COMMISSION IMPLEMENTING DECISION (EU) 2016/2008

of 15 November 2016

concerning animal health control measures relating to lumpy skin disease in certain Member States

(notified under document C(2016) 7023)

(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), Articles 19(1)(a) and 19(3)(a), and Article 19(4) 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) Lumpy skin disease (LSD) is a vector transmitted viral disease of bovine animals. According to the Scientific Opinion of the European Food Safety Authority (the EFSA) on lumpy skin disease, adopted on 3 December 2014, (the EFSA Opinion) ([5]) direct and indirect transmission of LSD may occur. LSD is characterised by severe losses of livestock production and has the potential to spread very quickly, notably through live animals, vectors and certain products obtained from infected animals.

(2) Directive 92/119/EEC lays down general control measures to be applied in the event of an outbreak of certain animal diseases, including LSD. These include control measures to be taken in the event of a suspicion and the confirmation of the presence of LSD in a holding, including the establishment of protection and surveillance zones around outbreaks and other additional control measures to prevent the spread of the disease and eliminate the infection. Those control measures also provide for vaccination in the event of an outbreak of LSD as a supplement to other control measures.

(3) Commission Implementing Decisions (EU) 2015/1500 ([6]) and (EU) 2016/645 ([7]) lay down certain protective measures in relation to the confirmation of LSD in Greece in 2015 and in Bulgaria in 2016. Those protective measures include the establishment of an infected zone in those Member States, which is described in the Annex to each of those Implementing Decisions, and which includes the area where LSD was confirmed and the protection and surveillance zones duly established by Greece and Bulgaria in accordance with Directive 92/119/EEC. Implementing Decisions (EU) 2015/1500 and (EU) 2016/645 have been amended several times due to the evolution of the disease situation, including the extension of the infected zone in order to include additional regional units of Greece and Bulgaria. Those Implementing Decisions apply until 31 December 2016.

([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]) *EFSA Journal* 2015; 13(1): 3986.
([6]) 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).
([7]) 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) Commission Implementing Decisions (EU) 2015/2055 [1] and (EU) 2016/1183 [2] provide that Greece and Bulgaria may carry out emergency vaccination of bovine animals kept on holdings in the vaccination zone as set out in Annex I to those Implementing Decisions.

(5) Apart from Greece and Bulgaria, between April and August 2016, a considerable number of third countries in South East Europe have also reported outbreaks of LSD in their territories for the first time, namely Albania, the former Yugoslav Republic of Macedonia, Kosovo [3], Montenegro and Serbia. All those third countries have notified the Commission that vaccination against LSD has been included in their current disease control policy, amongst other measures.

(6) According to the EFSA Opinion [4] only live attenuated vaccines against LSD are commercially available. The EFSA 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 to be recommended, subject to availability by vaccine producers which are exclusively operating outside the Union. Also, according to the EFSA Opinion, the causative agent of LSD may be present up to 92 days in the skin of affected animals even without visible lesions.

(7) 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 [5], which permits Member States to provisionally allow the use of immunological veterinary medicinal products without a marketing authorisation in the event of a serious epizootic disease as it is the case with LSD.

(8) According to the Urgent Advice on Lumpy Skin Disease of the EFSA, adopted on 29 July 2016 [6], vaccination against LSD is the most effective way to reduce the spread of that disease. In order to eradicate LSD, it is necessary to implement the vaccination of the entire susceptible population in regions at risk for the introduction of LSD and those affected by LSD in order to minimise the number of outbreaks, and high animal- and farm-level vaccination coverage should be achieved. Therefore, a 'solid' preventive and control policy for LSD should provide for vaccination.

(9) The risk of the spread of LSD from vaccinated animals and products thereof is different from the risks arising from non-vaccinated and possibly incubating animals. Therefore, it is necessary to lay down conditions for the dispatch of vaccinated bovine animals and of products derived from such animals. Also, the risk of the spread of LSD from animals, whether or not vaccinated, originating in an area where vaccination against LSD is applied but where no LSD outbreaks have occurred, is different from the risk posed by such animals when they originate from LSD affected areas. Therefore, specific conditions should also be laid down for these animals.

(10) Scientific 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, in order to minimise the risk, it should only be permitted to dispatch consignments of vaccinated animals after a period of at least 28 days, which is the maximum incubation period for LSD, following vaccination.

(11) In terms of the risk of the spread of LSD, different commodities pose different levels of risk. As indicated in the EFSA Opinion, the movement of live bovine animals, bovine semen and raw hides and skins from infected bovine animals pose a 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. However scientific or experimental evidence is lacking on their role of transmission of LSD. Therefore, the control measures provided for in this Decision should be balanced and proportionate to the risks. Similarly, the transmission of LSD through semen, ova and embryos of animals of the bovine species cannot be excluded.

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(1) 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 (OJ L 300, 17.11.2015, p. 31).

(2) 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 (OJ L 195, 20.7.2016, p. 75).

(3) This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence.

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

(5) 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).

(6) *EFSA Journal* 2016;14(8):4573 [27 pp.].

Therefore, certain protective measures should be provided for those commodities based on the EFSA Opinion and the relevant most updated standards and recommendations from the World Organisation for Animal Health (OIE).

(12) Skeletal muscle meat from bovine animals is considered to be a safe commodity according to the OIE Scientific Commission for Animal Diseases ([1]) and as indicated in Annex 36 of Part B of the Report of the OIE Terrestrial Animal Health Standards Commission meeting of February 2016 ([2]). There is no scientific or experimental evidence suggesting that the LSD virus can be transmitted to susceptible animals through fresh meat, meat preparations or meat products. Although the EFSA Opinion indicates that the LSD virus may survive in meat for a non-indicated period of time, the existing Union ban on feeding ruminant proteins to ruminants laid down in Regulation (EC) No 1069/2009 of the European Parliament and of the Council ([3]) and Article 7 of Regulation (EC) No 999/2001 of the European Parliament and of the Council ([4]) rules out the possibility of a possible oral transmission of LSD.

(13) Milk and dairy products, as well as colostrum, may represent a risk for the spread of LSD only when destined for feeding to animals of the susceptible species. Therefore, risk mitigation measures intended to prevent the spread of LSD through such products when intended for animal feeding should be laid down.

(14) Council Directive 64/432/EEC ([5]) and Commission Decision 93/444/EEC ([6]) provide that health certificates are to accompany the movements of animals. Where derogations from the prohibition on the dispatch of live animals from the areas listed in Annex I to this Decision are applied to live animals intended for intra-Union trade or for export to a third country, those health certificates should include a reference to this Decision so to ensure that adequate and accurate health information is provided in the relevant certificates.

(15) For reasons of clarity and simplification Implementing Decisions (EU) 2015/1500, (EU) 2015/2055, (EU) 2016/645 and (EU) 2016/1183 should be repealed and replaced by this Decision which introduces amended and uniform measures for all Member States affected by LSD or implementing vaccination against LSD.

(16) The approval of the vaccination programmes submitted by the Member States concerned and now included in Implementing Decisions (EU) 2015/2055 and (EU) 2016/1183 for Greece and Bulgaria respectively, as well as the approval of the vaccination programme submitted by Croatia should be subject to another Implementing Decision to be adopted.

(17) Bulgaria has advised the Commission that the vaccination of all bovine animals against LSD was completed on 15 July 2016 and the last occurrence of LSD on its territory was confirmed on 1 August 2016. Accordingly, certain areas of Bulgaria where LSD has never occurred but where vaccination against that disease has been carried out, should be listed in Part I of the Annex I to this Decision as a 'free zone with vaccination', while the remaining part of the territory of that Member State should be listed as an 'infected zone'.

(18) 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

Subject matter and scope

This Decision lays down animal health control measures in relation to lumpy skin disease in the Member States or parts thereof as listed in Annex I (the Member States concerned) including the minimum requirements for vaccination programmes against lumpy skin disease submitted by the Member States to the Commission for approval.

([1]) http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2016.pdf (Annex 15, Article 11.11.1-bis. Safe commodities).
([2]) http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/A_TAHSC_Feb_2016_Part_B.pdf
([3]) 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).
([4]) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).
([5]) 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).
([6]) Commission Decision 93/444/EEC of 2 July 1993 on detailed rules governing intra-Community trade in certain live animals and products intended for exportation to third countries (OJ L 208, 19.8.1993, p. 34).

Article 2

Definitions

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

(1) 'bovine animal' means ungulates of the species *Bos taurus, Bos indicus, Bison bison* and *Bubalus bubalis*;

(2) 'captive wild ruminants' means wild ruminants of species known to be involved in the transmission and spread of lumpy skin disease according to the latest available scientific knowledge;

(3) 'infected zone' is the part of the territory of a Member State listed in Part II of Annex I 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, and where vaccination against lumpy skin disease may be implemented following the approval of vaccination programmes by the Commission;

(4) 'free zone with vaccination' is the part of the territory of a Member State listed in Part I of Annex I to this Decision which includes the areas outside the infected zone for lumpy skin disease, where vaccination against lumpy skin disease is implemented following the approval of vaccination programmes by the Commission.

Article 3

Restrictions on the dispatch on bovine animals and captive wild ruminants and certain animal products from the areas listed in Annex I

The Member States concerned shall prohibit the dispatch of consignments of:

(a) live bovine animals and captive wild ruminants from the areas listed in Parts I and II of Annex I;

(b) semen, ova and embryos of bovine animals and captive wild ruminants from the areas listed in Parts I and II of Annex I;

(c) colostrum, milk and dairy products of bovine animals and captive wild ruminants destined for animal feed from the areas listed in Part II of Annex I;

(d) unprocessed animal by-products from bovine animals and captive wild ruminants, other than those referred to in point (e), from the areas listed in Parts I and II of Annex I;

(e) untreated raw hides and skins destined for human consumption or untreated hides and skins not intended for human consumption of bovine animals and captive wild ruminants from the areas listed in Parts I and II of Annex I.

Article 4

Derogation from the prohibition on the dispatch of live bovine animals and captive wild ruminants from the areas listed in Part I of Annex I

1. By way of derogation from the prohibition provided for in point (a) of Article 3, the competent authority may authorise the dispatch of live bovine animals and captive wild ruminants from holdings situated in the areas listed in Part I of Annex I provided that those animals comply with at least one of the following sets of conditions:

(a) the animals are dispatched to areas listed in Part I or II of Annex I of the same or another Member State or to a third country and comply with the following conditions:

   (i) the animals were vaccinated against lumpy skin disease at least 28 days prior to date of dispatch and come from a holding on which the animals have been resident for a period of at least 28 days and in which all animals of susceptible species have been vaccinated against lumpy skin disease at least 28 days prior to the date of dispatch;

   (ii) all the animals on the holding of origin were clinically checked on the day of loading for dispatch and did not show any clinical symptoms of lumpy skin disease;

(iii) the animals are not subject to any of the restrictions provided for in Directive 92/119/EEC;

(iv) the competent authority at the place of origin is implementing a vaccination programme against lumpy skin disease which complies with the conditions laid down in Annex II and which has been approved by the Commission and it has informed the Commission and the other Member States of the commencement date of its vaccination programme; and

(v) a channelling procedure in accordance with Article 12 has been set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the animals are transported in a safe manner and that they are not subsequently dispatched to another Member State or third country; or

(b) the animals are dispatched to any area of the same or another Member State or a third country and comply with the following conditions:

(i) the animals were vaccinated against lumpy skin disease at least three months prior to the date of dispatch and come from a holding on which all animals of susceptible species were vaccinated against lumpy skin disease at least 28 days prior to the date of dispatch;

(ii) all the animals on the holding of origin were clinically checked on the day of loading for dispatch and did not show any clinical symptoms of lumpy skin disease;

(iii) the animals are not subject to any of the restrictions provided for in Directive 92/119/EEC;

(iv) the animals have been resident since birth, or for a period of at least 28 days prior to the date of dispatch, on a holding where, in a radius of at least 20 km, no presence of lumpy skin disease has been confirmed during the three months prior to the date of dispatch and before that any confirmation of infection with lumpy skin disease was subject to culling and destruction of all susceptible animals on the affected holdings, located in an area listed in Part I of Annex I in a Member State where all animals in all its areas listed in Part I of Annex I have been vaccinated or revaccinated against lumpy skin disease, in accordance with Annex II, at least three months prior to the date of dispatch and remain within the immunity period of time stated in the specifications of the vaccine by the manufacturer;

(v) the competent authority at the place of origin has implemented a vaccination programme against lumpy skin disease, which complied with the conditions laid down in Annex II and which was approved by the Commission and it has informed the Commission and the other Member States of commencement date and the completion date of its vaccination programme; and

(vi) a channelling procedure in accordance with Article 12 has been set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the animals are transported in a safe manner and that they are not subsequently dispatched to another Member State or third country; or

(c) the animals are dispatched to any area of a Member State or a third country and comply with the following conditions:

(i) the animals comply with any other appropriate animal health guarantees, based on a positive outcome of a risk assessment of measures against the spread of lumpy skin disease, required by the competent authority of the Member State of the place of origin and approved by the competent authorities of the countries of places of transit and of destination, prior to the date of dispatch of such animals;

(ii) the animals were vaccinated against lumpy skin disease at least 28 days prior to date of dispatch and come from a holding on which all animals of susceptible species were vaccinated against lumpy skin disease at least 28 days prior to the date of dispatch;

(iii) all the animals on the holding of origin were clinically checked on the day of loading for dispatch and did not show any clinical symptoms of lumpy skin disease;

(iv) the animals are not subject to any of the restrictions provided for in Directive 92/119/EEC;

(v) the animals have been resident since birth, or for a period of at least 28 days prior to date of dispatch, on a holding where, in a radius of at least 20 km no presence of lumpy skin disease has been confirmed during the three months prior to the date of dispatch and before that any confirmation of infection with lumpy skin disease was subject to culling and destruction of all susceptible animals on the affected holdings;

(vi) a channelling procedure in accordance with Article 12 has been set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the animals, dispatched in accordance with the animal health guarantees provided for in point (i) are transported in a safe manner and are not subsequently dispatched to another Member State or third country;

(vii) the competent authority at the place of origin is implementing a vaccination programme against lumpy skin disease, which complies with the conditions laid down in Annex II and which has been approved by the Commission and it has informed the Commission and the other Member States of the commencement date of its vaccination programme; and

(viii) the Member State of the place of origin must immediately inform the Commission and the other Member States of the animal health guarantees and the approval by the competent authorities provided for in point (i).

2. Where bovine animals and captive wild ruminants comply with the requirements for the derogation provided for in paragraph 1 of this Article, the following additional wording shall be added to the corresponding health certificate for those animals as laid down in Directive 64/432/EEC, or in Decision 93/444/EEC:

'..... (*Animals*) in compliance with ..... (*Article 4(1)(a) or (b) or (c)*, indicate as appropriate) of Commission Implementing Decision (EU) 2016/2008 concerning animal health control measures relating to lumpy skin disease in certain Member States'.

Article 5

Derogation from the prohibition on the dispatch of live bovine animals and captive wild ruminants from the areas listed in Part II of Annex I

1. By way of derogation from the prohibition provided for in point (a) of Article 3, the competent authority may authorise the dispatch of live bovine animals and captive wild ruminants from holdings situated in the areas listed in Part II of Annex I to any area of a Member State or a third country provided that those animals comply with the following conditions:

(a) the animals comply with appropriate animal health guarantees, based on a positive outcome of a risk assessment of measures against the spread of lumpy skin disease, required by the competent authority of the Member State of the place of origin and approved by the competent authorities of the countries of the places of transit and of destination, prior to the date of dispatch of such animals;

(b) the animals were vaccinated against lumpy skin disease at least 28 days prior to date of dispatch and come from a holding on which all animals of susceptible species were vaccinated against lumpy skin disease at least 28 days prior to the date of dispatch;

(c) all the animals on the holding of origin were clinically checked on the day of loading for dispatch and did not show any clinical symptoms of lumpy skin disease;

(d) the animals are not subject to any of the restrictions provided for in Directive 92/119/EEC;

(e) the animals have been resident since birth, or for a period of at least 28 days prior to the date of dispatch, on a holding where, in a radius of at least 20 km no presence of lumpy skin disease has been confirmed during the three months prior to the date of dispatch and before that any confirmation of infection with lumpy skin disease was subject to culling and destruction of all susceptible animals on the affected holdings, located in an area listed in Part II of Annex I in a Member State where all animals in all its areas listed in Part II of Annex I have been vaccinated or revaccinated against lumpy skin disease, in accordance with Annex II, at least three months prior to the date of dispatch and remain within the immunity period stated in the specifications of the vaccine by the manufacturer;

(f) the competent authority at the place of origin is implementing a vaccination programme against lumpy skin disease, which complies with the conditions laid down in Annex II and which has been approved by the Commission and it has informed the Commission and the other Member States of the commencement date and the completion date of its vaccination programme in accordance with Annex II;

(g) a channelling procedure in accordance with Article 12 has been set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the animals, dispatched in accordance with the animal health guarantees provided for in point (a) are transported in a safe manner and are not subsequently dispatched to another Member State or third country; and

(h) the Member State of the place of origin must immediately inform the Commission and the other Member States of the animal health guarantees and the approval by the competent authorities provided for in point (a).

2. Where bovine animals and captive wild ruminants comply with the requirements for the derogation provided for in paragraph 1 of this Article, the following additional wording shall be added to the corresponding health certificate for those animals as laid down in Directive 64/432/EEC, or in Decision 93/444/EEC:

'..... (*Animals*) in compliance with *Article 5(1)* of Commission Implementing Decision (EU) 2016/2008 concerning animal health control measures relating to lumpy skin disease in certain Member States'.

Article 6

Special conditions for the dispatch of live bovine animals and captive wild ruminants within the areas listed in Parts I and II of Annex I of the same Member State

1. By way of derogation from the prohibition provided for in point (a) of Article 3, and subject to compliance with paragraph 2 of this Article, the competent authority may authorise the dispatch of consignments of live bovine animals and captive wild ruminants from holdings situated in an area listed in:

(a) Part I of Annex I to a destination situated within another area listed in Part I or Part II of Annex I of the same Member State;

(b) Part II of Annex I to a destination situated within another area listed in Part II of Annex I of the same Member State.

2. The derogation provided for in paragraph 1 shall only apply to consignments of live bovine animals and captive wild ruminants provided that the animals comply with at least one of the following conditions:

(a) the animals were vaccinated against lumpy skin disease at least 28 days prior to date of dispatch and come from a holding on which all animals of susceptible species were vaccinated against lumpy skin disease at least 28 days prior to the date of dispatch;

(b) the animals, irrespective of their individual vaccination status or vaccination in their holding of origin against lumpy skin disease may be moved for emergency slaughter to a slaughterhouse, provided that the holding of origin is not subject to any of the restrictions provided for in Directive 92/119/EEC in relation to lumpy skin disease, that prohibit such a movement;

(c) the animals are unvaccinated offspring less than four months old born to dams vaccinated at least 28 days prior to parturition and may be moved to another holding provided that all animals of susceptible species on the holding of origin have been vaccinated or revaccinated according to the manufacturer's instructions of the vaccine used at least 28 days prior to the date of the intended movement and the holding is not subject to any of the restrictions provided for in Directive 92/119/EEC in relation to lumpy skin disease, that prohibit such a movement.

Article 7

Derogations from the prohibition on the dispatch of semen, ova and embryos of bovine animals and captive wild ruminants from the areas listed in Part I of Annex I

1. By way of derogation from the prohibition provided for in point (b) of Article 3, the competent authority may authorise the dispatch of semen, ova and embryos of bovine animals and captive wild ruminants from semen collection centres or other establishments situated in an area listed in Part I of Annex I to another area listed in Part I or II of Annex I of the same or another Member State provided that the donor animals and the semen, ova and embryos comply with the following conditions:

(a) the donor animals were vaccinated and revaccinated against lumpy skin disease according to the manufacturer's instructions of the vaccine used, the first vaccination being administrated at least 60 days prior to the date of collection of the semen, ova or embryo; or the donor animals were subjected to a serological test to detect specific antibodies against lumpy skin disease virus on the day of the collection and at least 28 days after the semen collection period or the day of collection for embryos and ova, with negative results;

(b) the donor animals were kept, during the 60 days prior to the date of collection of the semen, ova or embryos, in an artificial insemination centre or other appropriate establishment where, in a radius of at least 20 km, no presence of lumpy skin disease has been confirmed during the three months prior to the date of collection of the semen, ova or embryos and before that any confirmation of infection with lumpy skin disease was subject to culling and destruction of all susceptible animals on the affected holdings;

(c) the donor animals were clinically checked 28 days prior to the date of collection, as well as throughout the entire collection period, and did not show any clinical symptoms of lumpy skin disease;

(d) the donor animals were subjected to lumpy skin disease agent detection by polymerase chain reaction (PCR) conducted on blood samples collected at commencement and at least every 14 days thereafter during the semen collection period or on the day of collection for embryos and ova, with negative results;

(e) the semen was subjected to lumpy skin disease agent detection by PCR with negative results; and

(f) the competent authority at the place of origin is implementing a vaccination programme against lumpy skin disease, which complies with the conditions laid down in Annex II and which has been approved by the Commission and it has informed the Commission and the other Member States of the commencement date and the completion date of its vaccination programme in accordance with Annex II.

2. By way of derogation from the prohibition provided for in point (b) of Article 3, the competent authority may authorise the dispatch of semen, ova and embryos of bovine animals and captive wild ruminants from semen collection centres or other establishments situated in the areas listed in Part I of Annex I to any area of a Member State or a third country provided that the donor animals and the semen, ova and embryos comply with the following conditions:

(a) the conditions laid down in paragraph 1(a) to (f);

(b) the donor animals comply with any other appropriate animal health guarantees, based on a positive outcome of a risk assessment of the impact of such dispatch and of the measures against the spread of lumpy skin disease, required by the competent authority of the Member State of the place of origin and approved by the competent authorities of the countries of the places of transit and of destination, prior to the dispatch of such semen, ova or embryos; and

(c) the Member State of the place of origin must immediately inform the Commission and the other Member States of the animal health guarantees and the approval by the competent authorities provided for in point (b).

3. Where semen, embryos and ova which comply with the requirements of paragraph (1) or (2) of this Article are dispatched to another Member State or third country, the following additional wording shall be added to the corresponding health certificates laid down in Directives 88/407/EEC, 89/556/EEC or in Decision 93/444/EEC:

'..... (*Semen, ova and/or embryos, indicate as appropriate*) in compliance with ..... (*Article 7(1) or (2), indicate as appropriate*) of Commission Implementing Decision (EU) 2016/2008 concerning animal health control measures relating to lumpy skin disease in certain Member States'.

Article 8

Derogation from the prohibition on the dispatch of unprocessed animal by-products from bovine animals and captive wild ruminants from the areas listed in Parts I and II of Annex I

By way of derogation from the prohibition provided for in point (d) of Article 3, the competent authority may authorise the dispatch of unprocessed animal by-products from bovine animals and captive wild ruminants from:

(a) an area listed in Part I of Annex I to a destination located within the same Member State or in an area listed in Part I or Part II of Annex I of another Member State;

(b) an area listed in Part II of Annex I to a destination located within the same Member State or in an area listed in Part II of Annex I of another Member State provided that:

(i) the unprocessed animal by-products are dispatched under the official supervision of the competent authorities for processing or disposal in an plant approved in accordance Regulation (EC) No 1069/2009; and

(ii) when the destination is located in another Member State a channelling procedure in accordance with Article 12 is set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the unprocessed animal by-products are transported in a safe manner to the place of destination and are not subsequently dispatched to another Member State or third country.

Article 9

Derogations from the prohibition on the dispatch of hides and skins of bovine animals and captive wild ruminants from the areas listed in Parts I and II of Annex I

1. By way of derogation from the prohibition provided for in point (e) of Article 3, the competent authority may authorise the dispatch of hides and skins of bovine animals and captive wild ruminants from an area listed in Part I of Annex I to another area listed in Part I or II of Annex I of the same or another Member State provided that:

(a) these are untreated raw hides and skins destined for human consumption or untreated hides and skins dispatched under the official supervision of the competent authorities for processing or disposal in an approved plant;

(b) when the destination is located in another Member State a channelling procedure in accordance with Article 12 is set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the hides and skins are transported in a safe manner to the place of destination and are not subsequently dispatched to another Member State or third country before being processed at least in accordance with Article 9(2)(b); and

(c) the hides and skins originate from holdings which are not subject to any of the restrictions provided for in Directive 92/119/EEC in relation to lumpy skin disease.

2. By way of derogation from the prohibition provided for in point (e) of Article 3, the competent authority may authorise the dispatch of hides and skins of bovine animals and captive wild ruminants from an area listed in Part I or II of Annex I to any area of the same or another Member State or third country provided that:

(a) these are untreated raw hides and skins destined for human consumption or untreated hides and skins originating from holdings which are not subject to any of the restrictions provided for in Directive 92/119/EEC in relation to lumpy skin disease;

(b) the hides and skins have been:

(i) treated in accordance with point 28(b) to (e) of Annex I to Commission Regulation (EU) No 142/2011 ([1]); or

(ii) subjected to one of the treatments set out in point (4)(b)(ii) of Chapter I of Section XIV of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council ([2]); and

(c) the hides and skins have undergone all precautions to avoid recontamination with pathogenic agents after treatment.

3. By way of derogation from the prohibition provided for in point (e) of Article 3, the competent authority may authorise the dispatch of hides and skins of bovine animals and captive wild ruminants from an area listed in Part II of Annex I to another area listed in Part II of Annex I of the same or another Member State provided that:

(a) these are untreated raw hides and skins destined for human consumption or untreated hides and skins dispatched under the official supervision of the competent authorities for processing or disposal in an approved plant;

(b) when the destination is located in another Member State a channelling procedure in accordance with Article 12 is set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the hides and skins are transported in a safe manner to the place of destination and are not subsequently dispatched to another Member State, before being processed at least in accordance with Article 9(2)(b); and

([1]) 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).

([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).

(c) the hides and skins originate from holdings which are not subject to any of the restrictions provided for in Directive 92/119/EEC in relation to lumpy skin disease.

4. By way of derogation from the prohibition provided for in point (e) of Article 3, the competent authority may authorise the dispatch of hides and skins of bovine animals and captive wild ruminants from an area listed in Part I or II of Annex I to any area of the same or another Member State or third country provided that:

(a) the hides and skins comply with any other appropriate animal health guarantees based on a positive outcome of a risk assessment of measures against the spread of lumpy skin disease, required by the competent authority of the Member State of the place of origin and approved by the competent authorities of the countries of the places of transit and destination, prior to the dispatch of such hides and skins;

(b) the hides and skins originate from holdings which are not subject to any restrictions provided for by Directive 92/119/EEC in relation to lumpy skin disease;

(c) a channelling procedure in accordance with Article 12 is set up, under the control of the competent authorities of the Member States of the places of origin, transit and destination, in order to ensure that the hides and skins, dispatched in accordance with the additional animal health guarantee requirements provided for in point (a) of this paragraph, are transported in a safe manner to the place of destination and are not subsequently dispatched to another Member State before being processed at least in accordance with Article 9(2)(b); and

(d) the Member State of the place of origin must immediately inform the Commission and the other Member States of the animal health guarantees and the approval by the competent authorities provided for in point (a).

Article 10

Derogation from the prohibition on the dispatch of colostrum, milk and dairy products destined for animal feed from the areas listed in Part II of Annex I

1. By way of derogation from the prohibition provided for in point (c) of Article 3, the competent authority may authorise the dispatch of colostrum, milk and dairy products destined for animal feed obtained from bovine animals and captive wild ruminants kept on holdings situated in the areas listed in Part II of Annex I provided that the colostrum, milk and dairy products have been subjected to a treatment to ensure the destruction of the foot-and-mouth virus as described in points 1.1 to 1.5 of Part A of Annex IX to Council Directive 2003/85/EC [1] and the consignment complies with paragraph 2 of this Article.

2. The competent authority shall only authorise the dispatch to other Member States of consignments of colostrum, milk and dairy products in accordance with the derogation provided for in paragraph 1 of this Article where the consignments are accompanied by an official health certificate, as set out in the Annex to Commission Regulation (EC) No 599/2004 [2], and Part II of that health certificate shall be completed with the following attestation:

'Colostrum, milk or dairy products complying with Article 10 of Commission Implementing Decision (EU) 2016/2008 concerning animal health control measures relating to lumpy skin disease in certain Member States'.

Article 11

Requirements concerning transport vehicles, cleansing and disinfection

1. The competent authority shall ensure that before any transport vehicle which has been in contact with animals of susceptible species in an area listed in Part II of Annex I leaves that area, the operator or driver of that vehicle provides evidence showing that, since the last contact with those animals, the vehicle has been cleansed and disinfected in a manner to inactivate the lumpy skin disease virus and treated with authorised insecticides that are effective against vectors of lumpy skin disease.

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[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).

[2] 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).

2. The competent authority shall specify the information to be submitted by the operator or driver of the transport vehicle, as provided for in paragraph 1, in order to demonstrate that the required cleansing, disinfection and disinsectisation have taken place.

Article 12

Channelling procedure

The competent authority shall ensure that the channelling procedure for the transport of live bovine animals and captive wild ruminants, unprocessed animal by-products and untreated hides and skins as covered by the derogations provided for in Articles 4, 5, 6, 8 and 9 comply with the following requirements:

(a) each vehicle that is used for the transport of those live animals, unprocessed animal by-products or untreated hides and skins has been:

  (i) individually registered by the competent authority of the Member State of the place of dispatch either for the purpose of the transport of live animals, or for unprocessed animal by-products or for untreated hides and skins using the channelling procedure;

  (ii) sealed by the official veterinarian after loading for dispatch; only an official from the competent authority of the place of destination may break the seal and replace it with a new one; each loading or replacement of seals must be notified to the competent authority at the place of destination;

(b) the transport takes place:

  (i) under official supervision;

  (ii) directly, without stopping unless a rest period required by Council Regulation (EC) No 1/2005 ([1]) takes place in a control post. When a rest period of one day or more is foreseen at a control post during the movement through an area listed in Part II of Annex I, the animals are protected against attacks by vectors;

  (iii) taking the route that has been authorised by the competent authority at the place of origin;

(c) the consignment includes only live animals or unprocessed animal by-products or untreated hides and skins of the same health status;

(d) the official veterinarian responsible for the holding of the place of destination must confirm each arrival to the competent authority of the place of origin;

(e) after the unloading of the live animals, or the unprocessed animal by-products or untreated hides and skins the vehicle and any other equipment which have been used in the transport, are cleaned, disinfected and treated with authorised insecticides that are effective against known vectors of lumpy skin disease in their entirety within a closed area of the place of destination under the supervision of the official veterinarian;

(f) before the first dispatch from areas listed in Part I or II of Annex I for which a channelling procedure takes place, the competent authority of the place of origin shall ensure that the necessary arrangements are in place with the relevant competent authorities in order to ensure the emergency plan, the chain of command and full cooperation of services in case of accidents during the transport, a major breakdown of the vehicle or any fraudulent action of the operator or driver and the driver or the operator of the truck or other vehicle shall immediately notify the competent authority of any accident or major breakdown of the vehicle; and

(g) in the case of untreated hides and skins or unprocessed animal by-products, the vehicles must be completely leak proof from all sides including their door closure.

Article 13

Vaccination programmes against lumpy skin disease

Vaccination programmes against lumpy skin disease submitted by the Member States to the Commission for approval shall comply with the minimum requirements set out in Annex II.

([1]) Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).

Article 14

Repeal

Implementing Decisions (EU) 2015/1500, (EU) 2015/2055, (EU) 2016/645 and (EU) 2016/1183 are repealed and their measures replaced by the measures provided for in this Decision.

Article 15

Applicability

This Decision shall apply until 31 December 2019.

Article 16

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 15 November 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

PART I

'Free zones with vaccination'

1. *Croatia*

   The entire territory of Croatia.

2. *Bulgaria*

   A. The following provinces in Bulgaria:

   — Province of Burgas
   — Province of Varna
   — Province of Dobrich
   — Province of Razgrad
   — Province of Silistra
   — Province of Ruse
   — Province of Pleven

   B. The following municipalities in Bulgaria:

   — The municipalities of Opaka, Popovo and Antonovo in the province of Targovishte.
   — The municipalities of Shumen, Kaspichan, Novi Pazar, Nikola Kozlevo, Kaolinovo, Venets and Hitrino in the province of Shumen.
   — The municipalities of Svishtov, Polski Trambesh and Strazhitsa, in the province of Veliko Tarnovo.

PART II

'Infected zones'

1. *Greece*

   A. The following regions in Greece:

   — Region of Attica
   — Region of Central Greece
   — Region of Central Macedonia
   — Region of Eastern Macedonia and Thrace
   — Region of Epirus
   — Region of Peloponnese
   — Region of Thessaly
   — Region of Western Greece
   — Region of Western Macedonia

   B. The following regional units in Greece:

   — Regional unit of Limnos

2. *Bulgaria*

   The entire territory of Bulgaria excluding the areas listed in Part I.

ANNEX II

MINIMUM REQUIREMENTS FOR LUMPY SKIN DISEASE VACCINATION PROGRAMMES (REFERRED TO IN ARTICLE 13)

1. GENERAL REQUIREMENTS

The vaccination programmes submitted by the Member States shall provide at least for:

(a) vaccination of all bovine animals and where applicable captive wild ruminants, independently of their sex, age and gestational or productive status within the area where vaccination will be implemented;

(b) vaccination of the offspring of vaccinated bovine animals and where applicable captive wild ruminants, in accordance with the instructions of the manufacturer of the vaccine used at the age of not less than 4 months;

(c) revaccination of all bovine animals and where applicable captive wild ruminants, in accordance with the instructions of the manufacturer;

(d) measures that will be in place to avoid the spread of possible vaccine 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 and subsequently safely destroyed under official supervision;

(e) vaccination to be carried out under the supervision and control of the competent authority, by an official of the competent authority or a veterinarian authorised by and under supervision of the competent authority;

(f) entry of the details for each vaccinated bovine animal by the 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 shall ensure a link between the vaccinated dam and the offspring;

(g) establishment of an increased surveillance area of at least 20 km around the area where vaccination is practiced, in which intensified surveillance shall be carried out and the movement of bovine animals shall be subject to controls by the competent authority.

2. MINIMUM INFORMATION TO BE PROVIDED

The vaccination programmes submitted by the Member States shall provide at least the following information:

(a) the exact areas where vaccination will be implemented;

(b) the type or types of vaccine that will be used;

(c) the number of holdings and animals, per species and categories that will be vaccinated, per area;

(d) the method and line of command regarding the implementation of the vaccination (storage, distribution of the vaccine, personnel that will perform vaccination, recording or special identification of vaccinated animals, prioritisation of vaccination per areas, official supervision of the vaccination, vaccination of new-born calves, revaccination of animals according to the manufacturer's instructions);

(e) the timeline for the vaccination programme (inauguration, expected date of completion per area, date of completion in the entire area where vaccination is implemented);

(f) all measures accompanying vaccination including restrictions in the movements of animals and dispatch of products and by-products thereof.

3. MINIMUM REPORTING REQUIREMENTS

The Member States which have submitted a vaccination programme shall report to the Commission at least the following:

(a) immediate notification of the exact date of launching of the vaccination campaign;

(b) monthly progress reports providing the exact vaccine coverage achieved in each area;

[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).

(c) immediate notification of the exact date of completion of vaccination in each area (vaccine coverage of at least 95 %, both at herd as well as at animal level);

(d) after completion of the first round of vaccination monthly reports submitted within the first week of each month, providing an account of the animals that were vaccinated during the previous month and the reason for vaccination (e.g. new calves, revaccination etc.);

(e) other information derived from the dedicated online database upon request from the Commission.