Minutes of the meeting of the expert group

to discuss a working document in relation to a draft delegated acts on germinal products under Regulation (EU) 2016/429 –E00930

16 April 2018, Brussels

1. APPROVAL OF THE AGENDA

A preliminary agenda was circulated and agreed at the beginning of the meeting. The working document to be discussed was provided in advance.

2. NATURE OF THE MEETING

The meeting was non-public. The Member States' and EEA countries' representatives from the competent veterinary authorities were participating in the meeting. The Chair noted that the Council of the European Union and the European Parliament were not represented in the meeting.

3. INTRODUCTION, OPENING, GENERAL REMARKS

The Commission delivered a presentation on the general context of the working document and its place amongst the delegated acts in preparation under Regulation (EU) 2016/429 of the European Parliament and of the Council[1] (AHL).

The Commission highlighted in its presentation those listed diseases which will result in establishing animal health requirements for movement of germinal products between Member States.

The Commission also informed about the structure of the delegated act on approval of germinal product establishments, traceability and animal health requirements for the movements within the Union of germinal products of certain kept terrestrial animals, covered by the working document, and its scope which is explained in details in the recitals and Article 1 of that delegated act.

In addition, to keep Member States informed about the full process for the preparation of delegated and implementing acts related to germinal products, the Commission provided indications which of the AHL provisions would be covered by implementing acts and which of the Regulation (EU) 2017/625 of the European Parliament and of the Council (OCR)[2] provisions by delegated and implementing acts.

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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).

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).

4. DISCUSSION/CONCLUSIONS/RECOMMENDATIONS/OPINIONS

The conclusions of the meeting were the following:

1. A definition of "**approved germinal product establishment**" should be added to the working document. This would make clear that amongst germinal product establishments, defined in Article 4(46) of the AHL, there are in the Union approved germinal product establishments, in particular semen collection centres, embryo collection teams, embryo production teams, germinal product processing establishments and germinal product storage centres, from which germinal products can be moved to other Member States.

2. The experts confirmed the need of provisions for movement of germinal products which were collected long ago and/or not in compliance with the new animal health legislation, and which are stored at **gene banks**. The experts were not keen in linking the genetic material with endangered breeds as defined in Article 2(24) of Regulation (EU) 2016/1012 of the European Parliament and of the Council[3]. In addition, the experts have not opposed to having rules on movement of **germinal products for scientific purposes other than those regulated in the Animal by-product Regulation**.

3. If addition of **antibiotics** into semen diluent should be on voluntary basis, this approach should be first discussed at the OIE level as a possible amendment to the international standards for trade in semen.

4. Semen of animals of the ovine species is sometimes not placed into straws but frozen into pellets on which it is not possible to indicate individual identification numbers of semen donors. With regard to fresh or chilled semen of small ruminants, it is not possible to mark straws directly but instead the marking is applied on the goblet in which the straws are placed. The experts requested for special requirements for **marking of semen in pellets and fresh or chilled semen of small ruminants**.

5. Some experts asked to include in this working document animal health requirements for the movement of **semen of deer**, **bees, llamas or other camelids**. This is also related to the approach which should be taken in case there are no EU requirements for entry into the Union of germinal products of those species and the competent authorities are responsible for setting out the conditions for such entry. The Commission undertook to reflect on this issue.

6. The experts requested for a definition of "**quarantine accommodation**" where animals are quarantined and tested in order to check their eligibility as donor animals before they are introduced into a semen collection centre. The Commission explained that the conditions of such quarantine are already provided in the Annex to the discussed working document.

7. The experts were of the opinion that only general principles, in line with the OIE requirements, for the **biosecurity plan** for the operation of the germinal product establishment should be laid down in this draft Regulation.

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[3] Regulation (EU) 2016/1012 of the European Parliament and of the Council of 8 June 2016 on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') (OJ L 171, 29.6.2016, p. 66)

8. The experts agreed that storage of germinal products, without compromising their animal health status, may last long, even longer than activities of an approved germinal product establishment. Therefore, there is a need for rules which would allow movement between Member States of germinal products collected or produced at/by an approved **germinal product establishment which ceased its activity**.

9. The experts suggested that the **names of the centre and team veterinarians** should be included in the registers of germinal products establishments kept by the competent authority. The Commission confirmed that it is a practice nowadays in case of lists of approved embryo collection and production teams of third countries, however there is a need to look into this aspect from data protection perspective.

10. The experts explained that oocytes collected from more than one female donor are not mixed in one straw, therefore provisions on **mixed semen** would be sufficient in this working document. There was also a request to make a reference that for zootechnical reasons such mixed semen cannot be used in the framework of breeding programmes approved under Regulation (EU) 2016/1012.

11. One expert was against **self-declaration document** issued by the operator to accompany consignments of semen for processing to a germinal product processing establishment and coming back to the semen collection centre. According to the expert it should be an animal health certificate. Another expert requested for information on animal health status of the donor to be added to the self-declaration document. The Commission explained this special situation where semen is moved only between a semen collection centre and a germinal product processing establishment, both approved and complying with animal health conditions for the movement of germinal products between Member States, and that this semen cannot be released on the market (closed circle). In each other case a consignment of germinal products is to be accompanied by an animal health certificate.

12. Operators should be obliged to provide a minimum (but not less than referred to in the AHL) of information in the **making of straws** containing germinal products. Therefore, the specification of the breed, since it is not related to animal health, will not be a required information and at the same time addition of any other relevant information will be allowed but on the voluntary basis.

13. The experts suggested that animal health requirements for **ovine epididymitis (*Brucella ovis*)** should only concern ovine animals, not caprine animals.

14. In relation to the **infection with *Brucella abortus, Brucella melitensis* and *Brucella suis***, the experts informed that current procedure which should be implemented in case of suspicion of brucellosis in pigs, provided for in Directive 90/429/EC, should be simplified. The problems come from different sensitivity, availability and costs of different tests (i.e. Rose Bengal, cELISA or iELISA, agent identification tests), or complex procedures sometimes prolonged in time due to the epidemiological enquiry on the establishment(s) of origin of animals suspected of being infected with B. spp., when animals originate from a different Member State. The Commission will look into this problem, consult the procedure with experts on brucellosis, including the

European Union reference laboratory for brucellosis, and report to Member States of the outcome of those consultations.

15. In relation to the infection with **porcine reproductive and respiratory syndrome** (PRRS), the experts informed that two parallel systems exist at the moment, one covering semen donor animals vaccinated against PRRS and the second including animals not infected with PRRS virus and not vaccinated against PRRS. Those two systems co-exist and industry is managing movement of two types of semen well. Therefore there was a request to preserve both systems in this working document, despite the fact that the OIE recommendations speak only about movement of semen collected from animals not vaccinated against PRRS and free of that disease. The Commission will reflect on this, bearing in mind that PRRS is a D+E disease and that no additional guarantees can be provided for self-declared free regions.

5. NEXT STEPS

The Commission invited experts to provide written comments to the presented working document by 27 April 2018.

The outcome of the discussion and opinions provided by the participants of this expert group as well as written comments/suggestions received will be used by the Commission to improve text of the working document.

6. NEXT MEETING

The Commission intends to organise a follow up meeting where a revised version of the document will be presented.