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COMMISSION IMPLEMENTING DECISION (EU) 2015/2055

of 10 November 2015

laying down the conditions for setting out the programme for emergency vaccination of bovine animals against lumpy skin disease in Greece and amending Implementing Decision (EU) 2015/1500

(notified under document C(2015) 7671)

(Only the Greek text is authentic)

(Text with EEA relevance)

(OJ L 300, 17.11.2015, p. 31)

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(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 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 ([3]), and in particular Article 19(1)(a), (3)(a) and (6) 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 ([4]), and in particular Article 4(3) thereof,

Whereas:

(1) Directive 92/119/EEC lays down general measures for the control of certain animal diseases. These include measures to be taken in the event of a suspicion and the confirmation of lumpy skin disease (LSD) in a holding, the measures to be taken in restriction zones and other additional measures to control the disease. Those measures also provide for emergency vaccination in case of an outbreak of LSD as a supplement to other control measures.

(2) On 20 August 2015, the Greek authorities notified the Commission of two outbreaks of LSD in 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 LSD in the Union.

([1]) OJ L 395, 30.12.1989, p. 13.
([2]) OJ L 224, 18.8.1990, p. 29.
([3]) OJ L 62, 15.3.1993, p. 69.
([4]) OJ L 18, 23.1.2003, p. 11.

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(3) In order to prevent the spread of LSD to other parts of Greece, to other Member States and to third countries, the Commission adopted Commission Implemening Decision (EU) 2015/1423 ([1]) 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.

(4) In the light of further information on the epidemiological situation in Greece those interim protective measures were replaced by the more complex protection measures laid down in Commission Implemening Decision (EU) 2015/1500 ([2]).

(5) Moreover, on 10 September 2015 Greece informed the Commission and Member States about 24 confirmed and 17 suspected outbreaks of LSD on holdings situated in the established protection and surveillance zones in the regional unit of Evros.

(6) Additionally, on 27 September 2015, the Greek authorities notified the Commission of an outbreak of LSD in the South-East of the regional unit of Xanthi and again, on 2 October 2015, of a new outbreak of LSD in the regional unit of Kavala, located west of the regional unit of Xanthi.

(7) Furthermore, on 7 October 2015 the Greek authorities notified the Commission of an outbreak of LSD in one bovine holding in the regional unit of Limnos.

(8) In the event of an outbreak of LSD, Article 19 of Directive 92/119/EEC provides for the possibility to apply vaccination against that disease.

(9) On 26 August 2015 Greece submitted to the Commission a programme for emergency vaccination against LSD of bovine animals kept on holdings in the regional unit of Evros in Greece. The programme provided details concerning the geographical and administrative definition of the vaccination zone, the number of holdings and animals to be vaccinated and the time when vaccination should be accomplished and the circumstances motivating the decision to implement the measures.

(10) In accordance with the Scientific Opinion of the European Food Safety Authority (the EFSA) on lumpy skin disease ([3]) only live attenuated vaccines against LSD are commercially available. The opinion describes the Neethling attenuated LSD virus vaccine as highly effective in preventing morbidity. Because homologous

([1]) 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).

([2]) 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 (OJ L 234, 8.9.2015, p. 19).

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

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LSD vaccines are more effective than vaccines based on attenuated sheep pox viruses, their use is to be recommended, subject to availability by vaccine producers which are exclusively operating outside the Union.

(11) There is no vaccine against LSD with the marketing authorisation in the Union. Emergency vaccination in accordance with Article 19 of Directive 92/119/EEC can therefore only be carried out in accordance with Article 8 of Directive 2001/82/EC of the European Parliament and of the Council [1], permitting Member States to provisionally allow the use of vaccines without a marketing authorisation in the event of a serious epizootic disease as it is the case of LSD.

(12) In accordance with Article 19(6) of Directive 92/119/EEC, Greece informed the Commission on 5 September 2015 of the acquisition of a sufficient number of doses of homologous LSD vaccine and the start of emergency vaccination in protection and surveillance zones in the regional unit of Evros according to the vaccination programme described in recital 9. In addition, on 27 September and 2 October 2015 respectively, the Greek authorities informed the Commission of their decision to introduce vaccination of bovine animals kept on holdings in the regional units of Rodopi, Xanthi and Kavala in line with the vaccination programme submitted on 26 August 2015.

(13) The purpose of this Decision is to define the conditions under which Greece should apply emergency vaccination. The rapid spread of LSD in Greece constitutes a risk to other parts of the territory of Greece and to neighbouring countries. Therefore, it is also the purpose of this Decision to reinforce the disease control measures applied in Greece by restricting the movement of unvaccinated bovine animals older than 3 months to other holdings within the restricted area. This age limitation allows the necessary movement of young calves to other holdings for further rearing during a period after birth when they cannot be effectively immunised. At the same time, it is necessary to allow the movement of unvaccinated animals directly to a slaughterhouse within the restricted area.

(14) The area where vaccination against LSD is to be carried out may cover the entire restricted zone as defined in Implementing Decision (EU) 2015/1500, which is set out in the Annex to that Decision.

(15) The first round of vaccination should be completed as soon as possible and not later than 31 October 2015 and 30 November 2015 in the regional unit of Evros and in the regional units of Rodopi, Xanthi and Kavala respectively. In case of further outbreaks in other regional units, the vaccination in the affected regional unit should be completed within 2 months after the

[1] 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 (OJ L 311, 28.11.2001, p. 1).

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confirmation of the first outbreak of LSD in that regional unit subject to availability of vaccines. Because the success of the control measures in Greece also depends on the success of the control measures in a neighbouring third country which had reported outbreaks of LSD in close proximity to those notified in Greece, it may be necessary to vaccinate offspring born to vaccinated bovine animals and to revaccinate bovine animals in the affected area. The period of application of this Decision on vacination against LSD in Greece has therefore been set until the end of 2016.

(16) The risk of spreading the disease from vaccinated animals and products thereof is different to the risks arising from non-vaccinated and possibly incubating animals. Therefore, it is necessary to lay down conditions for the movement of vaccinated bovine animals and for the placing on the market of products derived from such animals.

(17) The knowledge about LSD is incomplete. Vaccinated bovine animals are protected from clinical signs but not necessarily from infection and not all vaccinated animals respond with a protective immunity. Therefore, such animals after the period of at least 28 days following the vaccination shall be allowed to be sent directly for immediate slaughter to slaughterhouses situated on the territory of Greece.

(18) Consequently, fresh meat and meat preparations thereof, as well as meat products subjected to a non-specific treatment may constitute a non-negligible risk of spreading LSD. Therefore, it is justified to limit the placing on the market of the fresh meat, meat preparations and meat products thereof to the territory of Greece, provided that such fresh meat, meat preparations and meat products are subjected to special marking which is not oval and cannot be confused with 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]) and 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]).

(19) However, a specific treatment of meat products in hermetically sealed containers to a F_o value of three or more and a treatment described in points 1.1 to 1.5 of Part A of Annex IX to Council

([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).

([2]) 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).

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Directive 2003/85/EC ([1]) of milk and dairy products sufficiently inactivate LSD virus in such products destined for human consumption and therefore such milk and dairy products should be allowed to be placed on the market on the whole of the teritorry of Greece and in other Member States and to be dispatched to third countries.

(20) Implementing Decision (EU) 2015/1500 should therefore be amended accordingly.

(21) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

1. In addition to the measures taken by Greece in accordance with Articles 4, 5 and 10 of Directive 92/119/EEC, Greece may carry out emergency vaccination against lumpy skin disease of bovine animals kept on holdings in the area as set out in Annex I under the conditions set out in Annex II.

2. The programme submitted by Greece to the Commission on 26 August 2015 for emergency vaccination against lumpy skin disease of bovine animals kept on holdings in the area as set out in Annex I is approved.

3. Any movement to other Member States of bovine animals vaccinated against lumpy skin disease is prohibited.

4. Any movement to other Member States of bovine animals younger than 6 months and not vaccinated against lumpy skin disease but born to dams vaccinated against lumpy skin disease is prohibited.

Article 2

Greece shall take the necessary measures to comply with this Decision and shall inform the Commission and Member States in accordance with Article 19(5) of Directive 92/119/EEC.

Article 3

Implementing Decision (EU) 2015/1500 is amended as follows:

(1) in Article 1, paragraph 3 is deleted;

(2) in Article 4, paragraph 1, is replaced by the following:

([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).

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‘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 to a slaughterhouse located in other parts of Greece provided that:

(a) the animals have been 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 checked 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,

(d) the slaughterhouse is designated for this purpose by the competent authority,

(e) the competent authority of the slaughterhouse has to be informed by the dispatching competent authority of the intention to send animals and notifies the dispatching competent authority of their arrival,

(f) on arrival at the slaughterhouse, these animals are kept and slaughtered separately from other animals within less than 36 hours,

(g) the animals intended to be moved

(i) were either not vaccinated against lumpy skin disease and have been kept on holdings:

— where vaccination was not carried out and which are situated outside protection and surveillance zones; or

— where vaccination was carried out and which are situated outside protection and surveillance zones, and a waiting period of at least 7 days after vaccination in the herd has elapsed; or

— which are situated in a surveillance zone maintained beyond 30 days because of the occurrence of further cases of the disease; or

(ii) were vaccinated against lumpy skin disease at least 28 days prior to movement and come from a holding on which all susceptible animals had been vaccinated at least 28 days prior to the intended movement.’

(3) Article 5 is replaced by the following:

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'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 points (a) and (c) of Article 3(2), the competent authority may authorise the placing on the market outside the restricted zone of fresh meat, excluding offal other than liver, and meat preparations thereof, as well as fresh hides and skins obtained from bovine animals and wild ruminants:

(a) kept on holdings in the restricted zone that were not under restrictions in accordance with Directive 92/119/EEC, or

(b) slaughtered or hunted before 21 August 2015, or

(c) referred to in paragraph 1 of Article 4.

The competent authority shall ensure that the fresh meat, excluding offal other than liver, and meat preparations thereof, as well as fresh hides and skins referred to in the first subparagraph 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 that such meat and meat preparations were produced, stored and handled without coming into contact with meat and meat preparations not authorised for dispatch to other Member States, and the consignments are accompanied by an official health certificate as set out in the Annex to Commission Regulation (EC) No 599/2004 (*) and of which Part II shall be completed with the following attestation:

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

(*) Commission Regulation (EC) No 599/2004 of 30 March 2004 concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin (OJ L 94, 31.3.2004, p. 44).'

(4) Article 6 is replaced by the following:

'Article 6

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 meat products produced in the restricted zone from fresh meat of bovine animals and wild ruminants:

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(a) kept on holdings in the restricted zone that were not under restrictions in accordance with Directive 92/119/EEC, or

(b) slaughtered or hunted before 21 August 2015, or

(c) referred to in paragraph 1 of Article 4, or

(d) 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), (b) or (c) 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 meat products referred to in the first subparagraph are not dispatched to other Member States or third countries.

3. The competent authority shall only authorise the dispatch of consignments of meat products produced from fresh meat obtained from the animals referred to in paragraph 1(a), (b) and (c) to other Member States, provided that the meat products have been subjected to a specific treatment in hermetically sealed containers to an F_o value of three or more, and are accompanied by an official health certificate as set out in the Annex to Regulation (EC) No 599/2004 and of which Part II shall be completed with the following attestation:

"Meat products complying with Commission Implementing Decision (EU) 2015/1500 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 produced from fresh meat obtained from the animals referred to in paragraph 1(d), 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 health certificate as set out in the Annex to Regulation (EC) No 599/2004 and of which Part II shall be completed with the following attestation:

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

(5) Article 7 is replaced by the following:

'Article 7

Derogation from the prohibition on the dispatch and placing on the market 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

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obtained from bovine animals kept on holdings situated in the restricted zone, 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 (*).

2. The competent authority shall only authorise the dispatch to other Member States of consignments of milk and dairy products obtained from bovine animals kept on holdings situated in the restricted zone, provided that the milk and dairy products are intended for human consumption, have undergone the treatment referred to in paragraph 1 and the consignments are accompanied by an official health certificate as set out in the Annex to Regulation (EC) No 599/2004 and of which Part II shall be completed with the following attestation:

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

(*) 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).'

(6) the title of Article 8 is replaced by the following:

'Article 8

Special marking of fresh meat, meat preparations and meat products referred to in Articles 5(1) and 6(2) respectively'

(7) the date in Article 12 is replaced by '31 December 2016'.

(8) the Annex is replaced by the text in Annex III.

Article 4

This Decision is addressed to the Hellenic Republic.

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ANNEX I

The following regional units in Greece:

— Regional unit of Evros

— Regional unit of Rodopi

— Regional unit of Xanthi

— Regional unit of Kavala

— Regional unit of Chalkidiki

— Regional unit of Thessaloniki

— Regional unit of Kilkis

— Regional unit of Limnos

— Regional unit of Drama

— Regional unit of Serres.

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ANNEX II

Conditions for the use of emergency vaccination in the control and eradication of lumpy skin disease in application of Article 19 of Directive 92/119/EEC

1.	Extent of the geographical area in which emergency vaccination is to be carried out	The vaccination zone shall be within the area defined in Annex I. The restrictions applicable in the vaccination zone shall be those provided for in this Decision and in Implementing Decision (EU) 2015/1500, without prejudice to the provisions of Article 10 of Directive 92/119/EEC.
2.	Species and age of the animals to be vaccinated	All bovine animals independently of their sex, age and gestational or productive status shall be vaccinated in the first round of vaccination referred to in point 3. Offspring of vaccinated bovine animals shall be vaccinated in accordance with the instructions of the manufacturer at the age of not less than 4 months.
3.	Duration of the vaccination campaign	The first round of vaccination in the regional unit of Evros shall be completed by 31 October 2015. The first round of vaccination in the regional units of Rodopi, Xanthi and Kavala shall be completed by 30 November 2015. The first round of vaccination in any of the other regional units listed in Annex I shall be completed as soon as possible and not later than 2 months after the confirmation of the first outbreak in that regional unit.
4.	Specific standstill of animals and products thereof	Irrespective of any other measures that may be in place in the restricted zone as defined in Implementing Decision (EU) 2015/1500, animals older than 90 days shall not be moved to another holding except if they were vaccinated and regularly re-vaccinated at least 28 days before movement. Upon expiry of the 28 days after vaccination, the measures for movement of vaccinated bovine animals and for placing on the market of products derived from vaccinated bovine animals as laid down in Implementing Decision (EU) 2015/1500 apply without prejudice to the provisions of Article 10 of Directive 92/119/EEC. Unvaccinated animals may be moved for direct slaughter to a slaughterhouse situated within the restricted area. Except in the case of emergency slaughter, a waiting period of 7 days after vaccination in the herd shall be observed before unvaccinated animals from holdings on which vaccination was carried out are sent for slaughter. Unvaccinated offspring younger than 6 months born to dams vaccinated at least 28 days prior to labour may be moved to another holding situated within the restricted zone.
5.	Special registration of the vaccinated animals	For each vaccinated bovine animal vaccination details shall be entered by the local competent authority in the dedicated online database connected with the central database established in accordance with Regulation (EC) No 1760/2000 of the European Parliament and of the Council ([1]). The records must ensure a link between the vaccinated dam and the offspring.

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6.	**Other matters appropriate to the emergency vaccination**	
6.1.	Surveillance area in Greece surrounding the vaccination zone	A surveillance area of at least 10 km around the vaccination zone referred to in point 1 shall be established, in which intensified surveillance shall be carried out and the movement of bovine animals shall be subject to controls by the competent authority. Bovine animals not vaccinated against lumpy skin disease and kept on holdings situated in the surveillance area surrounding the vaccination zone shall not leave their holdings until a waiting period of at least 7 days has elapsed following the completion of the vaccination on holdings situated in the vaccination zone at a distance of less than 10 km.
6.2.	Period for which the measures applied in the zones established in accordance with Article 10 of Directive 92/119/EEC and Implementing Decision (EU) 2015/1500 are maintained	The measures applied in the vaccination zone shall remain in force until they are abrogated in accordance with Article 19(6) of Directive 92/119/EEC.
6.3.	Execution of the vaccination campaign	Vaccination shall be carried out by an official of the competent authority or private veterinarian appointed by and under supervision of the competent authority. The priority for vaccination should be given to the animals kept on holdings situated within the protection and surveillance zones and in areas bordering other Member States and regional units in Greece which are free of LSD. Necessary measures shall be in place to avoid the spread of possible virus. Any residual quantities of vaccine shall be returned to the point of vaccine distribution with a written record on the number of animals vaccinated and the number of doses used.
6.4.	Vaccine to be used	Homologous live attenuated virus vaccine against LSD (Neethling strain), 'Lumpy Skin Disease Vaccine For Cattle', Onderstepoort Biological Products, South Africa. Alternatively: live attenuated virus vaccine against LSD (SIS type), 'Lumpyvax', MSD Animal Health, Intervet, South Africa. The vaccine shall be used in accordance with the instructions of the manufacturer and Article 8 of Directive 2001/82/EC under the responsibility of the central competent authorities.
6.5.	Progress Reports and Final Report	A progress report on the execution of the programme shall be provided to the Commission and the Member States in accordance with Article 19(5) of Directive 92/119/EEC. A detailed report on the completion of the programme shall be provided to the Commission and the Member States in accordance with Article 19(5) of Directive 92/119/EEC before the restrictions referred to in points 6.1 and 6.2 are removed.

([1]) Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 (OJ L 204, 11.8.2000, p. 1).

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ANNEX III

The Annex to Implementing Decision (EU) 2015/1500 is replaced by the following:

'ANNEX

Greece:

The following regional units in Greece:

— Regional unit of Evros;

— Regional unit of Kavala;

— Regional unit of Limnos;

— Regional unit of Rodopi;

— Regional unit of Xanthi.'