REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON AVIAN INFLUENZA

Paris (France), 11–13 June 2019

The OIE ad hoc Group on avian influenza (the ad hoc Group) met at OIE Headquarters in Paris from 11–13 June 2019.

The agenda and the list of participants are presented in Annex I and in Annex II, respectively.

1. Introduction

A representative from the Standards Department delivered a short presentation to provide the context of ad hoc Group work within the OIE’s mandate and the OIE standard-setting process, with particular emphasis on the roles and responsibilities of ad hoc Groups, Specialist Commissions and the OIE Secretariat.

The Secretariat also provided a summary of the history of this work and the outcomes of the last two ad hoc Group meetings, relevant discussions of meetings of the Terrestrial Animal Health Standards Commission (Code Commission) and the Scientific Commission for Animal Diseases (Scientific Commission) since the last ad hoc Group meeting. The Secretariat noted that due to the unavailability of some previous ad hoc Group members a new member was invited to participate.

2. Welcome

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, on behalf of Dr Monique Eloit, Director General of the OIE, welcomed members of the ad hoc Group and the representatives from the Code Commission and the Scientific Commission and thanked them for their continued support for this important OIE work.

Dr Stone noted that in addition to the ad hoc Group’s task to review Members’ comments received on the revised draft chapter circulated in the Code Commission’s September 2018 report, the ad hoc Group had also been requested to undertake an assessment of H5 and H7 low pathogenicity avian influenza (LPAI) against the criteria in Chapter 1.2. of the Terrestrial Animal Health Code (Terrestrial Code). He further noted that the experiences of this ad hoc Group in conducting the assessment would provide valuable feedback for OIE Headquarters to develop the internal standard operating procedure and guidance documents for these assessments, and encouraged the ad hoc Group to share their opinions with the Secretariat.

Dr Stone also emphasised the importance of the participation of representatives of the Code and Scientific Commissions in this ad hoc Group noting that coordination between these Specialist Commissions will be important in order to ensure this work progresses in a coordinated manner at their September 2019 meetings.

Note: This ad hoc Group report reflects the views of its members and may not necessarily reflect the views of the OIE. This report should be read in conjunction with the September 2019 report of the Terrestrial Animal Health Standards Commission because this report provides its considerations and comments. It is available at http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/code-commission-reports/meetings-reports/
Dr David Swayne, Chair of the ad hoc Group, welcomed the experts, noting a change of membership, and appreciated their commitment to the work, in particular their engagement in pre-meeting activities. He also commended the Secretariat’s preparatory work for this meeting.

3. **Assessment of ‘H5 and H7 low pathogenicity avian influenza’ against the criteria for the inclusion of diseases, infections and infestations in the OIE list in Chapter 1.2. of the Terrestrial Code**

At the request of the Code Commission, at its September 2018 meeting, the ad hoc Group undertook the assessment of ‘H5 and H7 low pathogenicity avian influenza (LPAI)’ against the criteria in Article 1.2.2. of Chapter 1.2. ‘Criteria for the inclusion of diseases, infections and infestations in the OIE list’.

It was agreed that the assessment undertaken would be for the ‘low pathogenicity avian influenza viruses’ as defined in point 1(b) of Article 10.4.1., i.e. ‘low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not avian influenza viruses’ of the 2018 edition of Chapter 10.4. ‘Infection with avian influenza viruses’ of the Terrestrial Code. In advance of the meeting, members of the ad hoc Group were provided with detailed information on the assessment process and were requested to undertake assessments against each criterion. During the ad hoc Group meeting each criterion was discussed, based on the scientific evidence available, and a consensus was reached by the ad hoc Group.

In summary, the ad hoc Group agreed that H5 and H7 low pathogenicity avian influenza does not meet the criteria for the inclusion of diseases, infections and infestations in the OIE list disease described in Chapter 1.2. of the Terrestrial Code. The complete assessment is presented in Annex III.

4. **Consideration of comments received on the revised draft Chapter 10.4. ‘Infection with avian influenza viruses’**

At its February 2019 meeting, the Code Commission considered comments received on the revised draft Chapter 10.4. ‘Infection with avian influenza viruses’ that had been circulated in its September 2018 report. The Commission addressed some comments and referred those that needed further expert advice to this ad hoc Group for its consideration.

The ad hoc Group considered comments received from Argentina, Australia, Canada, China (People’s Republic), Costa Rica, Guatemala, Honduras, India, Japan, Malaysia, South Africa, Thailand, United States of America (USA), the Member States of European Union (EU) and the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE. Comments received from the International Poultry Council and other experts were also considered, as well as comments made by some Members at the 87th General Session on the proposed draft chapter.

The ad hoc Group reviewed all comments and proposed amendments to the text of the chapter, where appropriate. The ad hoc Group did not address comments where a rationale had not been provided or that were difficult to interpret.

In response to general comments regarding notification or surveillance of LPAI and the scope of the chapter, the ad hoc Group agreed that the conclusion and rationale of the assessment presented in Annex III should provide an adequate response, and therefore individual responses were not provided in this report. However, the ad hoc Group did provide some specific comments relating to the issues around LPAI in relevant sections of this report. In addition to amendments in response to comments, the ad hoc Group also proposed other amendments for clarity, consistency and improved readability.
General comments

The ad hoc Group noted the overall support for amendments made by the ad hoc Group at its previous meeting and that had been circulated for comment.

In response to a comment questioning the appropriateness of associating monitoring of H5 and H7 LPAI strains with free status of HPAI, the ad hoc Group clarified that continued monitoring of any hemagglutinin subtype of LPAI is recommended for the following reasons: 1) monitoring of LPAI can provide useful information to verify biosecurity plans in place on farms; and 2) changes in virus virulence and its zoonotic potential needs to be captured; and 3) a surveillance programme for HPAI normally can provide a certain degree of monitoring function of LPAI viruses considering its similarities in designs, sampling and diagnostic flow, and the commonly deployed virus detection and antibody screening test for diagnosis and surveillance detect all influenza A viruses and their infections making monitoring of non-HPAI cost effective and structurally simple.

Based on the conclusions of the assessment of H5 and H7 LPAI (presented in Annex III), the ad hoc Group agreed with a comment requesting to revise the relevant listed diseases in Chapter 1.3., and noted that this would be considered by the Code Commission at its September 2019 meeting based on its assessment.

Although the ad hoc Group recognised the possibility of referring to the same pathogenic agent in different ways, it did not agree with a comment suggesting to replace ‘high pathogenicity avian influenza virus’ with ‘highly pathogenic avian influenza virus’ throughout the chapter. The ad hoc Group agreed that the use of ‘high pathogenicity’ allowed for a better alignment with the English use of ‘low pathogenicity’, which could not be named ‘lowly’ pathogenic.

The ad hoc Group did not agree with a comment requesting to change the chapter title to ‘Infection with avian influenza viruses with potential to become highly pathogenic and pandemic’ as ‘pandemic’ by definition refers to the worldwide spread of a new disease in humans, which is outside of the remit of the Terrestrial Code.

Article 10.4.1. General provisions

In response to a comment questioning to the use of the terms ‘avian influenza’, ‘infection with avian influenza viruses’, or ‘low pathogenicity avian influenza’ without clear definitions for each, the ad hoc Group noted that the objective of this chapter was to mitigate animal and public health risks posed by infection with high pathogenicity avian influenza viruses and amended the text accordingly for clarity.

The ad hoc Group discussed a comment requesting to amend the text for the definition of ‘high pathogenicity avian influenza’ and agreed to delete the definition and refer to the definition in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual) to avoid any inconsistencies. The ad hoc Group recognised that the chapter in the Terrestrial Code needs to be well aligned with the corresponding chapter in the Terrestrial Manual, and noted that the description of the methods used for the determination of strain virulence in the Terrestrial Manual could be further improved; consequently, the ad hoc Group requested that OIE Headquarters raise this issue with the Biological Standards Commission and consider revising the Terrestrial Manual Chapter 3.3.4. ‘Avian influenza (infection with avian influenza viruses)’.

In response to a comment questioning with respect to disease notifications how to deal with “H5 or H7 viruses with an intravenous pathogenicity index (IVPI) of less than 1.2 and a polybasic cleavage site sequence not previously described”, which is not covered in the current definition of HPAI but is considered to be important in OFFLU, a joint worldwide network of expertise on avian influenza, the ad hoc Group requested OIE Headquarters refer this comment to the Biological Standards Commission for its consideration for the relevant definitions in the Terrestrial Manual. On a related note, the ad hoc Group also noted that ‘specific viral ribonucleic acid’ in point 2(b) to define an occurrence of infection with high pathogenicity avian influenza virus was not specified in the Terrestrial Manual chapter and therefore this issue should also be considered by the Biological Standards Commission.
The *ad hoc* Group acknowledged a comment requesting the alignment of the definitions for ‘poultry’ used in this chapter and the Glossary and considered that the Code Commission was best placed to consider this comment. The *ad hoc* Group also considered the Code Commission could better address another comment asking that “breeding flocks producing offspring raised for restocking supplies of game”, be explicitly included in the ‘all birds used for restocking supplies of game’.

The *ad hoc* Group agreed with a comment requesting to exclude birds kept in zoos from the definition of poultry and added ‘zoological collections’ to the birds that are not considered poultry.

The *ad hoc* Group did not agree with a comment on the revised definition of ‘poultry’, requesting to include a specific reference stating that “birds in a single household for self-consumption” should “have no epidemiological link with poultry” for them not to be considered poultry. Although the *ad hoc* Group partially agreed with the rationale, it considered that if an epidemiological link existed, it would only be due to a lack of biosecurity.

In response to comments requesting to maintain the current wording for the definition of poultry in order to maintain “including backyard poultry” and to a comment seeking clarification on why birds in a household were not considered poultry, the *ad hoc* Group stressed that the intention was not to exclude all so-called ‘backyard poultry’ from the definition but to rather improve its clarity. The *ad hoc* Group reiterated that the revised definition does not consider birds that are kept in a single household and their products are only used in that same household as poultry, because those birds do not represent an epidemiological risk of spreading the disease. The *ad hoc* Group referred Members to its June 2018 meeting report (Annex 25 of the September 2018 Code Commission report) that noted ‘in many countries, the poultry sector was integrated in such a way that no clear separation could be made between different sectors. Due to the wide range of combinations of different types of production systems, the term ‘backyard flocks’ could not be defined.’

The *ad hoc* Group did not agree with a suggestion to create an independent article for surveillance in domestic birds other than poultry, and reiterated that, despite the removal of backyard poultry’ from the text, the part of such population that is epidemiologically significant with respect to avian influenza (i.e. traded beyond the household where kept) would continue to be considered ‘poultry’ after the change in the definition. The *ad hoc* Group further noted that proposed new wording to replace ‘backyard poultry’ was clearer and the definition of poultry is now well aligned with the risk of disease spread.

The *ad hoc* Group did not agree with a comment requesting to modify a sentence in the revised definition for poultry to read “If birds are kept in a household and their products are used for local consumption, these birds are not considered poultry” as it considered that ‘local’ was too broad and non-specific (e.g. town, municipality, province, state) and that this word may introduce further confusion.

The *ad hoc* Group further discussed the incubation period at the flock level referred to in point 1(d) and noted that for some avian species in the order Anseriformes the incubation period may be longer than 14 days or may not exist due to a lack of clinical signs with such virus infections. Notwithstanding, the *ad hoc* Group agreed that it was important to define this period in the regulatory arena, which can reasonably be applied to all bird species so that Members can make relevant decisions.

Taking into account the outcome of the assessment of H5 and H7 low pathogenicity avian influenza viruses against the criteria in Chapter 1.2. (refer to Item 3), the *ad hoc* Group amended text referring to notification obligations. This amendment addressed several comments received. The *ad hoc* Group clarified that based on the outcomes of its assessment and if agreed by the Specialist Commissions, notification would only be mandatory for high pathogenicity avian influenza. Nonetheless, it highlighted that immediate notifications as emerging diseases as described in Article 1.1.4. would apply upon detection of a sudden and unexpected increase in virulence of low pathogenicity avian influenza viruses in poultry, or infection of domestic and captive wild birds with low pathogenicity avian influenza viruses that had been proven to be naturally transmitted to humans associated with severe consequences.
The *ad hoc* Group also reaffirmed that occurrences of avian influenza viruses of high pathogenicity in birds other than poultry including wild birds should continue to be notified to the OIE in accordance with Article 1.3.6. In this regard the *ad hoc* Group considered that the current name in Chapter 1.3. ‘Infection with influenza A viruses of high pathogenicity in birds other than poultry including wild birds’ should be amended to ‘infection with avian influenza viruses of high pathogenicity in birds other than poultry including wild birds’.

The *ad hoc* Group did not agree with a comment opposing the addition of text stating that vaccination would not affect the status of a country or zone. The *ad hoc* Group reiterated that the absence of the disease and infection could be effectively demonstrated, even after vaccination, by adequate surveillance in accordance with Chapter 1.4. and relevant articles in this chapter of the *Terrestrial Code* and the corresponding chapter in the *Terrestrial Manual*.

The *ad hoc* Group agreed with a comment suggesting to replace ‘vaccination against high pathogenicity avian influenza’ with ‘vaccination against avian influenza viruses of H5 and H7 subtypes’, and amended the text to clarify that the vaccination against any avian influenza viruses may be recommended under specific conditions.

**Article 10.4.2. Country or zone free from high pathogenicity avian influenza**

The *ad hoc* Group did not agree with a comment claiming that monitoring of H5 and H7 LPAI in poultry is not justified in all situations to support freedom from high pathogenicity avian influenza, and reiterated its rationale noted under ‘General comments’ section above. Nevertheless, the *ad hoc* Group deleted text relating to monitoring of LPAI from this article and included cross-reference to relevant articles.

**Article 10.4.2bis. Compartment free from high pathogenicity avian influenza**

Although the *ad hoc* Group did not completely agree with the rationale provided by some Members suggesting that a compartment should be free from all influenza viruses, the *ad hoc* Group amended the text of point 1 of Article 10.4.2.2. to add a sentence stating that surveillance is aimed at ensuring that biosecurity and control measures are fit for purpose.

**Article 10.4.2quater. Recovery of free status**

In response to a comment requesting to provide a rationale to support reducing the minimum recovery period to less than 3 months, the *ad hoc* Group emphasised that two flock-level incubation periods, i.e. 28 days, should be considered as a minimum to recover free status if supported by surveillance to demonstrate the absence of infection, in accordance with provisions in Chapter 1.4. and the relevant articles in this chapter.

**Article 10.4.3. Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza – for live poultry (other than day-old poultry)**

In response to a comment seeking clarification on the scope of vaccination referred to in this article, the *ad hoc* Group clarified that it covers vaccination against any subtypes of avian influenza virus. The *ad hoc* Group agreed there was no need to amend the text and noted that this would also apply to similar references in other articles.

The *ad hoc* Group agreed with a comment questioning the reference to a “flock free from infection with any H5 or H7 influenza A viruses” as it was not defined in the draft chapter. The *ad hoc* Group amended the text to refer to a flock of origin that should have been monitored for avian influenza viruses, with negative results. The same change was applied to other relevant articles. This response also addressed similar comments raised in other articles.

The *ad hoc* Group did not agree with a comment requesting to add text stating that “an exporting country must provide evidence to an importing country showing the absence of infection when vaccination is applied”, as it considered that this was addressed in Article 10.4.22. This response also addressed similar comments raised in other articles.
Annex 30 (contd)

**Article 10.4.4. Recommendations for importation of live birds other than poultry**

In response to a comment querying whether, in point 3, the wording ‘a diagnostic test for influenza A viruses’ means only virological testing, the ad hoc Group clarified that it includes both serological and virological testing for avian influenza viruses, and consequently amended the text to improve clarity.

**Article 10.4.6. Recommendations for importation of day-old live birds other than poultry**

The ad hoc Group agreed with a comment requesting to include reference to “a statistically valid sample” in point 3, to ensure consistency with Article 10.4.4. The ad hoc Group also agreed with a comment suggesting that the parent flock should be tested negative for any avian influenza virus and modified the text accordingly.

**Article 10.4.11. Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza – for eggs for human consumption**

The ad hoc Group did not agree with a comment requesting the reinstatement of the previous point 2 that read ‘the eggs have had their surfaces sanitized (in accordance with Chapter 6.5.)’. The ad hoc Group explained that this article was intended to provide measures to mitigate the risk of international spread of the disease via importation of eggs for human consumption, and not for food safety per se, and that the risk of disease transmission arising from unwashed eggs for human consumption was deemed negligible. The ad hoc Group also noted that Chapter 6.5. addressed sanitisation of hatching eggs only.

**Article 10.4.12. Recommendations for importation of egg products of poultry**

The ad hoc Group did not agree with a comment requesting to delete the reference to ‘high pathogenicity’ in the context of virus inactivation given that procedures required for inactivation of avian influenza viruses are the same irrespective of their pathogenicity. The ad hoc Group noted that this chapter is to mitigate the risks posed by high pathogenicity avian influenza and therefore this should be clearly addressed in this chapter.

**Article 10.4.13. Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza – for fresh meat of poultry**

In response to a comment referring to the absence of provisions regarding the status of the exporting country for H5 and H7 low pathogenicity avian influenza in poultry, the ad hoc Group noted that this chapter is to mitigate the risks posed by high pathogenicity avian influenza and therefore this should be clearly addressed in this chapter. Furthermore, the ad hoc Group reiterated that H5 and H7 LPAI posed a lower risk than HPAI for spread through fresh meat, which was strongly supported by the risk assessment undertaken by the European Food Safety Authority (see the ‘assessment of low pathogenic avian influenza virus transmission via raw poultry meat and raw table eggs’ at [https://www.efsa.europa.eu/en/efsajournal/pub/5431](https://www.efsa.europa.eu/en/efsajournal/pub/5431)).

This response also addressed similar comments raised in other articles.

**Article 10.4.18. Procedures for the inactivation of high pathogenicity avian influenza viruses in egg products of poultry**

In response to a comment the ad hoc Group reviewed and amended the text accompanying the table to improve clarity.

The ad hoc Group did not agree with a comment to modify the presentation of the target reference for the reduction of avian influenza virus infectivity as it considered that log reduction was a mathematical term that could be widely used to quantify virus infectivity in any commodities.
Article 10.4.19bis. Procedures for the inactivation of high pathogenicity avian influenza viruses in scientific specimens and skins and trophies

In response to a request to share scientific literature that supports the specific parameters in this article, the ad hoc Group explained that they were developed based on parameters used in other disease-specific chapters such as foot and mouth disease, classical swine fever and African swine fever, and taking into consideration the characteristics of the pathogenic agent. The ad hoc Group also noted that this kind of extrapolation was often done, when deemed appropriate, in the Terrestrial Code.

Article 10.4.20. Principles of surveillance for avian influenza

Taking into consideration comments regarding the content and scope of this article, the ad hoc Group emphasised that this article addresses “Principles of surveillance for avian influenza” and was intended to be considered together with provisions provided in the following articles on surveillance and monitoring. In addition, the ad hoc Group amended the title and some text to improve clarity and to highlight the possibility for Members to adapt these provisions to their local context when demonstrating the absence of infection. The ad hoc Group also amended the text to clarify the relevance of monitoring of H5 and H7 low pathogenicity avian influenza viruses in poultry.

In response to a comment highlighting the importance of a monitoring system for LPAI in poultry, the ad hoc Group noted that monitoring activities for LPAI were extremely unlikely to detect infection, on a single establishment, in time for control measures to be taken to avoid mutation to high pathogenicity avian influenza on that single establishment. The ad hoc Group considered that the key goal to adequately manage the risk of spread of LPAI would be to detect clusters of infected poultry establishments where H5 and H7 low pathogenicity viruses spread between poultry establishments.

The ad hoc Group also added a new paragraph highlighting the value of the application of sequencing technologies and phylogenetic analyses to enhance the evidence for surveillance and disease prevention and control.

Article 10.4.22. Surveillance for demonstrating freedom from high pathogenicity avian influenza

The ad hoc Group did not agree with a comment to include an additional reference to the level of confidence, as this was already addressed in the cross-referenced Article 1.4.6.

The ad hoc Group did not agree with a comment that considered it contradictory to include a reference to monitoring of H5 and H7 LPAI in this article. The ad hoc Group considered that monitoring of these low pathogenicity viruses was important as described in Article 10.4.20. The ad hoc Group also highlighted that a “free status” depends not only on demonstrating freedom through surveillance, but also requires the implementation of effective biosecurity and sanitary measures to prevent the introduction of the disease. The ad hoc Group amended the text to improve clarity.

The ad hoc Group also added new text throughout this article to provide more details on transparency in the application of surveillance methodologies, some important variables for surveillance, different sampling strategies and overall surveillance sensitivity.

In response to a comment, the ad hoc Group agreed to revise the text of point 3 ‘Additional requirements for the recovery of free status’, by deleting ‘moved from or’ from the text as there was no need to include such a subpopulation of poultry under the surveillance programme for recovery of free status.

Article 10.4.22bis. Surveillance of wild bird populations

The ad hoc Group deleted the first generic paragraph agreeing that this was broadly addressed elsewhere in the chapter.

In response to a comment requesting to clarify whether active surveillance in wild birds included sampling of live and apparently healthy birds, the ad hoc Group amended the text accordingly to clarify this point.
Annex 30 (contd)

The ad hoc Group did not agree with a comment suggesting to add a sentence stating that regular testing of sentinel ducks in contact with wild waterfowl was recommended as active surveillance, as there was not strong evidence to support such a method for wild birds.

Previous Article 10.4.27. Surveillance for the avian influenza free establishments

In line with the amendments to delete the term ‘avian influenza free establishment’ from the draft chapter, and in response to a comment, the ad hoc Group deleted this article from the draft chapter as it was no longer considered necessary.

Diagnostic diagrams in the existing chapter

The ad hoc Group noted that the Biological Standards Commission did not support moving the diagnostic diagrams in Article 10.4.33. to the Terrestrial Manual. The ad hoc Group supported the approach proposed by the Code Commission to publish them, after updating if necessary, on an OIE webpage, once the revised chapter is adopted.

5. Any other business

The ad hoc Group agreed to develop a scientific paper which reviewed the global epidemiology of avian influenza and which would provide Member Countries with relevant technical advice on a range of issues such as surveillance methodologies, to support them in the implementation of the chapter, once adopted.

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../Annexes
REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON AVIAN INFLUENZA
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Adopted agenda

1) Introduction

2) Welcome

3) Assessment of ‘H5 and H7 low pathogenicity avian influenza’ against the criteria for the inclusion of diseases, infections and infestations in the OIE list in Chapter 1.2. of the Terrestrial Code

4) Consideration of comments received on the revised draft Chapter 10.4. ‘Infection with avian influenza viruses’

5) Any other business
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Overall assessment

The OIE ad hoc Group on avian influenza (the ad hoc Group) assessed H5 and H7 low pathogenicity avian influenza (LPAI) against the criteria for the inclusion of a disease, infection or infestation in the OIE list in accordance with Article 1.2.2. of the Terrestrial Code. The ad hoc Group noted that the criteria, in particular criteria 4(a) and 4(b), were difficult to interpret and apply to H5 and H7 LPAI because of the complexities of assessing a group of viruses where the characteristics of different strains or lineages/genotypes vary and the diversities of poultry sector and avian species involved. Taking into account the difficulty of interpretation of criteria 4(a) and 4(b) and the caveats documented in their assessment (see below), as well as the outcomes of assessments for the other criteria, the ad hoc Group agreed that H5 and H7 LPAI viruses did not meet the criteria for inclusion in the OIE list. Nonetheless, notification of events involving viruses in this category with specific characteristics indicating a significant risk to animal or public health should continue to be encouraged.

Table 1. Summary of assessment of H5 and H7 low pathogenicity avian influenza

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<th>Listing criteria</th>
<th>Conclusion</th>
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<td>H5 and H7 LPAI</td>
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Taking into account the caveats noted under criteria 4(a) and 4(b), the ad hoc Group concluded that H5 and H7 LPAI does not meet the criteria for listing.

Background

At the request of the Code Commission at its September 2018 meeting, the ad hoc Group undertook an assessment of ‘H5 and H7 low pathogenicity avian influenza viruses’ against the criteria in Article 1.2.2. of Chapter 1.2. ‘Criteria for the inclusion of diseases, infections and infestations in the OIE list’ of the Terrestrial Code.

The disease assessed was infection with the ‘low pathogenicity avian influenza viruses’ as defined in point 1(b) of Article 10.4.1, i.e. ‘low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses’ of the 2018 edition of Chapter 10.4. ‘Infection with avian influenza viruses’ of the Terrestrial Code.

In advance of the meeting, members of the ad hoc Group were provided with detailed information on the assessment process and were requested to undertake assessments against each criterion based on the scientific evidence available. During the meeting, the ad hoc Group considered all of the assessments made for each criterion and reached an agreed position which is documented below.

Criteria for the inclusion of a disease, infection or infestation in the OIE list (Article 1.2.2.)

Criterion No. 1

International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.
Annex 30 (contd)

Annex III (contd)

Assessment
H5 and H7 LPAI has moved beyond geographic boundaries by both wild bird movement and human activity, mostly by trade of infected live birds which shed LPAI viruses in their respiratory secretions and faeces. International spread of H5 and H7 LPAI has been proven in numerous outbreaks with these viruses, although extensive transboundary spread has not necessarily occurred. Nevertheless, international spread of the pathogenic agent should be considered a pathway. Spread via poultry products is not a specified pathway for most strains. The trade of live birds is the major risk with the best evidence being the movement of: 1) H5N2 LPAI in poultry in the late 1990s from Mexico to Guatemala, El Salvador and some Caribbean Islands; 2) a single episode of H5N2 LPAI between Canada and the USA in domestic ducks; and 3) H7N1 and H7N8 LPAI in global pet bird trade [1], as described below.

The H5N2 LPAI virus is highly adapted to chickens and not to migratory waterfowl, and the lack of virus in surveillance samples from the wild waterfowl populations, and the endemicity of the virus in Mexican chickens over much of central and southern Mexico, provided indirect evidence of the source being movement of live chickens across the porous national borders with appearance of the virus in poultry of neighbouring countries.

In the second example, domestic ducks infected with H5N2 LPAI virus were exported from Ontario, Canada to New York state, USA without spread beyond the importing premise. In the third example, during the 1990s, H7 LPAI were moved between countries via unregulated trade in live pet/captive passerine/psittacine birds [1].

The movement of H5 and H7 LPAI virus by wild birds is well documented for Canada-USA and European countries within numerous surveillance programmes [2,3], but the ad hoc Group did not use such information in assessing Criterion 1. The ad hoc Group only acknowledged the factualness of the spread within wild bird populations, but the assessment was focused only on spread through human activity.

On rare occasions, H5 or H7 LPAI viruses have been detected in illegally imported raw poultry meat [4] or eggs of turkeys or chickens, but the systemic spread required to produce the virus in such products appears to be virus strain specific and host species specific, and of much lower titers than seen with high pathogenicity avian influenza virus (HPAI) infections. These rare detections of H5 and H7 LPAI virus have not been associated with onward transmission and infections in poultry.

Conclusion
The criterion is met.

AND

Criterion No. 2

At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Assessment
The global distribution of avian influenza viruses is widely accepted in wild aquatic birds with demonstration of virus or antibodies against the virus on all seven continents. The spillover of these viruses into domestic poultry can be problematic as most such infections fail to cause disease, especially in domestic waterfowl, and surveillance for freedom is only able to be demonstrated in countries with well-developed active surveillance programmes. The declaration of freedom from H5 and H7 LPAI has some potential problems as surveillance for H5 and H7, especially in small holder poultry, is often inadequate to demonstrate freedom, and reporting of infection for the most part is done by those doing active surveillance; i.e. negative surveillance results allows some countries to declare H5 and H7 LPAI freedom, but surveillance system design requires careful evaluation to ensure such results are supportable.
In support of this position above, Member States of the European Union have carried out and reported results of active surveillance for avian influenza in poultry flocks using serology for H5 and H7 subtypes. Details of the surveillance and results of each year are available online [5]. During 2004–2010 (inclusive), the following countries carried out the required surveillance and did not detect any seropositive holdings to H5 or H7 avian influenza viruses in the poultry sampled: Austria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Luxembourg, Slovenia and Slovakia. The data available through the reports to the European Commission provide evidence of freedom from H5 and H7 LPAI in the poultry populations of these countries.

As a separate point, most countries provide sufficient surveillance data for the self-declarations of freedom from H5 and H7 LPAI that have been reported to the OIE. Also in support of this position is the self-declaration of the recovery of country freedom from avian influenza provided by Denmark and reported to the OIE. The self-declaration covers the whole country and describes the two outbreaks of LPAI reported in May and June 2018 [6].

**Conclusion**

The criterion is met.

AND

**Criterion No. 3**

**Reliable means of detection and diagnosis exist, and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations.**

**Assessment**

Specific and sensitive serological, virological and molecular methods exist to identify the H5 and H7 LPAI virus or their infections in domestic poultry [7,8]. There are very precise case definitions that require underpinning laboratory diagnosis which enables the safe distinction between LPAI and HPAI [9], and allow differentiation of H5 and H7 LPAI from other diseases. The methodology currently used will reliably detect infection at flock level if present, and then subsequent differentiation of pathogenicity. However, the clinical case definition is not pathognomic given there are a number of pathogenic agents that can cause similar presentation, including infections with non-H5 and H7 LPAI virus. Laboratory diagnosis is essential.

The primary methods for screening for virus or infections are sensitive and specific and identify type A influenza viruses; e.g. matrix RRT-PCR, ELISA and AGP serological tests. The secondary tests are slightly less sensitive methods that are used to differentiate the infections or the viruses of H5 and H7 from those of non-H5/H7; e.g. H5 and H7 RRT-PCR tests and hemagglutination inhibition test. The methods are not in question, but the lack of capacity for diagnosis and surveillance to detect and differentiate the H5 and H7 from non-H5/H7 LPAI virus infections that are for the most part asymptomatic infections is still a challenge in some countries.

**Conclusion**

The criterion is met.

AND

**Criterion No. 4 (a)**

**Natural transmission to humans has been proven, and human infection is associated with severe consequences.**

**Assessment**

The ad hoc Group agreed that the complexity of the H5 and H7 group of viruses as being genetically and phenotypically heterogeneous presented challenges for a conclusive unambiguous assessment for this criterion. The ad hoc Group agreed that in order to reach consensus a series of underpinning caveats needed to be noted and should be taken into account when considering its recommendations, i.e.
Annex 30 (contd)

Annex III (contd)

- The complexity and understanding of influenza A virus characteristics contrast to other pathogens (e.g. *Brucella* spp.) where either all strains cause zoonotic infection, or the genetic correlates/nuances are not understood at all at strain level.

- The occurrence of zoonotic infections with the H7N9 Chinese lineage LPAI virus since 2013 with severe outcomes (i.e. 40% case fatality rate) [10-12] could not be discounted; however the *ad hoc* Group agreed that this related to a single strain or ‘virus lineage/genotype’. On this point alone all *ad hoc* Group members agreed the answer to the question under criterion 4(a) is yes: However the following caveats must accompany this assessment.
  - This ‘unique virus lineage’ was restricted in its range being limited to China to date.
  - Consistent with the genetic characteristics not all strains of H7N9 subtype are zoonotic.
  - Occurrences of infection of humans with other H5 and H7 LPAI viruses have been reported infrequently (e.g. H7N2 UK, H7N3 Canada and UK [noting of different genetic characteristics]) [13]. In most cases these did not cause ‘severe consequences’, rather typically being characterised by mild infection i.e. conjunctivitis or mild uneventful respiratory illness (also including some immunocompromised patients) with recovery.
  - Increased awareness in the last 15 years has resulted in more surveillance (avian-human interface).

- The *ad hoc* Group agreed that given the complexity of these viruses and difficulties in interpreting the criterion, its assessment for this criterion was inconclusive when applied to all H5 and H7 viruses of low pathogenicity for poultry.

**Conclusion**
The assessment for this criterion was inconclusive.

**OR**

**Criterion No. 4 (b)**

*The disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.*

**Assessment**
The *ad hoc* Group recognised that the reason for including H5 and H7 LPAI viruses in Chapter 10.4. of the *Terrestrial Code* was because of the potential for some of these viruses to mutate to a highly pathogenic form. However, the *ad hoc* Group also acknowledged that infection of poultry with the majority of H5 and H7 LPAI viruses as well as non-H5 and H7 viruses does not result in significant disease in the absence of co-factors that include secondary pathogens. This is supported by results from experimental infections of specific pathogen free chickens where no or only mild clinical disease has been observed. That being said, infection with some H5 and H7 LPAI viruses can cause production losses in specific poultry sectors. Examples of this include moderate to severe drops in egg production in breeder turkeys and to a lesser extent broiler breeders [14]. For these reasons the *ad hoc* Group’s assessment of this criterion was inconclusive.

**Conclusion**
The assessment for this criterion is inconclusive.

**OR**
Criterion No. 4(c)

The disease has been shown to, or scientific evidence indicates that it would have a significant impact on the health of wildlife taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population.

Assessment

The natural reservoir for H5 and H7 LPAI viruses is in wild birds. In these populations the virus generally has a benign or subclinical affect and therefore probably has no impact on the biodiversity of wildlife associated with infection [15, 16].

Conclusion

The criterion is not met.

References