



Updates from the European Commission

28th Annual meeting of the NRLs for Avian Influenza and Newcastle Disease of EU

Verona, 20 – 21 September 2022

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

Health and
Food Safety

Outline of the presentation

Updates related to AHL framework (focus on AI & ND)

- ❑ Future rules on vaccination
- ❑ Registration of establishments
- ❑ Amendments to the current rules for:
 - prevention and control (Delegated Regulation (EU) 2020/687)
 - notification and reporting (Implementing Regulation (EU) 2020/2002)

Draft Delegated act

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

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.

Proposed 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)

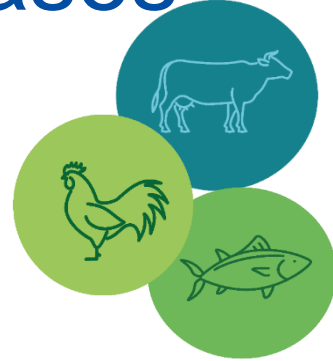
Disease-specific conditions

Implementation + post vaccination surveillance

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

Recovery of the previous animal health status

Use of vaccines in animals for Category A diseases



Member States allow

The competent authority decides and controls

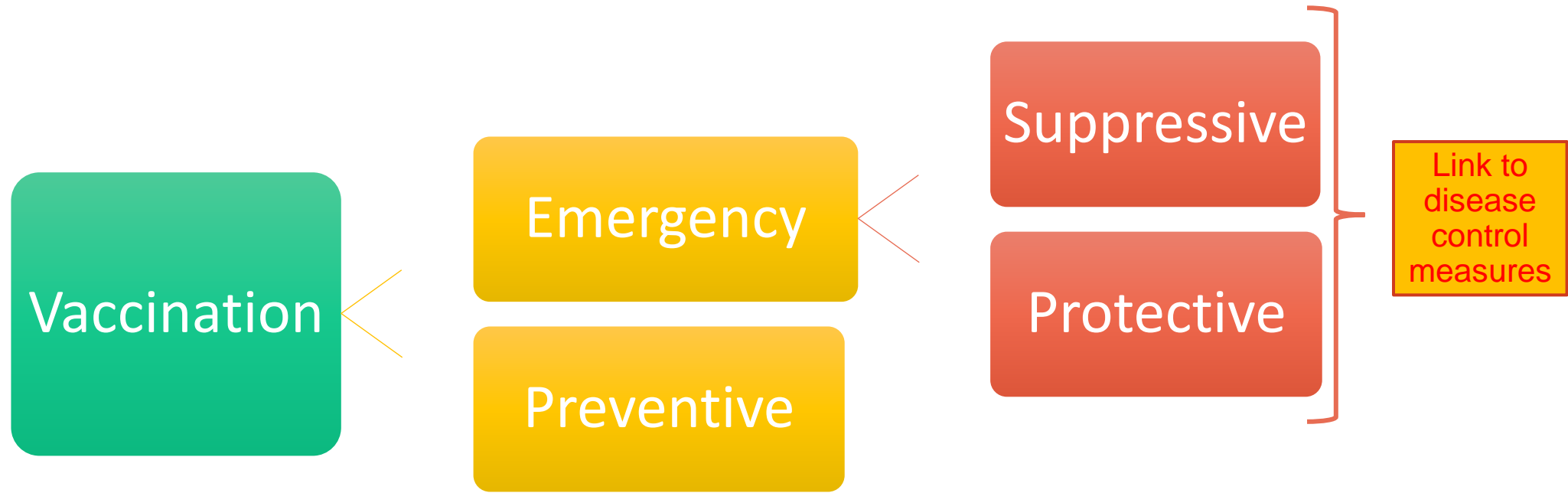
Vaccination is part of official measures put in place by the CA for prevention and control of category A diseases

Exceptions for Newcastle disease

In accordance with the general rules/measures in the Regulation

In accordance with the disease-specific conditions in Annexes (Terrestrial)

Vaccination strategies for prevention and control of category A diseases of poultry



SPECIAL CASES



Preventive vaccination

- ✓ General rules
- ✓ Disease-specific conditions **available only for HPAI** [for the moment]

Vaccination against Newcastle Disease

- ✓ **Special status** for “*routine precautionary vaccination*”



Decision Making - Implementation process for the use of vaccines in animals for Category A diseases

Member
state

- **Assessment of the situation** based on specific criteria (*Annexes*)
- **DECISION TO VACCINATE** (*strategy selection etc.*)
- (*Preparation of official vaccination plan*)

Member
State

- Preliminary information sent *to the other MS and the COM*
- **INITIATION OF VACCINATION**
- Official vaccination plan sent *to the other MS and the COM*

COM

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

Member
State

- **Regular reports** sent *to the other MS and the COM*
(*content / intervals according to the vaccination strategy – Annexes*)
- **Disease-specific Surveillance – Risk mitigation measures**

State of play

- Rules discussed in 8 Expert group meetings (incl. a questionnaire to MS experts) (Doc SANTE 7144/2020) from March 2020 until May 2022
- Finalisation of internal consultation and final modifications: July 2022
- Public feedback: 5 August – 2 September 2022
- Translation: August – October 2022
- Adoption by the COMM: November 2022
- EP and Council objection period: November – December 2022
- OJ Publication: December 2022 / January 2023

EFSA mandate

COM request to EFSA for a new scientific opinion on vaccination against HPAI

- ✓ formally sent to EFSA in July 2022
- ✓ accepted by EFSA

Questions for opinion regarding:

1. Vaccines
2. Vaccination strategies
3. Surveillance
4. Risk mitigation measures

Delivery of opinion:

- ✓ by 31 July 2023 for questions 1 and 2
- ✓ by 31 March 2024 for questions 3 and 4

Commission Implementing Regulation (EU) 2022/1345

with regard to registration and approval of establishments keeping terrestrial animals

Registration of establishments

- The main principle laid down in Article 84 of the AHL : **All establishments keeping terrestrial animals shall be registered by the competent authority**
- The **possibility** for the Member States **to exempt**, on a limited basis, from the registration obligation certain types of **establishments posing an insignificant risk**
- Harmonised implementation to prevent exemptions of establishments which pose more than insignificant risk to
 - animal health
 - public health

Article 3:

- Types of establishments keeping terrestrial animals that may be exempted by the Member States from the registration requirement
- Focus on establishments posing an insignificant risk
- Flexibility and responsibility to the Member States by setting criteria which have to be fulfilled
- Member States may lay down additional criteria (paragraph 2)
 - Number of animals kept
 - Proximity to registered or approved establishments

Relevant when exempting poultry establishments

Article 3 (1) (c) and (d):

(c) the **establishment is not involved** in any **movement** of kept terrestrial animals, germinal products or products of animal origin **to or from another Member State or third country**;

(d) the kept terrestrial **animals, germinal products or products** of animal origin on the establishment **are not intended to be moved out** of the establishment.

Amendments to current rules

Delegated Regulation (EU) 2020/687

- *prevention and control* -

Draft Delegated Regulation SANTE/7322/2021 propose amendments to:

- **Article 21 (3)** – to introduce possibility to **derogate from** establishing restricted zone when outbreak confirmed in **< 50 captive birds**;
- **Article 46 (a)** – movements of day-old chicks hatched from eggs originating from establishments within the *restricted* zone
 - condition added: *‘(iii) the means of transport is sealed at the moment of loading by the competent authority or under its supervision.’*

Based on comments from Member States, further amendments are under consideration by COM.

Implementing Regulation (EU) 2020/2002

- *notification and reporting* -

Amendments for the data to be registered with the notification of outbreaks of Category A diseases:

- date of completion of the preliminary cleaning and disinfection following an outbreak in kept animals
- indicate if the outbreak occurred in location already subject to restrictions following the establishment of restricted zone

Amendments are in force since August 2022 (CIR (EU) 2022/1183)

Thank you



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