



# **THE DRAFT DELEGATED ACT ON MOVEMENT OF GERMINAL PRODUCTS WITHIN THE EU UNDER REGULATION (EU) 2016/429 (Animal Health Law)**

**Advisory Committee meeting  
20 May 2019**



European  
Commission

# AHL

Part I – General rules

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

Part III – Disease awareness, preparedness, control

**Part IV, Title I – Registration , approval, traceability and movements (terrestrial)**

Part IV, Title II – Registration , approval, traceability and movements (aquatic)

Part IV, Title III – 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**



## Subject matter and scope

1. Requirements for the approval of germinal product establishments for bovine, porcine, ovine, caprine and equine animals
2. Registers of the competent authority
3. Record-keeping by operators
4. Traceability requirements (marking of straws)
5. Animal health requirements for germinal products of bovine, porcine, ovine, caprine and equine animals
6. Self-declaration, certification and notification of movements
7. Animal health requirements for germinal products of dogs, cats, animals kept at confined establishments, camelids, cervids
8. Movement of germinal products for scientific purposes and stored at gene banks



## 4-week stakeholders consultations (I)

- The document and comments can be found under the following link:  
[https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-112597\\_en#isc-2018-06861](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-112597_en#isc-2018-06861)
- Time frame for comments: 9 January – 6 February 2019



## 4-week stakeholders consultations (II)

- 34 feedbacks were received in total
- Stakeholders: ETS-Holland, European Association of Zoos and Aquaria (EAZA ), European Association of Zoo and Wildlife Veterinarians, European Forum of Farm Animal Breeders (EFFAB), Association of Embryo Technologies in Europe, British and Irish Association of Zoos and Aquariums
- Public authorities: Canadian Food Inspection Agency, Animal and Plant Health Agency of the United Kingdom and U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS-IS)
- Some anonymous opinions



## 4-week stakeholders consultations (III) COMMENTS

### ANTIBIOTICS

- to adjust the list of antibiotics and mixtures of antibiotics used in ovine and caprine semen diluents in accordance with existing practices

INCLUDED - gentamicin (250 µg) or a mixture of penicillin (500 IU) and streptomycin (500 µg)

- to make voluntary use of antibiotics and mixtures of antibiotics in porcine semen

NOT INCLUDED – researches for the alternatives to the use of antibiotics are on-going, first results are encouraging, but it is too early to claim the equivalence

- do not oblige operators to disclose name(s) of the antibiotic(s) added and its(their) concentration

INCLUDED – instead of name(s) of the antibiotic(s) added and its(their) concentration the commercial name of the semen diluent containing antibiotics may be stated in the animal health certificate accompanying the consignment



## 4-week stakeholders consultations (IV) COMMENTS

- to include provisions supporting the existing practice for traceability of the ovine semen

INCLUDED - group identification of pellets of frozen semen and tubes with fresh or chilled semen allowed

- the operators of confined establishments disagree with the requirement of no natural breeding to have taken place for at least 30 days prior to the collection of germinal products

INCLUDED – “as much as possible, were not used for natural breeding during a period of at least 30 days prior to the date of first collection and during the collection period”

- to remove a derogation allowing collection of semen of ovine and caprine animals, which is to be moved to another Member State, at the establishment of origin of those animals instead of at a semen collection centre

NOT INCLUDED – retained based on Directive 92/65/EEC and the possible risk posed by the movement of such semen



## 4-week stakeholders consultations (V) COMMENTS

- to adjust requirements for testing for CSF at porcine semen collection centres based on the disease status of the country of semen collection

**INCLUDED** – testing for CSF: for disease-free countries at quarantine accommodation and annually; for countries not free of disease - before entering the quarantine accommodation and annually

- the request to take into account germinal products donors vaccinated against infection with bluetongue virus

**NOT INCLUDED** – in line with recommendations of the Terrestrial Animal Health Code of the OIE





## 4-week stakeholders consultations (VI) COMMENTS

- to include the following caprine diseases: Caseous lymphadenitis (*Corynebacterium pseudotuberculosis*); Caprine arthritis encephalitis; Q-fever

**NOT INCLUDED** – diseases not listed or not categorised for the measures

- to allow vaccinated for IBR/IPV seropositive semen donors (one comment)

**NOT INCLUDED** – in accordance with the position of most of MSs' experts, current rules introduced by Council Directive 2003/34/EC should be preserved = control and eradication of the disease should continue



## 4-week stakeholders consultations (VII) COMMENTS

- to allow clinical examination of donor animals before oocytes and embryos collection also to be done by the members of the embryo teams

INCLUDED

- to allow sealing the transport containers also to be done by the staff supervised by the centre veterinarian and the members of the embryo teams

INCLUDED – change of the wording from “the centre veterinarian or the team veterinarian shall:” into “the centre veterinarian or the team veterinarian shall ensure:”



## 4-week stakeholders consultations (VIII) COMMENTS

- to differentiate two types of embryo production teams:
    - one which deals with ovum pick up (OPU) and where is no need for permanently sited laboratory (as they send collected oocytes for further processing to ‘a real’ embryo production team);
    - second one dealing with the later fertilization, culture and processing.
- NOT INCLUDED**
- in accordance with the definition and requirements laid down in the Regulation embryo production team is responsible for all steps of embryo production, including ovum pick up;
    - however, this Regulation foresees that embryo production team may outsource the collection of oocytes to a group of specialised professionals provided that their activity is included in the approval by the competent authority of the embryo production team and the responsibilities of the team veterinarian are extended to their activities



## 4-week stakeholders consultations (IX) COMMENTS

- to allow transport of germinal products of different species in one container  

PARTLY INCLUDED – MSs' experts supported the idea of transport of different types of germinal products of a single species in one container. The rationale behind this was a complex situation as regards animal health certification. A derogation allowing common transport of germinal products of ovine and caprine animals
- the acknowledgements for the conditions laid down in this Delegated Regulation for the movement of germinal products stored at national gene banks to other Member States, including definition of a gene bank

THANK YOU



## **NEXT STEPS**

- Translation until 23 May 2019
- Adoption by the Commission together with other delegated acts
- 2-months consultation period with the European Parliament and the Council
- Publication in the Official Journal