Brussels, 9 February 2021

Minutes of the meeting of the Expert Group
to discuss draft Delegated Regulation supplementing Animal Health Law
as regards the Union antigen, vaccine and diagnostic reagent banks – E00930
Brussels, 5 February 2021

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 the participation of the European Council and the absence of a representative from the European Parliament.

3. INTRODUCTION, OPENING, GENERAL REMARKS

The Commission presented an overview of Union legislation related to the Union antigen, vaccine and diagnostic reagent banks.

This is the first expert group meeting related to this subject. The working document on the rules for the management, storage and replacement of stocks of antigens, vaccines and diagnostic reagents in the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio–containment requirements for the operation of those banks was presented for the first time as well.

4. DISCUSSION/CONCLUSIONS/RECOMMENDATIONS/OPINIONS

The conclusions of the meeting were the following:

1. Delegated Regulation supplementing Animal Health Law as regards the Union antigen, vaccine and diagnostic reagent banks will only cover kept terrestrial animals. In case vaccines against category A disease for aquatic animals are available, this Regulation could be amended to include aquatic animals as well.
2. One Member State pointed out that WHO published "Laboratory biosafety manual, 4th edition"[1]. The new WHO manual promotes a risk-based approach which is the novelty. It was asked if this manual could be considered as good practice for the purpose of management of the Union antigens, vaccines and diagnostic reagents banks. The Commission commented that WHO manual is not feet for vaccine banks as it lays down biosafety rules for laboratories.
3. The Commission will check on the possible reference to the Good Distribution Practices (GDP) as referred to in Regulation (EU) 2019/6 in relation to the supply and storage requirements for the Union antigens, vaccines and diagnostic reagents banks.

[1] https://www.who.int/publications/i/item/9789240011311

4. One Member State asked if the Union foot-and-mouth disease virus antigens bank can be established while Delegated Regulation adopted under Article 47(1) of AHL provides for a prohibition for vaccination against foot-and-mouth disease. The Commission clarified that there will be exemptions from that prohibition foreseen in above mentioned Delegated Regulation.
5. There were also some other comments provided by experts and the Commission committed to reflect on them and carefully verity the text of the working document.

5. NEXT STEPS

The Commission invited experts to provide written comments to the presented working document by 22 February 2021.

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 5 February 2021, 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, except the case when substantial comments are received from the experts. However, the revised version of the working document, after internal consultations within the Commission services, will be presented to the experts electronically.