Brussels, 14 October 2021

Minutes of the meeting of the expert group to discuss possible amendments to Delegated Regulations (EU) 2020/686 and 2020/692 as regards germinal products - E00930

14 October 2021, Brussels

1. Approval of the agenda

An annotated agenda was circulated prior to the meeting and approved at the beginning of the meeting.

2. Nature of the meeting

The meeting was non-public. Because of the constraints related to COVID-19 situation the meeting was attended via Skype for Business by the representatives of the competent veterinary authorities of Member States (MSs) and EEA countries. The Chair noted the absence of the European Parliament and the Council.

3. List of points discussed

3.1. Introduction

The Commission recalled that the purpose of the meeting was to discuss possible amendments to Delegated Regulations (EU) 2020/686 and 2020/692 as regards germinal products. In this sense, an annotated agenda was circulated prior to the meeting.

3.2. Exchange of views as regards possible amendments to Delegated Regulation (EU) 2020/686 supplementing Regulation (EU) 2016/429 in relation to animal health requirements for movement of germinal products between Member States.

3.2.1. Processing and storage of semen at a semen collection centre different from the semen collection centre of its collection.

MSs supported a possibility of processing and storing of semen collected at a semen collection centre different from a semen collection centre of its collection. Therefore, in this respect, there is no need to amend Part 1 of Annex I to Delegated Regulation (EU) 2020/686.

However, as according to the current rules, semen can be dispatched only from a semen collection centre of its collection (in addition to a germinal product processing establishment or germinal product storage centre), there was also a request from one MS to consider a possibility of dispatch semen from any semen collection centre where it is processed and stored. This must still be reflected by other MSs and the Commission.

3.2.2. Testing of boars for PRRS.

The following has been agreed:

a) It is the responsibility of the competent authority to elaborate a protocol how to deal with tests results obtained before an animal is admitted into the semen collection centre and at the semen collection centre. More strict approach should

be taken with regard to a PCR test positive result (immediate removal from the quarantine accommodation/ semen collection centre), than to a serological test positive result (repeated test). For that, the competent authority should apply the case definitions laid down in Article 9 of Delegated Regulation (EU) 2020/689;

b) It is important to ensure that donor animals present at the semen collection centre are negative to PRRS;

c) There is a need of an adaptation of the text in Part 2 of Annex II to Delegated Regulation (EU) 2020/686 in this respect.

3.2.3. Semen of equine animals: antibiotics or mixtures of antibiotics added to semen or contained in semen diluents.

In general, MSs support the idea to establish in point 3 of Part 1 of Annex III to Delegated Regulation (EU) 2020/686 a specific list of antibiotics to be added to equine semen diluent. One MS provided a number of publications concerning this subject and their content will be reviewed by the Commission before any further step in taken in this regard.

Some MSs are in favour of voluntary use of antibiotics in semen diluent for all species, justifying this by compatibility with the EU Action Plan against antimicrobial resistance (AMR). Others emphasised that use of antibiotics in semen diluent does not contribute to AMR, hence already compatible with the EU AP.

3.2.4. Requirements as regards infection with epizootic haemorrhagic disease virus (EHD).

MSs did not object as regards the correction of the name of EHD in Annex II to Delegated Regulation (EU) 2020/686. The name will be changed from infection with epizootic haemorrhagic disease virus (serotypes 1-7) (EHDV 1-7) to infection with epizootic haemorrhagic disease virus, what is in line with nomenclature provided for in Delegated Regulation (EU) 2018/1629 and Implementing Regulation (EU) 2018/1882.

This will also be corrected in model certificates for germinal products laid down in Implementing Regulation (EU) 2021/403.

In addition, the Commission raised a point on EHD seasonal freedom, mainly in relation to third countries which have this status in respect of entry into the Union of animals (Annex II to Implementing Regulation (EU) 2021/404 based on Article 10 of Delegated Regulation (EU) 2020/692). The Commission offered to align Annexes IX and X of Implementing Regulation (EU) 2021/404 with Annex II to this Implementing Regulation in this regard, also in line with the relevant OIE standard. Moreover, in order to add EHD seasonally freedom option to the relevant model certificates, Chapter III of Part 5 to Annex II to Delegated Regulation (EU) 2020/686 would need to be amended accordingly. MSs did not express any opinion and the Commission stated that it will proceed along the above lines while this point may be still for further discussion.

3.2.5. Annex I to Delegated Regulation (EU) 2020/686.

MSs did not object to the correction and alignments of the text in Annex I to Delegated Regulation (EU) 2020/686 proposed by the Commission, concerning the use of terms “prevented” and “effectively prevented”.

3.2.6. Age of animals used for semen collection.

MSs confirmed that nowadays very young animals are being selected for semen collection (genomic selection). However, it is decided on later stage if they are going to be intended for semen collection. Only then all testing required by Delegated Regulation (EU) 2020/686 starts and there is a period for performing of that testing provided in the legislation. Overall, the currently used term "during the 60 days period prior to…" in point 1(b) of Part 3 of Annex II to Delegated Regulation (EU) 2020/686 seems to be appropriate and does not need to be amended.

3.3. Exchange of views as regards possible amendments to Delegated Regulation (EU) 2020/692 supplementing Regulation (EU) 2016/429 in relation to animal health requirements for entry into the Union of germinal products.

3.3.1. Animal health requirements for semen used for *in vitro* production of bovine embryos intended for entry into the Union.

MSs need more time for internal consultations to provide their position in this respect. However, most of MSs highlighted the importance of EU policy in combating IBR/IPV and of equal animal health requirements for MSs and third countries.

3.3.2. Residency periods for semen donor bovine animals.

MSs supported the Commission's proposal to amend Article 80 of Delegated Regulation (EU) 2020/692 to provide for a derogation, which existed in Commission Decisions 2011/630/EU and 2010/472/EU, for a residency period to 30 days in a third country of semen dispatch and six months in other listed third countries or MSs for bovine, ovine and caprine animals which are donors of semen, oocytes and embryos.

3.3.3. Animal health requirements for entry into the Union of germinal products of dogs, cats, camelid and cervid animals.

Some MSs prefer harmonisation of animal health requirements for entry into the Union of germinal products of dogs, cats, camelid and cervid animals, in line with the requirements for movements of those germinal products between Member States. Some other MSs suggested to be prudent with harmonisation of those requirements as overregulating may cause sometimes obstacles in trade. This point is for further discussion. The Commission asked the MSs to supply objective data on, and experience with, actual and specific animal health risks which are to be mitigated by harmonisation, otherwise supported a prudent approach to avoid unnecessary burden on various stakeholders.

3.3.4. Animal health requirements for entry into the Union of germinal products of animals other than bovine, ovine, caprine, porcine or equine animals intended to confined establishments.

Some MSs see a need of amendment of Article 117 of Delegated Regulation (EU) 2020/692. This point is for further discussion based on the written comments from MSs.

3.3.5. Requirements as regards foot and mouth disease for entry into the Union of *in vivo* and *in vitro* embryos of bovine, ovine, caprine and porcine animals.

MSs need more time for internal consultations to provide their position.

4. Miscellaneous

One MS enquired:

- for an amendment of Part 3 of Annex I to Delegated Regulation (EU) 2020/686 to differentiate requirements for an embryo production team only collecting and selling oocytes from requirements for an embryo production team collecting oocytes and producing embryos;
- which model certificate is appropriate to accompany a consignment of ovine semen collected and dispatched from a registered establishment. The Commission confirmed that it is OV/CAP-SEM-A-INTRA.

5. Conclusions

The Commission thanked MSs for their input and invited them to provide their written feedback by 12 November 2021.

6. Next steps

The Commission will use the outcomes of the discussion and the opinions obtained during this expert group meeting, and the requested written comments to develop a draft Delegated Regulation amending Delegated Regulations (EU) 2020/686 and 2020/692.

The Commission plans to organise a next meeting of the Expert Group in 2022.