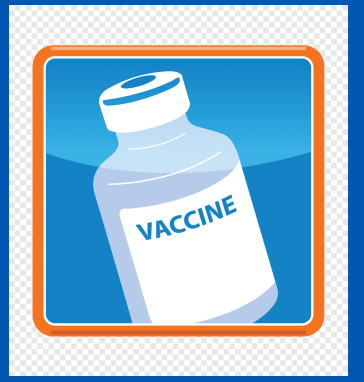
AHAC – the Union antigen, vaccine and diagnostic reagent banks



26 March 2021

Unit G2 – Animal Health

Animal Health Law legal framework

- **Part I**
  - DR List of diseases
  - IR Categories of diseases
- **Part II**
  - DR surveillance, eradication & disease free status
  - IR Disease notification/ reporting
  - IR Listing Union Surveillance Programmes & Compartments
  - IR Listing of existing disease free and eradication programmes (MSs & zones)
- **Part III**
  - DR Prevention & control of Cat A, B & C diseases
  - DR Use of vet medicinal products for disease control
  - DR Management of vaccine banks
  - IR Rules for vaccine banks
  - IR Contingency plans
- **Part IV**
  - **Part IV.I**
    - DR Registration & approval establishments & traceability (T)
    - DR Approval establishments & intra EU movements (G)
    - IR Registration & identification horses
    - IR Operators application for approval (G) & Traceability (G) (marking of straws)
    - IR Registration & identification (T except horses)
    - DR Intra EU movements (T)
    - DR Intra EU movements (TPAO)
  - **Part IV.II**
    - DR Rules for aquaculture animal establishments & transporters of aquatic animals (A)
    - DR Movement of aquatic animal (A) and their products (APAO)
    - IR Derogation from registration & for record keeping by certain transporters (A)
    - IR Recognition of existing national measures (A)
- **Part V**
  - DR Entry into the EU (T/ A/ G/ TPAO/ APAO)
  - IR List of Third Countries
  - IR Entry into the EU Certificates

IR intra EU animal health Certificates (T/ A/ G/ TPAO/ APAO)

T	Terrestrial animals & hatching eggs
TPAO	Terrestrial products of animal origin
A	Aquatic animals
APAO	Aquatic products of animal origin
G	Germinal products

(⬭) Delegated Regulation (DR)

(▭) Implementing Regulation (IR)

European Commission

Legal acts involved (I)

- ✓ **Animal Health Law (Regulation (EU) 2016/429) as regards rules for the prevention and control of certain listed diseases: Part III, Articles 48-52**
- ✓ Commission Delegated Regulation (EU) on the management of the EU vaccine banks – document SANTE/7210/2020
  - Legal base - Article 48(3) of the AHL
- ✓ Commission Implementing Regulation (EU) on the rules for the EU vaccine banks – document SANTE/7212/2020
  - Legal base - Article 50(1) of the AHL

Legal acts involved (II)

✓ Veterinary Medicinal Products (VMP) Regulation (Regulation (EU) 2019/6) – in particular Articles 106 and 110

'immunological veterinary medicinal product' means a veterinary medicinal product intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity;

1. the Multiannual Financial Framework (MFF) 2021-2027
2. the new Single Market Programme Regulation (SMP)
3. Financing Decision (FD)

Animal Health Law

- **Articles 48 and 51 of AHL**: Union antigen, vaccine and diagnostic reagent banks
  - for category A diseases of which vaccination is not prohibited
  - sufficient stocks
    - appropriate type of antigens, vaccines, vaccine master seed–stocks and diagnostic reagents
    - estimated in the context of the contingency plans of Member States
  - receive regular supplies and timely replacements
  - in conformity with biosecurity, biosafety and bio–containment requirements
  - classified information
- **Article 49 of AHL**: Access to the Union antigen, vaccine and diagnostic reagent banks
- **Article 52 of AHL**: National antigen, vaccine and diagnostic reagent banks

Will be published for public consultations

Delegated Regulation

Article 48(3) of AHL - Document SANTE/7210/2020 - presented at EG on 05.02.2021

1. The rules for the management, storage and replacement of stocks of antigens, vaccines and diagnostic reagents in the Union banks, and in particular on:
   a. property of the antigens, vaccines and diagnostic reagents in the Union banks
   b. storage of the antigens, vaccines and diagnostic reagents in the Union banks
   c. principles of selecting strains and variations of antigens, vaccines and diagnostic reagents
   d. possibilities of buy-back of the antigens for which the validity period has expired
   e. destruction and safe disposal of antigens, vaccines and diagnostic reagents which have reached the end of their validity period
2. The biosecurity, biosafety and bio–containment requirements for the operation of the Union antigens and vaccine banks
3. Transitional measures for the Union banks established before 21 April 2021

Implementing Regulation

Article 50(1) of AHL - Document SANTE/7212/2020 – presented at PAFF on 15-16.03.2021

1. The biological products to be included in the Union antigen, vaccine and diagnostic reagent banks
2. FMD virus antigen bank and CSF, LSD and PPR vaccine banks
3. The provisions allowing for the Union bank of antigens and vaccines against other category A diseases, and for diagnostic reagents
4. The requirements for types (strains) and quantities of the antigens and vaccines
5. The requirements concerning the supply, storage and replacement of antigens, vaccines and diagnostic reagents
6. The procedures for the release, shipment and delivery of vaccines and diagnostic reagents
7. The procedural and technical requirements for

    - the inclusion of antigens, vaccines and diagnostic reagents in the Union banks
    - the access to the Union banks

Thank you

Slide xx: element concerned, source: e.g. Fotolia.com; Slide xx: element concerned, source: e.g. iStock.com

European Commission