European Union Lumpy Skin Disease and other exotic diseases antigen/vaccine banks
Current status, policy and future considerations

Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards
European Medicines Agency (31 January 2017, London, UK)
EU Lumpy Skin Disease (LSD) vaccine bank

- History
- Structure - Operation
- Vaccine grants to date

Other EU vaccine / antigen banks

- Foot-and-Mouth Disease
- Classical Swine Fever

General EU Policy on vaccine banks

Future trends on EU vaccine banks
LSD in the EU: situation in 2013 – 2015, disease spread

May 2015 (Reported in June)

Nov – Dec 2014, in the areas not under the effective control of the Government of the Republic of Cyprus
LSD in the EU

Lumpy Skin Disease outbreaks in 2015

(Aug-Dec 2015)

1st Occurrence in continental Europe
(Greece, 117 outbreaks)
LSD outbreaks in SE Europe (April – late Nov 2016)

- Greece: 104 (last on 25/11/2016)
- Bulgaria: 217 (last on 1/8/2016)
- FYROM: 1.591 (Sep report)
- Serbia: 225 (last on 01/10/2016)
- Kosovo*: 76 (Aug report)
- Montenegro: > 400
- Albania: 1.932 (Oct report)

(* This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence).
LSD vaccination in South East Europe – Situation as at mid Nov 2016

Vaccination completed in:
- Bulgaria
- Greece (Northern part)
- Serbia
- FYROM
- Montenegro
- Kosovo
- Croatia

Vaccination in progress in:
- Albania
- Southern part of continental Greece

EU LSD vaccine bank - History

LSD outbreaks as at 1 Jan - 30 Nov 2016 (ADNS)
LSD in the EU in 2016-2017 (Situation as at Jan 2017)

- All affected countries quickly resorted to vaccination against LSD
- Croatia, a country not affected by LSD became the first to implement preventive vaccination
- Further spread of LSD to the north or west seems to be halted for the moment (vaccination + winter)
- No new LSD outbreaks reported in those affected countries where full vaccination coverage has been achieved (one LSD outbreak reported in ADNS in early 2017, under investigation)
- Disease spread reported from countries with low vaccine coverage (e.g. Albania), also sporadic cases reported from the former Yugoslav Republic of Macedonia and isolated cases in non-vaccinated animals (e.g. Greece)
- Affected countries where vaccination is still in progress put their efforts to complete their vaccination campaign as soon as possible and achieve high vaccine coverage.
EU LSD vaccine bank - History

European Commission (DG SANTE) response to LSD occurrence in continental Europe in 2015 -2016

- Legal measures
  Com Implementing Decisions on safeguard measures and vaccination

- Expert support :
  4 CVET LSD Missions in 2016 (Greece, Serbia, FYROM, Romania)

- EFSA expert opinions

- Training (EU MS+ non-EU Member countries)
  - 4 BTSF seminars in Greece (1 in 2015 + 3 in 2016)
  - Workshop on LSD (Sofia 22-25 November 2016)
  - 5 Sustained Technical assistance Missions (STMs) in Montenegro, Bosnia & Herzegovina, Kosovo*, Albania and Moldova in 2016.

- International coordination (EU MS+ non-EU Member countries)
  - Joint EFSA –DG SANTE Workshop (Brussels, 11-12 May 2016)
  - Ministerial Conference on Lumpy Skin Disease, 8-9 Sep 2016, Sofia-Bulgaria.

- Appointment of EURL for diseases caused by capripox viruses (lumpy skin disease and sheep and goat pox) [COMMISSION REGULATION (EU) 2017/140 of 26 January 2017]

- EU LSD Vaccine bank (April 2016)
EU LSD vaccine bank - History

Legal Measures

Implementing Decisions (now repealed) for GREECE

COMMISSION IMPLEMENTING DECISION (EU) 2015/1423 of 21 August 2015 concerning certain interim protective measures against lumpy skin disease in Greece

COMMISSION IMPLEMENTING DECISION (EU) 2015/1500 of 7 September 2015 concerning certain protective measures against lumpy skin disease in Greece and repealing Implementing Decision (EU) 2015/1423

Amended by:
- Commission Implementing Decision (EU) 2015/2055 of 10 November 2015
- Commission Implementing Decision (EU) 2015/2311 of 9 December 2015
- Commission Implementing Decision (EU) 2016/1116 of 7 July 2016
- Commission Implementing Decision (EU) 2016/1255 of 29 July 2016

COMMISSION IMPLEMENTING DECISION (EU) 2015/2055 of 10 November 2015 laying down the conditions for setting out the programme for emergency vaccination of bovine animals against lumpy skin disease in Greece and amending Implementing Decision (EU) 2015/1500

Amended by:
- Commission Implementing Decision (EU) 2015/2311 of 9 December 2015
- Commission Implementing Decision (EU) 2016/1116 of 7 July 2016
- Commission Implementing Decision (EU) 2016/1255 of 29 July 2016
EU LSD vaccine bank - History

**Legal Measures**

**Implementing Decisions *(now repealed)* for BULGARIA**

COMMISSION IMPLEMENTING DECISION (EU) *2016/645* of 22 April 2016

concerning certain protective measures against lumpy skin disease in Bulgaria

Amended by:


COMMISSION IMPLEMENTING DECISION (EU) *2016/1183* of 14 July 2016

approving the **emergency vaccination programme** against lumpy skin disease of bovine animals in Bulgaria and amending the Annex to Implementing Decision (EU) *2016/645*
New Commission Implementing Decisions on LSD

- COMMISSION IMPLEMENTING DECISION EU (2016)/2008, of 15 November 2016 concerning animal health control measures relating to lumpy skin disease in certain Member States

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

Advantages

- Uniformity (one set of measures for LSD across the EU)
- Proportionality (establishment of specific rules for affected zones and free with vaccination zones respectively)
- Sustainability (reduced impact on trade)
- Flexibility (e.g. possibility for bilateral agreements)
- Lifting – refining of measures related to safe / low risk products (meat, milk)

Note: All measures of Directive 92/119 on stamping out, suspicion, confirmation of LSD (e.g. surveillance – protection zones, measures and duration thereof) remain in place.
LSD measures at EU level


**Free zones with Vaccination (Part I):**
- Croatia
- Bulgaria (certain areas in the North and East part)

**Infected zones (Part II):**
- Continental Greece (including the island of Limnos)
- Bulgaria (excluding the "free with vaccination" zones)

- **Croatia**
- **Bulgaria**
- **Greece**

**LSD outbreaks**
2015 - 30.11.2016 (ADNS)
**EFSA Opinions on LSD**

EFSA Opinions on LSD (at the request of the European Commission)

- **Scientific Opinion on lumpy skin disease** ([EFSA Journal 2015; 13(1):3986](#)), published 13 Jan 2015. The opinion provides an update on the characterisation of the disease assessing the risk of introduction into the European Union (EU) and the speed of spread, the risk of becoming endemic and its impact.

- **Urgent advice on lumpy skin disease - EFSA Panel on Animal Health and Welfare** ([EFSA Journal 2016; 14(8):4573](#)), published 9 Aug 2016. The opinion concludes that total stamping out and partial stamping out result in a similar probability of eradicating LSD only when vaccination is evenly applied so that 95% of the farms are vaccinated with 75% of vaccinated animals effectively protected. In the same opinion it is also stressed that vaccination is the most effective option in reducing LSDV spread provided that it is implemented upon the entire susceptible population in regions at risk for LSDV introduction or affected by LSDV and high animal- and farm-level vaccination coverage is achieved.

- **Additional mandate for an updated epidemiological analysis of the LSD data** (2 reports to be produced, one in early 2017 and the other in early 2018).
EU LSD vaccine bank—Structure & Operation

- **Basic Concept of the EU LSD vaccine bank:**
  "To support the *initial stages of an LSD vaccination campaign* before the competent authorities of the country concerned can initiate national procurement of LSD vaccines"

- **Vaccines used**
  Homologous – live attenuated vaccines against Lumpy Skin Disease (EFSA opinion + OIE specifications)
  Note: no LSD vaccines with an EU marketing authorisation (use in the EU under Dir 2001/82/EC, art 8).

- **Vaccine Supply**
  - 1st Tender (launched on Dec 2015, contract signed on April 2016 for 400,000 doses + extension for another 200,000 doses signed in June 2016)
  - 2nd Tender (launched on July 2016, contract signed on Nov 2016 for up to 525,000 doses)
  - 3rd Tender (to be launched soon for up to ~2,3 million doses)

- **Vaccine Production- Storage -Consignment**
  Vaccine produced in the supplier's facilities within set contractual time and stored in dedicated storage facility within own premises (initial vaccine bank stock).
  Consignments carried out as requested by EC within minimum contractual time.
  Replenishment of stock according to contract rules (minimum time).

In cases of emergency, where the available vaccine bank stock cannot cover the needs according to contractual terms a consignment can be arranged directly from the supplier's own stock.
## EU LSD Vaccine Bank grants

**European Union Lumpy Skin Skin Disease Vaccine Bank**

*(Operational since April 2016)*

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of doses granted</th>
<th>Delivery date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>150,000 + 50,000</td>
<td>April &amp; Dec 2016</td>
</tr>
<tr>
<td>Greece</td>
<td>100,000 + 50,000</td>
<td>April, July &amp; Dec 2016</td>
</tr>
<tr>
<td>the former Yugoslav Republic of Macedonia</td>
<td>50,000</td>
<td>May 2016</td>
</tr>
<tr>
<td>Serbia</td>
<td>50,000</td>
<td>June 2016</td>
</tr>
<tr>
<td>Kosovo*</td>
<td>25,000</td>
<td>July 2016</td>
</tr>
<tr>
<td>Albania</td>
<td>25,000 + 50,000</td>
<td>July &amp; Dec 2016</td>
</tr>
<tr>
<td>Montenegro</td>
<td>25,000</td>
<td>July 2016</td>
</tr>
<tr>
<td>Croatia</td>
<td>50,000</td>
<td>Sep 2016</td>
</tr>
</tbody>
</table>

**625,000 doses of LSD vaccine (live-homologous) already granted to various countries**

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*EMA - Stakeholder group on LSD vaccines (London, 31 January 2017)*
Other EU vaccine /antigen banks

- **Foot-and-Mouth Disease (FMD)**
  antigen and vaccine bank

- **Classical Swine Fever**
  Vaccine bank
Other EU vaccine /antigen banks

Foot-and-Mouth Disease (FMD) antigen and vaccine bank

Other EU vaccine /antigen banks

Foot-and-Mouth Disease antigen and vaccine bank

Currently stored ~ **18.000.000 doses** of 9 foot-and-mouth disease (FMD) virus antigen **strains** in the Union antigen and vaccine bank established in accordance with Article 80(1) of Council Directive 2003/85/EC.

Purchase and supply of FMD virus antigens to the bank is based on **procurement (tendering) procedure**.

Information on quantities and strains of FMD virus antigens stored in the bank shall be treated as **classified** (Article 80(3)).
Foot-and-Mouth Disease antigen and vaccine bank

Until 30 April 2017 there will be 5 additional strains supplied to the bank under procurement that has been carried out in 2016 (11.000.000 doses).

Next procurement is planned for 2017 in order to purchase and supply FMD virus antigens to the bank until the end of 2017 and additional quantities until the end of 2018.

Selection of strains of FMD virus antigens to be stored in the bank is made based on vaccine strain recommendations of World Reference Laboratory for FMD/ EuFMD/ FMD EURL.
Operation of the vaccine bank in 2016

Mauritius

FMD was reported for the first time on 7th July 2016 on the island of Rodrigues (>158 outbreaks). It subsequently spread to the main island of Mauritius on 1st August where five outbreaks were reported up to 5th September. The virus was identified as FMD type O (O/ME-SA/Ind-2001d)

EU provided 300 000 doses of bivalent O3039/O-Manisa oil adjuvanted vaccine
CSF vaccine bank

Since 31/12/2015 the Commission has a contract for:

- the purchase & storage of 1,000,000 doses of live attenuated vaccine against CSF;
- the replacement of 1,000,000 doses of live attenuated vaccine against CSF

- Contract duration: 60 months

**Basic concept**: rapid delivery of vaccine in case of emergency vaccination of domestic pigs

**Vaccine**: classical swine fever virus (CSFV) live attenuated strain indicated for active immunisation of pigs against classical swine fever (the vaccine has an EU Marketing Authorisation)
General EU Policy on vaccine banks (1)

- New animal health challenges from recent incursions of exotic diseases (e.g. Lumpy Skin Disease) in EU Member States
- Several exotic diseases are present or endemic in the EU neighbouring countries (Foot and Mouth Disease, Peste des Petits Ruminants, Sheep Pox e.t.c.)
- Proactive approach, to be prepared for use of all available means for disease control, including vaccination, as and when appropriate.
- Vaccination is not a universal solution for all animal diseases, however recent experience has shown that it may be inevitable for some of them (particularly vector-borne diseases).
- Vaccine banks can be a valuable tool in supporting the early stages of a country's vaccination campaign against an exotic disease.
- Vaccine banks are meant to support the initial stages of an LSD vaccination campaign before the competent authorities of the country concerned can initiate national procurement of LSD vaccines (not a substitute for national procurement procedures).
General EU Policy on vaccine banks (2)

The decision on the creation and maintenance of an EU vaccine bank has to be examined on a case by case basis for each disease taking into account:

- The EU legal framework
- The disease epidemiology (transmissibility & mode of transmission, spread, occurrence history, host range, immunity e.t.c.)
- The available scientific knowledge and available tools in the areas of diagnosis (e.g. tests), control (e.g. vaccines) e.t.c.
- The available resources
- A cost–benefit analysis (when possible !!)
- Any other relevant factor

Our mission: to support the control of communicable disease using the most appropriate means (including vaccine banks as and when indicated) in the best possible, cost–effective manner.
Future Trends on EU vaccine banks (1)

Lumpy Skin Disease:

- More sophisticated vaccine requirements. Active involvement of the EURL in quality / safety controls.

- Tender for 2.3 million doses (to be published in https://etendering.ted.europa.eu/general/page.html?name=home)

Note: The South East Europe countries that vaccinated in 2016 are expected to repeat vaccination campaigns in 2017.

Future Trends on EU vaccine banks (2)

Peste des Petits Ruminants:
- New EU vaccine bank to be created
- Planned to be operated under the same principles like the LSD vaccine bank
- Call for tender is planned for early 2017 for 200,000 PPR vaccine doses initial purchase and up to 4 additional replacements upon request from the Commission = 1,000,000 doses maximum for a period of up to 48 months (4 years). To be published in https://etendering.ted.europa.eu/general/page.html?name=home

Sheep pox
- Creation of an EU vaccine bank under examination
EU Policy on Bluetongue

Future Trends on EU vaccine banks (3)

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’)

Listing and categorisation of diseases in the framework of the Animal Health Law and possible review of measures
THANK YOU