

# Frequently Asked Questions (FAQ) on Lumpy skin disease (LSD) Vaccination

## Benefits, availability, access and vaccine types

- 1. What are the benefits of LSD vaccination?
  - the most effective tool for LSD control and potential eradication;
  - Easier to implement and more effective than other measures (i.e. stamping out) and, in most cases, less costly.
  - Reduces the total number of susceptible animals within the population, thus preventing entry (in the case of preventive vaccination) and spread of the disease;
  - Protects the animals from getting infected with LSD and further vector-transmission of LSD virus, thus preventing direct and indirect economic losses.
- 2. What type of LSD vaccines are available commercially and what do you mean by homologous and heterologous LSD vaccines?

<u>Chapter 3.4.12</u> of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE Manual), sets out the requirements for the vaccines to be used for LSD control. An appropriate vaccine to control LSD should provide good immunity for cattle against LSD, be safe to use for all cattle breeds, ages and pregnant animals, and be correctly labelled. Live attenuated strains of capripoxvirus have been used as vaccines to control LSD. The capripoxviruses are cross-reactive within the genus and consequently, it is possible to protect cattle against LSD using strains of capripoxvirus derived from cattle as well as from sheep or goats.

Homologous vaccines mean you are vaccinating cattle with a LSDV-based vaccine, or sheep/ goat with a sheep/ goat pox virus based vaccine. Heterologous means you are using a sheep pox/ goat pox virus based vaccine to protect cattle against LSDV. For clarity, we will refer here to the virus used in the vaccine rather than to heterologous/homogenous denomination. For the purpose of LSD prevention and control, LSD vaccines are based on Neethling-type strains of LSD virus (homologous vaccine); Vaccines based on strains of either sheep pox virus (SPPV) or goat pox virus (GTPV) (heterologous vaccines) may be used as an alternative in those countries where both LSD and sheep and goat pox occur or for those countries that already have manufacturing capacity for these vaccines. However, if a sheep/goat pox virus vaccine is selected for use in cattle, the vaccine product should be well characterised, the dose adjusted and the protection provided by the vaccines should be evaluated using a vaccine challenge trial.

There is no **Differentiating Infected from Vaccinated Animals (DIVA)** vaccine available in the market. But PCR-based DIVA assays with the current vaccines for discrimination between field and vaccine virus strains exist (Agianniotaki et al., 2017). To do so, care must be exercised in selecting the regions for PCR targeting.





**Live-attenuated** vaccines (LSD and sheep/goat pox vaccines) are commercially available. While **inactivated LSD vaccines** are not yet described in the *OIE Manual*, some manufacturers have developed inactivated vaccines against LSD that countries may be willing to consider. Inactivated vaccines may be preferred in LSD-free countries when there is risk of LSD introduction from neighbouring countries. Inactivated vaccines generate a shorter duration of immunity than live attenuated vaccines. Therefore, initial vaccinations comprise two vaccinations one month apart and then revaccination every six months is required to maintain immunity (Hamdi *et al.*, 2020).

#### 3. Does the OIE have an emergency LSD vaccine bank?

The OIE does not have a vaccine bank for LSD. Countries are invited to launch a national procurement process to buy LSD vaccines. The time needed for this process should be taken into account in order to prepare the call for tender as early as possible in order to have timely access to the vaccines.

For vaccine quality control, the OIE can facilitate contact with OIE Reference Laboratories in South Africa and UK and a Collaborating Centre in Belgium (Validation, Quality Assessment and Quality Control of Diagnostic Assays and Vaccine for Vesicular Diseases in Europe).

## **LSD Vaccination Programme**

#### 4. When and how cattle should be vaccinated against LSD?

The recommendations of the vaccine manufacturer should always be followed for those countries using LSD vaccination. For most of the vaccines:

- Annual vaccination of the adult cattle will protect animals from LSD.
- Calves from vaccinated animals or naturally infected mothers should be vaccinated usually at the age of 3 to 6 months, depending on the vaccine. Calves from unvaccinated dams can be vaccinated at any age.
- Newly purchased animals should be vaccinated 28 days before the introduction to the herd.
- Animals should be vaccinated 28 days before the transport or movement to another place.
- Same dosage and protocol should be applied to domestic buffaloes as for cattle.
- Pregnant, healthy cows/ heifer can be safely vaccinated.
- 5. How many doses of LSD vaccine provide full protection to susceptible animals, and how long does protection from LSD vaccine last?

Here again, please follow the recommendations from the manufacturer.

Most of the time, a single dose of live attenuated LSD vaccine should confer adequate protection to the vaccinated animals after three weeks of vaccination and for at least one year. Annual vaccination is recommended in affected countries, and harmonized vaccination campaigns across regions provide the best protection.





As an example: Once some Balkan Countries reached a vaccination coverage higher that 80 % they controlled LSD within one to three months."

#### 6. In which context is preventive vaccination recommended in an LSD-free country?

In accordance with Article <u>11.9.3</u>. of the *OIE Terrestrial Animal Health Code*, a country practicing vaccination is not considered as an LSD-free country or zone. Therefore, a country or zone carrying out LSD vaccination will have to trade in compliance with the provisions for countries not free from LSD, such as the provisions of Article <u>11.9.6</u>. for live bovines and water buffaloes.

Therefore, preventive vaccination should be only considered after evaluation of the specific country situation and local context. If LSD is widely present in a neighbouring country, threatening the LSD-free country, initiating preventive vaccination in protection zones (in accordance with <u>Chapter 4.4.</u> and Article 4.4.6. of the *OIE Terrestrial Animal Health Code*) along the borders, with an implementation of strict movement control of animals to the interior part of the country should be considered. If successfully implemented, it may prevent the introduction of LSD in the country (e.g.: Croatia who implemented preventive vaccination, prevented LSD introduction and stopped its further spread in Europe).

#### 7. Can we inject LSD and FMD vaccine at the same time in the same animal?

There is limited scientific publication on this matter. However, the vaccination of two different vaccines at the same time in the same animal had been practiced for many years, for obvious practical and logistical reasons. The immune system of a healthy animal is capable of responding to two antigens at the same time. However, it is critical not to mix the vaccines (except specified otherwise by the manufacturer).

Israël has conducted combined LSD and FMD vaccination, following the rules below: LSD and FMD vaccines are not mixed at any stage; separate syringes and needles are used; vaccines are injected into the neck, but far from each other and preferably on different sides of the neck. From this practical experience, an OIE LSD Expert indicated that there was no report of vaccination failure that could be linked to this combined vaccination (Galon, 2021).

### Immune response and vaccine efficacy

#### 8. How can you monitor the efficacy of LSD vaccination or herd immunity post-vaccination?

Active clinical surveillance is a very effective tool to assess the efficacy of vaccination campaign. Due to the highly characteristic clinical manifestation of LSD, a thorough physical examination carried out by experienced veterinarians is considered as an effective tool for active clinical surveillance. Passive surveillance provides an additional support if LSD awareness level to identify typical LSD clinical signs are high, and the farmers, field vets and others who come into contact with cattle are willing to report any suspicious cases.





Antibody ELISA can be used for post-vaccination monitoring 2 to 3 months after vaccination taking into account that not all animals will seroconvert.

#### 9. Can live-attenuated vaccine be used safely on infected animals (with or without any clinical signs)?

Most of the vaccine manufacturers recommend vaccination of only of healthy animals with a live vaccine.

Clinically infected animals will be naturally immunised. Once these animals recover from disease it is recommended that they receive an annual vaccination booster as we do not know how long natural immunity lasts.

Non-clinical animals: There is no evidence that vaccination of latently infected or sub-clinically infected animals would lead to severe disease. Due to the risk of spread of the LSD virus via needles used on non-clinical animals, it is critical to only use single-use needles.

#### 10. Can live attenuated vaccine regain its virulence or lead to recombination with field virus?

A study undertaken in Europe from 2016-2020 on three live attenuated LSD vaccines did not show regaining of LSD vaccine strain's virulence or recombination with field virus. One Croatian study reported that after passage of the vaccine virus in cattle, the genome of vaccine virus remained totally attenuated with 100% similarity to the original vaccine virus (Lojkic *et al.*, 2018). A recombination of vaccine and field viruses has been reported by Russian Scientists (Sprygin *et al.*, 2018). There is still much we do not understand how and when these events are occurring, therefore more detail studies are required to investigate the importance of this findings.

The Neethling-type strain vaccine has been used for more than 60 years, vaccinating millions of animals, and there is NO reports of vaccine virus regaining its virulence.

#### 11. Can vaccinated animals still get LSD infection?

Development of full protection from the vaccine takes approximately three weeks. During this time, cattle may still get infected by the field virus, and may show clinical signs despite being vaccinated. Some animals may also be incubating the virus when vaccinated, and in such cases clinical signs are detected in less than ten days after vaccination.

In some exceptional cases, the vaccination may not provide adequate protection, resulting in a clinical disease. There may be number of reasons for the vaccination failure which may be associated with either the vaccine itself (the level of attenuation is too low or high, low titre of vaccine seed virus or contaminated vaccine batch), host response (vaccine may be administered correctly but the animal may fail to mount an appropriate immune response), and due to lapses in delivery of vaccines (route of administration or dosage, timing, and cold chain maintenance during the storage and transport of vaccines). Clinical signs may also be due to other diseases, such as bovine herpesvirus 2, also called pseudo LSD. Vaccination failure has therefore to be properly investigated to identify its source and cause.





## Side effects and negative impact of LSD vaccination

#### 12. What are the common side effects of LSD vaccination?

Live-attenuated LSD vaccines may cause mild adverse reactions in cattle. Local reaction at the vaccination site is common and acceptable. Common adverse reactions include temporary fever and a brief drop in milk yield. Some animals may show mild generalised reaction called **Neethling response**. This is rare and usually involves appearance of superficial and smaller skin lesions, different from those caused by the fully virulent field strain. They disappear within 2-3 weeks without converting into necrotic scabs or ulcers. Side effects are seen only when animals are vaccinated with LSD vaccine for the first time and are hardly seen after the revaccination. Adverse reactions and side effects of LSD vaccination should be well explained to farmers in advance to prevent their reticence to have their animals vaccinated and to prevent loss of trust if this happens.

# **Exit Strategy**

#### 13. When can an LSD vaccination programme be stopped?

The FAO "*Guide to develop lumpy skin disease emergency vaccination plan*" provides guidance to member countries on how to plan and implement emergency LSD vaccination as a response to LSD outbreaks within the national territory, as well as when outbreaks are detected in the neighbouring countries. A country that wishes to regain freedom from LSD (for the entire territory or a zone) should cease vaccination and forbid further LSD vaccination in the country. LSD vaccination withdrawal decision and tactics would depend on individual country situation and risk (estimated through specific risk assessment).

The important criteria/ discussion points should be:

- Was the virus circulation stopped after emergency vaccination?
- Is the likelihood of introduction or re-introduction of LSD sufficiently reduced, based on the situation in neighbouring countries?
- Is the sensitivity of surveillance (early detection) high enough to detect re-emergence?
- Is the level of preparedness adequate in case of re-emergence (contingency plan, early response), with special attention on containing disease, maintaining a vaccine stock and carrying out emergency vaccination?

#### 14. How to regain LSD-free status following effective LSD control, including vaccination?

The ideal outcome of the control strategy in affected countries is to eventually gain/regain LSD freedom in the country (or zone). The requirements to gain/re-gain freedom of LSD are described in the OIE *Terrestrial Animal Health Code*.

Timeline for recovery would depend whether a stamping-out policy was implemented or not (and on the surveillance in place). If a stamping out policy was implemented, recommendations (and timelines) from





Article <u>11.9.4</u> should be followed; if there was no stamping-out policy, recommendations (and timelines) from Article <u>11.9.3</u>. should be followed.

The specific case of a country having conducted a preventive vaccination campaign without having detected the presence of LSD in its territory is also covered in Article 11.9.4.

Upon fulfilling the requirement of the relevant articles (as described above) of OIE *Terrestrial Animal Health Code*, countries may wish to self-declare freedom from LSD (as a country or for a zone). Countries should document compliance of their Veterinary Services with the provisions of Chapters <u>1.1</u>., <u>3.1</u>, <u>3.2</u>. and <u>11.9</u>. of the Terrestrial Code and Chapter <u>3.4.12</u>. of the *Manual*.

OIE Members may request the OIE to publish this self-declaration to give it more visibility. To do so, they should follow the dedicated <u>Standard Operating Procedures</u>. The responsibility contained in a self-declaration lies entirely with the OIE Delegate of the Member concerned and does not reflect the official opinion of the OIE.

