



Project: Technical assistance to improve implementation of food safety standards and disease crisis preparedness

**Training course: Animal Health Law – Regulation (EU)
2016/429**

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Date:

Place: Nicosia, Cyprus

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- Why new AH legislation?
- The reasoning behind
- Legislation before AHL
- Content of the AHL
- Underpinning regulation to AHL
- Delegated act VS Implementing act



- Why new Law and what it regulates?



Reasoning for new AHL



- Old legislation
- EU Strategy
- Proactive and not Reactive
- One health!

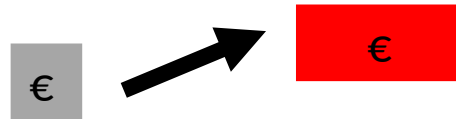


World Organization for Animal Health



Animals + humans = One health

Reactive
cure

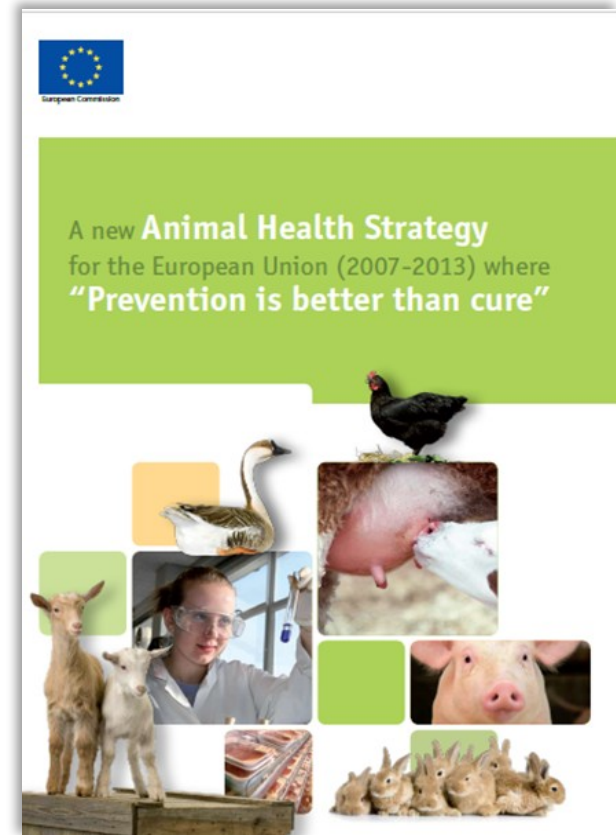


Proactive
Prevention





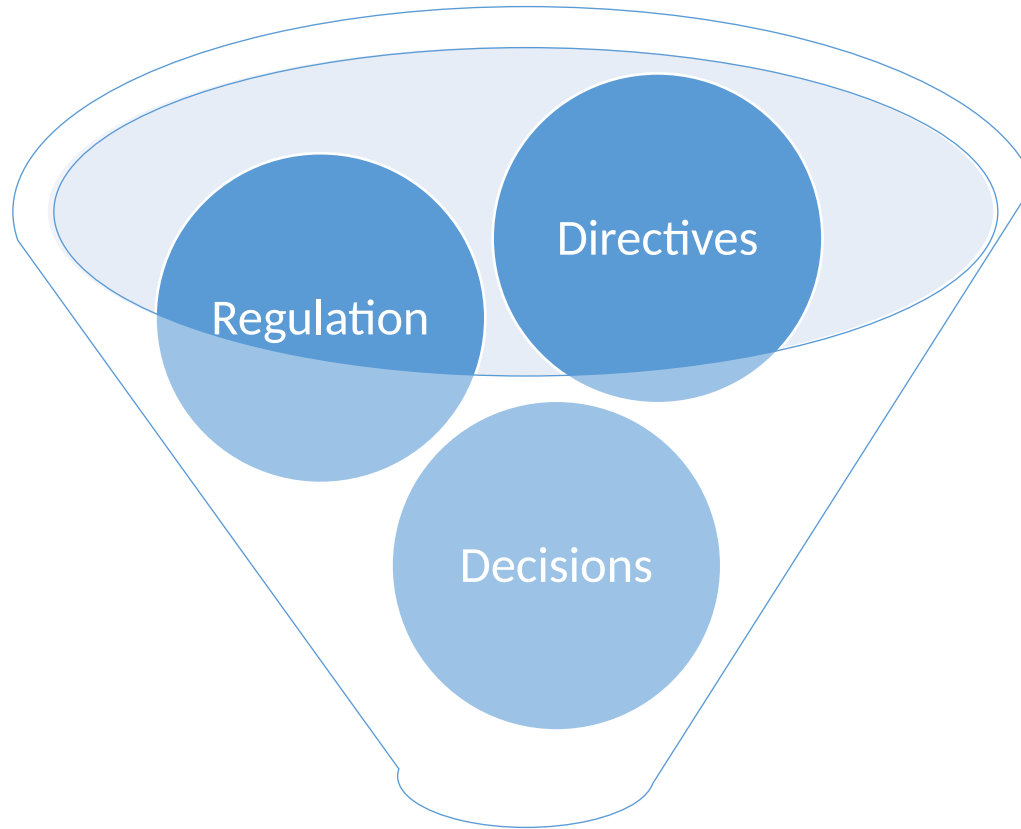
- Regulation (EU) 2016/429 is based on EU strategic documents and risk assessment
 - Evaluation of the EU Animal Health policy 1995- 2004 (2006)
 - AH Strategy “Prevention is better than cure” (2007)
 - AHS Action Plan (2008)
 - Impact Assessments (Strategy and AHL)



Legislation before AHL



- Council Directive 1964/432/EEC - on animal health problems affecting intra-Community trade in bovine animals and swine
- Council Directive 91/68/EEC - on animal health conditions governing intra-Community trade in ovine and caprine animals
- Council Directive 92/65/EEC - laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC
- Council Directive 2006/88/EC - on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals



New approach



- Regulation (EU) 2016/429 on transmissible animal diseases ('Animal Health Law') (AHL)
 - adopted by the European Parliament and the Council in March 2016
 - applies from 21 April 2021
 - it is complemented by additional rules, mainly adopted in 2020

New element of AHL



- Responsibilities of keepers, operators, veterinarians, competent authorities, etc.
- More risk based approach including prioritisation and categorisation of animal diseases for EU intervention
 - more prevention
 - biosecurity
 - surveillance
 - knowledge on animal health
 - use of vaccines
 - emerging diseases
 - AMR
- Easy and safe trade
- NB:
 - some rules (e.g. responsibilities) apply to all animals, species, regardless of diseases
 - some disease specific rules apply only to listed diseases



- Regulation 2016/429 (AHL) is directly applicable to the all Member States (MS)
- However, some rules (designation of authorities for the application, national measures, stricter measures, penalties etc.) are to be laid down by the MSs
- The AHL is supported by Delegated acts (DA) and Implementing acts (IA)
 - DAs have general application and supplement or amend certain non-essential elements of the basic act 'what do we do'? Parliament & Council have a say
 - IAs are more technical in nature..... 'how do we do it'? Objective is to ensure uniform application of the Basic Act or the DA - agreed via Comitology process (Standing Committee on Plants, Animals, Food and Feed where all 27 MSs are represented)
- Basic Act (in this case the AHL), provides 'empowerments' for the Commission to bring forward Delegated Acts and Implementing Acts



OCR (Official control regulation) – Regulation (EU)

2017/625

AHL

- List of disease
- Disease categorization and species
- Disease notification, surveillance and control
- Registration and approval
- Movement within union
- Entry into union
- Etc...

OCR

- Official controls
- Delegating of task to natural and legal persons
- Laboratories
- Sampling and diagnostic
- IMSOC
- Etc...



• AHL structure and content?

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► **B** 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)
(OJ L 84, 31.3.2016, p. 1)

Amended by:

| | Official Journal | | | |
|-------------|---|-------|------|------------|
| | No | page | date | |
| ► M1 | Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 | L 95 | 1 | 7.4.2017 |
| ► M2 | Commission Delegated Regulation (EU) 2018/1629 of 25 July 2018 | L 272 | 11 | 31.10.2018 |

Corrected by:

- **C1** Corrigendum, OJ L 57, 3.3.2017, p. 65 (2016/429)
- **C2** Corrigendum, OJ L 137, 24.5.2017, p. 40 (2017/625)
- **C3** Corrigendum, OJ L 48, 11.2.2021, p. 3 (2016/429)



Part I – General rules

Part II – disease notification, reporting, surveillance, eradication programmes, disease freedom

Part III – Disease awareness, preparedness

Part IV

Title 1 – registration, approval, traceability and movements (terrestrial)

Title 2 – registration, approval, traceability and movements (aquatic)

Title 3 – other animals and their products

Part V Entry into EU

Part VI – non-commercial pets

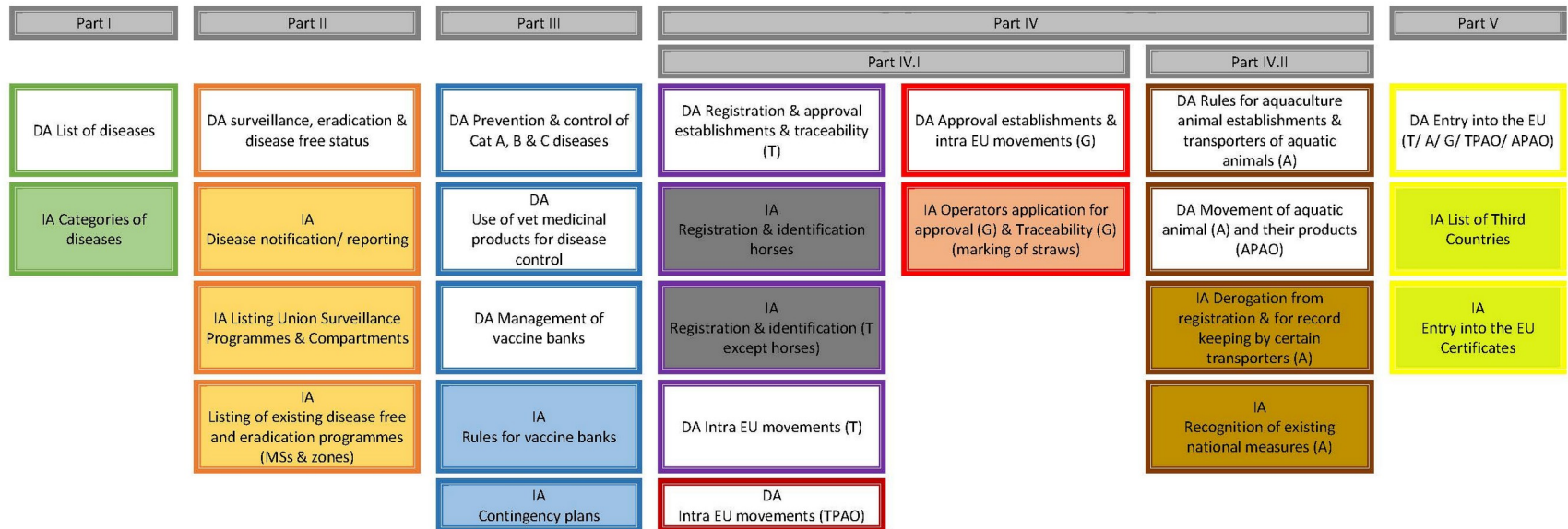
Part VII – Emergency measures

Parts VIII/IX – Common and transitional provisions

AHL - underpinning legal frame



AHL Regulation (EU) 2016/429



| | |
|------|---------------------------------------|
| T | Terrestrial animals & hatching eggs |
| TPAO | Terrestrial products of animal origin |
| A | Aquatic animals |
| APAO | Aquatic products of animal origin |
| G | Germinal products |
| DA | Delegated Act (DA) |
| IA | Implementing Act (IA) |



Microsoft Word Document



Subject matter, aim, scope and definitions

Listed diseases, emerging diseases and listed species

Responsibilities for animal health

Apply to

- 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 product
 - Emergency measures



Do not apply to ...

- Animal welfare
- EU veterinary expenditure (incl. compensations)
- Feed, medicated feed
- Veterinary medicines (VMP)
- Veterinary education
- Official controls

- Specific rules remain in place for:
 - Animal by-products
 - TSE rules
 - Certain zoonoses



Definition – Article 4



- 56 definitions / terms that are used in that Regulation

Some key definitions:

- Kept vs. wild animals, pet animals
- Terrestrial, aquatic and other animals
- Epidemiological unit,
- Operators, establishments, etc...
- Annex I is a part of definition (11) "pet animal"
- Annex III is a part of definition (45) "ungulates"

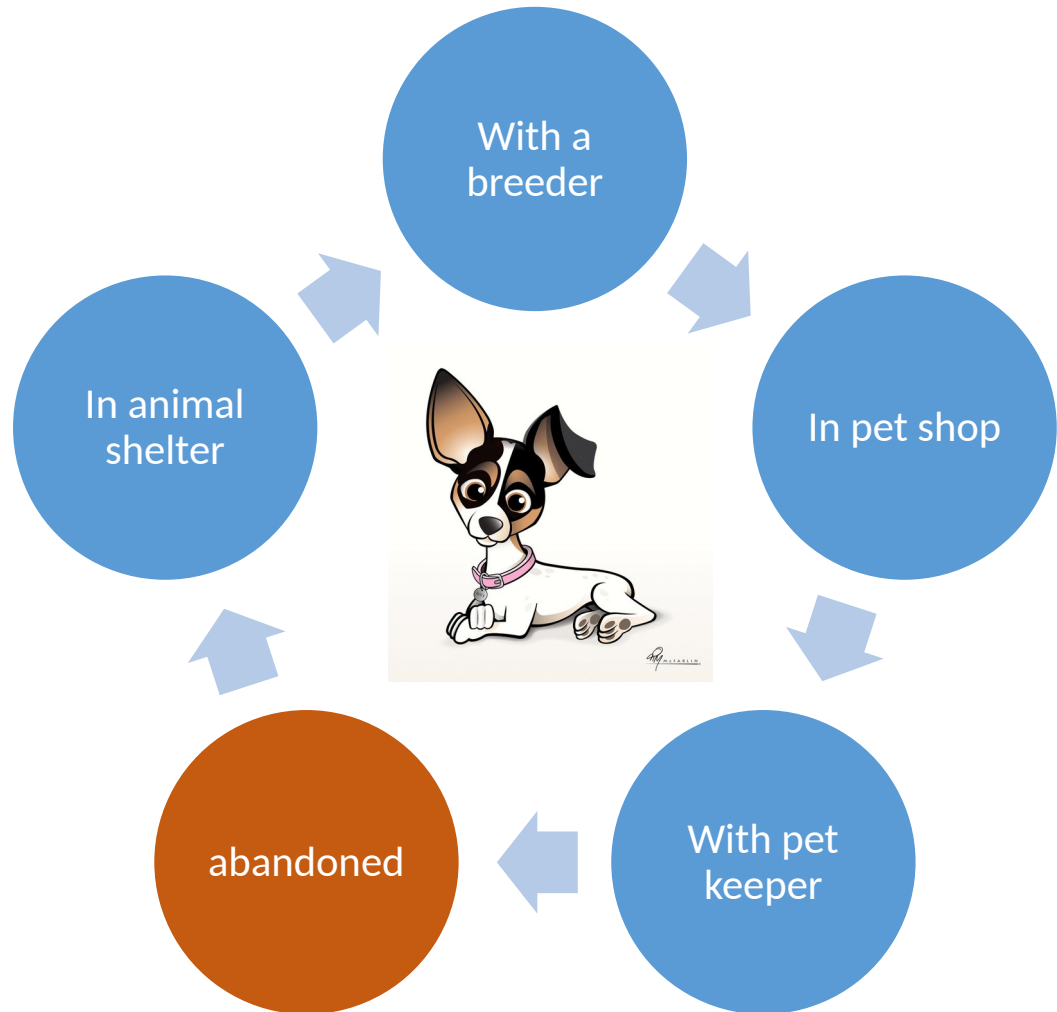
NB:

- DAs and IAs adopted on its basis have additional definitions, and that
- AHL definitions automatically apply for all DAs and IAs on its basis

IMPORTANT



- Different situations in respect of “kept” and “wild” animals
- Note that in the context of AHL: “kept” and “wild” animals depend on the fact if they are kept by humans or not:
- a camel or a giraffe are not necessarily wild animals (if in zoo, they are kept animals)
- domestication of species doesn't play a role



Animal diseases under the AHL



- EU limits its intervention with regard to certain measures to certain “listed” diseases
 - List of diseases for the EU intervention
 - Categories diseases by assigning measures to them for:
 - disease preparedness, awareness and disease control measures
 - disease eradication and disease freedom
 - relevant for some MS prevent from spreading, disease eradication and disease freedom
 - animal health requirements for movements and trade
 - disease notification and reporting, surveillance
- EU intervention possible for emerging diseases
 - Defines what is considered as emerging disease
 - Sets the EU reaction on them

Responsibilities - (operators, veterinarians)



- Operators:
 - health of their animals, biosecurity, etc.
 - knowledge on animal health
 - Animal diseases, biosecurity, interaction with animal welfare, good husbandry practices and antimicrobial resistance
 - more preventive behavior, better biosecurity
 - Contribute to better overall husbandry
 - Result with healthier animals and possible lower use of veterinary medicines
- Veterinarians to play a more active role in:
 - raising animal health awareness,
 - awareness on interaction between animal health, animal welfare and human health and on resistance to treatments

NB: Roles of veterinarians apply equally to aquatic animal health professionals, if **recognised by national rules!**

MS responsibilities and delegation of tasks



- Member States to ensure resources, personnel, laboratories, etc.
- Public information, e.g. passengers information
- Delegation by a competent authority of official tasks to veterinarians other than official veterinarians in relation to
 - Practical application of eradication programmes
 - Support to the CA on surveillance activities
 - Activities related to disease awareness, preparedness and control
 - Registration, approval, I&R

NB: rules for delegation of tasks according to OCR Regulation apply!



Laboratories: what is in the AHL?



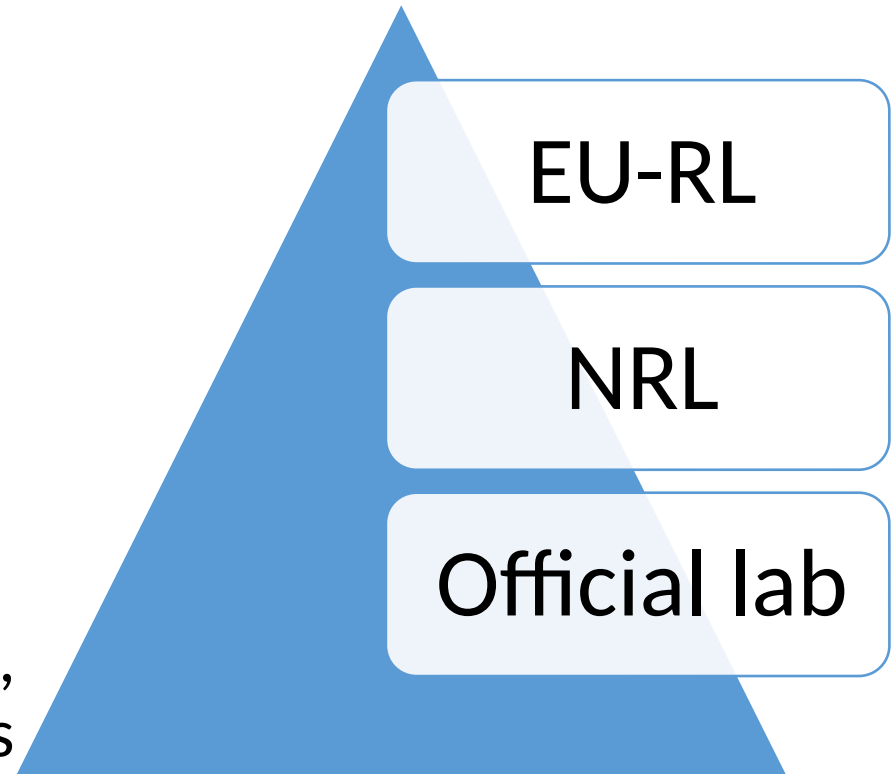
- Biosecurity, biosafety and bio-containment obligation of all laboratories, facilities and other handling disease agents, vaccines etc.
- Requirements for movements of disease agents
- Laboratory network
- Notification of disease

Laboratory Network



- Network of official laboratories in animal health consists of:
- Reference laboratories:
 - European Union Reference Laboratories (EU-RL)
 - National Reference Laboratories (NRL)
- Official laboratories in Member States

NB: Remember: designation and obligations of official laboratories, including reference laboratories is set out in the OCR





Disease notification

Surveillance

Eradication programmes

Disease- fee status



- Rules for notification of animal diseases (in MSs)
 - Notification of natural and legal persons to veterinarians and the CA Union notification and reporting
- Computerised information system (ADIS)





- Surveillance (responsibilities):
 - Obligation of operators for surveillance (incl. Animal Health Visits)
 - Obligations of competent authorities
 - Laboratories
 - Union surveillance programmes
- Aim:
 - Early detection
 - Prevalence
 - Incidence
 - Disease freedom
 - Eradication

Eradication and disease free status



- Compulsory and optional eradication programmes
 - Compulsory for Category B diseases
 - Optional for Category C diseases
- Measures under programmes and contents
- Disease free status
 - Countries
 - Zones
 - Compartments (n.b. only rules for aquatic compartments developed)
 - Maintenance, suspension, withdrawal and restoration

Part II –underpinning Regulations



- **COMMISSION DELEGATED REGULATION (EU) 2020/689** of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for **surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases**
- **COMMISSION IMPLEMENTING REGULATION (EU) 2020/690** of 17 December 2019 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the listed diseases subject to **Union Surveillance programmes**, the geographical scope of such programmes and the listed diseases for which the disease-free status of compartments may be established
- **REGULATIONS COMMISSION IMPLEMENTING REGULATION (EU) 2020/2002** of 7 December 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to **Union notification and Union reporting of listed diseases**, to formats and procedures for submission and reporting of Union surveillance programmes and of eradication programmes and for application for recognition of disease-free status, and to the computerised information system



Contingency plans and simulation exercises

Use of veterinary medicinal products for disease prevention and control

Antigen, vaccine and diagnostic reagent banks

Disease control measures for Category A diseases

Disease control measures for Category B and C diseases

Disease awareness, preparedness and control

- Contingency plans and simulation exercises
- The use of VMPs for disease prevention and control
- Union antigen, vaccine and diagnostic reagent banks for cat A diseases
 - Establishment of the banks
 - Access to the banks
 - Confidentiality
- National antigen, vaccine and diagnostic reagent banks for cat A diseases
- Disease control measures for Cat A, B and C diseases

Part III – underpinning Regulations



- COMMISSION DELEGATED REGULATION (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases
- Not published
 - Delegated act on vaccination
 - Delegated act on vaccine bank
 - Implementing act vaccine bank
 - Implementing act contingency plans

Terrestrial animals, germinal products and products of animal origin



Registration and approval

Traceability

Movement of kept terrestrial animals

Movement of wild terrestrial animals

Movement of Germinal Products

Production, processing and distribution of POA

National measures



Part IV: Registration, approval, traceability and movements



- Terrestrial animals, germinal products, products of animal origin
- Aquatic animals, products of animal origin from aquatic animals
- Other animals, germinal products, products of animal origin



Part IV – underpinning Regulations



- **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**
- **COMMISSION IMPLEMENTING REGULATION (EU) 2021/520** of 24 March 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the **traceability of certain kept terrestrial animals**
- **COMMISSION IMPLEMENTING REGULATION (EU) 2021/963** of 10 June 2021 laying down rules for the application of Regulations (EU) 2016/429, (EU) 2016/1012 and (EU) 2019/6 of the European Parliament and of the Council with regard to the identification and registration of **equine** animals and establishing model identification documents for those animals
- IA on establishments registration – exemptions



- **COMMISSION DELEGATED REGULATION (EU) 2020/688** of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for **movements** within the Union of terrestrial animals and hatching eggs
- **COMMISSION IMPLEMENTING REGULATION (EU) 2021/403** of 24 March 2021 laying down rules for the application of **Regulations (EU) 2016/429 and (EU) 2017/625** of the European Parliament and of the Council as regards **model animal health certificates** and model animal health/official certificates, for the entry into the Union and movements between Member States of consignments of certain categories of terrestrial animals and germinal products thereof, official certification regarding such certificates and repealing Decision 2010/470/EU



- **COMMISSION DELEGATED REGULATION (EU) 2020/686** of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the **approval of germinal product establishments** and the **traceability** and animal health requirements for **movements** within the Union of germinal products of certain kept terrestrial animals
- **COMMISSION IMPLEMENTING REGULATION (EU) 2020/999** of 9 July 2020 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the approval of germinal product establishments and **the traceability of germinal products of bovine, porcine, ovine, caprine and equine animals**
- **COMMISSION IMPLEMENTING REGULATION (EU) 2021/403**

Aquatic animals and products of animal origin from aquatic origin



Registration, approval, records, registers,
traceability

Movement of aquatic animals

Production, processing and distribution of POA from
aquatic animals

National measures

Movements of aquatic animals within the Union – specific requirements – the approach



- Free zone, compartment
- Under eradication programme
- Under surveillance programme
- Other, no status



Part IV – underpinning Regulations



- **COMMISSION DELEGATED REGULATION (EU) 2020/691** of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for **aquaculture establishments** and transporters of aquatic animals
- **COMMISSION IMPLEMENTING REGULATION (EU) 2020/2236** of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal **health certificates** for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008
- **COMMISSION DELEGATED REGULATION (EU) 2020/990** of 28 April 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards **animal health and certification** requirements for movements within the Union of aquatic animals and products of animal origin from aquatic animals
- IA on exemption from registration obligation



- Basic animal health requirements for other animals, if they are of listed species for one of the listed diseases
- In such case:
 - Requirements for registration, approval and traceability would apply, rules for movements and animal health certificates
 - A delegated and an implementing act will develop such rules



Entry into EU of animals, germinal products and products of animal origin

Entry into EU of certain goods other than animals, GP and POA

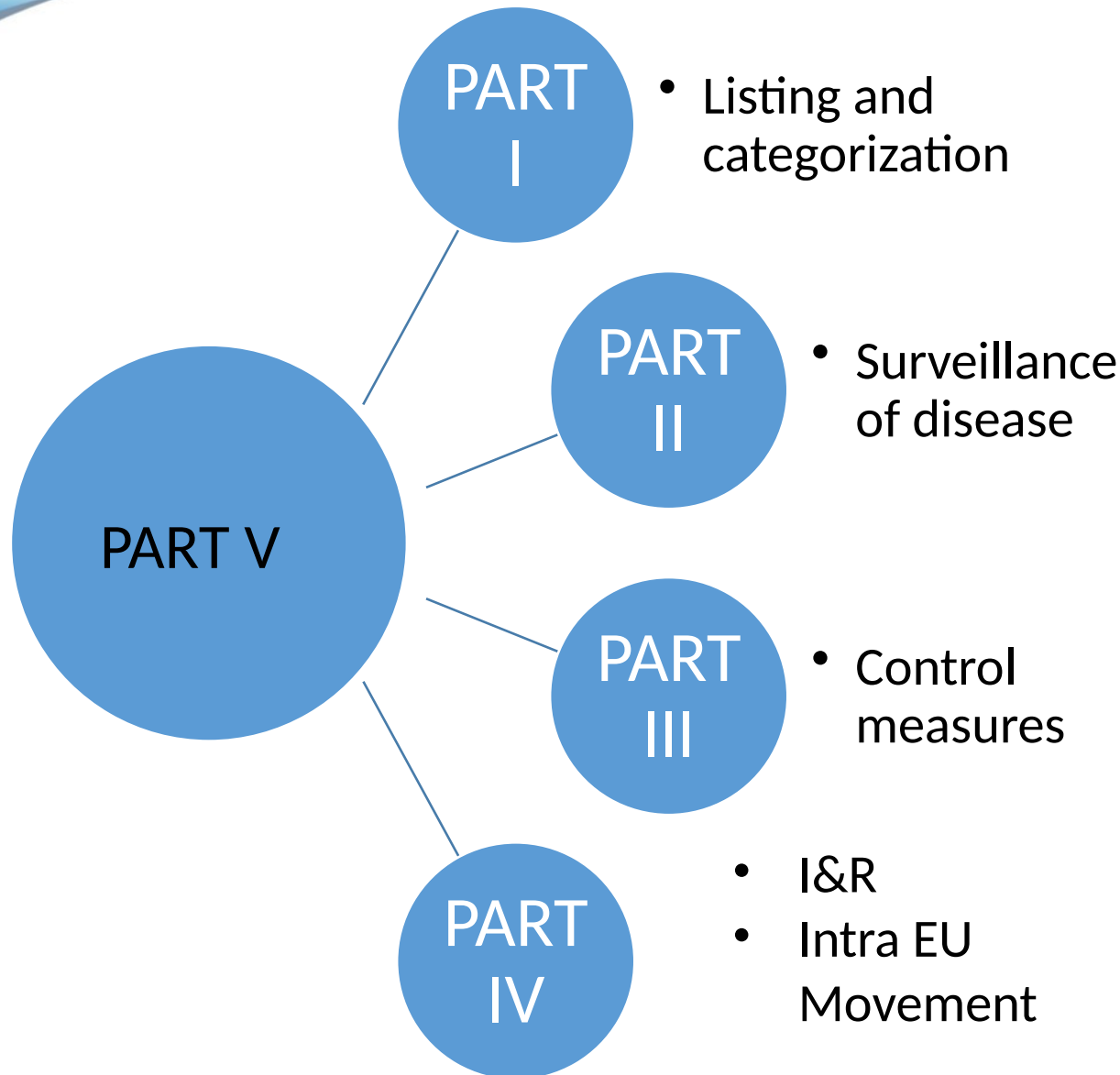
Export from the EU

Entry into EU of animals, germinal products and products of animal origin



- Requirements for entry into Union
- List of third countries and territories
- Approval and listing of establishments in third countries and territories
- Animal health requirements for entry into the EU of species and categories of animals, germinal products and products of animal origin
- Animal health certificates, declarations and other documents
- Derogations and special rules

Requirements for entry into the Union



Entry into EU of certain other goods and export from Union



- Entry of other goods:
 - Disease agents
 - Plant material
 - Additional rules
 - Means of transport, equipment, packaging material, transport water and fodder
- Export from the Union

NB:

- Main objective: the export should not hamper animal health in third countries and territories, and their health statuses

Part V – Underpinning regulation



- COMMISSION **DELEGATED** REGULATION (EU) **2020/692** of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards **rules for entry into the Union**, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin
- COMMISSION IMPLEMENTING REGULATION (EU) 2020/2235
- COMMISSION IMPLEMENTING REGULATION (EU) 2020/2236
- COMMISSION IMPLEMENTING REGULATION (EU) 2021/403
- COMMISSION **IMPLEMENTING** REGULATION (EU) **2021/404** of 24 March 2021 laying down the **lists of third countries, territories or zones thereof** from which the entry into the Union of animals, **germinal products** and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council

Part VI: Non-commercial movements of pet animals



- Part VI of the AHL
- Will apply after 21 April 2026
- Until that date: Regulation (EU) No 576/2013 applies





- Emergency measures in EU
 - By MSs and by the Commission
- Emergency measures on consignments from third countries and territories
 - By MSs and by the Commission

NB:

- these are “old” safeguard measures from Dir 90/425, 89/662, 97/78 and 91/496
- emergency measures also exist in Regulation (EU) No 178/2002 and Regulation (EU) 2017/625

Member States' national (stricter) measures



- Additional and more stringent measures by MSs in areas (Article 269):
 - Responsibilities on animal health (Articles 10-17)
 - Surveillance (Articles 24-30)
 - Registration, approval, record keeping and registers (Articles 84-107 and Articles 172-190)
 - Traceability (Articles 108-123)
- National disease control and movements measures in terrestrial animals
 - for Category D and E diseases (Article 170) and to limit the impact of diseases other than listed diseases in terrestrial animals (Article 171)
- National measures to limit the impact of diseases other than listed diseases in aquaculture animals (Article 226)
 - Currently under Decision (EC) 2010/221

Common and Final Provisions



- • “Grandfathers” rights
 - Existing operators and establishments (including I&R)
 - Existing disease free MSs, zones and compartments and existing MSs eradication and surveillance programmes
- Transitional provisions
 - Transitional measures for rules on identification and registration – will not be used!
 - Transitional measures for disease control rules (Category A diseases) – will not be used!
 - Transitional measures for rules on non commercial movements of pets
- Amendments to Regulation (EC) 1760/2000 – removing rules for “bovine animals”



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THANK YOU FOR YOUR ATTENTION



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