COMMISSION IMPLEMENTING DECISION (EU) 2016/1183

of 14 July 2016

approving the emergency vaccination programme against lumpy skin disease of bovine animals in Bulgaria and amending the Annex to Implementing Decision (EU) 2016/645

(notified under document C(2016) 4360)

(Only the Bulgarian 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 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 14(2) and 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 control measures to be applied in the event of an outbreak of certain animal diseases, including lumpy skin disease (LSD). Those control measures include the establishment of protection and surveillance zones around the infected holding, and they also provide for emergency vaccination in the case of an outbreak of LSD as a supplement to other control measures.

(2) On 12 April 2016, Bulgaria informed the Commission of the suspicion of LSD in two bovine holdings situated, respectively, in the Voden and Chernogorovo villages in the municipality of Dimitrovgrad in the region of Haskovo in the central-southern part of Bulgaria, about 80 km from the borders with neighbouring countries. Following the confirmation of those two initial outbreaks in the Haskovo region, on 13 April 2016, Bulgaria reported outbreaks of LSD in several regions. On 20 May 2016 Bulgaria notified the Commission of the presence of 98 confirmed outbreaks of LSD of which 19 were in Haskovo, eight were in Stara Zagora, five were in Plovdiv, 54 were in Blagoevgrad, six were in Kjustendil, one was in Pernik and five were in the Smolyan region.

(3) To prevent the spread of LSD to other parts of Bulgaria, to other Member States and to third countries, the Commission adopted Commission Implementing Decision (EU) 2016/645 ([5]). That Implementing Decision lays down certain protective measures in relation to the confirmation of LSD in Bulgaria and establishes, at Union level, a restricted zone which is described in the Annex thereto and which includes the area where LSD was confirmed and the protection and surveillance zones that were established by Bulgaria in accordance with Article 10 of Directive 92/119/EC.

([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.
([5]) Commission Implementing Decision (EU) 2016/645 of 22 April 2016 concerning certain protective measures against lumpy skin disease in Bulgaria (OJ L 108, 23.4.2016, p. 61).

(4) During the same period, from 6 April 2016 to 19 May 2016, new outbreaks of LSD were reported in Greece and in the former Yugoslav Republic of Macedonia.

(5) In accordance with the Scientific Opinion of the European Food Safety Authority on lumpy skin disease ([1]), only live attenuated vaccines against LSD are commercially available. That Opinion describes the Neethling attenuated LSD virus vaccine as highly effective in preventing morbidity. As homologous LSD vaccines are more effective than vaccines based on attenuated sheep pox viruses, their use is recommended, subject to availability by vaccine producers which are exclusively operating outside the Union.

(6) There is no vaccine against LSD with a marketing authorisation in the Union. Emergency vaccination in accordance with Article 19 of Directive 92/119/EEC may, therefore, only be carried out in accordance with Article 8 of Directive 2001/82/EC of the European Parliament and of the Council ([2]), 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.

(7) On 25 April 2016, Bulgaria submitted to the Commission a programme for the emergency vaccination against LSD of bovine animals kept on holdings in the affected areas and also in certain adjoining areas of that Member State ('the emergency vaccination programme'). The emergency vaccination programme contains information concerning the decision to implement the measures, the details concerning the geographical and administrative definition of the vaccination zone, the number of holdings and the animals to be vaccinated and the time when the vaccination should be completed. On 20 May 2016, Bulgaria informed the Commission of its intention to expand the emergency vaccination programme to the entire territory of Bulgaria. This requires enlarging the restricted zone as described in the Annex to Implementing Decision (EU) 2016/645. The Annex to Implementing Decision (EU) 2016/645 should therefore be amended accordingly.

(8) In accordance with Article 19(6) of Directive 92/119/EEC, Bulgaria notified the Commission on 28 April 2016 of the acquisition of a sufficient number of doses of homologous LSD vaccine from the vaccine bank established by the Commission in accordance with Commission Implementing Decision of 18 December 2015 ([3]) and the start of emergency vaccination in a 20 km radius around confirmed LSD outbreaks according to the emergency vaccination programme.

(9) It is necessary to lay down the conditions under which Bulgaria should apply emergency vaccination. The rapid spread of LSD in Bulgaria constitutes a risk to other parts of the territory of Bulgaria and to neighbouring countries. Therefore, it is also necessary to reinforce the control measures applied in Bulgaria by restricting the movement of unvaccinated bovine animals older than three months to other holdings within the restricted zone. That age limitation would allow 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 bovine animals directly to a slaughterhouse within the restricted zone.

(10) The area where vaccination against LSD is to be carried out may cover the entire restricted zone as defined in Implementing Decision (EU) 2016/645, which is set out in the Annex to that Decision.

(11) The first round of emergency vaccination should be completed as soon as possible and not later than 30 June 2016. In the case of further outbreaks in other areas, the emergency vaccination in the affected areas should be completed within two months after the confirmation of the first outbreak of LSD in those areas subject to the availability of vaccines.

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

([1]) Scientific Opinion on lumpy skin disease — EFSA Panel on Animal Health and Welfare (AHAW), *EFSA Journal* 2015;13(1):3986.
([2]) 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).
([3]) Commission Implementing Decision of 18 December 2015 on the adoption of a financing decision regarding the Union financial contribution to emergency measures to combat lumpy skin disease in Greece in 2015 and establishing a stock of vaccines against lumpy skin disease (C(2015) 9573 final).

HAS ADOPTED THIS DECISION:

Article 1

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

2. The programme submitted by Bulgaria to the Commission on 20 May 2016 for the emergency vaccination against lumpy skin disease of bovine animals kept on holdings in the regions set out in Annex I is approved.

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

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

Article 2

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

Article 3

The Annex to Implementing Decision (EU) 2016/645 is replaced by the text set out in Annex III to this Decision.

Article 4

This Decision is addressed to the Republic of Bulgaria.

Done at Brussels, 14 July 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

Bulgaria:

The following regions in Bulgaria:

— The entire territory of Bulgaria.

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 regions in Bulgaria described in Annex I to this Decision. The restrictions applicable in the vaccination zone shall be those provided for in this Decision and in Implementing Decision (EU) 2016/645 in addition to those laid down in Article 10 of Directive 92/119/EEC.
2.	Species and age of the animals to be vaccinated	All bovine animals as defined in Article 2(a) of Implementing Decision (EU) 2016/645 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 when they are four months of age or older.
3.	Duration of the vaccination campaign	The first round of vaccination in the affected areas shall be completed by 30 June 2016. The first round of vaccination in the remaining areas of the region listed in Annex I shall be completed as soon as possible and not later than two months after the confirmation of the first outbreak in that area.
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) 2016/645, bovine 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 the date of the movement. Upon expiry of the period of 28 days after the date of the vaccination, the measures for the movement of vaccinated bovine animals and for the placing on the market of products derived from vaccinated bovine animals as laid down in Implementing Decision (EU) 2016/645 shall apply in addition to those laid down in Article 10 of Directive 92/119/EEC. Unvaccinated bovine animals may be moved for direct slaughter to a slaughterhouse situated within the restricted zone. Except in the case of emergency slaughter, a waiting period of seven days after vaccination in the herd shall be observed before unvaccinated bovine animals from holdings on which vaccination was carried out are sent for slaughter. Unvaccinated offspring younger than six months born to and fed the colostrum of 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.

6.	Other matters appropriate to the emergency vaccination	
6.1.	Surveillance area in Bulgaria 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 LSD 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 seven 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) 2016/645 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 a private veterinarian appointed by and under the supervision of the competent authority. The priority for vaccination shall be given to the bovine animals kept on holdings situated within the protection and surveillance zones and in areas bordering other Member States and regions in Bulgaria which are free of LSD. The 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 bovine 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 emergency vaccination 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 emergency vaccination 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 of this Annex 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).

ANNEX III

The Annex to Implementing Decision (EU) 2016/645 is replaced by the following:

'ANNEX

Bulgaria:

The following regions in Bulgaria:

— The entire territory of Bulgaria'.