the provisions of this Decision not later than 31 December 1990. They shall forthwith inform the Commission thereof.

Article 12

This Decision is addressed to the Member States.

Done at Luxembourg, 15 June 1988.

For the Council

The President

I. KIECHLE

ANNEX

ELEMENTS OF DEPARTURE FROM THE COMMUNITY AVERAGE

1. **Reductions**

Member States may reduce the central standard rate for fees pursuant to Article 2 (2):

(a) in general, where there are substantial differences in the cost of living and salary costs;

(b) for individual establishments where the following conditions are met:

— a minimum daily slaughter rate enabling the deployment of the relevant inspection staff to be planned in advance,

— the number of slaughtered animals must be constant, so that animal deliveries may de planned in advance thus enabling rational use to be made of the inspection staff,

— strict organization and planning within the establishment together with a rapid slaughter rate and optimum use of inspection staff,

— no waiting or otherwise non-productive periods for inspection staff,

— the animals for slaughter must so far as possible be uniform in age, size, weight and state of health.

2. **Increases**

In order to cover increased costs, Member States may increase the central standard rate for fees pursuant to Article 2 (2).

This would be subject, for example, to one or more of the following conditions:

— higher inspection costs due to a particular lack of uniformity in the animals for slaughter from the point of view of age, size, weight and state of health,

— longer waiting and otherwise non-productive periods for inspection staff owing to inadequate advance planning by the establishment of animal deliveries or technical inadequacies or failures, for example in older establishments,

— frequent delays in the slaughtering process, e.g. as a result of insufficient slaughter staff and hence under-employment of inspection staff,

— higher costs due to special travelling times,

— more time taken up on inspections due to frequently changing slaughter periods beyond the control of inspection staff,

— frequent interruptions in the slaughtering process to meet cleaning and disinfecting requirements,

— inspections of animals for slaughter and of meat at the request of the person liable for fees, outside established inspection times.

The amount of the increases in the central standard rate for fees shall depend on the level of the costs to be covered.

COUNCIL DIRECTIVE

of 15 June 1988

laying down the health rules applying to meat intended for the domestic market and the levels of the fees to be charged, pursuant to Directive 85/73/EEC, in respect of the inspection of such meat

(88/409/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 (3),

Whereas, Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat (4), as last amended by Regulation (EEC) No 3805/87 (5), provides for health inspections and controls in respect of fresh meat intended for intra-Community trade;

Whereas it is appropriate to undertake the same inspections in respect of fresh meat intended for trade on the internal market of each Member State in order to guarantee free movement inside the Community as well as in order to avoid distortions of competition for products subject to the common organization of the market whilst assuring, at the same time, uniform conditions of health protection to consumers;

Whereas according to Article 2 (1) of Council Directive 85/73/EEC of 29 January 1985 on the financing of health inspections and controls of fresh meat and poultry meat (6) the levels of fees to be collected for fresh meat coming from slaughterhouses that are not approved under Directive 64/433/EEC shall not be fixed except in connection with the adoption of rules of inspection for that meat;

Whereas, in view of the extension of the inspection rules laid down in Directive 64/433/EEC to all animals slaughtered for local consumption and of the obligation of this meat to be subject to the controls referred to in Council Directive 85/358/EEC of 16 July 1985 supplementing Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action (7) and in view of Council Directive 86/469/EEC of 16 September 1986 concerning the examination of animals and fresh meat for the presence of residues (8) it is appropriate to adopt for meat intended for local consumption the same levels of fees as those laid down in Council Decision 88/408/EEC of 15 June 1988 on the levels of the fees to be charged for health inspections and controls of fresh meat pursuant to Directive 85/73/EEC (9);

Whereas however it is not opportune at this stage to regulate, at Community level, the matter of slaughter for the personal needs of the farmer;

Whereas, owing to difficulties inherent in the particular geographical characteristics of its territory, a further two-year period should be granted so as to enable the Hellenic Republic to apply the inspection rules and to introduce the necessary machinery for collecting the fees relating to inspections and controls,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down, without prejudice to the arrangements to be adopted pursuant to Article 15 (b) of Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultrymeat (10), as last amended by Regulation (EEC) No 3805/87, the health inspection rules and the level of the health fees applying to meat intended for the domestic market in the Member States.

For the purposes of this Directive the definitions given in Article 2 of Directive 64/433/EEC shall apply

This Directive shall not affect national rules on the slaughter of an animal for the farmer's personal needs, provided that such rules prescribe guarantees for checking that the meat from the animal is not sold for public consumption.

(1) OJ No C 302, 27. 11. 1986, p. 4 and OJ No C 298, 7. 11. 1987, p. 4.
(2) OJ No C 281, 19. 10. 1987, p. 202.
(3) OJ No C 83, 30. 3. 1987, p. 2.
(4) OJ No 121, 29. 7. 1964, p. 2012/64.
(5) OJ No L 357, 19. 12. 1987, p. 1.
(6) OJ No L 32, 5. 2. 1985, p. 14.
(7) OJ No L 191, 23. 7. 1985, p. 46.
(8) OJ No L 275, 26. 9. 1986, p. 36.
(9) See page 24 of this Official Journal.
(10) OJ No L 55, 8. 3. 1971, p. 23.

Article 2

As from 1 January 1990 the Member States shall take the necessary steps to ensure that, by the date specified in Article 6 at the latest, all fresh meat produced in their territory for marketing there is inspected in accordance with the inspection rules laid down in Chapter V, points 25, 26 and 27, in Chapters VI, VII and VIII, and in Chapter IX in the second, fifth and sixth indents of point 47, of Annex I to Directive 64/433/EEC. Such meat shall not bear the health mark provided for in Chapter X of that Annex if it does not meet the other requirements of the said Directive.

The provisions in Chapters VI, VIII and Chapter IX, point 47 of Annex I to Directive 64/433/EEC shall not apply to operations involving the storage and cutting of small quantities on the premises where they will be sold to the final consumer.

Article 3

The following Article is inserted in Directive 85/73/EEC:

'Article 2a

Member States shall ensure that the expenses entailed by the controls referred to in Articles 6, 8 and 9 of Directive 86/469/EEC are charged against the fees laid down in Article 1.'

Article 4

The level of the fees resulting from Article 2 of Decision 88/408/EEC shall be applicable in respect of fresh meat produced and inspected in accordance with Article 2 of this Directive and of meat referred to in Article 16a of Directive 71/118/EEC.

Article 5

1. Before 1 October 1989 the Council, acting by a qualified majority on a proposal from the Commission, shall decide on the conditions under which the other requirements of Directive 64/433/EEC may be extended to establishments or slaughterhouses not approved under the said Directive, shall, to that end, review the criteria laid down in particular in Article 3 (1) (A) (d) and in Article 5 of that Directive for the purpose of preventing trade in certain meat and shall adopt minimum rules regarding hygiene and inspection that must be complied with by a slaughterhouse intending to restrict its production to the local market.

2. By the same date and in accordance with the same procedure, the following shall be adopted for meat currently restricted to the domestic market:

— new ante mortem and post mortem health inspection rules for poultrymeat,

— provisions regarding the professional qualifications of assistant inspectors, their required training and the tasks they are to perform.

Article 6

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 January 1991. They shall forthwith inform the Commission thereof.

However, the Hellenic Republic shall have an additional period of two years in which to comply with it.

Article 7

This Directive is addressed to the Member States.

Done at Luxembourg, 15 June 1988.

For the Council

The President

I. KIECHLE