Brussels, 14 July 2022

Summary of the meeting of the expert group on possible amendments to Delegated Regulations (EU) 2020/686 and 2020/692 as regards germinal products

E00930

on 1 July 2022

1. Approval of the agenda

The agenda was approved as circulated prior to the meeting as part of the invitation.

2. Nature of the meeting

The meeting was non-public. The meeting was organised remotely and the representatives of the competent veterinary authorities of Member States (MSs) and EEA countries attended it via WebEx. 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, based on experience with the implementation of these rules with a view to fine-tune them. To assist that, relevant drafts were circulated prior to the meeting. The Commission explained however that the initiative and draft to amend Delegated Regulation (EU) 2020/692 as regards the entry of germinal products (circulated as *PLAN/2021/13117*) will be incorporated after this meeting to a broader initiative and draft addressing other commodities, also amending Delegated Regulation (EU) 2020/692 (*PLAN/2022/1319*). The Commission explained that discussions during this meeting should be very thorough and open to be clear and to inform all concerned parties about particular issues, positions and supporting arguments, based on science and/or international standards. The Commission explained that silence on the part of the Member States (MS) is assumed to mean agreement or at least no problems and/or no stake. As time goes ahead, it will be more difficult to raise new issues and/or re-discuss current ones.

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. Definition and regulation of oocytes collection teams

The Commission explained the drivers and possible regulatory changes. Those MSs which spoke, supported the amendments proposed, while one MS advocated an additional rule to maintain traceability and suggested a possible solution. The Commission concluded that seemingly only a couple of MS are concerned by this issue.

3.2.2. Derogation on movements between semen collection centres

The Commission explained the significance of Article 19 of CDR (EU) 2020/686, especially for movement of boars (donors or future donors) and some questions and concerns stakeholders raised. The Commission also explained a possible minor change to Article 19 to clarify the issue and confirmed that implementation of that Article is the responsibility of centre veterinarians and operators. Subsequently also the official certificates for the movement of donors or future donors between Member States are planned to be streamlined by eliminating the relevant attestations.

3.2.3. Movements between Member States of germinal products of dogs and cats

The Commission explained experiences with the recent harmonisation of this topic and that stakeholders and Member States alike raised several problems. In summary, the Commission proposed de-regulation. Some MS asked questions to clarify some aspects, including the entry into the Union of germinal products of dogs and cats and many other, non-harmonised species, requesting at least a harmonised declaration to facilitate the work of Union border control posts (BCPs), which sometimes have problems to know what the national rules are. The Commission explained the legality to maintain national rules for the entry of non-harmonised commodities under the Animal Health Law. The Commission considered that the issue is much wider then germinal products (also relevant for live animals). The solution to the experienced problems is linked to better implementation of rules by the Member States and better communication between BCPs and their competent authority or with the competent authority of the MS of destination or with importers. The Commission insisted that further policy development and harmonisation is conditional to mitigating risks on non-harmonised areas and invited MSs to signal if they are aware of, or have experienced negative consequences due to, such risks.

3.2.4. Testing for classical swine fever

The Commission explained recent criticism from competent authorities of trading partner third countries in light of international standards of the World Organisation for Animal Health (WOAH) as regards testing for classical swine fever (CSF). The Commission explained that it plans to amend the rules for the entry to align it with WOHA standards and considered that the MSs could also benefit from the same changes relevant for production within the EU. At least compulsory routine testing should be discontinued, but even testing in quarantine accommodations, which testing is now required in countries without CSF outbreaks and vaccination. The Commission asked the MSs to reflect further but concluded that seemingly no MS is against such amendment.

3.2.5. Testing for infection with porcine reproductive and respiratory syndrome virus (PRRS)

The Commission explained the drivers and current rules in relation to raised problems relevant to handle PRRS, especially suspicions and false positives, as well as a possible solution using the generic case definitions laid down in Article 9 of CDR (EU) 2020/689. Those MSs, which spoke, supported the Commission's proposal for PRRS, to be more proportionate. Some considered that the same approach could be extended to other diseases too (e.g. Brucellosis). The Commission considered that as those rules were recently revamped on the basis of advice from the relevant EURL, they are assumed to

be fit for regulatory application and more experience is preferred to evaluate and to see if it is necessary to change them. Availability of brucellin was also discussed.

3.2.6. Antibiotics in semen

The Commission explained the drivers and current rules in relation to problems raised in handling antibiotics in semen, also in light of diseases listed by the AHL and of the forthcoming amendments to international standards of the WOAH. Those MSs which spoke, supported de-regulation, some asked questions to clarify certain aspects.

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. Definition and regulation of oocytes collection teams

The Commission explained that this is an automatic ramification from the change of the identical definition in CDR (EU) 2020/686, see point 3.2.1.

3.3.2. Derogation for vaccination against foot and mouth disease

The Commission explained recent criticism from the competent authority of a trading partner third country in light of international standards of the WOAH and in light of previous EU rules, which allowed, as well as current EU rules in CDR (EU) 2020/686, which still allow, sourcing germinal products from animals vaccinated against foot and mouth disease under certain circumstances. The Commission explained that it is necessary to provide a derogation in CDR (EU) 2020/692 to align the current blanket ban with the specific rules in the WOAH standards and with those in CDR (EU) 2020/686.

3.3.3. Germinal products intended to confined establishments

The Commission re-captured previous discussion (EG meeting on 14 October 2021) on this issue and explained the proposed changes, which will allow the MSs to exercise the necessary flexibility and caution to take into account the specificity of these entries.

3.3.4. Issues indirectly having an effect on entry into the Union by way of amendment of DCR (EU) 2020/686

The Commission explained that such issues are the (i) testing for classical swine fever as well as (ii) a slight amendment to the rules on infection with epizootic haemorrhagic disease virus (i.e. to provide for the possibility of a vector-free period in line with the WOAH standards).

3.3.5. Issues previously raised but not included in the amendment

The Commission briefly explained for transparency that derogation from residency periods for semen donor bovine animals in third countries, further harmonisation of entry rules for non-harmonised germinal products (see issue also under point 3.2.3) and derogation from entry requirements in relation to infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV), are not part of the

amendment to CDR (EU) 2020/692, along with the respective reasons. The MS took note with only one comment shared.

4. Miscellaneous

One MS enquired about *Brucella ovis* rules for young sheep and goats, which the Commission clarified.

5. Conclusions

The Commission concluded that the elements of this revision seem to be in line with what MS experts consider relevant to improve the current rules. The Commission noted that the majority agrees with the proposals contained in the two drafts, either expressly or tacitly. Some smaller technical adjustments, wording etc. may still need to be necessary, based on the already shared comments, or those, which are still to arrive.

6. Next steps

The Commission thanked MSs for their input and invited them to provide their written feedback by 11 July on amendment of CDR (EU) 2020/692 (*PLAN/2021/13117*), and by 21 July on amendment of CDR (EU) 2020/686 (*SANTE/7338/2021 + Annex*). The Commission emphasised that after that, the further steps will be decided based on the number and significance of the comments in relation to changing the main elements of the drafts. Most likely is a written circulation of a next version of the draft(s) but no further expert group meeting. Some other follow-up will also be in the context of the Standing Committee on PAFF as those concern amendments of Commission implementing rules, e.g. containing model certificates and such.

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