

Regulation (EU) 2016/429 on transmissible animal diseases "Animal Health Law" State of play

Animal Health Advisory Committee Brussels, 18 December 2017

Unit G2 Animal Health and Welfare Directorate-General for Health and Food Safety European Commission

> Health and Food Safety



Contents: Animal Health Law – work on delegated and implementing acts

- Structure of delegated (DAs) and implementing (IAs) acts
- State of play of development of DAs and IAs
- Timeline for the meetings



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Reminder of main dates

- Regulation (EU) 2016/429 <u>on transmissible</u> <u>animal diseases (</u>"Animal Health Law")*
 - <u>adopted</u>: 9 March 2016
 - OJ publication: 31 March 2016
 - Regulation in force: 21 April 2016
 - <u>apply</u> as of: <u>21 April 2021</u> (within 5 years of entry into force)

*Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (Text with EEA relevance)

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Structure of DAs and IAs

- DAs and IAs to complement the basic act
 - COM to adopt <u>"key"</u> DAs and IAs 24 months before the date of application of the Regulation
 - "Key" acts determined by the EP and the Council (AHL, Article 274)
 - **Other rules** will be developed later (2019 onwards)
- <u>Structure "reviewed" in summer 2017</u>:
 - "Bundling" issue
 - Inter-institutional considerations (EP)
 - Objective reasons for "bundling" empowerments
 - Follow closely the structure of the basic act
 - Cross references
 - Legislative drafting constraints





Structure AHL

Commission

Part 1 – General rules

Part 2 – Disease notification, reporting, surveillance, eradication programmes, disease freedom

Part 3 – Disease awareness, preparedness, control

Part 4, Title 1 – Registration , approval, traceability and movements (terrestrial) Part 4, Title 2 – Registration , approval, traceability and movements (aquatic) Part 4, Title 3 – Other animals and their products

Part 5 – Entry into EU

Part 6 – Non-commercial pets

Part 7 – Emergency measures

Parts 8-9 – Common and transitional provisions

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Part 1 (General rules)

AHL Part	Delegated Act	Implementing Act	Articles	Adoption by
Part 1	Amending Annex II – List of diseases		Article 5	April 2019
		Categorisation of diseases list of species	Articles 8(2), 9(2)	April 2019

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Commission

Part 2 (Notification, reporting, surveill., eradic., dis. freedom)

AHL Part	Delegated Act	Implementing Act	Articles	Adoption by
Part 2	Notification, reporting, surveillance, eradication programmes, disease freedom		Articles 18(3), 20(3), 29, 31(5), 32(2), 37(5), 39, 41(3), 42(6) and Article 280	April 2019
		Disease notification, reporting, animal health visits, surveillance	Articles 23, 25, 30(1) and (2)	April 2019 (2021*)
		Eradication programmes and disease freedom, incl. compartments	Articles 35, 37(4)(b), 40	April 2019 (2021*)

• 2021* - theoretical deadline is the date of the application of the AHL. For practical reasons, to construct cross-references between DA and IA, it has to be done simultaneously with DA, in 2019

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Part 3– Awareness, preparedness, control

AHL Part	Delegated Act	Implementing Act	Articles	Adoption by
Part 3	Disease control measures – List A, B, C diseases		Articles 47,53, 54(3), 55(2), 58(2), 63, 64, 67, 68, 70, 72(2), 73(3), 74(4), 76(5), 77	April 2019, (2024 - some disease specific rules: for some A diseases)
		Practical implementation of contingency plans, simulation exercises	Articles 44, 45(4)	2021
		Union and national antigen, vaccine and diagnostic banks	Articles 50(1), 52(3)	2021



Part 4/1: reg, approval, I&R, terrestr movements

European **Articles** Adoption by **AHL Part Delegated Act Implementing Act** Animals (terrestrial): Registration Articles 87(3), 94(3), 97(2), 101(3) 106 (1), April 2019, **Part 4/1** and approval of establishments, 109(2), 118(1), 118(2), 119 and (2024 - Art. 118, 119) identification and registration of Article 279 animals Movement of terrestrial animals Articles 3(5), 125(2), 131(1), 132(2), 135, April 2019 and PAO 136(2), 137(2), 138(3), 139(4), 140, 144, 146(1), 147, 149(4), 151(3), 154(1), 156(1), 166(3), 167(4), 167(5), 168(3) 169(5) Germinal products – registration Articles 94(3), 97(2), 106 (1), 122, 160(1), April 2019 and approval of establishments, 160(2), 161(5), 161(6), 162(3), 162(4), traceability and movements 163(5), 164(2), 165 Terrestrial animals: information for April 2019 Articles 86(1), 86(2), 89(1), 89(2), 92(1), (2021*) registration and approval, exempted 92(2), 96(3), 107 establishments, transporters, exemptions from record keeping Animal identification Articles 120(1), 120(2) April 2021 (2024 - for bovine, sheep & goats, pigs) Terrestrial animals and PAO: Model AH Articles 146(2), 151 (4), 154(2), 156(2), April 2019 (2021*) certificates, self-declarations, notification 168(4), 169(6) movements Articles 86(1), 86(2), 96(3), 107, 123, April 2019 GP: information for registration and approval, exempted establishments, 162(5), 163(6) and Article 279 (2021*) transporters, exemptions from record keeping, traceability, model AH certificates, self-declarations, movement notification

Part 4 (Title 2) reg, approval, aqua movements



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AHL Part	Delegated Act	Implementing Act	Articles	Adoption by
Part 4/2	Information for registration and approval, types of establishments, transporters exempted, exemptions from record keeping		Articles 176(4), 181(2), 185(5), 189(1), Article 279	2019
	Movement of aquatic animals and PAO from aquatic animals		Articles 3(5), 192(2), 197(3), 200(3), 201(3), 202(3), 203(2), 204(3), 205(2), 211(1), 213(1), 214, 216(3), 218(3), 221(1), 222(3), 223(5) and (6), 224(3), 225(3)	2019
		Information for registration and approval, types of establishments, transporters exempted, exemptions from record keeping and model AH certificates, self-declarations, notification movements – aquaculture animals and PAO of aquatic animals	Articles 175(1), 175(2), 180(3), 190, 211(2), 213(2), 218(4), 221(2) and 224(4)	2019 (2021*)



Part 5 (Entry into the EU – animals, GP and PAO)

AHL Part	Delegated Act	Implementing Act	Articles	Adoption by
Part 5	Entry into the EU of animals, GP and PAO		Articles 3(5), 230(3), 237(4), 234(2), 239(2)	April 2019
		List of third countries and territories Establishments in TCs	Articles 230(1), 233(4)	April 2019 (2021*)
		Animal health certificates for entry into the EU	Articles 238(3), 239(3)	April 2019 (2021*)

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Total (to be ready 2019-2021)

AHL Part	No. of DA	No of IA	No. of DA & IA
Part 1	1	1	2
Part 2	1	2	3
Part 3	1	2	3
Part 4/1	3	4	7
Part 4/2	2	1	3
Part 5	1	2	3
Parts 1-5: Total	9	12	21

Note: This is not a complete overview of DA and IA under the AHL (only priority acts, necessary for the application)





State of play of development of DAs and IAs

- DAs and IAs are in preparation
 - Some topics discussed with MSs in 2017: Germinal Products, Equidae, Products of Animal Origin, Bees, Listing and categorisation of diseases
 - Others under internal preparation: Intra EU movements, Aquatic, Surveillance, Disease Control, etc.

Adoption April 2019

- <u>1st priority</u>: DA and IA listing and categorisation of animal diseases and listing of species
 at the latest summer 2018
- All other <u>"key" and related acts</u>: Discussions should be broadly concluded by September 2018
 Text finalised end 2018

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Overview meetings 2017

Date	Expert/Working Group
Date	
13-Jan	Bee health
14-March	Animal Health Advisory Committee (AHAC)
04-Apr	Identification and movements of equidae
24-Apr	Germinal products
02-Oct	Products of animal origin
27-Oct	Identification and movements of equidae
17-Nov	Disease listing and categorisation
24-Nov	Germinal products
24-Nov	Disease listing and categorisation
6-7 Dec	CVOs - Council
18-19 Dec	Disease listing and categorisation
18-Dec	Animal Health Advisory Committee (AHAC)



Planned meetings 2018*

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Date	Working group	Confirmed
18-19 Jan	Disease listing and categorisation	Y
23-Jan	PAO - Entry into EU	Y
5-6 Feb	Disease listing and categorisation	Y
19-20 Feb	Disease listing and categorisation	N
21-Feb	Topic to be confirmed (terrestrial/aquatic)	N
22-Feb	PAO - Entry into EU	Υ
15-Mar	Surveillance, eradication, disease freedom	N
19-Apr	Topic to be confirmed	N
23-Apr	Topic to be confirmed	N
16-17 May	Topic to be confirmed	N
28-May	Topic to be confirmed	N
6-7 June	Topic to be confirmed	N
18-Jun	Topic to be confirmed	N
11-Jul	Topic to be confirmed	N
12-Jul	Topic to be confirmed	N

* Non-exhaustive list

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Thank you



Important links to follow the process:

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

https://ec.europa.eu/food/animals/health/expert group en

