Animal Health Law and EU update

26th Annual meeting of the NRLs for Avian Influenza and Newcastle Disease of EU

European Commission,
DG Health and Food Safety
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Health and Food Safety

Outline of the presentation

PART I – AHL, update on future implementation

- Short introduction to the AHL
- Where are we in the process?
- Updates with focus on AI & ND

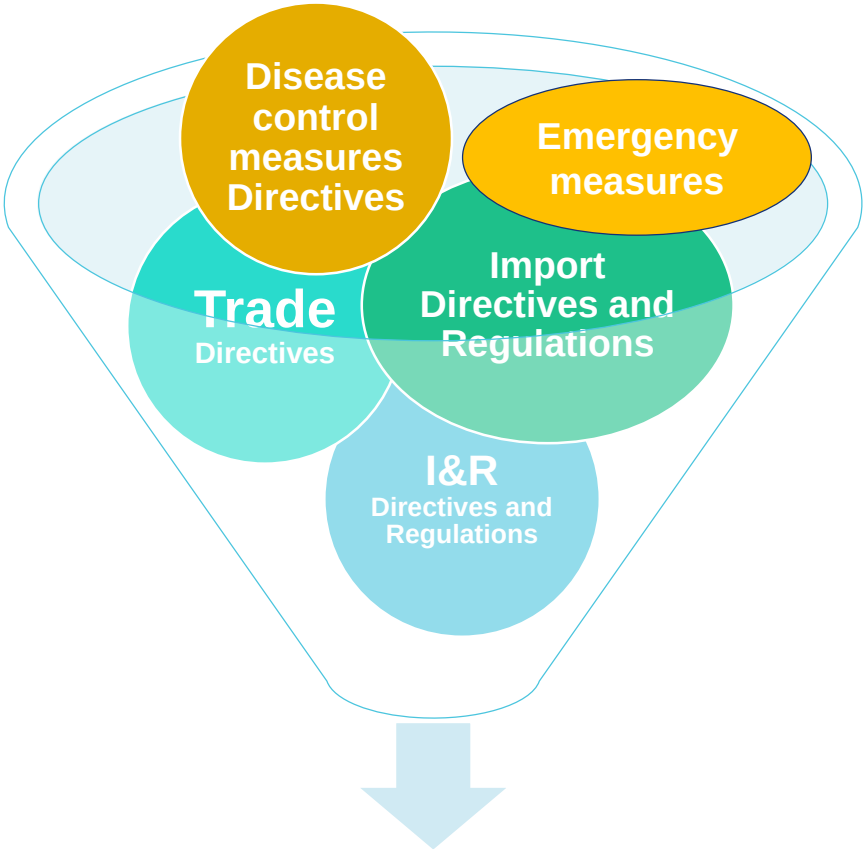
PART II - EU update on Avian Influenza and Newcastle disease

PART I

Animal Health Law
(AHL, Regulation (EU) 2016/429)

Update on future implementation

AHL



- ✓ Adopted : 9 March 2016
- ✓ In force: 21 April 2016
- ✓ Apply : **21 April 2021**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Contents

I *Legislative acts*

REGULATIONS

* 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') (1) 1

AHL: one single legal framework for the EU animal health policy

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AHL: what it is

About?

- ✓ General principles for **transmissible animal diseases** in:
  - ✓ Kept and wild animals and their products
  - ✓ Terrestrial, aquatic and other animals (e.g. reptiles)
- ✓ Animal health rules for:
  - ✓ **Disease prevention**
  - ✓ **Disease surveillance, control and eradication**
  - ✓ **Intra-EU movements and entry into the EU of animals and products**
  - ✓ **Emergency measures**

Not about?

✓Not in scope:

- ✓**Animal welfare**
- ✓**EU veterinary expenditure**
- ✓**Feed, medicated feed**
- ✓**Veterinary medicines (VMP)**
- ✓**Veterinary education**
- ✓**Official controls**

✓Specific rules remain in place for:

- ✓**Animal by-products**
- ✓**TSE rules**
- ✓**Certain zoonoses**

Structure of the AHL

PART I – General rules

PART II – Disease notification, reporting, surveillance, eradication programmes, disease freedom

PART III – Disease awareness, preparedness, control

PART IV

TITLE 1 – Registration, approval, traceability and movements (terrestrial)

TITLE 2 – Registration, approval, traceability and movements (aquatic)

TITLE 3 – Other animals and their products

Part V – Entry into EU

Legally speaking

- AHL is a Regulation = directly applicable in all MS

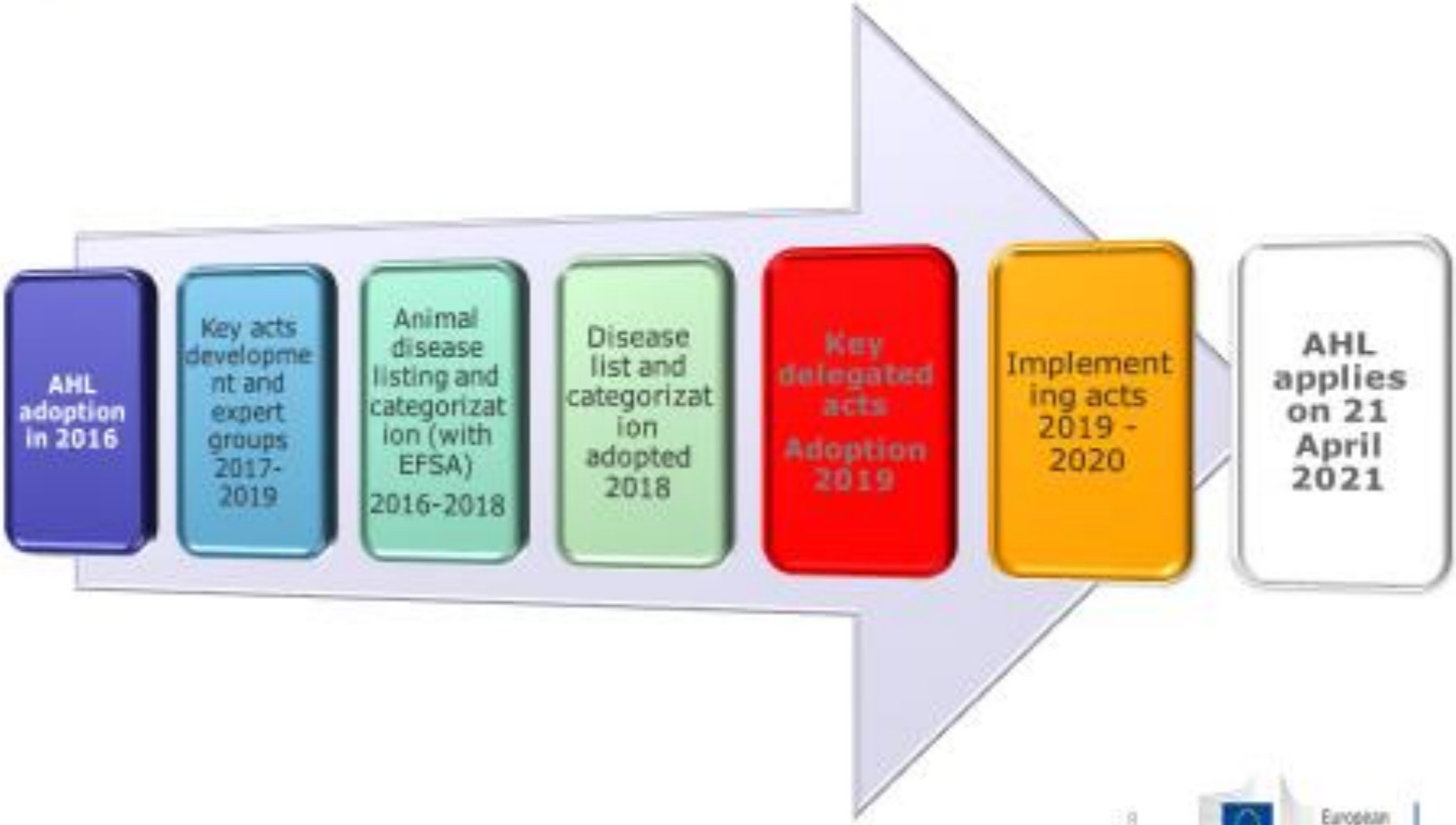
But!

- a number of provisions to be laid down by MS (designation of authorities for the application, national measures, stricter measures, penalties, etc.)
- AHL is complemented by various Delegated acts (DA) and Implementing acts (IA), which make it operational

  - DAs have general application and supplement or amend certain non-essential elements of the basic act ……**'what do we do'?**

  - IAs are more technical in nature…….**'how do we do it'?** Objective is to ensure uniform application of the Basic Act or the DA

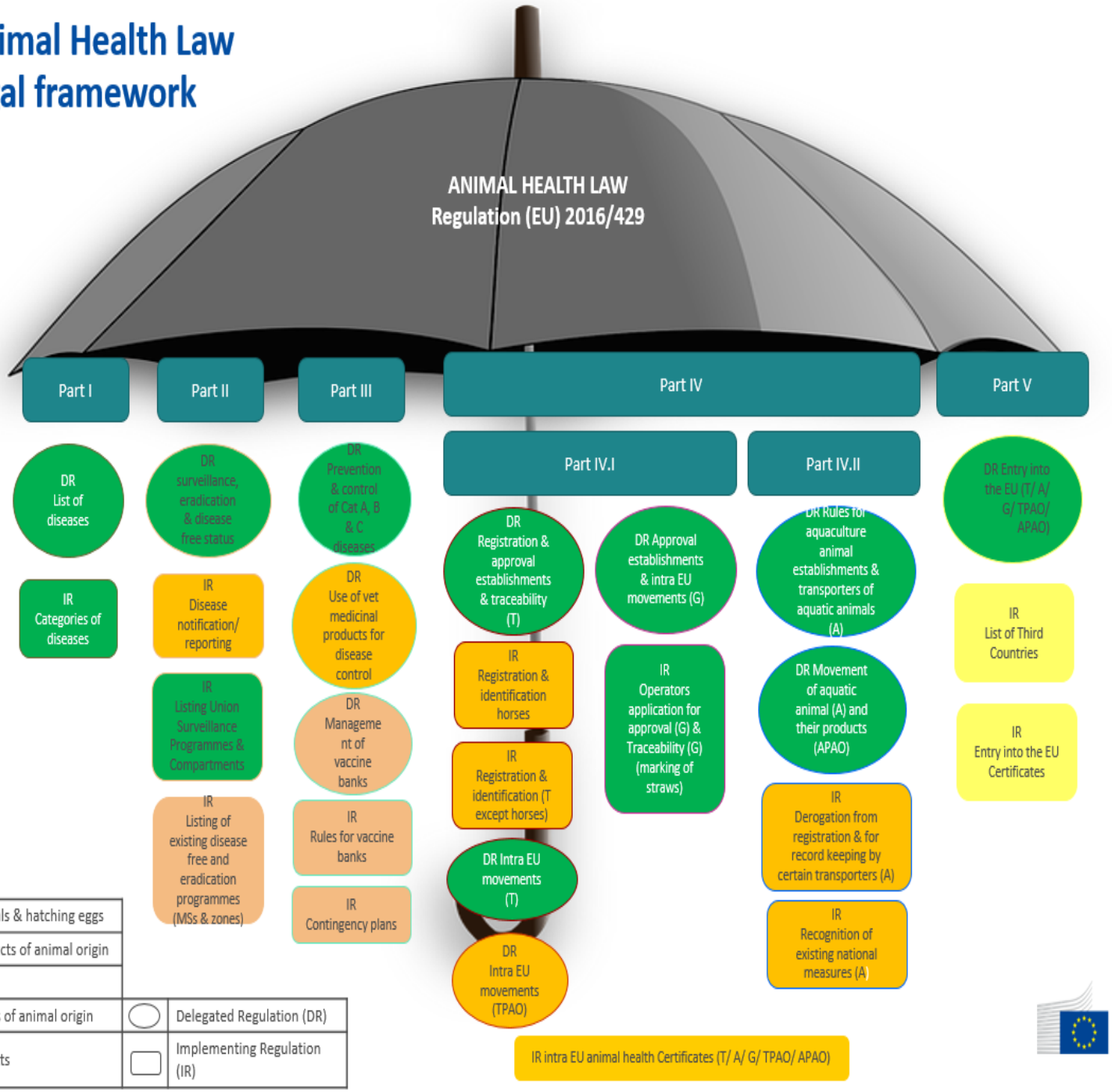
Process overview



Overview of priority acts

Part AHL	Act	Status
1	DA on list of animal diseases	Regulation (EU) 2018/1629
	IA on categorisation of diseases	Regulation (EU) 2018/1882
2	DA on surveillance, eradication programmes, disease freedom	Regulation (EU) 2020/689
3	DA on disease control	Regulation (EU) 2020/687
4/1	DA on establishments and I&R of animals	Regulation (EU) 2019/2035
	DA on Germinal Products (establishments, traceability, Intra EU movements)	Regulation (EU) 2020/686
	DA on movements of terrestrial animals and hatching eggs	Regulation (EU) 2020/688
	DA on movements of products of animal origin	ONGOING
4/2	DA on aquaculture establishments	Regulation (EU) 2020/691
	DA on movements of aquatic animal	Regulation (EU) 2020/990
5	DA on entry into the EU	Regulation (EU) 2020/692

Animal Health Law legal framework



T	Terrestrial animals & hatching eggs		
TPAO	Terrestrial products of animal origin		
A	Aquatic animals		
APAO	Aquatic products of animal origin	◯	Delegated Regulation (DR)
G	Germinal products	▭	Implementing Regulation (IR)

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AHL implementation with focus on AI and ND

List of animal diseases, disease categories and Union surveillance

Listed disease	Category of listed disease (Reg. (EU) 2018/1882)	Subject to Union surveillance programmes in all Member States and for the entire territory of a Member State (Reg. (EU) 2020/690)
Highly pathogenic avian influenza	A+D+E	YES
Infection with Newcastle disease	A+D+E	
Infection with low pathogenic avian influenza viruses	D+E	YES

Case definition

Specific definitions for HPAI, LPAI, ND in Annex I to Reg. (EU) 2020/689

Suspicion

- Clinical, post mortem, laboratory examinations or results from a diagnostic method which are indicative of a particular disease
- Epidemiological link with a confirmed case

Confirmation

- Isolation (excluding vaccine strains)
- Animal with clinical signs or with an epidemiological link with a suspected or confirmed case where:
  - Antigen or nucleic acid (excluding vaccine strains) is identified *or*
  - Positive to an indirect diagnostic method (excluding vaccinations strains)

Definition of disease agent

Annex I to Reg. (EU) 2020/689

HPAI		LPAIV	NDV	
an influenza A virus of H5 and H7 subtypes or any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2	an influenza A virus of H5 and H7 subtypes with a sequence of multiple basic amino acids present at the cleavage site of the haemagglutinin molecule (HA0) that is similar to that observed for other HPAI isolates	any influenza A virus of H5 and H7 subtypes that are not HPAI viruses	any isolated avian paramyxovirus type 1 (APMV-1) (avian *Avulavirus* type 1)	
			has an intracerebral pathogenicity index (ICPI) of 0.7 or greater	presents multiple basic amino acids at the C-terminus of the F2 protein and phenylalanine at residue 117, which is the N-terminus of the F1 protein. The term ‘multiple basic amino acids’ refers to at least three arginine or lysine residues between residues 113 and 116

AI Union surveillance programme

Annex II to Reg. (EU) 2020/689

- Early detection of HPAI in poultry
- Early detection of HPAI in wild birds: targeted populations in EURL web
- Detection of HPAI in poultry species not showing significant clinical signs: targeted populations defined
- Detection of LPAI that may spread between flocks: targeted populations defined
- Contribution to increase the knowledge of zoonotic risks
- Sampling and laboratory testing methods

ND surveillance

Reg. (EU) 2020/689

- Early detection of infection with NDV

  - general requirements in point (a) of Art. 3(1)

- Specific testing regime for granting of status free from infection with NDV without vaccination (Section 1, Part IV of Annex V)

  - screening for presence of antibodies of all establishments keeping breeding poultry, *or*

  - survey on representative sample of establishments

Laboratories: what is in the AHL?

PART I – General rules

- Biosecurity, biosafety and bio-containment obligations of all laboratories, facilities and other handling disease agents, vaccines etc.

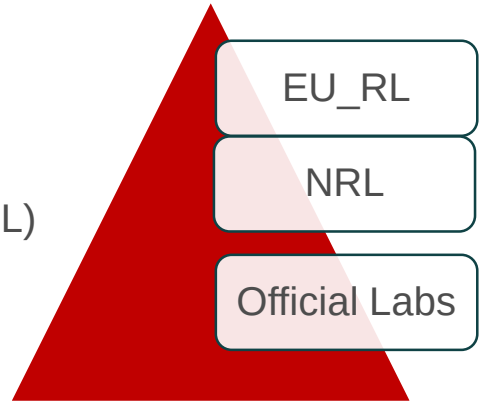
- Requirements for movements of disease agents

EU official animal health laboratories network

PART I – General rules

Network of official laboratories for animal health consists of:

- Reference laboratories:
  - European Union Reference Laboratories (EU-RL)
  - National Reference Laboratories (NRL)
- Official laboratories in Member States
- Remember: designation and obligations of official laboratories, including reference laboratories is set out in OCR



Diagnostic methods

From

- **Prescriptive rules for diagnostic methods:**
- Dec. 2006/437/EC for AI
- Annex III to Directive 92/66/EEC for ND

To

- **Basic rules only** for the purposes of surveillance (Art. 6 of Reg. (EU) 2020/689)

- **Details either in:**
- **EURLs and COM guidance**
- **OIE Manuals**
  - When the above not available, as in Art 34 of OCR (Reg. EU 2017/625)

- in case of urgency, NRL (in absence, other designated lab) may use methods which have not been validated

Follow the process:

http://ec.europa.eu/food/animals/health/regulation/index_en.htm

https://ec.europa.eu/food/animals/health/expert_group_en

https://ec.europa.eu/food/animals/health/advisory_committees_en

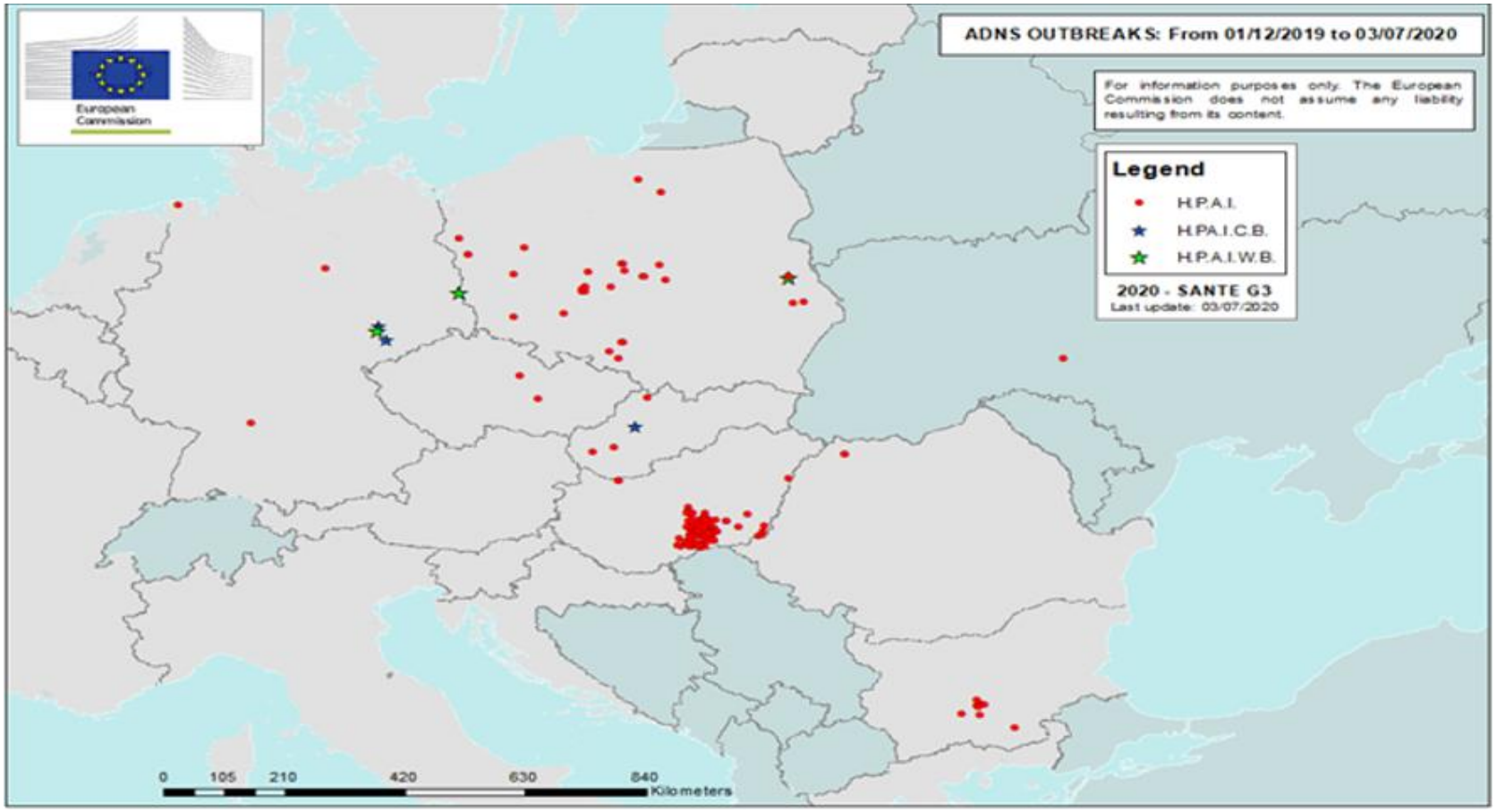
PART II

EU update on Avian Influenza and Newcastle disease

HPAI in EU in Jan-Sept 2020 (1)
Overview

Member State	Poultry	Captive birds	Wild birds	Virus subtype
HUNGARY	273			H5N8
POLAND	35		1 hawk	H5N8
BULGARIA	9			5 x H5N8 3 x H5N2 1 x H5N8/H5N2
GERMANY	3	2	1 white fronted goose 1 common buzzard	H5N8
SLOVAKIA	3	1		H5N8
CZECHIA	2			H5N8
ROMANIA	2			H5N8
Total	**327**	**3**	**3**	

HPAI in EU in Jan-Sept 2020 (2)
Distribution map



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HPAI in EU in Jan-Sept 2020 (3)
Phylogenetic analysis of HPAI H5N8 virus

The 2020 H5N8 HPAI virus:

- **different from the previous viruses** that circulated in Europe.

- **reassortant virus which has emerged in EurAsia** before reaching the EU countries:

  - ✓ similarity at HA, NE gene segment with a virus collected in Nigeria in 2019 and with the South African virus A/quail/South Africa/AI5930/2018 (H5N8)

  - ✓ similarity with LPAI viruses (H3N8, H12N5) identified in wild birds in those areas of EurAsia (near Kazakhstan) during 2017-2018

HPAI in EU in Jan-Sept 2020 (4)
Commission's actions

Protective measures at Union level
20 Implementing Decisions adopted to:
- ✓ establish or amend regionalisation
- ✓ extend duration of the restrictions
- ✓ introduce additional protective measures

Technical support
1 Sustain Technical Assistance mission (STM) (WEB) in BG, in April

2 EUVET missions
- ✓ January, in PL
- ✓ July, in HU, with a team of experts from FR (experience in similar poultry production system)

Financial support for emergency measures

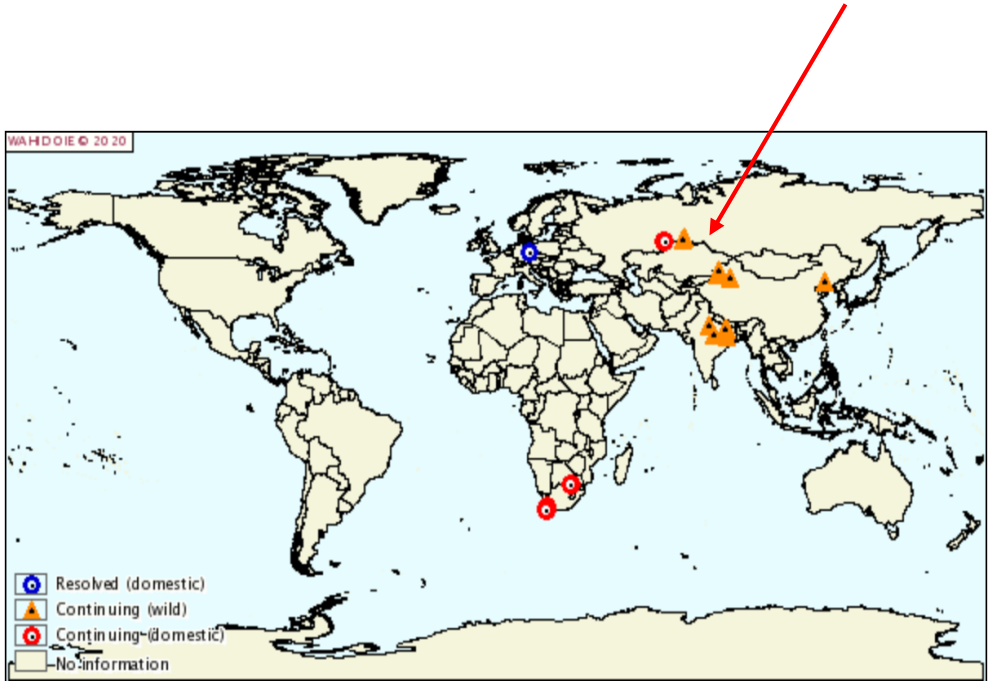
HPAI in EU in Jan-Sept 2020 (5)
Particularities

- First detection in poultry not in wild birds
- Limited number of detection in wild birds. **Why?**

  - changes in the movement of migratory birds from Asia?
  - passive surveillance not enough to detect if the prevalence of infection is low?
  - reduction of surveillance activities due to the COVID-19 restrictions?
  - increased resistance due to herd immunity?
  - surveillance system for wild birds unsuitable if odd migratory flyways?

HPAI - alerting signs

- H5N8 detected in last months in poultry and wild birds in Rusia and Kazakhstan
- possible spread via wild birds migrating to the EU in the coming months



Get prepared for early detection

- ✓ increase awareness
- ✓ strenghten passive surveillance

Reinforce biosecurity in poultry farms

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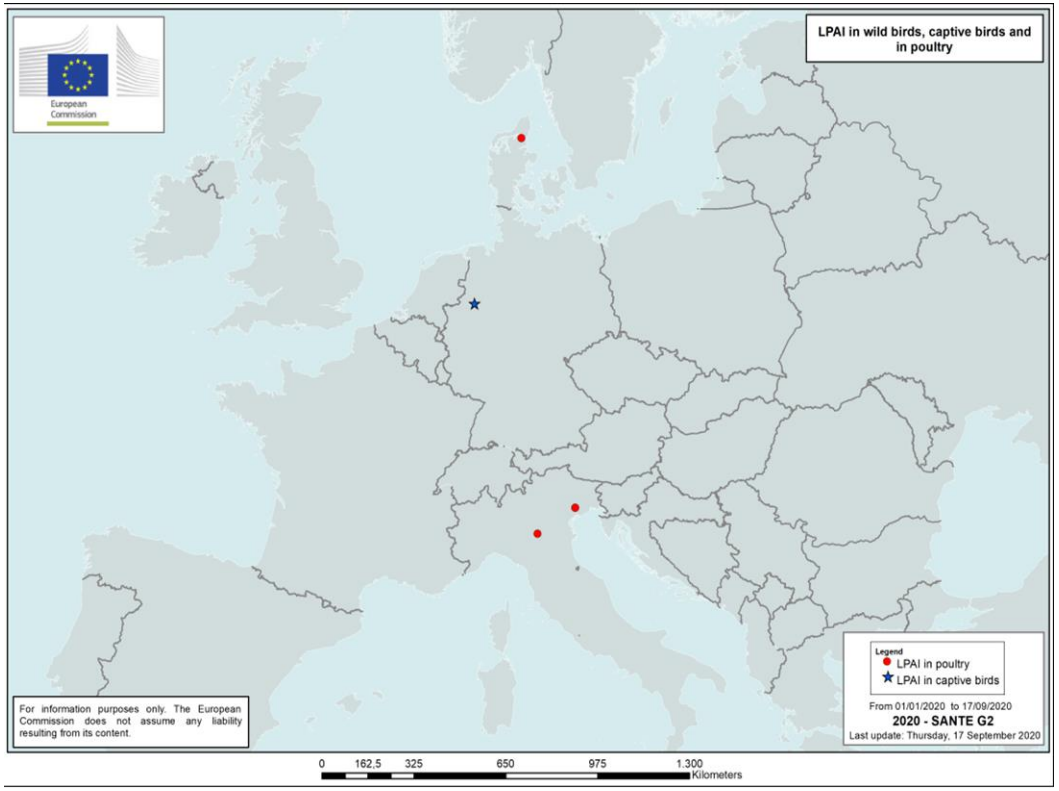
LPAI in EU in Jan-Sept 2020



Denmark
(poultry)

H5N1
organic laying hens

Italy
(poultry)

2 x H7N1
turkeys

1x H5N3
ostriches

Germany
(captive birds)

H5N8
guinea fowl

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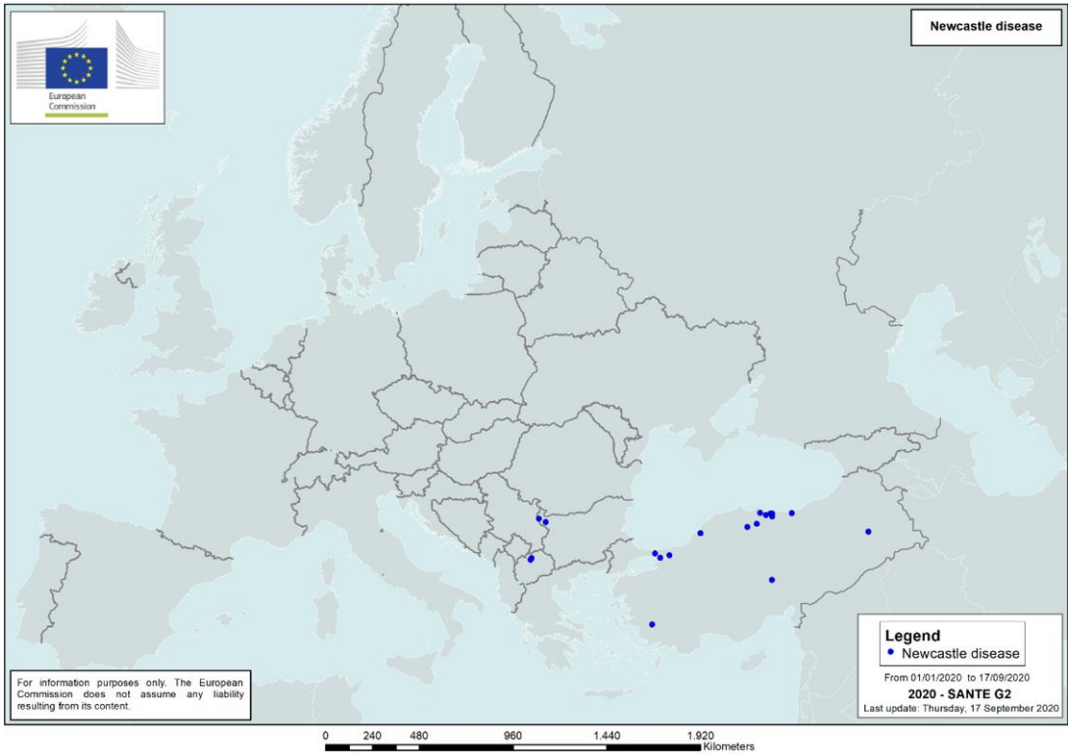
ND in Europe in Jan-Sept 2020

ADNS notifications:

- 2 outbreaks in backyards in Bulgaria
- 3 outbreaks in North Macedonia
- 15 outbreaks in Turkey



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Thank you

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