



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

Training course: Registration, approval and record keeping

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- Registration
- Approval
- Keeping records
- Obligation of operators
- Obligation of competent authority
- Transitional provisions



- 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 establishment which may be exempted

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 IV, Title I, Chapter 1, Section 2
- Delegated Regulation (EU) 2019/2035, Part II, Title I, Chapter 2 to 4
- Delegated Regulation (EU) 2019/686, Part II, Chapter 1, Article 3 to 5 and Annex I
- Implementing Regulation (EU) 2020/999, Article 3 to 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.



- Regulation (EU) 2020/686
- 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



- Regulation (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.



- Regulation (EU) 2020/686
- 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



- AHL Part IX
- Delegated Regulation (EU) 2020/686
- Delegated Regulation (EU) 2019/2035



- 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



- AHL Part IV, Title I, Chapter 1, Section 3
- Delegated Regulation (EU) 2019/686, Part II, Chapter 1, Article 6 and 7
- Delegated Regulation (EU) 2019/2035, Part II, Title II, Chapter 1 and 2



- 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
- Regulation (EU) 2019/2035, Part II Title III Chapters 1 to 4
- Regulation (EU) 2020/686 Part II, Chapter 3 Section 1
Articles 8 and 9
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- 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



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THANK YOU FOR YOUR ATTENTION



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