COMMISSION IMPLEMENTING DECISION (EU) 2015/1500

of 7 September 2015

concerning certain protective measures against lumpy skin disease in Greece and repealing Implementing Decision (EU) 2015/1423

(notified under document C(2015) 6221)

(Only the Greek text is authentic)

(Text with EEA relevance)

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 (1), 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 (2), and in particular Article 10(4) thereof,

Having regard to 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 (3), and in particular Article 4(3) thereof,

Whereas:

- Lumpy skin disease is a primarily vector-transmitted viral disease of bovine animals characterised by severe losses and with the potential for important spread, notably through movements of and trade in susceptible live animals and products thereof. The disease is not of public health importance because the lumpy skin disease virus is not transmissible to humans.
- Council Directive 92/119/EEC (*) lays down general measures for the control of certain animal diseases, including (2) lumpy skin disease. These include measures to be taken in the event of a suspicion and a confirmation of lumpy skin disease in a holding, the measures to be taken in restriction zones and other additional measures to successfully control the disease.
- On 20 August 2015, the Greek authorities notified the Commission of two outbreaks of lumpy skin disease in (3) bovine holdings with approximately 200 bovine animals in Feres area of the regional unit of Evros in Greece. These outbreaks represent the first occurrence of lumpy skin disease in the Union.
- (4) Greece applied measures within the framework of Directive 92/119/EEC and in particular established protection and surveillance zones around the outbreaks according to Article 10 of that Directive.
- (5) The risk of spread of the lumpy skin disease virus to other areas of Greece and to other Member States, particularly through trade in live bovine animals and their germinal products, the movement of certain wild ruminants and the placing on the market of certain products derived from bovine animals should be controlled.
- (6)In order to prevent its spread to other parts of Greece, to other Member States and third countries, the Commission adopted Commission Implementing Decision (EU) 2015/1423 (5) providing for interim protective measures and prohibiting the movement and dispatch of bovine animals and semen thereof as well as the placing on the market of certain animal products from the regional unit of Evros.

⁽¹) OJL 395, 30.12.1989, p. 13. (²) OJL 224, 18.8.1990, p. 29. (³) OJL 18, 23.1.2003, p. 11.

Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease (OJ L 62, 15.3.1993, p. 69).

Commission Implementing Decision (EU) 2015/1423 of 21 August 2015 concerning certain interim protective measures against lumpy

skin disease in Greece (OJ L 222, 25.8.2015, p. 7).

- (7) Following receipt of further information on the epidemiological situation in Greece it is possible to supplement those measures by the application of risk mitigating measures.
- (8) The definitions used for the purposes of this Decision are those provided for in existing legislation and in particular in Article 2 of Directive 92/119/EEC, Article 2 of Council Directive 64/432/EEC (1) and Article 2 of Council Directive 92/65/EEC (2). However, some specific terms are specifically created and used for the purposes of this Decision and should therefore be defined herein.
- It is necessary to define the part of the territory of Greece which is considered to be free of lumpy skin disease and not subject to the restrictions pursuant to Directive 92/119/EEC and the present Decision. It is therefore appropriate to outline a restricted zone in an Annex, taking into account the level of risk for the spread of the disease. The geographical boundaries of such zone should be based on the risk and the outcome of the tracing of possible contacts to the infected holding, possible role of vectors and the possibility to implement sufficient controls on the movement of animals and products. Such zone should include any protection and surveillance zone established under Directive 92/119/EEC. Based on information provided by Greece, the whole territory of the regional unit of Evros in Greece should be regarded as a restricted zone.
- (10)It is also necessary to provide for certain restrictions on the dispatch of animals of susceptible species and their germinal products from this restricted zone, as well as restrictions for the placing on the market of certain products of animal origin and animal by-products from such a zone.
- In the event of an outbreak of lumpy skin disease, Article 19 of Directive 92/119/EEC provides for the possibility to apply vaccination against that disease. At present, the vaccination against lumpy skin disease in Greece is prohibited. However, Greece has indicated their intention to proceed with emergency vaccination against the lumpy skin disease. The risk of spreading the disease by means of animals and products thereof of vaccinated animals is different to those of non-vaccinated animals. Therefore, those risks should be addressed separately and are not subject of this decision.
- In terms of risk of spreading of lumpy skin disease, different commodities pose different levels of risk. As indicated in the Scientific Opinion of the European Food Safety Authority (the EFSA) on lumpy skin disease (3) the movement of live bovine animals, bovine semen and raw hides and skins from infected bovine animals pose higher risk in terms of exposure and consequences than other products such as milk and dairy products, treated hides and skins or fresh meat, meat preparations and meat products originating from bovine animals, where scientific or experimental evidence is lacking on their role of transmission of the disease. Therefore, measures in this Decision need to be balanced and proportionate to the risks.
- The movements of live bovine animals out of the regional unit of Evros should continue to be prohibited in order to prevent the spread of the disease. According to the Scientific Opinion of the EFSA on lumpy skin disease and the Word Organisation for Animal Health (OIE) wild fauna, i.e. certain exotic wild ruminants may play a potential role in the transmission of the disease, in particular in Africa where the disease is endemic. Therefore some preventive measures should also apply to wild ruminants. In the absence of more precise rules in the Union legislation, the appropriate international standards for such movements provided for in the Terrestrial Animal Health Code of the OIE (OIE Terrestrial Animal Health Code) (4) should be used for this purpose.
- As Greece has requested for an exemption from the prohibition of the dispatch of bovine animals for direct slaughter from holdings situated in the restricted zone outside protection and surveillance zones and such exemption is foreseen in Article 11.11.5 of the OIE Terrestrial Animal Health Code, it is appropriate to allow the dispatch of such consignments under certain conditions.
- Similarly, the transmission of the disease through semen and embryos of animals of the bovine species cannot be excluded. Therefore, certain protective measures should be provided for those commodities. In the absence of the Union standards, the Scientific Opinion of the EFSA on lumpy skin disease and the appropriate OIE Animal Health Terrestrial Code recommendations should be used for this purpose.

⁽¹) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and

swine (OJ 121, 29.7.1964, p. 1977/64).
(2) 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 (OJ L 268, 14.9.1992, p. 54).

EFSA Journal 2015;13(1):3986 [73 pp.].

²⁴th Edition, 2015.

- (16) According to the Scientific Opinion of the EFSA on lumpy skin disease, transmission of lumpy skin disease virus through semen (natural mating or artificial insemination) has been experimentally demonstrated, and lumpy skin disease virus has been isolated in the semen of experimentally infected bulls. The collection and use of semen of animals of the bovine species originating in the restricted zone should therefore be prohibited.
- (17) In accordance with Article 4.7.14 of the OIE Terrestrial Animal Health Code, the lumpy skin disease is assigned in accordance with the Manual of the International Embryo Transfer Society to Category 4 diseases or pathogenic agents, which are those for which studies have been done, or are in progress, that indicate that no conclusions are yet possible with regard to the level of transmission risk or that the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled in accordance with that Manual between collection and transfer. The collection and use of embryos of animals of the bovine species originating in the restricted zone should therefore be prohibited.
- (18) There is no scientific or experimental evidence suggesting the transmission of the virus to susceptible animals through fresh meat, meat preparations or meat products. Although the Scientific Opinion of the EFSA on lumpy skin disease indicates that the virus may survive in meat for a non-indicated period of time, the existing Union ban on feeding ruminant proteins to ruminants would exclude the possibility of an unlikely oral transmission of possible virus. To avoid any risk of spreading the disease, the placing on the market of fresh meat, meat preparations and meat products produced from bovine animals originating in the regional unit of Evros should only be allowed where the fresh meat was produced from bovine animals kept on disease-free holdings situated in the restricted zone outside established protection and surveillance zones. Such meat should only be placed on the market in the territory of Greece.
- (19) Furthermore, the dispatch of consignments of fresh meat, meat preparations and meat products obtained from such fresh meat obtained from animals kept outside the restricted zone and processed in establishments situated in the restricted zone outside protection and surveillance zones may be allowed under certain conditions.
- (20) Colostrum, milk and dairy products used as animal feed may play an important role in spreading the disease, in particular, where the colostrum, milk and dairy products have not been sufficiently heat-treated or acidified to inactivate the virus.
- (21) Greece has requested for exemption from prohibition of the dispatch of pasteurised milk and dairy products for human consumption from establishments situated in the restricted zone outside protection and surveillance zones, As the Scientific Opinion of the EFSA on the animal health risks of feeding animals with ready-to-use dairy products without further treatment (¹) specifies more precisely some methods that can mitigate the risks of spreading lumpy skin disease through milk and dairy products, it is possible to allow the dispatch of consignments of milk and dairy products for human consumption under certain conditions.
- (22) Commission Regulation (EU) No 142/2011 (²), lays down implementing rules for Regulation (EC) No 1069/2009 of the European Parliament and of the Council (³), including requirements for the safe processing of animal byproducts and derived products. For the prevention of spreading of lumpy skin disease, placing on the market of unprocessed animal by-products shall be prohibited. A reference to processed animal by-products in this Decision shall be read as a reference to animal health standards set out in Regulation (EU) No 142/2011.
- (23) The measures provided for in this Decision should replace the interim protective measures against lumpy skin disease in Greece provided for in Implementing Decision (EU) 2015/1423. That Decision should therefore be repealed.
- (24) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

(1) EFSA Journal (2006) 347, p. 1.

(*) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

⁽²⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

- 1. This Decision lays down certain protective animal health control measures in relation to the lumpy skin disease confirmed in Greece.
- 2. In case of conflict, the measures provided for in this Decision shall supersede the measures adopted by Greece in the framework of Directive 92/119/EEC.
- 3. Derogations provided for in Articles 4, 5, 6 and 7 do not apply to bovine animals vaccinated against lumpy skin disease and products thereof.

Article 2

Definitions

For the purposes of this Decision, the following definitions apply:

- (a) 'bovine animal' means ungulates of the species Bos taurus, Bos indicus, Bison bison and Bubalus bubalis;
- (b) 'restricted zone' is the part of the territory of a Member State listed in the Annex to this Decision which includes the area where lumpy skin disease was confirmed and any protection and surveillance zones established in accordance with Article 10 of Directive 92/119/EEC.

Article 3

Prohibition on the movement and dispatch of certain animals and semen and embryos thereof, and placing on the market of certain products of animal origin and animal by-products

- Greece shall prohibit the dispatch of the following commodities from the restricted zone to other parts of Greece, to other Member States and to third countries:
- (a) live bovine animals and captive wild ruminants;
- (b) semen, ova and embryos of animals of the bovine species.
- 2. Greece shall prohibit the placing on the market outside the restricted zone of the following commodities produced from bovine animals and wild ruminants kept in or hunted in the restricted zone:
- (a) fresh meat and meat preparations and meat products produced from such fresh meat;
- (b) colostrum, milk and dairy products of bovine animals;
- (c) fresh hides and skins of bovine animals and wild ruminants, other than those referred to in point (d);
- (d) unprocessed animal by-products of bovine animals and wild ruminants, unless destined and channelled under official supervision of the competent authority for disposal or processing in an approved plant under Regulation (EC) No 1069/2009 within the territory of Greece.

Derogation from the prohibition on the dispatch of live bovine animals and captive wild ruminants for direct slaughter and dispatch of fresh meat, meat preparations and meat products obtained from such animals

- 1. By way of derogation from the prohibition provided for in point (a) of Article 3(1), the competent authority may authorise the dispatch of bovine animals and captive wild ruminants from holdings situated in the restricted zone outside protection and surveillance zones to a slaughterhouse located in other parts of Greece provided that:
- (a) the animals were resident since birth, or for the past 28 days, on a holding where no case of lumpy skin disease was
 officially reported during that period;
- (b) the animals were clinically inspected at loading and did not present any clinical symptoms of lumpy skin disease;
- (c) the animals are transported for immediate slaughter directly, without stopping or unloading to the slaughterhouse;
- (d) the slaughterhouse is designated for the slaughtering of those animals by the competent authority;
- (e) the competent authority responsible for the slaughterhouse has to be informed by the dispatching competent authority of the intention to send bovine animals and notifies the competent authority of dispatch of their arrival;
- (f) on arrival at the slaughterhouse, these animals are kept and slaughtered separately from other animals within less than 36 hours.
- 2. Any dispatch of bovine animals and captive wild ruminants in accordance with paragraph 1 shall only take place if the following conditions are fulfilled:
- (a) the means of transport has been properly cleansed and disinfected before and after loading of such animals in accordance with Article 9;
- (b) before and during the transport, animals are protected against the attacks of vector insects.
- 3. The competent authority shall ensure that fresh meat, meat preparations and meat products obtained from those animals are placed on the market in accordance with the requirements provided for in Articles 5 and 6, respectively.

Article 5

Derogation from the prohibition on the placing on the market of fresh meat and meat preparations of bovine animals and wild ruminants

- 1. By way of derogation from the prohibition provided for in point (a) of Article 3(2), the competent authority may authorise the placing on the market of consignments of fresh meat, excluding offal and fresh hides and skins, obtained from bovine animals and wild ruminants from the restricted zone outside protection and surveillance zones and meat preparations thereof, provided that the fresh meat and meat preparations were obtained from animals:
- (a) kept on holdings in the restricted zone that were not under restrictions in accordance with Directive 92/119/EEC; or
- (b) slaughtered before 21 August 2015.

The competent authority shall ensure that the consignments referred to in this paragraph are not dispatched to other Member States or third countries.

2. The competent authority shall only authorise the dispatch to other Member States of consignments of fresh meat and meat preparations produced from such fresh meat obtained from bovine animals kept and slaughtered outside the restricted zone, provided the consignments are accompanied by an official certificate with the following attestation:

Fresh meat or meat preparations complying with Commission Implementing Decision (EU) 2015/1500 [C(2015)6221] of 7 September 2015 concerning certain protective measures against lumpy skin disease in Greece'.

Derogation from the prohibition on the placing on the market of meat products consisting of or containing meat of bovine animals and wild ruminants

- 1. By way of derogation from the prohibition provided for in point (a) of Article 3(2), the competent authority may authorise the placing on the market of consignments of meat products produced from fresh meat of bovine animals and wild ruminants from the restricted zone outside protection and surveillance zones, provided that the fresh meat was obtained from animals:
- (a) kept on holdings in the restricted zone that were not under restrictions in accordance with Directive 92/119/EEC; or
- (b) slaughtered before 21 August 2015; or
- (c) kept and slaughtered outside the restricted zone.
- 2. The competent authority shall authorise the placing on the market of meat products referred to in paragraph 1, conforming to conditions of points (a) or (b) of that paragraph, only on the territory of Greece, provided that the meat products have been subjected to a non-specific treatment which ensures that the cut surface of the meat products shows no longer the characteristics of fresh meat.

The competent authority shall ensure that the consignments referred to in this paragraph are not dispatched to other Member States or third countries.

3. The competent authority shall only authorise the dispatch of consignments referred to in paragraph 1(a) and (b) to other Member States, provided that the meat products have been subjected to a specific treatment in a hermetically sealed container to an F_o value of three or more, and are accompanied by an official certificate with the following attestation:

'Meat products complying with Commission Implementing Decision (EU) 2015/1500 [C(2015)6221] of 7 September 2015 concerning certain protective measures against lumpy skin disease in Greece'.

4. The competent authority shall only authorise the dispatch to other Member States of consignments of meat products referred to in paragraph 1(c), provided that the meat products have been subjected to a non-specific treatment, which ensures that the cut surface of the meat products shows no longer the characteristics of fresh meat and is accompanied by an official certificate with the following attestation:

'Meat products complying with Commission Implementing Decision (EU) 2015/1500 [C(2015)6221] of 7 September 2015 concerning certain protective measures against lumpy skin disease in Greece'.

Article 7

Derogation from the prohibition on the dispatch and placing on the marked of milk and dairy products

- 1. By way of derogation from the prohibition provided for in point (b) of Article 3(2), the competent authority may authorise the placing on the market of milk for human consumption obtained from bovine animals in the restricted zone outside protection and surveillance zones, and dairy products thereof, provided that the milk and dairy products have been subjected to a treatment described in points 1.1 to 1.5 of Part A of Annex IX to Council Directive 2003/85/EC (¹).
- 2. The competent authority shall only authorise dispatch to other Member States of consignments of milk and dairy products referred to in paragraph 1, provided that the consignments are accompanied by an official certificate, with the following attestation:

'Milk or dairy products complying with Commission Implementing Decision (EU) 2015/1500 [C(2015)6221] of 7 September 2015 concerning certain protective measures against lumpy skin disease in Greece'.

⁽¹) Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).

Special health mark for fresh meat, meat preparations and meat products referred to in Articles 5(1) and 6(2) respectively

Greece shall ensure that the fresh meat, meat preparations and meat products referred to in Article 5(1), and Article 6(2) respectively are marked with a special health mark or identification mark that is not oval and cannot be confused with:

- (a) the health mark for fresh meat as set out in Chapter III of Section I of Annex I to Regulation (EC) No 854/2004 of the European Parliament and of the Council (1);
- (b) the identification mark for meat preparations and meat products consisting of or containing meat of bovine animals, as set out in Section I of Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council (2).

Article 9

Requirements concerning transport vehicles, cleansing and disinfection

- The competent authority shall ensure that, for any vehicle which has been in contact with the susceptible species in the restricted zone and intends to leave this same zone, the operator or driver of this vehicle provides evidence showing that, since the last contact with the animals, the vehicle has been cleansed and disinfected in a manner to inactivate lumpy skin disease virus.
- The competent authority should define the information to be presented by the operator/driver of the livestock vehicle in order to demonstrate the required disinfection has taken place.

Article 10

Information requirements

Greece shall inform the Commission and the other Member States, in the framework of the Standing Committee on Plants, Animals, Food and Feed, of the results of the surveillance for lumpy skin disease carried out in the restricted zone.

Article 11

Repeal

Implementing Decision (EU) 2015/1423 is repealed.

Article 12

Application

This Decision shall apply until 30 October 2015.

⁽¹⁾ 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 (OJ L 139, 30.4.2004, p. 206).

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 (OJ L 139, 30.4.2004, p. 55).

Addressees

This Decision is addressed to the Hellenic Republic.

Done at Brussels, 7 September 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

Greece:

The following regional units in Greece:

- Regional unit of Evros