Delegated Acts under Animal Health Law

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Introduction
Animal Health Law and the process
Based on:
- AH Strategy “Prevention is better than cure” (2008)
- 2 Impact Assessments (Strategy and AHL)
- Number of consultations

AHL: one single legal framework for the EU animal health policy
AHL: what it is about?

- General principles for transmissible animal diseases in:
  - Kept and wild animals and their products
  - Terrestrial, aquatic and other animals (e.g. reptiles)
- Animal health rules for:
  - Disease prevention
  - Disease surveillance, control and eradication
  - Intra-EU movements and entry into the EU of animals and products
  - Emergency measures

AHL: what it is not about?

- Not in scope:
  - Animal welfare
  - EU veterinary expenditure
  - Feed, medicated feed
  - Veterinary medicines (VMP)
  - Veterinary education
  - Official controls

- Specific rules remain in place for:
  - Animal by-products
  - TSE rules
  - Certain zoonoses
Regulation (EU) on transmissible animal diseases (AHL)
Process overview

- **AHL adoption in 2016**
- **Key acts development and expert groups 2017-2019**
- **Animal disease listing and categorization (with EFSA) 2016-2018**
- **Disease list and categorization adopted 2018**
- **Key delegated acts Adoption 2019**
- **Implementing acts 2019 - 2020**
- **AHL applies on 21 April 2021**

**TODAY**
Overview of dedicated expert and working group meetings

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76 meetings
AHL supplementing delegated acts

- Adopted and published
- Adopted and under objection period
Adopted and published acts (I):
List of animal diseases, disease categories and list of animal species (supplementing Part I of AHL)

Regulation (EU) 2018/1629 published on 31/10/2018
List of animal diseases (63)

Regulation (EU) 2018/1882 published on 4/12/2018
Assigning to each listed disease a category and animal species of relevance
Adopted and published acts (II): establishments and identification & traceability of animals

✓ Regulation (EU) 2019/2035 published in OJ on 5/12/2019
✓ Amendment (derogation for young sheep and goats) is being developed

COMMISSION DELEGATED REGULATION (EU) 2019/2035
of 28 June 2019

supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs

(Text with EEA relevance)
Delegated acts under objection period

✓ The Commission has adopted on 17/12/2019 **four (4) delegated acts:**

✓ DA on disease surveillance, eradication, disease freedom
✓ DA on disease control measures
✓ DA on movements of terrestrial animals
✓ DA on traceability and movements of germinal products

✓ These acts are supplementing Regulation (EU) 2016/429 ("Animal Health Law" – AHL)
  
✓ These acts represent an interlinked package
Commission Delegated Regulation as regards rules on disease surveillance, eradication programmes and disease-free status C(2019)4056
Overview

Existing rules

New legal basis
+ new list of diseases
+ gained experience
+ new EFSA opinions
+ update Ref Labs
+ OIE standards

New harmonized framework for all category B and C diseases in one legal act


☑ Clearer obligations for the operators
☑ More flexibility for the CA
☑ Risk based provisions, particularly when maintaining disease-free status
CONTENT (I)

✓ Supplements the rules for disease surveillance, eradication programmes and disease freedom (Part II of the AHL)
✓ General surveillance requirements for listed and emerging diseases
  ✓ terrestrial and aquatic animals (kept and wild)
  ✓ including diagnostic methods
  ✓ criteria for case confirmation
✓ Union surveillance programmes (for diseases that are relevant for the whole Union-HPAI)
  ✓ criteria and content
**CONTENT (II)**

- **Rules for eradication programmes**
  - For diseases subject to compulsory eradication in the EU - i.e. “category B” diseases: MTBC, Brucellosis, rabies
  - For diseases subject to optional eradication in the EU - i.e. “category C” diseases: EBL, IBR, ADV, BVD, BT and certain aquatic diseases
  - including establishment categorisation, movement control, disease control measures and testing regime
- **Rules to grant disease free status**
  - for Member States, zones or compartments*
  - Rules to maintain, withdraw or suspend disease free status
- **Transitional provisions recognising the existing disease status**

*(for aquatic animals)*
Commission Delegated Regulation as regards rules for the prevention and control of certain listed diseases
C(2019)4057
Overview

Existing rules in disease-specific Directives

- All existing disease-specific Directives (2003/85/EC for FMD, 2005/94/EC for AI, 2002/60/EC for ASF, 92/119/EEC, etc.) and Implementing acts (e.g. on diagnostic manuals 2003/422/EC, 2002/106/EC, or 709/2014 on ASF, LSD) will cease to apply by April 2021
- The content of existing Implementing acts should be adapted to the new legal basis

New legal basis
- + new list of diseases
- + gained experience
- + new EFSA opinions
- + OIE standards

New harmonized framework for all category A diseases in one legal act

- Covers kept and wild terrestrial and aquatic animals
- Specificities linked to the epidemiology of each disease are provided in Annexes
- Provides for clearer obligations for operators and more flexibility for the CA
Supplements the rules for disease awareness, preparedness and control (Part III of AHL)

Disease control measures in terrestrial and aquatic animals for “dangerous animal diseases subject to immediate eradication in the EU – “category A” diseases, FMD, CSF, ASF, HPAI, etc.

General provisions: new approach regarding sampling

Include detailed rules on:

- Measures in the event of a suspicion and confirmation of a category A disease in kept animals: obligations for operators and the competent authority and derogations from killing
- Establishment of the restricted zone: size and duration, prohibitions and derogations regarding movements of animals and products
- Repopulation of affected establishments
- Measures in the event of a suspicion and confirmation of a category A disease in wild animals
Commission Delegated Regulation as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs
C(2019)4057
Overview

Existing rules

New legal basis
+ new list of diseases
+ gained experience
+ new EFSA opinions
+ OIE standards

New harmonized framework for movements of all terrestrial species in one legal act

✓ Covers kept and wild terrestrial animals
✓ Aligns rules with new list of diseases
✓ Provides for clearer obligations for operators and more flexibility for the CA
✓ requirements for movements to other Member States of wild terrestrial animals

CONTENT (1)

✓ Supplements the rules for registration, approval, traceability and movements of terrestrial animals and hatching eggs (Part IV of AHL)
✓ General biosecurity requirements for the means of transport and containers transporting terrestrial animals and hatching eggs
✓ Animal health requirements for movements to other Member States
  ✓ depending on the species and category of animals (ungulates, poultry, captive birds, primates, honeybees and bumble bees, dogs, cats, ferrets and other carnivores) and hatching eggs
✓ Specific rules for assembly operations
  ✓ Time limits and biosecurity rules
CONTENT (II)

✓ Special rules for movements into confined establishments

✓ Special rules and exemptions for movements to other Member States of
  ✓ travelling circuses and animal acts
  ✓ animals intended for exhibitions and sporting events

✓ Detailed rules on animal health certificates and notification of movements
  ✓ contents of animal health certificates and notification requirements
Commission Delegated Regulation as regards animal health requirements for movements of germinal products within the Union C(2019)4055
Overview

Existing rules

New legal basis
+ new list of diseases
+ gained experience
+ scientific development
+ new EFSA opinions
+ OIE standards

New harmonized framework for movements of all species in one legal act

- All existing Directives (88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC) will cease to apply by April 2021
- GP of bovine, ovine, caprine, equine and porcine animals, of dogs, cats and families Camelidae and Cervidae, and of animals kept at confined establishments
- Introduces a new type of germinal products establishment (processing establishment)
- Rules regarding cessation of activities
- Aligns rules with a new list of diseases
- Updates rules on transport of GP
CONTENT (I)

✓ Supplements the rules for **registration, approval, traceability and movements of germinal products** (Part IV of AHL)

✓ Rules for germinal products of bovine, porcine, ovine, caprine and equine animals on
   ✓ Requirements for the approval of establishments
   ✓ Registers of the competent authority
   ✓ Record-keeping by operators
   ✓ Traceability requirements (marking of straws)
   ✓ Animal health requirements for movements of those germinal products
CONTENT (II)

✓ Rules for germinal products of
  ✓ dogs, cats,
  ✓ animals kept at confined establishments
  ✓ Camelids and cervids
✓ Movement of germinal products:
  ✓ for scientific purposes and stored at gene banks
✓ Certification and notification
  ✓ Self-declaration,
  ✓ Animal health certificates
  ✓ notification of consignments of germinal products
Thank you

Follow the process:

http://ec.europa.eu/food/animals/health/regulation/index_en.htm

https://ec.europa.eu/food/animals/health/expert_group_en

https://ec.europa.eu/food/animals/health/advisory_committees_en