



# Updates from the European Commission related to AHL framework (focus on AI & ND)

**29<sup>th</sup> Annual meeting of the NRLs for Avian Influenza  
and Newcastle Disease of EU Member States**

European Commission,  
DG Health and Food Safety  
Unit G2 – Animal Health

# Outline of the presentation

- ❑ Rules on vaccination
- ❑ Rules on compartments
- ❑ Amendments to the current rules :
  - Delegated Regulation (EU) 2020/687 on prevention and control
  - Delegated Regulation (EU) 2020/689, on surveillance, eradication programmes, and disease-free status

# Delegated Regulation (EU) 2023/361

on the use of veterinary medicinal products for disease prevention and control

- Adopted on 28 November 2022
- Published in the OJEU on 20 February 2023
- **Applicable since mid-March 2023**

# AHL: Rules for the use of VMPs for disease prevention and control

## Article 46(1)

Provides for the possibility for the Member States to take measures concerning **the use of (ALL) veterinary medicinal products** to ensure the most efficient **prevention or control of (ALL) listed diseases**. These measures may cover prohibitions, restrictions and compulsory use of veterinary medicinal products and must be previously assessed as proportionate and necessary.

## Article 47(1) (empowerment)

Empowers the Commission to adopt delegated acts concerning:

- ✓ prohibitions and restrictions on the use of veterinary medicinal products;
- ✓ specific conditions for the use of veterinary medicinal products for a specific listed disease;
- ✓ risk-mitigation measures to prevent the spread of listed diseases through animals treated with the veterinary medicinal products or products from such animals;
- ✓ surveillance for specific listed diseases following the use of vaccines and other veterinary medicinal products.

# 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

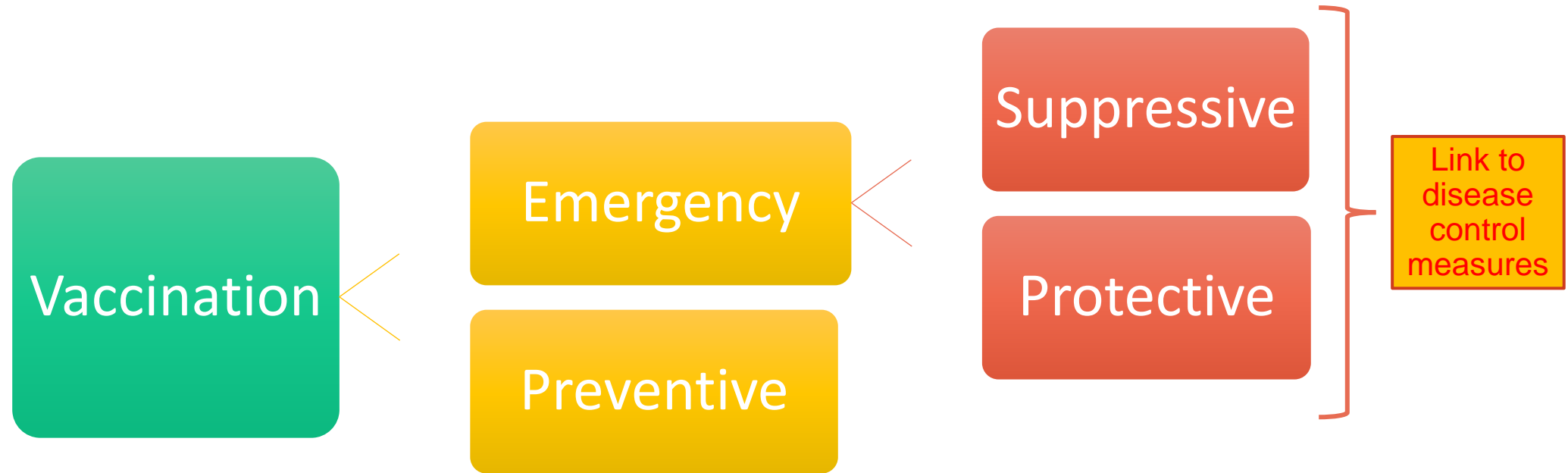
Implementation + post vaccination surveillance

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

Recovery of the previous animal health status



# Vaccination strategies



Stamping out : remains compulsory measure in all establishments where disease is detected

# Decision Making - Implementation process for the use of vaccines against HPAI

Member  
State

- **Assessment of the situation** based on specific criteria (*Annex II of DR (EU) 2023/361*)
- **DECISION TO VACCINATE** (*strategy selection etc.*)
- Preparation of official vaccination plan (*in accordance with information required in Annex III of DR (EU) 2023/361*)

Member  
State

- Preliminary information sent *to the other MS and the COM* (*at least 2 days before start of vaccination*)
- **INITIATION OF VACCINATION**
- Official vaccination plan sent *to the other MS and the COM* (*at the latest 2 weeks after start of vaccination*)

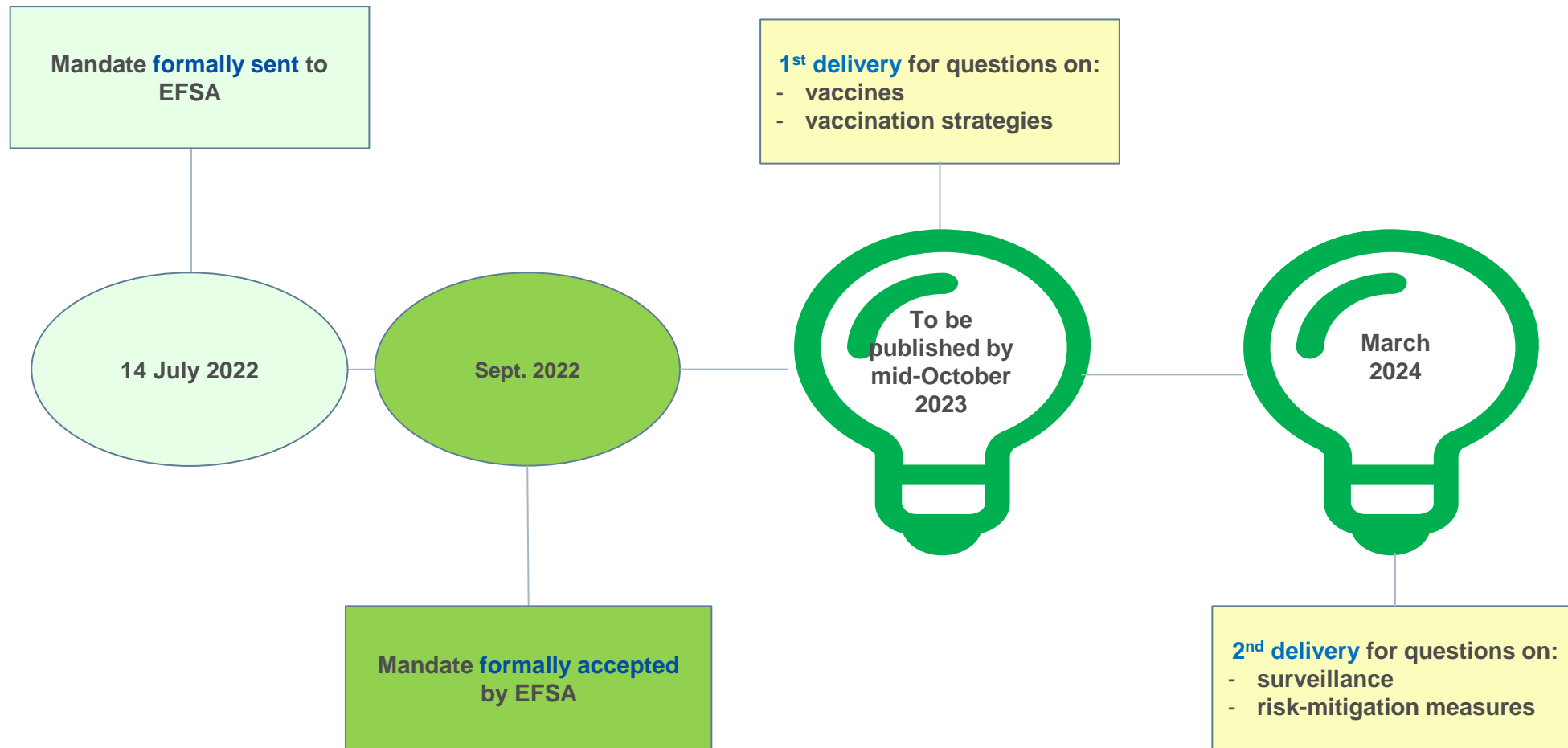
COM

**Review of the national measures in the official vaccination plan. May act with additional measures** in accordance with Article 71 of Regulation (EU) 2016/429

Member  
State

- **Disease-specific surveillance – Risk mitigation measures** (*Annex XIII of DR (EU) 2023/361*)
- **Regular reports** sent *to the other MS and the COM* (*content / intervals according to the vaccination strategy – Annexes V and VI of DR (EU) 2023/361*)

# EFSA mandate for HPAI vaccination





# HPAI VACCINATION, SCIENTIFIC TRIALS

in certain EU Member States



## **CZECH REPUBLIC**

### **emergency vaccination**

in 2022 in one establishment to  
preserve geese of high genetic  
value

## **HUNGARY**

**Field trial 2022** in geese

## **ITALY**

**vaccine efficacy trial**  
in turkeys in 2022

## **FRANCE**

**Preventive vaccination** of  
ducks  
start fall 2023

## **NETHERLANDS**

**Field trial** in laying hens  
start fall 2023

# COMPARTMENTS

**with disease-free status**

# AHL: Rules for compartments (1)

## Article 37 - possibility

Member States may apply for :

- **recognition** of the disease-free status of **compartments**, and protection of the disease-free status of compartment in the event of an outbreak

## Article 37(4) - implementing acts

Commission to adopt to:

- **recognise** the disease-free status of compartments
- for **which listed disease** compartments may be established



## Article 37(5) - delegated acts

Commission to adopt on:

- **requirements** for recognition of disease-free status of compartments (e.g. surveillance, biosecurity)
- detailed **rules for the approval** by the competent authority

# AHL: Rules for compartments (2)

## Commission Implementing Reg. (EU) 2020/690

- ✓ based on Article 37(4)(b) of AHL
- ✓ in Annex II, the listed diseases for which the disease-free status of **compartments may be established**
- ✓ **only diseases of aquatic animals** are listed in Annex II

## Commission Implementing Reg. (EU) 2021/620

- ✓ based on Article 37(4)(a) of AHL
- ✓ **lists the compartments** of Member States with recognized disease-free status.
- ✓ Annex XI – **Compartments free from HPAI**
  - based on “**grandfather rights**” (already approved based on Commission Regulation (EC) 616/2009)
  - **no use with the EU rules** for prevention and control of HPAI

# Draft Delegated Regulation

on rules for approval and recognition of **disease-free status of compartments** keeping terrestrial animals

- ✓ Based on Article 37(5) of AHL
- ✓ **Only for poultry** (HPAI and Newcastle Disease), for now
- ✓ Under discussions within the Expert Group on Animal Health
  - *first meeting took place on 27 June 2023*

# Amendments to current rules

# Delegated Regulation (EU) 2020/687

- *prevention and control* -

## Amended by **Delegated Regulation (EU) 2023/751**

- ✓ published in the OJEU on 13 April 2023
- ✓ applicable after 20 days following publication

## **New draft amendment**

- ✓ under discussions within the Expert Group on Animal Health (*first meeting took place on 13 September 2023*)
- ✓ amendments based on:
  - **experience** following implementation since April 2021
  - **EFSA opinions** following assessment of the control measures, prohibitions in the restricted zones, risk-mitigating treatments



# Delegated Regulation (EU) 2020/689 *-surveillance and disease-free status-*

## Amended by **Delegated Regulation (EU) 2023/1798**

- ✓ **Section 10 added to Part I of Annex II** “Surveillance in species that are not listed for HPAI” (mammals):

*“ HPAI surveillance must include surveillance activities in kept and wild animals of species not listed when the epidemiological situation indicates that those species may constitute a risk for animal and human health “*

- ✓ **Revised text of point 2 of Section 2, Part IV, Annex V**

To **clarify the conditions for maintenance** of the status free from infection with NDV virus without vaccination **in the event of an outbreak**

# Thank you



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