



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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