Minutes of the meeting of the expert group to discuss a draft delegated regulation on rules for the use of veterinary medicinal products for prevention and control of certain listed diseases under Regulation (EU) 2016/429 and to discuss draft delegated regulation amending Delegated Regulation (EU) 2020/687 as regards rules for the prevention and control of certain listed diseases

29 November 2021, Brussels

1. Approval of the agenda

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

2. Nature of the meeting

The meeting was non-public. Because of the constraints related to the COVID-19 situation, the meeting was held via Skype for business with the representatives of the competent veterinary authorities of Member States and EEA countries attending. The Chair noted the presence of the Council and the absence of the European Parliament.

3. List of points discussed

3.1. Introduction

The Chair recalled that the purpose of the meeting was to discuss:

- the draft Commission Delegated Regulation supplementing Regulation (EU) 2016/429 (the 'Animal Health Law') (AHL) as regards the use of veterinary medicinal products (VMPs) to prevent and control certain listed animal diseases and in particular the use of vaccines (SANTE/7144/2020) (the draft) following the last meeting held on 28 October 2021. This is the seventh expert group meeting discussing this draft.
- draft Commission Delegated Regulation amending Delegated Regulation (EU) 2020/687 as regards rules for the prevention and control of certain listed diseases (SANTE/7322/2021).

The Commission circulated documents relevant to both drafts prior to the meeting.

The Chair thanked delegations for sending their comments following the Meeting of 28 October 2021.

3.2. Presentation and discussion on the draft-Delegated act as regards the use of veterinary medicinal products (VMPs) to prevent and control certain listed animal diseases (SANTE/7144/2020)

The Commission presented an overview of the main changes introduced in the text of the draft after the meeting held on 28 October 2021.

The Commission explained the main changes in the draft, which include several new recitals, new definitions added in Article 4 and some other more notable changes in Articles 7, 8 and 12. Delegations had no further comments to Part I of the draft (Articles 1-4), nor to Article 5 and 6 on preconditions for vaccination against Category A diseases.

The group discussed changes to Article 7, which aim to clarify vaccination strategies and definitions of vaccination strategies. During the discussion on that article, for which the Commission presented two options, all Member States speaking supported the clarified approach with a slight preference to one of the two options. One delegation raised the issue of applying the suppressive emergency vaccination in contact establishments, while another one asked for a clearer provision with regard to which vaccination strategies can be used in a form of vaccination to live. The Commission acknowledged both comments and agreed to address this issue in the next revision of the draft.

One Member State asked to take into account derogations from killing in the event of a disease outbreak as per Article 13 of Delegated Regulation (EU) 2020/687 in the vaccination strategies. The Commission confirmed its awareness of the issue and that the intention is to introduce proposed solutions to address this point in the relevant Parts 4 of the disease specific annexes.

There were no further comments to Articles 8 to 11, nor to Articles 13 to 15. There was one comment to Article 12(1)(a)(i) to correct the wording regarding the killing of animals which will be taken on board.

The Commission informed about the latest changes introduced in Annexes I to VI of the draft. These were mainly smaller corrections, with the exemption of two new parts 2 to Annexes II and III with simplified criteria for deciding for vaccination and for information included in the vaccination plan. One Member State requested to keep in the report a total number of vaccinated animals by date vs. planned number to be vaccinated and the respective % of coverage by date, so the progress is measurable and visible.

The Commission further presented updated disease-specific Annexes VII to XIV. Main changes in Annex VII on foot and mouth disease are in the part on surveillance. Two Member States asked for a more flexible approach for the laboratory examination of animals, i.e. not for all animals as such requirement would be too burdensome, but be focused on a representative sample. This would be in line with the relevant draft OIE standards currently under revision. On Annex IX for lumpy skin disease, the Commission informed that the final version would be without part 3 of the Annex. One Member State asked that the single condition for the vaccine should be that a vaccine is homologous. Concerning Annex XIV on African horse sickness, two Member States requested to remove the requirement of live attenuated vaccines, as in their opinion, the new inactivated vaccines should be prioritised. One Member State questioned a general approach about the level of details across various Annexes. The Commission explained that this depends on the available knowledge and scientific data. For example where there are recent EFSA opinions, annexes may include more precise details. The annex on rift valley fever is such example.

3.3. Presentation and discussion on the draft Commission Delegated Regulation amending Delegated Regulation (EU) 2020/687 as regards rules for the prevention and control of certain listed diseases (SANTE/7322/2021)

The Commission introduced a new draft Delegated Regulation, with amendments to Articles 2, 21, 46, 52 and Annex VIII of Regulation (EU) 2020/687. Several Members States had questions

on the interpretation of small establishments keeping the birds for their own production and consumption. Some Member States asked for the possibility to send hatched day old chicks to establishments in the restricted zone. Two Member State thought that a threshold of 50 birds is too low for exemptions and that wild bird refugee centres should also be exempted. Their inclusion is disproportionate and not productive, as these are the main channels for collecting dead birds in the framework of the passive surveillance of highly pathogenic avian influenza.

One Member State also asked for the possibly to derogate based on a risk assessment from the destruction of the hatching eggs identified by tracing after confirmation of an outbreak.

4. Conclusions/recommendations/opinions

The Commission thanked Member States for their input and invited them to provide their written feedback to both drafts by 10 December 2021.

5. 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 revised versions of the draft-Delegated acts, which will include disease-specific rules for all category A diseases.

6. Next meeting

The Commission plans to organise another meeting for the document SANTE/7144/2020 of the Expert Group in first quarter of 2022 following the completion of internal procedures on the draft.

The Commission does not envisage another meeting on the draft SANTE/7322/2021. Depending on the received written comments, particular provisions of this draft might be distributed for written consultation.

END