

**COMMISSION DECISION**  
**of 19 January 2011**  
**concerning certain protection measures against foot-and-mouth disease in Bulgaria**

(notified under document C(2011) 179)

(Text with EEA relevance)

(2011/44/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market <sup>(1)</sup>, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market <sup>(2)</sup>, and in particular Article 10(4) thereof,

Whereas:

- (1) On 5 January 2011 Bulgaria reported a case of foot-and-mouth disease in a wild boar shot in Burgas region in the South-East of Bulgaria within a zone of reinforced surveillance along the border with Turkey. The Commission therefore adopted Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria <sup>(3)</sup>.
- (2) On 9 January 2011 Bulgaria reported outbreaks of foot-and-mouth disease in livestock in the same area. The new epidemiological situation requires to review the measures previously adopted, also in the light of the information provided by Bulgaria and the discussions with Member States at the meeting of the Standing Committee on the Food Chain and Animal Health of 12 January 2011.
- (3) The foot-and-mouth disease situation in Bulgaria is liable to endanger the herds of other Member States in view of trade in live biungulate animals and the placing on the market of certain of their products.
- (4) Bulgaria has taken measures in the framework of Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease <sup>(4)</sup>, in particular the measures provided for in Section 3 of Chapter II and in Article 85(4) thereof.
- (5) The whole territory of Bulgaria is subject to the restrictions of Articles 2, 4, 5, 6, 8b and 11 of

Commission Decision 2008/855/EC of 3 November 2008 concerning animal health control measures relating to classical swine fever in certain Member States <sup>(5)</sup>. However, being listed in Part II of the Annex to that Decision allows Bulgaria to dispatch under certain health conditions fresh pig meat and meat preparations and products produced from such meat.

- (6) The disease situation in Bulgaria makes it necessary to reinforce the control measures for foot-and-mouth disease taken by the competent authorities in Bulgaria.
- (7) It is appropriate to define as a permanent measure the high and low risk areas in the affected Member State and to provide for a prohibition on the dispatch of susceptible animals from the high and low risk areas and on the dispatch of products derived from susceptible animals from the high risk area. The Decision should also provide for the rules applicable to the dispatch from those areas of safe products that either had been produced before the restrictions, from raw material sourced from outside the restricted areas or that had undergone a treatment proven effective in inactivating possible foot-and-mouth disease virus.
- (8) The size of the defined risk areas is a direct function of the outcome of tracing of possible contacts to the infected holding and takes into account the possibility to implement sufficient controls on the movement of animals and products. At this point of time and based on information provided by Bulgaria, the whole of Burgas region should currently remain a high risk area.
- (9) The prohibition of dispatch should only cover products derived from animals of susceptible species coming from or obtained from animals originating in the high risk areas listed in Annex I and should not affect transit through these areas of such products coming from or obtained from animals originating in other areas.
- (10) Council Directive 64/432/EEC <sup>(6)</sup> concerns animal health problems affecting intra-Community trade in bovine animals and swine.
- (11) Council Directive 91/68/EEC <sup>(7)</sup> concerns animal health conditions governing intra-Community trade in ovine and caprine animals.

<sup>(1)</sup> OJ L 395, 30.12.1989, p. 13.

<sup>(2)</sup> OJ L 224, 18.8.1990, p. 29.

<sup>(3)</sup> OJ L 6, 11.1.2011, p. 15.

<sup>(4)</sup> OJ L 306, 22.11.2003, p. 1.

<sup>(5)</sup> OJ L 302, 13.11.2008, p. 19.

<sup>(6)</sup> OJ L 121, 29.7.1964, p. 1977/64.

<sup>(7)</sup> OJ L 46, 19.2.1991, p. 19.

- (12) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC<sup>(1)</sup> concerns, amongst others, trade in other biungulates and in semen, ova and embryos of sheep and goats, and in embryos of porcine animals.
- (13) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>(2)</sup> concerns, amongst others, the health conditions for the production and marketing of fresh meat, minced meat, mechanically separated meat, meat preparations, farmed game meat, meat products, including treated stomachs, bladders and intestines, and dairy products.
- (14) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>(3)</sup> concerns, amongst others, the health marking of food of animal origin.
- (15) Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption<sup>(4)</sup> provides for specific treatment of meat products that ensure inactivation of the foot-and-mouth disease virus in products of animal origin.
- (16) Commission Decision 2001/304/EC of 11 April 2001 on marking and use of certain animal products in relation to Decision 2001/172/EC concerning certain protection measures with regard to foot-and-mouth disease in the United Kingdom<sup>(5)</sup> concerns a specific health mark to be applied to certain products of animal origin that shall be restricted to the national market. It is appropriate to lay down in a separate Annex a similar marking in the case of foot-and-mouth disease in Bulgaria.
- (17) Council Directive 92/118/EEC<sup>(6)</sup> lays down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.
- (18) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption<sup>(7)</sup> provides for a range of treatments of animal by-products suitable to inactivate the foot-and-mouth disease virus.
- (19) Council Directive 88/407/EEC<sup>(8)</sup> lays down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species.
- (20) Council Directive 89/556/EEC<sup>(9)</sup> concerns the animal health conditions governing intra-Community trade in and imports from third countries of embryos of domestic animals of the bovine species.
- (21) Council Directive 90/429/EEC<sup>(10)</sup> lays down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species.
- (22) The model health certificates for trade within the Union in semen, ova and embryos of animals of the ovine and caprine species and in ova and embryos of animals of the porcine species are laid down in Commission Decision 2010/470/EU of 26 August 2010 laying down model health certificates for trade within the Union in semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species<sup>(11)</sup>.
- (23) In so far as medicinal products defined in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products<sup>(12)</sup>, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>(13)</sup>, and Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use<sup>(14)</sup> no longer fall under the scope of Regulation (EC) No 1774/2002 they should be excluded from animal health related restrictions set up by this Decision.

<sup>(1)</sup> OJ L 268, 14.9.1992, p. 54.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 55.

<sup>(3)</sup> OJ L 139, 30.4.2004, p. 206.

<sup>(4)</sup> OJ L 18, 23.1.2003, p. 11.

<sup>(5)</sup> OJ L 104, 13.4.2001, p. 6.

<sup>(6)</sup> OJ L 62, 15.3.1993, p. 49.

<sup>(7)</sup> OJ L 273, 10.10.2002, p. 1.

<sup>(8)</sup> OJ L 194, 22.7.1988, p. 10.

<sup>(9)</sup> OJ L 302, 19.10.1989, p. 1.

<sup>(10)</sup> OJ L 224, 18.8.1990, p. 62.

<sup>(11)</sup> OJ L 228, 31.8.2010, p. 15.

<sup>(12)</sup> OJ L 311, 28.11.2001, p. 1.

<sup>(13)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(14)</sup> OJ L 121, 1.5.2001, p. 34.

- (24) Article 6 of Commission Decision 2007/275/EC of 17 April 2007 concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC<sup>(1)</sup> provides for a derogation from the veterinary checks for certain products containing animal products. It is appropriate to allow dispatch from the high risk areas of such products under a simplified certification regime.
- (25) The possible risk of spread of foot-and-mouth disease within the European Union through the movements of consignments of products of animal origin of a non-commercial character should be considered in view of the foot-and-mouth disease situation in Bulgaria. Therefore such movements should be prevented in order to avoid further spread of the disease. Bulgaria should ensure that compliance with the restrictions imposed by this Decision on certain products derived from animals of species susceptible to foot-and-mouth disease is also ensured as regards the non-commercial movement of these products. Member States should cooperate in monitoring personal luggage of passengers travelling in particular from the high risk areas and in information campaigns carried out to prevent introduction of products of animal origin into the territory of Member States other than Bulgaria.
- (26) Member States other than Bulgaria should support the disease control measures carried out in the affected areas by ensuring that live susceptible animals are not dispatched to those areas.
- (27) Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field<sup>(2)</sup> provides for a mechanism to compensate affected holdings for losses incurred as a result of disease control measures.
- (28) The foot-and-mouth disease situation has been reviewed at the meeting of the Standing Committee on the Food Chain and Animal Health of 12 January 2011 and the measures provided for in Decision 2011/8/EU were adapted in the light of the information received from Bulgaria on the development of the epidemiological situation. Decision 2011/8/EU should therefore be repealed and replaced by this Decision.
- (29) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

#### Article 1

##### Live animals

1. Bulgaria shall ensure that the conditions set out in paragraphs 2 to 7 of this Article are met, without prejudice to the measures taken by that Member State within the framework of:

- (a) Directive 2003/85/EC; and
- (b) Decision 2008/855/EC.

<sup>(1)</sup> OJ L 116, 4.5.2007, p. 9.

<sup>(2)</sup> OJ L 155, 18.6.2009, p. 30.

2. No live animals of the bovine, ovine, caprine and porcine species and other biungulates shall move between the areas listed in Annex I and Annex II.

3. No live animals of the bovine, ovine, caprine and porcine species and other biungulates shall be dispatched from or moved through the areas listed in Annex I and Annex II.

4. By way of derogation from paragraph 3, the competent authorities of Bulgaria may authorise the direct and uninterrupted transit of biungulate animals through the areas listed in Annex I and Annex II on main roads and railway lines.

5. The health certificates, as provided for in Directive 64/432/EEC for live bovine animals and, without prejudice to Article 8b and 9 of Decision 2008/855/EC, for porcine animals and in Directive 91/68/EEC for live ovine and caprine animals, accompanying animals consigned from parts of the territory of Bulgaria not listed in Annex I and Annex II to other Member States shall bear the following words:

‘Animals conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.’

6. The health certificates accompanying biungulates other than those covered by the certificates referred to in paragraph 5, consigned from parts of the territory of Bulgaria not listed in Annex I and Annex II to other Member States shall bear the following words:

‘Live biungulates conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.’

7. Animals accompanied by an animal health certificate as referred to in paragraphs 5 and 6 may be moved to other Member States only if the local veterinary authority in Bulgaria has, 3 days before the move, notified the central and local veterinary authorities in the Member State of destination.

8. By way of derogation from paragraph 2 the competent authorities of Bulgaria may authorise the transport of animals of species susceptible to foot-and-mouth disease from holding situated in areas listed in Annex II to a slaughterhouse situated in the areas listed in Annex I.

9. By way of derogation from paragraph 2, the competent authority of Bulgaria may authorise the transport of pigs from holdings outside the surveillance zone established in accordance with Article 21 of Directive 2003/85/EC for immediate slaughter at designated slaughterhouses situated in the areas listed in Annex II under the following conditions:

(a) the pigs originate from holdings in the area listed in Annex I from which consignments of fresh pigmeat and meat preparations and meat products consisting of, or containing meat of those pigs may be dispatched in accordance with Article 6 of Decision 2008/855/EC.

The central veterinary authority of Bulgaria shall communicate to the other Member States and to the Commission the list of holdings which they have approved for the purpose of application of this paragraph;

(b) during the 21 days prior to the date of transport to the slaughterhouse, the animals have remained under the supervision of the competent veterinary authority on a single holding which is situated in the centre of a circle around the holding of at least 10 km radius, where there has been no outbreak of foot-and-mouth disease during at least 30 days prior to the date of loading;

(c) no animals of species susceptible to foot-and-mouth disease have been introduced into the holding referred to in the introductory sentence of this paragraph during the 21 days prior to the date of loading, except in the case of pigs coming from a supplying holding which complies with the conditions laid down in point (b), in which case the period of 21 days may be reduced to 7 days;

(d) the transport of pigs is only authorised after the satisfactory completion of the measures provided for in Article 22(2) of Directive 2003/85/EC.

#### Article 2

##### Meats

1. For the purposes of this Article, 'meats' means 'fresh meat', 'minced meat', 'mechanically separated meat' and 'meat preparations' as defined in points 1.10, 1.13, 1.14 and 1.15 of Annex I to Regulation (EC) No 853/2004.

2. Bulgaria shall not dispatch meats of the bovine, ovine, caprine and porcine species and other biungulates coming from or obtained from animals originating in the areas listed in Annex I.

3. Meats not eligible for dispatch from Bulgaria in accordance with this Decision shall be marked in accordance with the second subparagraph of Article 4(1) of Directive 2002/99/EC or in accordance with Annex IV.

4. Without prejudice to Articles 6 and 8b of Decision 2008/855/EC, the prohibition set out in paragraph 2 shall not apply to meats bearing the health mark in accordance with Chapter III of Section I of Annex I to Regulation (EC) No 854/2004, provided that:

(a) the meat is clearly identified, and has been transported and stored since the date of production separately from meat which is not eligible, in accordance with this Decision, for dispatch outside the areas listed in Annex I;

(b) the meat complies with one of the following conditions:

(i) it was obtained before 9 December 2010; or

(ii) it is derived from animals that have been reared for at least 90 days, or since birth if less than 90 days of age, prior to the date of slaughter and which have been slaughtered, or in the case of meat obtained from wild game of species susceptible to foot-and-mouth disease killed, outside the areas listed in Annexes I and II; or

(iii) it complies with the conditions set out in points (c), (d) and (e);

(c) the meat was obtained from domestic ungulates or from farmed game of species susceptible to foot-and-mouth disease, as specified for the respective category of meat in one of the appropriate columns 4 to 7 in Annex III, and complies with the following conditions:

(i) the animals have been reared for at least 90 days prior to the date of slaughter, or since birth if less than 90 days of age, on holdings situated within the areas specified in columns 1, 2 and 3 of Annex III, where there has been no outbreak of foot-and-mouth disease during at least 90 days prior to the date of slaughter;

(ii) during the 21 days prior to the date of transport to the slaughterhouse, or in the case of farmed game of species susceptible to foot-and-mouth disease prior to the date of on-farm slaughtering, the animals have remained under the supervision of the competent veterinary authorities on a single holding which is situated in the centre of a circle around the holding of at least 10 km radius, where there has been no outbreak of foot-and-mouth disease during at least 30 days prior to the date of loading;

(iii) no animals of species susceptible to foot-and-mouth disease have been introduced into the holding referred to in point (ii) during the 21 days prior to the date of loading, or in the case of farmed game of species susceptible to foot-and-mouth disease prior to the date of on-farm slaughtering, except in the case of pigs coming from a supplying holding which complies with the conditions laid down in point (ii), in which case the period of 21 days may be reduced to 7 days.

However, the competent authority may authorise the introduction into the holding referred to in point (ii) of animals of species susceptible to foot-and-mouth disease which comply with the conditions set out in points (i) and (ii) and which:

— come from a holding where no animals of species susceptible to foot-and-mouth disease have been introduced during the 21 days prior to the date of transport to the holding referred to in point (ii), except in the case of pigs coming from a supplying holding in which case the period of 21 days may be reduced to 7 days; or

— were subjected with negative results to a test for antibodies against the foot-and-mouth disease virus carried out on a blood sample taken within 10 days prior to the date of transport to the holding referred to in point (ii); or

- come from a holding that was subjected with negative results to a serological survey pursuant to a sampling protocol suitable to detect 5 % prevalence of foot-and-mouth disease with at least a 95 % level of confidence;
  - (iv) the animals or, in the case of farmed game of species susceptible to foot-and-mouth disease slaughtered on the farm, the carcasses have been transported under official control in means of transport that have been cleansed and disinfected before loading from the holding referred to in point (ii) to the designated slaughterhouse;
  - (v) the animals have been slaughtered less than 24 hours following the time of arrival at the slaughterhouse and separately from animals the meat of which is not eligible for dispatch from the area listed in Annex I;
- (d) the meat, if positively marked in column 8 of Annex III, was obtained from wild game of species susceptible to foot-and-mouth disease, that was killed in areas where there has been no outbreak of foot-and-mouth disease for at least a period of 90 days before the date of killing and at a distance of at least 20 km from areas not specified in columns 1, 2 and 3 of Annex III;
- (e) meat referred to in points (c) and (d) must in addition comply with the following conditions:
- (i) the dispatch of such meat is only to be authorised by the competent veterinary authority of Bulgaria, if
    - the animals referred to in point (c)(iv) have been transported to the establishment without contact to holdings situated in areas not specified in columns 1, 2 and 3 of Annex III, and
    - the establishment is not situated in a protection zone;
  - (ii) the meat is at all times clearly identified, handled, stored and transported separately from meat which is not eligible for dispatch from the area listed in Annex I;
  - (iii) during post-mortem inspection by the official veterinarian in the establishment of dispatch, or in the case of on-farm slaughtering of farmed game of species susceptible to foot-and-mouth disease on the holding referred to in point (c)(ii), or in the case of wild game of species susceptible to foot-and-mouth disease at the game-handling establishment, no clinical signs or post-mortem evidence of foot-and-mouth disease were established;
  - (iv) the meat has remained in the establishments or holdings referred to in point (e)(iii) for at least 24 hours following the post-mortem inspection of the animals referred to in points (c) and (d);
  - (v) any further preparation of meat for dispatch outside the area listed in Annex I shall be suspended:
    - in the case where foot-and-mouth disease has been diagnosed in the establishments or holdings referred to in point (e)(iii), until the slaughter of all animals present and the removal of all meat and dead animals has been completed, and at least 24 hours have elapsed since the completion of the total cleansing and disinfection of those establishments and holdings under the control of an official veterinarian, and
    - in the case of slaughter in the same establishment of animals susceptible to foot-and-mouth disease coming from holdings situated in areas listed in Annex I that do not comply with the conditions set out in point 4(c) or (d), until the slaughter of all such animals and the cleansing and disinfection of those establishments have been completed under the control of an official veterinarian;
  - (vi) the central veterinary authorities shall communicate to the other Member States and the Commission a list of those establishments and holdings which they have approved for the purposes of application of points (c), (d) and (e).
5. Compliance with the conditions set out in paragraphs 3 and 4 shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.
6. Without prejudice to Articles 6 and 8b of Decision 2008/855/EC, the prohibition set out in paragraph 2 of this Article shall not apply to fresh meat obtained from animals reared outside the areas listed in Annex I and Annex II and transported, by way of derogation from Article 1(2) and (3), directly and under official control without contact to holdings situated in areas listed in Annex I to a slaughterhouse situated in the areas listed in Annex I outside the protection zone for immediate slaughter, provided that such fresh meat is only placed on the market in the areas listed in Annex I and Annex II and complies with the following conditions:
- (a) all such fresh meat is marked in accordance with the second subparagraph of Article 4(1) of Directive 2002/99/EC or in accordance with Annex IV to this Decision;
  - (b) the slaughterhouse:
    - (i) is operated under strict veterinary control;
    - (ii) suspends any further preparation of meat for dispatch outside the areas listed in Annex I in the case of slaughter in the same slaughterhouse of animals susceptible to foot-and-mouth disease coming from holdings situated in areas listed in Annex I until the slaughter of all such animals and the cleansing and disinfection of the slaughterhouse have been completed under the control of an official veterinarian;
  - (c) the fresh meat is clearly identified, and transported and stored separately from meat which is eligible for dispatch outside Bulgaria.
- Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.
- The central veterinary authority of Bulgaria shall communicate to the Commission and to the other Member States the list of the establishments which they have approved for the purposes of application of this paragraph.

7. Without prejudice to Article 6 of Decision 2008/855/EC, the prohibition set out in paragraph 2 shall not apply to fresh meat obtained from cutting plants situated in the areas listed in Annex I under the following conditions:

(a) only fresh meat as described in paragraph 4(b) is processed in that cutting plant, on the same day.

Cleansing and disinfection shall be carried out after processing of any meat not meeting this requirement;

(b) all meat bears the health mark in accordance with Chapter III of Section I of Annex I to Regulation (EC) No 854/2004;

(c) the cutting plant is operated under strict veterinary control;

(d) the fresh meat is clearly identified, and transported and stored separately from meat which is not eligible for dispatch outside the areas listed in Annex I.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

The central veterinary authority of Bulgaria shall communicate to the other Member States and the Commission the list of the establishments which they have approved for the purpose of application of this paragraph.

8. Meat dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Meat conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

9. Without prejudice to Articles 6 and 8b of Decision 2008/855/EC, the prohibition set out in paragraph 2 of this Article shall not apply to fresh meat obtained from pigs reared in the areas listed in Annex I and transported in accordance with Article 1(9) to a slaughterhouse situated in the areas listed in Annex II for immediate slaughter, provided that such fresh meat complies with the following conditions:

(a) the fresh meat is marked in accordance with the second subparagraph of Article 4(1) of Directive 2002/99/EC or in accordance with Annex IV to this Decision and is placed on the market only in the areas listed in Annex I and Annex II;

(b) the slaughterhouse:

(i) is operated under veterinary control;

(ii) suspends any further preparation of meat for dispatch outside the areas listed in Annex I in the case of slaughter in the same slaughterhouse of animals susceptible to foot-and-mouth disease coming from

other holdings situated in areas listed in Annex I until the slaughter of all such animals and the cleansing and disinfection of the slaughterhouse have been completed under the control of an official veterinarian;

(c) the fresh meat is clearly identified and is transported and stored separately from meat which is eligible for dispatch outside Bulgaria.

Compliance with the conditions set out in paragraph 1 shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

The central veterinary authority of Bulgaria shall communicate to the other Member States and to the Commission the list of the establishments which they have approved for the purpose of application of this paragraph.

### Article 3

#### Meat products

1. Bulgaria shall not dispatch meat products, including treated stomachs, bladders and intestines, of animals of the bovine, ovine, caprine and porcine species and other biungulates ('meat products') coming from the areas listed in Annex I or prepared using meat obtained from animals originating in those areas.

2. Without prejudice to Articles 6 and 8b of Decision 2008/855/EC, the prohibition set out in paragraph 1 shall not apply to meat products, including treated stomachs, bladders and intestines, bearing the health mark in accordance with Chapter III of Section I of Annex I to Regulation (EC) No 854/2004, provided that the meat products:

(a) are clearly identified and have been transported and stored since the date of production separately from meat products not eligible, in accordance with this Decision, for dispatch outside the areas listed in Annex I;

(b) comply with one of the following conditions:

(i) they are made from meats described in Article 2(4)(b); or

(ii) they have undergone at least one of the relevant treatments laid down for foot-and-mouth disease in Part 1 of Annex III to Directive 2002/99/EC.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

The central veterinary authorities shall communicate to the other Member States and the Commission a list of the establishments which they have approved for the purpose of application of this paragraph.

3. Meat products dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Meat products, including treated stomachs, bladders and intestines, conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

4. By way of derogation from paragraph 3 it shall be sufficient, in the case of meat products which comply with the requirements of paragraph 2 and have been processed in an establishment operating Hazard Analysis and Critical Control Points (HACCP) and an auditable standard operating procedure which ensures that standards for treatment are met and recorded, that compliance with the conditions required for the treatment laid down in point (b)(ii) of the first subparagraph of paragraph 2 is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

5. By way of derogation from paragraph 3 it shall be sufficient, in the case of meat products heat treated in accordance with point (b)(ii) of the first subparagraph of paragraph 2 in hermetically sealed containers so as to ensure that they are shelf stable, to be accompanied by a commercial document stating the heat treatment applied.

#### Article 4

##### Colostrums and milk

1. Bulgaria shall not dispatch colostrums and milk from animals of species susceptible to foot-and-mouth disease intended or not intended for human consumption from the areas listed in Annex I.

2. The prohibition set out in paragraph 1 shall not apply to milk produced from bovine, ovine and caprine animals kept in areas listed in Annex I which has been subjected to a treatment in accordance with:

- (a) Part A of Annex IX to Directive 2003/85/EC, if the milk is intended for human consumption; or
- (b) Part B of Annex IX to Directive 2003/85/EC, if the milk is not intended for human consumption or is intended for feeding to animals of species susceptible to foot-and-mouth disease.

3. The prohibition set out in paragraph 1 shall not apply to milk from bovine, ovine and caprine animals prepared in establishments situated in the areas listed in Annex I under the following conditions:

- (a) all milk used in the establishment must either conform to the conditions set out in paragraph 2 or be obtained from animals reared and milked outside the areas listed in Annex I;
- (b) the establishment is operated under strict veterinary control;
- (c) the milk must be clearly identified, and transported and stored separately from milk and dairy products which are not eligible for dispatch outside the areas listed in Annex I;
- (d) transport of raw milk from holdings situated outside the areas listed in Annex I to the establishments situated in

the areas listed in Annex I is carried out in vehicles which were cleansed and disinfected prior to operation and had no subsequent contact with holdings in the areas listed in Annex I keeping animals of species susceptible to foot-and-mouth disease.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent veterinary authority under the supervision of the central veterinary authorities.

The central veterinary authorities shall communicate to the other Member States and the Commission a list of the establishments which they have approved for the purpose of application of this paragraph.

4. Milk dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Milk conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

5. By way of derogation from paragraph 4 it shall be sufficient, in the case of milk which complies with the requirements of paragraph 2 and has been processed in an establishment operating HACCP and an auditable standard operating procedure which ensures that standards for treatment are met and recorded, that compliance with those requirements is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

6. By way of derogation from paragraph 4 it shall be sufficient, in the case of milk which complies with the requirements in paragraph 2(a) or (b) and which has been heat treated in hermetically sealed containers so as to ensure that it is shelf stable, to be accompanied by a commercial document stating the heat treatment applied.

#### Article 5

##### Dairy products

1. Bulgaria shall not dispatch dairy products produced from colostrums and milk from animals of species susceptible to foot-and-mouth disease intended or not intended for human consumption from the areas listed in Annex I.

2. The prohibition set out in paragraph 1 shall not apply to dairy products:

- (a) produced before 9 December 2010; or
- (b) prepared from milk complying with the provisions in Article 4(2) or (3); or
- (c) for export to a third country where import conditions permit such products to be subject to treatment other than those laid down in Article 4(2) which ensures the inactivation of the foot-and-mouth disease virus.

3. Without prejudice to Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004, the prohibition set out in paragraph 1 of this Article shall not apply to the following dairy products intended for human consumption:

- (a) dairy products produced from milk of a controlled pH less than 7 and subject to a heat treatment at a temperature of at least 72 °C for at least 15 seconds, on the understanding that such treatment was not necessary for finished products, the ingredients of which comply with the respective animal health conditions laid down in Articles 2, 3 and 4 of this Decision;
- (b) dairy products produced from raw milk of bovine, ovine or caprine animals which have been resident for at least 30 days on a holding situated, within an area listed in Annex I, in the centre of a circle of at least 10 km radius in which no outbreak of foot-and-mouth disease has occurred during 30 days prior to the date of production of the raw milk, and subject to a maturation or ripening process of at least 90 days during which the pH is lowered below 6.0 throughout the substance, and the rind of which has been treated with 0,2 % citric acid immediately prior to wrapping or packaging.

4. The prohibition set out in paragraph 1 shall not apply to dairy products prepared in establishments situated in the areas listed in Annex I under the following conditions:

- (a) all milk used in the establishment either complies with the conditions laid down in Article 4(2) or is obtained from animals outside the areas listed in Annex I;
- (b) all dairy products used in the final products either comply with the conditions set out in paragraph 2(a) and (b) or paragraph 3 or are made from milk obtained from animals outside the areas listed in Annex I;
- (c) the establishment is operated under strict veterinary control;
- (d) the dairy products are clearly identified and transported and stored separately from milk and dairy products which are not eligible for dispatch outside the areas listed in Annex I.

Compliance with the conditions set out in the first subparagraph shall be checked by the competent authority under the responsibility of the central veterinary authorities.

The central veterinary authorities shall communicate to the other Member States and the Commission a list of the establishments which they have approved for the purposes of application of this paragraph.

5. The prohibition set out in paragraph 1 shall not apply to dairy products prepared in establishment situated outside the areas listed in Annex I using milk obtained before 9 December 2010, provided that the dairy products are clearly identified and transported and stored separately from dairy products which are not eligible for dispatch outside those areas.

6. Dairy products dispatched from Bulgaria to other Member States shall be accompanied by an official certificate, which shall bear the following words:

'Dairy products conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

7. By way of derogation from paragraph 6 it shall be sufficient, in the case of dairy products which comply with the requirements of paragraph 2(a) and (b) and paragraphs 3 and 4 and have been processed in an establishment operating HACCP and an auditable standard operating procedure which ensures that standards for treatment are met and recorded, that compliance with those requirements is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

8. By way of derogation from paragraph 6 it shall be sufficient, in the case of dairy products which comply with the requirements of paragraph 2(a) and (b) and paragraphs 3 and 4 and which have been heat treated in hermetically sealed containers so as to ensure that they are shelf stable, to be accompanied by a commercial document stating the heat treatment applied.

#### Article 6

##### **Semen, ova and embryos**

1. Bulgaria shall not dispatch semen, ova and embryos of the bovine, ovine, caprine and porcine species and other biungulates ('semen, ova and embryos') from the areas listed in Annex I and Annex II.

2. Without prejudice to Article 5 of Decision 2008/855/EC, the prohibitions set out in paragraph 1 shall not apply to:

- (a) semen, ova and embryos produced before 9 December 2010;
- (b) frozen bovine semen and in-vivo derived embryos, frozen porcine semen, and frozen ovine and caprine semen and embryos imported into Bulgaria in accordance with the conditions laid down in Directives 88/407/EEC, 89/556/EEC, 90/429/EEC or 92/65/EEC respectively, and which since their introduction into Bulgaria have been stored and transported separately from semen, ova and embryos not eligible for dispatch in accordance with paragraph 1;
- (c) frozen semen and embryos obtained from bovine, porcine, ovine and caprine animals kept for at least 90 days prior to the date of and during collection outside the areas listed in Annex I and Annex II and which:

- (i) have been stored in approved conditions for a minimum period of 30 days prior to the date of dispatch; and
- (ii) have been collected from donor animals standing in centres or on holdings which have been free from foot-and-mouth disease for at least 3 months prior to the date of collection of the semen or embryos and 30 days after the date of collection and which are situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease for at least 30 days prior to the date of collection.
- (d) Before the dispatch of the semen or embryos referred to in points (a), (b) and (c) the central veterinary authorities shall communicate to the other Member States and the Commission a list of centres and teams approved for the purpose of application of this paragraph.

3. The health certificate provided for in Directive 88/407/EEC and accompanying frozen bovine semen dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen bovine semen conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

4. Without prejudice to Article 9(b) of Decision 2008/855/EC, the health certificate provided for in Directive 90/429/EEC and accompanying frozen porcine semen dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen porcine semen conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

5. The health certificate provided for in Directive 89/556/EEC and accompanying bovine in-vivo derived embryos dispatched from Bulgaria to other Member States shall bear the following words:

'Bovine in-vivo derived embryos conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

6. The health certificate provided for in Directive 92/65/EEC and accompanying frozen ovine or caprine semen dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen ovine/caprine semen conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

7. The health certificate provided for in Directive 92/65/EEC and accompanying frozen ovine or caprine embryos dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen ovine/caprine embryos conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

8. Without prejudice to Article 9(c) of Decision 2008/855/EC, the health certificate provided for in Directive 92/65/EEC and accompanying frozen porcine embryos dispatched from Bulgaria to other Member States shall bear the following words:

'Frozen porcine embryos conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

#### Article 7

#### Hides and skins

1. Bulgaria shall not dispatch hides and skins of animals of the bovine, ovine, caprine and porcine species and of other biungulates ('hides and skins') from the areas listed in Annex I.

2. The prohibition set out in paragraph 1 shall not apply to hides and skins which:

- (a) were produced in Bulgaria before 9 December 2010; or
- (b) comply with the requirements provided for in point 2(c) or (d) of Part A of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002; or
- (c) were produced outside the areas listed in Annex I in accordance with the conditions laid down in Regulation (EC) No 1774/2002, and have since introduction into Bulgaria been stored and transported separately from hides and skins not eligible for dispatch in accordance with paragraph 1.

Treated hides and skins shall be separated from untreated hides and skins of animals of species susceptible to foot-and-mouth disease.

3. Bulgaria shall ensure that hides and skins to be dispatched to other Member States shall be accompanied by an official certificate which bears the following words:

'Hides and skins conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

4. By way of derogation from paragraph 3 it shall be sufficient, in the case of hides and skins which comply with the requirements of points (1)(b) to (e) of Part A of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002, to be accompanied by a commercial document stating compliance with those requirements.

5. By way of derogation from paragraph 3 it shall be sufficient, in the case of hides and skins which comply with the requirements of point 2(c) or (d) of Part A of Chapter VI of Annex VIII to Regulation (EC) No 1774/2002, that compliance with those requirements is stated in the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

#### Article 8

##### Other animal products

1. Bulgaria shall not dispatch products of animals of the bovine, ovine, caprine and porcine species and other biungulates not mentioned in Articles 2 to 7 produced after 9 December 2010 and coming from the areas listed in Annex I, or obtained from animals originating in the areas listed in Annex I.

Bulgaria shall not dispatch dung and manure of the bovine, ovine, caprine and porcine species and other biungulates from the areas listed in Annex I.

2. The prohibition set out in the first subparagraph of paragraph 1 shall not apply to:

(a) animal products which:

(i) have been subjected to a heat treatment:

— in a hermetically sealed container with a  $F_0$  value of 3,00 or more, or

— in which the centre temperature is raised to at least 70 °C; or

(ii) were produced outside the areas listed in Annex I in accordance with the conditions laid down in Regulation (EC) No 1774/2002, and which since introduction into Bulgaria have been stored and transported separately from animal products not eligible for dispatch in accordance with paragraph 1;

(b) blood and blood products as defined in points 4 and 5 of Annex I to Regulation (EC) No 1774/2002 which have been subjected to at least one of the treatments provided for in point 4(a) of Part A of Chapter IV of Annex VIII to Regulation (EC) No 1774/2002, followed by an effectiveness

check, or have been imported in accordance with Part A of Chapter IV of Annex VIII to Regulation (EC) No 1774/2002;

(c) lard and rendered fats which have been subject to the heat treatment prescribed in point 2(d)(iv) of Part B of Chapter IV of Annex VII to Regulation (EC) No 1774/2002;

(d) animal casings complying with the conditions in Part A of Chapter 2 of Annex I to Directive 92/118/EEC and which have been cleaned, scraped and then either salted, bleached or dried, followed by steps to prevent the recontamination of the casings;

(e) sheep wool, ruminant hair and pigs bristles which have undergone factory washing or have been obtained from tanning and unprocessed sheep wool, ruminant hair and pigs bristles which are securely enclosed in packaging and dry;

(f) petfood conforming to the requirements of points 2, 3 and 4 of Part B of Chapter II of Annex VIII to Regulation (EC) No 1774/2002;

(g) composite products which are not subject to further treatment containing products of animal origin, on the understanding that the treatment was not necessary for finished products, the ingredients of which comply with the respective animal health conditions laid down in this Decision;

(h) game trophies in accordance with points 1, 3 or 4 of Part A of Chapter VII of Annex VIII to Regulation (EC) No 1774/2002;

(i) packed animal products intended for use as in-vitro diagnostic, laboratory reagents;

(j) medicinal products as defined in Directive 2001/83/EC, medical devices manufactured utilising animal tissue which is rendered non-viable as referred to in Article 1(5)(g) of Directive 93/42/EEC, veterinary medicinal products as defined in Directive 2001/82/EC, and investigational medicinal products as defined in Directive 2001/20/EC.

3. Bulgaria shall ensure that the animal products referred to in paragraph 2 to be dispatched to other Member States shall be accompanied by an official certificate which bears the following words:

'Animal products conforming to Commission Decision 2011/44/EU of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria (\*).

(\*) OJ L 19, 22.1.2011, p. 20.'

4. By way of derogation from paragraph 3, it shall be sufficient, in the case of the products referred to in paragraph 2(a) to (d) and (f) of this Article that compliance with the conditions for the treatment stated in the commercial document required in accordance with the respective Union legislation is endorsed in accordance with Article 9(1).

5. By way of derogation from paragraph 3 it shall be sufficient, in the case of products referred to in paragraph 2(e) to be accompanied by a commercial document stating either the factory washing or origin from tanning or compliance with the conditions laid down in points 1 and 4 of Part A of Chapter VIII of Annex VIII to Regulation (EC) No 1774/2002.

6. By way of derogation from paragraph 3 it shall be sufficient, in the case of products referred to in paragraph 2(g) which have been produced in an establishment operating HACCP and an auditable standard operating procedure which ensures that pre-processed ingredients comply with the respective animal health conditions laid down in this Decision, that this is stated on the commercial document accompanying the consignment, endorsed in accordance with Article 9(1).

7. By way of derogation from paragraph 3, it shall be sufficient, in the case of products referred to in paragraph 2(i) and (j), to be accompanied by a commercial document stating that the products are for use as in-vitro diagnostic, laboratory reagents, medical products or medical devices, provided that the products are clearly labelled 'for in-vitro diagnostic use only' or 'for laboratory use only', as 'medicinal products' or as 'medical devices'.

8. Derogating from the provisions in paragraph 3, it shall be sufficient, in the case of composite products that fulfil the conditions set out in Article 6(1) of Decision 2007/275/EC that they are accompanied by a commercial document, which bears the following words:

'These composite products are shelf stable at ambient temperature or have clearly undergone in their manufacture a complete cooking or heat treatment process throughout their substance, so that any raw material is de-natured'.

#### Article 9

##### Certification

1. Where reference is made to this paragraph, the competent authorities of Bulgaria shall ensure that the commercial document required by Union legislation for trade between Member States is endorsed by the attachment of a copy of an official certificate stating that:

- (a) the products concerned have been produced:
  - (i) in a production process that has been audited and found in compliance with the appropriate requirements in Union animal health legislation and suitable to destroy the foot-and-mouth disease virus; or
  - (ii) from pre-processed materials which had been certified accordingly; and
- (b) provisions are in place to avoid possible re-contamination with the foot-and-mouth disease virus after treatment.

Such certification of the production process shall bear a reference to this Decision, shall be valid for 30 days, shall state the expiry date and shall be renewable after inspection of the establishment.

2. In case of products for retail sale to the final consumer, the competent authorities of Bulgaria may authorise consolidated consignments of animal products other than fresh meat, minced meat, mechanically separated meat and meat preparations, each of which is eligible for dispatch in accordance with this Decision, to be accompanied by a commercial document endorsed by the attachment of a copy of an official veterinary certificate confirming that:

- (a) the premises of dispatch have in place a system to ensure that goods can only be dispatched if they are traceable to documentary evidence of compliance with this Decision; and
- (b) the system referred to in (a) has been audited and found satisfactory.

Such certification of the traceability system shall bear a reference to this Decision, shall be valid for 30 days, shall state the expiry date and shall be renewable only after the establishment had been audited with satisfactory results.

The competent authorities of Bulgaria shall communicate to the other Member States and the Commission the list of establishments which they have approved for the purpose of application of this paragraph.

#### Article 10

##### Cleansing and disinfection

1. Without prejudice to Article 11 of Decision 2008/855/EC, Bulgaria shall ensure that vehicles which have been used for the transport of live animals in the areas listed in Annex I and Annex II are cleansed and disinfected after each operation, and that such cleansing and disinfection is recorded in accordance with Article 12(2)(d) of Directive 64/432/EEC.

2. Bulgaria shall ensure that vehicles which have been used within the areas listed in Annex I and Annex II for the transport of animals and parts of animals of species susceptible to foot-and-mouth disease referred to in Article 5(1)(e) of Regulation (EC) No 1774/2002 and of other animal by-products and processed animal by-products derived from animals of species susceptible to foot-and-mouth disease are cleansed and disinfected after each operation, and that such cleansing and disinfection and all contacts with holdings keeping animals of species susceptible to foot-and-mouth disease are recorded in the journey log of the vehicle concerned.

#### Article 11

##### Certain exempted products

The restrictions laid down in Articles 3, 4, 5 and 8 shall not apply to the dispatch from the areas listed in Annex I of the animal products referred to in those Articles if such products were:

- (a) not produced in Bulgaria and remained in their original packaging indicating the country of origin of the products; or

(b) produced in an approved establishment situated in the areas listed in Annex I from pre-processed products not originating from those areas, which:

- (i) have, since introduction into the territory of Bulgaria, been transported, stored and processed separately from products which are not eligible for dispatch outside the areas listed in Annex I;
- (ii) are accompanied by a commercial document or official certificate as required by this Decision.

*Article 12*

**Cooperation between Member States**

Member States shall cooperate in monitoring personal luggage of passengers travelling from the areas listed in Annex I and in information campaigns carried out to prevent introduction of products of animal origin into the territory of Member States other than Bulgaria.

*Article 13*

**Measures to be taken by Member States other than Bulgaria**

1. Without prejudice to Article 1(4), Member States other than Bulgaria shall ensure that live animals of species susceptible to foot-and-mouth disease are not dispatched to the areas listed in Annex I.

2. Member States other than Bulgaria shall take appropriate precautionary measures in relation to susceptible animals dispatched from Bulgaria between 9 December 2010 and 6 January 2011. Those measures may include any of the following:

- (a) isolation and clinical inspection;

(b) where necessary, laboratory testing to detect or rule out infection with the foot-and-mouth disease virus.

*Article 14*

**Implementation**

Member States shall amend the measures which they apply to trade so as to bring them into compliance with this Decision. They shall immediately inform the Commission thereof.

*Article 15*

**Repeal**

Decision 2011/8/EU is repealed.

References to the repealed Decision shall be construed as references to this Decision.

*Article 16*

This Decision shall apply until 31 March 2011.

*Article 17*

**Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 19 January 2011.

*For the Commission*

John DALLI

*Member of the Commission*

## ANNEX I

The following areas in Bulgaria:

Region of Burgas.

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## ANNEX II

The following areas in Bulgaria:

Regions of Kardjali, Haskovo, Yambol, Sliven, Shumen and Varna.

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## ANNEX III

The following areas in Bulgaria:

1	2	3	4	5	6	7	8
GROUP	ADNS	Administrative Unit	B	S/G	P	FG	WG
Bulgaria	00002	Region of Burgas	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—
	—	—	—	—	—	—	—

ADNS = Animal Disease Notification System Code (Decision 2005/176/EC)

B = bovine meat

S/G = sheep and goat meat

P = pig meat

FG = farmed game of species susceptible to foot-and-mouth disease

WG = wild game of species susceptible to foot-and-mouth disease

## ANNEX IV

The health mark referred to in Article 2(3):

Dimensions:

BG = 7 mm

Establishment No = 10 mm

Circle outer diameter = 50 mm

Line thickness of Circle = 3 mm

