Minutes of the meeting of the expert group

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

18 June 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. Experts of the Member States and EEA countries participated in the meeting. The Chair noted that the Council of the European Union and the European Parliament were not represented at the meeting.

3. INTRODUCTION, OPENING, GENERAL REMARKS

The working document on the approval of germinal product establishments, traceability and animal health requirements for the movement within the Union of germinal products of certain kept terrestrial animals was presented by the Commission and discussed during this expert group meeting.

The working document was a revised version of the working document already presented during the expert group meeting on 18 May 2018. The amendments introduced in the working document were the outcome of the comments received by the Commission from the Member States.

4. DISCUSSION/CONCLUSIONS/RECOMMENDATIONS/OPINIONS

The conclusions of the meeting were the following:

1. Only four Member States were in favour of allowing admission to a semen collection centre of seropositive bulls vaccinated with the marker vaccine (DIVA vaccines) against **infectious bovine rhinotracheitis/infectious pustular vulvovaginitis**. They were of the opinion that by excluding those seropositive bulls a lot of genetic value is lost and by testing semen with PCR there is an assurance that only semen negative for the virus is moved to other Member States (supported by the OIE). Five other Member States strongly opposed that possibility as in their view there should be focus on the control and eradication of this disease. Vaccination may not protect against wild virus and there could be some obstacles in movement of vaccinated bulls between Member States as some Member States have already introduced a ban on vaccination against IBR/IPV. One Member State had a flexible approach under condition that new techniques as regards vaccination and testing are used.

   Concluding, current provisions laid down in Council Directive 88/407/EEC, as amended by Council Directive 2003/43/EC, allowing only seronegative bulls for IBR/IPV to be admitted into a semen collection centre, should be preserved in this working document in order to continue the policy introduced in 2003.

2. Member States were in favour of using PCR for testing semen for **bovine viral diarrhoea** virus.

3. Consultations with the EURL for brucellosis on the procedure to be followed in case of suspicion of **infection with *Brucella abortus, Brucella melitensis* and *Brucella suis*** in porcine animals in the quarantine accommodation have not yet been finalised. By now, a serum agglutination test (SAT) is deleted from the list in the working document as its sensitivity is very low in pigs and it is not recommended by the OIE and a brucelin skin test is added following the advice of the EURL for brucellosis as it is very specific but it must be used on the group of animals.

4. Based on the comment of one Member State, in the working document for **infection with porcine reproductive and respiratory syndrome virus** in the quarantine accommodation a serological test (IPMA, IFA, or ELISA) and a test for virus genom (RT-PCR), nested set RT-PCR, real-time RT-PCR) should be required, while prior to entering the quarantine accommodation and as compulsory routine testing only a serological test should be necessary.

5. One Member State clearly stated that it is against the use of **antibiotics** in semen, mainly because of antimicrobial resistance. Having regard to the current situation, in particular with a view to possible international trade, this working document should preserve the approach for the use of antibiotics provided for in Council Directives 88/407/EEC, 90/429/EEC and 92/65/EEC, as well as that recommended by the OIE. In case antibiotics are included, information about the active substance(s) and their concentration should be indicated in the accompanying health certificate.

6. One Member State suggested the improvement of the text of the working document as regards **frequency of compulsory routine testing of donor boars**. Currently the requirement is that the tests shall be carried out on samples taken from at least 25% of the animals in the semen collection centre every 3 months under condition that all animals are tested at least every 12 months (100% of animals tested annually). The expert proposed to include another testing regime in addition to those laid down at present, where the tests are carried out on samples taken from at least 10% of the animals in the semen collection centre every month (120% of animals tested annually). There has been no opposition by other Member States to this proposal. The Commission undertook to amend the text of the working document accordingly.

7. Animal health requirements presented in the working document for movements to other Member States of germinal products of kept animals of the families ***Camelidae*** and ***Cervidae*** are in line with the requirements for movement of those kept animals. **Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis** is a relevant disease in relation to the movement conditions of those animals. However, even infected, the animals of the families *Camelidae* and *Cervidae* do no show clinical signs of this disease. There is also no available test for this species. The Commission will follow up on this issue.

8. The Member States were not in favour of the Commission proposal on additional rules for the granting of derogations by competent authorities for **germinal products moved to gene banks**. The experts were of the opinion that the obligation to carry out testing on 5% (with minimum of five straws) of each collection being a part of the consignment of germinal products is too restrictive and could be impossible because of the quantity of the consignment. The Commission undertook to amend the text of the working document, taking

into account the risk based approach suggested by the experts and the need to prevent the spread of foot-and-mouth disease, infection with rinderpest virus and other listed diseases.

9. The Commission clarified that **CWD**, and other TSEs, will continue to be regulated by a different legislation, covering specifically transmissible spongiform encephalopathies.

5. NEXT STEPS

The Commission invited experts to provide written comments to the presented working document at any moment, preferably until the end of August 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.

After the meeting of the expert group of 18 June 2018, the Commission is planning to submit the working document for internal consultations within the Commission services.

6. NEXT MEETING

The Commission does not intend to organise another expert group meeting to discuss the working document. However, the revised version of the working document, after internal consultations within the Commission services, will be presented to the experts electronically.