



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE AND FOOD
BULGARIAN FOOD SAFETY AGENCY

**Official vaccination programme for prevention and control of Lumpy skin disease in
Bulgaria, 2023**

In accordance with CDR 2023/361

/update Nov 2023/

GENERAL INFORMATION:

Member State: **Republic of Bulgaria**

Disease: **Lumpy skin disease**

Implementation period: **2023**

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1. Description and the results of the assessment performed in accordance with Annex II of CDR 2023/361.

Further to the epidemiological situation in Bulgaria and the region in the past years and the occurrence of Lumpy skin disease (LSD) in 2016 in the country leading to serious economic and social consequences, Bulgaria has implemented an emergency protective vaccination of the entire bovine population for the prevention and control of LSD. Since 2016, the entire bovine population in the country has been a subject of annual vaccination. The current vaccination programme is a continuation of the vaccination programmes implemented annually in the period 2016 - 2022.

2. Objectives and targets: control and prevention against LSD.

The prevention and control activities for LSD are carried out within the implementation of the National Program for surveillance of Transboundary animal diseases (Foot-and-mouth disease,

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Sheep and goat pox , Peste des petits ruminants, Lumpy skin disease, Crimean-congo hemorrhagic fever) in Bulgaria, 2022-2024.

3. Geographic description of the vaccination zone – the vaccination is carried out on the whole territory of the country

4. Targeted species, number of establishments and kept animals of listed species to be vaccinated

The table below provides data on animal species, number of establishments/herds and estimated number of animals located in the vaccination zone, number of establishments/herds and estimated number of animals to be vaccinated in 2023.

Region	Animal species	Total number of herds	Total number of animals	Number of herds expected to be vaccinated	Number of animals expected to be vaccinated	Number of doses of vaccine expected to be administered	Number of adults expected to be vaccinated	Number of young animals expected to be vaccinated
BG	Bovines	49 992	735 749	49 992	735 749	760000	0	0

Table 1 – animal species, number of establishments/herds and estimated number of animals located in the vaccination zone, number of establishments/herds and estimated number of animals to be vaccinated in 2023

The minimum vaccine coverage planned is to be at least 95 % of the establishments keeping bovine animals representing at least 90 % of the bovine animal population in the country, as the vaccination programme foresees:

- Revaccination of the entire bovine population vaccinated in 2022;
- Vaccination of calves above 4 months of age born from vaccinated cows in the previous year;
- Vaccination of non-vaccinated bovine subject of international or intra-community trade.

5. Intended final use of vaccinated animals and products – the vaccinated animals and products do not pose a risk to public health. The animals will be kept for production purposes according to their technology designation.

6. Categories of animals exempted from vaccination and reasoning - n/a

7. The arrangements to administer the vaccine and the system to supervise the administration of the vaccine.

The vaccination will be carried out by registered private veterinarians under the supervision of the Regional Food Safety Departments.

The institutions and organizations responsible for the administration of the vaccines, the system of supervision and reporting are, as follows:

8.1 Bulgarian Food Safety Agency (BFSA):

8.1.1. HQ of BFSA, Animal Health and Welfare Directorate is responsible for:

- Developing, updating and controlling the implementation of the programme;

- Collaborating with the Legal Department for the organization of the tender procedures for purchasing and supplying the vaccine doses;

- Collecting and analyzing the data related to the vaccinated animals and administration of the vaccines;

8.1.2. Regional Food Safety Departments (RFSDs) are responsible for

- Organizing and controlling the implementation of the vaccination against LSD at the local level, including receipt, proper storage and distribution of the vaccines;

- Collecting, analyzing and reporting the data related to vaccinated animals and administration of the vaccines to HQ of the BFSA;

8.2 Bulgarian Veterinary Union (BVS)/registered veterinarians are responsible for:

- Conducting clinical examinations and vaccination against LSD;

- Recording the vaccination activities in the integrated information system of BFSA-VetIS.

- Reporting the data related to vaccinated animals and administered vaccine doses as well as the suspected occurrence of the disease and occurrence of adverse effects following administration of the vaccine.

7.3 National Diagnostic Research Veterinary Medical Institute (NDNIVMI): National Reference Laboratory "Foot-and-mouth disease and Peste des petits ruminants" is responsible for:

- Maintaining constant diagnostic readiness;

- LSD laboratory-diagnostic tests of all samples received under the program;

- Informing the HQ of the BFSA and RFSDs about the results of the laboratory tests;

- Provides summary data on the laboratory tests performed.

8. The envisaged duration of the vaccination, from the start of the vaccination to the end of the surveillance carried out after vaccination.

The programme foresees the vaccination to be discontinued at the end of 2023 followed by clinical and laboratory surveillance within 8 months according to the provisions of Part 4 of Annex IX of CDR 2023/361.

9. Summary of the characteristics of the vaccine, including the name of the product(s) and the name of the manufacturer(s), and routes of administration.

Live attenuated homologous vaccine against the LSDV is to be used, namely: BOVIVAX LSD-N, produced by MCI Sante Animale, market authorization № 0022-3153, issued in accordance with Article 26 of Regulation (EU) 2019/6.

- Method of application of the vaccine: according to the manufacturer's instructions.

- Vaccine quality control - upon arrival and acceptance of the vaccine before each vaccination campaign, a documentary and physical control are carried out in a central storage warehouse, according to the instructions of the HQ of the BFSA.

10. The details of the reinforced clinical and laboratory surveillance referred to in Article 9, point 1(c) and Article 10, point 2(b) of CDR 2023/361

There are no additional disease-specific requirements for clinical and laboratory surveillance during vaccination according to Part 2, Annex IX of CDR 2023/361. A clinical examination including a check of the records relating to production and health kept by the holding, including an evaluation of its clinical history and clinical examinations of the animals will be carried out before the vaccination.

Passive surveillance is in place, the farmer/operators are obliged to notify any suspicions to the registered/private or official veterinarian as well as any post-vaccine adverse reaction.

Laboratory methods to be used:

- PCR (polymerase chain reaction) – a molecular method for determining the presence of the virus genome. It is performed on blood (whole blood), organ samples, nodules. The method is applied when the disease is suspected.
- DIVA PCR – a molecular method for differentiating between vaccine and field strains. It is used for post-vaccination adverse reactions.
- ELISA (enzyme-linked immunosorbent assay) – a serological method for determining the presence of antibodies against the virus. Performed on serum samples.

11. Hygiene and biosecurity rules

The veterinary requirements for biosecurity measures are stipulated into the national law ([Ordinance 44 for the veterinary requirements in animal holdings](#)). The holdings are subject to official inspections for biosecurity measures with frequency based on the risk assessment.

12. Record keeping system on the vaccination

The vaccination against LSD is accompanied by a system for traceability to ensure satisfactory administration of the vaccines and post-vaccination surveillance.

Standard operating procedure lays down the rules for transport, storage, administration, and reporting of the vaccination against LSD. The vaccine doses are distributed from the storehouse accompanied by transmission-reception protocol and stored at the temperature specified by the manufacturer (from 4 to 8 degrees Celsius). The temperature values during the storage are monitored, measured, and recorded in a daily protocol. The RFSDs organize the distribution of the doses to the registered veterinarians, which is documented with a transmission-reception protocol.

The animal owner/farm operators are obliged to keep a register on treatment with VMPs including vaccination and make it available for official control.

The registered veterinarians record the data on vaccination in the integrated information system of the BFSA VetIS.

The minimum vaccination data required to be recorded in accordance with the Annex V of the CDR 2023/36 consist:

- Individual identification, in accordance with Regulation (EU) 2019/2035;
- Registration number of the establishment;
- number of vaccinated animals;
- number of vaccine doses administered;
- type and name of the vaccine;
- date of vaccination.

The adverse reactions are reported to the RFSD via "Report on suspected and serious or unexpected adverse reactions in humans and animals after the use of VMP" approved by Order of the Executive Director of BFSA.

13. The restrictions on movements of vaccinated animals and products thereof and other risk-mitigating measures to control the potential spread of disease to be put in place and their duration

The entire bovine population and products are subject to movement restrictions according to Article 13 of CDR 2023/361 and derogations from this article listed in Part 3 of Annex IX of the same Regulation.

14. Communication campaign

The communication campaign aims to describe the procedures related to conduction the vaccination, to educate on the use of vaccination as a supplement to the control measures against LSD; to inform to industry and public about the benefits of vaccination. The target group for communication are farmers, bovine associations, traders, transporters, government department, registered veterinarians, media and public.

As the LSD vaccination programme for 2023 is a continuation of the vaccination programmes carried out annually within the period 2026-2022, no specific campaigns to be planned in 2023. Information related to the Programme for control of LSD is published on BFSA's website: <https://bfsa.egov.bg/wps/portal/bfsa-web/activities/animal.health.and.welfare/animal-health>

15. Other matters deemed appropriate to the situation: n/a