



EU H5N1 vaccine views/trade considerations EU Lumpy Skin Disease outbreaks in Europe, vaccination use and trade considerations.

USAHA GAHT Committee

4 November 2025

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EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY (DG SANTE)

Head of Unit G2 - Animal Health

2025 Emerging diseases context in the EU

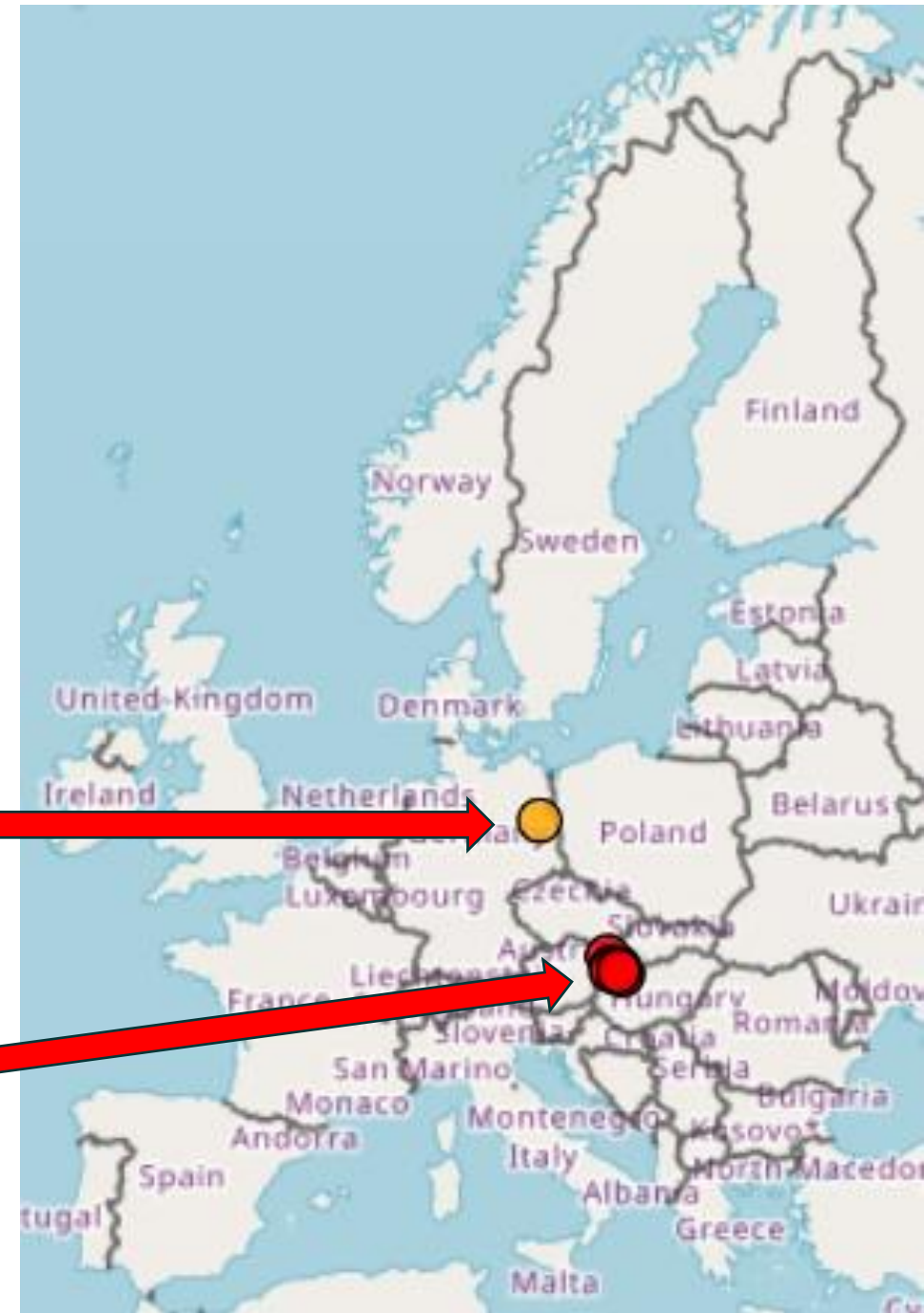


FMD in the EU



FMD Outbreaks in the EU

- The EU was free from FMD since 2011 (Bulgaria)
- Two **UNRELATED** events in 2025:
- **10/01/2025** in **Germany**: FMD ser. O
 - 1 outbreak
 - O/ME-SA/**SA-2018** lineage
- **06/03/2025** Hungary + Slovakia: FMD ser. O
 - 11 outbreaks
 - O/ME-SA/**Pan-Asia2/ANT-10** sub-lineage



EU Regionalization/zoning

- Since Monday 11 March 2025, the Commission **adopted 5** Commission Implementing Decisions with emergency measures demarcating regionalization at EU level:
 - restricted zones in Hungary, Slovakia and Austria
 - protection (3km) and surveillance (10km) zones with severe restrictions
 - 3 sufficiently large “further restricted zones” with moderate restrictions that confer protection to the rest of the EU

Tuesday
11/03/25

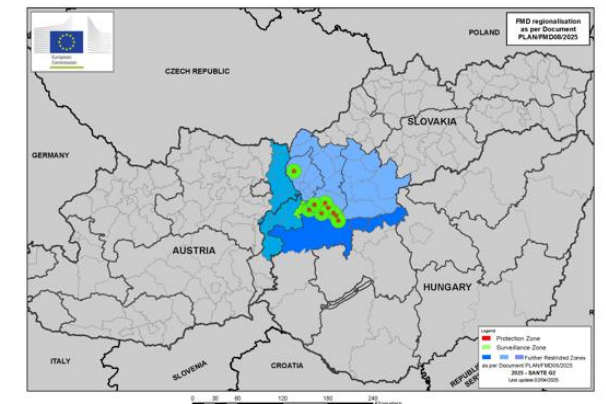
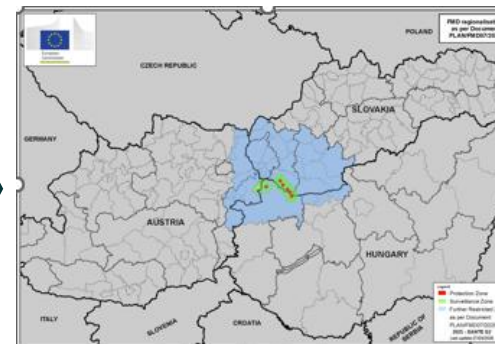
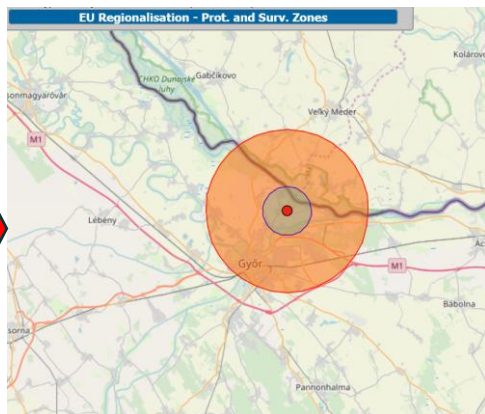
Monday
24/03/25

Wednesday
26/03/25

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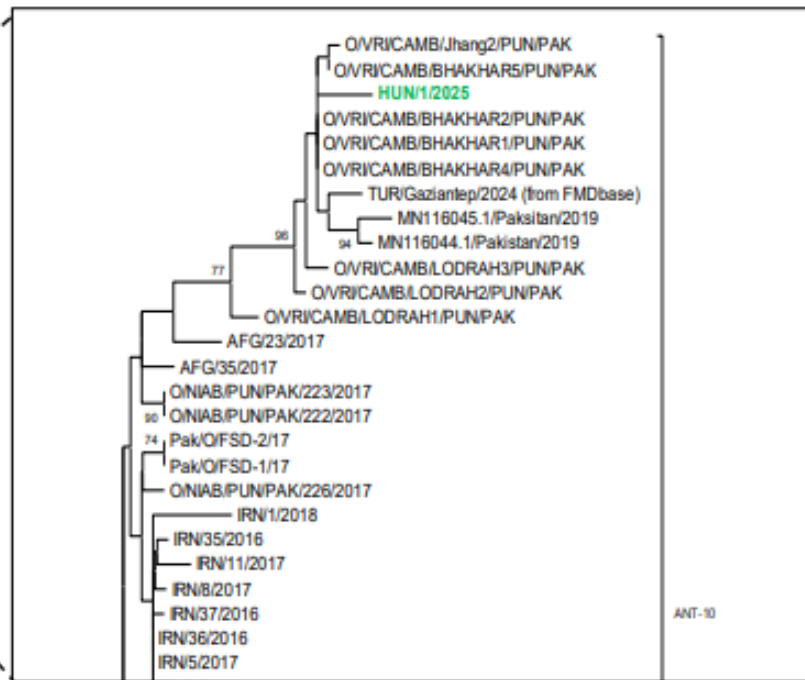
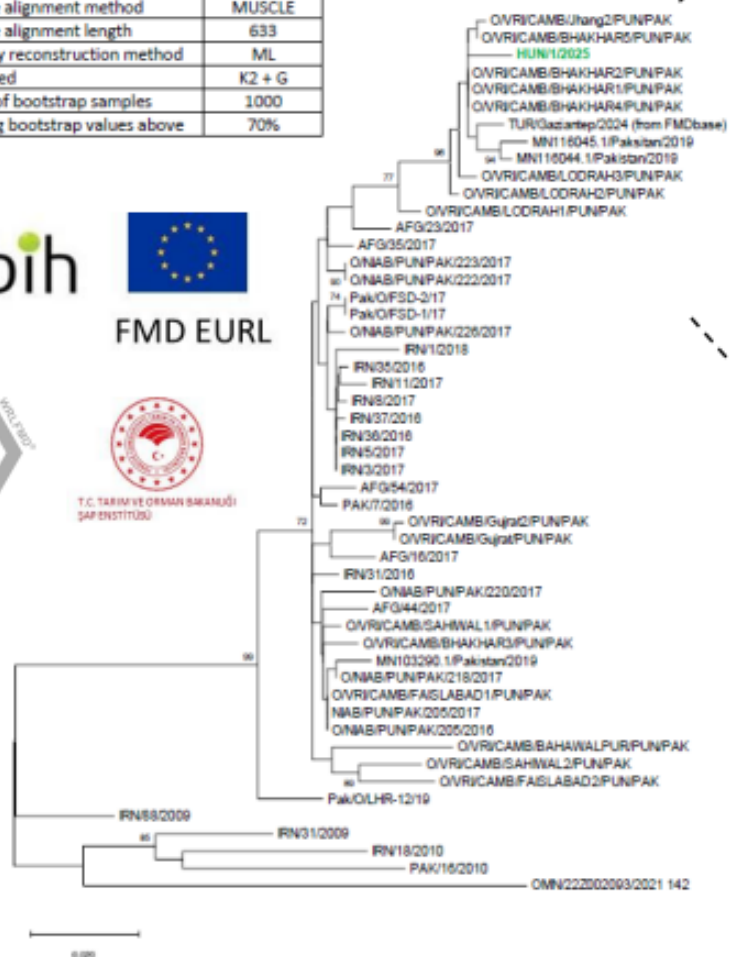
08/03 Phylogenetic analysis

EURL genotyping report confirmed O/ME-SA/PanAsia-2^{ANT-10}

Most closely related to isolates from Pakistan (2017, 2018) 99.22% and Türkiye (2024) 98.58%

Analysis parameters

Sequence alignment method	MUSCLE
Sequence alignment length	633
Phylogeny reconstruction method	ML
Model used	K2 + G
Number of bootstrap samples	1000
Displaying bootstrap values above	70%



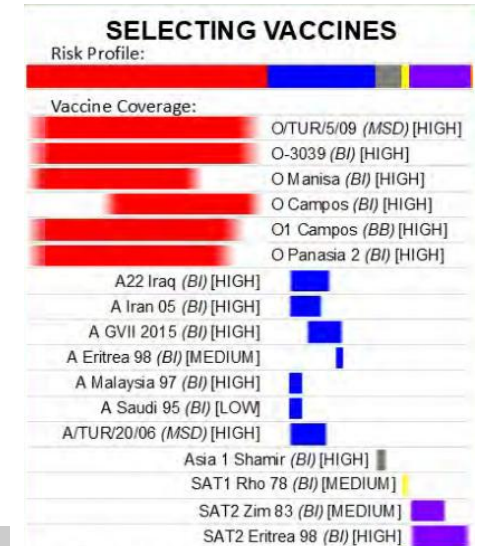
Most closely related sequences

Virus Name	Serotype	Topotype	Lineage	Sublineage	Length	Identity (best hit)
O/VR/CAMB/BHAKHAR2/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	99.22
O/VR/CAMB/BHAKHAR1/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	99.22
O/VR/CAMB/BHAKHAR4/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	99.22
O/VR/CAMB/BHAKHAR5/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	99.06
O/VR/CAMB/Jhang2/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	98.90
O/VR/CAMB/LODRAH3/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	98.75
O/VR/CAMB/LODRAH2/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	98.75
TUR/Gaziantep/2024 (from FMDbase)	O	ME-SA	PanAsia-2	ANT-10	633	98.58
MN116044.1/Pakistan/2019	O	ME-SA	PanAsia-2	ANT-10	634	98.11
O/VR/CAMB/LODRAH1/PUN/PAK	O	ME-SA	PanAsia-2	ANT-10	639	97.65



EU Measures

- Disease control measures based on **Commission Delegated Regulation (EU) 2020/687**
 - Full and immediate stamping out, cleaning & disinfection, movement restrictions on animals and products (regionalisation), surveillance
 - emergency suppressive vaccination → 5 outb. in SK and 4 outb. in HU (over 13K animals)
- EU antigen bank for FMD is regulated by **Commission Implementing Regulation (EU) 2022/140**
 - Over 36 million doses of inactivated antigens ready for rapid formulation and delivery
 - All serotypes covered with different amounts based on the risk for the EU



EU Regionalization **Commission Implementing Decision (EU) 2025/672**

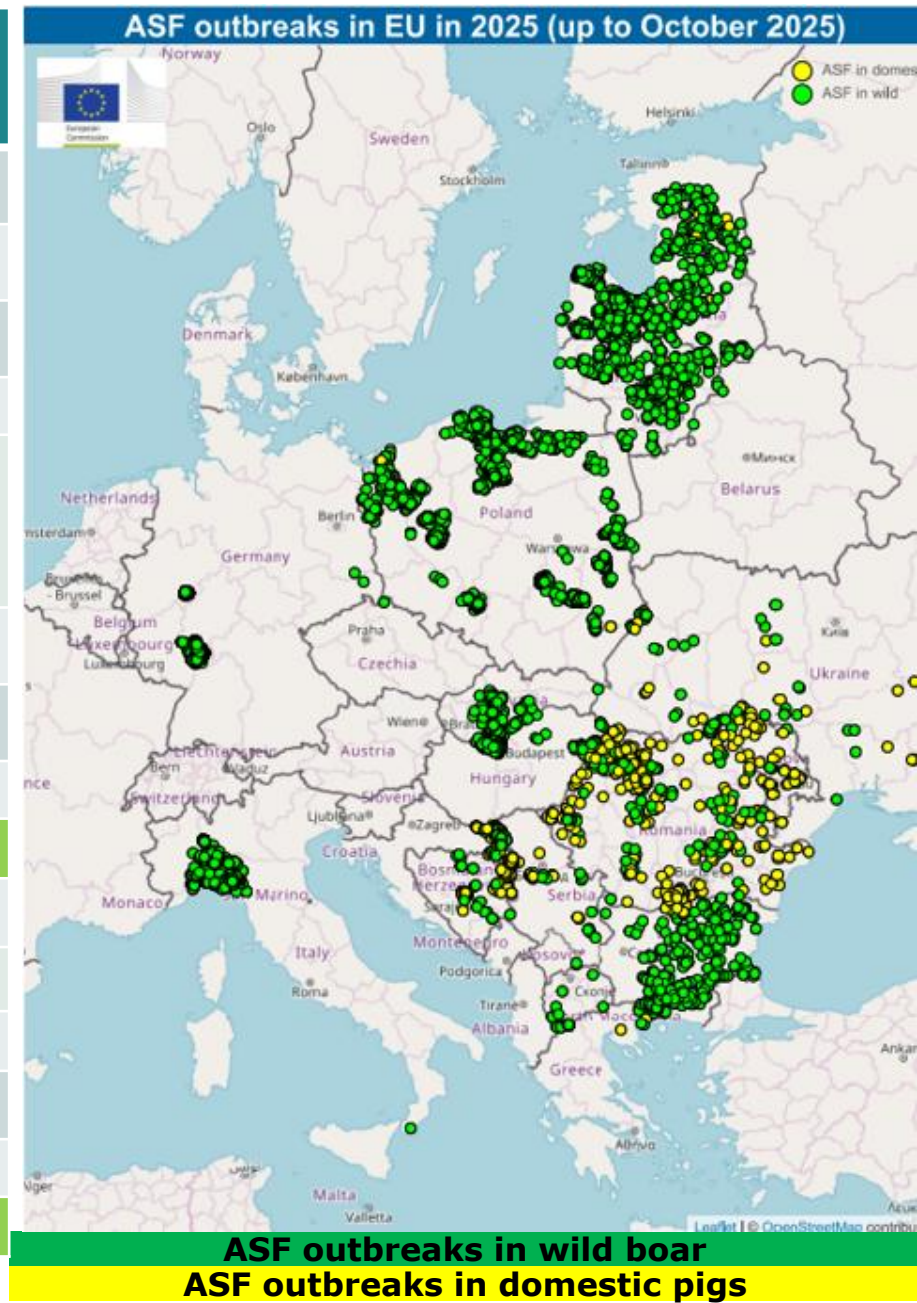


ASF situation the EU



ASF in the EU in 2014 - 2025

No	MS	1 st ASF detection	Wild boar	Pigs	Remarks on the ASF situation in 2025
1.	LT	1/2014	+	+	mainly in wild boar; 8 outbreaks in pigs in 2025 =
2.	PL	1/2014	+	+	mainly in wild boar; 18 outbreaks in pigs in 2025 ↓
3.	LV	6/2014	+	+	mainly in wild boar; 11 outbreaks in pigs in 2025 ↑
4.	EE	7/2015	+	+	mainly in wild boar; 11 outbreaks in pigs in 2025 ↑↑
5.	CZ	6/2017	+		ASF eradicated in 2019 ; new cases in wild boar at the border with PL since 12/2022. In 2025 1 outbreaks in wild boars in a carcass dated in August 2024
6.	RO	7/2017	+	+	in wild boar; 417 outbreaks in pigs in 2025 ↑↑↑
7.	HU	4/2018	+		in wild boar only
8.	BG	6/2018	+	+	mainly in wild boar. No outbreaks in domestic pigs in 2025 ↓
	BE	9/2018	+		free from ASF since 11/2020
9.	SK	7/2019	+	+	mainly in wild boar; 1 outbreak in pigs in 2025 =
10.	EL	2/2020	+	+	mainly in wild boar; 4 outbreaks in pigs in 2025 ↓
11.	DE	9/2020	+	+	mainly in wild boar; no outbreaks in pigs in 2025 ↓↓
12.	IT	1/2022	+	+	mainly in wild boar; 1 outbreak in pigs in 2025 ↓↓
13.	HR	6/2023	+	+	mainly in wild boar; 53 outbreaks in pigs in 2025 ↑↑↑
	SE	9/2023	+		free from ASF since 09/2024



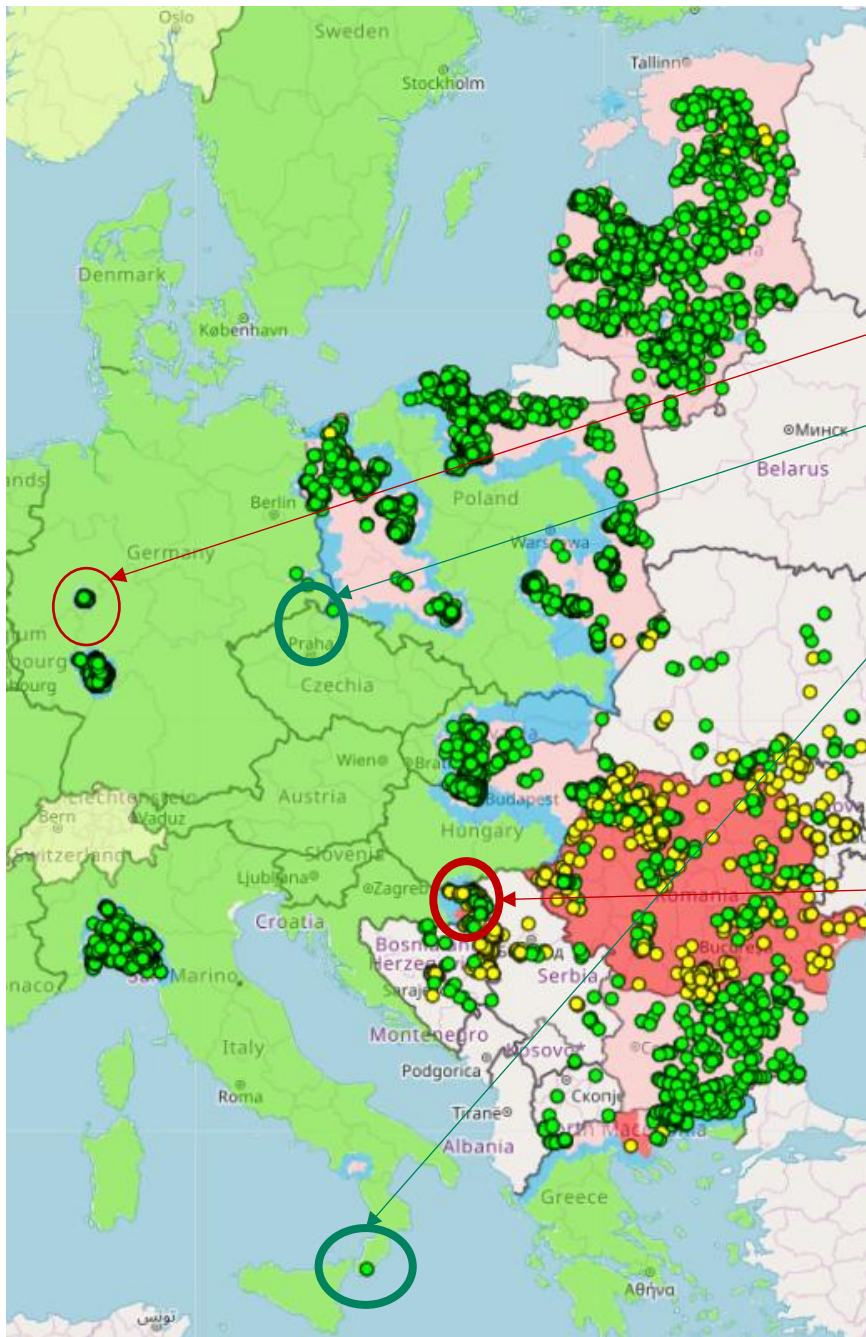
↑ = ↓ Trends respect to 2024

Highlights - EU 2025

Prevalence of outbreaks in wild boar in the majority of affected Member States

- In Germany new affected area in wild boar
- In Czechia and in Southern Italy, no outbreaks in wild boar since August 2024. Progressively reverting or lifting restricted zones
- During the high-risk period for pig sector (summer) outbreaks were detected mainly in Baltic States (Estonia, Latvia and Lithuania), in Croatia and Poland.
- In Croatia a new affected area at the border with Serbia: outbreaks in pigs and wild boar

We strictly monitor the situation in both wild boar and pigs and adapt the control measures as needed.



SPGP situation the EU



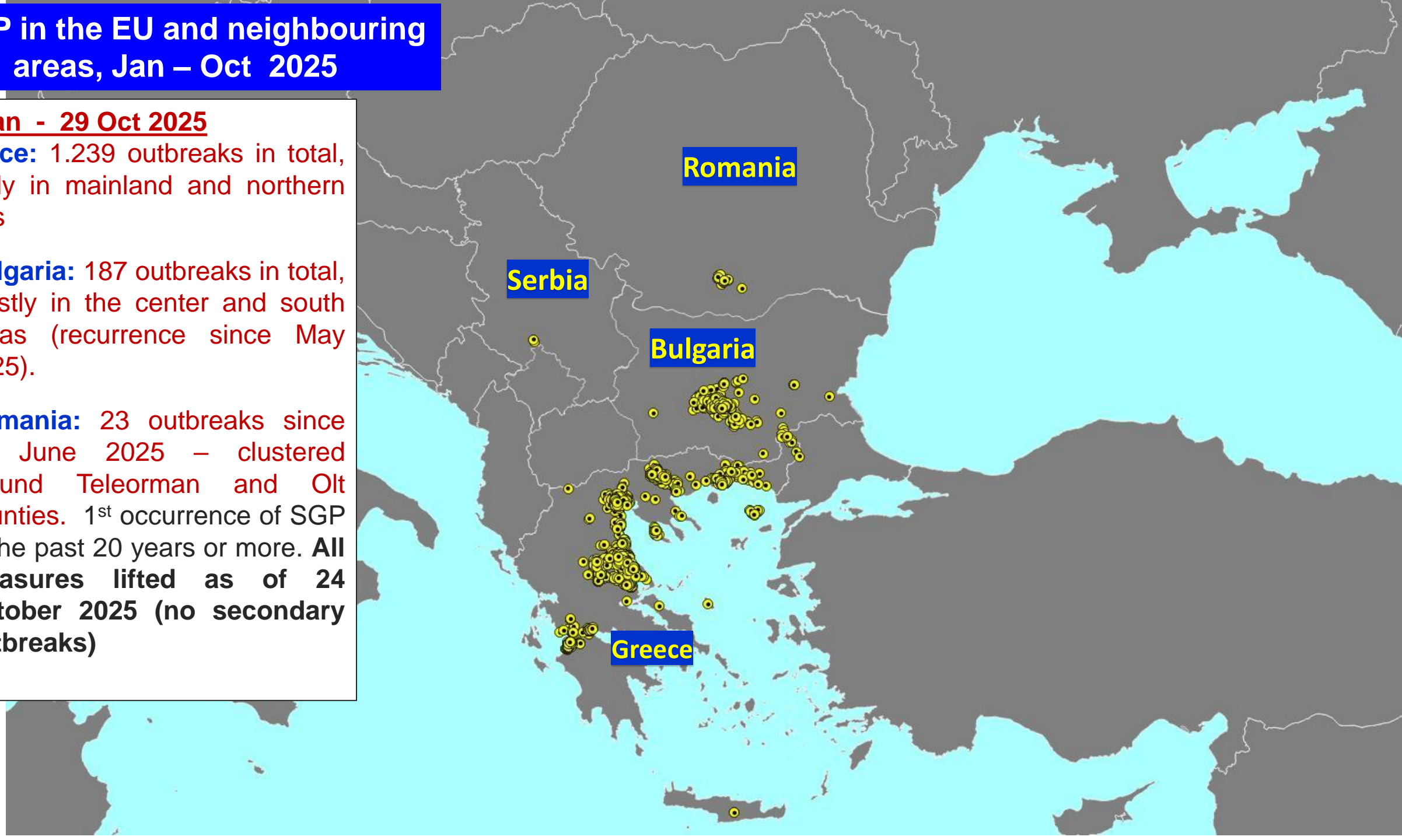
SPGP in the EU and neighbouring areas, Jan – Oct 2025

01 Jan - 29 Oct 2025

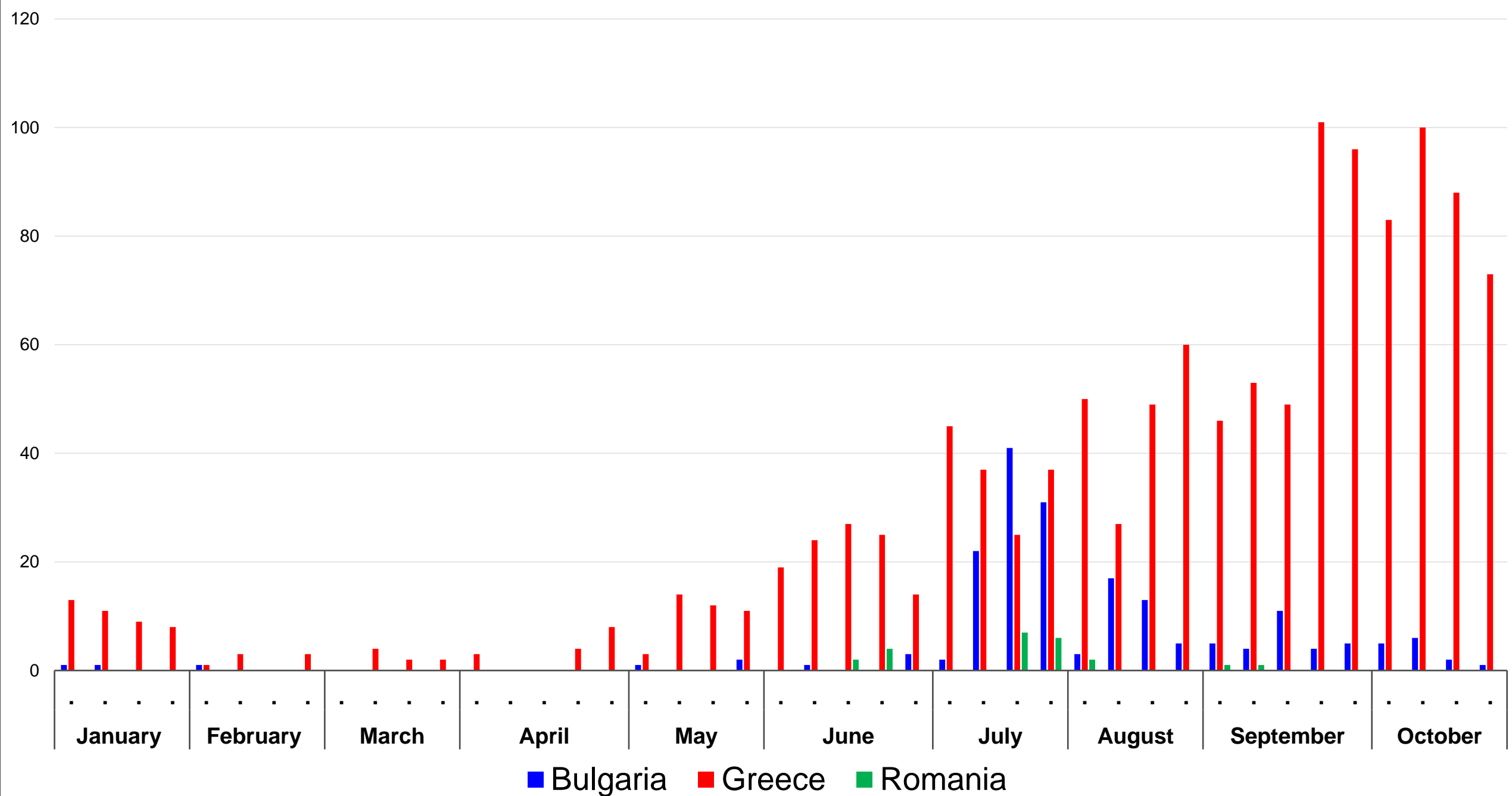
Greece: 1.239 outbreaks in total, mostly in mainland and northern areas

➤ **Bulgaria:** 187 outbreaks in total, mostly in the center and south areas (recurrence since May 2025).

➤ **Romania:** 23 outbreaks since 18 June 2025 – clustered around Teleorman and Olt counties. 1st occurrence of SGP in the past 20 years or more. **All measures lifted as of 24 October 2025 (no secondary outbreaks)**



SPGP in the EU - Number of new outbreaks per week, 01 Jan - 29 Oct 2025



SPGP regionalization in Greece and Bulgaria

As of 29 Oct 2025

Protection Zones

5 km radius – 45d

Surveillance Zones

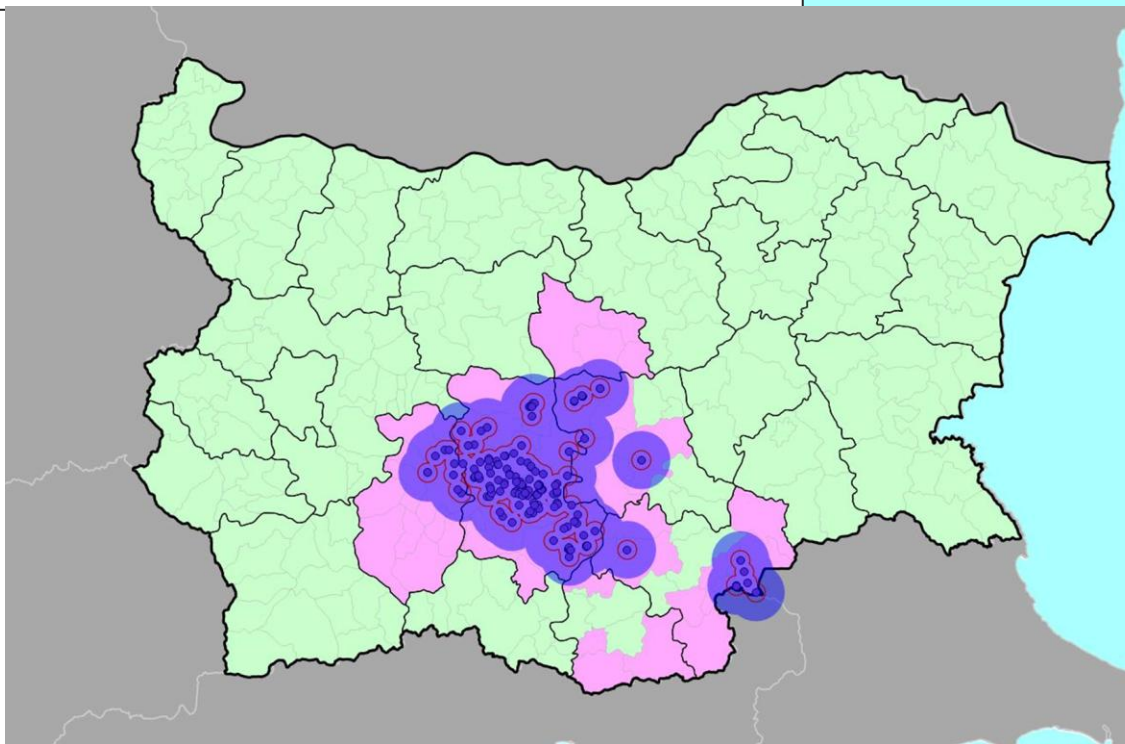
20 km radius – 55d

Further Restricted Zone (FRZ)

appr. 40 km radius (admin. boundaries), 85d ,
encasing all outbreaks

Entire countries (EL,BG):

Prohibition of movements of small ruminants to
other countries (extended to 31 January
2026).



PPR situation the EU



PPR in the EU

January – September 2025



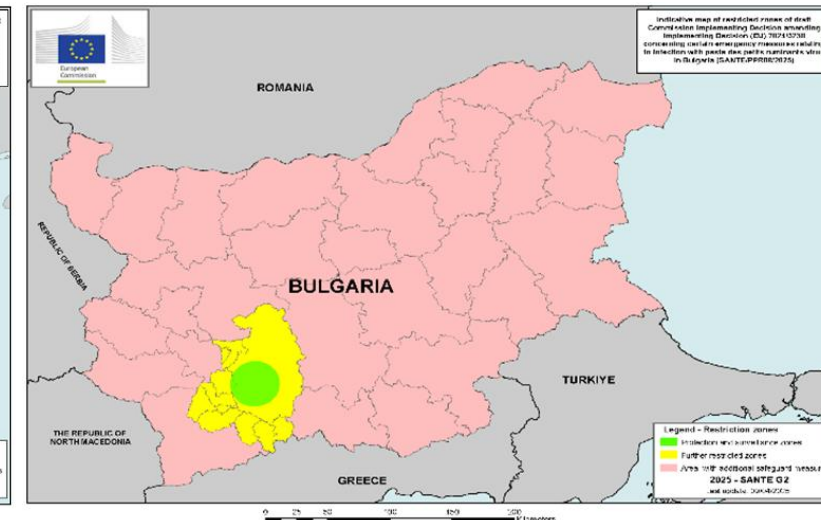
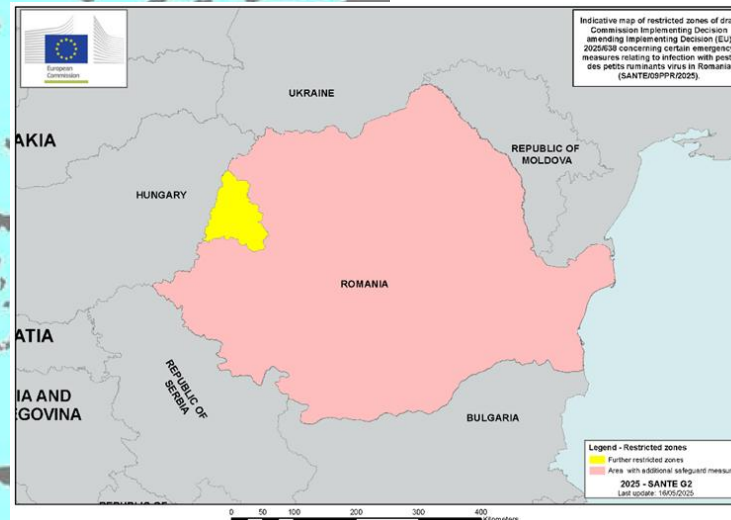
Major outbreaks of 2024 swiftly eradicated (Greece – Romania)

2025 – “Spill overs”

- **Bulgaria:** one single outbreak reported in Nov 2024
Unresolved
- **Hungary:** 3 outbreaks reported between Jan –Feb 2025.
Resolved

No PPR vaccination

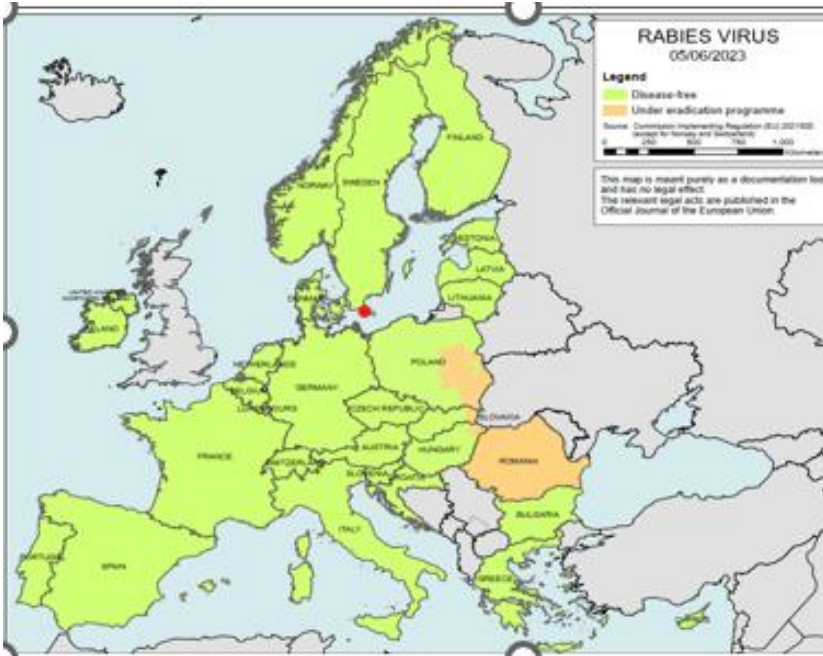
Regionalization PPR Bulgaria and Romania
prohibition of animal movements to other Member States/countries;



Rabies situation the EU



Highlights - EU 2025

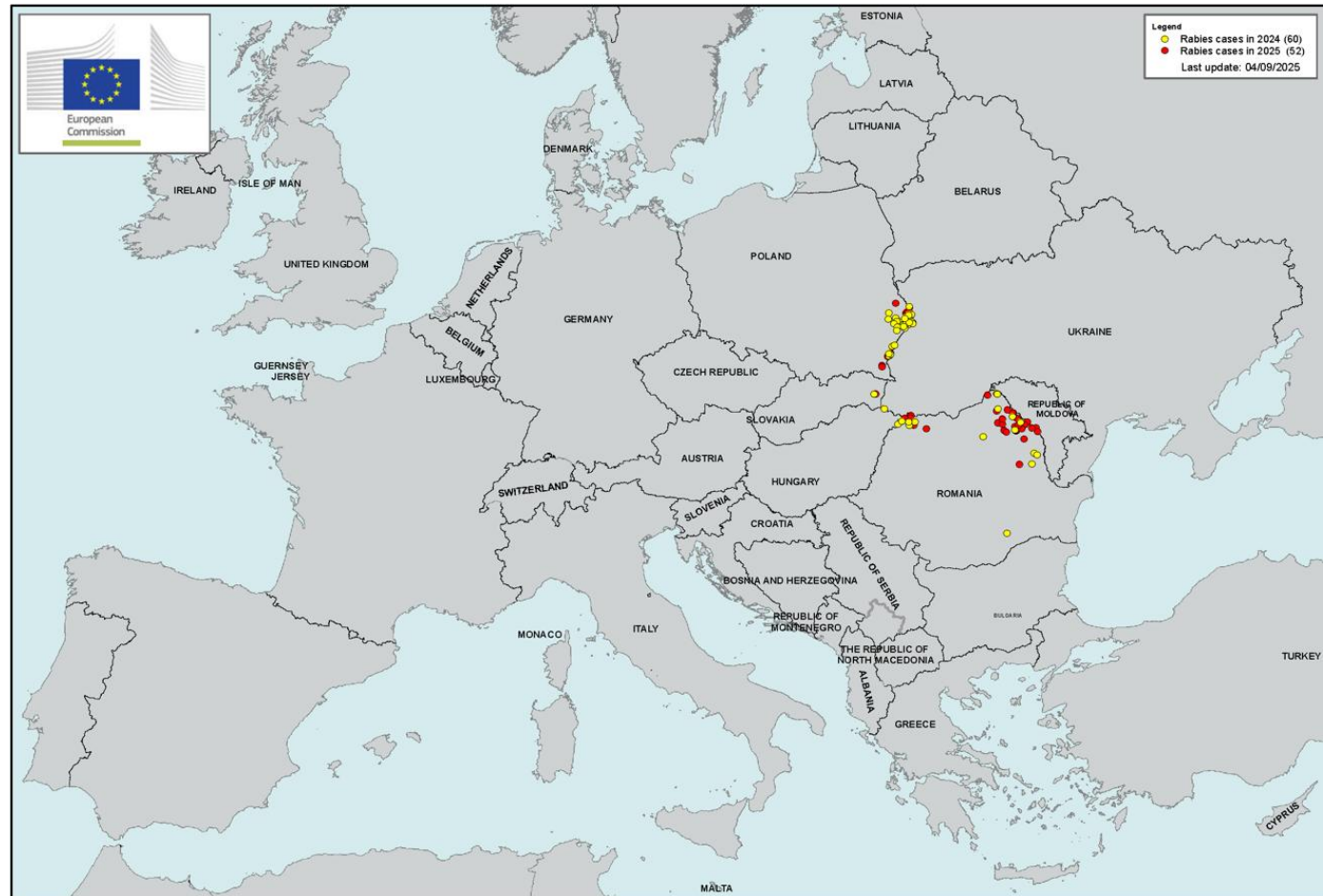


Re-incursions from rabies endemic zones at eastern borders:

- in former free MS (eastern border): Hungary (2024: 18, 2025: 0) and Slovakia (2024: 1, 2025: 1)
- in North – Northeast: Romania (2024: 28, 2025: 40)
- In Southeast: Poland (2024: 48, 2025: 14)

‘Compulsory eradication programme’ in MS not free which must consist of

- surveillance
- disease control measures
- wildlife vaccination



HPAI
LSD

2025 Situation and vaccination in the EU

General aspects

Specific aspects

EU AHL rules for vaccination

Dedicated measures for Category A (and two B diseases)

- Delegated Regulation (EU) 2023/361
 - Harmonized conditions, surveillance, recovery, restrictions

Eradication programmes for Category C (and B diseases)

- Delegated Regulation (EU) 2020/689
 - Approval of programmes
 - Granting free status

Vaccine banks

- AHL (Art 48-52): only for Category A diseases
 - CDR (EU) 2022/139 and CIR (EU) 2022/140
 - Financial support

General approach

Rules on the use of **certain VMPs** for prevention and control of **certain listed diseases - Terrestrial and Aquatic animals**

Circumstances under which **vaccines for category A** diseases can be used

Which **VMPs cannot be used for category A and B** diseases (including some vaccines, i.e. *Rinderpest and Mycobacterium tuberculosis complex*)

Rules on the use of **vaccines** for prevention and control of category A diseases – **Terrestrial animals (partially Aquatic)**

Preconditions

Strategies

General rules

Risk-mitigation measures (movement restrictions)

Disease-specific conditions

Implementation + post vaccination surveillance

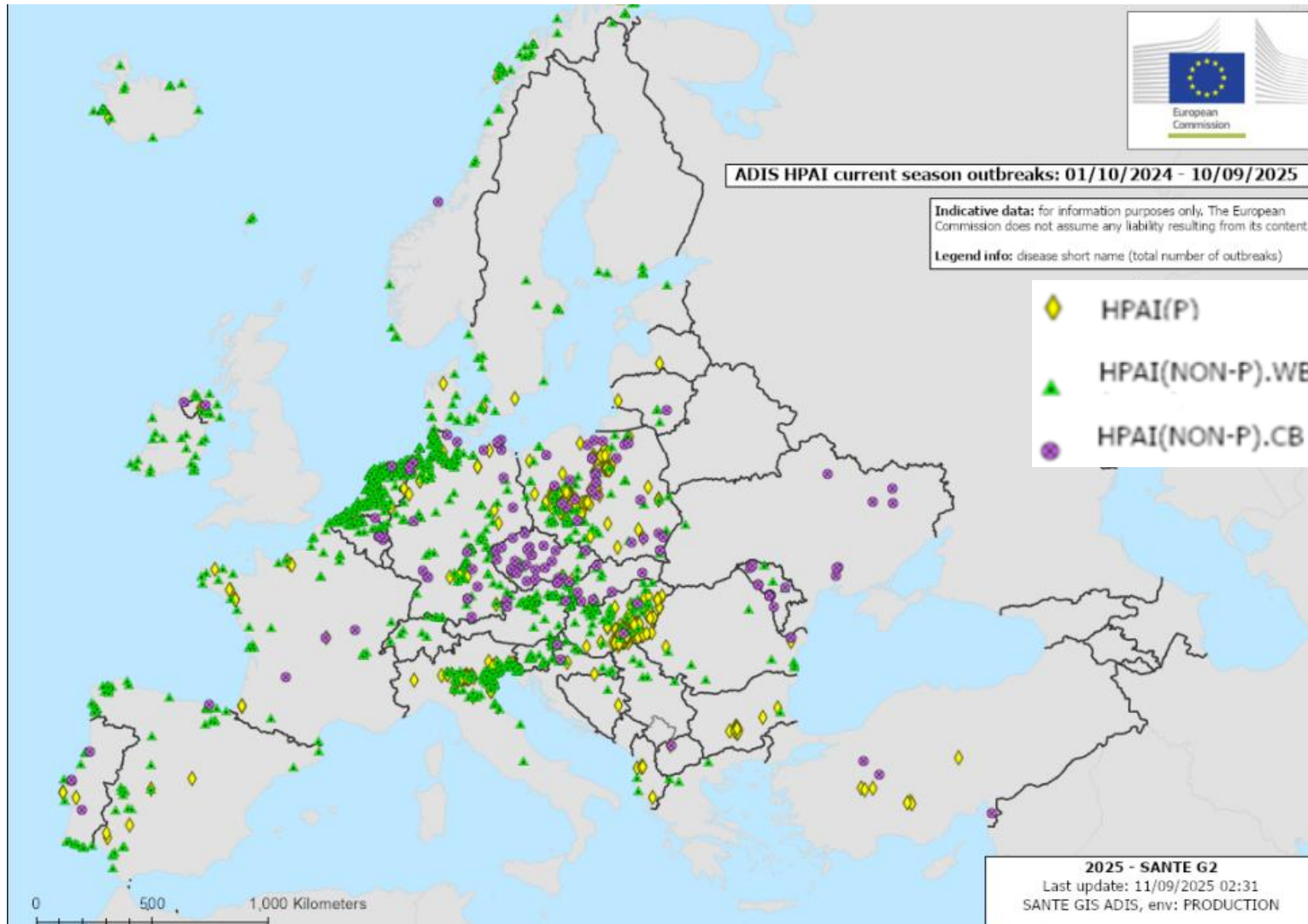
Measures (movement prohibitions for animals and products) in the vaccination zone

Recovery of the previous animal health status

HPAI situation and vaccination in the EU



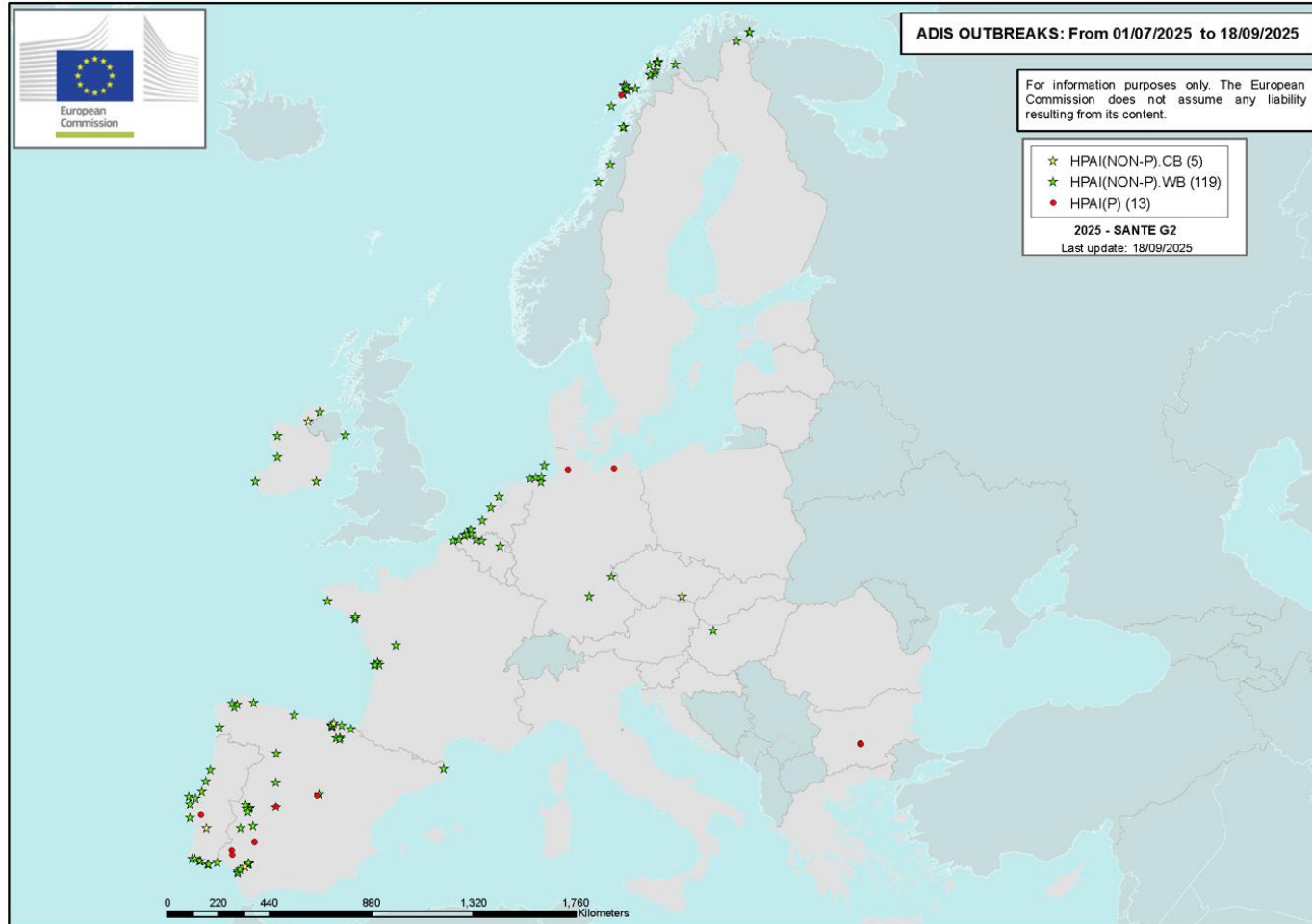
HPAI situation in 2024-2025 epidemic season



EU Member States:

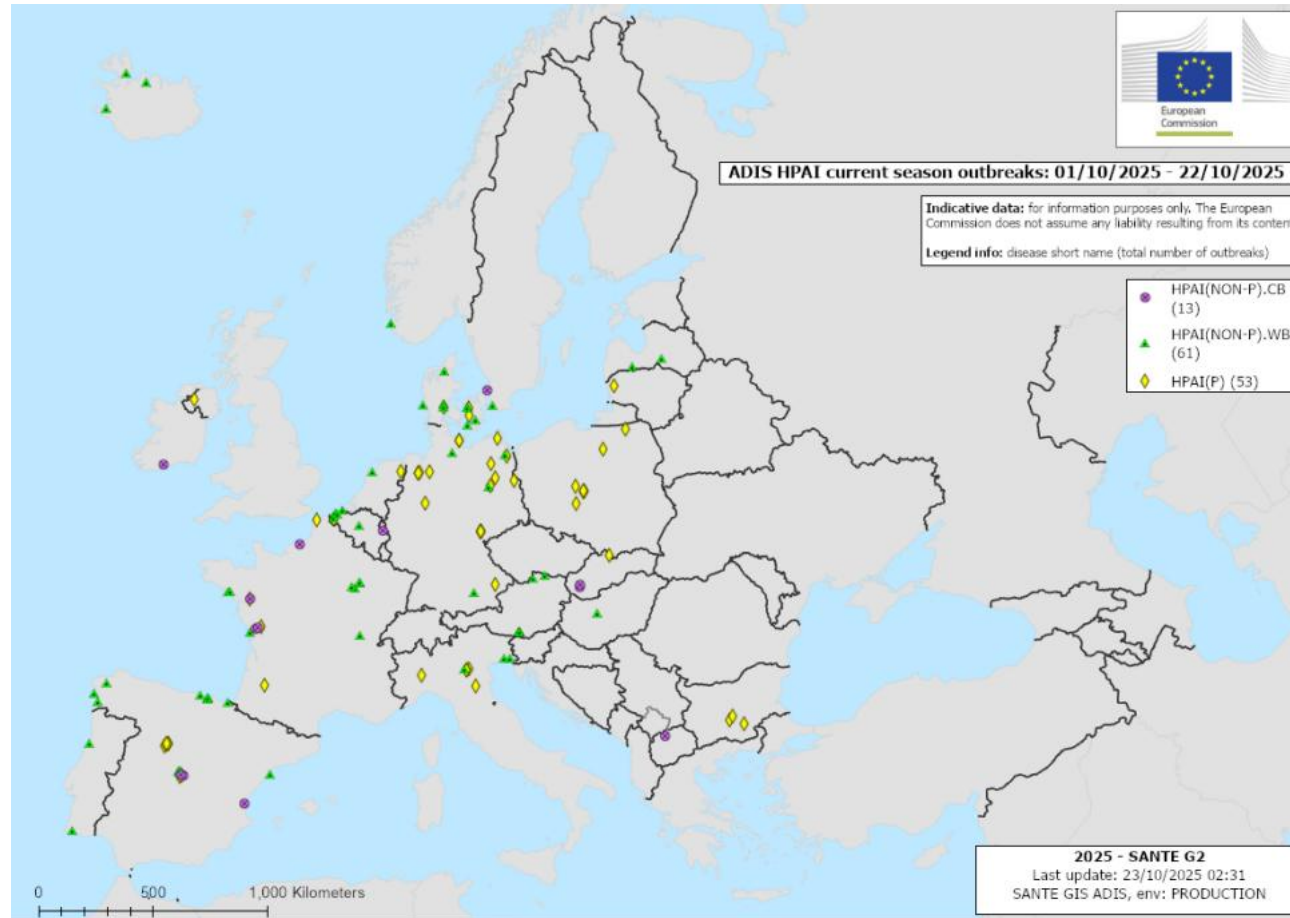
- **1039 outbreaks in wild birds** in 23 Member States
- **544 outbreaks in poultry** confirmed in 19 Member States
- **22.4 million poultry** in the outbreak establishments (dead or culled)
- **in certain areas, clusters of outbreaks involving ducks and turkeys**

HPAI situation in Europe in summer 2025 (!)



- **119 outbreaks in wild birds**
- **5 outbreaks in captive birds**
- **13 outbreaks in poultry** (mainly turkeys and ducks)
- predominant in **W and S-W** of Europe
- **more than 75%** of detections in wild birds concerned **colony-breeding seabirds**, particularly European **herring gulls**

HPAI situation since 1 October 2025



- **61 outbreaks in wild birds**
- **13 outbreaks in captive birds**
- **53 outbreaks in poultry** (mainly turkeys and ducks)
- Already spread in many parts of EU
- **Common Cranes** – top of the list as affected species in the last week

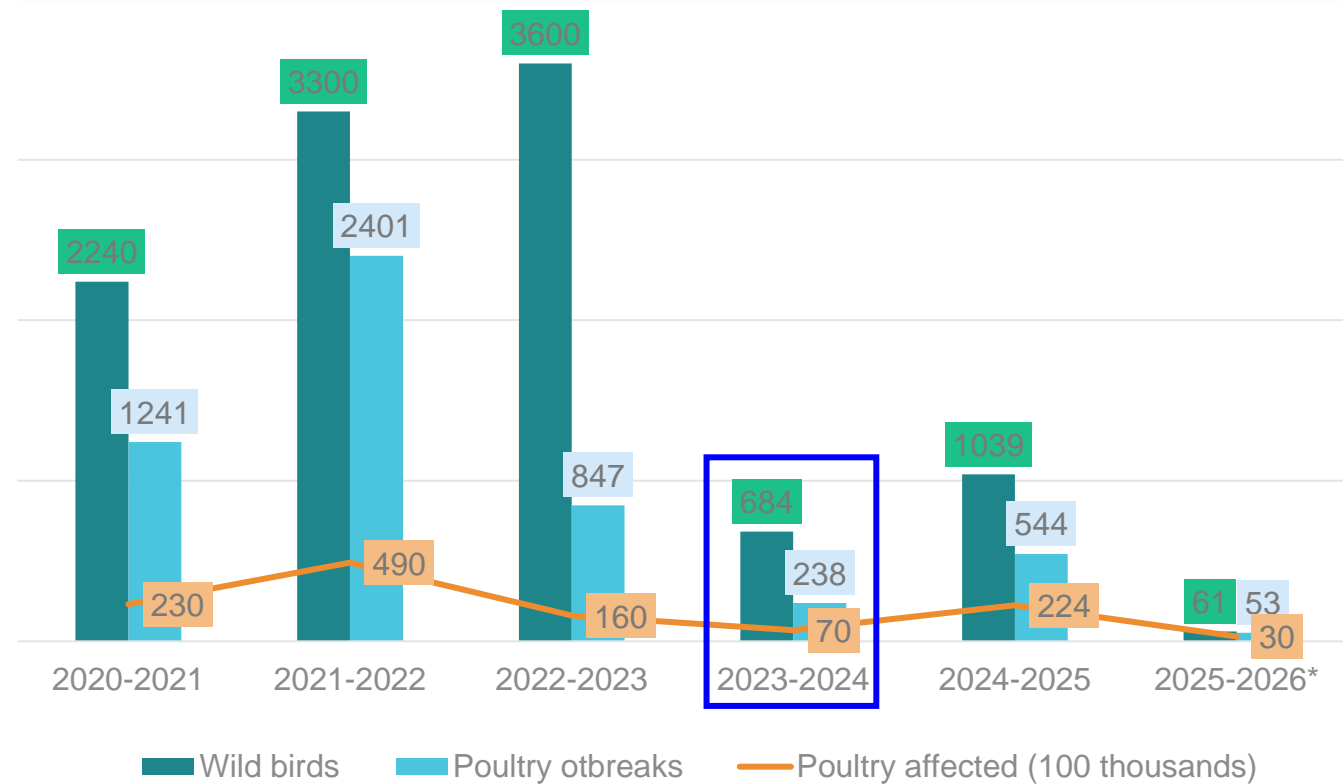
Summary of HPAI epidemic seasons

2021-2022:
the most severe HPAI epidemic season ever experienced by EU

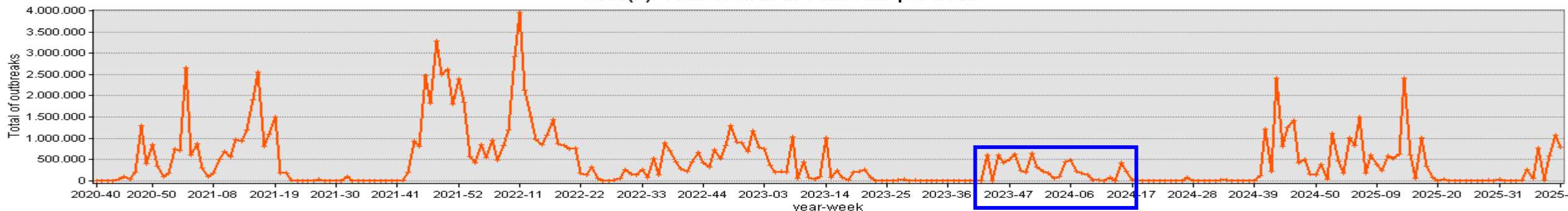
2022-2023:
even with higher number of outbreaks in wild birds, less poultry outbreaks (improved biosecurity and preventive measures e.g. reduced density in high risk areas)

2023 - 2024:
the least severe epidemic season since 2020 Start preventive vaccination of poultry (ducks) in France

2024 - 2025 and the new epidemic season:
Earlier start of season, increased number of outbreaks than 2023 - 2024 season. Vaccination of ducks in France continues

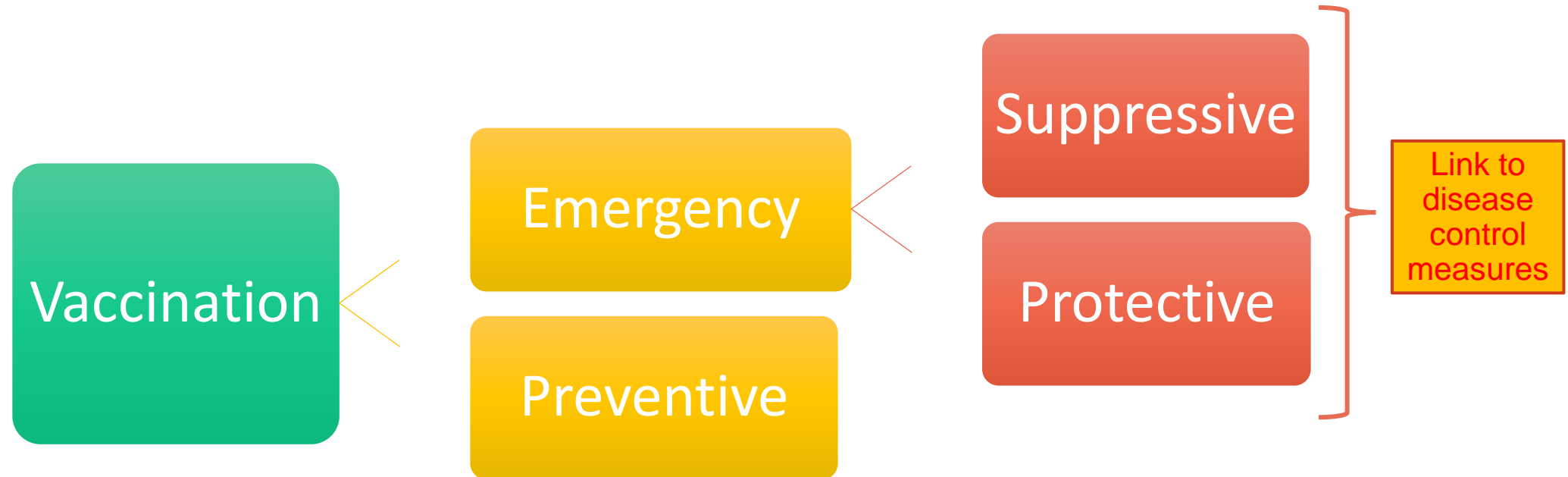


HPAI(P): Total of birds in outbreaks per week



Up to 22 October 2025

Allowed vaccination strategies for HPAI



- **Biosecurity** remains the cornerstone as preventive measure to protect poultry from HPAI-infection
- **Stamping out** is still always a compulsory measure in all establishments where HPAI is detected

Specific rules for vaccination against HPAI

Vaccines

- that do not contain live AI virus (attenuated or not)

Reinforced surveillance

- clinical and laboratory (official activity)
- to assess effectiveness (emergency protective vaccination)
- to early detect infection with HPAI virus

Risk mitigation measures

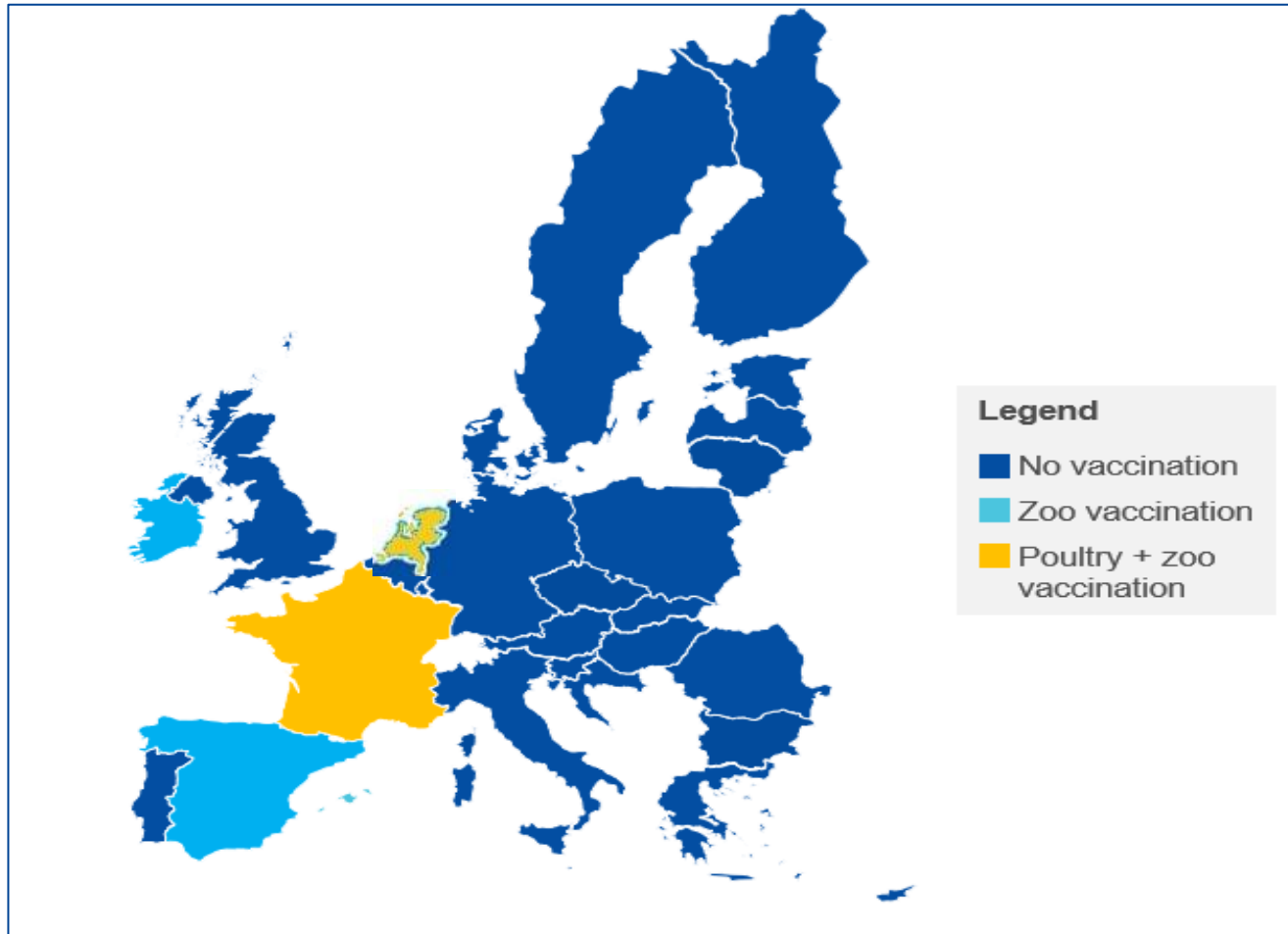
- General prohibition for movements of vaccinated poultry and their products
- Derogations to move, under conditions

Traceability/Certificates

- Emergency vaccination: certificates for movements from vaccination zone within MS and to other MS
- Preventive vaccination: certificates for poultry and hatching eggs when moved to other MS

Vaccination against HPAI in EU

Preventive vaccination in the EU



HPAI vaccination in poultry in the EU

Country	Icon	Strategy	Species	Period
France		• Large scale preventive vaccination	• Ducks for meat/foie gras production (Barbarie, mulard and Pékin)	• Started 1 October 2023
the Netherlands		• Small scale PILOT preventive vaccination (1 farm)	• Laying hens	• Started 10 March 2025

European Commission



HPAI vaccination in poultry in the EU

France



Strategy

- **Wide preventive** vaccination

Species

- **Ducks for meat/foie gras production** (Barbarie, mulard and Pékin)

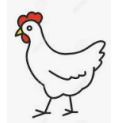
Period

- **Started 1 October 2023, extended for one year**, until end September 2025

Number of ducks

- First year of vaccination: **61,5 million ducks vaccinated** on **2300 establishments**. Second year, so far, **32,5 million ducks vaccinated**

the Netherlands



Strategy

- **Small scale pilot Preventive** vaccination

Species

- **Laying hens**

Period

- **Started 10 March 2025**

Number of establishments

- Started with 1 laying hen establishment

New: Compartments for HPAI and ND within the EU (only)

based on AHL (Art. 37) + Delegated Regulation (EU) 2024/2623

General rules:

- Member States **may** apply for recognition of disease-free status of compartments, if:
- **introduction** of the disease **can be effectively prevented** at compartment level
- compartment is subject to a **single common biosecurity management** system for all establishments forming part of it
- has been **approved by the Competent Authority**

Specific rules:

- Compartments possible **for HPAI and ND**
- Compartment status based on higher level of **biosecurity management and surveillance plans** developed and implemented by operators, and verified and approved by Competent Authorities
- **not an alternative to regionalization/zoning**, but a voluntary mechanism, complementing it
- **not a replacement** but an addition **to compulsory biosecurity (higher level)** according to EU and national legislations

EU preparedness for zoonotic HPAI



SIMEX exercise focussed on zoonotic HPAI

- in Brussels on **10-11 December 2024**
- **Participants: public health and animal health** experts from EU/EEA countries, ECDC, EFSA, DG SANTE, DG HERA

EFSA scientific work

- **Opinion on preparedness, prevention and control** related to zoonotic avian influenza (j.efsa.2025.9191)
- *Jointly with ECDC* – **report on coordinated One Health investigation and management of outbreaks** in humans and animals caused by zoonotic avian influenza viruses
- **Report on risk posed by the HPAI virus H5N1, clade 2.3.4.4b. genotype B3.13**, currently circulating in the US (j.efsa.2025.9508)

EC guidance document

- **supports MS in their actions and in decision making process**
- **shares EC internal reflections on possible EU actions** to address the specific events of HPAI in dairy
- gives a comprehensive overview of **ongoing actions and scenarios for possible future measures** and available tools to react
- https://food.ec.europa.eu/animals/animal-diseases/diseases-and-control-measures/avian-influenza_en#Zoonotic

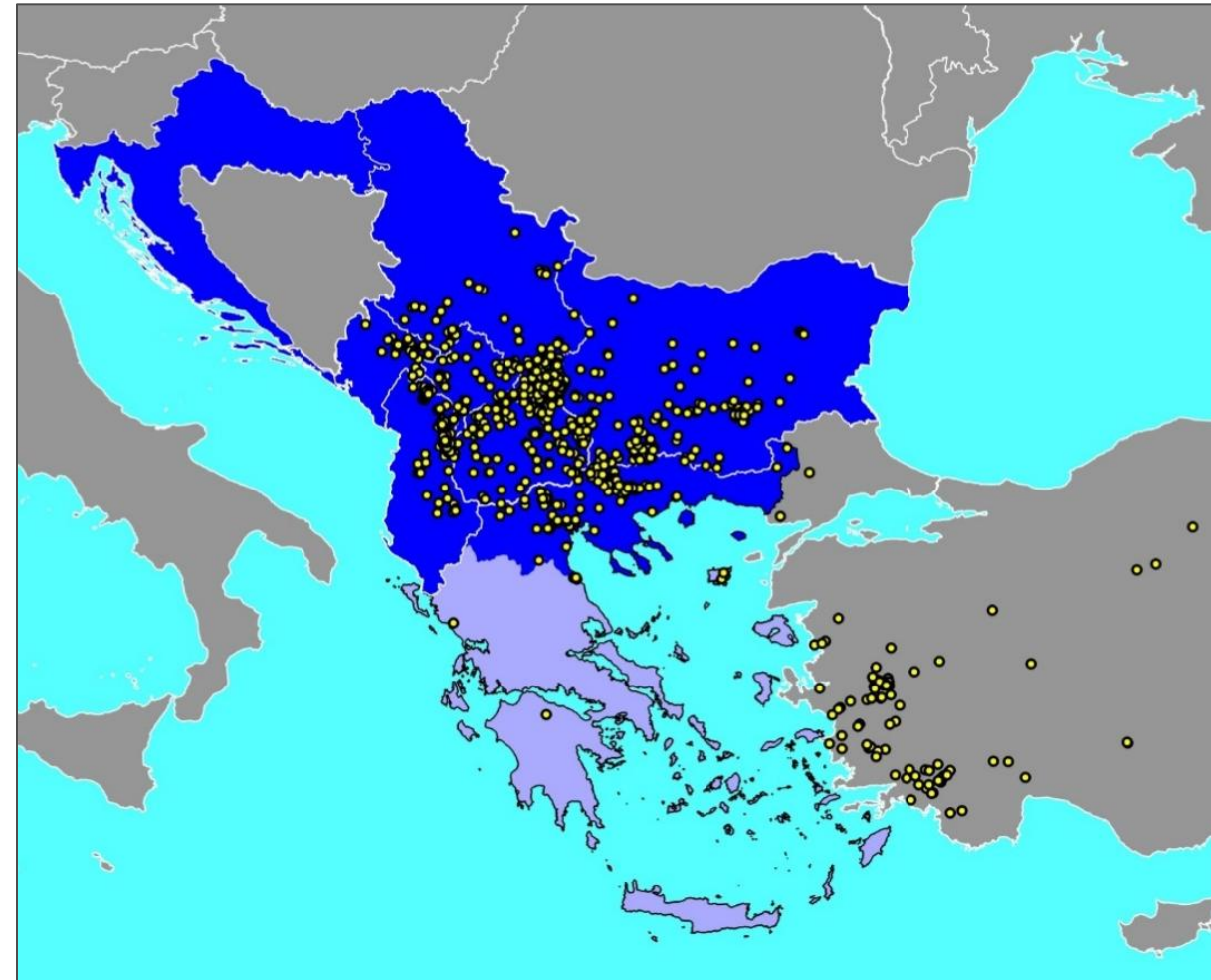
LSD situation and vaccination in the EU



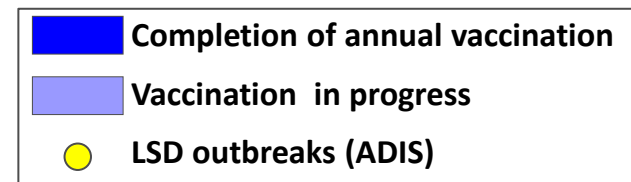
Lumpy Skin Disease (LSD) Background (2013 - May 2025)

- ✓ LSD endemic in Africa – present in the Middle East
- ✓ 2013 : LSD enters Turkiye
- ✓ 2015: First incursion of LSD in Greece
- ✓ 2016: Numerous outbreaks of LSD in South East Europe. Mass vaccination campaigns launched in affected countries.
- ✓ 2017: Outbreaks in Albania, Greece and North Macedonia. Annual revaccination in all previously affected countries.
- ✓ 2018-2019: No outbreaks of LSD (excluding Turkiye), annual revaccination continues
- ✓ 2019-2022: Countries gradually stop LSD vaccination and replace it with surveillance (2021: Last LSD outbreak reported in Turkiye)
- ✓ 2023: Last year of vaccination in Greece and Bulgaria. Vaccination continues only in Turkiye (East Anatolia)
- ✓ 2024 – May 2025: No LSD outbreaks in South East Europe. Reports of LSD outbreaks in Northern Africa

LSD outbreaks-vaccination in 2016
(peak of the epidemic in South East Europe)



>7.000 outbreaks in 7 countries (excl. Turkiye)



LSD in the EU in 2025

23 June 2025

ITALY reports 1st ever outbreak in Sardinia – secondary outbreaks

(76 outbr. in total. Last report on 22/10/2025)

25 June 2025

ITALY reports 2nd outbreak in Mantua - Lombardy (farm that received animals from Sardinia)

no secondary outbreaks

30 June 2025

FRANCE reports 1st ever outbreak in Savoie - secondary outbreaks

(94 outbr. in total. Last report on 27/10/2025)

4 October 2025

SPAIN reports 1st ever outbreak in Gerona - secondary outbreaks

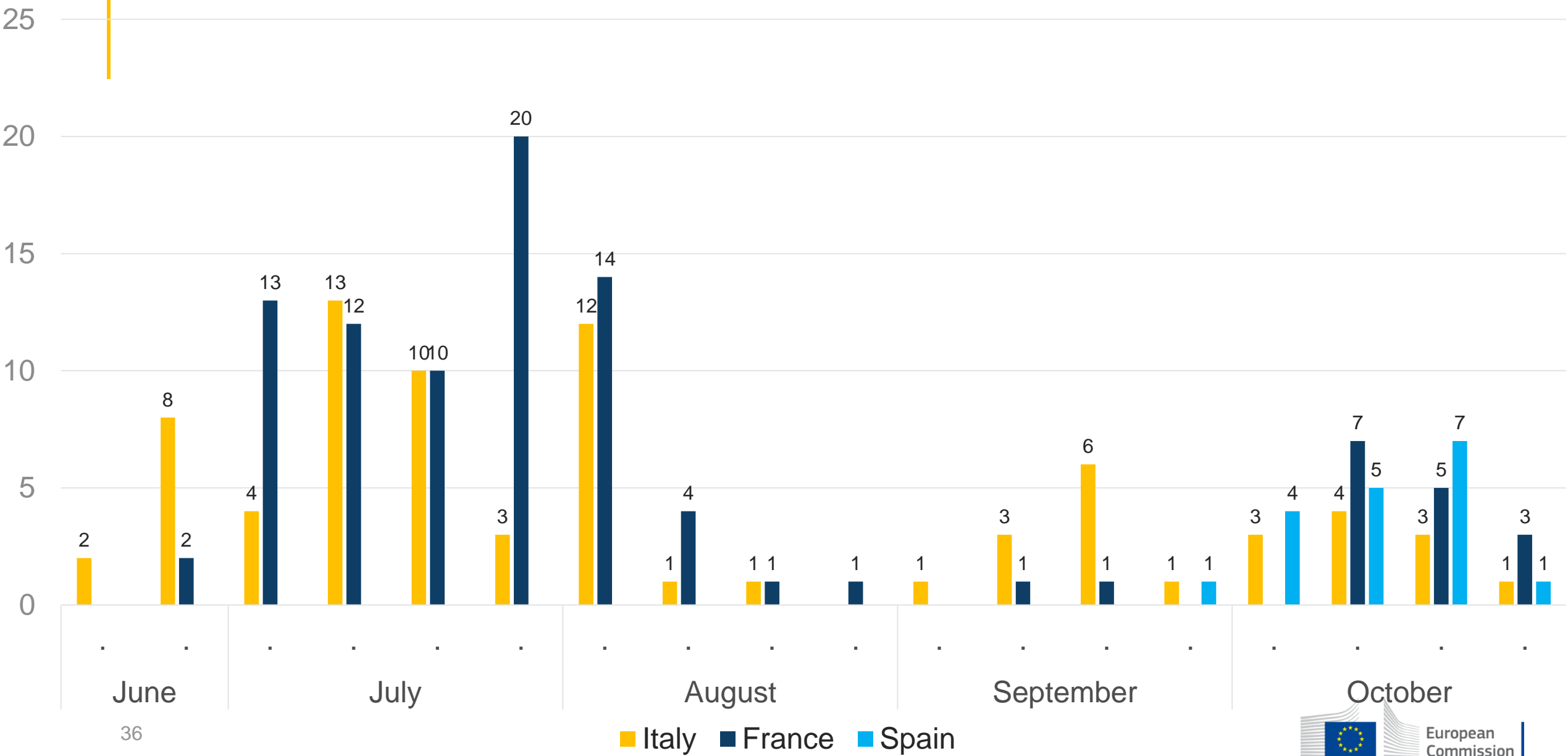
(18 outbr. in total. Last report on 27/10/2025)

July 2025- October 2025

Vaccination launched in Italy, France, Spain and Switzerland with progressive enlargement of vaccination zones

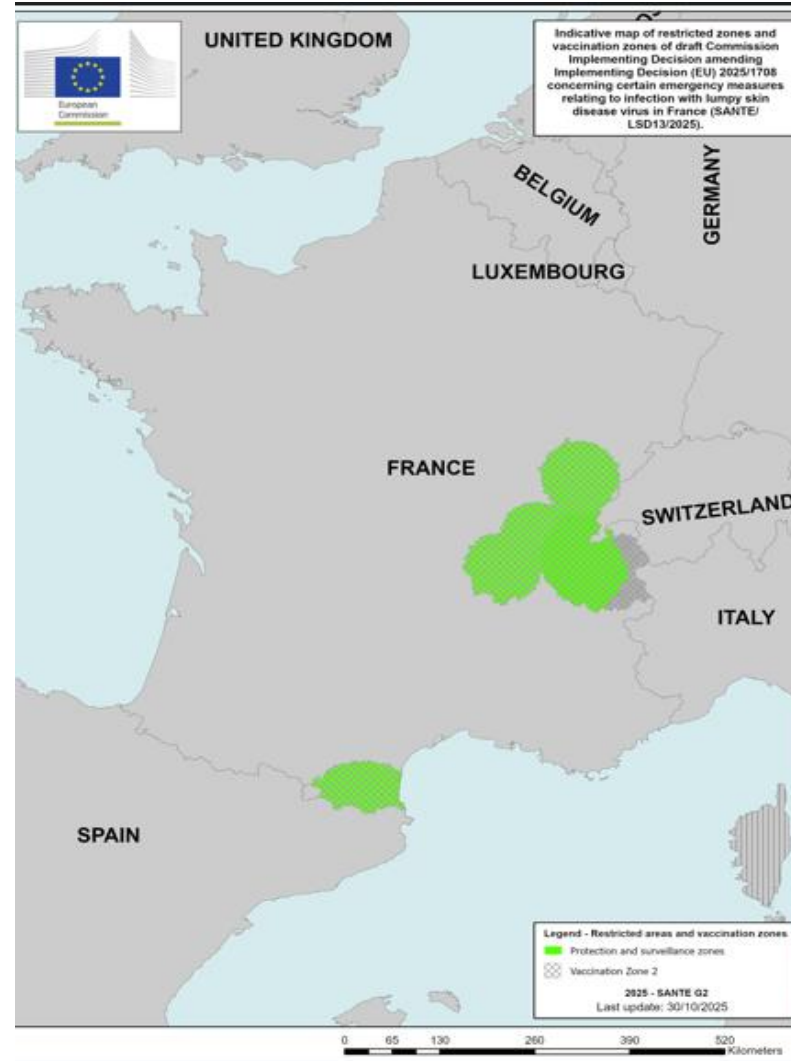


Number of new LSD outbreaks per week in the EU (June-October 2025)



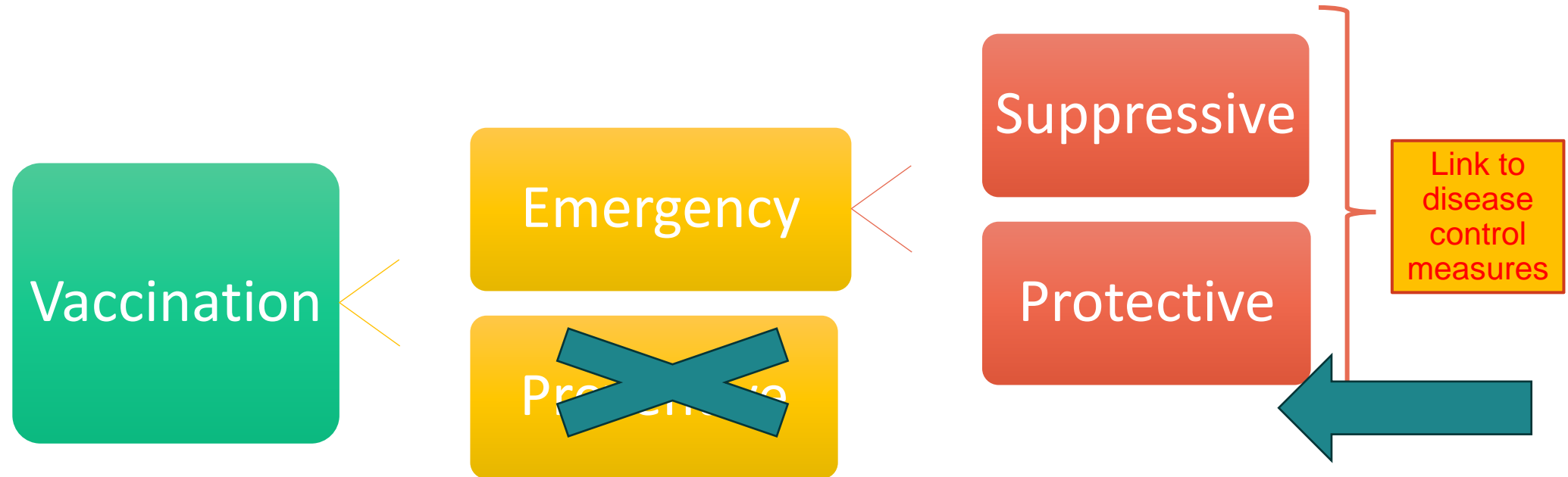
Incursion of LSD in the EU in 2025

regionalisation and vaccination



Revision in progress to include restricted zones + vaccination area France and Spain

Allowed vaccination strategies for LSD



- **Biosecurity** remains the cornerstone as preventive measure
- **Stamping out** is still always a compulsory measure in all establishments where LSD is detected

Specific rules for vaccination against LSD

Vaccines

- Live attenuated homologous vaccines

Reinforced surveillance

- clinical and laboratory (official activity)

Risk mitigation measures

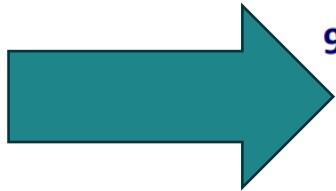
- General prohibition for movements of vaccinated cattle and some products (NOT MEAT)
- Derogations to move, under conditions

Traceability/Certificates

- Emergency vaccination: certificates for movements from vaccination zone within MS and to other MS

Vaccination in France

Vaccination campaign in Restricted Zone of Savoie



90% of vaccinated cattle in the restricted zone (as of today).

91% of vaccinated cattle was achieved on August 27, in the previous restricted zone.

July 1st

Ordering doses to the European Commission.

15th

Receipt of doses in France.

16th

Ministerial decree acting mandatory vaccination of cattle in the restricted zone.

July 18th

First vaccinations, covered by the government, administered by veterinarians.

Vaccination in Corsica

- Disease-free island
- Geographical proximity to Sardinia, where LSD outbreaks have occurred



General Directorate of Food



941 cattle farm

75% cattle in 442 holdings



40 413 cattle

Vaccination with MSD vaccine began on September 1st and will last 4 months

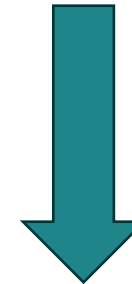
Vaccination in Italy

Vaccination campaign

Region	Start date	No. of establishments with vaccinated animals	% vaccinated establishments	No. of vaccinated animals	% vaccinated animals	Status
Valle d'Aosta	09/08/2025	1,024	97.62%	33,291	98.01%	Completed on 05/09/25
Sardinia	23/07/2025	5,571	71.85%	185,790	65.30%	In progress



SCHEMA VACCINAZIONI LUMPY SKIN DISEASE								
ASL	N DI STAB CAPI > 0	N DI STAB VACCINATI	% STAB VACCINATI	TOT CAPI BDN	N CAPI PRESENTI SU STAB VACCINATI	N CAPI VACCINATI	% CAPI VACCINATI SU PRESENTI	% CAPI VACCINATI SU CONSISTENZA
1 SASSARI	1803	1364	75,65%	54524	39195	38439	98,07%	70,50%
2 GALLURA	1503	1242	82,63%	32234	27856	27351	98,19%	84,85%
3 NUORO	1920	1254	65,31%	75150	45291	38723	85,50%	51,53%
4 OGLIASTRA	497	166	33,40%	30880	9042	7618	84,25%	24,67%
5 ORISTANO	1126	928	82,42%	60926	55693	53343	95,78%	87,55%
6 MEDIO CAMPIDANO	106	92	86,79%	4124	3378	3260	96,51%	79,05%
7 SULCIS	125	112	89,60%	3359	3031	3071	101,32%	91,43%
8 CAGLIARI	674	370	54,90%	23319	14523	12908	88,88%	55,35%
Totale	7754	5571	71,85%	284516	199103	185790	93,31%	65,30%

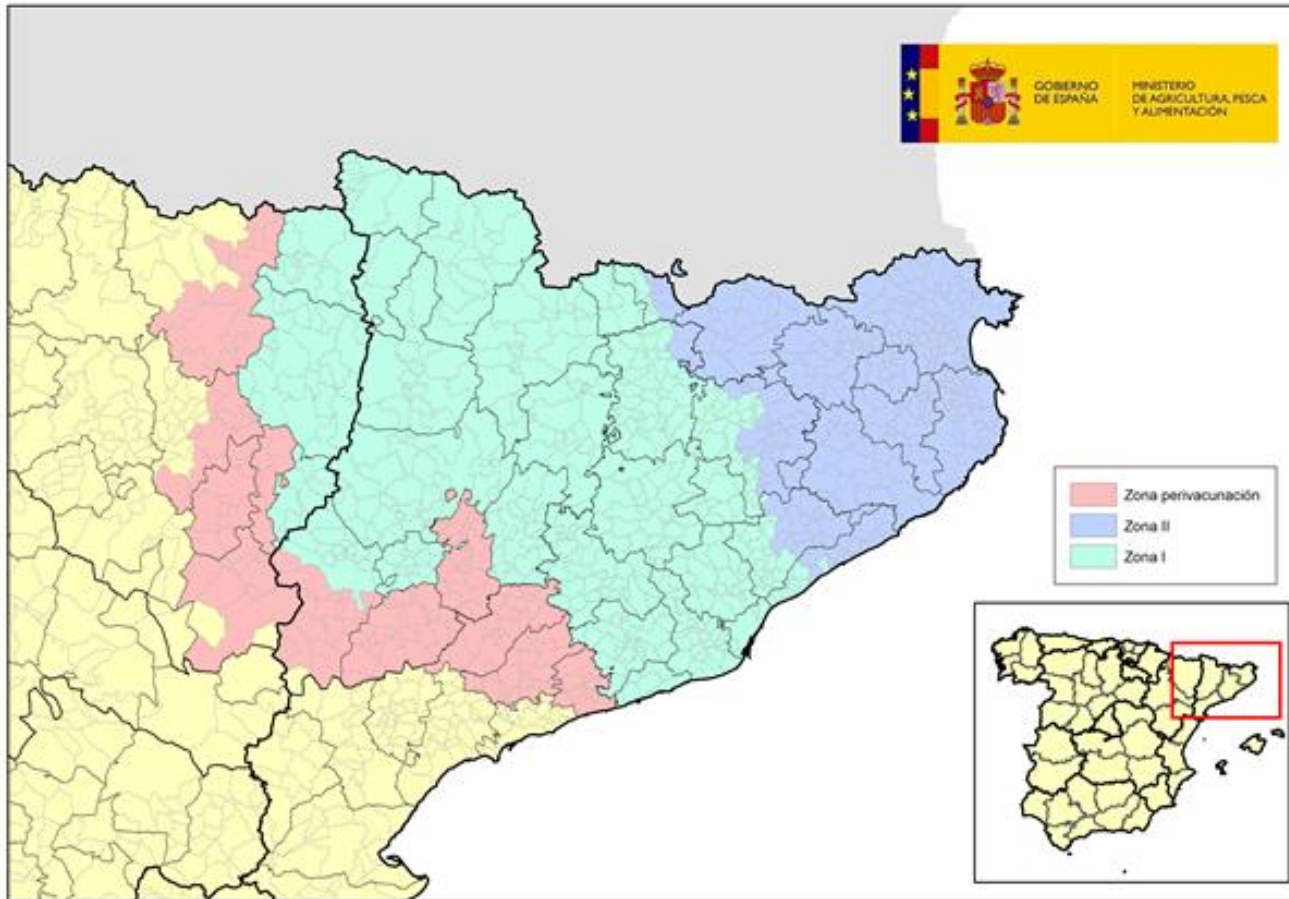


Side effects reported in 15 farms (**0.28%**):

- Local reaction at injection site
- Neethling disease
- Fever



Vaccination in Spain



LSD in the EU in 2025

regionalisation

REGIONALISATION (Commission Delegated Regulation (EU) 2020/687)

Around each and every outbreak establishment of :

- **A Protection zone (PZ)** - mandatory: At least 20 km radius, for 28 days
- **Surveillance zone (SZ)** - mandatory: At least 50 km radius, for 45 days
- PZ and SZ defined on the basis of radius (IT) or as a list of administrative units (FR, list of municipalities).
- Duration may be extended due to occurrence of secondary outbreaks or delays in the implementation of stamping out in affected establishments.
- **A Further restricted zone (FRZ)** - optional: Size and measures adapted to the epidemiological situation.
 - Currently 1 FRZ in place, in ITALY (entire Sardinia, prohibition of shipments of cattle).

VACCINATION (Commission Delegated Regulation (EU) 2023/361)

Vaccination is a **key measure** for LSD control and eradication, **in combination with stamping out** due to its vector born nature.

An LSD outbreak usually triggers vaccination, unless clearly an isolated incident (e.g. the single outbreak in Lombardy – ITALY).

Vaccines used

Freeze-dried, live attenuated virus vaccine composed of Neethling strain.

Manufacturers:

- Onderstepoort Biological Products (OBP), South Africa.
- Bovilis Lumpyvax-E vaccine, (produced by Intervet International B.V. and sold by Merck Sharp and Dohme (MSD)).

IncurSION of LSD in the EU in 2025

regionalisation and vaccination

VACCINATION (Commission Delegated Regulation (EU) 2023/361)

Two different vaccination zones with different conditions/restrictions:

- Vaccination Zone II: Areas with confirmed LSD (e.g. Sardinia in Italy, Savoie and surrounding areas in France, Alt d'Amporda in Spain....)
Vaccination area = **Vaccination zone II** (includes at least the PZ, SZ and FRZ around confirmed outbreaks, restrictions in place for animals and products).
- Vaccination zone I: Areas at risk due to nearby LSD outbreaks (e.g. Corsica in France, Valle D' Aosta in Italy).
Vaccination area = **Vaccination zone I** (size adapted to the epidemiological situation, geographical boundaries, administrative limits etc.).

EU support against LSD in 2025

- **DG SANTE Coordination** - Remote meetings , PAFF Committee meetings, adoption of specific safeguard measures (11 Commission Implementing Decisions), regular info notes (46), mandates to EFSA
- **EU Reference Laboratory for Capripox virus diseases (LSD and SPGP)**
Sciensano Belgium appointed 2017, financed by the EU - Technical and Diagnostic support
- **EUVET expert team:** technical support on spot (**Italy** (26-27 June 2025) , **France** (15-16 July 2025))
- **EU financial support to MS:** EU co-financing of selected control measures incurred by the Member States,
- **EU support for LSD surveillance activities (early detection):** Transboundary Animal Diseases (TADs) programme (*Greece, Bulgaria*) and the T.H.R.A.C.E programme (*Greece, Bulgaria, Turkiye*).
- **International coordination meetings**
- **EU LSD Vaccine Bank** – more than 750 000 doses delivered to Italy (340 000), France (352 500 2,500 doses of those were transferred to Switzerland and Spain (82 000)

Some conclusions

The EU policy relies on key elements for HPAI and LSD (and other major diseases) that operate simultaneously:

1-Stamping out, Regionalization, Biosecurity - always

2-Vaccination used in addition to 1 – is revealing as a necessary measure - sometimes

3-Vaccination under strict rules adapted to different scenarios – is safe - always

Thanks