FINAL REPORT OF AN AUDIT
CARRIED OUT IN
HUNGARY
FROM 26 FEBRUARY 2018 TO 02 MARCH 2018
IN ORDER TO
EVALUATE THE APPLICATION OF MEASURES FOR THE PREVENTION AND CONTROL OF AVIAN INFLUENZA
Executive Summary

This report describes the outcome of an audit in Hungary, carried out from 26 February to 2 March 2018 as part of the published Directorate-General for Health and Food Safety's audit programme.

The objective of this audit was to evaluate the application by the Hungarian competent authorities of EU measures for controlling outbreaks of avian influenza. In pursuance of that objective, particular attention was paid to:

- The effectiveness (in terms of their implementation) of the measures taken in the affected poultry populations.
- The implementation of the applicable contingency plan.
- The adherence to rules concerning the dispatch for intra-EU trade of consignments of live poultry, day-old chicks and hatching eggs.

The report concludes that the Hungarian competent authorities had neglected considerably their preparedness to respond effectively and quickly to a disease epidemic like the one caused by avian influenza in 2016/17. The Commission services had identified in September 2015 the main weaknesses and deficiencies of the animal health emergency preparedness system in Hungary. The fact that they had not been properly addressed yet by October 2016 undoubtedly contributed to the size and duration of the avian influenza epidemic.

At the time of this audit, the competent authorities had already taken some satisfactory steps in the good direction, but they were still in the process of analysing the lessons learnt from the epidemic with the objective of enhancing their preparedness for future emergency situations. In particular, the competent authorities were about to finalise a new contingency plan for avian influenza, they had set out plans to better harmonise the preparation by the counties of measures to respond to the disease – whose adequacy they plan to verify in the future –, and they had started to address the significant disease prevention problems that were identified in the domestic waterfowl production sector, the most affected by far during the epidemic.

Despite the difficulties experienced with the management of the epidemic, risks of transmission of the disease to other Member States through intra-EU trade of poultry commodities were mitigated properly and in line with EU legislation.

The report contains recommendations to the Hungarian competent authorities aimed at rectifying the shortcomings identified and enhancing the implementation of control measures.
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### Abbreviations and Definitions Used in This Report

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<th>Abbreviation</th>
<th>Explanation</th>
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<tr>
<td>ABP</td>
<td>Animal by-products not for human consumption, as defined in Regulation (EC) No 1069/2009</td>
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<tr>
<td>CA</td>
<td>Competent Authorities</td>
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<td>CCA</td>
<td>Central Competent Authority</td>
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<td>EU</td>
<td>European Union</td>
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<td>HPAI</td>
<td>Highly pathogenic avian influenza</td>
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<tr>
<td>ISO/EN 17025</td>
<td>General requirements for the competence of testing and calibration laboratories, from the International Organisation for Standardisation</td>
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<td>NRL</td>
<td>National reference laboratory</td>
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<td>PAFF Committee</td>
<td>Section on animal health and welfare of the Standing Committee on Plants, Animals, Food and Feed</td>
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<tr>
<td>Previous audit</td>
<td>Audit carried out in September 2015 in order to evaluate the area of contingency planning for exotic animal diseases (Ref.: DG(SANTE)/2015-7568)</td>
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1. **INTRODUCTION**

This audit took place in Hungary from 26 February to 2 March 2018 and was undertaken as part of the Directorate General for Health and Food Safety’s planned audit programme. The audit team comprised two auditors from the said Directorate General.

The audit team was accompanied throughout the audit by representatives of the Central Competent Authority (CCA), the National Food Chain Safety Office, in particular by representatives of the Directorate for Animal Health and Animal Welfare.

In addition, during the visits at local level, the audit team was accompanied by representatives of the relevant competent authorities (CA) of the counties, the Department of Food Chain Safety and Agriculture/Plant Protection and Soil Conservation of the County Government Offices (hereafter, the county CA).

2. **OBJECTIVES AND SCOPE**

The objective of this audit was to evaluate the application by the Hungarian competent authorities of EU measures for the control of outbreaks of avian influenza\(^1\). In pursuance of that objective, particular attention was paid to:

- The effectiveness (in terms of their implementation) of the measures taken in the affected poultry populations.
- The implementation of the applicable contingency plan.
- The adherence to rules concerning the dispatch for intra-EU trade of consignments of live poultry, day-old chicks and hatching eggs.

The scope of the audit covered:

- The outbreaks of highly pathogenic avian influenza (HPAI) that occurred in years 2016 and 2017.
- The production chain for poultry, in particular the domestic waterfowl and turkey production sectors, from primary production (e.g. hatcheries, raising farms) to the placing on the market, including for intra-EU trade purposes, of live poultry, day-old chicks and hatching eggs.
- All levels and departments of the national, regional and local administrations involved in the planning and application of the disease prevention and control measures covered by the scope of this audit, including approved bodies with delegated responsibilities in that respect.
- The operation of the laboratory network designated for the diagnosis of avian influenza.

\(^1\) Unless indicated otherwise, the terminology used in this report is defined in Article 2 of Council Directive 2005/94/EC.
In pursuit of this objective, the following sites were visited and meetings held:

<table>
<thead>
<tr>
<th>MEETINGS / VISITS</th>
<th>no.</th>
<th>COMMENTS</th>
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<tbody>
<tr>
<td>Competent Authorities</td>
<td></td>
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<tr>
<td>Central</td>
<td>2</td>
<td>Opening and closing meetings with representatives of the relevant services of the CCA.</td>
</tr>
<tr>
<td>County</td>
<td>3</td>
<td>The meetings were held with the CAs of three counties (Bács-Kiskun, Csongrád and Békés).</td>
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<tr>
<td>District</td>
<td>2</td>
<td>The meetings were held with the CAs of two district offices.</td>
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<tr>
<td>Laboratories</td>
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<tr>
<td>1</td>
<td></td>
<td>The national reference laboratory for avian influenza.</td>
</tr>
<tr>
<td>Holdings</td>
<td>2</td>
<td>Two poultry holdings, one keeping ducks and geese, and one keeping turkeys.</td>
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3. LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular:


Full legal references to EU legal acts quoted in this report are provided in Annex 1 and refer, where applicable, to the last amended version. Besides, a table is included as an Appendix to this report summarising the main legal requirements related to the specific provisions and measures laid down in EU legislation pertaining to the control of avian influenza.

4. BACKGROUND

4.1 RECENT EPIDEMICS OF HPAI IN THE EU

In recent years (since 2015, and throughout 2017), several epidemic waves of HPAI have caused havoc in the domestic poultry sector in numerous Member States.

In 2015, and up until early 2016, outbreaks of HPAI in poultry occurred in Germany, Hungary, Bulgaria, the United Kingdom, France and Italy. The outbreaks affecting the domestic waterfowl production sector revealed that some production practices inherent to it and the absence of effective disease prevention policies – notably the limited awareness about their relevance —, alongside the slow deployment of measures to control the transmission of the avian influenza virus and eradicate the disease; brought about a long-lasting and costly epidemic.

From October 2016, the most recent HPAI epidemic affected domestic poultry and wild and captive birds in at least 21 Member States. Its unprecedented dimension (well in excess of a
thousand outbreaks), minimized the impact of the previous large epidemic that occurred in 2005/2006 (with 230 outbreaks), and caused very significant direct and indirect economical and societal costs to the EU as a whole.

The main HPAI strain associated with that epidemic – of an H5N8 subtype – was introduced by migratory wild birds. The high levels of infection in wild birds facilitated the geographical spread of the disease and contributed to a higher than usual risk of transmission of the avian influenza virus to domestic poultry. The industry made a costly investment to mitigate those risks and, thereby, prevent the infection of poultry holdings. That made the standard production practices more difficult and inefficient (e.g. the confinement indoors of free-range poultry for long periods of time), and disrupted commercial flows significantly (e.g. in the free-range and organic sectors).

During the most recent epidemic there have been multiple cases of secondary virus spread within the domestic poultry population in some Member States, notably in those with a large domestic waterfowl production sector (i.e. France, Poland, Hungary and Bulgaria). Also, unexpected secondary outbreaks of the disease occurred in other poultry species in other Member States in areas with a high density of poultry; e.g. in the turkey production sector in Germany and in Italy.

The EU measures on control of avian influenza2 aim to prevent further infection of domestic poultry populations, and stop the spread of the disease as soon as possible, to ensure the safe placing on the market, and exports, of EU poultry and their products. Those measures were adapted regularly to the epidemiological evolution of the disease in Member States3.

Further to previous information, the European Food Safety Authority published in October and December 2017 two Scientific Reports analysing the recent epidemic of HPAI in the EU and providing an update of the epidemiological evolution of the disease4. Those reports highlight a number of relevant issues in relation to the application of control measures for the disease in the affected Member States.

In light of the seriousness of the epidemics mentioned above, of the preliminary lessons learned from them, of the specificities and disease risk factors occurring in the main production sectors affected, and of the ever-changing dynamics of the disease in domestic poultry and in wild birds; the Commission services consider important to review the application of those EU measures to maintain trust among Member States and non-EU countries in the efficacy of the operation of the animal health control system in the EU.

The Directorate General for Health and Food Safety has planned a series of audits to be carried out between 2018 and 2019 in Member States affected by the recent epidemic.

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2 As laid down in Directive 2005/94/EC, including additional detailed rules on prevention and control of avian influenza established in accordance with the said Directive (see next footnote).
3 https://ec.europa.eu/food/sites/food/files/animals/docs/ad_control-measures_hapai_decisions.pdf
The Commission services intend to summarise the main issues and conclusions from these audits and, if necessary, it will propose options to improve the control of avian influenza in the EU.

4.2 INFORMATION ON THE ANIMAL HEALTH CONTROL SYSTEM IN HUNGARY

Information on the structures of the Hungarian CAs can be found in the country profile, which is published on the Website of the Directorate General for Health and Food Safety at:

http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=HU

The country profile (valid as of December 2015) provides detailed information on the responsibilities of the CAs under normal circumstances and a brief description of their activities in the event of a disease outbreak.

An audit from the Directorate General for Health and Food Safety covering the area of contingency planning for exotic animal diseases, including, and focusing in particular on avian influenza, was carried out in Hungary in September 2015 (hereafter, the previous audit). The report of that audit (ref.: DG(SANTE)/2015-7568 – MR Final) is published on the Website mentioned above at:


The outcome of the previous audit highlighted a number of important deficiencies and weaknesses in the animal health emergency preparedness system in place in Hungary. That included, in particular, the inadequacy of contingency plans, the inadequacy of arrangements for animal depopulation and disposal of carcases in the event of large disease outbreaks, and the lack of sufficient expertise to perform a proper epidemiological evaluation of the disease situation and to adapt control measures accordingly.

This audit is not intended to specifically follow-up the actions taken by the CA to address the recommendations made after that previous audit, as the scope of the latter covered more diseases than avian influenza. Nevertheless, taking into account that some of those actions should have enhanced the preparedness of the CA to respond to outbreaks of HPAI; the effectiveness of their application has been evaluated, as appropriate, in chapter 5 here below.

4.3 HPAI IN HUNGARY IN 2016/17

The first outbreak of HPAI affecting poultry in Hungary was confirmed on 3 November 2016 in a commercial poultry holding keeping turkeys. The presence of the disease in the country had been detected in wild birds earlier, as infection with an H5N8 HPAI virus subtype had been confirmed in a mute swan on 26 October. The disease progressed rapidly and by the end of 2016 there had been 219 confirmed outbreaks of HPAI; another 21 happened in 2017 up until the last one was confirmed on 21 April. In brief, some of the descriptive features of this epidemic were:
• The epidemic affected mainly three counties; Bács-Kiskun, Csongrád and Békés, as they accounted for 184, 29 and 13 of the outbreaks, respectively.

• Out of the 240 outbreaks confirmed, 199 happened in commercial poultry holdings (out of which, 186 keeping domestic waterfowl and six keeping turkeys), and 41 in backyard holdings.

• In excess of 2.6 million poultry were killed during the epidemic; 600,000 as part of preventive killing initiatives in holdings and areas considered at risk (approximately 25% of them turned out to be in an infected asymptomatic poultry holding).

The maps here below, as provided by the CCA; show the geographical spread of the epidemic and the clustering of the outbreaks in the most affected counties mentioned above:

The European Commission and the other Member States have been kept regularly informed of the evolution of the situation with regard to HPAI in Hungary through regular presentations made at the section on animal health and welfare of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). The last update was provided during a meeting held on 17 January 2017. The presentation can be viewed at:


Besides, an EU Veterinary Emergency Team visited Hungary between 19 and 21 December 2016 in order to evaluate the epidemiological situation and to provide technical assistance and disease control advice to the Hungarian CA. The outcome of that visit was presented to the PAFF Committee also on 17 January 2017 and it can be accessed through the following link:

5. FINDINGS AND CONCLUSIONS

Legal requirements

The legal requirements applicable to the findings included in each chapter, as related to the provisions and measures specific for the control of avian influenza that have been evaluated, are listed on the Appendix to this report.

In addition, the general and specific legal requirements listed here below, which are also applicable within the scope of this audit, are laid down in Annex 1, and referred to in the findings, as appropriate:

- General requirements on official controls performed to ensure the verification of compliance with animal health and animal welfare rules laid down in Regulation (EC) No 882/2004, in particular, specific provisions on availability and applicability of contingency plans laid down in Article 4 (2)(f).

5.1 APPLICATION OF CONTROL MEASURES FOR HPAI

5.1.1 Early detection, handling of suspicion and confirmation of HPAI

5.1.1.1 Detection and notification of avian influenza – Handling of suspicion

1. Avian influenza is a compulsorily notifiable disease in Hungary in accordance with Annex V to Council Directive 2009/158/EC. Despite increased levels of alertness throughout the EU on the high risk of infection of poultry from wild birds with the H5N8 avian influenza virus subtype; at the time of the first outbreak in Hungary (at the end of October 2016), awareness in that respect amongst the industry (e.g. farmers, feed industry, private laboratories, private veterinary practitioners) was very low. At this particular time, the situation could not be considered in compliance with the early detection measures set out in Article 1 (1) (a) of Directive 2005/94/EC.

2. The suspicion of the first outbreak was notified to the CA, officially investigated, and eventually confirmed; only several days after the increasing mortality rate amongst the affected turkey flock had started. In the interim and despite the daily increment in the animals reported dead and the non-response to any treatment initiated; the CA were not involved in the preliminary investigations pursued to exclude the presence of other possible causes for the problem. That cannot be considered in compliance with requirements on notification of avian influenza laid down in Article 5 of Directive 2005/94/EC or in line with the guidelines on how to approach a suspicion of avian
influenza laid down in Chapter III of the EU Diagnostic Manual.

3. Immediately after the first outbreak the CA intensified their communication campaigns to ensure that further suspicions of HPAI would be notified immediately. The audit team could evaluate the organisation of those campaigns, which covered a very wide scope of stakeholders (e.g. poultry keepers at all levels, the feed and food industry, highly integrated poultry organisations and the general public) and tailored the information, the messages conveyed and the mechanisms to do that, to the particularities of each of them (e.g. leaflets describing the disease and biosecurity measures to prevent it, press releases, radio and TV reports and very elaborated information available in specially dedicated Webpages).

4. According to the representatives of the CA, that intensified and continuous communication effort paid dividends, as during the following weeks and months, the rate and speed of notification increased dramatically. Therefore, despite the deficiencies present at the beginning of the epidemic; the communication and awareness initiatives set out by the CA in response to it – which remained in place once the epidemic was finished –, can be considered in line with requirements laid down in Article 5 of Commission Implementing Decision (EU) 2017/263.

5. However, while most of the suspicions that occurred after the problems experienced with the investigation of the first HPAI outbreak in October 2016 were investigated earlier and better – usually in accordance with the guidelines laid down in Chapter IV of the EU Diagnostic Manual – delays in confirming cases – some of which had not even been communicated initially to the county CA as suspicions – still happened during the period where the majority of the outbreaks were detected (November 2016 to January 2017). This deficiency cannot be considered in compliance with Article 7 of Directive 2005/94/EC.

6. As a result of the delays mentioned above, measures applied on the relevant suspected holdings were not necessarily in place (at least, their application was not documented) from the moment of the suspicion to the day when the presence of HPAI was confirmed. This is not in line with requirements laid down in Article 9 to Directive 2005/94/EC.

7. Representatives of the CA met advised the audit team that one of the major lessons learned from the epidemic was that they had identified the main affected geographical areas – intensely populated with domestic waterfowl and turkey flocks – as high risk areas for the incursion and further transmission of HPAI viruses in Hungary. In addition to the intensified awareness campaigns mentioned in previous points; the CA have introduced other measures in those areas to reinforce surveillance for early detection of avian influenza in poultry holdings, such as more frequent on-the-spot inspections and sampling protocols. This is in line with Article 7 of Commission Implementing Decision (EU) 2017/263.
8. Official veterinarians of the county CA are responsible for performing the epidemiological inquiries related to the suspicion or confirmation of HPAI. They have generic questionnaires available for those purposes to facilitate their recording of the relevant information and the official veterinarians met by the audit team in the visited counties were well aware of them and had used them during the recent disease outbreaks as required in accordance with Article 6 of Directive 2005/94/EC.

9. The contingency plan for avian influenza available to the CA in October 2016 laid down general practical arrangements to address a suspicion of HPAI, but it had not been properly updated after the previous audit to add specific guidance to tailor epidemiological investigations to the specific nature of HPAI suspicions and outbreaks. Nevertheless, the information gathered in most of the cases studied by the audit team covered important aspects in line with Article 6 of Directive 2005/94/EC, such as:

- The possible length of time during which the disease could have been present in the holding and, in most cases, although rarely justified with documentary evidence; the inquiries had concluded that the infection could have originated as a result of direct or indirect contact with wild birds.
- Details on all animal movements that had occurred within that approximate time, and also details on other factors that could have contributed to the transmission of the disease (means of transport, feed, human visits, etc.). Related to that, in all cases information had been gathered on possible contact holdings that needed to be further investigated.

10. When HPAI was suspected in holdings with abnormal morbidity and mortality rates; the presence of clinical sings in most of them was quite obvious, and the suspicions were in general confirmed promptly once the samples were collected and sent to the national reference laboratory (NRL) for avian influenza (see though chapter 5.1.1.1 on delays in this context). Therefore, the CA did not consider necessary to take more samples from the poultry present in those holdings to further confirm the presence of the disease, as they always decided that the entire holdings were going to be killed as a matter of urgency in response to the outbreak. This can be considered in line with provisions laid down in Article 10 (3) of Directive 2005/94/EC.

11. Many of the outbreaks occurred in areas with a high density of poultry holdings, but the conclusions of the epidemiological inquiries rarely considered the possibility that an outbreak could have been the result of a secondary transmission from a previous one. In many of the cases checked by the audit team, possible factors such as the air transmission of the HPAI virus due to the proximity of other affected holdings (which had not been depopulated quickly enough), or the several fomites that could have facilitated that (e.g. feed trucks, crews of workers helping to collect waterfowl to be transported elsewhere for the force-feeding, etc.), had not been properly investigated at the time of suspicion when the preliminary epidemiological inquiry had to be carried
12. As a result of the deficient performance of those initial investigations, the relevant county CA, or the local disease control centres (LDCCs), once established, did not get adequate information to perform a risk analysis and be in a position to quickly introduce temporary restrictions in a defined area to reduce the risks of further transmission of the disease via live poultry or the other many possible contributing factors. This was exacerbated in a number of cases by the slow investigation of the suspicions (see 5.1.1.1) and setting out of protection and surveillance zones once the disease had been confirmed (see 5.1.3). This cannot be considered in line with requirements laid down in Article 10 (1) and (2) of Directive 2005/94/EC.

5.1.1.3 Handling of confirmation – Derogations

13. Procedures to confirm the presence of HPAI have followed the requirements and criteria laid down in point 4 of Chapter I of the EU Diagnostic Manual, in particular the combination of detecting clinical sings in the affected poultry and specific genetic material in the samples taken in the suspected holdings from organs and tissues of dead poultry.

14. Once the presence of HPAI was confirmed, the priority for the county CA was to kill all poultry present in the affected holdings under official supervision. However, problems encountered with regard to the application of adequate animal depopulation methods (see 5.1.4.1) and to the availability of sufficient transportation and carcass disposal capacity (see 5.1.4.2), let alone the difficulties deriving from the harsh weather in the middle of the winter; caused delays in doing that. The CA did not apply any derogation in this respect in any of the affected holdings. This is only partly in line with Article 11 (1) to (3) of Directive 2005/94/EC.

15. When appropriate, in accordance with the information gathered during the epidemiological inquiry; the CA carried out traceability investigations to find live poultry (for instance, after an outbreak in a holding with a hatchery), poultry meat and eggs collected or obtained from the affected holdings during the period between the probable date of introduction of HPAI on the holding and the application of movement restrictions as a result of the suspicion.

16. The audit team could check some of those cases. In relation to poultry originating from a hatchery that was part of an affected epidemiological unit; the comprehensive records available showed that no consignments had been dispatched during that high risk period. In the few cases when traced meat or eggs were still available, they had been disposed of under official supervision. These measures were applied in accordance with Article 11 (4) and (5) of Directive 2005/94/EC.

17. Despite the delays mentioned above, notably in this case as a result of the very bad weather conditions (e.g. preventing the use of disinfectants due to freezing temperatures), but also due to insufficient knowledge about how to inactivate the HPAI
virus in some materials (e.g. uncertain effectiveness of a period of 60 days to achieve that in stacked feed); the CA made significant efforts to comply with Article 11 (6) and (7) of Directive 2005/94/EC in order to dispose of and disinfect, as appropriate, all substances bearing any risk related to the transmission of the HPAI virus, in particular feed, manure and bedding.

18. During the HPAI epidemic in Hungary, the CA did not grant any of the derogations contemplated by Articles 12, 13 and 14 of Directive 2005/94/EC.

5.1.1.4 Contact holdings – Specific measures

19. In some cases, as a result of the information collected during the epidemiological inquiries or due to the high density of poultry holdings in some of the affected areas, the county CA identified potential contact holdings that could have a high risk of having been infected by the HPAI virus. In those cases where a direct contact with an affected holding had been identified, contact holdings were immediately considered as suspect cases and official veterinarians proceeded to visit them and to carry out production checks and clinical inspections of the poultry kept. In addition, and regardless of the outcome of those checks, the CA always collected samples to exclude the presence of the HPAI virus. These measures were applied in accordance with the EU Diagnostic Manual (point 8.5 of Chapter IV).

20. In most cases the results of those investigations were negative, and the CA opted for keeping the poultry in those holdings alive, and under official surveillance, as appropriate taking into account the expected incubation period of the disease (when a direct contact with an affected holding was suspected or had been confirmed) and the level of risk present in the geographical area involved (to ensure early detection of the disease when there was a high risk of transmission at local level). Those measures were applied in accordance with Article 15 of, and Annex IV to Directive 2005/94/EC.
Conclusions on early detection, handling of suspicion and confirmation of HPAI

21. The significant underperformance of the early detection system for HPAI during the first months of the epidemic – in particular the insufficient awareness about the importance of a quick notification of the early signs of the disease, and the delayed official investigation and response to disease suspicions and confirmations, respectively – quite likely contributed to exacerbate the risks of transmission of the disease in the affected geographical areas and to slow down its eradication.

22. Once the CA acknowledged and addressed those deficiencies with intensive and well-tailored communication campaigns, and with a quicker investigation of disease suspicions and management of affected holdings; the increase in notification rates and the prompt official response thereto, finally contributed to accelerate eradication of HPAI.

23. As the HPAI epidemic evolved, the timely performance of epidemiological investigations in case of suspicion and confirmation of HPAI got better, which contributed to improve the effectiveness of disease control measures in the affected areas, in particular by identifying contact holdings bearing a high risk of being infected.

24. In general, the response of the CA to the confirmation of HPAI outbreaks tried to prioritise the quick depopulation of the infected flocks and epidemiological units, while not granting any derogation in that respect; although it could not be applied always as planned. Considerable uncertainty remains in relation to the effectiveness – or lack of – of this approach to facilitate the mitigation of the risks of transmission of HPAI at local level and to other holdings in the country.

5.1.2 Diagnosis of avian influenza

25. The laboratory designated as the NRL for avian influenza is the only laboratory involved in the diagnosis of the disease in Hungary; therefore, most of the diagnosis coordinating responsibilities laid down in Annex VIII to Directive 2005/94/EC are not applicable in this case. The NRL maintained close and regular cooperation with the EU reference laboratory for avian influenza during the HPAI epidemic in Hungary. This is in compliance with requirements laid down in Article 51 of Directive 2005/94/EC.

26. The NRL uses validated and fit-for-purpose tests for the diagnosis of avian influenza which have been accredited according to norm ISO/EN 17025 and operates in accordance with appropriate biosecurity standards to prevent the spread of the avian influenza viruses they manipulate. In all cases, the diagnostic techniques used by the NRL for the diagnosis of avian influenza have been validated either by the EU reference laboratory or by internal validation procedures carried out in accordance with appropriate international standards.

27. Well updated standard operating procedures were in place for the relevant tests in the context of the quality management system set up in the NRL. Those procedures follow the provisions laid down in the EU Diagnostic Manual for avian influenza (e.g. point 3
of Chapter IV, points 3 and 4 of Chapter V, and Chapter VI), and in other relevant EU – as set out by the EU reference laboratory – and international standards, as appropriate. This is in line with requirements laid down in Article 50 of Directive 2005/94/EC.

28. The NRL participates regularly with satisfactory results in inter-laboratory comparison tests organised by the EU reference laboratory for avian influenza.

29. The NRL opted for the adequate strategy for testing for, and diagnosis of avian influenza, according to the situation under investigation; e.g. a suspect case, serological tests related to application of derogations, etc. This effective approach, which is in line with provisions laid down in Chapter X of the EU Diagnostic Manual, provided the county CA with quick results when suspicions of avian influenza were under investigation, which prevented that delays in applying disease control and eradication measures could be attributed to this activity.

30. In addition, the NRL made a considerable testing effort to accommodate the many and frequent requests with regard to samples that have to be collected when derogations to movement restrictions of poultry in protection and surveillance zones were going to be applied (see chapter 5.1.3.4).

31. The NRL had sufficient technical capability to perform very advanced genetic studies of the avian influenza viruses isolated during the HPAI outbreaks as required by the EU Diagnostic Manual (point 4 (c) of Chapter V, and Chapter VI). Nevertheless, they submitted several of those virus isolates, including the one from the index case, to the EU reference laboratory for avian influenza. This is in line with requirements laid down in Article 11 (10) of Directive 2005/94/EC and in the said Manual.

Conclusions on diagnosis of avian influenza

32. The high diagnostic standards provided by the laboratory designated for diagnosis of avian influenza represent a fundamental pillar of the preparedness and early response system set up by the CA to quickly detect and effectively control outbreaks of HPAI, as demonstrated by its operation during the recent epidemic of the disease.

5.1.3 General measures in relation to protection and surveillance zones

5.1.3.1 Establishment of protection and surveillance zones

33. The weaknesses described in chapter 5.1.1.1 with regard to the notification and investigation of suspect cases of HPAI, alongside shortages of sufficiently qualified staff in the county CA to perform those investigations; caused delays in the confirmation of the disease and in establishing protection and surveillance zones around the affected holdings. In some cases seen by the audit team, those delays had postponed the setting out of these zones for two to five days.

34. Once the county CA, usually with the support of the national disease control centre (NDCC) were in a position to establish the protection and surveillance zones, in general
they took into account the criteria laid down in Article 16 (3) of Directive 2005/94/EC for doing so.

35. In some of the cases checked by the audit team, notably at the beginning of the epidemic and in some counties in particular; the county CA had got limited availability of properly georeferenced information on the affected poultry holdings and on other (commercial and backyard holdings) potentially covered by those zones. Moreover, in those cases, the county CA had to establish those zones on their own, while they lacked the adequate technical equipment and software (e.g. a geographical information system) to do that. That deficiency created further delays during the first weeks of the epidemic and made difficult the accurate and wide communication of that information to all relevant stakeholders. Eventually, the NDCC took over the responsibility to assist the county CA and address properly this issue.

36. The time elapsed before the necessary restrictions were implemented, and the deficiencies mentioned above and their impact on delaying communication about those restrictions may have contributed to the transmission of the disease at local level and further afield in the affected and in the neighbouring counties. This is not in line with requirements laid down in Articles 16 (1) and (3) and 17 of Directive 2005/94/EC.

37. When the establishment of protection and surveillance zones in response to some outbreaks in the south and southeast of the country covered the territory of neighbouring countries; e.g. Romania and Serbia; the CCA of those countries were properly informed in order to get their cooperation with regard to the application of restrictions in those zones. This is in line with Article 16 (5) of Directive 2005/94/EC.

38. The intensified communication measures introduced by the CA in response to the increasing impact of the epidemic (see 5.1.1.1) – which further targeted poultry keepers in protection and surveillance zones – included adequate advice on the biosecurity measures that should be applied to prevent the introduction of the disease. Nevertheless, the CA kept that as advisory material during the height of the epidemic, and did not opt for making compliance with those additional measures mandatory – as proposed by Article 34 of Directive 2005/94/EC to prevent the spread of avian influenza – until February 2017, when that was done for commercial poultry holdings (see chapter 5.1.7).

5.1.3.2 Application of measures in protection and surveillance zones

39. Considerable efforts were made by the county CA to apply the necessary measures in protection and surveillance zones in accordance with Articles 18 and 30 of Directive 2005/94/EC, but the shortage of adequately trained official staff to do that caused important delays in their implementation. The main impact of those delays affected the performance of:

- An updated census of backyard holdings keeping poultry in both types of zones.
- Visits to commercial holdings situated within the protection zones, which often could not be carried out within reasonable deadlines, or at all.
• The necessary disease surveillance activities required by the EU Diagnostic Manual in protection zones (points 8.6. and 8.7 of Chapter IV), which were not properly applied in many cases.

40. All the county CA met by the audit team had set out the necessary administrative provisions related to HPAI outbreaks that would enable them to check application of those measures, but those provisions were very often set out quite late. In addition, the communication mechanisms necessary to ensure that all relevant holdings were made aware of, and applied them, were usually further delayed; while there was little evidence proving that those holdings had actually got that information.

41. The application of on-the-spot inspections on poultry holdings to verify application of those provisions and the health status of their poultry – notably as required to all of those within protection zones – were, at the very least, delayed, and often, in special for backyard holdings and in areas with a high density of poultry; not carried out in most of them.

42. The CA did carry out sampling activities in holdings that were part of preventive culling activities (see 5.1.3.3) and also carried out investigations in some cases where increased morbidity and mortality had been reported. Those cases were investigated in accordance with the EU Diagnostic Manual (points 8.6, 8.7 and 8.12 of Chapter IV, as appropriate for the situation in the holding and for the zone involved) and sometimes confirmed as new cases. The results in nearly 25% of the holdings sampled as part of the preventive culling initiative turned out to be positive, while in most cases the clinical symptoms of the disease had not appeared yet.

43. Save for those specific cases mentioned in the previous point, in general, the audit team could see little, if any evidence of how the on-the-spot inspections required for other holdings had verified that all the measures covered by Articles 19, 20 and 30 of Directive 2005/94/EC were properly applied.

44. Adequate measures (e.g. intensified road checks and inspections on food business operators) were taken to enforce compliance with restrictions on unauthorised movements of live poultry and poultry commodities within, between, and from both types of zones, as required by provisions laid down in Articles 22 and 30 of Directive 2005/94/EC.

45. Upon confirmation of an HPAI outbreak and establishment of the protection and surveillance zones, the county CA had prohibited within both types of zones the organisation of fairs, markets and other similar poultry gatherings, as well as the release of game birds for restocking purposes. This was done in compliance with Articles 21 and 30 of Directive 2005/94/EC.

5.1.3.3 Further restricted zones

46. As the HPAI epidemic progressed, in particular in the most affected county ( Bács-Kiskun), but also in counties Csongrád and Békés during certain moments of the
epidemic; the NDCC in cooperation with the county CA established wider restricted zones in the affected areas as a result of the overlapping of several surveillance, mainly, but also protection zones between those counties (see the pictures in chapter 4.3).

47. The objective of that approach was to harmonise the application of control and restriction measures – applied in the wider protection and surveillance zones, as appropriate, as described in chapter 5.1.3.2 – and to facilitate the eventual lifting of restrictions at the same time in the whole area considered. The establishment of these further restricted zones was done in accordance with provisions laid down in Article 16 (4) of Directive 2005/94/EC.

48. The CA decided to implement specific additional measures, notably preventive culling, in the further restricted zones as provided for in Article 32 (2) of, and taking into account the criteria laid down in Annex IV to Directive 2005/94/EC. Preventive culling was applied in the one kilometre areas surrounding affected holdings and it represented more than 25% of the animals culled during the epidemic. As mentioned in chapter 5.1.3.2, this policy also contributed to the early detection of new outbreaks.

5.1.3.4 Derogations to measures applied in protection and surveillance zones

49. All along the epidemic of HPAI, the county CA prioritised the dedication of available human resources to apply preventive measures to ensure that movements of hatching eggs, day-old-chicks and other live poultry did not cause any risk of transmission of avian influenza within Hungary.

50. Given the high density of holdings present in the affected geographical areas, and the duration in many cases of the restrictions imposed; the CA opted for facilitating the continuation of business activities as much as possible and ensuring compliance with animal welfare requirements related to poultry production. Nevertheless, in doing that, they tried to mitigate the risks related to the disease taking into account the options contemplated by EU legislation to derogate from those restrictions.

51. The CCA laid down detailed conditions and rules for the application of those derogations, as required by Article 33 of Directive 2005/94/EC, but prioritisation of those activities had as a consequence that the application of disease control and eradication measures in suspected and confirmed outbreaks in the same counties were often delayed. The main reason for that was that the available personnel had to frequently visit holdings intending to move animals in order to inspect them and take the relevant samples, as appropriate in accordance with the EU Diagnostic Manual.

52. In the particular epidemiological context of the HPAI epidemic in Hungary, the prioritisation of this approach was done without a proper prior definition of the arrangements under which the derogations might be granted; e.g. only when personnel was not needed for other purposes, and without performing a proper risk assessment on which to base that application; e.g. taking into account the demands associated with the clustering in time and space of new outbreaks in some of the affected counties. This
cannot be considered in line with requirements laid down in Article 33 (1) of Directive 2005/94/EC.

53. The audit team could check comprehensive data on the movements that took place and could study examples of the derogations granted in all the visited counties. Those movements took place from – or between – areas under restriction (the immense majority, with involvement of holdings from surveillance zones), mostly to slaughterhouses, but also to facilitate the transport of hatching eggs from parent flocks to hatcheries, and of day-old-chicks from those to other holdings.

54. All the examples checked showed that on-the-spot inspections had been carried out, samples had been taken and tested before the movements were authorised, and adequate risk management measures had been applied in line with Articles 23 to 26 of Directive 2005/94/EC and, as appropriate, with the provisions laid down in Chapter IV (points 8.8. and 8.10) of the EU Diagnostic Manual.

Conclusions on general measures in relation to protection and surveillance zones

55. The delayed establishment of, and, often, inadequate application of some restriction measures and disease surveillance activities in the protection and surveillance zones resulting from the confirmation of HPAI outbreaks, are certainly in contradiction with the necessary deployment of an early response to mitigate the risks of disease transmission associated to these situations. Besides, those deficiencies have quite likely contributed, notably at the beginning of the epidemic, to the fast and wide spread of the HPAI epidemic in the most affected geographical areas.

56. The decision taken by the CCA to apply preventive culling targeted to high risk areas surrounding large affected holdings, while accelerating the detection of infected holdings, contributed significantly to reduce the speed of transmission of HPAI in areas with a high density of poultry, in particular where highly susceptible species such as turkeys were present.

57. The significant efforts made by the CA to exclude the presence of risks of infection associated with derogated movements of poultry commodities within and from restricted zones have effectively prevented endangering disease control in the geographical areas involved in those activities. However, prioritisation of that option without a proper risk analysis is highly questionable from the disease management point of view while other fundamental control measures were simultaneously neglected in the midst of a serious and gradually worsening animal health crisis.

5.1.4 Animal depopulation for the purpose of disease control

5.1.4.1 Animal welfare considerations

58. As mentioned in chapter 5.1.1.3, the NDCC and the county CA considered a priority the quick depopulation of infected holdings. However, the CA had not anticipated in their
contingency plans (at national or county level) the situation they confronted with the evolution of this HPAI epidemic in areas with a high density of poultry with numerous holdings keeping domestic waterfowl. As a consequence, their preparedness to cope with the challenges related to the need to kill without delay a high number of those animals, while respecting EU requirements on animal welfare, was inadequate. This had been one of the main deficiencies identified by the Commission services during the previous audit, and little if any progress was noted in relation to addressing it.

59. The CCA had undertaken in response to the recommendations of the previous audit to widen the level of competence and the technical capabilities of staff available to the LDCCs to perform the tasks related to animal depopulation factoring in the relevant animal welfare requirements laid down in Regulation (EC) No 1099/2009. However, little attention had been paid to that during 2016.

60. The generic national guidance on animal depopulation for disease control purposes that had been drafted in 2015, which the county CA have to use to develop action plans in line with the requirements of Article 18 of Regulation (EC) No 1099/2009; had not been incorporated yet to the generic contingency plan available to respond to animal health crises at the time of the HPAI epidemic. The chapter of that contingency plan incorporating those preparatory arrangements was still under revision at the time of this audit. Nevertheless, progress had been made in that respect after the HPAI epidemic, and a nearly finished version had already incorporated the experience from it and taken into account comments and suggestions from the county CA.

61. In the main affected counties, official veterinarians conceded that they had had many difficulties to deploy sufficiently trained staff to apply depopulation measures. As a result of that, delays occurred in that respect and adherence to the relevant animal welfare requirements could not be guaranteed during the height of the epidemic. As an example, the audit team could confirm that action plans for the specific killing activities carried out in most of the affected holdings were not drawn up in line with provisions of Article 18 (2) of Regulation (EC) No 1099/2009.

62. The competent authorities did not have adequate plans for alternative killing options in case they had to derogate from EU requirements as a result of the exceptional animal health circumstances in accordance with provisions envisaged in Article 18 (3) of Regulation (EC) No 1099/2009.

63. The killing method used (dry ice – carbon dioxide at high concentration) is not one of the methods listed for domestic waterfowl in Annex I to Regulation (EC) No 1099/2009 (or in the national guidance), which is not in line with requirements laid down in Article 18 (1) of the said Regulation. According to the CA, this method was the only practical alternative that they found given the bad weather conditions and, mainly, the evolution and size of the epidemic. However, its use was chosen:

- Without having sufficient experience with regard to its key using parameters and estimated maximum kill rates in those species, and, consequently, ignoring its
possible impact on the animals.

- Not having suitable standard operating procedures for that use, while not being in a position to ensure that situations to be avoided in line with requirements laid down in Chapter II (point 8) of the said Annex were properly monitored.

5.1.4.2 Disposal of carcasses

64. The contingency plan for avian influenza indicates that the method of choice for disposal of carcasses in the event of an outbreak should be sending them to ABP processing plants approved in accordance with Regulation (EC) No 1069/2009. Rules for disposal of poultry killed for disease control purposes in the event of HPAI outbreaks in Hungary include the identification of the ABP plant that can be used for that purpose. Besides, the NDCC has the legal powers to require the use of the available capacity in other authorised ABP processing plants to facilitate the eradication of the disease, but that option was not taken during the HPAI epidemic.

65. The CCA informed the audit team that during the HPAI epidemic they did not consider the possibility to resort to burning or burial of carcasses from large commercial holdings, as those methods of disposal would only be used in very exceptional circumstances, or for very small holdings, as it was done in some cases this time. Although there was a potential high risk of spreading the disease at the height of the epidemic with the transport of infected carcases, given the number of affected holdings and the density of poultry in the affected areas; the NDCC did not opt for either of those options.

66. Despite the undertakings provided by the CCA during the previous audit, at the time of the HPAI epidemic, no progress had yet been made with regard to the evaluation of the overcapacity available in the ABP processing plants operating in Hungary, or to setting up arrangements for the up-scaling of their activities. Preliminary agreements with the ABP plant chosen for this purpose were in place so that mobilisation of all available rendering and incineration capacity in the event of a large disease outbreak would be ensured; but that proved to be insufficient to cope with the size of the HPAI epidemic.

67. As a result of those deficiencies, the preparatory steps that had been taken to ensure that sufficient carcass disposal would be available in the event of a major animal health crisis, like the one confronted during the recent HPAI epidemic, were inadequate to ensure compliance with requirements laid down in Article 11 (2) and (3) of, and in point 6 of Annex X to Directive 2005/94/EC.
Conclusions on animal depopulation for the purpose of disease control

68. Inadequate preparatory measures had been taken to ensure that animal welfare requirements would be complied with when animal depopulation had to be used for disease control purposes in the poultry species most likely affected in the geographical areas involved in the HPAI epidemic. Consequently, those poultry were not effectively spared of unnecessary pain, suffering and distress. The main causes for that were a shortage of properly trained personnel, the lack of standard operating procedures fit for purpose according to the killing methods that may be used in that situation, and the insufficient attention paid to prepare action plans tailored to the depopulation activities to be carried out.

69. Although some preparatory steps had been taken to make arrangements for the disposal of animal carcases in the event of a disease outbreak in Hungary, these were largely insufficient to ensure that the available capacity and its timely deployment could match the demands of the recent HPAI epidemic. As a consequence, delays in the application of animal depopulation for disease control purposes occurred, in particular in large poultry holdings and high densely populated areas; which is usually a major contributing factor to the spread of infection in those high risk environments.

5.1.5 Cleaning and disinfection

70. Since the HPAI epidemic stretched over to the middle of the 2016-17 winter, the county CA experienced considerable difficulties to apply cleaning and disinfection measures in the affected holdings and, even more, to quickly and properly treat and dispose of manure, slurry and bedding under freezing conditions. Despite that, and although delays occurred in a number of cases; the CA demonstrated a good level of preparedness in this respect – as anticipated in the relevant arrangements made for contingency planning – and proper equipment was available to perform those tasks. There was no evidence that those control measures were not applied effectively; e.g. no reoccurrence of the disease was found in any of the holdings previously affected and where cleaning and disinfection measures had been applied.

71. In the majority of cases, those activities were applied as swiftly as possible and in line with requirements laid down in Article 48 of Directive 2005/94/EC. In the cases checked by the audit team, those activities were always applied under official supervision, using disinfectants authorised by them, and in accordance with the general and specific principles and procedures laid down in Annex VI to the said Directive, including proper documenting of their implementation.
Conclusions on cleaning and disinfection

72. Application of cleaning and disinfection measures was done as adequately and quickly as possible given the weather constraints faced by the CA and, according to the epidemiological evidence presented by them; it did contribute as envisaged to eliminate the risks of residual infection at local level and of disease transmission in wider areas.

5.1.6 Lifting of restrictions

73. As indicated in chapter 5.1.3.3, in most of the geographical areas affected by the HPAI epidemic there was a frequent overlapping of protection and surveillance zones resulting from the gradual detection of more and more outbreaks up until January 2017. As a result of that, the CA approach with regard to the evaluation of the situation before deciding on lifting restrictions in those zones was to wait until that could be done in the whole wider affected area at the same time. Therefore, for many affected holdings the duration of the restrictions was longer than the minimum periods laid down in Articles 29 and 31 of Directive 2005/94/EC.

74. Restrictions were lifted always after an appropriate period of time had elapsed after cleaning and disinfection measures had been applied in accordance with Articles 29 and 31 of Directive 2005/94/EC. However, as mentioned in chapter 5.1.3.2, in numerous cases the holding inspections and surveillance activities that have to be applied in protection zones before restrictions can be lifted in accordance with Article 29 (1) of the said Directive, and point 8.11 of Chapter IV of the EU Diagnostic Manual, had not been carried out, or were not properly documented; i.e. there was insufficient evidence that they had been done.

Conclusions on lifting of restrictions

75. The CA opted for a very prudent approach in relation to the lifting of restrictions in the affected holdings and wider restricted zones which, owing to its duration – longer than usual –, and despite insufficient epidemiological evidence in some cases to convincingly prove absence of virus circulation; quite likely contributed to prevent the further spread of the disease to other areas of the country.

5.1.7 Re-population of affected holdings

76. After lifting restrictions in accordance with EU legislation once the outbreaks had been controlled, repopulation activities were carried out incorporating additional requirements conducive to reducing animal density and enhancing biosecurity measures, in particular in holdings keeping domestic waterfowl. Those measures were incorporated in February 2017 via a specific Order of the Chief Veterinary Officer laying down detailed operational arrangements and biosecurity measures, whose adherence to became compulsory and had to be closely monitored by the county CA.

77. The county CA met considered this approach one of the main lessons learnt from the
epidemic; i.e. the need to reduce the size of those holdings so that poultry could be kept indoors to prevent their exposure to the risks of avian influenza deriving from the presence of wild birds, and to upgrade the biosecurity measures applied in those holdings to further mitigate those risks and those related to the transmission of diseases in general. These risk mitigation measures properly address the requirements laid down in Articles 4 and 5 of Decision (EU) 2017/263, by targeting in particular their application to holdings keeping ducks and geese in areas considered at high risk of infection with avian influenza.

78. Further to that, the CCA set out an official control programme to verify that all new holdings can comply with those new measures before they are granted an authorisation to initiate their activities, and that includes annual checks on the holdings already in operation to verify that they keep complying with them. The audit team saw examples of those checks and of the actions taken by some of the county CA to correct the deficiencies found, and even to close down some holdings situated in a high density area that could not upgrade their activities to cope with the new requirements.

79. In addition to the measures mentioned above, the county CA applied in re-populated holdings the measures required by Article 49 of Directive 2005/94/EC, in particular the specific on-the-spot inspections, and the strict sampling regime required by the EU Diagnostic Manual (point 8.22 of Chapter IV), in particular in the holdings keeping domestic waterfowl; i.e. cloacal and tracheal swaps.

Conclusions on repopulation of affected holdings

80. The measures taken in relation to repopulation of holdings in the geographical areas affected by the HPAI epidemic, besides paying proper attention to exclude the presence of residual infection; represent a very positive step forward to enhance disease prevention and encourage effective application of tailored biosecurity measures in the most susceptible poultry species and holdings, in particular in high densely populated production areas. This should contribute significantly to prevent the reoccurrence of disease episodes like the one experienced in 2016-17.

5.2 OPERATION OF THE ANIMAL HEALTH EMERGENCY PREPAREDNESS SYSTEM – APPLICATION OF THE SPECIFIC CONTINGENCY PLAN

5.2.1 Contingency plan – Availability, drawing up and regular updating

81. A national contingency plan for avian influenza was already in place at the time of the previous audit; however, the CCA had not complied with EU legal requirements in relation to the need to update it regularly (it had been last updated in 2006). In response to a specific recommendation contained in the report of that audit, the CCA had informed the Commission services that they had plans to finish with that update during 2016.

82. The CCA informed the audit team that, up until they confronted the recent epidemic,
updating of the contingency plan for avian influenza had not been prioritised, unlike the one for African swine fever, which is considered a major threat for the pig industry in Hungary. In addition, they stressed the fact that during 2016 they had experienced a shortage of suitable human resources to perform that task and, later on, the eradication of the disease was the main priority rather than drawing up a new plan.

83. Despite some good steps taken in the good direction to improve the operation of the national animal disease emergency preparedness system; the fact that the specific national contingency plan for avian influenza has not been properly updated for more than 10 years – and not yet after the lessons learnt from the recent epidemic – is not in line with requirements laid down in Article 62 of Directive 2005/94/EC.

84. The contingency plan is still available on the CCA official webpage for its use by all staff of the county CA and to be consulted by the general public. As it was the case in 2015, the visited county CA had developed their own contingency plans following the principles and measures contained in the national plan.

- Those plans had been adapted to the local conditions, in particular as regards the structure and composition of the LDCCs, and the allocation of staff responsibilities and tasks, but they had not been updated either, as the county CA were waiting for the development of the new generic national contingency plan before doing so.
- The CCA informed the audit team that no specific verification activity has been carried out on the county CA after the audit carried out in 2015 in order to evaluate the suitability of their contingency plans for avian influenza.

85. As a consequence, at the time of the recent epidemic; the CCA was still not aware of the suitability and applicability of those plans. This is not in line with EU requirements for the preparation of a contingency plan for avian influenza (Annex X to Directive 2005/94/EC) and with provisions laid down in Article 4 (2)(f) of Regulation (EC) No 882/2004.

5.2.2 Registration of poultry holdings – Areas with high density of poultry

86. The CA had taken adequate measures to register – and approve when appropriate – all relevant poultry holdings in accordance with Article 7 of Directive 2009/158/EC and with additional requirements laid down in the body of EU legislation related to control of salmonella, namely for those keeping breeding animals, laying hens, broilers and turkeys (see footnote 5 in the Appendix to this report).

87. In doing that the CA have gathered appropriate information to:

- Make available to all relevant CA information on their location, and the number and species of poultry present in those holdings, as required by Articles 10 (1), 15 (2) and 62 (2) of, and points 10 and 12 of Annex X to Directive 2005/94/EC, in particular to facilitate the identification of areas with a high density of poultry.
- Facilitate the performance of the risk analyses provided for in Annex IV to the said
Directive and in Chapter X of the EU Diagnostic Manual.

- Contribute to the identification of high risk areas for the introduction of HPAI viruses, as required by criteria laid down in Article 3 (c)(i) and (ii) of Decision 2017/263.

5.2.3 Operation of the NDCC / LDCCs – Information management tools and data analysis

88. Provisions laid down in the contingency plans established that the Chief Veterinary Officer in the CCA directs the eradication of the disease through the NDCC. The NDCC directly manages the work of the LDCCs which, in cooperation with the counties and districts administrative governing entities, must coordinate the activities for the containment and eradication of the disease in the geographical area under the responsibility of the relevant county CA.

89. Although the specific contingency plan for avian influenza was still in the process of being updated, in the meantime, and after the most recent structural reorganisation of the CCA; they introduced new specific arrangements to streamline the operation of the NDCC in the event of a major disease outbreak. The main purpose of those changes was to provide additional help and quick advice to the county CA in order to facilitate the operation of the LDCCs by better coordinating from the national level the availability of adequate logistics, equipment and additional personnel, as appropriate.

90. According to staff of the county CA met, this additional support proved to be useful during the recent epidemic. Some of the specific examples given included: a) quick availability of more financial support, equipment and personnel, b) a more streamlined coordination of works with other CA (e.g. police, fire brigades), and c) performance of some administrative tasks, such as dealing with compensation claims.

91. In accordance with EU requirements, arrangements were in place for both the NDCC and the county CA to receive support from a group of pre-defined experts on avian influenza, mainly from the NRL and academia, but also from the CCA (e.g. on animal welfare) and the poultry industry. This group provided advice on aspects such as disease diagnosis and transmission (e.g. contributing to the decision to use preventive culling), epidemiology and crisis management, and disease prevention and biosecurity (e.g. supporting the introduction of the new measures in this respect in February 2017).

92. However, the NRL expertise in molecular epidemiology; i.e. performance of virus sequencing and phylogenetic analysis from the virus isolates they obtained from affected holdings, was not shared timely enough, or at all, with the experts and decision-makers of the NDCC or the LDCCs. This prevented the use of this valuable information for the analysis of the epidemiological evolution of the disease in the affected geographical areas (e.g. routes of transmission between holdings, etc.) and for the prioritisation of checks and additional prevention, surveillance and control activities to be carried out by those centres.
93. Further to that, the NDCC did not have a suitable information management system available that allowed the quick visualisation and analysis of the vast amount of data and information received on a daily basis from the LDCCs and from the NRL, so that the decisions taken and the actions they were recommending on a daily basis could be properly informed.

94. The deficiencies mentioned above cannot be considered in line with requirements laid down in Chapter X of the EU Diagnostic Manual on the need to provide the best available diagnostic and epidemiological evidence to the CA responsible for disease risk analysis and decision-making activities in the context of a developing epidemic like the one that occurred in Hungary.

5.2.4 Availability of human resources – Responsibilities, instructions and training

95. Staff of the CCA and of the county CA visited who were involved in the operation of the NDCC and the LDCCs in the context of the HPAI epidemic were in general capable of performing most of the associated tasks, but had been overwhelmed by the number of outbreaks and the fast evolution of the epidemiological situation.

96. As the epidemic worsened, in particular in some areas, the NDCC took the decision to allocate more temporary human resources – usually deployed from other counties – to the relevant county CA. While these personnel had generic technical qualifications to assist in the disease containment and eradication activities; according to managerial staff of the most affected counties, they had little, if any experience in dealing with animal health crises and they lacked the necessary local knowledge to contribute more effectively to manage the outbreaks. Some of them emphasised that managing this additional staff was sometimes an added burden rather than a relief.

97. Despite the recommendations provided to the CCA as a result of the previous audit, practical arrangements necessary to make operational the contingency plan did not include yet ready-to-use solutions for staff dealing with the epidemic; e.g. standardised forms and administrative documents, or standard operating procedures that have to be used within short deadlines in these situations.

98. According to representatives of all the CA met, after the difficult experiences of the HPAI epidemic, the ongoing revision of the contingency plans and of the animal health emergency preparedness system as a whole, should mean a major leap forward in relation to availability of more adequate instructions and the ready-to-use documentation mentioned in the previous point (e.g. to save time in relation to administrative arrangements, such as imposing restrictions, granting derogations, filing compensation claims, etc.), as well as to training of personnel throughout the country. The audit team could see several draft documents going in that direction that had taken into account the lessons learnt from the recent epidemic.

99. While engagement in a properly founded change in order to improve current contingency planning arrangements and training levels for official staff potentially
involved in dealing with animal health crises was already in place at the time of this audit; insufficient steps had still been taken to ensure compliance with requirements in that respect laid down in points 3, 6 and 7 of Annex X to Directive 2005/94/EC.

5.2.5 Availability of equipment and materials

100. Arrangements that had been made by the CCA and, in particular, by the affected county CA in the context of contingency planning to ensure the availability of adequate equipment to facilitate the rapid deployment of disease containment and eradication measures in the event of an exotic disease outbreak proved to be very useful for some aspects. Examples included availability of protective clothing, performance of sampling in poultry holdings, and availability of equipment for cleaning and disinfection (e.g. vehicles provided by other county CA).

101. However, gaps in relation to other areas were important, such as the insufficient anticipation of the material necessary to properly implement animal depopulation and carcass disposal (see 5.1.4.1 and 5.1.4.2). Therefore, the CA could not ensure full compliance with provisions laid down in Article 62 (2) of, and point 5 of Annex X to Directive 2005/94/EC.

5.2.6 Diagnostic capacity in case of an emergency

102. As indicated in the report of the previous audit, the NRL had developed its own laboratory contingency plan to be prepared to respond to the expected additional demands in diagnostic capacity deriving from a large HPAI outbreak.

103. The NRL provided detailed data to the audit team showing that during the recent epidemic, they kept on operating to very high technical standards, mostly providing comprehensive diagnostic services within short deadlines, while having to adapt quickly to a much higher demand than usual for their diagnostic activities. The additional diagnostic capacity provided by the NRL contributed significantly to the control of the disease and to facilitate trade of poultry commodities within Hungary. This is in line with requirements laid down in point 8 of Annex X to Directive 2005/94/EC.
## Conclusions on the application of the specific contingency plan for avian influenza

104. Contrary to the recommendations provided by the Commission services in 2015, the CCA had not given due consideration to update and render more operational the contingency plan for avian influenza before the occurrence of the HPAI epidemic. Moreover, the CCA had not fulfilled either the verification responsibilities necessary to ensure that that plan had been adapted appropriately to the local conditions present in the counties, so that all necessary resources would be available and prompt effective action can be taken to control outbreaks of the disease. The neglect of those aspects played a significant role in undermining the effectiveness of the response to, and eradication of outbreaks of HPAI.

105. The changes made during 2016 to streamline the operation of the NDCC, and its coordination with the LDCCs, have positively contributed to enhance the animal health emergency preparedness system in place in Hungary.

106. The number of properly trained staff available at county level to cope with the numerous and demanding tasks associated with the quickly worsening epidemiological situation was clearly insufficient and it had a determining impact on the difficulties experienced to cope with the HPAI epidemic.

107. The NRL for avian influenza has prepared, and applied successfully, an internal contingency plan to adapt swiftly and respond effectively to the diagnostic overcapacity resulting from the HPAI epidemic.

108. The expert group for avian influenza available to the NDCC and LDCCs – operational before, and during the recent epidemic – provided assistance, operational advice and technical expertise to the CA that speeded up the application of a more effective response to contain the spread of the disease; but it had been ineffective in ensuring that adequate levels of preparedness against these situations were in place before the recent one occurred.

109. The CA have access to largely adequate and updated information on the poultry population that enable them to identify high densely populated areas so that they can tailor disease management options according to specific risk factors usually associated to them.

110. The NDCC did not have timely access to all necessary epidemiological data to analyse the potential determinants of the evolution of the HPAI epidemic. Moreover, the data recording and information management tools available to the CA in order to deal with animal health crisis situations were not properly integrated and suitable to provide sufficient and quick epidemiological analytical support. Those deficiencies hindered both the coordination of the early response to the outbreaks and the decision-making of the NDCC and LDCCs to select and prioritise the most suitable control and eradication actions according to the evolution of the epidemic.
5.3 OFFICIAL CONTROLS ON RESTRICTIONS AND DEROGATIONS THERETO RELATED TO TRADE OF POULTRY COMMODITIES WITHIN THE EU

5.3.1 Measures on the approval of commercial poultry holdings

111. The county CA took appropriate measures to ensure that approval for intra-EU trade purposes of commercial holdings affected by HPAI outbreaks were suspended or withdrawn, as appropriate when suspicions and confirmation of the disease occurred, and restored, once restrictions were lifted, in accordance with points 1 (b), 2 (a), and (3) in Chapter IV of Annex II to Directive 2009/158/EC.

5.3.2 Implementation of restrictions on intra-EU trade and derogations thereto

112. As indicated in chapter 5.1.3.4, the county CA prioritised the application of strict official checks to comply with the necessary provisions governing granting of derogations and allowing movements of hatching eggs, day-old-chicks and other live poultry from restricted zones in order to mitigate risks of transmission of avian influenza to other parts of the country.

113. Save for some sporadic cases of poultry sent from a protection zone to be immediately slaughtered under official supervision, those movements happened from surveillance zones to other areas of Hungary not affected by HPAI that could participate in intra-EU trade; e.g. movements of hatching eggs or of day-old-chicks.

114. In those cases, the CA applied adequate disease risk management measures, such as quarantine for 21 days and surveillance for avian influenza in the holdings of destination, and ensured compliance with requirements of Article 33 (8) of Directive 2005/94/EC, and with the relevant requirements laid down in Directive 2009/158/EC (see the Appendix to this report for further details) to prevent that those commodities were marketed outside of the country.

115. During the HPAI epidemic, transport of day-old-chicks and other live poultry that were dispatched to other Member States took place from non-restricted zones of the country that, in most cases, were far from the affected geographical areas. In those cases, the CA took due account of the restrictions laid down in Article 19 of Directive 2009/158/EC to ensure that their transportation routes did not increase their risk of infection with the HPAI virus.

116. According to information provided by the CA, they have not availed of the specific provisions laid down in Article 3 (a) of Commission Implementing Decision (EU) 2017/247 that entered into force in April 2017 that govern the authorisation of dispatch to other Member States of consignments of live poultry, day-old chicks and hatching eggs from areas established as protection and surveillance zones.
6. **OVERALL CONCLUSIONS**

The Hungarian CA had neglected considerably their preparedness to respond effectively and quickly to a disease epidemic like the one caused by avian influenza in 2016/17. The Commission services had identified in September 2015 the main weaknesses and deficiencies of the animal health emergency preparedness system in Hungary. The fact that they had not been properly addressed yet by October 2016 undoubtedly contributed to the size and duration of the avian influenza epidemic.

At the time of this audit, the CA had already taken some satisfactory steps in the good direction, but they were still in the process of analysing the lessons learnt from the epidemic with the objective of enhancing their preparedness for future emergency situations. In particular, the competent authorities were about to finalise a new contingency plan for avian influenza, they had set out plans to better harmonise the preparation by the counties of measures to respond to the disease – whose adequacy they plan to verify in the future –, and they had started to address the significant disease prevention problems that were identified in the domestic waterfowl production sector, the most affected by far during the epidemic.

Despite the difficulties experienced with the management of the epidemic, risks of transmission of the disease to other Member States through intra-EU trade of poultry commodities were mitigated properly and in line with EU legislation.

7. **CLOSING MEETING**

A closing meeting was held on 2 March 2018 with representatives of the CCA. At this meeting, the main findings and conclusions of the audit were presented by the audit team. The representatives of the CCA did not indicate any major disagreement with the findings and preliminary conclusions.
### 8. **Recommendations**

<table>
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| 1.  | To update the national contingency plan for avian influenza taking into account the lessons learnt from the analysis of the strengths and weaknesses identified with regard to the operation of the animal health emergency preparedness system during the recent epidemic of HPAI.  
  
  
  *Based on conclusions (104) and (108), and associated findings (9), (60), (83), (85) and (99).* |
| 2.  | To take appropriate action to verify that the operational arrangements made by the county CA to apply the national contingency plan for avian influenza, in particular in relation to availability of adequately trained staff and equipment; are fit for purpose so that an effective early response, particularly in the event of a widespread disease outbreak affecting an area with a high density of poultry, can be deployed without delay.  
  
  *Article 4 (2)(f) of Regulation (EC) No 882/2004; and Annex X (points 3, 5, 6 and 7) to Directive 2005/94/EC.*  
  
  *Based on conclusions (104), (106) and (108), and associated findings (85) and (99).* |
| 3.  | In the event of a suspicion of avian influenza, and when the presence of HPAI is confirmed in those cases; to take appropriate action without delay so that: a) the potential risk of transmission of the disease is immediately mitigated, and b) targeted epidemiological inquiries are carried out by specifically trained personnel on the basis of instructions and standardised questionnaires tailored to the specific features of the disease and that make part of the relevant contingency plan.  
  
  *Articles 6, 7, 9, 10 (1) and (2), and 11 (1) and (3) of, and Annex X (points 6 and 7) to Directive 2005/94/EC.*  
  
  *Based on conclusions (21), (24) and (106), and associated findings (5), (6), (12), (14) and (99).* |
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| 4.  | To take appropriate action to ensure that when HPAI is confirmed in a poultry holding, protection and surveillance zones are established without delay and all necessary restriction measures and disease surveillance activities, in particular on-the-spot inspections of holdings, are swiftly applied therein so as to effectively prevent the spread of the disease beyond those restricted areas.  
*Articles 16 (1) and (3), 17, 18, 19, 20 and 30 of Directive 2005/94/EC; points 8.6 and 8.7 of the EU Diagnostic Manual.*  
*Based on conclusions (55) and (110), and associated findings (36), (39), (43), (52), (74) and (99).* |
| 5.  | To make arrangements to ensure that the NDCC has timely access to: a) all necessary epidemiological data to analyse the potential determinants of the evolution of large outbreaks of HPAI, and b) adequate information management tools to provide sufficient and quick epidemiological analytical support to the deployment of control measures in the field. Thus, coordination of the early response to those outbreaks will be enhanced, and the NDCC and LDCCs will be in a better position to select the most suitable control and eradication actions according to the evolution of the disease.  
*Article 33 (1) and 62 (2) of, and points 1 and 2 of Annex X to Directive 2005/94/EC; Chapter X of the EU Diagnostic Manual.*  
*Based on conclusions (21), (57) and (110), and associated findings (5), (6), (12), (36), (43), (52), (74) and (94).* |
| 6.  | In the event of another large HPAI epidemic, before deciding on granting derogations provided for in Articles 16 and 23 to 27 of Directive 2005/94/EC, to define the detailed arrangements under which that may be done on the basis of the result of a risk assessment that ensures that dedication of resources to their application will not undermine the implementation of other control measures fundamental for the early and effective response to the animal health crisis.  
*Article 33 (1) of Directive 2005/94/EC.*  
*Based on conclusions (21), (55) and (57), and associated findings (5), (6), (36), (39), (43) and (52).* |
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| 7.  | To take decisive action to ensure that animal welfare requirements are complied with when animal depopulation has to be used for disease control purposes so that poultry are effectively spared of unnecessary pain, suffering and distress, in particular by: a) training personnel adequately, in particular to draw action plans tailored to the depopulation activity they have to carry out, b) preparing standard operating procedures fit for purpose according to the killing methods that may be used in the poultry species most likely affected by avian influenza outbreaks, and c) making available the necessary equipment to apply those methods without delay.  


*Based on conclusions (68), and associated findings (59), (61), (62), (63) and (101).* |
| 8.  | To make arrangements to ensure that there is sufficient carcass disposal capacity available that can be timely deployed to match the demands of a large outbreak of HPAI. Thus, animal depopulation for disease control purposes will be speeded up, in particular in areas with high density of poultry, and the spread of infection in those high risk environments will be prevented more effectively.  

*Article 11 (2) and (3) of, and point 6 of Annex X to Directive 2005/94/EC.*  

*Based on conclusion (69), and associated finding (67).* |

The competent authority's response to the recommendations can be found at:

### APPENDIX – SPECIFIC LEGAL REQUIREMENTS RELATED TO SPECIFIC PROVISIONS AND MEASURES

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<th>APPLICABLE LEGISLATION CORRESPONDING TO THE SPECIFIC PROVISIONS AND CONTROL MEASURES FOR AVIAN INFLUENZA AND TO RELATED REQUIREMENTS ON ANIMAL WELFARE AND ABP[^5]</th>
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[^5]: For further details on the specific legislation, please refer to Annex 1.

[^6]: Specific provisions laid down in Commission Implementing Decision (EU) 2017/247 concerning the authorisation by the competent authorities of dispatch to other Member States of consignments of live poultry, day-old chicks and hatching eggs from areas established as protection and surveillance zones, and from areas established as further restricted zones, entered into force on 11 April and 10 October 2017, respectively.
| 5.1.2 | Diagnosis of avian influenza | Art. 50 (1)  
Art. 51 (2) and (3)  
Annex VIII and Annex X (8)  
Art. 11 (10) | Chapter I (points 2 and 6)  
Chapter IV (points 3, 4 and 5)  
Chapter V (points 3 and 4)  
Chapters VI, VIII and X |
| 5.1.3.1 | Establishment of protection and surveillance zones | Art. 16 and 17 |
| 5.1.3.2 | Application of measures in protection and surveillance zones | Art. 18 to 22  
Art. 30  
Art. 34 | Chapter IV (points 8.6, 8.7 and 8.12) |
| 5.1.3.3 | Further restricted zones | Art. 16 (4)  
Art. 32 and Annex IV  
Art. 34 |
| 5.1.3.4 | Derogations to measures applied in protection and surveillance zones | Art. 16 (2)  
Art. 23 to 27  
Art. 33 | Chapter IV (points 8.8 and 8.10) |
| 5.1.4.1 | Animal depopulation – Animal welfare considerations⁷ | Art. 11 (1) and (2) |
| 5.1.4.2 | Animal depopulation – Disposal of carcases⁸ | Art. 11 (3) and Annex X (6) |

⁷ The animal welfare requirements related to animal depopulation in the event of an animal health crisis are laid down in Council Regulation (EC) No 1099/2009, in particular in its Article 18, and apply when control measures for avian influenza include slaughter or killing of poultry or other captive birds for the purpose of disease control (as required by Article 11 of Directive 2005/94/EC).
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8 General legal requirements in relation to disposal of ABP in the event of a disease outbreak are laid down in Regulation (EC) No 1069/2009 of the European Parliament and of the Council, in particular on Article 19 (1)(e), and on Article 15 (a) of, and Annex VI (Section I of Chapter III) to Commission Regulation (EU) 142/2011.

9 Besides Directive 2009/158/EC, additional requirements related to availability of data on registration of commercial poultry holdings – namely for those keeping breeding animals, laying hens, broilers and turkeys – are laid down in the body of EU legislation related to control of salmonella. That information must be an integral part of the national control programmes for that zoonosis. See: [https://ec.europa.eu/food/safety/biosafety/food_borne_diseases/salmonella_en](https://ec.europa.eu/food/safety/biosafety/food_borne_diseases/salmonella_en)
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| 5.3.2   | Implementation of restrictions on intra-EU trade and derogations thereto | Art. 33 (8) | Art. 5 (a), (b), and (c) – General conditions for intra-EU trade of poultry and hatching eggs Art. 6 (a) (ii) and (iii), Art 11 (b) and (d), and Art. 12 (b) and (d) – Specific conditions for intra-EU trade of poultry and hatching eggs related to animal health restrictions Art. 18 (5) and Art. 19 – Transport of poultry through infected areas and contact with other birds | Article 3a – Concerning protection and surveillance zones Article 3c – Concerning further restricted zones |
### ANNEX 1 – LEGAL REFERENCES

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