



Vaccination as a tool against vector borne diseases in the EU

VECTOR – BORNE DISEASES *How to live with them*

International Conference

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Andrea GAVINELLI
European Commission
Directorate-General for Health and Food Safety
G3 – Official controls and eradication of diseases in animals

- **Importance of Vector-Borne Diseases (VBDs) for the EU**
- **EU Legal framework for VBDs**
- **Vaccination against VBDs: modalities**
- **Case study: Lumpy Skin Disease**
- **Future priorities**

VBDs constant pressure in the EU

- **Incursion of new VBDs or new types of existing VBDs (e.g. *Lumpy Skin Disease*, *new serotypes of Bluetongue*, *African Horse Sickness*)**
- **Recurrence of VBDs epidemics (e.g. *Bluetongue*)**
- **Occurrence of VBDs with a zoonotic potential (e.g. *West Nile Fever*)**
- **Restrictions in place to prevent entry of various VBDs into the EU via commercial pathways (e.g. *trade restrictions on live animals' imports against various VBDs*)**
- **Direct losses (morbidity-mortality) + indirect losses (trade restrictions)**

Significant resources are allocated for VBDs in the EU in relation to :

- **Surveillance measures**
 - **Control measures (stamping out, vaccination, awareness campaigns e.t.c.)**
 - **Scientific assessment and Risk analysis (e.g. EFSA)**
 - **Research**
- e.t.c.**

**SURVEILLANCE AND CONTROL MEASURES
OFTEN ACCOMPANIED BY EU CO-FINANCING**

Current EU legal framework for VBDs

Current EU legal framework = Disease-specific legal acts , e.g. :

- **Dir. 92/119/EEC** (*Lumpy Skin Disease, Rift Valley Fever*)
- **Dir. EEC 2000/75/EC** and **Reg. (EC)1266/2007** (*Bluetongue*)
- **Dir. 92/35/EEC** (*African Horse sickness*)
- **Dir 2009/156/EC** (*Equine Encephalitis of various types*)

e.t.c....

Legal framework for VBDs following the adoption of Regulation (EU) 2016/429 (Animal Health Law - AHL)

Ongoing procedures for various acts directly or indirectly connected to the management of VBDs

Part AHL	Act	Status
1	DA on list of animal diseases	COMPLETED
	IA on categorisation of diseases	COMPLETED
2	DA on surveillance	ONGOING
3	DA on disease control	ONGOING
4/1	DA on establishments and I&R of animals	ONGOING
	IA on I&R of animals	ONGOING
	DA on Germinal Products (establishments, traceability, movements)	ONGOING
	IA on Germinal Products (traceability, movements)	ONGOING
	DA on movements of terrestrial animals	ONGOING
4/2	DA on aquaculture establishments	ONGOING
	DA on movements of aquatic animal	ONGOING
5	DA on entry into the EU	ONGOING

**Legal framework for VBD following the adoption of Regulation (EU) 2016/429
(Animal Health Law - AHL)**

**List of animal diseases, disease categories, list of
animal species**

Act	Status
<i>DA on list of animal diseases</i>	COMPLETED
<i>IA on categorisation of diseases</i>	COMPLETED

List of animal diseases (63 animal diseases listed)

- Regulation (EU) 2018/1629 published on 31/10/2018

Categories of animal diseases and list of species

- Implementing act (*assigning to each listed disease a category and animal species of relevance*)
 - Voted in PAFF Committee
 - To be adopted on 3/12/2018 and published in OJ soon

12 VBDs LISTED AND CATEGORISED

DISEASE CATEGORISATION *(Animal Health Law)*

- (1) **'category A disease'**: a listed disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected, as referred to in Article 9(1)(a) of Regulation (EU) 2016/429;
- (2) **'category B disease'**: a listed disease which must be controlled in all Member States with the goal of eradicating it throughout the Union, as referred to in Article 9(1)(b) of Regulation (EU) 2016/429;
- (3) **'category C disease'**: a listed disease which is of relevance to some Member States and for which measures are needed to prevent it from spreading to parts of the Union that are officially disease-free or that have eradication programmes for the listed disease concerned, as referred to in Article 9(1)(c) of Regulation (EU) 2016/429;
- (4) **'category D disease'**: a listed disease for which measures are needed to prevent it from spreading on account of its entry into the Union or movements between Member States, as referred to in Article 9(1)(d) of Regulation (EU) 2016/429;
- (5) **'category E disease'**: a listed disease for which there is a need for surveillance within the Union, as referred to in Article 9(1)(e) of Regulation (EU) 2016/429.

12 VBDs LISTED AND CATEGORISED - 3 "subgroups"

DISEASE	CATEGORY	SPECIES AND GROUP OF LISTED SPECIES	LISTED VECTOR SPECIES
Infection with Rift Valley fever virus	A+D+E	<i>Perissodactyla, Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Hippopotamidae, Moschidae, Proboscidea</i>	Culicidae
Infection with lumpy skin disease virus	A+D+E	<i>Bison ssp., Bos ssp., Bubalus ssp.</i>	Haematophagous arthropods
African horse sickness	A+D+E	<i>Equidae</i>	Culicoides spp.
African swine fever	A+D+E	<i>Suidae</i>	Ornithodoros
Infection with bluetongue virus (serotypes 1-24)	C+D+E	<i>Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae, Tragulidae</i>	Culicoides spp.
Infection with epizootic haemorrhagic disease virus	D+E	<i>Antilocapridae, Bovidae, Camelidae, Cervidae, Giraffidae, Moschidae, Tragulidae</i>	Culicoides spp.
Surra (<i>Trypanosoma evansi</i>)	D+E	<i>Equidae, Artiodactyla</i>	Tabanidae
Equine infectious anaemia	D+E	<i>Equidae</i>	Tabanidae
Venezuelan equine encephalomyelitis	D+E	<i>Equidae</i>	Culicidae
Japanese encephalitis	E	<i>Equidae</i>	Culicidae
West Nile fever	E	<i>Equidae, Aves</i>	Culicidae
Equine encephalomyelitis (Eastern and Western)	E	<i>Equidae</i>	Culicidae

Animal Health Law – Some Acts Relevant for VBD in the pipeline

Act	Content (indicative)	Status
DA on disease control	<p>Delegated act on disease control measures</p> <ul style="list-style-type: none"> – Mainly <u>Cat. A diseases</u> – Rules for diseases such as <ul style="list-style-type: none"> • Classical and African Swine fever, Foot-and-Mouth, Avian Influenza, Lumpy Skin disease etc., • “Category A” aquatic diseases <p>Technical discussion on the draft ongoing</p> <ul style="list-style-type: none"> –not controversial –expected to be completed in December 2018 	UNDER DEVELOPMENT/CONSULTATION
DA on surveillance	<p>Delegated act on surveillance, eradication programmes, disease freedom</p> <p>General requirements on surveillance:</p> <ul style="list-style-type: none"> • Design • Targeted animal population • Diagnostic methods • Disease confirmation • Case definition 	UNDER DEVELOPMENT/CONSULTATION

Decision to implement vaccination against VBD (Current EU legislation)

- **Scenario 1:**
Vaccination may not be carried out except as a supplement to control measures taken when the disease in question broke out (e.g. Lumpy Skin Disease) **Decision : MS + E. Commission**
- **Scenario 2:**
Vaccination is part of the control measures laid down in the relevant EU legislation (e.g. Bluetongue) **Decision : MS (± E. Commission)**
- **Scenario 3:**
No specific provisions are laid down for vaccination in the relevant EU legislation (e.g. West Nile Fever) **Decision : MS**

Choice and supply of vaccines against VBDs

- **Vaccine availability** (is there a vaccine for the disease in question ?)
- **Type(s) of vaccine available** (live attenuated, inactivated, DIVA e.t.c), immunogenic properties and consequences from the use of each type
- **Vaccine matching – use of vaccine specific for the type of the pathogen present** (e.g. Bluetongue)
- **International trade rules** (EU legislation/ OIE Code)
- **Vaccine supply** (availability of the desirable vaccine in sufficient quantities within a reasonable time)
- **Availability of resources to procure the desirable vaccine in the desirable quantities**
- **Existence of appropriate emergency procurement procedures (national)**
- **Vaccines with an EU marketing authorisation or exceptional use of vaccines without EU Marketing authorisation when such vaccines are not available in accordance with Article 8 of Dir. 2001/82/EC on the Community code relating to veterinary medicinal products:**

"In the event of serious epizootic diseases, Member States may provisionally allow the use of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use".

Choice of vaccination policy against VBDs

- **Animal population to be vaccinated:** species, age, expected vaccination coverage e.t.c.
- **Vaccination scheme:** depending on the type of vaccine , Single dose? Booster? Annual revaccination ?
- **Timing and duration of vaccination campaign:** time of launch and estimated time of completion, overall duration of vaccination (1-2 years ? more?)
- **Disease seasonality**
- **Mandatory vs voluntary vaccination**
- **Vaccination zone** (depending on the disease epidemiology, geographical, administrative factors e.t.c.)
- **Implementation of vaccination in the field**
 - Personnel administering the vaccine
 - Identification and registration of vaccinated animals
 - Livestock breeding systems
 - e.t.c

Additional measures in relation to vaccination against VBDs

- **Zoning following the implementation of vaccination**
- **Specific surveillance measures during and after completion of vaccination**
- **Monitoring scheme to check immunity levels**
- **Rules for the movement of vaccinated animals and their products (special safeguard measures)**
- **Trade related measures (national /international)**
- **Adoption of specific EU decisions**
- **Coordination with neighbouring countries**

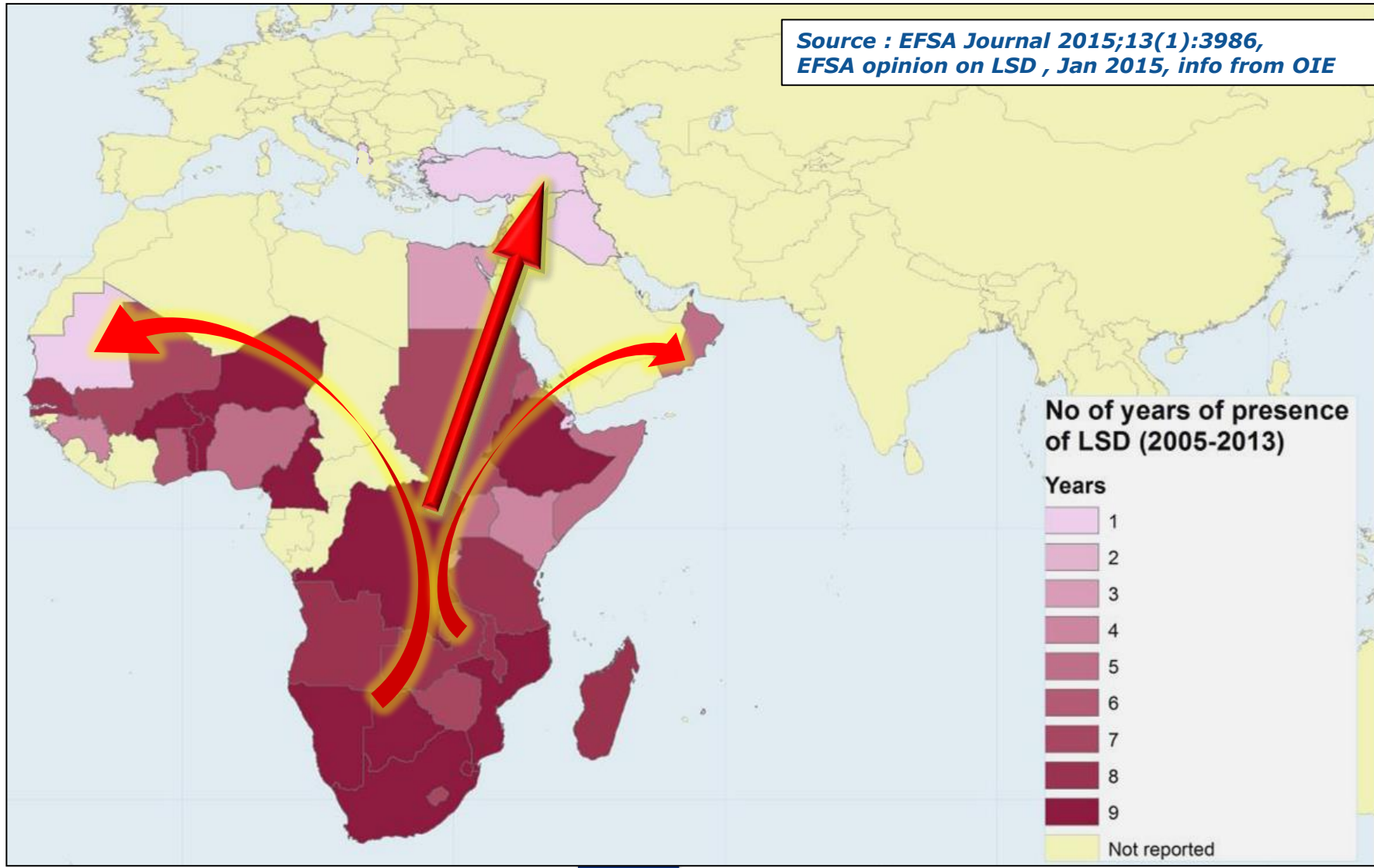


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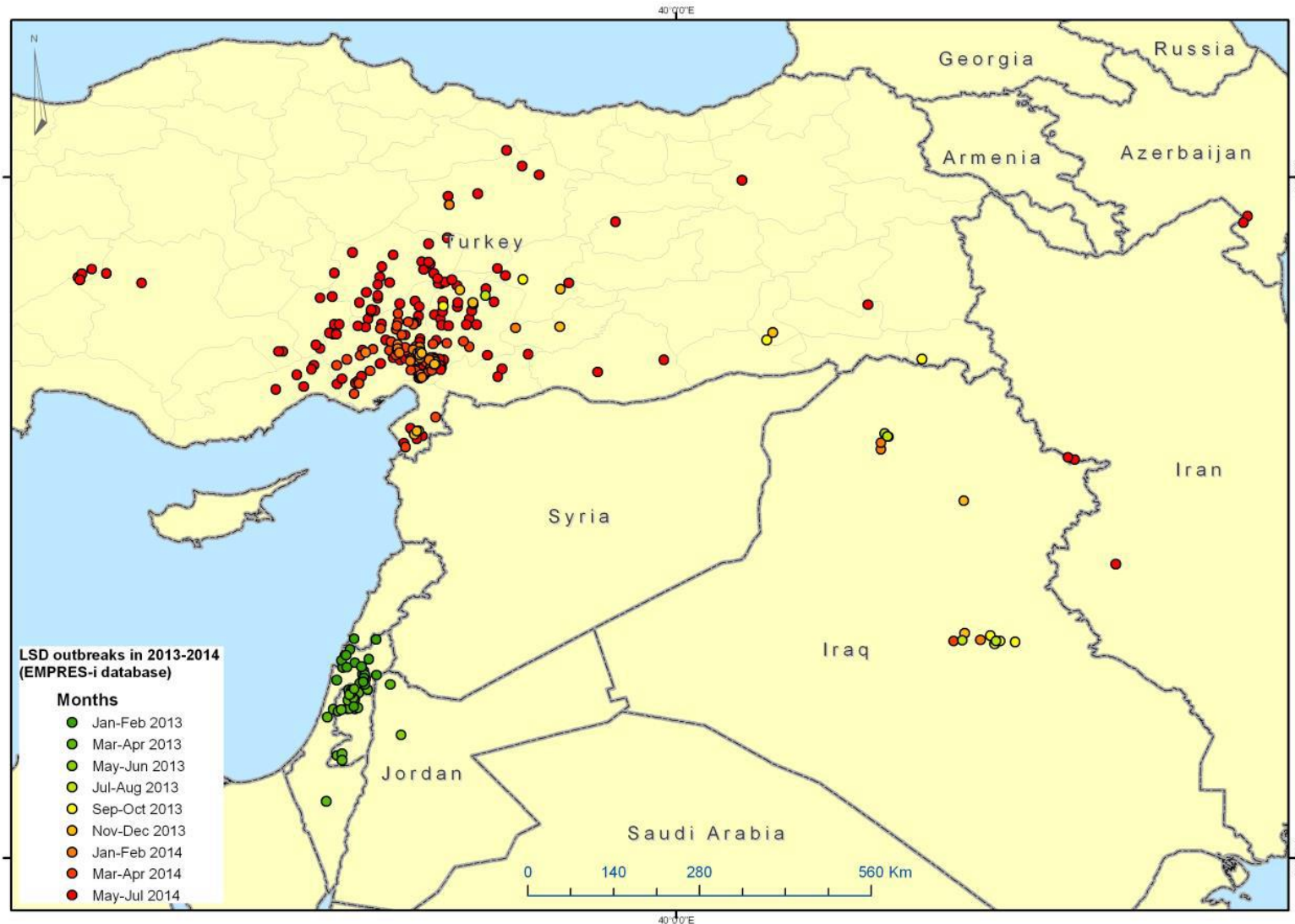
Case study: LSD

Lumpy Skin Disease global evolution: 2005 - 2013

Source : EFSA Journal 2015;13(1):3986,
EFSA opinion on LSD , Jan 2015, info from OIE



Outbreaks of LSD in Middle Eastern countries reported bimonthly in 2013 and 2014



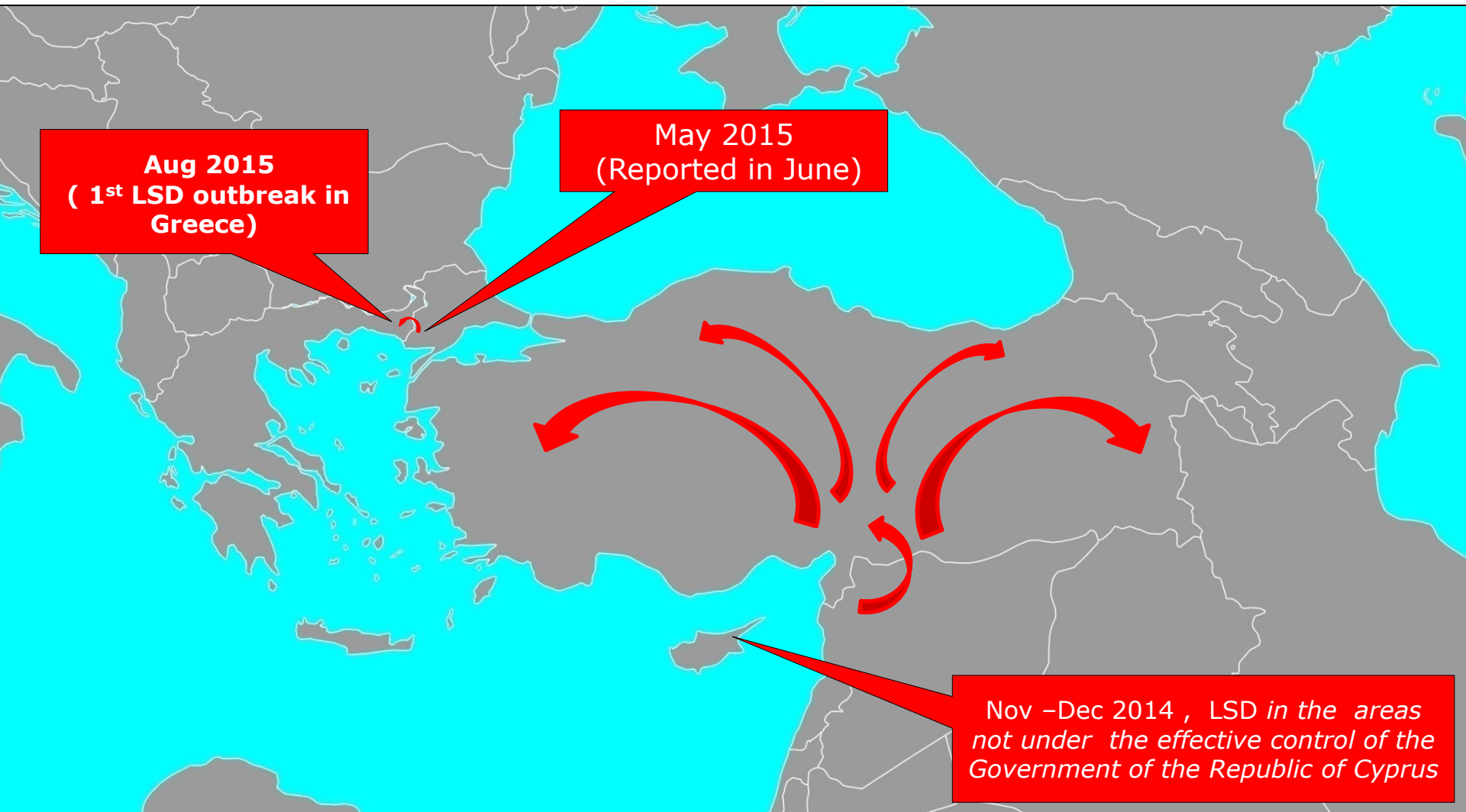
Data source: OIE
 Map reproduced from:
 EFSA Journal
 2015;13(1):3986



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Case study: LSD

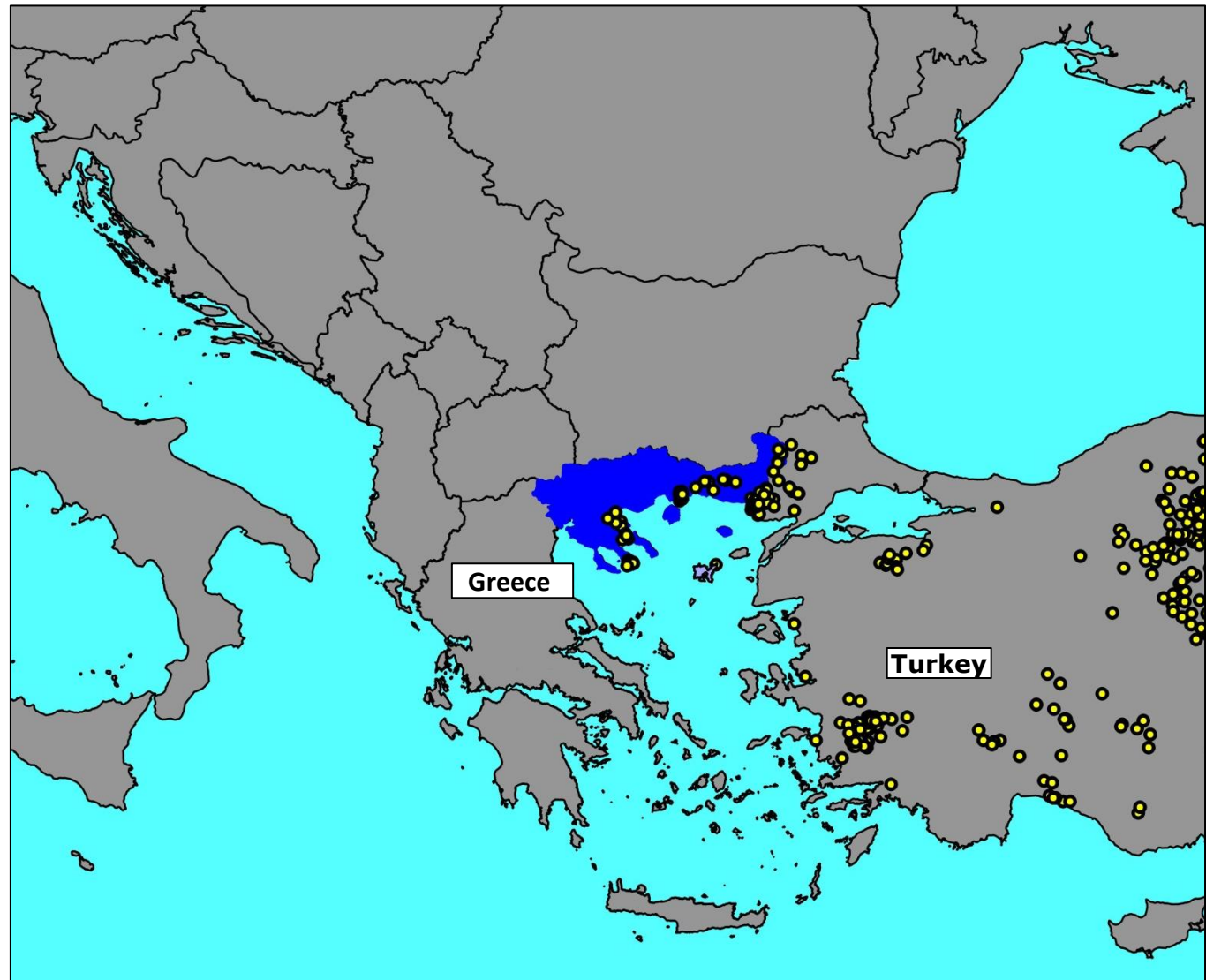
LSD in SE Europe: situation in 2013 – 2015, disease spread



2015 LSD vaccination – occurrence in South East Europe *(situation as at Dec 2015)*

Vaccination in:

- Greece (Northern part), not full vaccine coverage every where



 Vaccination area
(not full coverage)

 LSD outbreaks as at
1 Jan -31 Dec 2015 (ADNS)

2016 LSD vaccination-occurrence in South East Europe (situation as at early 2017)

Vaccination completed in:

- Bulgaria
- Greece (Northern part)
- Serbia
- FYROM
- Montenegro
- Kosovo
- Croatia
- Albania

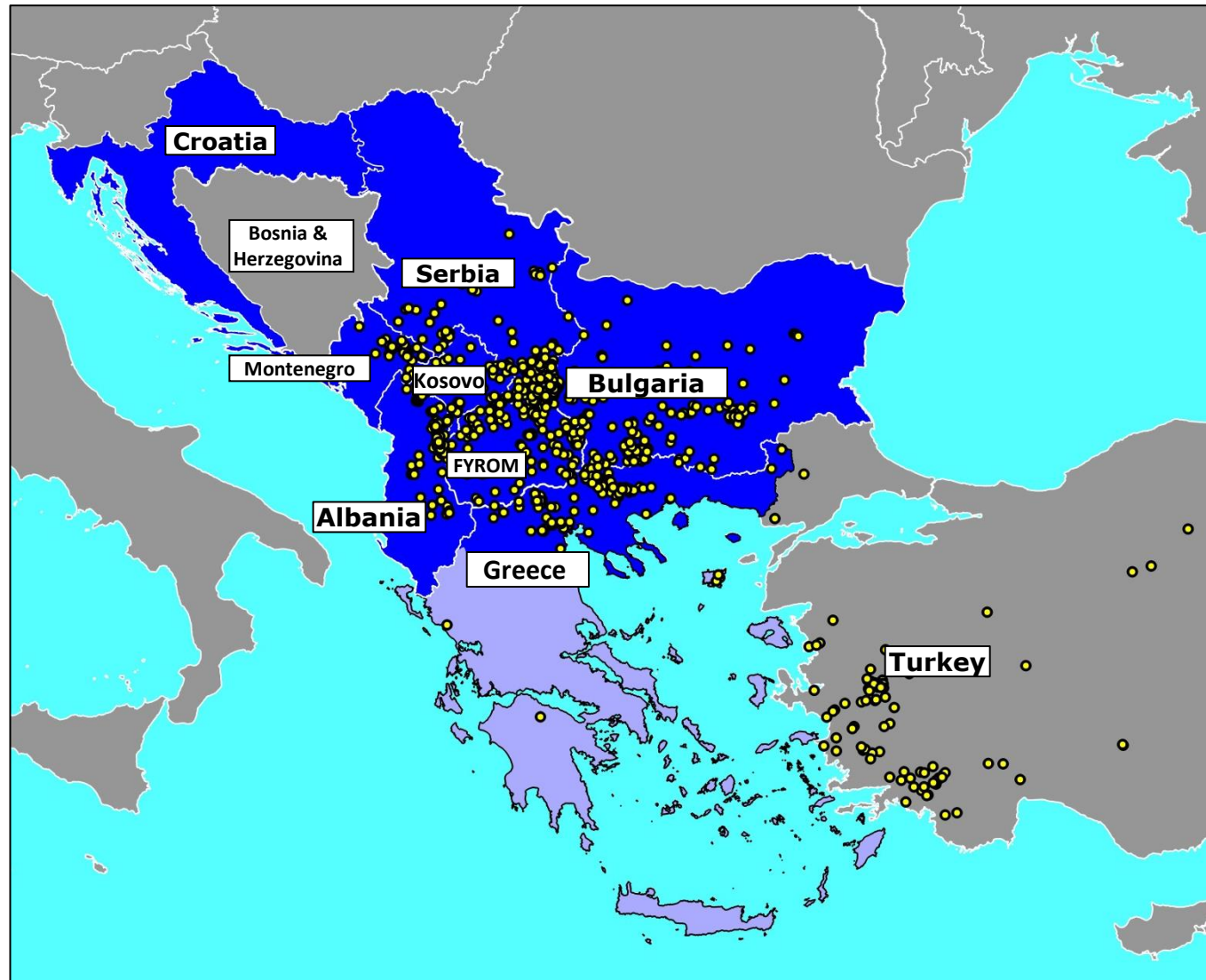
Vaccination in progress in

- Southern part of continental Greece

 Vaccination Completed by end 2016 - early 2017

 Vaccination in progress

 LSD outbreaks as at 1 Jan -31 Dec 2016 (ADNS)



LSD timeline of events in 2015

June 2015

LSD reported for the first time in European Turkey – close to the border with Greece.

August 2015

LSD reported for the first time in Greece – close to the border with Turkey.

September 2015

LSD outbreaks in Greece keep increasing, disease continues to spread, decision to implement vaccination with live homologous vaccine- European Commission grants relevant permission. Initiation of LSD vaccination in Greece.

October to December 2015

LSD continues to spread, to the west of Greece, while vaccination keeps progressing. Last LSD outbreaks recorded in Greece in December, disease comes to halt, thanks to a combination of winter and vaccination progress.

LSD timeline of events in 2016 (A)

April 2016

Creation , for the first time of an **EU LSD vaccine bank**. Recurrence of LSD in **Greece** in an area of low vaccine coverage.

First occurrence of LSD in **Bulgaria** and then the **former Yugoslav Republic of Macedonia**.
Emergency shipments of vaccines from the EU LSD vaccine bank.

May 2016

Joint EFSA – DG SANTE Workshop in Brussels with all LSD affected and at risk countries.

June 2016

Kick off meeting of the **GF TADS LSD Expert Group**, first discussions for a coordinated LSD vaccination strategy.

First occurrence of LSD in **Serbia** and **Kosovo***, vaccination launched in these countries too.
Emergency shipments of vaccines from the EU LSD vaccine bank.

July 2016

LSD reported in **Montenegro** and **Albania**, vaccination to be launched in these countries too. Bulgaria becomes the first country in the region to complete a full vaccination campaign (100 % coverage of cattle nationwide).

Emergency shipments of vaccines from the EU LSD vaccine bank.

LSD timeline of events in 2016 (B)

September 2016

- **LSD Ministerial Conference in Sofia – Bulgaria** . Chief Veterinary Officers + Ministers of all countries in the region of South East Europe, along with the European Commission (and Commissioner Andriukaitis himself). A coordinated regional LSD control policy, with EU support, is agreed by the CVOs and officially approved by their Ministers (political support).
- Voting of **new Implementing Decisions on LSD** (2016/2008 and 2016/2009) providing for proportionate measures and proposing for the first time the concept of zones that are “free with vaccination” for LSD.
- **2nd GF TADs** LSD expert group meeting in Lisbon

October to December 2016

- **LSD outbreaks effectively stopped** in those countries where LSD vaccination was completed.
- **3rd GF TADs meeting in Istanbul**. Participating countries agree to continue vaccination in 2017..



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Case study: LSD

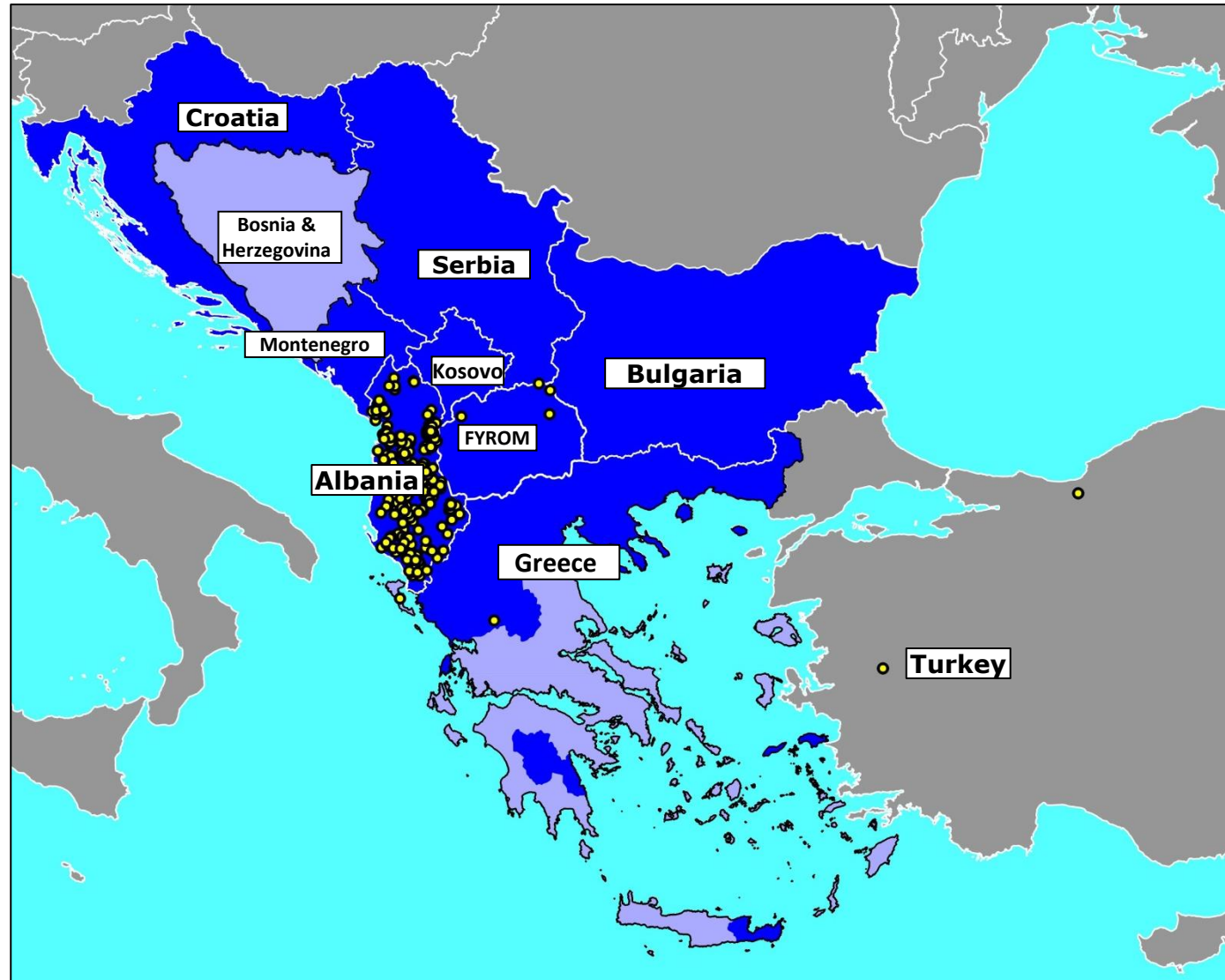
2017 LSD vaccination – occurrence in South East Europe (situation as at mid- October 2017)


Vaccination completed since 2016 (annual revaccination in progress) or completion of primary vaccination:

- Bulgaria
- Greece (Northern part)
- Serbia
- FYROM
- Montenegro
- Kosovo
- Albania

Vaccination in progress in

- Southern part of continental Greece & islands
- Bosnia & Herzegovina



 Annual revaccination
in progress or completion
of primary vaccination

 Primary vaccination
in progress

 LSD outbreaks as at
1 Jan-15 Oct 2017 (ADNS)



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Case study: LSD


2018 LSD vaccination – occurrence in South East Europe (situation as at mid- October 2018)

Vaccination (annual revaccination in progress) or completion of primary vaccination:

- Bulgaria
- Greece
- Serbia
- FYROM
- Montenegro
- Kosovo
- Albania

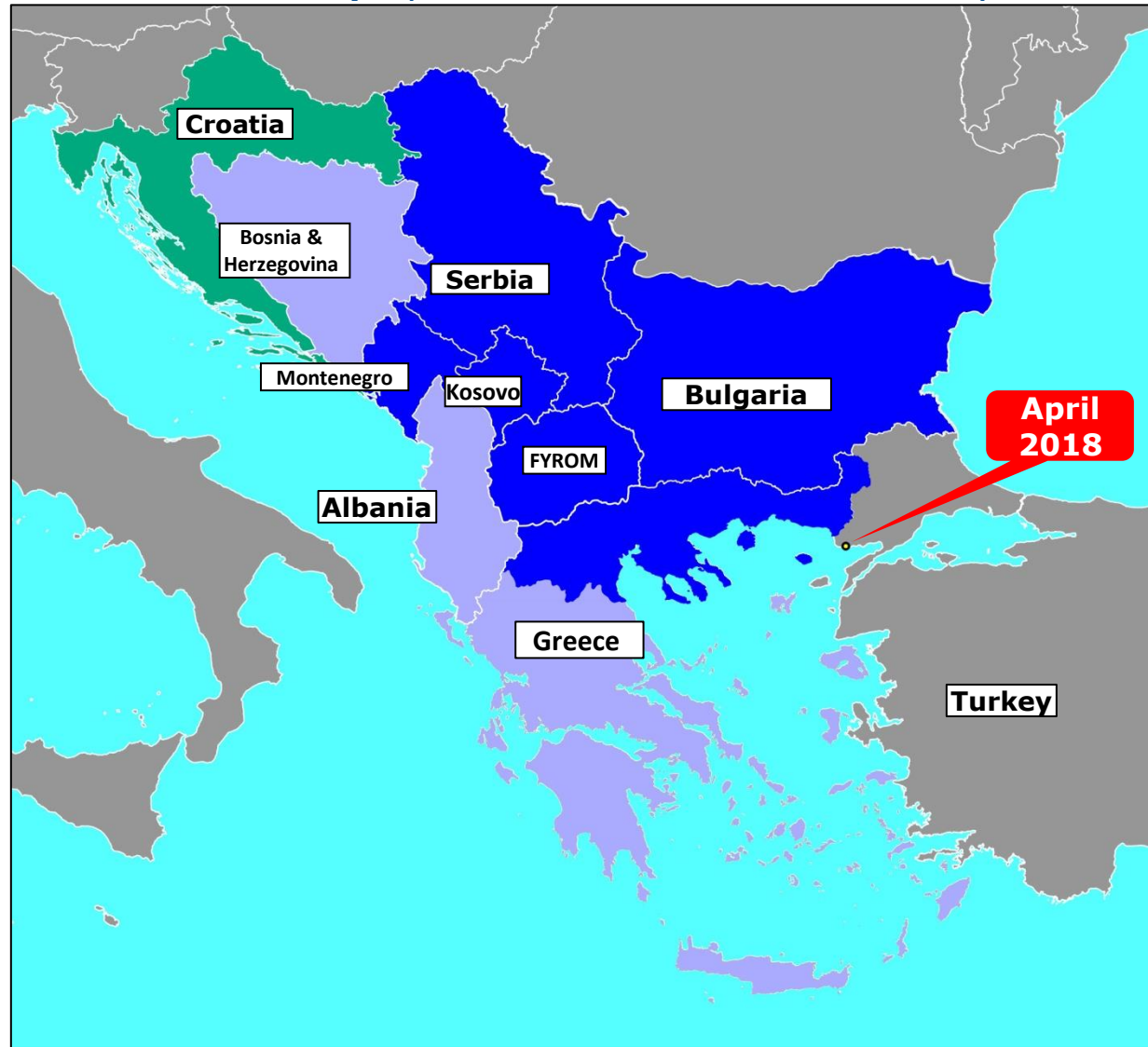
Vaccination in progress in

- Parts of continental Greece & islands
- Bosnia & Herzegovina (southern part)

 Annual revaccination in progress or completion of primary vaccination

 Vaccination in progress  Cease of vaccination

 LSD outbreaks as at 1 Jan-15 Oct 2018 (ADNS)



LSD occurrence in SE Europe: Situation as at mid October 2018

LSD outbreaks in South East Europe in 2018 :

No outbreaks reported in any country of South East Europe since the beginning of 2018 (except Turkey see below)

Outbreaks in the vicinity of South East Europe in 2018 :

- **Turkey: 43 outbreaks** reported in ADNS to date (1 in East Thrace Region - European Turkey, April 2018)
- **Georgia: 5 outbreaks** reported in Aug-Sep 2018 (OIE, WAHIS)
- **Russia: 63 outbreaks** reported in July-Nov 2018 (OIE, WAHIS)

LSD vaccination in SE Europe

2015

- LSD vaccination in the **North – Eastern Provinces of Greece**

2016

- All LSD affected countries (**Greece, Bulgaria, the former Yugoslav Republic of Macedonia, Serbia, Kosovo*, Albania, Montenegro**) implemented mass vaccination of all their cattle against LSD in their entire territory.
- **Croatia**, not affected by LSD, became the 1st country to implement preventive vaccination of its entire country population against LSD (July 2016)

2017

- All countries in SE Europe that vaccinated against LSD in 2016 repeat vaccination in 2017 (annual revaccination + vaccination of new-born animals, campaigns completed or in progress).
- **Bosnia and Herzegovina**, not affected by LSD, began implementing preventive vaccination against LSD since 2017 (2nd country to implement preventive vaccination after Croatia).

2018

- All countries in SE Europe that vaccinated against LSD in 2017 repeated vaccination in 2018 except Croatia (cease of vaccination in view of the favourable epidemiological situation).

NOTE :

In all cases the vaccines used in the above countries were **live, homologous vaccines against LSD** imported from outside the EU (except Turkey)

EFSA : LSD vaccination progress in 2016-2017 and reported LSD outbreaks in SE Europe



Commission Implementing Decisions on LSD in force

- 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** and **2018/744**)

Amendments related to zoning, refinement of measures for germinal products, holdings subject to revaccination and domestic movements of bovines after cessation of vaccination in free zones with vaccination.

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

CROATIA : lifting of restrictions in relation preventive vaccination against LSD (amendments of the above decisions voted in the PAFF Committee meeting of 11 December 2018).


LSD zoning - Commission Impl. Dec. (EU) 2016/2008 (before removal of Croatia)

Free zones with Vaccination (Part I):

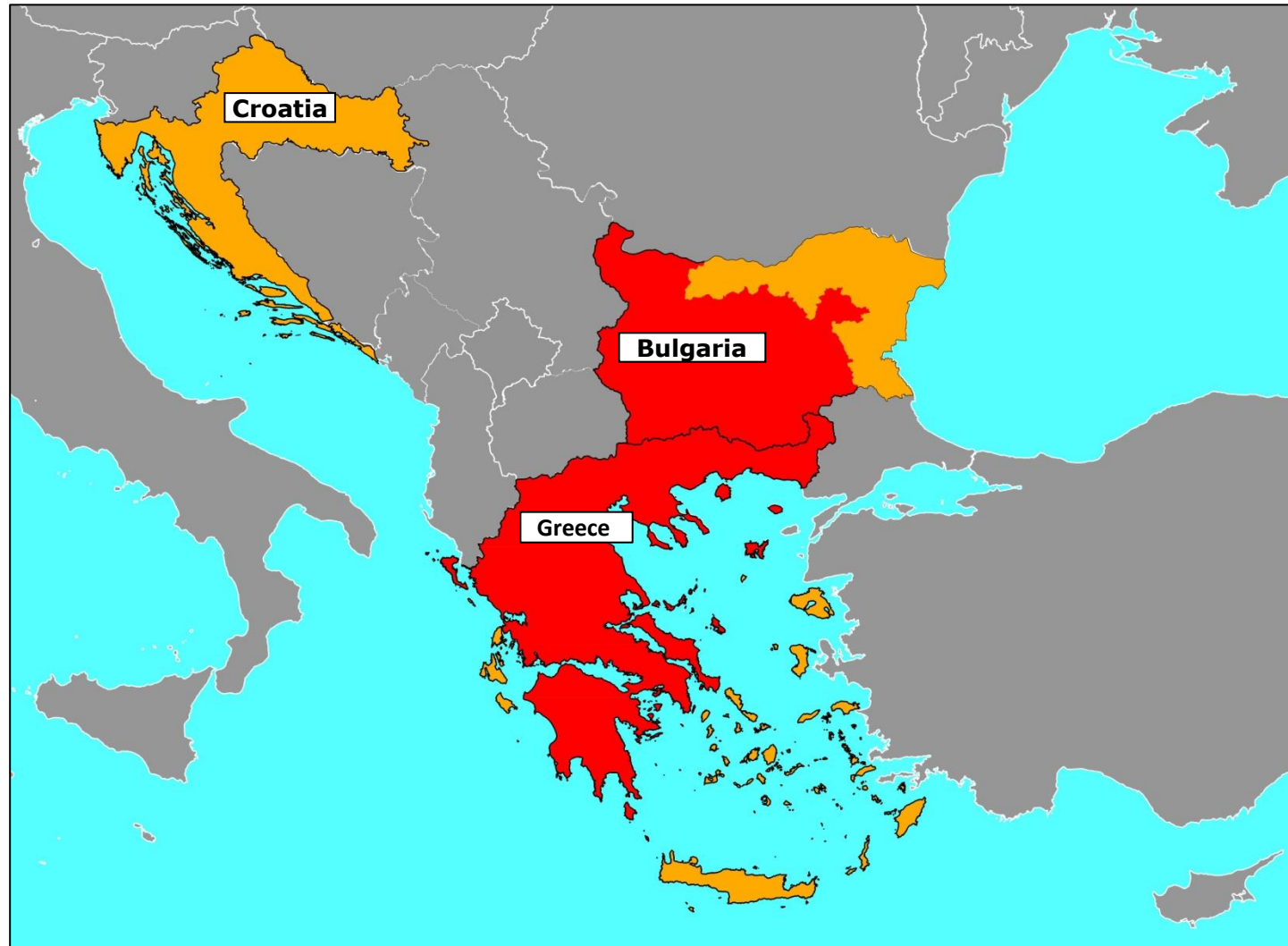
- Croatia
- Bulgaria (certain areas in the North and East part)
- Greece (islands except Kerkyra and Limnos)

Infected zones (Part II):

- Continental Greece (including the islands of Limnos and Kerkyra)
- Bulgaria (excluding the "free with vaccination" zones)

 Free with
Vaccination zone

 Infected zone



European Commission support against Lumpy Skin Disease

- **EU LSD vaccine bank** (*vaccine donations to various countries in 2016-2018*)
Expansion – replenishment in progress (tender in progress for 1,8 million doses , <https://etendering.ted.europa.eu/general/page.html?name=home>)
- **EU financial support**
 - *For EU Member countries* : cost of LSD homologous vaccines purchased and used through national procedures up to 1,1 EURO per dose
 - *For non EU Member countries* : reimbursement for the cost of LSD homologous vaccines purchased and used through national procedures up to 1,1 EURO per dose
- **Technical support: EUVET** (EU Veterinary Emergency Team, 7 LSD missions so far available upon request), EURL (2 proficiency tests , 2 NRL workshops, lab training e.t.c.)
- **LSD training activities**
LSD Sustained Technical Missions (STMs) in Ukraine and Belarus in 2018, mission in Georgia planned for early 2018
- **Scientific support: EFSA Opinions on LSD** (2 opinions & 3 reports published so far, latest on 16/10/2018) <https://www.efsa.europa.eu/en/topics/topic/lumpy-skin-disease>, **2 more LSD reports expected in early 2019 and early 2020**).
- **Awareness – Regional Cooperation: GF TADs SGE, LSD Ministerial Conference in Sofia (Sep 2016) e.t.c.**

European Union Lumpy Skin Disease Vaccine Bank 2016 -2017 – October 2018 grants

Year	Country	Number of doses granted	
2016	Bulgaria, Greece , the former Yugoslav Republic of Macedonia, Serbia, Kosovo*, Albania, Montenegro, Croatia	625.000	
2017	Bosnia & Herzegovina, Montenegro, Greece, Albania, Kosovo*	325.000	
2018	The Former Yugoslav Republic of Macedonia	230.000	776.000
	Kosovo*	170.000	
	Montenegro	95.000	
	Greece	100.000	
	Albania	81.000	
	Georgia	100.000 (+100.000 in progress)	

1.726.000 doses of LSD vaccine (live-homologous) granted in 2016-2018 (until October) to various countries (EU + non EU MS)



GF TADs Standing Group of Experts on Lumpy Skin Disease in the South East Europe region under the GF-TADs umbrella

http://web.oie.int/RR-Europe/eng/Regprog/en_GF_TADS%20-%20Standing%20Group%20LSD.htm#LSD1

MEETINGS

- 1st Meeting, Brussels on 4-5 July 2016
- 2nd meeting, Lisbon (Portugal) on 21 September 2016
- 3rd meeting, Istanbul, (Turkey) on 12-13 December 2016
- Teleconference on LSD vaccine procurement , 23 February 2017
- 4th meeting, Paris , 24 May 2017
- 5th meeting, Budva (Montenegro), 19-20 October 2017
- **Teleconference on LSD vaccination and vaccine supply , 26 February 2018**
- **6th meeting, Paris , 23 May 2018**
- **7th meeting, Ohrid (the Former Yugoslav Republic of Macedonia), 18-19 October 2018**

EXPERT MISSIONS

First GF TADs expert mission on LSD in **Kazakhstan** (19-23 February 2018) at the request of the competent authorities of this country, to provide technical support, based on the experience gained in SE Europe.

Current state of play in the region South East Europe

For 3 years on a row (2016-2017-2018) :

➤ **Coordinated vaccination control policy against LSD**

Mass vaccination, with live homologous vaccines, uniformly adopted across South East Europe (EU + non EU countries, excl. Turkey) with support from the EU (vaccines from the EU vaccine bank + financial assistance for vaccine purchase)

➤ **Meetings - Exchange of info**

Regular meetings of GF TADs LSD SGE (at least 3 per year), report of all LSD outbreaks in SE Europe in ADNS

➤ **Coordination in supply of LSD vaccines**

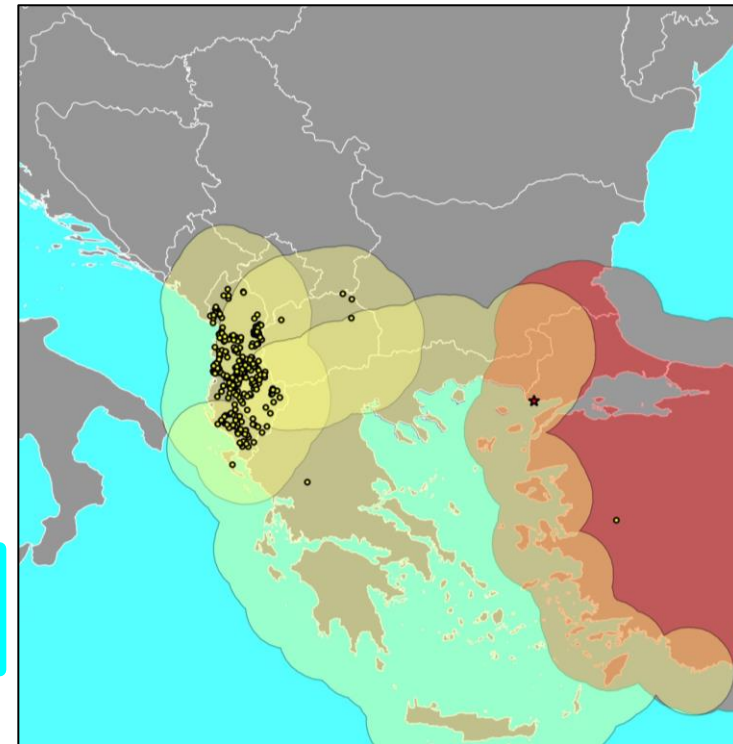
EU financial support for purchase of LSD vaccines , vaccine grants from the EU LSD vaccine bank , transfer of national stocks of LSD vaccines (Austria & Hungary) for immediate use before expiry (Bulgaria).

GF TADs SGE LSD 7

(Standing Group of Experts on Lumpy Skin Disease in the South East Europe region under the GF-TADs umbrella)
7th meeting, Ohrid (the Former Yugoslav Republic of Macedonia), 18-19 October 2018

GF TADs SGE LSD 7 Recommendations (excerpt)

3. Cessation of LSD vaccination should take place in a coordinated manner ensuring the continuation of the regional coordinated policy of the previous years;
4. The decision to continue or stop LSD vaccination in a country or zone in 2019 should be based, among other factors, on the LSD occurrence in the country or zone in the previous years, the vaccination coverage achieved and the epidemiological situation in neighbouring countries or zones (map in annex);
5. It is recommended that previously LSD affected countries or zones consider stopping LSD vaccination only if:
 - a. They have achieved a high vaccine coverage, using effective LSD vaccines, for at least the last 2 consecutive years;
 - b. No outbreak of LSD has occurred during the last 2 years in and within a distance of at least 80 km (preferably 100 km) of the country or zone;
6. Based on the information made available during the meeting in the individual reports of the countries, at least Albania, Bulgaria (all or part of), Kosovo*, Greece, Montenegro, Serbia (all or part of), the former Yugoslav Republic of Macedonia and Turkey should not stop vaccination;
7. Countries and zones implementing vaccination should still aim at sufficiently high vaccine coverage as previously recommended;
8. The cessation of LSD vaccination should be accompanied by the implementation of an appropriate LSD surveillance for a period of at least two years or more to prove the absence of LSD and ensure early detection in case of resurgence or reintroduction from affected areas. This surveillance needs to include periodical clinical visits in holdings as well as serological testing of non-immune animals;



EFSA Report : high risk areas 80 km zone around borders of LSD affected countries (zones)

80 km zones around areas where the last LSD outbreaks occurred in 2017

80 km zones around countries where the last LSD outbreaks occurred in 2017 -2018

Full text: [http://web.oie.int/RR-Europe/eng/Regprog/docs/docs/LSD7/SGE%20LSD7%20\(Ohrid%20Oct%202018\)%20-%20Recommendations%20final.pdf](http://web.oie.int/RR-Europe/eng/Regprog/docs/docs/LSD7/SGE%20LSD7%20(Ohrid%20Oct%202018)%20-%20Recommendations%20final.pdf)

EC Priorities for VBDs

The European Commission will continue to :

- Follow closely the **epidemiological situation of VBDs** inside and in the vicinity of the EU as well as globally
- Follow closely the **scientific knowledge on VBDs** (EURLs-EFSA) to optimise the relevant surveillance – control measures
- Seek up-to-date **risk assessment and analysis for VBDs** as needed, to identify possible imminent threats from such diseases
- Provide **technical assistance for VBDs** (EUVET missions , STM missions, EU Ref. Laboratories) for EU and non EU Member Countries
- Provide **training opportunities for VBDs** (e.g. BTSF workshops) for EU and non EU Member Countries
- Adjust as appropriate **the level of intervention and possible support to the MS and neighbouring 3rd countries** in their combat against listed VBDs bearing in mind:
 - The impact of each disease
 - The available resources



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**THANK YOU
FOR YOUR ATTENTION**