Minutes of the meeting of the expert group on Regulation (EU) 2016/429 - to discuss Delegated Acts on germinal products 24 November 2017, Brussels

1. **Approval of the agenda**

2. **Nature of the meeting**

   The Member States' animal health experts on germinal products were participating in the meeting. The Council and the European Parliament were not represented.

3. **List of points discussed**

   1. Exchange of views on the provisions and empowerments of Regulation (EU) 2016/429 of the European Parliament and of the Council ("Animal Health Law")[1] and suggestions for a future Commission Delegated Regulation supplementing the Animal Health Law in relation to germinal products, and in particular as regards:

      a. Conditions for approval of germinal product storage centres.

         The experts supported the idea of a **germinal product storage centre** where semen, oocytes or embryos of one or more species (bovine, porcine, ovine, caprine and equine species), or any combination of those germinal products, are stored. Special conditions for such storage should be laid down, including separate storage containers and separate storage areas for each type and species of germinal products, biosecurity rules, and traceability and listing requirements. Particular attention should be paid to the animal disease situation relating to the species from which germinal products originate. While such germinal product storage centres are to be established in the Union, they should also be allowed in third countries.

         The experts taking the floor were in favour of a biosecurity plan as a part of application submitted by the operator for an approval of a germinal product establishment. Whether those should be either principles or detailed harmonised provisions in the delegated act will be decided at the later stage.

         The experts acknowledged that it is important to allow movement between Member States of germinal products stored at the **gene banks**. As germinal products stored at the gene banks were not collected in compliance with the existing legislation, but they have a particular value being a genetic material of endangered breeds, special conditions for their movement should be laid down in the delegated act. It was suggested that movement of germinal products between gene banks should be harmonised in the delegated act and rules of national distribution of germinal products from gene banks to the operators should be left to the competent authorities. Special attention should be paid to animal health conditions for such movement, where testing for particular diseases should possibly be required.

         The experts were of the opinion that usage of **antibiotics**, in a semen diluent, should be reduced and that it should not be an obligation. If antibiotics are used information about the active substance and the amount should be indicated in the certificate. It was suggested that if this approach is followed in the Union (reduction of antibiotics), it should be also discussed at the OIE level as possible amendment to the international standards in trade of semen.

[1] 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') (OJ L 84, 31.3.2016, p. 1)

This subject is closely related to the list of the diseases laid down in Animal Health Law, because treatment with the antibiotics can only be justified if they are effective against agents of the listed diseases.

b. **Germinal product processing establishments** [Semen sexing units] and rules for transport of semen to and from such units (in the Member State of semen collection or in a different Member State).

The experts explained that the units where semen is sexed are highly specialised. They do not only process semen but also prepare the final product ready to be used or for storage. Therefore the conclusion was that such units should be considered as germinal product establishments where processing and storage of germinal products takes place. The draft text of delegated act will be adapted accordingly.

However, one Member State was of the opinion that a different option should be foreseen as well. In some cases semen may be sent out outside the semen collection centre for processing (mainly sexing) and then comes back to that semen collection centre. In case of this scenario a mark on the straw must include approval/ registration number of the semen processing unit in order to ensure proper traceability of the semen.

c. Rules for storage and movement of germinal products collected by germinal product **establishment which ceases its activity**.

The experts agreed that germinal products should not be moved to other Member States from a germinal product establishment after the date on which that germinal product establishment ceased its activities. That date on which the germinal product establishment ceased its activity should be indicated in the list of approved germinal products establishments and that 'inactive' germinal product establishment should be kept on that list for a particular period of time. It is difficult to estimate how long such germinal product establishment should stay in the list because of long-lasting suitability for use of germinal products, however a period of 10 or 25 years was mentioned. That period will be decided later on during further works on the text of the delegated act or implementing act.

d. Sealing of the containers.

The experts agreed on the **sealing** of containers transporting germinal products from approved germinal products establishments to other Member States or nationally from approved germinal product establishments to germinal product storage centres.

The discussion was whether a centre/ team veterinarian or an official veterinarian should apply such seal and at which moment it should be done (before, during or after a certificate was issued). Some of the experts were in favour of allocating this task to the official veterinarian, in accordance with the OIE requirements. Finally, when a particular role and status of a centre/ team veterinarian was explained, the experts supported the idea that sealing of the containers should be a task of the centre/ team veterinarian responsible for the germinal products establishment, whose name is specified in the approval of that establishment.

There was also suggestion that movement of germinal products between Member States should be regulated similarly to the placing on the market of food and that a centre/ team veterinarian should be responsible for certification of such movement. However, the experts were reminded by the Commission that only official veterinarians are aware of current animal health situation of a particular region, therefore consignment of germinal products may be certificate only by those official veterinarians.

e. Rules for transport of germinal products of different types, or collected from different species, in one container.

The discussion mainly focused on whether it should be allowed to **transport in one container all possible types of germinal products** (semen, oocytes, embryos) either obtained from different species or only from one species. The majority of 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. It is less risky to refer to animal diseases affecting one species than to ensure that the consignment is safe for the five species concerned.

The Commission, based on scientific publications, suggested several additional requirements for transport of germinal products of different types in one container which should ensure that there is no risk of cross contamination of transported commodities. The experts were not in favour of sterilising the surfaces of straws but supported the idea of physically separated compartments in the transport container or double-bag system protecting the commodity of one type from the other.

f. Movement within the Union of **mixed/pooled semen**.

The experts were of the opinion that this subject requires caution and they still need time to consult the stakeholders. However they supported the following criteria for the provisions to be laid down in the delegated act on movement of mixed/ pooled semen:

(a) provisions will cover semen of porcine, bovine, caprine and ovine animals;

(b) mixed semen should be dispatched only from a [single] semen collection centre where the semen was collected;

(c) straws or other packages in which mixed semen is placed should be marked with (individual) identification numbers of all donor animals;

(d) the operator should have procedures in place as regards processing of mixed semen and should include, in its records, details of movement of such semen from semen collection centre;

(e) a model animal health certificate will foresee an option of movement of mixed semen.

Some of the experts suggested that movement of mixed semen should require consent of competent authority of Member State of destination. It was also pointed out that when movement between Member States of mixed semen is allowed, then entry into the Union of such semen cannot be prohibited.

The expert also mentioned that indication of individual identification numbers of all semen donors on the straw could be problematic as the place is limited. Therefore, this information could be provided in a form of a code. Details on the straws' marking will be developed during further discussions at the working groups for the implementing acts to the Animal Health Law.

g. Rules on **marking of straws** (traceability of germinal products).

As it was mentioned in point (f), details on the straws' marking will be developed during further discussions at the working groups for the implementing acts to the Animal Health Law and the delegated act will only include a list of requirements for such marking in a view of assured traceability of germinal products.

The experts provided following comments to the Commission proposal of an Article on traceability of germinal products to be laid down in the delegated act:

(a) an ISO code of the country of origin instead of its name should be indicated on a straw or other package in which semen or oocytes, or embryos are placed;

(b) semen of animals of the ovine species is not placed into straws but pellets on which it is not possible to indicate individual identification numbers of semen donors;

(c) in regard to fresh semen of animals of the ovine species, it is not possible to mark straws directly but instead the marking is done on the goblet in which the straws are placed.

h. Samples for testing.

It was concluded that general rules on sampling for bacterial and viral contamination resulting from activities of an embryo team for official examination should be laid down in in the delegated act. It is no longer possible to make references to the Manual of the International Embryo Transfer Society, as those are private standards without open access. However, the experts suggested to more focusing on the donor animals' health, including testing of those animals, than on testing of flushing fluids, embryo washings or unfertilized ova and non-transferable embryos.

Account should be taken of Article 34 of Regulation (EU) 2017/625 (Official Controls Regulation)[2] which lays down provisions on rules for methods used for sampling, analyses, tests and diagnoses.

In case samples for testing are sent to another Member State, Article 17(4) of the Animal Health Law applies. In the event that an official laboratory in one Member State conducts diagnostic analyses on samples from animals originating in another Member State, that official laboratory shall notify the competent authority of the Member State from which the samples originated of any results indicating the suspicion or detection of a listed disease. However, the experts had some doubts how this is going to be implemented in practise.

2. Miscellaneous.

a. One Member State was seeking advice on the procedures for approval of mobile semen processing units. Those processing units are offering service of semen delivery to the breeders. In the opinion of the Commission they cannot be considered as germinal product establishments (mobile), therefore they are not falling under the scope of this delegated act on germinal products.

b. Three Member States were in favour of approving quarantine facilities for the purpose of the quarantine of donor animals before entering semen collection centres. One Member State was against over regulation and supported national approach towards this area.

4. Conclusions/recommendations/opinions

The Commission obtained an up-date on the current situation in the Union, and the expectations of Members States for the future legislation as regards germinal products and plans for its implementation.

The main conclusions of the meeting were the following:

1. The support for a germinal product storage centre where semen, oocytes or embryos of one or more species (bovine, porcine, ovine, caprine and equine species), or any combination of those germinal products, are stored under additional special conditions.

2. The need for the rules allowing movement between Member States of germinal products stored at the gene banks. As germinal products stored at the gene banks were not collected in compliance with the existing legislation, but they have a particular value being a genetic material of endangered breeds, special conditions for their movement should be laid down in the delegated act.

[2] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/ EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1)

3. The reduction of usage of antibiotics in a semen diluent. If antibiotics are used information about the active substance and the amount should be indicated in the certificate. This subject is closely related to the list of the diseases laid down in Animal Health Law, because treatment with the antibiotics can only be justified if they are effective against agents of the listed diseases.
4. The semen sexing units should be considered as germinal product establishments where processing and storage of germinal products takes place. They do not only process semen but also prepare the final product ready to be used or for storage. However, the option for processing (mainly sexing) of semen outside the semen collection centre and then return of that processed semen to the semen collection centre of semen origin should be foreseen as well.
5. The containers transporting germinal products from approved germinal products establishments to other Member States or nationally from approved germinal product establishments to germinal product storage centres should be sealed. A centre/ team veterinarian should be responsible for applying the seal.
6. The transport in one container of different types of germinal products of a single species, under additional special conditions, should be allowed.
7. Movement within the Union of mixed/pooled semen of porcine, bovine, caprine and ovine animals, under additional special conditions, should be allowed.
8. The general rules on sampling for bacterial and viral contamination resulting from activities of an embryo team for official examination should be laid down in in the delegated act. However, more focus should be put on the donor animals' health, including testing of those animals, than on testing of flushing fluids, embryo washings or unfertilized ova and non-transferable embryos.

A follow up expert group meeting is required to discuss a draft legal text prepared based on the above conclusions.

5. Next steps

The outcome of the discussion and the opinions provided by the participants of this expert group will be used by the Commission during further Commission work towards delegated acts under Animal Heath Law, and as relevant, in the context of the Animal Health and Welfare Section of the Standing Committee on Plants, Animals, Food and Feed (PAFF)[3].

6. Next meeting

The next meeting will take place in April 2018.

[3] http://ec.europa.eu/food/animals/health/regulatory_committee_en