



## **B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation laying down special control measures related to infection with lumpy skin disease virus.**

**PAFF – Section Animal Health and Welfare**

**19 May 2021**

*Unit G2 – Animal Health*

# Infection with LSDV outbreaks in Europe and neighbouring areas

Since 2017, no infection with lumpy skin disease virus outbreaks were reported in South-Eastern Europe. Data from Animal Disease Information System (**ADIS**).

COUNTRY	2015	2016	2017	2018	2019	2020	2021	Total
GREECE	117	104	2					223
BULGARIA		217						217
TURKEY	487	106	14	46	180	5	1	839
NORTH MACEDONIA		117	4					121
SERBIA		225						225
MONTENEGRO		64						64
ALBANIA		250	494					744
KOSOVO		46						46
<b>Total</b>	<b>604</b>	<b>1129</b>	<b>514</b>	<b>46</b>	<b>180</b>	<b>5</b>	<b>1</b>	<b>2479</b>

Data until 19/05/2021

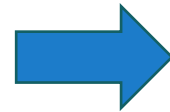
# Legal framework for LSD

## Legal framework until 21 April 2021

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

COMMISSION IMPLEMENTING DECISION (EU) 2016/2008, of 15 November 2016 concerning animal health control measures relating to lumpy skin disease in certain Member States (amended by Commission Implementing Decisions (EU) 2017/1178 & 2017/1460)

COMMISSION IMPLEMENTING DECISION (EU) 2016/2009 of 15 November 2016 approving the vaccination programmes against lumpy skin disease submitted by the Member States



ANIMAL HEALTH LAW

Part III: Disease control measures.

Delegated Regulation (EU) 2020/687 on disease control measures for category A, B and C diseases

AHL ARTICLE 71 (3)



Commission Implementing Regulation (EU) laying down special control measures for a limited period of time related to infection with lumpy skin disease virus.

## DRAFT DOCUMENT

**Commission Implementing Regulation (EU) laying down special control measures for a limited period of time related to infection with lumpy skin disease virus.**

### CHAPTER I GENERAL RULES

Subject matter and scope:

To be applied for a **limited period of time (2 years)** by:

Member States in which the **disease has been confirmed**; or

Member States in which the disease **has not been confirmed** but decide to carry out vaccination against the disease in accordance with this Regulation.

To the **movements from establishments** located in the **restricted zones I or II** of:

(a) **bovine animals**;

(b) Animal **by-products** and **germinal products**, obtained from bovine animals.

## RESTRICTED ZONES I AND II

**'Restricted zone I'** means a part of the territory:

- **outside the area where infection** with lumpy skin disease virus was confirmed;
- **in which vaccination** against infection with lumpy skin disease virus is carried out.

**'Restricted zone II'** means a part of the territory:

- which includes the area where infection with lumpy skin disease virus **was confirmed**;
- in which **vaccination** against infection with lumpy skin disease virus is carried out.

## CHAPTER II. SPECIAL DISEASE CONTROL MEASURES FOR INFECTION WITH LUMPY SKIN DISEASE VIRUS

1. In the **event of confirmation of infection with LSDV** the competent authority shall **implement vaccination** as follows:
  - (a) covering at least the areas included in any **protection, surveillance** in accordance with Article 21 of Regulation (EU) 2020/687;
  - (b) in accordance with a **vaccination plan**;
  - (C) prioritising the use of **homologous live attenuated vaccines**.

 **RESTRICTED ZONE II**  **PART II ANNEX**

2. The competent authority **may implement vaccination** against that disease in areas **where the disease has not been confirmed.**  **RESTRICTED ZONE I**  **PART I ANNEX**

Where a **single outbreak** of infection with LSDV in an area of a previously disease-free Member State, and where the measures in accordance with Regulation (EU) 2020/687 showed effective results, the member state concerned may decide not to implement vaccination in that area.

**THERE ARE TWO WAYS TO ENTER IN RESTRICTED ZONE I (area with vaccination against infection with LSDV where no outbreak has been officially confirmed):**

- (1) Where, for epidemiological reasons, an area of a Member State in which infection with **LSDV has not been confirmed**, is **included** in Part I of Annex I as a **restricted zone I** the competent authority shall immediately:
  - (a) implement vaccination;
  - (b) implement the prohibitions of movement.
  
- (2) Where a **Member State** in which infection with LSDV has not been confirmed **decides to implement vaccination**, the area where vaccination is implemented shall be included in **restricted zone I**.

The competent authority of the Member States applying vaccination against infection with lumpy skin disease virus shall provide the information listed in Annex II, of this regulation to the Commission and the other Member States.

## PROHIBITION OF MOVEMENTS:

The competent authority shall prohibit movements of the following consignments in restricted zones:

- **bovine animals** from restricted zone I and II;
- **semen, ova and embryos** of bovine animals from the restricted zones I and II;
- **unprocessed animal by-products** from bovine animals from restricted zones I and II. **Milk, colostrum, dairy products and colostrum-based products** from bovine animals intended for animal feed (only from restricted zones II).

By way of derogation, the competent authority may authorise the movements provided for in Chapter III in accordance with the conditions provided therein

**Measures similar to those in the 2016/2008 Commission Decision are maintained, with the necessary modifications to adapt them to the new legal framework.**



# CHAPTER III. CONDITIONS FOR MOVEMENTS WITHIN AND FROM AREAS WHERE SPECIAL DISEASE CONTROL MEASURES FOR INFECTION WITH LUMPY SKIN DISEASE VIRUS ARE APPLIED

## SECTION 1. DEROGATIONS FROM PROHIBITIONS ON MOVEMENTS OF CONSIGNMENTS OF BOVINE ANIMALS FROM RESTRICTED ZONES I AND II

**Derogations from the prohibition on movements of consignments of bovine animals from restricted zone I. Conditions for movements to:**

**(a) restricted zones I or II of the same or another Member State:**

- (i) bovine animals have been **vaccinated at least 28 days** prior to the date of dispatch;
- (ii) all **other bovine** animals have been **vaccinated at least 28 days** prior to 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
  - if necessary, a laboratory examination.

(b) **any destination:** in addition to point a (ii),(iii) and (iv)

(i) the bovine animals in the consignment must have been **vaccinated** at least **three months** prior to the date of dispatch;

(ii) within a **radius of at least 20km** around the establishment of origin there have been **no outbreaks** during a period of at **least three months** prior to the date of dispatch; and

(iii) all bovine animals kept in the **same restricted zone I** have **been vaccinated at least three months prior to the date of dispatch.**

(c) **any destination:** if, in addition to the conditions laid down in **point (a)**, 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 or passage, prior to the date of dispatch;

(ii) within a **radius of at least 20km** around the establishment of origin there have been **no outbreaks** during a period of at **least three months** prior to the date of dispatch; and

(iii) all bovine animals kept in the **same restricted zone I** have **been vaccinated at least three months prior to the date of dispatch.**

## Derogations from the prohibition on movements of consignments of bovine animals from restricted zone II. Conditions for movements to:

### (a) any destination:

- (i) the bovine animals in the consignment must comply with any animal health guarantee, based on the favourable outcome of a **risk assessment**;
- (ii) the bovine animals in the consignment have been **vaccinated at least 28 days** prior to the date of dispatch;
- (iii) all **other bovine** animals have been **vaccinated at least 28 days** prior to the date of dispatch
- (iv) the competent authority shall carry out:
  - a clinical examination
  - if necessary, a laboratory examination
- (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 a holding where, within a radius of **at least 20km**, **no outbreak** has been confirmed during the **three months** prior to the date of dispatch;
- (vi) all bovine animals in all **restricted zones II** must have been vaccinated at least **three months** prior to the date of dispatch.

**(b) any destination located within another restricted zone II of the same Member State:**

- (i) **all other bovine** animals kept in the establishment have been **vaccinated at least 28 days** prior to the date of dispatch, and
- (ii) the bovine animals have been **vaccinated at least 28 days** prior to the date of dispatch or are unvaccinated offspring less than six months old, born to dams vaccinated, at least 28 days prior to parturition.

**Specific conditions for authorising movements of consignments of bovine animals from restricted zones I and II to a slaughterhouse**

competent authority of the Member State may authorise movements of consignments of bovine animals **from restricted zones I and II to a slaughterhouse outside those zones**, located in the territory of the **same Member State**, provided that the bovine animals are moved for the purpose of **immediate slaughter**.

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

**Conditions for movements** 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:**

(i) the **donor animals** were either:

- **vaccinated** and revaccinated, and the first vaccination must have been administered at least **60 days** prior to the date of collection, **or**
- subjected to a **serological test** on the day of the collection and at least **28 days after** the semen collection with negative results;

(ii) the **donor animals** were **kept**, during the 60 days prior to the date of collection in an centre within a radius of at **least 20 km**, **no outbreak** during the **three months** prior to the date of collection;

(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;

(b) a destination located in **another restricted zone I or II of another Member State:**

in addition to the conditions laid down in **point (a)**;

- (i) the **donor animals** were subjected to a **(PCR)** on blood samples collected at the **commencement** of collection at least **every 14 days** thereafter during the collection 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 to a third country:** 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**.

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 a destination located in **another restricted zone II of the same Member State**.

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

to any destination located in the same Member State or to a destination located in restricted zones I or II in another Member State, no special conditions.

to any destination, conditions for movements: hides and skins have been subjected to treatments.

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

### Conditions for movements to:

- (a) in the case of unprocessed animal by-products other than hides and skins, any destination if are dispatched for processing in a plant approved;
- (b) in the case of hides and skins of bovine animals:
  - (i) a destination located in restricted zone II of the same or another Member State provided that they are dispatched for processing or disposal in an approved plant;
  - (ii) any destination if have been subjected to treatments.
- (c) in the case of colostrum, milk and dairy products, any destination provided that they have been subjected to a risk-mitigating treatment.

## SECTION 2

### OBLIGATIONS ON OPERATORS WITH REGARD TO ANIMAL HEALTH CERTIFICATES

within the same Member State, the competent authority may decide that an animal health certificate does not have to be issued

#### **Attestations of certificates:**

Health certificates for movements of consignments of **bovine animals from restricted zones I and II** outside those zones:

- (a) '**Bovine animals from restricted zone I** in compliance with Article 7 of special control measures for infection with LSDV laid down in Commission Implementing Regulation (EU) .../... *[Office of Publication: Please insert reference to this Regulation].*';
- (b) '**Bovine animals from restricted zone II** in compliance with Article 8 of special control measures for infection with LSDV laid down in Commission Implementing Regulation (EU) .../... *[Office of Publication: Please insert reference to this Regulation].*';

movements of consignments of bovine animals to a **slaughterhouse:**

- (c) 'Bovine animals from restricted zone in compliance with Article 9 of special control measures for infection with LSDV laid down in Commission Implementing Regulation (EU) .../... *[Office of Publication: Please insert reference to this Regulation].*';



Health certificates for movements of consignments of **germinal products** obtained from bovine animals from establishments located in restricted zones I and II outside those zones:

(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 for infection with LSDV as laid down in Article 10 of Commission Implementing Regulation (EU) .../... [*Office of Publication: Please insert reference to this Regulation*].’;

(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 for infection with LSDV as laid down in Article 10 of in Commission Implementing Regulation (EU) .../... [*Office of Publication: Please insert reference to this Regulation*].

Health certificates for movements of consignments of unprocessed animal **by-products** from bovine animals from restricted zones I and II outside those zones

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;

## SECTION 3

### SPECIFIC CONDITIONS FOR AUTHORISING MOVEMENTS OF CONSIGNMENTS OF BOVINE ANIMALS KEPT IN RESTRICTED ZONES I AND II OUTSIDE THOSE ZONES AND CHANNELLING PROCEDURES

Obligations of the **competent authority of establishment of origin**:

1. Set up a **channelling procedure**, under the control of the competent authorities of the Member States of the places of origin, passage and destination.
2. Ensure that:
  - (a) each **means of transport** has been individually **registered**. Sealed or GPS accompanied;
  - (b) the **transport** takes place:
    - (i) under the **supervision** of an official veterinarian;
    - (ii) **directly**, without stopping unless a rest period. For a rest period of one day or more the consignment through a restricted zone II, the animals shall be protected against attacks by vectors;
3. 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**;
  - (b) the **chain of command** in case of accidents during the transport;
  - (c) **immediate notification** to the competent authority of any accident.

## Obligations of the competent authority of the establishment destination concerning channelling procedures

The competent authority of the Member State of the place of destination shall:

- (a) **confirm each arrival** to the competent authority of the establishment of origin;
- (b) ensure that the bovine animals **remain in the establishment** of destination for at least **28 days**;
- (c) ensure that after the unloading the means of transport and any other equipment which have been used in the transport are **cleaned, disinfected** and treated with authorised **insecticides**.

**Means of transport** must be cleaned and disinfected and only animals or by-products of the same health status may be transported.

# ANNEX I RESTRICTED ZONES I and II.

## PART I. Restricted zone I

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### 1. 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 Hitri in the province of Shumen.
- The municipalities of Svishtov, Polsk Trambesh and Strazhitsa, in the province of Veliko Tarnovo.

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### 2. Greece:

#### The following regions in Greece:

- Region of Ionian Islands, excluding the regional unit of Kerkyra
- Region of North Aegean, excluding the regional unit of Limnos
- Region of South Aegean
- Region of Crete

# PART II

## Restricted zone II

### 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

#### A. The following regional units in Greece:

- Regional unit of Limnos
- Regional unit of Kerkyra

### 1. Bulgaria

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

## ANNEX II

### RULES FOR VACCINATION PLANS OF INFECTION WITH LUMPY SKIN DISEASE VIRUS

#### PART I

##### Information to be included in the vaccination plan:

- (a) the description and the results of the **assessment** performed;
- (b) the main **objectives** and targets;
- (c) **geographic** description;
- (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 and the number of establishments to be vaccinated;
- (g) the estimated **number of bovine animals**, their categories and age of animals to be vaccinated;

(h) **duration** of the vaccination:

(i) characteristics of the **vaccine**;

(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;

(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 matters appropriate to the situation.

## PART II

### Minimum requirements for infection with LSDV vaccination plans:

- (a) vaccination of **all bovine** animals;
- (b) vaccination of the **offspring** of vaccinated bovine animals older than four months;
- (c) revaccination of all bovine animals in accordance with the instructions of the manufacturer;
- (d) entry of the details for each vaccinated bovine in the dedicated **online database**;
- (e) establishment of an **increased surveillance** area of at least 20 km around the restricted zone where vaccination is carried out;
- (f) vaccine **coverage of at least 95%**, both at herd and at animal level.



## PART III

### Preliminary information to be provided to the Commission and the other Member States before starting vaccination

- (a) a brief **justification** to start the vaccination;
- (b) species of **bovine animals** that are to be vaccinated;
- (c) estimated **number** of bovine animals that are to be vaccinated;
- (d) estimated **duration** of the vaccination;
- (e) 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**.

# Thank you



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