



# Delegated Regulation (EU) 2023/361

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

Animal Health Advisory Committee

Brussels, 2 June 2023

*DG SANTE, Unit G2*

# Animal Health Law: 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.

# Rules for the use of veterinary medicinal products (VMP) for disease prevention and control

- **Commission Delegated Regulation (EU) 2023/361** of 28 November 2022 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards rules for the use of certain veterinary medicinal products for the purpose of prevention and control of certain listed diseases
  - ***Published*** in the *EU Official Journal* on **20 February 2023** (OJ L 52, 20.2.2023)
  - ***In force*** since **12 March 2023**

# 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

# Rules for the use of VMPs: Contents

- **General rules for the use of VMPs** (e.g. vaccines etc.) for disease prevention and control (mostly category-A diseases):
  - prohibitions
  - preconditions – competent authority assessment & official vaccination plan
- *Rules on the **choice, initiation and implementation of vaccination strategies** (e.g. emergency protective, suppressive, preventive vaccination etc.)*
- **Annexes [II-V]** on the **minimum criteria for vaccination and requirements for vaccination plans**, including records and reporting
- **Disease-specific Annexes [VI-XIV]**: types of vaccines, vaccination zones, vaccinated species, post-vaccination surveillance, prohibitions of movements for vaccinated animals and products thereof, recovery periods (**FMD, RVF, LSD, PPR, AHS, CSF, HPAI, NCD**)
- Specific provisions for **preventive vaccination against HPAI** (**Annex XIII, part 5**)

# Thank you



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