European Commission

THE DRAFT DELEGATED and IMPLEMENTING ACTS ON GERMINAL PRODUCTS UNDER REGULATION (EU) 2016/429 (Animal Health Law)

This presentation does not necessarily represent the views of the European Commission

Advisory Committee
2 July 2018

Food Safety

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**

Species covered by the draft delegated act on germinal products

- kept terrestrial animals of the bovine, porcine, ovine, caprine and equine species;
- other:
  - dogs and cats,
  - terrestrial animals of species other than those of the bovine, porcine, ovine, caprine and equine species kept at confined establishments,
  - kept animals of the families *Camelidae* and *Cervidae*;

Part IV, Title I, Chapters 1 and 2

Approval, Registers, Record keeping, Traceability

- **Articles 97(2), 94(3)(c)** – approval requirements
- **Article 101(3)** – registers of the competent authority
- **Article 106(1)** – record-keeping by operators
- **Article 122(1) and (2)** – traceability requirements (marking of straws)

I. Articles 97(2), 94(3)(c) – approval requirements

‘**approved germinal product establishment**’

means a semen collection centre, an embryo collection team, an embryo production team, a germinal product processing establishment and a germinal product storage centre;

‘**germinal product processing establishment**’

means a germinal product establishment approved by the competent authority for the **processing, including semen sex-sorting, and the storage of semen, oocytes or embryos** of one or more species, or any combination of those germinal products, intended for movement to another Member State;

II. Articles 97(2), 94(3)(c) – approval requirements

‘**approved germinal product establishment**’

means a semen collection centre, an embryo collection team, an embryo production team, a germinal product processing establishment and a germinal product storage centre;

‘**germinal product storage centre**’ means a germinal product establishment approved by the competent authority for the **storage of semen, oocytes or embryos of one or more species, or any combination of those germinal products**, intended for movement to another Member State;

III. Articles 97(2), 94(3)(c) – approval requirements

- ✓ **Special rules for cessation of activities** for approved germinal product establishment for bovine, porcine, ovine, caprine and equine animals

When operator ceases the activity of germinal product establishment, semen, oocytes or embryos collected or produced and stored in that germinal product establishment shall be :

(a) removed to a germinal product storage centre for further storage; or

(b) removed for reproduction purposes to an establishment, where bovine, porcine, ovine, caprine or equine animals are kept; or

(c) safely disposed of or used as animal by-products in accordance with Article 13 of Regulation (EU) No 1069/2009,

before the date of withdrawal by the competent authorities.

I. Article 122(1) – traceability requirements (marking of straws) - germinal products of bovine, porcine, ovine, caprine and equine animals

- ✓ General rules are unchanged – mark on the straw must allow tracing back to the donor animal, place and date of collection or production.

- ✓ If in **a single straw** or another package **contains semen from more than one donor animal**, marking must allow establishing the identification of all donor animals;
- ✓ Where semen of animals of the ovine or caprine species is frozen in pellets, an operator may mark, instead of each pellet, the goblet containing semen pellets of a single donor;
- ✓ When the **semen** was **sex-sorted** at a germinal product processing establishment, marking must allow establishing the unique approval number of the germinal product processing establishment where that semen was sex-sorted.

II. **Article 122(2)** – traceability requirements (marking of straws) - germinal products of animals other than bovine, porcine, ovine, caprine and equine animals

- ✓ Mark on the straw must allow tracing back to:
  - ✓ the donor animal: the species, where necessary subspecies, and its identification,
  - ✓ place of collection or production, and
  - ✓ date of collection or production.
- ✓ If in **a single straw** or another package **contains semen from more than one donor animal**, marking must allow establishing the identification of all donor animals;
- ✓ Where semen of animals is frozen in pellets, an operator may mark, instead of each pellet, the goblet containing semen pellets of a single donor;
- ✓ When the **semen** was **sex-sorted** at a germinal product processing establishment, marking must allow establishing the place where that semen was sex-sorted.

Part IV, Title I, Chapter 5

Animal health requirements and certification for movement between MSs and notification

- **Article 160(1) and (2)** – animal health requirements for germinal products of bovine, porcine, ovine, caprine and equine animals
- **Article 151(3), Article 162(3) and (4)** – self-declaration and certification
- **Article 163(5)** – notification of movements
- **Article 164(2)** - animal health requirements for germinal products of other than bovine, porcine, ovine, caprine and equine animals
- **Article 165(3)** – movement of germinal products for scientific purposes and stored at gene banks

I. Article 160(1) and (2) – animal health requirements

- ✓ Germinal products of bovine, porcine, ovine, caprine and equine animals to be moved to another Member State must be collected or produced at or by an approved germinal products establishment.
- ✓ <u>Derogations:</u>
  - ✓ Ovine and caprine animals kept at establishment of their origin;
  - ✓ Animals kept at confined establishment.

IN LINE WITH CURRENT LEGISLATION

II. Article 160(1) and (2) – animal health requirements

✓ Listed diseases relevant for the species

Bovine animals
foot and mouth disease (**FMD**)
infection with **bluetongue** virus (serotypes 1-24)
epizootic haemorrhagic disease virus (serotypes 1-7) (**EHD**)
infection with ***Mycobacterium tuberculosis complex*** (*M. bovis, M. caprae* and *M. tuberculosis*)
infection with ***Brucella*** *abortus, Brucella melitensis* and *Brucella suis*
enzootic bovine leucosis (**EBL**)
infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis (**IBR/IPV**)
bovine viral diarrhoea (**BVD**)
bovine genital campylobacteriosis (***Campylobacter*** *fetus ssp. venerealis)*
trichomonosis (***Trichomonas*** *foetus*)

Porcine animals
foot and mouth disease (**FMD**)
infection with ***Brucella*** *abortus, Brucella melitensis* and *Brucella suis*
classical swine fever (**CSF**)
infection with porcine reproductive and respiratory syndrome virus (**PRRS**)
infection with **Aujeszky's disease**

New

III. Article 160(1) and (2) – animal health requirements

✓ Listed diseases relevant for the species

Ovine and caprine animals
foot and mouth disease (**FMD**)
infection with **bluetongue** virus (serotypes 1-24)
epizootic haemorrhagic disease virus (serotypes 1-7) (**EHD**)
infection with ***Brucella*** *abortus, Brucella melitensis* and *Brucella suis*
ovine epidydimitis (*Brucella ovis*) New *Only for ovine animals. For caprine animals if kept together with ovine animals.*

Equine animals
African horse sickness (**AHS**)
dourine
New **surra** (*Trypanosoma evansi*)
infection with *Burkholderia mallei* (**glanders**)
equine infectious anaemia (**EIA**)
equine arteritis virus (**EVA**)
contagious equine metritis (*Taylorella equigenitalis*) (**CEM**)

Border disease delisted

IV. Article 160(1) and (2) – animal health requirements

✓ Listed diseases relevant for the species

New

Kept animals of the families *Camelidae* and *Cervidae*
epizootic haemorrhagic disease virus (serotypes 1-7) (**EHD**)
infection with ***Mycobacterium tuberculosis complex*** (*M. bovis, M. caprae* and *M. tuberculosis*)
infection with ***Brucella*** *abortus, Brucella melitensis* and *Brucella suis*
infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis (**IBR/IPV**)
surra (*Trypanosoma evansi*)

All species
infection with **rabies** virus
anthrax

I. Movement of donor animals of the bovine, porcine, ovine, caprine and equine species between semen collection centres

- ✓ Without quarantine or testing, before and after the movement provided that the donor animal:
  - ✓ shows no disease symptoms or signs of listed disease;
  - ✓ was subjected to all compulsory routine tests no later than 12 months before the day of that movement; or in case the compulsory routine tests have not yet been carried out at the semen collection centre, all tests during the period preceding quarantine and during the quarantine period required before admission to a semen collection centre;
  - ✓ is permanently resident at a semen collection centre.

II. Movement of donor animals of the bovine, porcine, ovine, caprine and equine species between semen collection centres

- ✓ If consent of the centre veterinarian of the semen collection centre of destination has been obtained.
- ✓ Operators of semen collection centres of destination shall subject donor animals to all compulsory routine tests not later than 12 months after the last compulsory routine tests were carried out on those animals. [Information to accompany the animal to destination]

I. Rules on transport of germinal products animals of the bovine, porcine, ovine, caprine and equine species

- ✓ A **seal and number on the transport containers** prior to the dispatch of germinal products from the approved germinal product establishment shall be applied by the centre veterinarian or the team veterinarian or the official veterinarian.
- ✓ The centre veterinarian or the team veterinarian shall ensure that the mark on the straws or other packages coincides with the number provided either in the animal health certificate or in the self-declaration document and on the container in which they are transported.

II. Rules on transport of germinal products animals of the bovine, porcine, ovine, caprine and equine species

- ✓ A possibility to place **in one transport container semen, oocytes and embryos of the same species**.
- ✓ Conditions:
  - ✓ straws or other packages in which germinal products are placed are securely and hermetically sealed;
  - ✓ the germinal products of different types are separated from each other by physical compartments or in secondary protective bags.
- ✓ A possibility to place **in one transport container semen, oocytes and embryos of animals of the ovine and caprine species**.

III. Rules on transport of germinal products animals of the bovine, porcine, ovine, caprine and equine species

- ✓ A possibility to move to another Member State of mixed semen (collected from more than one donor animal) of the bovine, porcine, ovine or caprine species which is and placed in a single straw.
- ✓ Conditions:
  - ✓ semen is collected and dispatched from a single semen collection centre where it was collected, with the exception of two derogations (ovine and caprine animals, confined establishment);
  - ✓ operator must have procedures in place as regards processing of that semen in order to ensure its traceability.

I. Article 165(3) – movement of germinal products for scientific purposes

Germinal products intended for scientific purposes may be moved to another Member State if operator

- ✓ ensures that those germinal products are not used for other than scientific purposes,
- ✓ obtains the consent of the competent authority of the Member State of destination to accept the consignment of germinal products.

Only if the competent authorities of dispatch has granted derogation for movement of germinal products intended for scientific purposes to another Member State.

II. Article 165(3) – movement of germinal products stored at gene banks

New

'**gene bank**' means a repository of animal genetic material for *ex situ* conservation and sustainable use of kept animal genetic resources, held by a host institution authorised and/or recognised by the competent authority to fulfil these tasks;

Germinal products of endangered breeds as defined in Article 2(24) of Reg. (EU) 2016/1012 stored in a gene bank may be moved to another Member State

- ✓ only if they are moved to another gene bank,
- ✓ if the consent of the competent authority of the Member State of destination to accept the consignment of germinal products is obtained by the operator.

Only if the competent authorities of dispatch has granted derogation for movement to another Member State of germinal products stored in gene banks.

Part IX
Transitional measures

- Article 279(2) – "grandfather's rights"

- Semen collection and storage centres and embryo collection and production teams approved in accordance with legislation adopted pursuant to Directives 88/407/EEC, 89/556/EEC, 90/429/EEC and 92/65/EEC, and which will be repealed by Regulation (EU) 2016/429 as of 21 April 2021, should be deemed to be approved in accordance with this Regulation.

Part V

Entry into EU

- **Article 234(2)** - animal health requirements for:
  - the entry into the Union of germinal products from third countries or territories, or zones thereof;
  - the movement within the Union and handling of germinal products after their entry into the Union, in order to mitigate the risk involved;

- **Article 239(2)(c)** - special rules and additional requirements for the entry into the Union of germinal product.

Rules laid down in the delegated act on movement within the Union of germinal products will be mirrored in the relevant part of delegated act on entry into the Union

Part IV, Title I, Chapters 1, 2 and 5

Rules on:

- information to be provided by operators in the application for approval, form of the application, time limits - **Article 96(3)**
- technical requirements and specifications for marking of straws and other packages and operational requirements for their traceability - **Article 123**
- model forms of animal health certificates - **Article 162(5)**
- provision of information by operators and notification of movements between MSs - **Article 163(6)**

I. Traceability (marking of straws) of germinal products

✓ **Harmonization** of rules on marking of straws and other packages where germinal products are placed.

✓ **Practices already implemented by Member States** but also of the **recommendations of the ICAR** taken into account.

✓ Optional use of **barcodes** printed on the straws and other packages.

II. Traceability (marking of straws) of germinal products

Information included in the marking of straws and other packages (whether or not in the form of a code):

- ✓ the **date of collection or production** of semen, oocytes or embryos in one of the following **formats**: dd/mm/yy, yy/mm/dd, ddmmyy, yymmdd, dd.mm.yy, yy.mm.dd or number of days spent since fixed date expressed in 5-digit code;
- ✓ the **species** of donor animal(s);
- ✓ **identification code(s)** of donor animal(s);
- ✓ the **unique approval or registration number** of the establishment of collection or production of semen, oocytes or embryos which includes the name or ISO code of the country of origin.

Certification and notification of consignments of germinal products

✓ Notification by the operator to the competent authority of the planned dispatch of germinal products by TRACES (IMSOC) or by e-mail/fax.

✓ Notification by the competent authority of place of dispatch to the competent authority of place of destination about dispatched consignment of germinal products by TRACES (IMSOC) in a the form of an animal health certificate the latest on the day of the dispatch of that consignment.

OTHER INFORMATION

Official controls

European Commission

I. Delegated act

Legal base: Article 20(2)(a) of Regulation (EU) 2017/625 (OCR)

The competent authority shall ensure that official controls are carried out on each approved germinal product establishment by an official veterinarian as defined in Article 3(32) of Regulation (EU) 2017/625.

II. Implementing act

Legal base: Article 20(3)(a) of Regulation (EU) 2017/625 (OCR)

Frequency of official controls by an official veterinarian of each approved germinal product establishment.