

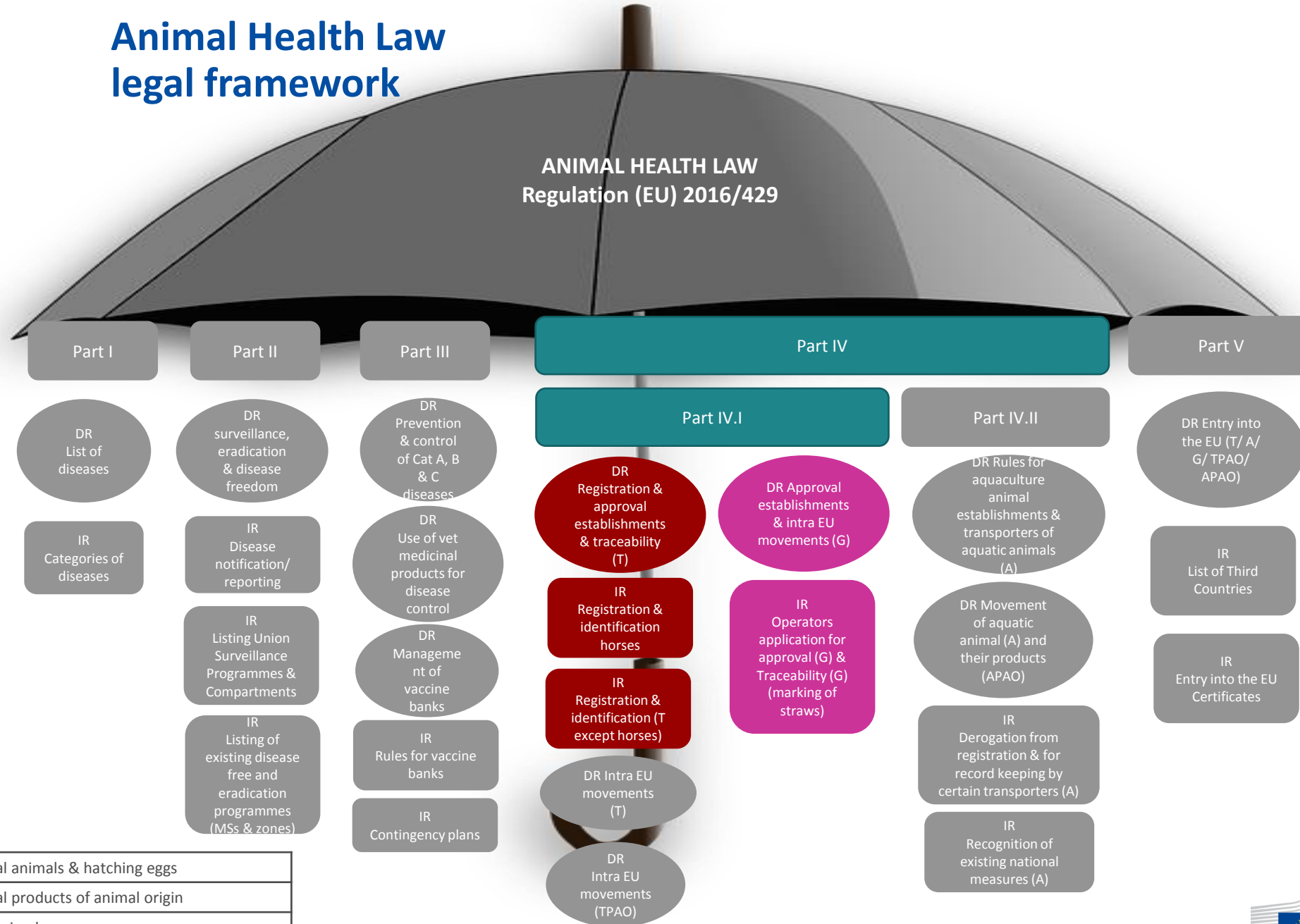


Registration, approval, record-keeping and registers

Rules for establishments keeping terrestrial animals,
hatcheries and germinal product establishments

BTSF AHL seminar

Animal Health Law legal framework



T	Terrestrial animals & hatching eggs		
TPAO	Terrestrial products of animal origin		
A	2 Aquatic animals	○	Delegated Regulation (DR)
APAO	Aquatic products of animal origin	□	Implementing Regulation (IR)
G	Germinal products		

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

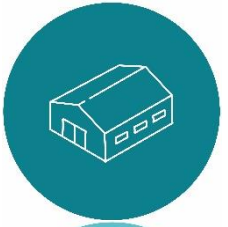
Registration of establishments

AHL Part IV,
Title I,
Chapter 1,
Section 1

Delegated
Regulation (EU)
2019/2035: Part II,
Title I, Chapter 1

Implementing
Regulation (EU) on
type of
establishments
which may be
exempted (tba)

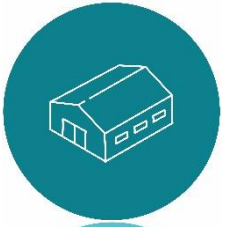
Registration of establishments and operators – obligations of the operators



- The following operators shall inform the competent authorities before they take up their activity:
 - Operators of establishments keeping terrestrial animals
 - Operators of establishments collecting, producing, processing or storing germinal products
 - Transporters engaged in transportation of kept ungulates, dogs, cats or ferrets or poultry between Member States (or to a third country)
 - Operators conducting assembly operations *for kept ungulates and poultry*, independently of an establishment
- The type of information *to be provided* is described in the AHL
- The operators shall also inform the competent authorities of any changes and any cessation of activity

Registration of establishments and operators – obligations of the **competent authorities**

- The competent authority shall register the establishments, the transporters and the operators
- The competent authority shall assign each establishment, transporter and operator with a unique registration number
- By way of derogation, Member States may exempt from the registration requirement certain categories of establishments, transporters and operators posing an insignificant risk (provided that the type of establishment, transporter or operator is listed in a Commission Implementing Regulation (under development))



Approval of certain establishments

AHL Part IV,
Title I,
Chapter 1,
Section 2

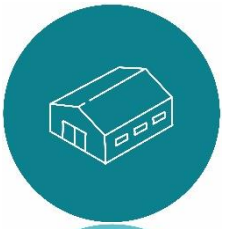
Delegated
Regulation (EU)
2019/2035: Part II,
Title I, Chapters 2
to 4

Delegated
Regulation (EU)
2020/686: Part
II, Chapter 1,
Articles 3 to 5
and Annex I

Implementing
Regulation (EU)
2020/999
Articles 3 and 4

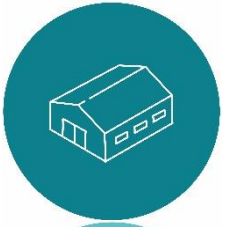
Operators of the following types of establishments shall apply for approval

- Establishments for assembly operations *of ungulates and poultry* (to or from another MS)
- Germinal product establishments *of bovine, ovine, caprine, porcine and equine animals* (to another MS)
- Hatcheries *of poultry* (eggs or poultry to another MS)
- Establishments keeping poultry (poultry *other than for slaughter* or eggs to another MS)
- Establishments wishing to obtain the status of confined establishment
- Other type of establishment (assembly centres and animal shelters for dogs, cats and ferrets, control posts, environmentally isolated production establishments for bumble bees (to another MS) and quarantine establishments (within the MS, to another MS and for imports))



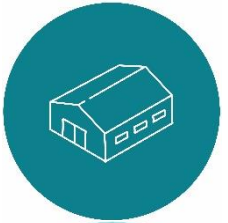
Approval of certain establishments – obligations of the operators

- Apply for approval – not take up the activity before the establishment is approved
- Provide information as provided for in AHL and/or DR and/or IR
- Cease the activity if the competent authority withdraws or suspends the approval
- Inform the competent authorities of any changes and any cessation of activity



Conditions for granting of approval – obligations of the **competent authorities**

- *Competent authorities shall grant approval where the establishments, depending on the type:*
 - *comply with specific requirements in relation to quarantine, isolation and biosecurity measures, surveillance and record keeping requirements*
 - *have adequate facilities, equipment and operational procedures*
 - *do not pose an unacceptable risk as regards the spread of diseases*
 - *have adequately trained personnel*
 - *are supervised by the competent authority*
- *Scope of approval: type of establishment, species and categories of animals or types of germinal products.*



Approval of germinal product establishments

Approval of germinal product establishments (I)



- *Types of approved germinal product establishments:*

- *a semen collection centre*
- *an embryo collection team*
- *an embryo production team*
- *a germinal product processing establishment*
- *a germinal product storage centre*



- *A possibility to process and/or store germinal products of more than one type or of more than one species in single germinal product processing establishment or storage centre*

Approval of germinal product establishments (II)



New

IR (EU)
2020/999

- *Rules covering the information to be provided by operators in applications for approval of germinal product establishments*
- *The animal health and biosecurity requirements for the operation of the germinal product establishment as part of the information in the application*
- *Rules concerning the time-limits for providing the application (not more than 90 days prior to the intended date of commencement of activity), the time-limits for informing the competent authority of any cessation of activity of approved germinal product establishments.*

New

New

Approval of germinal product establishments (III)

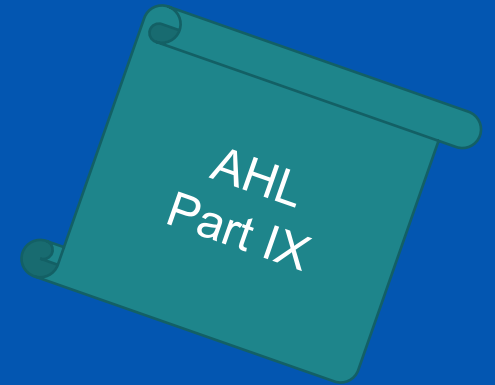


New



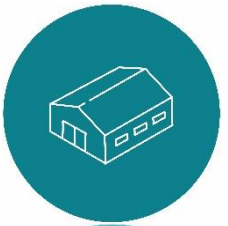
- *Special rules for cessation of activities:*
 - *Prior to the withdrawal date of the approval of germinal product establishment all consignments of semen, oocytes or embryos collected or produced and stored in that germinal product establishment shall be moved:*
 - *to a germinal product storage centre for further storage; or*
 - *for reproduction purposes to an establishment where bovine, porcine, ovine, caprine or equine animals are kept; or*
 - *for safe disposal or use as animal by-products in accordance with Article 13 of Regulation (EC) No 1069/2009*
 - *Germinal products not moved from the approved germinal product establishment prior the withdrawal date of the approval shall not be moved to another Member State*

Existing operators and establishments



Transitional measures – “grandfather rights”

- Establishments and operators registered or approved before 21 April 2021 shall be considered to have been registered or approved in accordance with the requirements in the AHL
- Information already registered in existing registers shall be included in “new” registers
- In all other respects, they shall be subject to the rules provided for in the AHL and in Delegated and Implementing Regulations



Registers of the competent authorities

AHL Part IV,
Title I,
Chapter 1,
Section 3

Delegated
Regulation (EU)
2019/2035: Part II,
Title II, Chapter 1
and 2

Delegated
Regulation (EU)
2020/686: Part
II, Chapter 2,
Articles 6 and 7

Registers

Each competent authority shall establish registers of

- establishments, transporters and operators registered with the competent authority
- establishments approved by the competent authority

Each competent authority shall make

- both registers available to the Commission and to the competent authorities of other Member States
- the register of approved establishments available to the public

in so far as information contained therein is relevant for the movements of kept terrestrial animals and germinal products thereof between MSs



Record-keeping

AHL Part IV,
Title I,
Chapter 1,
Section 4

Delegated
Regulation (EU)
2019/2035: Part II,
Title III, Chapters
1 to 4

Delegated
Regulation (EU)
2020/686: Part
II, Chapter 3,
Section 1,
Articles 8 and 9

Record-keeping obligations

- Operators of establishments and transporters registered in accordance with Article 93 of AHL or approved in accordance with Articles 97 and 99 of AHL shall keep and maintain records
- Operators of establishments and transporters presenting a low risk may be exempted by the Member State
- Rules on record-keeping for the operators of germinal product establishments that ceased their activity



Thank you



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