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COUNCIL DIRECTIVE of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (91/68/EEC)

(OJ L 46, 19.2.1991, p. 19)

Amended by:

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► <u>M1</u>	Commission Decision 94/164/EC of 18 February 1994	L 74	42	17.3.1994
► <u>M2</u>	<u>M2</u> Commission Decision 94/953/EC of 20 December 1994 L 371 14		31.12.1994	
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COUNCIL DIRECTIVE

of 28 January 1991

on animal health conditions governing intra-Community trade in ovine and caprine animals

(91/68/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 the harmonious operation of the common organization of the market in ovine and caprine animals will not have the results expected of it as long as disparities between Member States as regards health conditions act as a restraint on intra-Community trade;

Whereas in order to encourage such trade it is advisable to remove those disparities and introduce Community-wide rules on the marketing of ovine and caprine animals in such trade; whereas that objective will also contribute to the completion of the single market;

Whereas in order to be eligible for intra-Community trade, ovine and caprine animals should meet certain animal health requirements designed to avoid the spread of infectious or contagious diseases;

Whereas the animal health requirements applicable should vary depending on the purpose for which the animals are traded;

Whereas the health situation for ovine and caprine animals is not the same throughout the territory of the Community; whereas reference should therefore be made to 'regions' as defined in Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (⁴), as last amended by Directive 90/425/EEC (⁵), when dealing with parts of that territory;

Whereas there must be no barriers to trade between regions in which the animal health conditions are equivalent;

Whereas provision should be made for allowing the Commission to approve certain additional requirements in the light of the progress made by a Member State in eradicating certain diseases, provided that those requirements in no case exceed those applied nationally by the Member State concerned;

Whereas in order to avoid the spread of infectious or contagious diseases, conditions should be laid down as regards the transportation of the animals to their place of destination;

Whereas in order to ensure that the requirements applicable are complied with, provision should be made for introducing a health certificate which would be issued by an official veterinarian and which would accompany ovine and caprine animals until they reach their place of destination;

Whereas reference should be made, as regards the organization and follow up of the checks to be carried out by the Member States and as regards the protective measures to be introduced, to the general rules laid down in Council Directive 90/425/EEC of 26 June 1990 concerning

^{(&}lt;sup>1</sup>) OJ No C 48, 27. 2. 1989, p. 21.

^{(&}lt;sup>2</sup>) OJ No C 96, 17. 4. 1989, p. 187.

^{(&}lt;sup>3</sup>) OJ No C 194, 31. 7. 1989, p. 9.

^{(&}lt;sup>4</sup>) OJ No 121, 29. 7. 1964, p. 1977/64.

^{(&}lt;sup>5</sup>) OJ No L 224, 18. 8. 1990, p. 29.

veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view of the completion of the internal market;

Whereas provision should be made for allowing the Commission to conduct its own checks;

Whereas a procedure should be introduced which provides for close and efficient cooperation between the Member States and the Commission within the Standing Veterinary Committee,

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive defines the animal health conditions governing intra-Community trade in ovine and caprine animals.

Article 2

For the purposes of this Directive, the definitions laid down in Article 2 of Directive 64/432/EEC shall apply, with the addition of the following:

- 1. ovine or caprine animals for slaughter means animals of the ovine or caprine species intended to be taken either directly or via an approved market or assembly centre to a slaughterhouse in order to be slaughtered there under the conditions laid down in Article 6 of Directive 64/432/EEC;
- 2. ovine or caprine animals for breeding and fattening: ovine and caprine animals other than those mentioned in point 1 intended to be transported to the place of destination, either directly or via an approved market or assembly centre;
- 3. holding: a holding as defined in Article 2 (4) of Directive 90/425/EEC;
- 4. officially brucellosis-free ovine or caprine holding means a holding which satisfies the conditions laid down in heading I, Chapter 1 of Annex A;
- 5. brucellosis-free ovine or caprine holding means a holding which satisfies the conditions laid down in Chapter 2 of Annex A;
- 6. trade means trade between Member States within the meaning of Article 9 (2) of the Treaty;
- compulsorily notifiable disease means a disease as listed under Sections I and II of Annex B, the suspicion or appearance of which must be notified to the competent authorities of the Member State;
- 8. official veterinarian means a veterinarian designated by the competent central authority of the Member State;
- approved market or assembly centre means any place, other than the holding, where ovine or caprine animals are sold, bought and/or assembled or loaded, and which complies with Article 3 (7) of Directive 64/432/EEC and Article 5 (1) (b) (i) of Directive 90/425/EEC for approved markets or assembly centres;
- 10. region means a part of the territory of the Community as defined in Article 2 (o) of Directive 64/432/EEC.

Article 3

1. Ovine and caprine animals for slaughter may be the subject of trade only if they fulfil the conditions laid down in Article 4.

2. Ovine and caprine animals for breeding and fattening may be the subject of trade only if they fulfil the conditions laid down in Articles 4, 5 and 6, without prejudice to any additional guarantees which may be required pursuant to Articles 7 and 8.

However, the competent authorities of Member States of destination may grant general or limited derogations in respect of movement of ovine and caprine animals for breeding and fattening, intended solely for temporary pasturing near internal borders of the Community. Member States making use of such derogation shall inform the Commission of the content of the derogations granted.

Article 4

- 1. Ovine and caprine animals:
- (a) must be identified and registered in accordance with the requirements of Article 3 (1) (c) of Directive 90/425/EEC; the time limit for notifying the national systems for identifying and registering ovine and caprine animals begins running from the date of adoption of this Directive;
- (b) must show no clinical sign of disease when inspected by an official veterinarian, such inspection must take place during the 48 hours preceding the loading of the ovine and caprine animals;
- (c) must not come from a holding which is the subject of a prohibition on health grounds and must not have been in contact with animals from such a holding, it being understood that:
 - (i) such prohibition shall be linked to an outbreak of any of the following diseases to which the animals are susceptible:
 - brucellosis,
 - rabies,
 - anthrax,
 - (ii) after slaughter of the last animal suffering from or susceptible to one of the above diseases, the period of prohibition must be at least:
 - 42 days in a case of brucellosis,
 - 30 days in a case of rabies,
 - 15 days in a case of anthrax,

and must not come from a holding or have been in contact with animals from a holding situated in an established protection zone and from which animals are forbidden to leave pursuant to Article 3 (2) (b) (ii) of Directive 64/432/EEC;

(d) must not be the subject of animal health restrictions applied pursuant to Council Directive 85/511/EEC of 18 November 1985 introducing Community measures for the control of foot-and-mouth disease (¹), as amended by Directive 90/423/EEC (²).

Furthermore, the provisions of Article 4a of Directive 64/432/EEC shall apply.

2. Member States shall also ensure that the following are not the subject of trade:

- ovine and caprine animals which might have to be slaughtered under a national programme for the eradication of diseases not referred to in Annex C to Directive 90/425/EEC or in Chapter I of Annex B to this Directive,
- ovine and caprine animals which cannot be marketed on their own territory for health or animal health reasons justified by Article 36 of the Treaty.
- 3. Ovine and caprine animals must also:
- either have been born and reared since birth in the territory of the Community,

⁽¹⁾ OJ No L 315, 26. 11. 1985, p. 11.

^{(&}lt;sup>2</sup>) OJ No L 224, 18. 8. 1990, p. 13.

- or, if they have been imported, come from a third country included on the list drawn up in accordance with Article 3 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 and meat products from third countries (¹), as last amended by Directive 90/425/EEC, and
- (i) either meet the animal health conditions laid down in accordance with Article 8 of Directive 72/462/EEC,
- (ii) or, in the absence of such conditions, be subject to compliance with the conditions laid down in Article 7 (2) second, third and fourth subparagraphs of Directive 90/425/EEC.

Article 5

Without prejudice to the additional guarantees that may be required in accordance with Articles 7 and 8, ovine and caprine animals for breeding and fattening must, in addition to the conditions laid down in Article 4, meet — in order to be introduced onto an officially brucellosis-free or brucellosis-free ovine or caprine holding — respectively the requirements of Chapter I.D or Chapter 2.D of Annex A.

Article 6

Without prejudice to the additional guarantees that may be required in accordance with Articles 7 and 8, animals for breeding must furthermore meet the following requirements:

- (a) They must have been obtained from a holding and must only have been in contact with animals from such a holding:
 - (i) in which the following diseases have not been clinically diagnosed:
 - in the previous six months, contagious agalactia of sheep (Mycoplasma agalactiae) or contagious agalactia of goats (Mycoplasma agalactiae, M. capricolum, M. Mycoïdes var. mycoïdes'large colony'),
 - in the previous 12 months, paratuberculosis or caseous lymphadenitis,
 - in the previous three years, pulmonary adenomatosis, Maedi Visna or caprine viral arthritis/encephalitis. However, this period shall be reduced to 12 months if the animals infected with Maedi Visna or caprine viral arthritis/encephalitis have been slaughtered and the remaining animals have reacted negatively to two tests recognized under the procedure set out in Article 15,

or which, without prejudice to compliance with the requirements for other diseases, provides, for one or more of the abovementioned diseases, within the framework of a programme approved in accordance with Articles 7 and 8, health guarantees which are equivalent for the said disease or diseases;

- (ii) where no facts suggesting that the requirements of point (i) have not been met, have been brought to the attention of the official veterinarian responsible for issuing the health certificate;
- (iii) whose owner states that he has no knowledge of any such facts and, moreover, states in writing that the animal or animals intended for intra-Community trade comply with the criteria laid down in point (i);

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- (b) in addition, with regard to scrapie, they must:
 - (i) come from a holding satisfying the following requirements:
 - the holding is subject to official checks in accordance with Article 3 (1) (b) of Directive 90/425/EEC,
 - the animals must be marked,
 - no case of scrapie has been confirmed for at least two years,
 - checking by sampling must be carried out at slaughter on old ewes, intended for culling coming from that holding, except where that holding is situated in a region or a Member State benefiting from conditions to be adopted in accordance with Article 8,
 - female animals may only be introduced into that holding if they come from a holding which complies with the same requirements;
 - (ii) have been continuously kept on a holding or holdings complying with the requirements laid down in (i) since birth or for the last two years;
 - (iii) when they are destined for a Member State which benefits, for all or part of its territory, from the provisions laid down in Articles 7 or 8, satisfy the guarantees furnished pursuant to those Articles;
 - (c) whith regard to contagious epidydimitis (*B. ovis*), non castrated rams, for breeding, must:
 - come from a holding where no case of contagious epidydimitis (B. ovis) has been diagnosed in the preceding 12 months,
 - have been continuously kept on that holding for 60 days prior to dispatch,
 - in the 30 days prior to dispatch have undergone, with negative results, a serological test carried out in accordance with Annex D or satisfy equivalent health guarantees to be recognized under the procedure laid down in Article 15;
 - (d) the certificate corresponding to Model III of Annex E states that these requirements have been met.

Article 7

1. A Member State which has a compulsory or voluntary national control programme or a national monitoring programme for one of the infectious or contagious diseases referred to in Annex B, Sections II and III for all or part of its territory may submit the said programme to the Commission, outlining in particular:

- the distribution of the disease in the Member State,
- the reasons for the programme, taking into consideration the importance of the disease and the programme's likely benefit in relation to its cost,
- the geographical area in which the programme will be implemented,
- the various status categories to be applied to the holdings, the standards which must be attained in each category, and the test procedures to be used,
- the programme monitoring procedures,
- the action to be taken if, for any reason, a holding loses its status,
- the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive.

2. The Commission shall examine the programmes presented by the Member States. Programmes as referred to in paragraph 1 may be approved, in compliance with the criteria laid down in paragraph 1, in accordance with the procedure provided for in Article 15. According to the same procedure, the additional guarantees, general or limited, which may be required in intra-Community trade, shall be defined at the same time or at the latest three months after approval of the programmes. Such guarantees must not exceed those which the Member State implements nationally.

3. Programmes submitted by Member States may be amended or supplemented in accordance with the procedure laid down in Article 15. Amendments or additions to programmes which have already been approved or to guarantees which have been defined in accordance with paragraph 2 may be approved under the same procedure.

4. Programmes approved in accordance with this Article shall benefit from the Community funding provided for in Article 24 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (¹) for the diseases and under the conditions laid down therein.

Article 8

1. Where a Member State considers that its territory or part of its territory is free from one of the diseases listed in Annex B, Sections II and III to which ovine and caprine animals are susceptible, it shall present to the Commission appropriate supporting documentation, setting out in particular:

- the nature of the disease and the history of its occurrence in its territory,
- the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation and on the fact that the disease must by law be notified to the competent authorities,
- the period over which the surveillance was carried out,
- where applicable, the period during which vaccination against the disease has been prohibited and the geographical area concerned by such prohibition,
- the arrangements for verifying the absence of the disease.

2. The Commission shall examine supporting documentation submitted by Member States. The additional guarantees, general or limited, which may be required in intra-Community trade shall be defined in accordance with the procedure laid down in Article 15. Such guarantees must not exceed those which the Member State implements nationally. Where supporting documentation is submitted before 1 January 1992, decisions on additional guarantees shall be taken before 1 July 1992.

3. The Member State concerned shall notify the Commission of any change in the supporting documentation specified in paragraph 1 which relate to the disease. The guarantees defined as laid down in paragraph 2 may, in the light of such notification, be amended or withdrawn in accordance with the procedure laid down in Article 15.

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4. The Commission shall examine as quickly as possible the grounds submitted by Sweden asregards ovine paratuberculosis and ovine contagious agalactia. Following that examination and if it is justified, the provisions of paragraph 2 may be applicable. The appropriate decisions provided for in paragraph 2 shall be adopted as quickly as possible. Pending those decisions Sweden may, during a period of one year from the date of entry into force of the Accession Treaty, apply its

⁽¹⁾ OJ No L 224, 18. 8. 1990, p. 19.

national rules in force before that date as regards the abovementioned diseases. The period of one year may if necessary be extended in accordance with the procedure laid down in Article 15.

Article 8a

As regards Finland, for the purposes of applying Articles 7 and 8 and at its request, the Commission shall organize the necessary examinations for the diseases listed in Annex B, headings II and III, so that the appropriate decisions may be adopted, if necessary, in accordance with the procedure laid down in Article 15 before the date of entry into force of the Accession Treaty.

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Article 9

In trade between Member States, ovine and caprine animals must, during transportation to the place of destination, be accompanied by a health certificate, signed by an official veterinarian, which conforms to Annex E (Models I, II and III), and which must be drawn up, on the day of the inspection provided for in Article 4 (1) (b), in at least one of the official languages of the Member State of destination, and be valid for 10 days. The certificate shall consist of a single sheet.

Article 10

1. The rules laid down in Directive 90/425/EEC shall apply, in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the Member State of destination, and to the protective measures to be implemented.

2. In Annex A, heading I of Directive 90/425/EEC the following reference is added:

[•]Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals,

OJ No L 46, 19. 2. 1991, p. 19.'

3. In Annex B point A of Directive 90/425/EEC, the first indent is deleted.

Article 11

1. Veterinary experts from the Commission may, to the extent necessary to ensure uniform application of this Directive and in cooperation with the competent national authorities, carry out on-the-spot inspections. The Member State on whose territory inspections are carried out shall afford all necessary aid to the experts in the accomplishment of their task. The Commission shall inform the Member States of the outcome of such inspections.

2. General arrangements for the application of this Article shall be adopted in accordance with the procedure laid down in Article 15.

The rules applicable in respect of the inspections referred to in this Article shall be laid down in accordance with the same procedure.

Article 12

Member States which implement an alternative control system providing guarantees equivalent to those laid down in Article 5 and Article 6 (a) and (c) as regards movements within their territory of ovine and caprine animals may grant one another derogations from the inspection provided for under Article 4 (1) (b) and the obligation to produce a certificate provided for under Article 9 on a reciprocal basis. They shall notify the Commission thereof.

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Article 13

The provisions of this Directive shall be re-examined before 1 January 1993 in the framework of the proposals relating to the completion of the internal market, on which the Council will decide by a qualified majority.

Article 14

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

Annexes B, C and D shall be amended in accordance with the procedure laid down in Article 15.

Article 15

1. Where the procedure laid down in this Article is to be followed, the chairman shall refer the matter without delay to the Standing Veterinary Committee set up by Decision 68/361/EEC (¹) hereinafter referred to as the 'Committee', either on his own initiative or at the request of the representative of a Member State.

2. (a) The representative of the Commission shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The Chairman shall not vote.

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

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

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

Article 16

The Commission may, in accordance with the procedure laid down in Article 15, adopt — for a period of three years — the transitional measures necessary to facilitate the changeover to the new arrangements provided for in this Directive.

Article 17

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

- (i) Articles 7 and 8 of this Directive two months after the notification date thereof, it being understood that the corresponding national provisions shall continue to apply until the approval of the programmes and in the absence of programmes until the date referred to in (ii);
- (ii) the other provisions of this Directive not later than 31 December 1992.

⁽¹⁾ OJ No L 255, 18. 10. 1968, p. 23.

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

Article 18

This Directive is addressed to the Member States.

ANNEX A

CHAPTER 1

I. Officially brucellosis (B. melitensis)-free ovine or caprine holding

A. Grant of status

An officially brucellosis (B. melitensis)-free ovine or caprine holding means

- 1. a holding:
 - (a) in which all the animals which are susceptible to brucellosis
 (B. melitensis) have been free from clinical or any other signs of brucellosis (B. melitensis) for at least 12 months;
 - (b) which contains no ovine or caprine animals which have been vaccinated against brucellosis (*B. melitensis*), save those vaccinated at least two years previously with Rev. 1 vaccine or any other vaccine approved under the procedure laid down in Article 15 of this Directive;
 - (c) in which two tests separated by an interval of six months or more have been carried out, with negative results, in accordance with Annex C on all ovine and caprine animals on the holding over six months of age at the time of testing; and
 - (d) in which, following the tests referred to in point (c), there are only ovine or caprine animals born on the holding or which have come from an officially brucellosis-free or brucellosisfree holding under the conditions laid down in point D,

and in which, after qualification, the requirements laid down in point B continue to be fulfilled;

- 2. a holding situated in an officially recognized brucellosis-free Member State or region in accordance with point II.
- B. Maintenance of status
 - 1. In the case of officially brucellosis (*B. melitensis*)-free ovine or caprine holdings which are not situated in a part of the territory which is recognized as officially brucellosis-free, and in which, after qualification, the introduction of animals is carried out in accordance with the requirements of point D, a representative number of the ovine and caprine animals over six months old must be checked annually. The holding may retain its officially brucellosis (*B. melitensis*)-free status if the results of the tests are negative.

The representative number of animals to be tested must, for each holding, consist of the following:

- all non-castrated male animals over six months old,
- all animals brought onto the holding since the previous test,
- 25 % of the females which have reached the age of reproduction (i.e. which are sexually mature) or are in milk, with a minimum of 50 per holding — except in holdings where there are fewer than 50 such females, in which case all females must be tested.
- 2. For a region which is not officially brucellosis-free where more than 99 % of the ovine or caprine holdings are declared to be officially brucellosis (*B. melitensis*)-free, the frequency of checks of officially brucellosis-free ovine or caprine holdings may be extended to three years, provided that the holdings which are not officially brucellosis free are placed under official control or undergo an eradication programme.
- C. Suspected or actual cases of brucellosis
 - 1. Where, on an officially brucellosis-free ovine or caprine holding,
 - (a) one or more ovine or caprine animals are suspected of having brucellosis (*B. melitensis*), the holding's officially

brucellosis-free status must be withdrawn by the competent authority. However, that status may be provisionally suspended if the animal or animals are immediately destroyed or isolated, pending official confirmation of the disease or an official quashing of the suspicion of that disease;

- (b) brucellosis *(B. melitensis)* is confirmed, the provisional suspension may be lifted by the competent authority only if all animals infected or all the animals of species susceptible to infection are slaughtered and two tests, separated by an interval of at least three months or more, and carried out in accordance with Annex C on all the animals of the holding over six months old, give negative results.
- 2. If the holding referred to in paragraph 1 is in a region which is recognized as officially free from brucellosis (*B. melitensis*), the Member State concerned must immediately inform the Commission and the other Member States.

The competent authority of the Member State concerned must:

- (a) slaughter all infected animals and all animals of species susceptible to infection on the holding concerned. The Member State concerned must keep the Commission and the other Member States informed of the development of the situation;
- (b) conduct an epidemiological enquiry, and the herds linked epidemiologically to the infected herd must undergo the tests laid down in point 1 (b).
- 3. Should an outbreak of brucellosis be confirmed in accordance with point 2, the Commission after having assessed the circumstances of the renewed outbreak of brucellosis (*B. melitensis*) shall adopt, if that assessment so justifies, under the procedure laid down in Article 15, a decision suspending or withdrawing the status of that region. If the status is withdrawn, the conditions for a new qualification shall be specified in accordance with the same procedure.
- D. Introduction of animals onto an officially brucellosis (B. melitensis)free ovine or caprine holding

Ovine or caprine animals may not be introduced into an ovine or caprine holding which is officially free from brucellosis unless they either:

- 1. come from an officially brucellosis-free ovine or caprine holding;
- 2. or:
 - come from a brucellosis-free holding and,
 - are identified individually in accordance with Article 4 (1)
 (a) of this Directive,
 - have never been vaccinated against brucellosis or if they have been vaccinated, were so vaccinated more than two years previously. However, females over two years old which were vaccinated before the age of seven months may also be brought onto the holding, and
 - were isolated under official supervision on the holding of origin and, during such isolation underwent, with negative results, two tests separated by an interval of at least six weeks in accordance with Annex C.

II. Officially brucellosis-free Member State or region

Any Member State or region within the meaning of Article 2 (10) of this Directive may be recognized, under the procedure laid down in Article 15, as being officially brucellosis-free:

1. (a) in which at least 99,8 % of the ovine or caprine holdings are officially brucellosis-free holdings;

(b) which fulfils the following conditions:

- (i) ovine or caprine brucellosis is a disease that has been compulsorily notifiable for at least five years;
- (ii) no case of ovine or caprine brucellosis has been officially confirmed for at least five years;
- (iii) vaccination has been prohibited for at least three years; and
- (c) for which compliance with these conditions has been established under the procedure set out in Article 15 of this Directive;
- 2. in which the conditions set out in point 1 have been satisfied; and

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- (i) the first year following recognition of a Member State or region as brucellosis-free (*Br. melitensis*), random checks carried out at either holding or slaughterhouse level show with a confidence rating of 99 % that less than 0,2 % of the holdings were infected, or at least 10 % of the ovine and caprine animals over six months of age have undergone a test carried out in accordance with Annex C with negative results;
 - annually, from the second year following recognition of a Member State or region as brucellosis-free (*Br. melitensis*), random checks carried out at either holding or slaughterhouse level show with a confidence rating of 95 % that less than 0,2 % of the holdings were infected, or at least 5 % of the ovine and caprine animals over six months of age have undergone a test carried out in accordance with Annex C with negative results;
 - the provisions laid down in the above two indents may be amended in accordance with the procedure laid down in Article 15;

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This provision shall be reviewed before the entry into force of the Accession Treaty with a view toits possible amendment, to be carried out in accordance with the procedure laid down in Article 15.

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(ii) the conditions for qualification continue to be fulfilled.

CHAPTER 2

Brucellosis (B. melitensis)-free ovine or caprine holding

A. Grant of status

A. An ovine or caprine holding is considered to be brucellosis (B. melitensis)-free:

- 1. in which:
 - (a) all the animals susceptible to brucellosis (*B. melitensis*) have been free from clinical or other signs of brucellosis for at least 12 months;
 - (b) all or some of the ovine or caprine animals have been vaccinated with Rev. 1 vaccine or any other vaccine approved under the procedure laid down in Article 15 of this Directive. The vaccinated animals must have been vaccinated before the age of seven months;
 - (c) two tests separated by an interval of six months or more have been carried out, with negative results, in accordance with Annex C, on all vaccinated ovine and caprine animals on the holding which are over 18 months old at the time of testing;
 - (d) two tests separated by an interval of six months or more have been carried out, with negative results, in accordance with Annex C, on all non-vaccinated ovine and caprine animals on the holding which are over six months old at the time of testing; and

- (e) after the tests referred to under points (c) or (d) have been carried out, all the ovine and caprine animals on the holding were either born there or come from a brucellosis-free holding under the conditions laid down in section D; and
- 2. in which the requirements laid down under B continue to be fulfilled once it has qualified as brucellosis-free.
- B. Maintenance of status

An annual test must be carried out on a representative number of the ovine and caprine animals on each holding. The holding may retain its status only if the tests are negative.

The representative number of animals to be tested must, for each holding, consist of:

- all non-castrated male animals over six months old which have not been vaccinated,
- all non-castrated male animals over 18 months which have been vaccinated,
- all animals brought onto the holding since the previous test,
- 25 % of females which are of reproductive age (sexually mature) or in milk, with a minimum of 50 per holding — except in holdings where there are fewer than 50 such females, in which case all these females must be tested.
- C. Suspected or actual cases of brucellosis
 - 1. The brucellosis-free status of an ovine or caprine holding must be withdrawn if the holding contains one or more ovine or caprine animals which are suspected of having brucellosis (*B. melitensis*). However, that status may be provisionally suspended if the animal or animals are immediately destroyed or isolated pending official confirmation of the disease or an official quashing of the suspicion of that disease.
 - 2. If brucellosis *(B. melitensis)* is confirmed, the provisional suspension may be lifted only if all animals infected or all the animals of the species susceptible to infection are slaughtered and two tests, separated by an interval of three months or more and carried out in accordance with Annex C on,
 - all vaccinated animals over 18 months old,
 - all non-vaccinated animals over six months old, and

both give negative results.

D. Introduction of animals into a brucellosis (B. melitensis)-free ovine or caprine holding

The following animals only may be introduced into an ovine or caprine holding which is free from brucellosis:

- 1. ovine or caprine animals which come from an ovine or caprine holding which is free from or officially free from brucellosis (*B. melitensis*);
- 2. until the date laid down for holdings to qualify as brucellosis-free in accordance with the eradication plans adopted under Decision 90/242/EEC (¹) ovine or caprine animals from holdings other than those referred to in point 1, provided that they meet the following conditions:
 - (a) they must be individually identified in accordance with Article 4 (1)(a) of this Directive;
 - (b) they must originate in a holding on which all animals belonging to species which are susceptible to brucellosis (*B. melitensis*) have shown no clinical or other signs of brucellosis (*B. melitensis*) for at least 12 months;
 - (c) (i) they must not have been vaccinated during the previous two years;
 - they must have been kept under isolation under veterinary supervision on the holding of origin and, during that period, must have undergone, with negative results, two tests separated by an interval of at least six weeks in accordance with Annex C; or

(ii) they must have been vaccinated with Rev. 1 vaccine or any other vaccine approved in accordance with the procedure laid down in Article 15 of this Directive before the age of seven months and not less than 15 days before entering the holding of destination.

E. Change of status

A brucellosis (*B. melitensis*)-free ovine or caprine holding may qualify as an officially brucellosis (*B. melitensis*)-free herd after a minimum period of two years if:

- (a) it contains no animal which has been vaccinated against brucellosis (B. melitensis) during the preceding two years at least;
- (b) the conditions laid down in point D.2. have been complied with throughout that period;
- (c) at the end of the second year, a test carried out, in accordance with Annex C, on all animals aged over six months has in each case given a negative result.

ANNEX B

I(1)

- Foot-and-mouth disease
- Brucellosis (B. melitensis)
- Contagious epidydimitis (B. ovis)
- Anthrax
- Rabies

$\mathbf{II}(1)$

— Scrapie

III

- Contagious agalactia
- Paratuberculosis
- Caseous lymphadenitis
- Pulmonary adenomatosis
- Maedi Visna
- Caprine viral arthritis/encephalitis.

(¹) Compulsorily notifiable diseases

ANNEX C

Brucellosis (B. melitensis) tests

For a holding to qualify for brucellosis-free status, testing for brucellosis (*B. melitensis*) is performed by means of the Rose Bengal method or by the complement-fixation method described in the Annex to Decision 90/242/EEC or by any other method recognized in accordance with the procedure laid down in Article 15 of this Directive. The complement-fixation method is used for tests on individual animals.

When carrying out the Rose Bengal test, if more than 5 % of the animals on a holding show a positive reaction, a further test is carried out on every animal on the holding by means of the complement-fixation method.

Serum containing 20 or more ICFT units/ml must be regarded as positive in the complement-fixation test.

The antigens used must be approved by the national laboratory and must be standardized against the second international standard anti-brucella abortus serum.

ANNEX D

Official contagious epidydimitis (Brucella ovis) test

Complement-fixing test:

The specific antigen used must be approved by the national laboratory and must be standardized against the international standard anti-brucella ovis serum.

The working serum must be standardized with the international standard anti-brucella ovis serum prepared by the Central Veterinary Laboratory, Weybridge, Surrey, United Kingdom.

A serum containing 50 or more International Units per/ml must be regarded as positive.

ANNEX E

MODEL I

HEALTH CERTIFICATE (1)

for trade between Member States of the European Communities in ovine and caprine animals for slaughter

	No	 •••••	•••••
Member State of consignor:		 	
Competent Ministry :			
Competent department :		 	
I. Number of animals :			

II. Identification of animals

Number of animals	Male/female ovine/caprine animals	Bread	Age	Official individual identification (state number and location)	

III. Origin of the animals

The animals were either:

- (a) born and have been reared since birth on Community territory (2); or
- (b) imported from a third country appearing on the list drawn up in accordance with Article 3 of Directive 72/462/EEC and meet either (2):
 - the animal health conditions laid down in accordance with Article 8 of Directive 72/462/EEC (2), or
 - the conditions laid down in Article 8 (A) (2) of Directive 91/496/EEC and have spent at least 30 days in the Member State of consignment (2).

IV. Destination of the animals

The animals will be sent:

from :
(Place)
to :
(Member State and place of destination)
by : railway wagon, lorry/truck, air, boat/ship (2) :
Name and address of consignor :
Name and address of consignee :

- (1) Health certificates may be drawn up only for animals which are to be transported in the same railway wagon, truck/lorry, aircraft or boat/ship, which originate from the same holding and which are being sent to the same consignee.
 (2) Delete where not applicable.
 (3) Give the registration number in the case of railway wagons and lorries/trucks, the flight number in the case of aircraft and the name in the case of boats/ships.

V. Health information

- I, the undersigned, certify that the animals described above meet the following requirements :
- A. they have been inspected today (within 48 hours prior to loading) and show no clinical sign of disease;
- B. they are not animals which are to be destroyed under a scheme to eradicate a contagious or infectious disease;
- C. neither were they obtained from a holding which is the subject of a prohibition on animal health grounds nor have they been in contact with animals from such a holding, it being understood that :
 - 1. such prohibition is connected with the outbreak of one of the following diseases to which the animals are susceptible :
 - brucellosis,
 - rabies,
 - anthrax ;
 - 2. after destruction of the last animal suffering from or susceptible, the duration of the prohibition must be at least:
 - 42 days in a case of brucellosis,
 - 30 days in a case of rabies,
 - 15 days in a case of anthrax;

nor have they come from a holding or been in contact with animals from a holding in a protection zone which has been set up under Community legislation and which animals are prohibited to leave;

- D. they are not the subject of animal health measures pursuant to the Community legislation on footand-mouth disease nor have they been vaccinated against foot-and-mouth disease;
- E. they were obtained from :

— a holding('):	

- F. they were transported direct, without passing/passing through (1); an assembly centre (1)/a place of loading (1)/dealer's premises (1):
 - from a holding (1)/from a holding to market and thence (1),
 - to the actual place of loading, using means of transport and containment which had, beforehand, been cleaned and disinfected using an officially approved disinfectant, and in such a way as to provide effective protection of the animals' health status.

VI. This certificate is valid for 10 days from the date of inspection.

Date	at,	on
		(Date of inspection)
	Stamp	(Signature of official veterinarian)
		(Name and title, in block capitals)

▼<u>M1</u>

 ^{(&}lt;sup>1</sup>) Delete where not applicable.
 (²) Where appropriate, indicate the name.

MODEL II

HEALTH CERTIFICATE (')

for trade between Member States of the European Communities in ovine and caprine animals for fattening

1	No :
Member State of consignor :	
Competent Ministry :	
Competent department :	
I. Number of animals :	

II. Identification of animals

Number of animals	Male/female ovine/caprine animals	Breed	Age	Official individual identification (state number and location)
x				
· · · ·				

III. Origin of the animals

The animals were either:

- (a) born and have been reared since birth on Community territory (2); or
- (b) imported from a third country appearing on the list drawn up in accordance with Article 3 of Directive 72/462/EEC and meet either (2):
 - the animal health conditions laid down in accordance with Article 8 of Directive 72/462/EEC (2), or
 - the conditions laid down in Article 8 (A) (2) of Directive 91/496/EEC and have spent at least 30 days in the Member State of consignment (2).

IV. Destination of the animals

The animals will be sent:
from :
(Place)
to :
(Member State and place of destination)
by : railway wagon, lorry/truck, air, boat/ship (²) :
Name and address of consignor:
Name and address of consignee :

^{(&#}x27;) Health certificates may be drawn up only for animals which are to be transported in the same railway wagon, truck/lorry, aircraft or boat/ship, which originate from the same holding and which are being sent to the same consignee.
(') Delete where not applicable.
(') Give the registration number in the case of railway wagons and lorries/trucks, the flight number in the case of aircraft and the name in the case of boats/ships.

V. Health information

- I, the undersigned, certify that the animals described above meet the following requirements :
- A. they have been inspected today (within 48 hours prior to loading) and show no clinical sign of disease;
- B. they are not animals which are to be destroyed under a scheme to eradicate a contagious or infectious disease;
- C. neither were they obtained from a holding which is the subject of a prohibition on animal health grounds nor have they been in contact with animals from such a holding, it being understood that :
 - 1. such prohibition is connected with the outbreak of one of the following diseases to which the animals are susceptible:
 - brucellosis,
 - rabies,
 - anthrax ;
 - 2. after destruction of the last animal suffering from or susceptible, the duration of the prohibition must be at least :
 - 42 days in a case of brucellosis,
 - 30 days in a case of rabies,
 - 15 days in a case of anthrax;

nor have they come from a holding or been in contact with animals from a holding in a protection zone which has been set up under Community legislation and which animals are prohibited to leave;

- D. they are not the subject of animal health measures pursuant to the Community legislation on footand-mouth disease nor have they been vaccinated against foot-and-mouth disease;
- E. 1. either, they qualify for admission to an ovine or caprine holding which is officially brucellosisfree, (B. melitensis)('), i.e.:
 - (a) they come from an officially brucellosis-free (B. melitensis) holding (1); or
 - (b) they come from a brucellosis-free (B. melitensis) holding and :
 - they are identified individually,
 - they have never been vaccinated against brucellosis or if they have been vaccinated were so vaccinated more than two years previously. However, females over two years old which were vaccinated before the age of seven months may also be brought onto the holding, and
 - they were isolated under official supervision on the holding of origin and, during such isolation, underwent, with negative results, two tests for brucellosis in accordance with Annex C to Directive 91/68/EEC, separated by an interval of at least six weeks (1);

2. or they qualify for admission to a brucellosis-free ovine or caprine holding. (B. melitensis)(1), i.e.:

- (a) they come from an officially brucellosis-free (B. melitensis) holding (1); or
- (b) they come from a brucellosis-free (B. melitensis) holding (1);

or

- (c) until the qualifying date under eradication plans approved pursuant to Decision 90/242/EEC, they originate from a holding other than that referred to in (a) and (b) and satisfy the following conditions :
 - (i) they are identified individually;
 - and
 - (ii) they originate from a holding in which all the animals of species susceptible to brucellosis (*B. melitensis*) have shown no clinical or other signs of brucellosis for at least 12 months; and

^{▼&}lt;u>M1</u>

⁽¹⁾ Delete where not applicable.

- (iii) either: they have not been vaccinated against brucellosis (B. melitensis) in the last two years, and
 - they were isolated under veterinary supervision on the holding of origin and, during such isolation, underwent, with negative results, two tests for brucellosis in accordance with Annex C to Directive 91/68/EEC, separated by an interval of at least six weeks, or
 - they were vaccinated with Rev I vaccine before the age of seven months but not later than 15 days before their introduction into the holding of destination (');
- F. they were obtained from :
- G. they were transported direct, without passing/passing through (') an assembly centre ('), a place of loading ('), dealer's premises ('):
 - from a holding (1), from a holding to market and thence (1),
 - to the actual place of loading, using means of transport and containment which had, beforehand, been cleaned and disinfected using an officially approved disinfectant, and in such a way as to provide effective protection of the animals' health status.

VI. This certificate is valid for 10 days from the date of inspection.

(Name and title, in block capitals)

▼<u>M1</u>

⁽⁾ Delete where not applicable.

^{(&}lt;sup>2</sup>) Where appropriate, indicate the name.

MODEL III

HEALTH CERTIFICATE (1)

for trade between Member States of the European Communities in ovine and caprine animals for breeding

	No:
Member State of consignor :	
Competent Ministry :	
Competent department :	
I. Number of animals :	

II. Identification of animals

Number of animals	Male/female ovine/caprine animals	Breed	Age	Official individual identification (state number and location)

III. Origin of the animals

The animals were either:

- (a) born and have been reared since birth on Community territory (2);
 - or
- (b) were imported from a third country appearing on the list drawn up in accordance with Article 3 of Directive 72/462/EEC and meet either (2):
 - the animal health conditions laid down in accordance with Article 8 of Directive 72/462/EEC (2), or
 - the conditions laid down in Article 8 (A) (2) of Directive 91/496/EEC and have spent at least 30 days in the Member State of consignment (2).

IV. Destination of the animals

The animals will be sent:

(Place)
to :
(Member State and place of destination)
by : railway wagon, lorry/truck, air, boat/ship (2) :
Name and address of consignor :
Name and address of consignee :

^{(&}lt;sup>1</sup>) Health certificates may be drawn up only for animals which are to be transported in the same railway wagon, truck/lorry, aircraft or boat/ship, which originate from the same holding and which are being sent to the same consignee.
(²) Delete where not applicable.
(³) Give the registration number in the case of railway wagons and lorries/trucks, the flight number in the case of aircraft

and the name in the case of boats/ships.

V. Health information

- I, the undersigned, certify that the animals described above meet the following requirements :
- A. they have been inspected today (within 48 hours prior to loading) and show no clinical sign of disease;
- B. they are not animals which are to be destroyed under a scheme to eradicate a contagious or infectious disease;
- C. neither were they obtained from a holding which is the subject of a prohibition on animal health grounds nor have they been in contact with animals from such a holding, it being understood that :
 - 1. such prohibition is connected with the outbreak of one of the following diseases to which the animals are susceptible :
 - brucellosis,
 - rabies,
 - anthrax ;
 - 2. after destruction of the last animal suffering from or susceptible, the duration of the prohibition must be at least :
 - 42 days in the case of brucellosis,
 - 30 days in the case of rabies,
 - 15 days in the case of anthrax;

nor have they come from a holding or been in contact with animals from a holding in a protection zone which has been set up under Community legislation and which animals are prohibited to leave;

- D. they are not the subject of animal health measures pursuant to the Community legislation on footand-mouth disease nor have they been vaccinated against foot-and-mouth disease;
- E. as regards scrapie, they come from a holding meeting the following requirements :
 - the holding is under official supervision,
 - the animals must be marked,
 - no case of scrapie has been confirmed for at least two years,
 - a random check must be made on old ewes from the holding which are to be culled unless the holding is situated in a region or Member State qualifying for the conditions to be adopted pursuant to Article 8 of Directive 91/68/EEC,
 - females may not be introduced into the holding unless they come from a holding meeting the same requirements.

They must have been kept permanently on a holding or holdings meeting these requirements since their birth or for the last two years;

- F. 1. either they qualify for admission to an officially brucellosis-free (B. melitensis) ovine or caprine holding ('), i.e.:
 - (a) they come from an officially brucellosis-free (B. melitensis) holding (');
 - (b) they come from a brucellosis-free (B. melitensis) holding (1) and :
 - they are identified individually,
 - they have never been vaccinated against brucellosis or if they have been vaccinated were so
 vaccinated more than two years previously. However, females over two years old which
 were vaccinated before the age of seven months may also be brought onto the holding,

or

▼<u>M1</u>

and

⁽¹⁾ Delete where not applicable.

- they were isolated under official supervision on the holding of origin and, during such isolation, underwent, with negative results, two tests for brucellosis in accordance with Annex C to Directive 91/68/EEC, separated by an interval of at least six weeks (¹);
- 2. or they qualify for admission to a brucellosis-free ovine or caprine holding ('), i.e.:
 - (a) they come from an officially brucellosis-free (B. melitensis) holding (1);
 - or
 - (b) they come from a brucellosis-free (B. melitensis) holding (1);
 - or
 - (c) until the qualifying date under eradication plans approved pursuant to Decision 90/242/EEC, they originate from a holding other than referred to in (a) and (b) and satisfy the following conditions :
 - (i) they are identified individually;

and

 (ii) they originate from a holding in which all the animals of species susceptible to brucellosis (*B. melitensis*) have been free of clinical symptoms or any other symptom of brucellosis for at least 12 months;

and

- (iii) either: they have not been vaccinated against brucellosis (B. melitensis) in the last two years,
 - and
 - they were isolated under veterinary supervision on the holding of origin and, during such isolation, underwent, with negative results, two tests for brucellosis in accordance with Annex C to Directive 91/68/EEC separated by an interval of at least six weeks,
 - or
- they were vaccinated with Rev 1 vaccine before the age of seven months but not later than 15 days before their introduction into the holding of destination (');
- G. as regards contagious epididymitis of rams (B. ovis), where uncastrated breeding rams are concerned, they must :
 - come from a holding on which no case of contagious epididymitis of rams (B. ovis) has been recorded in the past 12 months,
 - have been kept permanently on that holding for the 60 days preceding consignment,
 - have undergone, within 30 days prior to consignment, with a negative result, a complementfixing test to detect contagious epididymitis of rams (B. ovis);
- H. to the knowledge of the undersigned and according to the written declaration made by the owner, they were not obtained from a holding or have not been in contact with animals from a holding in which the following diseases have been clinically detected :
 - within the last six months, contagious agalactica of sheep (Mycoplasma agalactiae) and contagious agalactica of goats (Mycoplasma agalactiae, M. capricolum, M. mycoides subsp. mycoides Large Colony),
 - within the last 12 months, paratuberculosis or caseous lymphadenitis,
 - within the last three years, pulmonary adenomatosis, maedi/visna or caprine viral arthritis/ ecephalitis. However, this time limit is reduced to 12 months if animals affected by maedi/visna or caprine viral arthritis/ecephalitis have been slaughtered and the remaining animals have reacted negatively to two tests.

▼<u>M1</u>

^{(&}lt;sup>i</sup>) Delete where not applicable.

▼	M1

I.	they were obtained from :	
	— a holding(')	(²),
	- an approved market (')	(²),
	— a third country(')	(²);

J. they were transported direct, without passing/passing through (1) an assembly centre (1)/a place of loading (1)/dealer's premises (1)/an approved frontier inspection post (1):

- from a holding (')/from a holding to market and thence ('):

- to the actual place of loading, using means of transport and containment which had, beforehand, been cleaned and disinfected using an officially-approved disinfectant, and in such a way as to provide effective protection of the animals' health status.

VI. This certificate is valid for 10 days from the date of inspection.

Done at on (Date of inspection) (Signature of official veterinarian) Stamp (Name and title, in block capitals)

^{(&}lt;sup>1</sup>) Delete where not applicable. (²) Where appropriate, indicate the name.