Publicat în Jurnalul Oficial nr. 121 din 29-07-1964

Abrogat(ă) de Directiva Consiliului 72/462/CEE din 12 decembrie 1972 privi...

COUNCIL DIRECTIVE of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (64/432/EEC)

THE COUNCIL OF THE EUROPEAN ECONOMIC COMMUNITY,

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

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament 1;

Having regard to the Opinion of the Economic and Social Committee 2;

Whereas Council Regulation No 20 on the progressive establishment of a common organisation of the market in pigmeat 3 is already in force and a similar regulation is to be adopted for beef and veal and whereas these regulations also concern trade in live animals;

Whereas Regulation No 20 substitutes for the numerous traditional means of protection at the frontier a single system designed in particular to facilitate intra-Community trade ; whereas the regulation to be adopted for beef and veal is also designed to eliminate obstacles to such trade;

Whereas, so long as intra-Community trade in bovine animals and swine is hindered by differences between the health requirements of Member States, the implementation of the above-mentioned regulations will not have the desired effect;

Whereas, to eliminate those differences, measures must be taken within the framework of the common agricultural policy and in line with regulations already adopted or in preparation on the progressive establishment of a common organisation of markets ; whereas the animal health provisions of Member States must therefore be approximated;

Whereas the right of Member States under Article 36 of the Treaty to continue to apply prohibitions or restrictions on imports, exports or goods in transit justified on grounds of the protection of health and life of humans and animals nevertheless does not exempt them from the obligation to approximate the provisions on which those prohibitions and restrictions are based, in so far as the differences between those provisions hinder the implementation and functioning of the common agricultural policy;

Whereas, in the context of such approximation, the exporting country must be required to ensure that bovine animals and swine for breeding, production or slaughter intended for intra-Community trade, the places from which those animals come and are shipped and the means of transport used satisfy certain animal health requirements so as to ensure that the animals are not a source of contagious or infectious disease;

Whereas, so that Member States may be sure that these requirements are satisfied, provision must be made for the issue by an official veterinarian of a health certificate which will accompany the animals to their destination;

Whereas Member States must have the right to prohibit the introduction into their territory of bovine animals and swine if they are found to be suffering or are suspected of suffering from a contagious or infectious disease, if they may spread such disease without actually suffering from it or if they do not comply with Community animal health provisions;

Whereas there is no reason to allow Member States to prohibit the introduction of bovine animals and 1 OJ No 61, 19.4.1963, p. 1254/63. 2 OJ No 121, 29.7.1964, p. 2009/64. 3 OJ No 30, 20.4.1962, p. 945/62. swine into their territory for reasons other than those of animal health and whereas, therefore, the consignor should at his own request or upon request of his representative be allowed to return the animals to the country of export unless there are reasons to the contrary;

Whereas, in case of prohibition or restriction, the reasons therefor should be made known to the consignor of the animals or his representative and to the competent central authority of the country of export so that they be aware of the reasons why such measures were imposed;

Whereas in the event of dispute between himself and the authority of the Member State of destination as to the justification for prohibition or restriction, the consignor should be enabled to obtain the opinion of a veterinary expert whom he may select from a panel drawn up by the Commission;

Whereas in some cases and for certain categories of animals it appears that the general provisions of this Directive may be relaxed without involving any health risk, by allowing consignee Member States to grant general or special derogations;

Whereas, in certain fields presenting special problems, the provisions in Member States cannot be approximated until a more thorough study has been made;

Whereas a simplified amendement procedure may be provided for Annexes B to D since the rules contained in those Annexes are of a technical nature and liable to change ; whereas the Commission should therefore be entrusted with making such amendments after consulting the Member States;

HAS ADOPTED THIS DIRECTIVE:

Article 1

This Directive shall apply to intra-Community trade in bovine animals and swine for breeding, production or slaughter.

Article 2

For the purposes of this Directive: (a) "holding" means an agricultural establishment or officially supervised dealer's premises situated in the territory of a Member State, in which animals for breeding, production or slaughter are regularly kept or bred;

(b) "animal for slaughter" means a bovine animal or swine intended to be taken on arrival in the country of destination direct to a slaughterhouse, or to a market adjoining a slaughterhouse under whose rules all animals may be removed, in particular after the market, only to a slaughterhouse approved for this purpose by the competent central authority. In the latter case, the animals must be slaughtered at that slaughterhouse not later than seventy-two hours after arriving at the market;

(c) "animals for breeding or production" means bovine animals and swine other than those referred to in (b), including those intended for breeding, milk or meat production, or draft purposes;

(d) "tuberculosis-free bovine animal" means a bovine animal which satisfies the conditions laid down in Annex A (I) (1);

(e) "officially tuberculosis-free bovine herd" means a bovine herd which satisfies the conditions laid down in Annex A (I) (2);

(f) "brucellosis-free bovine animal" means a bovine animal which satisfies the conditions laid down in Annex A (II) (1);

(g) "officially brucellosis-free bovine herd" means a bovine herd which satisfies the conditions laid down in Annex A (II) (A) (2);

(h) "brucellosis-free bovine herd" means a bovine herd which satisfies the conditions laid down in Annex A (II) (A) (3);

(i) "brucellosis-free swine" means swine which satisfy the conditions laid down in Annex A (II) (B) (1);

(k) "officially brucellosis-free swine herd" means a swine herd which satisfies the conditions laid down in Annex A (II) (B) (2);

(l) "epizootic free area" means an area 20 km in diameter in which, according to official findings, for at least thirty days prior to loading there has been: (i) no incidence of foot-and-mouth disease, in the case of bovine animals;

(ii) no incidence of foot-and-mouth disease, swine fever or contagious swine paralysis (Teschen disease) in the case of swine;

(m) "compulsorily notifiable diseases" means the diseases listed in Annex E;

(n) "official veterinarian" means the veterinarian designated by the competent central authority of the Member State;

(o) "exporting country" means the Member State from which bovine animals and swine are sent to another Member State;

(p) "country of destination" means the Member State to which bovine animals and swine are sent from another Member State.

Article 3

1. Each Member State shall ensure that only bovine animals and swine which fulfil the general conditions laid down in paragraph 2, account being taken where appropriate of the provisions of paragraph 7, and also the special conditions fixed for certain categories of bovine animals and swine in paragraphs 3 to 6, are sent from its territory to that of another Member State.

2. Bovine animals and swine covered by this Directive must: (a) show no clinical sign of disease on the day of loading;

(b) have been obtained from a holding which officially fulfils the following conditions: (i) it shall be situated in the centre of an epizootic free area;

(ii) it shall, for at least three months prior to consignment, have been free from foot-and-mouth disease and bovine brucellosis in the case of bovine animals and from foot-and-mouth disease, bovine and porcine brucellosis, swine fever and contagious porcine paralysis (Teschen disease) in the case of swine;

(iii) it shall, for a least thirty days prior to consignment, have been free from all other compulsorily notifiable diseases which are contagious or infectious for the animal species in question;

(c) in the case of animals for breeding and production, have remained on the holding referred to in 2 (b) during the thirty days preceding loading. The official veterinarian may certify that the animals have remained on the holding during the thirty days preceding loading, in the case of animals identified in the manner provided in subparagraph (d) and placed under official veterinary supervision, it being thus possible to certify that they belong to the holding;

(d) be identified by an official or officially approved earmark or, in the case of swine, by a permanent identification stamp;

(e) be sent direct from the holding to the actual place of loading: (i) without coming into contact with cloven-hoofed animals other than bovine animals and swine which fulfil the conditions laid down for intra-Community trade;

(ii) segregated into animals for breeding or production and animals for slaughter;

(iii) in transport vehicles or containers which have first been cleansed and disinfected with a disinfectant officially authorised in the exporting country;

(f) be loaded for transportation to the country of destination in accordance with the conditions set out in subparagraph (e) at a specific place at the centre of an epizootic free area;

(g) after loading be sent direct and as quickly as possible to the frontier post of the exporting country;

(h) be accompanied during transportation to the country of destination by a health certificate conforming to Annex F (Models I to IV) which shall be drawn up on the day of loading, in the language of the country of destination at least, and be valid for ten days.

3. Bovine animals for breeding or production must moreover: (a) have been vaccinated at least fifteen days and not more than four months before loading against types A, O and C of the foot-and-mouth disease virus using an inactivated virus vaccine approved and controlled by the competent authority of the exporting country;

(b) come from an officially tuberculosis-free bovine herd, be tuberculosis-free and in particular have reacted negatively to an intradermal tuberculin test carried out in accordance with the provisions of Annexes A and B;

(c) come from an officially brucellosis-free bovine herd, be brucellosis-free, and in particular have shown a brucella count lower than 30 international units of agglutination per millilitre when given a sero-agglutination test complying with the provisions of Annexes A and C;

(d) in the case of dairy cows, show no clinical evidence of mastitis ; in addition, upon analysis complying with the provisions of Annex D their milk must not have shown any sign of a characteristic inflammatory condition or of a specifically pathogenic micro-organism.

4. Swine for breeding or production must moreover come from brucellosis-free stock, themselves be brucellosis-free, and in particular have shown a brucella count lower than 30 international units of agglutination per millilitre when given a sero-agglutination test complying with the provisions of Annexes A and C ; the sero-agglutination test is only required for swine weighing more than 25 kilogrammes.

5. Animals for slaughter must not moreover be bovine animals or swine which are to be slaughtered under a contagious or inflectious disease eradication programme of a Member State.

6. Bovine animals for slaughter, if over four months old, must in addition: (a) have been vaccinated not less than fifteen days and not more than four months before loading against types A, O and C of the foot-and-mouth disease virus, using an inactivated virus vaccine approved and controlled by the competent authority of the exporting country ; however, the period of validity of the vaccination shall be extended to twelve months in the case of bovine animals revaccinated in Member States where such animals are vaccinated annually and where they are systematically slaughtered when they contract foot-and-mouth disease;

(b) if they do not come from an officially tuberculosis-free bovine herd, have reacted negatively to an intradermal tuberculin test carried out in accordance with the provisions of Annexes A and B;

(c) if they do not come from an officially brucellosis-free bovine herd nor from a brucellosis-free bovine herd have shown a brucella count lower than 30 international units of agglutination per millilitre when given a sero-agglutination test complying with the provisions of Annexes A and C.

7. The following shall also be approved for intra-Community trade : animals for breeding or production or animals for slaughter acquired on an officially approved market for consignment to another Member State, provided such market fulfils the following conditions: (a) it is supervised by an official veterinarian;

(b) it is situated in the centre of an epizootic free area and in a place where no other livestock market is held on the same day;

(c) it is used after disinfection either for animals for breeding or production or for animals for slaughter which meet the requirements of intra-Community trade as laid down in paragraphs 2 to 6 and in Article 4, provided these conditions apply to the animal species in question. The provisions of paragraph 2 (e) must in particular have been complied with when the animals were sent to market. Before being taken from the holding or market meeting the requirements of this paragraph to the place of loading, these animals may be taken to an officially supervised assembly point if the latter satisfies the conditions fixed for markets.

Animals acquired on such markets must be sent direct from the market or the assembly point to the actual place of loading in such manner that the provisions of paragraph 2 (e) and (g) are satisfied, and be exported to the country of destination.

The period during which the assembling of these animals takes place outside the holding of origin, in particular at the market, assembly point or actual place of loading may be counted in the thirty days prescribed in paragraph 2 (c) but shall not exceed four days.

8. The exporting country shall designate those markets referred to in paragraph 7 which are approved for animals for breeding or production and for animals for slaughter. It shall notify the competent central authorities of the other Member States and the Commission as to which markets are approved.

9. The exporting country shall determine the procedure for official supervision of the markets and assembly points referred to in paragraph 7 and shall ensure that this supervision is carried out.

10. In the case provided for in paragraph 7, corresponding entries must be made on the health certificates, in accordance with Annex F (Models I to IV).

11. The exporting country shall determine the procedure for official supervision of dealers' premises and shall ensure that this supervision is carried out.

12. If a holding or the area in which it is situated is the subject of official restrictions following the outbreak of a disease which is contagious or infectious for the animal species in question, the time limits set in paragraph 2 (b) (ii) and (iii) and Article 2 (e) shall take effect from the date on which these prohibition restrictions were officially lifted.

Article 4

1. All animals intended for intra-Community trade must have remained in the territory of the exporting Member State before the day of loading: (a) for not less than six months in the case of animals for breeding or production;

(b) for not less than three months in the case of animals for slaughter.

If such animals are respectively less than six or three months old they must have remained in the territory of the exporting Member State since birth.

2. In all cases to which paragraph 1 applies, appropriate entries must be made in the health certificates, as required by Annex F (Models I to IV).

Article 5

If the vaccines referred to in Article 3 (3) (a) and (6) (a) are not manufactured in a Member State, they shall be obtained from another Member State, except where new scientific data or the absence of vaccines which up to that time have been considered suitable makes it necessary to obtain vaccines from outside the European Economic Community. In the event of outbreaks of foot-and-mouth disease other than types A, O and C or variants of these types, against which the vaccines currently used afford inadequate protection or none at all, each Member State may take the necessary emergency measures to adapt the vaccine formulae and to use them accordingly. At the same time it shall inform the other Member States and the Commission thereof. The Commission may arrange for discussions to take place concerning the measures taken and to be taken.

Article 6

1. Each Member State shall communicate to the other Member States and the Commission the list of frontier posts to be used for the introduction of bovine animals and swine into its territory.

Subject to observance of the provisions relating to animal health, marketing channels and all means of transport available for use shall be taken into account in determining which frontier posts are to be used.

2. Each country of destination may require the consignor or his representative to notify it in advance of the entry into its territory of a consignment of bovine animals or swine, and of the type, nature and number of animals, the frontier post and the anticipated time of arrival. It may not, however, require this notification to be made more than forty-eight hours before the arrival of the consignment in its territory.

3. Each country of destination may prohibit the introduction of bovine animals and swine into its territory if an examination made at the frontier post by an official veterinarian reveals: (a) that the animals are affected by, or suspected of being affected by, or of being contaminated by a compulsorily notifiable disease;

(b) that the provisions of Articles 3 and 4 have not been observed as regards these animals.

The country of destination may take the necessary measures, including quarantine, to ascertain the position as regards animals suspected of being affected by or of being contaminated by a compulsorily notifiable disease or which might spread such disease.

Decisions taken under the first or second sentence must, at the request of the consignor or his representative, authorise the return of the animals, provided this is not contrary to considerations of health.

4. If the introduction of animals has been prohibited on any of the grounds set out in paragraph 3 (a) and the exporting country or the transit country, as the case may be, does not within eight hours authorise the return of them, the competent authority of the country of destination may order the animals to be slaughtered or destroyed.

5. Animals for slaughter must be slaughtered as soon as possible after their arrival at the slaughterhouse, in accordance with animal health requirements. Animals for slaughter which have been sent direct on arrival in the country of destination to a market adjoining a slaughterhouse under whose rules all animals may be removed, in particular after the market, only to a slaughterhouse approved for this purpose by the competent central authority must be slaughtered at that slaughterhouse not later than seventy-two hours after arriving at the market.

The competent authority of the country of destination may in the light of considerations of animal health designate the slaughterhouse to which these animals must be sent.

6. If, after the introduction into the territory of the country of destination of animals for breeding or production, facts come to light which would have justified the application of the first sentence of paragraph 3, the competent central authority of the exporting country must, at the request of the competent central authority of the country of destination, make the necessary investigations and notify that authority without delay of the outcome of such investigations.

7. The decisions taken by the competent authority under paragraphs 3 to 5 must be communicated to the consignor or his representative, together with the reasons for such decisions. These reasoned decisions must on request, be communicated to him forthwith in writing with an indication of what appeals against them are open under current legislation and the form and time in which they must be commenced. The decisions must also be communicated to the competent central authority of the exporting country.

Article 7

1. Countries of destination may grant to one or more exporting countries general authorisations or authorisations restricted to specific cases for the introduction into their territory or: A. Bovine animals for breeding, production or slaughter: (a) which, by way of derogation from Article 3 (3) (a) or 6 (a), have not been vaccinated against foot-and-mouth disease, if no case of foot-and-mouth disease has been officially recorded in the exporting country and in the transit countries concerned for at least six months preceding the date of loading;

(b) which, by way of derogation from Article 3 (3) (a) or (6) (a) have received anti-foot-and-mouth disease serum treatment, not more than ten days before loading, with an anti-foot-and-mouth disease serum approved and controlled by the competent authority of the exporting country and authorised by the competent authority of the country of destination.

B. Bovine animals for breeding or production which, by way of derogation from Article 3 (3) (c), come from a brucellosis-free herd.

C. Bovine animals for slaughter: (a) which, by way of derogation from Article 3 (6) (b), have reacted positively to an intradermal tuberculin test;

(b) which, by way of derogation from Article 3 (6) (c), have shown a brucella count equal to or higher than 30 international units of agglutination per millilitre when given a sero-agglutination test.

2. When a country of destination grants a general authorisation under paragraph 1, it shall forthwith inform the other Member States and the Commission thereof.

3. When a country of destination grants any authorisation under paragraph 1, a corresponding authorisation must, in the case of transit operations, be obtained from the transit countries concerned.

4. The exporting countries shall take all necessary measures to ensure that the health certificates, specimens of which are given in Annex F (Models I and II), mention that use has been made of one of the possibilities provided in paragraph 1.

Article 8

Until the entry into force of such provisions as may be adopted by the European Economic Community, this Directive shall not affect the provisions of Member States relating to: (a) bovine animals and swine which have been treated with antibiotics, oestrogens or thyreostatics;

(b) the prevention of trichinosis, on condition that those provisions are not applied in a discriminatory manner, having regard particularly to the implementation of systematic research to reveal trichina in exporting Member States.

Article 9

1. A Member State may take the following measures if there is a danger of animal diseases spreading as a result of the introduction into its territory of bovine animals or swine from another Member State: (a) in the event of an outbreak of an epizootic disease in the other Member State, temporarily prohibit or restrict the introduction of bovine animals or swine from the affected areas of that Member State;

(b) if an epizootic disease becomes widespread or if there is an outbreak of another serious contagious or infectious animal disease, temporarily prohibit or restrict the introduction of bovine animals and swine from any part of the territory of that State.

2. Measures taken by a Member State under paragraph 1 must be communicated within ten working days to the other Member States and the Commission together with the precise reasons for such measures.

3. If the Member State concerned considers that the prohibition or restriction referred to in paragraph 1 is unjustified, it may apply to the Commission for the immediate opening of discussions.

Article 10

1. Rights of appeal existing under current legislation in the Member States against decisions taken pursuant to this Directive by the competent authorities shall not be affected by this Directive.

2. Each Member State shall grant to consignors in respect of whose bovine animal and swine such measures as are provided for in Article 6 (3) have been taken, the right to obtain, before other measures are taken by the competent authority other than the slaughter or destruction of animals if essential for considerations of animal or public health, the opinion of a veterinary expert to determine whether the conditions of Article 6 (3) have been fulfilled.

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

The Commission, acting on a proposal from the Member States, shall drawn up a panel of veterinary experts who may be instructed to formulate such

opinions. After consulting the Member States it shall lay down general rules which are to be applied, in particular as regards the procedure for formulation of these opinions.

Article 11

If the Community provisions relating to importation of bovine animals and swine from third countries do not apply at the time when this Directive enters into force, or pending their becoming applicable, national provisions relating to bovine animals and swine imported from those countries shall not be more favourable than those governing intra-Community trade.

Article 12

The Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive and its Annexes within twelve months following its notification and shall forthwith inform the Commission thereof.

Article 13

This Directive is addressed to the Member States.

Done at Brussels, 26 June 1964.

For the Council

The President

C. HÉGER

ANNEX A

I. Tuberculosis-free bovine animals and herds

1. A bovine animal is considered to be tuberculosis-free if it shows no clinical signs of tuberculosis nor a reaction to an intradermal tuberculin test carried out in accordance with Annex B not more than thirty days before loading, nor any specific reaction, and when it is from an officially tuberculosis-free bovine herd within the meaning of paragraph 2.

2. A bovine herd is considered to be officially tuberculosis-free if: (a) all the animals are free from clinical signs of tuberculosis;

(b) all the animals over six weeks old have reacted negatively to at least two official intradermal tuberculin tests carried out in accordance with Annex B, the first one six months after completion of disinfection of the stock, the second one six months later and the remainder at one- or two-yearly intervals in the case of Member States whose entire bovine herd is under official veterinary supervision and has a rate of tubercular infection lower than 1 %;

(c) no bovine animal has been introduced without a certificate from an official veterinarian showing that the animal has reacted negatively to an intradermal tuberculin test assessed according to the criteria set out in Annex B 21 (a) and that it comes from an officially tuberculosis-free herd.

II. Brucellosis-free bovine animals and swine and bovine and swine herds

A. Bovine animals and herds

1. A bovine animal is considered to be brucellosis-free when it shows no clinical signs of the disease and has shown a brucella count lower than 30 international units of agglutination per millilitre when given a sero-agglutination test complying with the provisions of Annex C not more than thirty days before loading and is from an officially brucellosis-free bovine herd within the meaning of paragraph 2. In addition, in the case of bulls, the sperm must not contain brucellic agglutinins.

2. A bovine herd is considered to be officially brucellosis-free if: (a) it contains no bovine animals which have been vaccinated against brucellosis by use of a live vaccine;

(b) all the bovine animals have been free from clinical signs of brucellosis for at least six months;

(c) all the bovine animals over twelve months old: (aa) have shown a brucella count lower than 30 international units of agglutination per millilitre when given at six-monthly intervals two official sero-agglutination tests complying with Annex C ; the first sero-agglutination test may be replaced by three ring-tests carried out at three-monthly intervals provided, however, that the second sero-agglutination test is carried out at least six weeks after the third ring-test;

(bb) are checked annually, to establish that brucellosis is not present by means of three ring-tests carried out at intervals of at least three months or two ring-tests and one sero-agglutination test carried out at intervals of at least three months ; when the ring-test cannot be made, two sero-agglutination tests shall be carried out each year, at six-monthly intervals ; in Member States whose entire bovine herd is under official veterinary supervision and has a rate of brucellic infection lower than 1 %, only two ring-tests need be carried out each year or, if this cannot be done, one sero-agglutination test.

(d) no bovine animal has been introduced without a certificate from an official veterinarian showing that its brucella count was lower than 30 international units of agglutination per millilitre when given a sero-agglutination test not more than thirty days before it was taken into the herd and, in addition, that it is from an officially brucellosis-free bovine herd.

3. A bovine herd is considered to be brucellosis-free if: (a) by way of derogation from paragraph 2 (a), it contains bovine animals between five and eight months old which have been vaccinated only with live vaccine Buck 19;

(b) all the bovine animals fulfil the conditions laid down in paragraph 2 (b), (c) and (d) ; bovine animals less than thirty months old may however show a brucella count equal to or higher than 30 international units of agglutination per millilitre but lower than 80 international units of agglutination per millilitre, the complement fixation reaction being negative.

B. Swine and swine herds

1. A swine is considered to be brucellosis-free when it shows no clinical signs of the disease and shows a brucella count lower than 30 international units of agglutination per millilitre and a negative complement fixation reaction when given a sero-agglutination test complying with Annex C not more than thirty days before loading and, in addition, it comes from a brucellosis-free herd within the meaning of paragraph 2 ; the sero-agglutination test shall only be made on swine weighing more than 25 kilogrammes.

2. A swine herd is considered to be brucellosis-free if: (a) for at least one year no case of swine brucellosis nor any sign indicating that the disease might be present have been recorded in respect of it. If such signs are observed, clinical, bacteriological and, if necessary, serological tests must be carried out under official supervision to establish that the symptoms are non-brucellic;

(b) it is situated in the centre of an area of 20 km diameter in which no case of swine brucellosis has been officially recorded for at least one year;

(c) bovine animals kept contemporaneously on the holding are officially brucellosis-free.

ANNEX B Standards for the manufacture and use of tuberculins

1. Officially supervised tuberculin tests must be carried out with PPD (bovine) tuberculin or a tuberculin prepared on a synthetic medium and heat-concentrated.

2. For the control of PPD tuberculin, a standard tuberculin conforming the international PPD standard of the Staatens Seruminstitut in Copenhagen must be used.

Such standard tuberculin must be that supplied by the Centraal Diergeneeskundig Instituut, Afdeling Rotterdam.

3. For the control of tuberculins known as "synthetic" tuberculins, a standard tuberculin conforming with the international standard for old tuberculin of the Staatens Seruminstitut in Copenhagen must be used.

Such standard tuberculin must be that supplied by the Paul-Ehrlich-Institut in Frankfurt-am-Main.

4. Tuberculins must be prepared with one of the BK stocks of the bovine type indicated below: (a) An5

(b) Vallee

(c) Behring.

5. The pH of tuberculins must be between 6 75 and 7.

6. Only phenol with a concentration of 0 75 % may be used as a preservative in tuberculins.

7. Provided that tuberculins are preserved at a temperature of about 4 ºC, they may be used up to the end of the following periods: (a) Liquid PPD tuberculins : six months

Lyophilized PPD tuberculins : five years;

(b) Tuberculins known as "synthetic", non-diluted : five years

diluted : two years.

8. The state institutes listed below must be made responsible for the official testing of tuberculins in their respective countries: >PIC FILE= "T0019359">

9. Official testing must be carried out either of bottled tuberculins ready for use, or of a complete consignment of tuberculin before packaging provided it is subsequently bottled in the presence of a representative of the competent authority.

10. PPD tuberculin must be tested by biological methods and by the clinical method.

11. Tuberculins must be sterile.

12. An innocuity test of the tuberculin, to establish its non-toxicity and the absence of irritant properties, must be carried out as follows: (a) Non-toxicity : tests must be carried out on mice and guinea-pigs. >PIC FILE= "T0019360">

(aa) Tuberculin is injected into the abdominal skin of two guinea-pigs. The tuberculin may be considered to be satisfactory if the guineapigs treated in this way show, for not more than two days, a strong infiltration which is reabsorbed from the third day without having produced necrosis and is no longer visible after six days. If there is necrosis of the abdominal skin, or if the infiltration does not disappear within six days, the tuberculin shall be rejected.

(bb) The tuberculin is injected intraperitoneally into two guinea-pigs. The animals are observed for six weeks during which there must be no specific symptom or loss of weight. At the end of six weeks the animals are killed and a check made that there is no tubercular lesion;

in particular, histological incisions are made in the spleen, liver and lungs. The same procedure is followed for any animal which dies before the end of the time limit.

(b) Absence of irritant properties : an intradermal inoculation of 2 500 international units (IU) of tuberculin in a volume of 0 71 ml is made in the depilated skin of the flank of two guinea-pigs. There must be no reaction after forty hours.

13. Tuberculins must be chemically analysed in order to determine the exact amount of phenol and to establish whether any other preservative is present.

14. A test of non-sensitisation to tuberculin must be carried out as follows:

Three guinea-pigs which have never been used for scientific tests are given, at five day intervals, three intradermal injections of 500 international units of tuberculin in a volume of 0 71 ml. The guinea-pigs are tested fifteen days later by an intradermal injection of the same amount of tuberculin. They must not show a reaction different from that of guinea-pigs of the same weight which have never been used for scientific tests carried out for control purposes with the same amount of tuberculin.

15. An activity test must be carried out by the chemical method and by biological methods. (a) Chemical method : this method can be used for PPD and is based on the precipitation of tuberculo-protein by trichloracetic acid. The nitrogen content is determined by Kjeldahl distillation. The conversion factor of the total nitrogen PPD is 6 725.

(b) Biological methods : these methods can be used for tuberculins prepared on a synthetic medium and for PPD ; they are based on the comparison with standard tuberculins of the tuberculins to be tested.

16. The international standard for old tuberculin contains 100 000 international units of agglutination per millilitre.

17. The international PPD standard is delivered in the lyophelised state, one international unit = 0 700002 mg of tuberculo-protein. The ampoule contains 2 mg of tuberculo-protein.

Tuberculins submitted by manufacturers for testing by the state institutes listed in paragraph 8 must have the same activity as standard tuberculins, i.e. they must contain 100 000 international units of agglutination per millilitre.

18. (a) Potency testing on guinea-pigs:

Albino guinea-pigs weighing between 400 and 600 g must be used.

These guinea-pigs must be in good health and checked by palpation to determine whether, at the time of the tuberculin inoculation, their muscular tone has remained normal in spite of prior sensitisation.

(aa) Guinea-pigs shall be sensitised by inoculation injection of about 0 75 mg of live tuberculosis bacilli in physiological saline emulsion under the skin of the thigh or the nape of the neck.

The bovine type strain, supplied on request by the Paul-Ehrlich-Institut in Frankfurt-am-Main must be used for this purpose. An excessive dose must be avoided so that the guinea-pigs retain their weight until used;

(bb) Irrespective of the method of titration used, assessment must always be based on comparison with standard tuberculin of the tuberculin to be tested ; the result must be expressed in international units per ml.

(b) Potency testing on bovine animals

When tests are on bovine animals the reactions obtained on tubercular bovine animals by the tuberculin to be tested must be identical to those produced by the same amounts of standard tuberculin.

19. Tuberculin tests must be made by a single intradermal injection into either the neck or the shoulder.

20. The amount of tuberculin to be injected shall be 5000 international units of PPD or synthetic tuberculin.

21. The result of the intradermal tuberculin test must be read after seventy-two hours and assessed according to the following method: (a) Negative reaction : if only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin without clinical signs such as pasty consistency, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region and of the lymph nodes;

(b) Positive reaction : if clinical signs such as mentioned in (a) are observed or if there is an increase of more than 2 mm in the thickness of the skin.

ANNEX C Bovine brucellosis

A. Serum agglutination tests

1. The standard agglutinating serum must conform to the standard serum prepared by the Veterinary Laboratory, Weybridge, Surrey, England.

The ampoule must contain 1000 international agglutination units (IU) obtained by lyophilising 1 ml of bovine serum.

2. The standard serum must be that supplied by the Bundesgesundheitsamt, Berlin.

3. The degree of brucella agglutination in a serum must be expressed in international units per ml (i.e. Serum X ± 80 IU/ml).

4. Readings of slow sero-agglutination in tubes must be taken at 50 % or at 75 % agglutination, the antigen used having been titrated under identical conditions against the standard serum.

5. The agglutinating value of various antigens in relation to standard serum must be within the following limits: - If the reading is made at 50 % : between 1/600 and 1/1000;

- If the reading is made at 75 % : between 1/500 and 1/750.

6. Weybridge Strain No 99 and USDA 1119 or any other strain of equivalent sensitivity must be used for preparing the antigen for use in tube agglutination (slow method).

7. The culture media used for keeping the strain in the laboratory and for producing the antigen must be such that they do not encourage bacterial dissociation (S minus R) ; potato agar should preferably be used.

8. The bacterial emulsion must be made from physiological saline (NaCl 8 75 %) phenolized at 5 %. Formol must not be used.

9. The official institutes indicated below must be made responsible for the official testing of antigens: >PIC FILE= "T0019361">

10. Antigens may be delivered in the concentrated state provided the dilution factor to be used is indicated on the bottle label.

11. In order to carry out a sero-agglutination test, at least three dilutions must be prepared for each serum. Dilutions of suspect serum must be made in such a way that the reading of the reaction at the infection limit is made in the median tube. If there is a positive reaction in this tube, the suspect serum contains at least 30 international units of agglutination per millilitre.

B. Ring-test

12. The ring-test must be made on the contents of each milk churn from the farm.

13. The standard antigen to be used must come from one of the institutes listed in paragraph 9 (a) and (f).

14. The antigen may be stained only with hematoxylin or tetrazolium ; hematoxylin should preferably be used.

15. The reaction test must be carried out in 8 to 10 mm diameter tubes.

16. The reaction test must be carried out using 1 ml of milk to which 0 705 ml of one of the stained antigens has been added.

17. The mixture of milk and antigen must be incubated at 37 ºC for not less than forty-five minutes and not more than sixty minutes.

18. The reaction test must be carried out approximately eighteen hours after milking and assessed according to the following criteria: >PIC FILE= "T0019362">

19. Formol must not be added to the sample. The only product which may be added is mercuric chloride in a solution of 0 72 % and, in such case, the ratio between the amount of milk and the solution of mercuric chloride must be 10 to 1.

ANNEX D Milk analysis

1. All milk analyses must be carried out in official or officially approved laboratories.

2. Milk samples must be taken in accordance with the following conditions: (a) the teats must first be disinfected with 70 % alcohol.

(b) tubes must be kept in a sloping position while being filled.

(c) milk samples must be taken at the beginning of milking, after eliminating the first streams from each teat.

(d) a sample must be taken from each quarter ; the milk from these samples must not be mixed.

(e) each sample must contain at least 10 ml of milk.

(f) if a preservative is required boric acid at 0 75 % must be used.

(g) each tube must bear a label giving the following information: - the number of the earmark or any other means of identifying the animal;

- the quarter from which the sample was taken;

(h) samples must be accompanied by a document giving the following information: - the name and address of the official veterinarian;

- the name and address of the owner;

- the means of identifying the animal;

- the stage of lactation.

3. Milk analysis must be made not more than thirty days before loading and must always include a bacteriological test and a White Side Test (WST) or California Mastitis Test (CMT). The result of these two tests must be negative, subject as follows: (a) if the result of the bacteriological test is positive - although there is no characteristic inflammatory conditions but the result of the WST (or the CMT) is negative, a second bacteriological test must be carried out at least ten days later, within the thirty-day limit set above. This second test must establish that: (aa) the pathogenic micro-organisms have disappeared;

(bb) there are no antibiotics present.

In addition, the absence of inflammation must be established by a further WST (or a further CMT) which must be negative.

(b) if the bacteriological test is negative while the WST (or the CMT) is positive, a complete cytological test must be made which must be negative.

4. The bacteriological test shall include: (a) the seeding of milk in a Petri dish on blood agar of bovine animals or sheep;

(b) the seeding of milk in TKT or Edwards media.

The purpose of the bacteriological test is to identify all pathogenic micro-organisms and it must not be restricted to detecting specific pathogenic streptococci or staphylococci. For this reason, the identification of suspect colonies obtained from seeding in the above mentioned media shall be carried out by traditional methods of bacteriology differentiation such as the use of the Chapman medium to identify staphylococci and of various selective media for the detection of entero-bacteria.

5. The complete cytological test is intended to detect, where necessary, a characteristic inflammatory condition independent of any clinical symptom.

The existence of an inflammatory condition is established when the leucocyte count taken according to the Breed method attains 1 million leucocytes per millilitre and the proportion of mononuclear to polynuclear leucocytes is less than 0 75.

ANNEX E The following diseases are compulsorily notifiable:

(a) Bovine diseases:

Rabies

Tuberculosis

Brucellosis

Foot-and-mouth disease

Anthrax

Cattle plague

Pleuro-pneumonia

(b) Swine diseases:

Rabies

Brucellosis

Anthrax

Foot-and-mouth disease

Classical and African swine fever

Contagious swine Paralysis (Teschen disease).

ANNEX F

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