

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1070**of 28 June 2021****laying down special control measures for a limited period of time related to infection with lumpy skin disease virus****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 71(3) thereof,

Whereas:

- (1) Infection with lumpy skin disease virus, caused by the lumpy skin disease virus (LSDV), is a vector-borne disease of cattle and Asian water buffalo that can cause substantial economic losses, reduce milk yield, cause severe emaciation, permanent damage to hides, several secondary complications, chronic debility, and incur movement or trade bans. It is on the list of notifiable diseases of the World Organisation for Animal Health (OIE) ⁽²⁾.
- (2) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases. Infection with lumpy skin disease virus is listed in Annex II to Regulation (EU) 2016/429, and accordingly it is a listed disease for the purposes of that Regulation, and it is subject to the disease prevention and control rules laid down therein. In addition, infection with LSDV is listed in the Annex to Commission Implementing Regulation (EU) 2018/1882 ⁽³⁾ as a category A, D and E disease.
- (3) Commission Delegated Regulation (EU) 2020/687 ⁽⁴⁾ supplements the rules for the control of category A, B and C diseases laid down in Regulation (EU) 2016/429, including disease control measures against infection with LSDV. Regulation (EU) 2016/429, Implementing Regulation (EU) 2018/1882 and Delegated Regulation (EU) 2020/687 all apply from 21 April 2021.
- (4) Previously, Commission Implementing Decision (EU) 2016/2008 ⁽⁵⁾ laid down rules on animal health control measures in relation to infection with LSDV in the Member States or parts thereof listed in Annex I thereto, including the minimum requirements for vaccination programmes against infection with LSDV submitted by the Member States to the Commission for approval. Bulgaria and Greece are concerned by such listing. Implementing Decision (EU) 2016/2008 ceased to apply on 20 April 2021, and the rules laid down in this Regulation should replace those laid down in that Implementing Decision.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ OIE – Listed diseases, infections and infestations in force in 2021. OIE - Terrestrial Animal Health Code, Twenty-eighth edition, 2019, ISBN 978-92-95108-85-1 (<https://www.oie.int/en/animal-health-in-the-world/oie-listed-diseases-2021/>).

⁽³⁾ Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

⁽⁵⁾ Commission Implementing Decision (EU) 2016/2008 of 15 November 2016 concerning animal health control measures relating to lumpy skin disease in certain Member States (OJ L 310, 17.11.2016, p.51).

- (5) Since 2017, no outbreaks of infection with LSDV have been reported in Europe, but that disease is still present in Anatolia, Turkey, and in Russia, as well as in eastern Asia affecting Bangladesh, China and India. Therefore, the spread of that disease represents a potential risk for the agricultural sector in the Union.
- (6) Apart from Bulgaria and Greece, Croatia and a considerable number of neighbouring third countries, such as Bosnia and Herzegovina, Kosovo ⁽⁶⁾, Montenegro, North Macedonia, Serbia and Turkey have notified to the Commission that vaccination against infection with LSDV has been included in their disease control policy. Most of those third countries have now stopped vaccination and are maintaining surveillance measures.
- (7) The epidemiological situation in Eastern Europe and in neighbouring regions suggests that a certain risk of disease re-introduction or re-emergence, in high-risk areas where vaccination against infection with LSDV has ceased, may still exist.
- (8) Based on the available epidemiological information to date, the results of surveillance for infection with LSDV and vaccination against that disease, it is appropriate that vaccination against infection with LSDV should at least continue in the high-risk areas of Bulgaria and Greece. In addition, in all Member States or parts thereof where vaccination against that disease has been reduced or completely ceased, systematic surveillance, both active and passive, should continue.
- (9) According to the scientific report of the European Food Safety Authority (EFSA) on infection with LSDV, approved on 30 January 2020 ⁽⁷⁾ (the EFSA Report), a homologous vaccine should be used to reduce the risk of the further spread of infection with LSDV to south-eastern Europe. After vaccination has stopped, in the case of the re-emergence of that disease, a contingency plan and vaccine stockpiling, even on a regional basis, would be needed in order to react quickly with emergency vaccination.
- (10) The general disease control measures laid down in Regulation (EU) 2016/429, and the supplementing rules laid down in Delegated Regulation (EU) 2020/687, do not cover all necessary aspects of vaccination against infection with LSDV. It is therefore appropriate to lay down uniform implementing rules at Union level in this Regulation to cover special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation of that disease in the Union and in neighbouring third countries. The control measures laid down in this Regulation should take account of the experience gained in the application of Implementing Decision (EU) 2016/2008, as well as international standards set out in Chapter 11.9 'Infection with lumpy skin disease virus' of the Terrestrial Animal Health Code of the OIE (OIE Code) ⁽⁸⁾.
- (11) The rules laid down in this Regulation should provide for a regionalisation approach, and apply in tandem with the disease control measures laid down in Delegated Regulation (EU) 2020/687. In addition, this Regulation should list the restricted zones of Member States carrying out preventive vaccination plans with live attenuated vaccines where there are no outbreaks of infection with LSDV (restricted zone I); and areas with outbreaks of infection with LSDV (restricted zone II). The areas included in restricted zone I or in restricted zone II should be listed in Annex I to this Regulation taking account of the information provided by the competent authorities of the Member States affected by that disease.
- (12) Vaccinated bovine animals and products from those bovine animals may represent a risk for the spread of infection with LSDV. Therefore, this Regulation should provide for certain prohibitions and specific conditions on movements of consignments of bovine animals or different types of products from the restricted zones listed in Annex I to this Regulation. In order to avoid unnecessary disturbances for trade, certain derogations from those prohibitions and specific conditions should be laid down. Those derogations and specific conditions should take account of the principles of the OIE Code as regards risk mitigation measures against infection with LSDV, as well as the rules for the prevention and control of animal diseases laid down in Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/687.

⁽⁶⁾ This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

⁽⁷⁾ EFSA Journal 2020; 18(2):6010.

⁽⁸⁾ OIE – Terrestrial animal health code (2019). OIE - Terrestrial Animal Health Code, Twenty-eighth edition, 2019, ISBN 978-92-95108-85-1 (www.oie.int/en/standard-setting/terrestrial-code/access-online/).

- (13) In terms of the risk of the spread of infection with LSDV, different commodities pose different levels of risk. As indicated in the EFSA Report, the movement of live bovine animals, bovine semen and raw hides and skins from infected bovine animals pose a higher level of 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 on their role in transmitting lumpy skin virus is not yet sufficient. The transmission of lumpy skin disease virus through semen, ova and embryos of animals of the bovine species cannot be excluded. Milk and dairy products, as well as colostrum, may represent a risk for the spread of lumpy skin disease virus only when destined for feeding to animals of the susceptible species.
- (14) Therefore, certain protective measures should be provided for those commodities based on the EFSA Report and the relevant most updated standards and recommendations from the OIE.
- (15) Movements of consignments of animals for immediate slaughter pose a lower level of risk for the spread of animal diseases than other types of movements of animals provided that risk mitigation measures are in place. It is therefore appropriate that the Member States should be permitted exceptionally to grant derogations from certain prohibitions laid down in this Regulation for movements of consignments of bovine animals, from restricted zones I and II, for immediate slaughter to a slaughterhouse located outside of restricted zones I and II in the same Member State.
- (16) The derogations for movements of consignments of certain bovine animals from a restricted zones I or II to another restricted zones I or II of another Member State with a similar disease status are justified where specific risk mitigating measures are applied. This requires the establishment of a safe channelling procedure under the strict control of the competent authorities of the Member State of origin, passage and destination.
- (17) Article 143 of Regulation (EU) 2016/429 provides that animal health certificates are to accompany the movements of animals, including bovine animals. Where derogations from the prohibition on movements of consignments of bovine animals from restricted zones I and II are applied to consignments of bovine animals intended for intra-Union movements, those animal health certificates should include a reference to this Regulation, to ensure that adequate and accurate health information is provided in those animal health certificates.
- (18) Where this Regulation provides for derogations from prohibitions on movements of consignments of germinal products from restricted zones I and II, the accompanying animal health certificates should include a reference to this Regulation, so as to ensure adequate and accurate health information in accordance with this Regulation and Commission Delegated Regulation (EU) 2020/686 ⁽⁹⁾.
- (19) The transport of bovine animals and animal by-products from those animals from restricted zones I and II should be carried out under animal welfare and biosecurity measures to avoid the spread of infection with LSDV.
- (20) Delegated Regulation (EU) 2020/687 applies from 21 April 2021. Accordingly, in the interest of legal certainty, this Regulation should enter into force as a matter of urgency.
- (21) This Regulation should apply for a period until 21 April 2023, taking into account the Union's experience in the control of infection with LSDV, the current epidemiological situation of that disease in Member States and neighbouring third countries and any future rules on vaccination laid down pursuant to Article 47 of Regulation (EU) 2016/429.
- (22) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁹⁾ Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL RULES

Article 1

Subject matter and scope

This Regulation lays down special disease control measures against infection with the lumpy skin disease virus (LSDV) to be applied for a limited period of time by Member States in areas of their territory where:

- (a) an outbreak of that disease has been confirmed;
- (b) an outbreak of that disease has not been confirmed, but they decide to carry out vaccination against that disease in accordance with the rules laid down in this Regulation.

The special disease control measures laid down in this Regulation apply to bovine animals and by-products and germinal products obtained from such bovine animals, and are in addition to the disease control measures applicable to the protection, surveillance and further restricted zones established by the competent authority of a Member State following an outbreak of infection with LSDV, in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Delegated Regulation (EU) 2020/687 shall apply.

In addition, the following definitions shall also apply:

- (1) 'bovine animal' means an animal of the species of ungulates belonging to the genera Bison, Bos (including the subgenera Bos, Bibos, Novibos, Poephagus) and Bubalus (including the subgenus Anoa) and the offspring of crossings of those species;
- (2) 'restricted zone I' means a part of the territory of a Member State with a precise geographical delimitation:
 - (a) located outside an area where an outbreak of infection with LSDV has been confirmed;
 - (b) where vaccination against infection with LSDV is carried out in accordance with Article 3(2);
 - (c) listed or not in Part I of Annex I;
 - (d) subject to special disease control rules provided for in Articles 3 to 6;
- (3) 'restricted zone II' means a part of the territory of a Member State with a precise geographical delimitation:
 - (a) which includes an area where an outbreak of infection with LSDV has been confirmed;
 - (b) where vaccination against infection with LSDV is carried out in accordance with Article 3(1);
 - (c) listed or not in Part II of Annex I;
 - (d) subject to special disease control rules provided for in Article 3 to 6.

CHAPTER II

SPECIAL DISEASE CONTROL MEASURES AGAINST INFECTION WITH LSDV

SECTION 1

Establishment of restricted zones and vaccination against infection with LSDV*Article 3***Establishment of restricted zones I and II**

1. In the event of confirmation of an outbreak of infection with LSDV in bovine animals, the competent authority shall:
 - (a) establish a restricted zone II:
 - (i) covering at least the areas included in the protection, surveillance and further restricted zones established after the confirmation of that disease in accordance with Article 21 of Delegated Regulation (EU) 2020/687;
 - (ii) in accordance with the criteria laid down in Article 64 (1) of Regulation (EU) 2016/429;
 - (b) implement a vaccination against that disease in the restricted zone II referred to in point (a) as follows:
 - (i) in accordance with the rules for vaccination plans set out in Annex II;
 - (ii) under the control of the competent authority;
 - (iii) prioritising the use of homologous live attenuated vaccines;
 - (iv) vaccinating all bovine animals and their offsprings kept in the zone where vaccination is carried out, independently of their sex, age and gestational or productive status in accordance with the instructions of the manufacturer.

However, where a only one outbreak of infection with LSDV in kept bovine animals has been confirmed in an area of a Member State where that disease was not present before that outbreak, and where the measures carried out in accordance with Delegated Regulation (EU) 2020/687 prove to be effective in controlling the spreading of the disease, the competent authority may decide not to establish a restricted zone II.

2. The competent authority may establish a restricted zone I in areas where the presence of an outbreak of infection with LSDV has not been confirmed in order to prevent its spread, in accordance with the criteria laid down in Article 64(1) of Regulation (EU) 2016/429. In that restricted zone I, the competent authority shall carry out vaccination against that disease in accordance with paragraph 1, point (b), of this Article.
3. The competent authority of the Member States applying vaccination against infection with LSDV shall provide the information listed in Annex II, Part III of this Regulation to the Commission and the other Member States before starting the vaccination and the vaccination plan referred to in paragraph 1(b), point (i).

*Article 4***Prohibitions of movements in restricted zones I and II**

1. The competent authority shall prohibit movements of the following consignments in restricted zones II:
 - (a) bovine animals;
 - (b) germinal products from bovine animals;
 - (c) unprocessed animal by-products from bovine animals including milk, colostrum, dairy products and colostrum-based products intended for animal feed.

2. The competent authority shall prohibit movements of the following consignments in restricted zones I:
 - (a) bovine animals;
 - (b) germinal products from bovine animals;
 - (c) unprocessed animal by-products from bovine animals other than milk, colostrum, dairy products and colostrum-based products intended for animal feed.

3. By way of derogations from the prohibitions provided for in paragraphs 1 and 2, the competent authority may authorise the movements provided for in Chapter III in accordance with the conditions provided therein.

SECTION 2

Inclusion of a restricted zones I and II in Annex I

Article 5

Inclusion of restricted zone II in Annex I, Part II

Where, for epidemiological reasons, an area of a Member State covered totally or partially by a restricted zone II established in accordance with Article 3(1) is included in Part II of Annex I, the competent authority shall immediately:

- (a) adapt the boundaries of the initial restricted zone II to ensure that it corresponds to the restricted zone II described in that Annex;
- (b) extend the vaccination provided for in Article 3(1), point (b), and the prohibitions provided for in Article 4(1) to the restricted zone II described in that Annex.

Article 6

Inclusion of restricted zone I in Annex I, Part I

1. Where, for epidemiological reasons, an area of a Member State where an outbreak of infection with LSDV has not been confirmed is included in Part I of Annex I to this Regulation in accordance with the criteria laid down in Article 64(1) of Regulation (EU) 2016/429, the competent authority shall:

- (a) carry out vaccination in accordance with Article 3(1), point (b), in the restricted zone I described in that Annex;
- (b) implement the prohibitions provided for in Article 4(2) in the restricted zone I described in that Annex.

2. Where the competent authority decides to establish a restricted zone I in accordance with Article 3(2) that restricted zone shall be included in Part I of Annex I.

CHAPTER III

CONDITIONS FOR MOVEMENTS WITHIN AND FROM AREAS WHERE SPECIAL DISEASE CONTROL MEASURES AGAINST INFECTION WITH LUMPY SKIN DISEASE VIRUS ARE APPLIED

SECTION 1

Derogations from the prohibitions on movements of consignments of bovine animals from restricted zones I and II*Article 7***Derogations from the prohibition on movements of consignments of bovine animals from restricted zone I**

By way of derogations from the prohibition provided for in Article 4(2), point (a), the competent authority may authorise movements of consignments of bovine animals from establishments located in restricted zone I to:

- (a) a restricted zones I or II of the same or another Member State provided that all of the following conditions are fulfilled:
- (i) the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date;
 - (ii) all the other bovine animals kept in the same establishment of origin as the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on the date of dispatch;
 - (iii) the bovine animals in the consignment must have been kept in their establishment of origin since birth or for a continuous period of at least 28 days prior to the date of dispatch; and
 - (iv) the competent authority shall carry out:
 - a clinical examination, with favourable results, of all bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
 - if necessary, a laboratory examination, with favourable results, of bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
- (b) any destination – including areas outside restricted zones, other restricted zones I or restricted zones II – in the same Member State or in other Member States, if, in addition to the conditions laid down in point (a)(ii), (iii) and (iv) of this Article, all of the following conditions are fulfilled:
- (i) the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on the date of dispatch;
 - (ii) within a radius of at least 20 km around the establishment of origin of such consignments, there have been no outbreaks of infection with LSDV during a period of at least three months prior to the date of dispatch; and
 - (iii) all bovine animals kept in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against infection with LSDV at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or within their maternal immunity;

- (c) any destination – including areas outside restricted zones, other restricted zones I or restricted zones II – in other Member States or territories in third countries, if, in addition to the conditions laid down in point (a) of this Article, the following conditions are fulfilled:
- (i) the animals must comply with any animal health guarantee, based on the favourable outcome of a risk assessment of measures against the spread of infection with LSDV required by the competent authority of the Member State of origin and approved by the competent authority of the Member States of destination and passage, prior to the date of dispatch;
 - (ii) there must have been no confirmed outbreaks of infection with LSDV within a radius of at least 20 km around the establishment of origin of such consignments for a period of at least three months prior to the date of dispatch; and
 - (iii) all bovine animals kept in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against infection with LSDV at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or within their maternal immunity.

Article 8

Derogations from the prohibitions of movements of consignments of bovine animals from restricted zone II

By way of derogations from the prohibition provided for in Article 4(1), point (a), the competent authority may authorise movements of consignments of bovine animals from establishments located in restricted zone II to:

- (a) any destination, including areas outside restricted zones, restricted zones I, other restricted zones II in the same Member State and other Member States, provided that all of the following conditions are fulfilled:
- (i) the bovine animals in the consignment must comply with any animal health guarantee, based on the favourable outcome of a risk assessment of measures against the spread of infection with LSDV required by the competent authority of the Member State of origin and agreed with the competent authority of the Member States of destination or passage, prior to the date of dispatch;
 - (ii) the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date;
 - (iii) all other bovine animals kept in the same establishment of origin as the bovine animals in the consignment must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on that date;
 - (iv) the competent authority shall carry out:
 - a clinical examination, with favourable results, of all bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
 - if necessary, a laboratory examination, with favourable results, of bovine animals kept in the establishment of origin of such consignments, including the bovine animals in such consignments;
 - (v) the bovine animals must have been resident since birth, or for a period of at least 28 days prior to the date of dispatch, in an establishment where, within a radius of at least 20 km, no outbreak of infection with LSDV has been confirmed during the three months prior to the date of dispatch;

- (vi) all bovine animals in 50 km around the establishment of origin of the consignment must have been vaccinated or revaccinated against infection with LSDV, in accordance with the rules for vaccination plans set out in Annex II, at least 60 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer or within their maternal immunity;
- (b) any destination located within another restricted zone II of the same Member State, provided that all of the following conditions are fulfilled:
 - (i) all other bovine animals kept in the establishment of origin of such consignments must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or remain within the immunity period induced by previous vaccination or maternal immunity on that date; and
 - (ii) the bovine animals must have been vaccinated against infection with LSDV at least 28 days prior to the date of dispatch and remain within the immunity period in accordance with the instructions of the vaccine manufacturer on that date or are unvaccinated offspring less than four months old, born to dams vaccinated at least 28 days prior to parturition that remained within the immunity period according to the vaccine manufacturer on the date of parturition, and may be moved to another establishment.

Article 9

Specific conditions for authorising movements of consignments of bovine animals from restricted zones I and II to a slaughterhouse outside of those zones, located in the territory of the same Member State for the purpose of immediate slaughter

By way of derogations from the prohibitions provided for in Article 4(2), point (a), and Article 4(1), point (a), of this Regulation, the competent authority of the Member State may authorise movements of consignments of bovine animals from restricted zones I and II to a slaughterhouse outside of those zones, located in the territory of the same Member State, provided that the bovine animals are moved for the purpose of immediate slaughter in compliance with the general conditions laid down in Article 28(2) to (5) and Article 28(7) of Delegated Regulation (EU) 2020/687.

Article 10

Derogations from the prohibition on the movements of consignments of semen, ova and embryos of bovine animals from the restricted zones I and II

1. By way of derogations from the prohibition provided for in Article 4(2), point (b), the competent authority of a Member State may authorise movements of consignments of semen, ova and embryos of bovine animals, from approved germinal product establishments or other establishments located in restricted zone I to:

- (a) restricted zones I or II of the same Member State provided that all of the following conditions are fulfilled:
 - (i) the donor animals were either:
 - vaccinated and revaccinated against infection with LSDV according to the manufacturer's instructions of the vaccine used, and the first vaccination must have been administered at least 60 days prior to the date of collection of the semen, ova or embryo; or
 - subjected to a serological test to detect specific antibodies against the LSDV on the day of the collection and at least 28 days after the period of collection as regards semen or on the day of collection as regards embryos and ova, with negative results;
 - (ii) 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, within a radius of at least 20 km, no outbreak of infection with LSDV has been confirmed during the three months prior to the date of collection of the semen, ova or embryos;

- (iii) 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 infection with LSDV;
- (b) any destination located in another restricted zone I or II of another Member State, provided that, in addition to the conditions laid down in point (a), all of the following conditions are fulfilled:
 - (i) the donor animals were subjected to a LSDV detection by polymerase chain reaction (PCR) conducted on blood samples collected at the commencement of collection of the semen, ova or embryo 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;
 - (ii) the semen was subjected to a LSDV detection by PCR with negative results;
- (c) any destination located in the same or another Member State or, in case of restricted zone I, to a third country provided that, in addition to the conditions laid down in point (a), 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 infection with LSDV, required by the competent authority of the Member State of the establishment of origin and approved by the competent authorities of the Member States of the places of passage and of destination, prior to the dispatch of such semen, ova or embryos.

2. By way of derogations from the prohibition provided for in Article 4(1), point (b), the competent authority may authorise movements of consignments of semen, ova and embryos of bovine animals, from approved germinal product establishments or other establishments located in restricted zone II to any destination located in another restricted zone II of the same Member State.

Article 11

Derogations from the prohibition on the movements of unprocessed animal by-products from bovine animals from restricted zones I

By way of derogation from the prohibition provided for in Article 4(2), point (c), the competent authority of a Member State may authorise movements of consignments of unprocessed animal by-products from bovine animals from establishments located in restricted zone I to:

- (a) any destination located in the same Member State or to any destination located in restricted zones I or II in another Member State;
- (b) in the case of consignments of hides and skins, any destination located in any area of the same or another Member State or third country provided that one of the following conditions are fulfilled:
 - (i) the treated hides and skins have been subjected to one of the treatments referred to in point 28(b) to (e) of Annex I to Commission Regulation (EU) No 142/2011 ⁽¹⁰⁾; or
 - (ii) the treated hides and skin have been subjected to one of the treatments set out in Section XIV, Chapter I, point (4)(b) (ii), of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽¹¹⁾, and have undergone all precautions to avoid recontamination with pathogenic agents after treatment.

⁽¹⁰⁾ 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).

⁽¹¹⁾ 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).

*Article 12***Derogation from the prohibition on the movements of consignments of unprocessed animal by-products from bovine animals from restricted zones II**

By way of derogation from the prohibition provided for in Article 4(1), point (c), the competent authority of a Member State may authorise movements of consignments of unprocessed animal by-products from bovine animals from establishments located in restricted zone II to:

- (a) in the case of unprocessed animal by-products other than hides and skins, any destination located in the same Member State or any destination located in restricted zones I or II of another Member State provided that the unprocessed animal by-products are dispatched under the official supervision of the competent authorities for processing or disposal in a plant approved in accordance with Article 24 of Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽¹²⁾;
- (b) in the case of hides and skins of bovine animals:
 - (i) any destination located in restricted zone II of the same or another Member State provided that they 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;
 - (ii) any destination located in the same or another Member State provided that the conditions laid down in Article 11, point (b), are fulfilled;
- (c) in the case of colostrum, milk and dairy products, any destination located in any area of the same or another Member State provided that they have been subjected to a risk-mitigating treatment for infection with LSDV, as set out in Annex VII to Delegated Regulation (EU) 2020/687.

SECTION 2

Obligations on operators with regard to animal health certificates*Article 13***Operators' obligations with regard to animal health certificates for movements of consignments of bovine animals from restricted zones I and II outside of those zones**

Operators shall only move consignments of bovine animals from restricted zones I and II outside of those zones within the same Member State or to another Member State in the cases covered by Articles 7, 8 and 9 of this Regulation if the animals to be moved are accompanied by the animal health certificate provided for in Article 73 of Commission Delegated Regulation (EU) 2020/688 ⁽¹³⁾ that contains at least one of the following attestations of compliance with the requirements provided for in this Regulation:

- (a) 'Bovine animals from restricted zone I in compliance with the special control measures against infection with LSDV laid down in Article 7 of Commission Implementing Regulation (EU) 2021/1070.;
- (b) 'Bovine animals from restricted zone II in compliance with the special control measures against infection with LSDV laid down in Article 8 of Commission Implementing Regulation (EU) 2021/1070.;
- (c) 'Bovine animals from a restricted zone I or II in compliance with the special control measures against infection with LSDV laid down in Article 9 of Commission Implementing Regulation (EU) 2021/1070.'

⁽¹²⁾ 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).

⁽¹³⁾ Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

However, in the case of movements of the consignments referred to in the first paragraph of this Article within the same Member State, the competent authority may decide that an animal health certificate does not have to be issued as referred to in Article 143(2), second subparagraph, of Regulation (EU) 2016/429.

Article 14

Operators' obligations with regard to animal health certificates for movements of consignments of germinal products obtained from bovine animals from establishments located in restricted zones I and II outside of those zones

Operators shall only move consignments of germinal products obtained from bovine animals from restricted zones I and II outside of those zones within the same Member State or to another Member State in accordance with Article 10 of this Regulation, if those consignments are accompanied by an animal health certificate as referred to in Article 161(4) of Regulation (EU) 2016/429 that contains at least one of the following attestations of compliance with the requirements provided for in this Regulation:

- (a) 'Germinal products (semen, ova and/or embryos, indicate as appropriate) obtained from bovine animals kept in restricted zone I in compliance with special control measures against infection with LSDV as laid down in Article 10 of Commission Implementing Regulation (EU) 2021/1070.';
- (b) 'Germinal products (semen, ova and/or embryos, indicate as appropriate) obtained from bovine animals kept in restricted zone II in compliance with special control measures against infection with LSDV as laid down in Article 10 of Commission Implementing Regulation (EU) 2021/1070.'.

However, in the case of movements of the consignments referred to in the first paragraph of this Article within the same Member State, the competent authority may decide that an animal health certificate does not have to be issued as referred to in Article 161(2), second subparagraph, of Regulation (EU) 2016/429.

Article 15

Operators' obligations with regard to animal health certificates for movements of consignments of unprocessed animal by-products from bovine animals from restricted zones I and II outside of those zones

Operators shall only move consignments of unprocessed animal by-products from bovine animals from restricted zones I and II outside of those zones within the same Member State or to another Member State in the cases covered by Article 12, if those consignments are accompanied by:

- (a) a commercial document referred to in Chapter III of Annex VIII to Regulation (EU) No 142/2011; and
- (b) an animal health certificate referred to in Article 22(5) of Delegated Regulation (EU) 2020/687;

However, in the case of movements of the consignments referred to in the first paragraph of this Article within the same Member State, the competent authority may decide that an animal health certificate shall not be issued as referred to in Article 22(6) of Delegated Regulation (EU) 2020/687.

SECTION 3

Specific conditions for authorising movements of consignments of bovine animals kept in restricted zones I and II outside of those zones and channelling procedures

Article 16

Additional general conditions related to the means of transport used for the movement of consignments of bovine animals and unprocessed animal by-products from restricted zones I and II outside of those zones

The competent authority of the Member State shall only authorise movements of consignments of bovine animals and unprocessed animal by-products from restricted zones I and II outside of those zones if the means of transport used for the movement of those consignments:

- (a) in the case of transport of bovine animals, the means of transport:
 - (i) comply with requirements laid down in Article 24(1) of Delegated Regulation (EU) 2020/687; and
 - (ii) are cleaned and disinfected in accordance with Article 24(2) of Delegated Regulation (EU) 2020/687 under the control or supervision of the competent authority of the Member State;
- (b) only include animals or unprocessed animal by-products or untreated hides and skins of the same health status.

Article 17

Obligations of the competent authority of establishment of origin concerning channelling procedures

1. The competent authority of the Member State of the establishment of origin shall set up a channelling procedure, under the control of the competent authorities of the Member States of the places of origin, passage and destination for movements of consignments of bovine animals or unprocessed animal by-products covered by the derogations provided for in Articles 8, 9 and 12 when the destination is located in another Member State ('the channelling procedure').

2. The competent authority of the establishment of origin shall ensure that:

- (a) each means of transport, that is used for the movement of the consignments of bovine animals or unprocessed animal by-products referred to in paragraph 1, has been individually registered, by the competent authority of the Member State of the establishment of origin for the purpose of the transport of either bovine animals or unprocessed animal by-products using the channelling procedure, and is:
 - sealed by the official veterinarian after loading for dispatch. Only an official of 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, or
 - individually accompanied by a satellite navigation system to determine, transmit and record its real time location.
- (b) the transport takes place:
 - (i) under the supervision of an official veterinarian;
 - (ii) directly, without stopping unless a rest period required by Chapter V of Annex I of Council Regulation (EC) No 1/2005 ⁽¹⁴⁾ takes place in a control post;

⁽¹⁴⁾ 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).

Where a rest period of one day or more is foreseen at a control post during the movement of the consignment through a restricted zone II, the animals shall be protected against attacks by vectors;

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

3. For the purposes of the channelling, the competent authority of the establishment of origin shall, before the first dispatch of a consignment from restricted zones I or II from which a channelling procedure takes place, ensure that the necessary arrangements are in place with the relevant competent authorities of the places of passage and destination and operators in order to ensure:

- (a) the emergency plan is agreed;
- (b) the chain of command and full cooperation of services and operators in the case of accidents during the transport, a major breakdown of the means of transport or any fraudulent action;
- (c) immediate notification by operators to the competent authority of any accident or major breakdown of the means of transport.

Article 18

Obligations of the competent authority of the place of destination concerning channelling procedures

The competent authority of the place of destination, following a channelling procedure, shall:

- (a) confirm each arrival to the competent authority of place of origin;
- (b) ensure that the bovine animals remain in the establishment of destination for at least the duration of the monitoring period for infection with LSDV set out in Annex II to Delegated Regulation (EU) 2020/687, except when the establishment of destination is a slaughterhouse;
- (c) ensure that after the unloading of the bovine animals, or the unprocessed animal by-products the means of transport and any other equipment which have been used in the transport of the bovine animals or the unprocessed animal by-products, are cleaned, disinfected and treated with authorised insecticides that are effective against known vectors of infection with LSDV in their entirety within a closed area of the place of destination under the supervision of an official veterinarian.

Article 19

Obligations of the Member State of the place of origin of the consignments of bovine animals, germinal products or unprocessed animal by-products concerning information to the Commission and the Member States for derogations granted based on risk assessments

Where the competent authority authorises movements of consignments of bovine animals or germinal products based on the favourable outcome of a risk assessment of measures against the spread of infection with LSDV, as referred to in Articles 7, 8 or 10, the Member State of the place of origin shall immediately inform the Commission and the other Member States of the animal health guarantees, and of the approval by the competent authorities of place of the establishment of destination.

CHAPTER IV

FINAL PROVISIONS

*Article 20***Entry into force and date of application**

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

It shall apply until 21 April 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 June 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

RESTRICTED ZONES I and II

(as referred to in Article 3)

PART I

Restricted zone I

1. Bulgaria:
The entire territory of Bulgaria
2. Greece:
 - A. The following regions in Greece:
 - Region of Attica
 - Region of Central Greece
 - Region of Central Macedonia
 - Region of Crete
 - Region of Eastern Macedonia and Thrace
 - Region of Epirus
 - Region of the Ionian Islands, excluding the regional unit of Kerkyra
 - Region of North Aegean, excluding the regional unit of Limnos
 - Region of Peloponnese
 - Region of South Aegean
 - Region of Thessaly
 - Region of Western Greece
 - Region of Western Macedonia
 - B. The following regional units in Greece:
 - Regional unit of Limnos
 - Regional unit of Kerkyra

PART II

Restricted zone II

None

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ANNEX II

RULES FOR VACCINATION PLANS CONCERNING INFECTION WITH LUMPY SKIN DISEASE VIRUS

(as referred to in Article 3)

PART I

Information to be included in the vaccination plan as referred to in Article 3

Where a Member State carries out vaccination against infection with LSDV, such vaccination shall be carried out in accordance with a vaccination plan containing at least the following information:

- (a) the description and the results of the assessment performed in accordance with the criteria laid down in Article 46(2) of Regulation (EU) 2016/429, including the epidemiological situation and other relevant information used as a basis for the assessment;
- (b) the main objectives and targets with the chosen vaccination strategy and the vaccination plan;
- (c) the detailed geographic description of the vaccination zone in which vaccination is to be carried out and the location of establishments keeping bovine animals to be vaccinated, including maps;
- (d) the responsible authority to administer the vaccine to the bovine animals;
- (e) the system to supervise the administration of the vaccine;
- (f) the number of establishments keeping bovine animals located in the restricted zone and the number of establishments to be vaccinated, if different;
- (g) the estimated number of bovine animals, their categories and age of animals to be vaccinated;
- (h) the envisaged duration of the vaccination, from the start of the vaccination to the end of the surveillance carried out after vaccination;
- (i) the summary of the characteristics of the vaccine, including the name of the product and the name of the manufacturer, and routes of administration;
- (j) indicate if the vaccine is used in accordance with Article 110(2) and (3) of Regulation (EU) 2019/6 of the European Parliament and of the Council ⁽¹⁾;
- (k) the methods to assess the effectiveness of vaccination;
- (l) the hygiene and biosecurity rules to be applied;
- (m) the record keeping system on the vaccination;
- (n) other aspects of relevance for the specific situation.

PART II

Minimum requirements for infection with LSDV vaccination plans as referred to in Article 3

The vaccination plans against infection with LSDV shall be in accordance with the following technical requirements:

- (a) vaccination of all bovine animals independently of their sex, age and gestational or productive status within the restricted zones I and II where vaccination must be implemented;
- (b) vaccination of the offspring of vaccinated bovine animals older than four months of age in accordance with the instructions of the manufacturer of the vaccine used;
- (c) revaccination of all bovine animals in accordance with the instructions of the manufacturer;

⁽¹⁾ Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

- (d) 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 Article 42 of Regulation (EU) 2019/2035 of the European Parliament and of the Council ⁽²⁾;
- (e) establishment of an increased surveillance area of at least 20 km around the restricted zones I and II where vaccination is carried out, in which intensified surveillance shall be carried out and the movement of bovine animals shall be subject to controls by the competent authority;
- (f) vaccine coverage of at least 95% of herds representing at least 75% of bovine animals population.

PART III

Preliminary information to be provided to the Commission and to the other Member States before starting vaccination as referred to in Article 3, point 3

Member States applying vaccination against lumpy skin disease shall provide the following information to the Commission and to the other Member States before starting the vaccination:

- (a) a brief justification for starting the vaccination;
- (b) the species of bovine animals that are to be vaccinated;
- (c) the estimated number of bovine animals that are to be vaccinated;
- (d) the estimated duration of the vaccination;
- (e) the type and commercial name of the vaccine applied indicating if the vaccine is to be used in accordance with Article 110(2) and (3) of Regulation (EU) 2019/6;
- (f) a description of the estimated vaccination zone.

⁽²⁾ Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs (OJ L 314, 5.12.2019, p. 115).