

Delegated Acts under Animal Health Law

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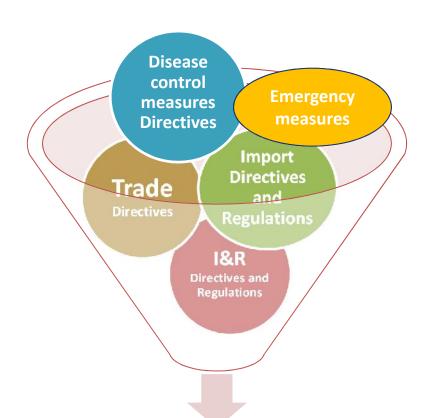
Food Safety



Introduction Animal Health Law and the process



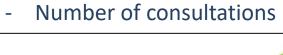




AHL: one single legal framework for the EU animal health policy

Based on:

- Evaluation of the EU Animal Health policy 1995-2004 (2006)
- AH Strategy "Prevention is better than cure" (2008)
- 2 Impact Assessments (Strategy and AHL)









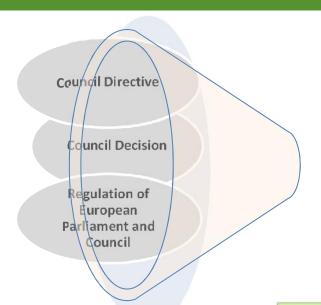
AHL: what it is about?

- ✓ 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







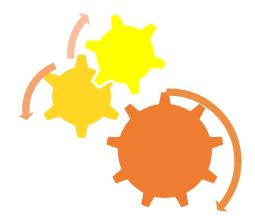
Regulation (EU) on transmissible animal diseases (AHL)



I. GENERAL RULES

II. DISEASE NOTIFICATION
AND REPORTING,
SURVEILLANCE,
ERADICATION PROGRAMMES,
DISEASE FREE-STATUS

III. DISEASE AWARENESS, PREPAREDNESS AND CONTROL



IV. REGISTRATION, APPROVAL, TRACEABILITY AND MOVEMENTS

V. ENTRY INTO THE UNION AND EXPORT

VI. NON-COMMERCIAL PETS

VII. EMERGENCY MEASURES

VIII-IX. COMMON AND TRANSITIONAL PROVISIONS



Process overview

AHL adoption in 2016 Key acts developme nt and expert groups 2017-2019 Animal disease listing and categorizat ion (with EFSA) 2016-2018

Disease list and categorizat ion adopted 2018 Key delegated acts Adoption 2019

Implement ing acts 2019 -2020 AHL applies on 21 April 2021

TODAY



Overview of dedicated expert and working group meetings

2017	
Jan	1
Feb	1
Mar	
Apr	2
May	
Jun	
Jul	
Aug	
Sep	1
Oct	3
Nov	4
Dec	2
Total	14

2018	
Jan	4
Feb	6
Mar	4
Apr	5
May	3
Jun	6
Jul	5
Aug	1
Sep	6
Oct	6
Nov	4
Dec	3
Total	53

2019	
Jan	3
Feb	2
Mar	
Apr	1
May	
Jun	1
July	1
Sept	1
Total	9

76 meetings



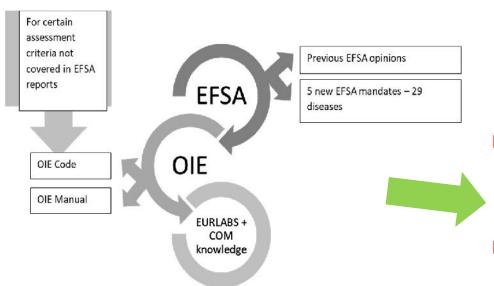


AHL supplementing delegated acts





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 <u>four (4)</u> <u>delegated acts:</u>
 - ✓ 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





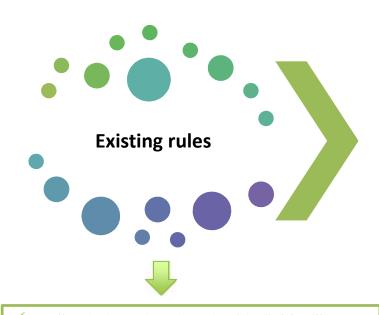
Commission Delegated Regulation as regards rules on disease surveillance, eradication programmes and disease-free status C(2019)4056







Overview



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



All existing Directives in this field will cease to apply by April 2021: Directives 64/432/EEC for MTBC, Bovine Brucellosis and EBL, Directive 91/68/EEC for small ruminants Brucellosis, Directive 200/75/EC for BT, Directive 2006/88/EC for aquatic animals, Decision 2008/185/EC for ADV

and Decision 2004/558 for IBR

- ✓ Clearer obligations for the operators
- ✓ More flexibility for the CA
- ✓ Risk based provisions, particularly when maintaining disease-free status

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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)

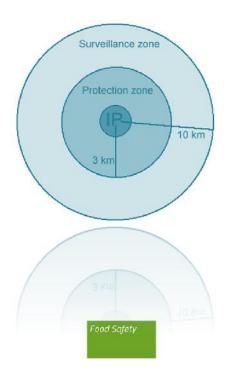
- ✓ Rules for eradication programmes
 - ✓ For diseases subject to compulsory eradication in the EU i.e. "category B" diseases: MTBC, Brucellosis, rabies
 - ✓ For diseases subject to optional eradication in the EU i.e. "category C" diseases: EBL, IBR, ADV, BVD, BT and certain aquatic diseases
 - ✓ including 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

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^{*(}for aquatic animals)

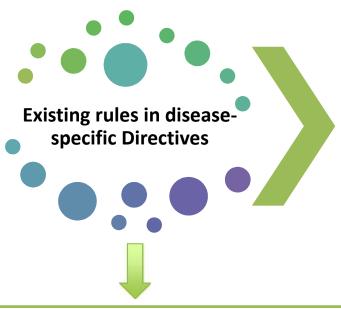


Commission Delegated Regulation as regards rules for the prevention and control of certain listed diseases C(2019)4057





Overview



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



- ✓ 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

- 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



CONTENT

- 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 <u>immediate eradication</u> 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





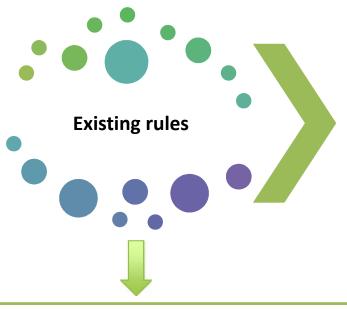
Commission Delegated Regulation as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs

C(2019)4057





Overview



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



- Existing Directives 64/432/EEC, 92/65/EEC, 91/68/EEC, 2009/156/EC and 2009/158/EC will cease to apply by April 2021
- ✓ 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 (I)

- ✓ 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



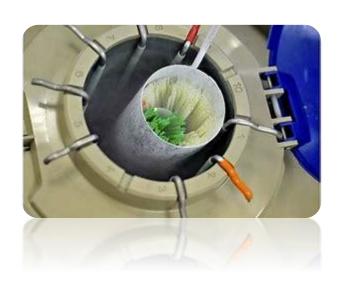


- ✓ Special rules for movements into confined establishments
- ✓ Special rules and exemptions for movements to other Member States of
 - ✓ travelling circuses and animal acts
 - ✓ animals intended for exhibitions and sporting events
- Detailed rules on animal health certificates and notification of movements
 - contents of animal health certificates and notification requirements



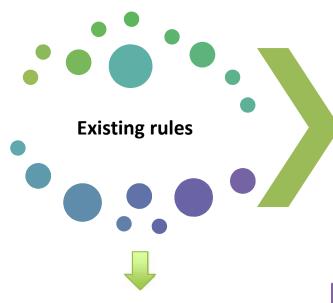


Commission Delegated Regulation as regards animal health requirements for movements of germinal products within the Union C(2019)4055





Overview



✓ All existing Directives (88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC) will cease to apply by April 2021

New legal basis + new list of diseases + gained experience

+ gained experience + scientific development

- + new EFSA opinions
 - + OIE standards



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



- ✓ 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 <u>registration</u>, <u>approval</u>, <u>traceability</u> <u>and movements of germinal products</u> (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

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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

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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

