Brussels, 15 March 2018

Minutes of the meeting of the expert group to discuss the delegated act on surveillance, eradication programmes and disease free status according to the Animal Health Law

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1. APPROVAL OF THE AGENDA

A preliminary agenda was circulated and agreed at the beginning of the meeting. The working document (called hereinafter 'the document') to be discussed was provided in advance.

On the day of the meeting the Commission also distributed the presentation on the provisions for surveillance in the *Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')* (AHL).

2. NATURE OF THE MEETING

The meeting was non-public. The Member States' and EEA countries' representatives from the competent veterinary authorities were participating in the meeting. The Chair noted that the Council and the European Parliament were not represented in the meeting.

3. DISCUSSION

3.1. Introduction, opening

The Commission delivered a presentation of the provisions on surveillance in the AHL which led to the structure of the delegated act on surveillance, eradication programmes and disease free status and its place amongst the other delegated acts in preparation.

This first meeting focussed on notification, surveillance and eradication programmes. Provisions regarding disease-free status and annexes with some disease specific provisions were included in the document to provide a more comprehensive and illustrated understanding of the future act, but were not discussed at the meeting.

The Commission pointed out that the document is shared at an early stage in order to exchange views on the general approach followed before developing further work. The approach proposed is to preserve flexibility and enact a limited set of provisions defining objectives with minimal rules, and without any prescriptive details.

The experts who expressed their opinions encouraged the approach proposed by the Commission. Several experts expressed concerns that the objective of simplification should be kept in mind and that the current document was difficult to read due to the wording and absence of certain provisions, while acknowledging being associated to the process at an early stage.

The Commission further explained that the document is a very preliminary draft, the wording and consistency will be improved and some provisions will need to be further detailed.

The document will also be reviewed to ensure it fits the specificities of aquatic animals. Compartmentalisation will be discussed at a later stage following internal discussions.

3.2. Exchange of views with experts on the document

The Commission presented the document, and experts were invited to express their comments or concerns.

3.2.1. Notification of diseases and abnormal mortalities

The Commission presented the criteria for notifying abnormal mortalities or other signs of diseases that are not defined as suspicion of a listed disease. The operator would be responsible to decide on the appropriate level triggering the notification according to the context; alerts may also be provided by surveillance system to which operators participate. The Commission informed the participants of a change of wording in paragraph 4: the words 'Natural or legal persons responsible for approved establishments collecting dead animals as laid down in' should be replaced with the words 'Operators registered or approved in accordance with Articles 23 or 24 of' Regulation (EC) No 1069/2009.

Some experts advocated for more details and definitions to ensure a common understanding of abnormal mortality and the area or the timeframe they relate to. The proposed approach may lead to difficulties to assess the correct implementation of the measures by the operator. Meanwhile, considering the diversity of production systems, several experts indicated that operators may provide more relevant alerts to their conditions than fixed quantitative criteria but that such criteria would be useful in certain situations where specific issues have been identified like infection with highly pathogenic avian influenza virus.

Several experts were concerned on the risk of additional burden due to the obligation of notification for the operator, especially in the context of an endemic disease (e. g. Varroa), which relates to the capacity to modulate the intensity of the surveillance system according to the expected outcome of the surveillance.

The Commission explained the purpose of the veterinary investigation, the possibility of derogation for physical visits. The difference between the veterinarian informing the operator or the competent authority of findings that may trigger obligations for notification or prevention measures and the communication to the operator of the final results of the investigations were also explained. This text will be reformulated in the revised version to make it clearer.

Several experts supported that the type of veterinarian conducting the investigation should not be further specified. Yet the reference to the veterinarian should be better harmonised in the text, the timeframe to conduct the investigations should be specified and the relationship with the competent authority should be clarified. For instance specific wording could differentiate the investigations conducted by private veterinarian from those conducted by the competent authority.

Some experts were concerned that the possibility for the veterinarian to give instruction to the operator without physical visit may lead to a misuse of antibiotics via prescription from the distance. The Commission clarified that this was not the intention. A more specific provision to address this issue will be added if necessary to make this point clear. On the other hand, several experts supported the possibility of

the derogation provided that the decision would be taken by the competent authority and that the decision criteria would be further developed, in particular taking into account the results of the animal health visits as referred to in Article 25 of the AHL.

3.2.1. Surveillance

The Commission presented the criteria for considering when the presence of the disease agent shall be suspected or confirmed, the principles of disease-specific criteria to be laid down in Annexes and the situations where the competent authority shall officially confirm the presence of the disease.

Several experts raised concerns on the consistency of wording across the document, and with the AHL and other delegated and implementing acts, the inclusion of definitions and the coverage of requirements for laboratory test in relation with the designation of Union reference laboratory. The rules for confirmation of the presence of disease according to disease agents and the type of results were further discussed.

The Commission presented the provisions on the design of surveillance system, the definition of the targeted animal population, the responsibility of the competent authority in terms of investigations or official activities that could participate in the surveillance and the responsibility of the operators. It furthermore explained how the provisions of the document intended to give to Member States the flexibility to adapt the intensity of the surveillance to the targeted objectives.

Some experts asked for clarification on the categories of persons concerned by the surveillance and the rules to apply these provisions including the role of the competent authority, the use of risk analysis, the links with the official control regulation, the timeframe and the responsibilities for notification by laboratories, veterinarians and operators.

The Commission presented criteria relevant for the eligibility of disease to Union surveillance programme and the content of the submission of such programmes, which currently would correspond to the programme for annual surveillance of avian influenza. Some experts pointed out that the current avian influenza surveillance was operating in a way that was not fulfilling all the proposed criteria and discussed the relevance of the criteria and the possibility not to define any.

The Commission confirmed that, although the empowerment to define criteria was optional, the criteria had to be laid down as they were referred to in the obligation for the competent authority to implement Union surveillance programme. The Commission further explained the difference between the surveillance designed by the competent authority for which reporting obligation may exist and the Union surveillance programme implemented by the competent authority on the basis of the design laid down in the legislation and for which reporting obligation must be established. The Commission confirmed that the submitted Union surveillance programme will be assessed but not approved.

3.2.1. Eradication programme

The Commission representative of Directorate F presented experiences and findings from audits in the area of control programmes for Brucellosis and for Tuberculosis. As regards the general approach proposed in the document, the Commission representative of Directorate F expressed that while detailed requirements were useful to verify conformity in the context of audits, a flexible approach based on specification of objectives was relevant for outcome-based policy assessment.

The Commission furthermore briefly explained the principles of the eradication programmes that would apply for diseases B and C. Targeted animal populations for granting disease free status have to be differentiated from additional targeted population that shall be considered for effective control of the disease. The detailed provisions would differ depending if the disease profile was compatible with granting the status at an establishment level or not. The Commission confirmed that the area covered by the eradication programme could concern zones or Member State and explained that the capacity to develop coordination at the border should not be an obstacle to apply eradication programme.

One expert raised concern on the available means to apply measures to certain additional targeted population.

The Commission informed that in Article E2-2(2) the word 'may' will be replaced with the word 'shall' in the revised version.

In reply to expert's questions, the Commission indicated that the detailed provisions for the eradication programmes included in the delegated act to be published in April 2019 will probably not cover all the diseases B and C given time constraints, the novelty of the measures in Union legislation for some of them and the current stage of development of scientific standards for certain diseases.

4. CONCLUSIONS/RECOMMENDATIONS/OPINIONS AND NEXT STEPS

The Commission obtained a valuable preliminary feedback on the approach developed and some useful information from experts on the issues of notification, surveillance and eradication programmes. Such inputs are important for the Commission in this phase of drafting of the future delegated act.

The Commission invited experts to provide written comments on the document by **4th of April 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 the document.

5. NEXT MEETING

The next meeting is scheduled for 23rd of April 2018 to discuss a revised version of the document, chapters on eradication programmes and on disease free status. If possible, discussions on the examples on infection with *Brucella* and infection with *Mycobacterium tuberculosis* complex will take place.