



# ANIMAL HEALTH ADVISORY COMMITTEE

## Working Group of the Advisory Group on the Food Chain

**Future rules for the use of VMPs  
for disease prevention and control**

*Brussels, 07 June 2022*

# 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)

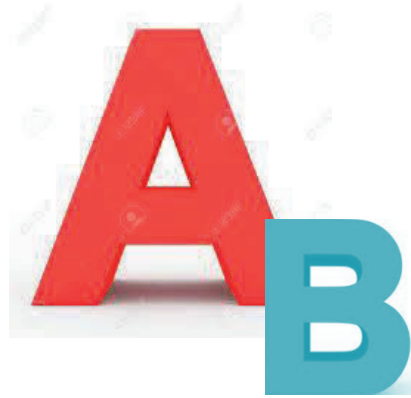
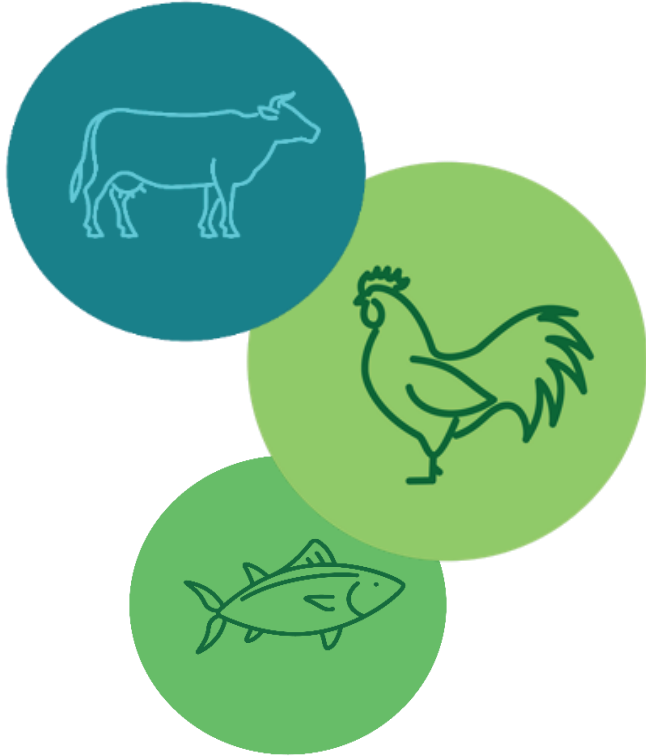
Provides for the possibility for the Member States to take measures concerning **the use of (ALL) veterinary medicinal products** to ensure the most efficient **prevention or control of (ALL)** listed diseases. These measures may cover prohibitions, restrictions and compulsory use of veterinary medicinal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

# Future rules for the use of VMPs for disease prevention and control



**Category C and D diseases**

**Article 46 of AHL,  
CDR (EU) 2020/688 (for  
movements within the Union)  
and CDR (EU) 2020/689 (for  
eradication programmes and  
freedom status) apply**

# 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

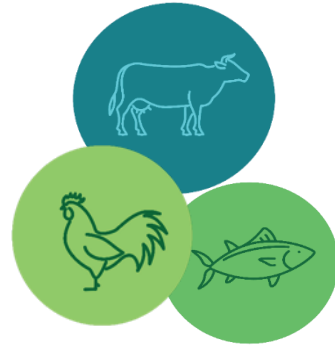
Measures (movement prohibitions for animals and products) in the vaccination zone

Recovery of the previous animal health status

This (draft) Act does not interfere with the scope of **Regulation (EU) 2019/6**

# Restrictions on the use of certain VMP's

## Category A and B diseases



Diagnostic immunological veterinary medicinal products

Hyper-immune serum

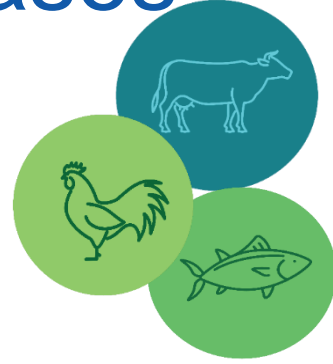
Antibiotics

Exceptions:  
tuberculine  
and bruceline

Inactivated immunological VMP, as referred to in Article 2(3) of Regulation (EU) 2019/6 [so-called 'auto-vaccines']

Antivirals

# 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

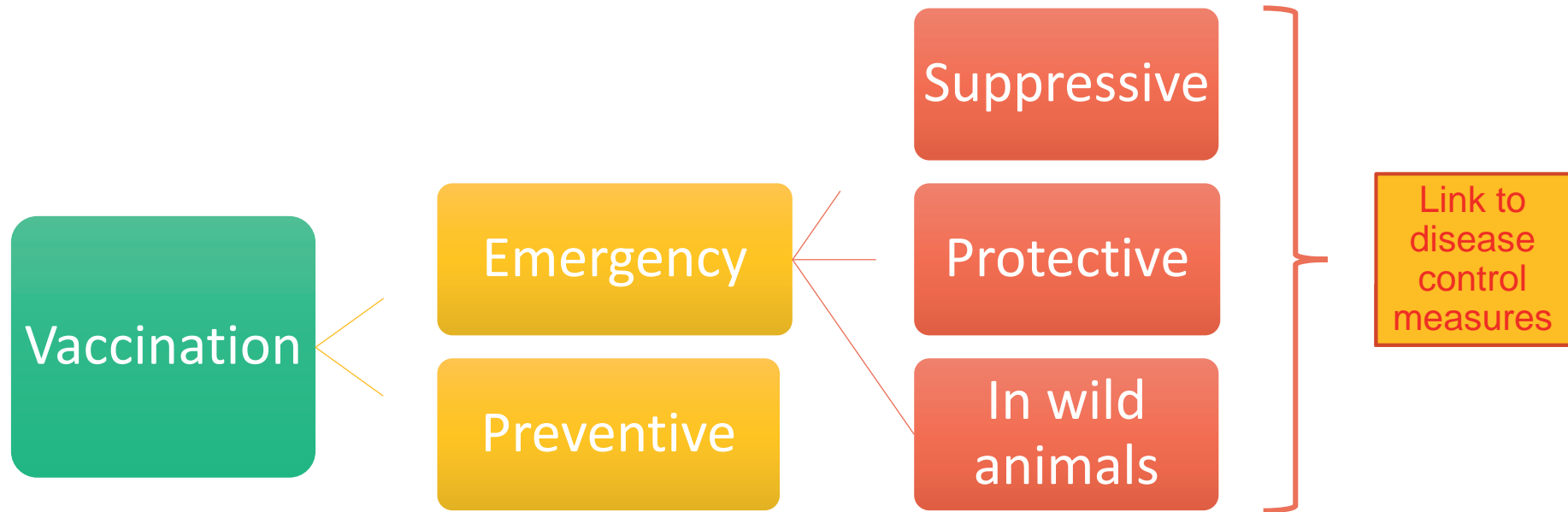
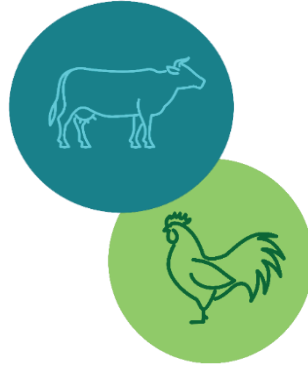
Exceptions for Newcastle disease

Only if their use is not prohibited in accordance with Annex I (i.e. *Rinderpest*)

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





# 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

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



# 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: June 2022
- Public feedback: June - July 2022
- Translation: July-August 2022
- Adoption by the COMM: August-September 2022
- EP and Council objection period: September-October 2022
- OJ Publication: November-December 2022

# Thank you



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