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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
ITALY
FROM 07 MARCH 2022 TO 11 MARCH 2022
IN ORDER TO
EVALUATE THE APPLICATION OF MEASURES FOR THE CONTROL OF AVIAN
INFLUENZA

Executive Summary

This report describes the outcome of an audit of Italy, carried out from 7 to 11 March 2022, as part of the published Directorate-General for Health and Food Safety's work programme.

The objective of this audit was to evaluate the application by the Italian competent authorities of EU measures for controlling outbreaks of highly pathogenic avian influenza (HPAI) during the 2021-2022 epizootic of the disease. 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 animal health rules concerning the dispatch for intra-EU trade of consignments of live poultry, day-old chicks and hatching eggs.*

This report concludes that the Italian competent authorities have not yet addressed satisfactorily some important structural and organisational shortcomings that undermined the capacity of the animal health emergency preparedness system, notably in Veneto and Lombardy, to respond rapidly and effectively to the 2021-2022 HPAI epizootic.

The Commission had highlighted those shortcomings in previous audits (in 2015 and 2019) and requested the competent authorities to resolve them as a priority. The delay in addressing those deficiencies, in particular in the Veneto region, had serious consequences as reiterated here below.

The areas of Veneto and Lombardy that were severely affected by the 2021-2022 epizootic have a high seasonal risk of introduction of HPAI via migratory wild birds. In addition, the poultry production sector in those areas is exposed to other intrinsic risk factors that may facilitate the rapid spread of the disease (e.g., high density of poultry establishments, intense network of frequent direct and indirect contacts). The competent authorities made significant efforts in recent years, including intensified official controls, to increase the levels of awareness and compliance with national rules on biosecurity in poultry establishments, but their effectiveness remains questionable.

Surveillance in wild birds was not effective to detect promptly the circulation of HPAI virus. This delayed the reinforcement of biosecurity measures to prevent its introduction in the poultry population, where that surveillance worked better, and the disease was usually confirmed quickly.

Despite previous experience and the strengths of the disease control system in those areas (e.g., experienced officials and production sector, availability of excellent technical and laboratory expertise, frequency of inspections in poultry establishments), the existing shortcomings favoured the epizootic to worsen rapidly.

The limited capacity to apply animal depopulation measures in affected establishments quickly and use preventive killing to reduce the infective pressure and the density of susceptible animals in the affected areas, in particular in Veneto alongside the risk factors mentioned above,

favoured the widespread transmission of the disease, and delayed the eventual control of the epizootic.

The main cause precluding the control of the spread was the limited capacity to depopulate affected establishments quickly and to kill poultry preventively to reduce the infective pressure and the density of susceptible animals in the affected areas, in particular in Veneto. That, alongside the shortages of staff to perform epidemiological enquiries timely and the absence of capacity to dispose quickly of carcasses and contaminated material, favoured the widespread transmission of the disease, and delayed the eventual control of the epizootic.

The activities of the competent authorities, including of the national disease control centre, and the control measures applied became more effective only after the sharp reduction of the density of poultry in the main affected areas resulting from the many disease outbreaks and the policy to empty non-affected establishments. In this context the national disease control centre did not evaluate the epidemiological situation adequately from the beginning in order to take the necessary actions timely.

During the epizootic, the competent authorities managed properly the risks of transmission of the disease to other Member States through intra-EU trade.

The report contains recommendations to the Italian competent authorities aimed at enhancing the implementation of control measures.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABP	Animal by-products not for human consumption, as defined in Regulation (EC) No 1069/2009
Central competent authority	Directorate-General for Animal Health and Veterinary Medicinal Products of the Ministry of Health
EFSA	European Food Safety Authority
EU	European Union
HPAI	Highly pathogenic avian influenza
NRL	National reference laboratory for avian influenza
PAFF Committee	Section on animal health and welfare of the Standing Committee on Plants, Animals, Food and Feed
Previous audit	Audit carried out in November 2019 to evaluate the application of measures for the prevention and control of avian influenza (Ref.: DG(SANTE)/2019/6599
RVS	Regional Veterinary Services
SVL	Veterinary Services (<i>Servizi Veterinary Locali</i>) of the Local Health Units (<i>Aziende Sanitarie Locali</i> , in Veneto / <i>Agenzie di Tutela della Salute</i> , in Lombardy)

1 INTRODUCTION

This audit took place in Italy from 7 to 11 March 2022 and was undertaken as part of the Directorate General for Health and Food Safety's planned work programme. The audit team comprised two auditors from the said Directorate General.

Representatives of the central competent authority, the Directorate-General for Animal Health and Veterinary Medicinal Products of the Ministry of Health, accompanied the audit team throughout the audit.

During the visits at regional and provincial level, representatives of the following competent authorities responsible for the preparedness for, and control of animal disease outbreaks at those levels also accompanied the audit team:

- the Regional Veterinary Services of Veneto and of Lombardy (RVS);
- the Veterinary Services of the Local Health Units (*Servizi Veterinari Locali* of the *Aziende Sanitarie Locali* (in Veneto) / *Agenzie di Tutela della Salute* (in Lombardy) – SVL).

2 OBJECTIVES, SCOPE AND AUDIT CRITERIA

The objective of this audit was to verify the application of EU measures for the control of highly pathogenic avian influenza (HPAI). In pursuance of that objective, the audit team paid particular attention 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 animal health conditions governing intra-EU trade of consignments of live poultry, day-old chicks and hatching eggs.

This audit also followed up the implementation of the actions proposed by the Italian competent authorities to address the recommendations from the previous Commission audit on HPAI, carried out in 2019 ('the previous audit', see section 4.3).

The scope of this audit covered:

- the outbreaks of HPAI that occurred since 16 October 2021 and up until the start of this audit (the 2021-2022 HPAI epizootic);
- the production chain for poultry, in particular the turkey, broiler and layer hens' 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 prevention, surveillance and control measures for HPAI, including delegated bodies and natural persons to which the competent authorities have delegated some of the relevant official control tasks in that respect;
- the operation of the laboratory network designated for the diagnosis of HPAI.

With regard to the audit criteria, since 21 April 2021, Regulation (EU) 2016/429 of the European Parliament and of the Council (the Animal Health Law) lays down the rules for prevention and control of HPAI. Those rules include the early detection, notification and reporting of the disease, surveillance and disease awareness, preparedness to respond to outbreaks and control them, registration and approval of establishments keeping poultry, and rules for their movements and traceability. Several Commission Delegated Regulations supplement the Animal Health Law as regards those animal health requirements, setting out additional ones specific for the areas mentioned above. The table included in the Appendix to this report presents the audit criteria deriving from those legal acts.

The audit was conducted by means of data and document review, interviews with officials and other concerned parties, and system verification on-the-spot.

In pursuit of this objective, the audit team held a number of meetings and visited the sites indicated in the following table:

MEETINGS / VISITS		no.	COMMENTS
Competent Authorities	Central	2	Opening and closing meetings with representatives of the central competent authority and with representatives of the relevant regional and local services of the competent authorities
	Regional	2	Meetings with representatives of the RVS in Veneto and Lombardy
	Local	4	Meetings with representatives of the SVL in both regions in the main areas affected by the HPAI epizootic (Verona and Padua, in Veneto, and Brescia and Mantua, in Lombardy)
Laboratories		3	Meetings with representatives of the national reference laboratory for avian influenza and of two laboratories also involved in diagnosis of HPAI in the two visited regions (Verona and Brescia)
Poultry establishments		2	Two establishments keeping turkeys, one in each of the visited regions

3 LEGAL BASIS

The general provisions of EU legislation that served as a basis for this audit are Articles 116, 117 and 119 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

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. In addition, the Appendix to this report includes a table summarising the main legal requirements related to the specific provisions and measures laid down in EU legislation pertaining to the control of HPAI (see further details in section 2 and at the beginning of section 5).

4 BACKGROUND

4.1 RECENT EPIDEMICS OF HPAI IN THE EU

In recent years, several epizootic waves of HPAI have caused significant direct and indirect economical and societal costs to the EU.

After the large HPAI epizootic that happened between 2016 and 2017 and the one that affected the EU during the first semester of 2020, the disease reappeared and caused numerous outbreaks in Member States since October 2020. The 2020-2021 epizootic, caused mainly by a HPAI virus of an H5N8 subtype, affected more poultry species besides turkeys and waterfowl when compared to previous ones, such as layer hens and broilers.

A new epizootic season began soon after and outbreaks caused mainly by a new H5N1 HPAI virus subtype were confirmed in several Member States since 30 September 2021. The new epizootic affected mainly Italy, and to a lesser extent Hungary, Poland and Germany. Later on, the impact of the disease started to decline in the North of Italy, but it continued to affect other European regions, such as Poland and Hungary, eventually causing important epizootics in France, Spain and the Netherlands.

By mid-March 2022, the 2021-2022 HPAI epizootic has already caused the (direct or indirect) death of more than 30 million poultry in the EU. The main poultry production sectors affected were again those dedicated to the fattening of turkeys and domestic waterfowl in areas of Italy, France, Poland and Hungary.

As it happened during previous epizootics in the EU, migratory wild birds were instrumental in the transmission of the HPAI virus to the poultry population in Member States.

The challenging reality of the COVID-19 pandemic slowed down the deployment of disease control measures and contributed to the fast spread of HPAI and to increase the number of secondary outbreaks.

The EU measures on control of HPAI aim to prevent further transmission of the disease to poultry populations, and stop its spread as soon as possible, to ensure the safe placing on the market, and exports, of EU poultry and their products. The Commission services adapt those measures regularly to the epidemiological evolution of the disease in Member States¹. The

¹ As laid down since 21 April 2021 in the Animal Health Law and in Delegated Regulation (EU) 2020/687, including additional protective measures in relation to outbreaks of HPAI in certain Member States established in accordance with that legislation. See:

https://ec.europa.eu/food/animals/animal-diseases/diseases-and-control-measures/avian-influenza_en#hpa-outbreaks

European Food Safety Authority (EFSA) publishes quarterly reports on the situation of avian influenza in Europe and at global level that include an update of that epidemiological evolution².

4.2 INFORMATION ON THE ANIMAL HEALTH CONTROL SYSTEM IN ITALY

The country profile of Italy, published on the Website of the Directorate General for Health and Food Safety and valid as of October 2021, provides detailed information on the responsibilities of the competent authorities under normal circumstances and a brief description of their activities in the event of a disease outbreak:

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

4.3 PREVIOUS AUDITS IN ITALY

The Directorate-General for Health and Food Safety carried out an audit to evaluate the application of measures for the control of avian influenza in 2019 (ref. DG(SANTE) 2019-6599-MR; the previous audit). The report of the previous audit is published at:

https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4305

The previous audit highlighted some shortcomings in the animal health emergency preparedness system in place related to:

- the evaluation and mitigation of the intrinsic risk factors for HPAI in the regions covered by the scope of this audit where it takes place most of the commercial poultry production of the country (e.g., high density of poultry establishments, complex network of contacts between them, suboptimal application of preventive biosecurity measures); and
- the arrangements in place to guarantee a quick and effective killing and depopulation of affected poultry establishments to ensure rapid containment of HPAI while guaranteeing compliance with EU requirements on animal welfare.

At the time of this audit, recommendation No. 4 from the previous audit remained open. The recommendation relates to need to draw and implement plans to depopulate poultry establishments ensuring the welfare of the animals.

That audit had also highlighted shortcomings in the level of preparedness of the competent authorities to respond to outbreaks of HPAI, in particular that the central competent authority had insufficient knowledge about:

- the level of preparation of the RVS in the regions covered by the scope of this audit to cope with a large number of HPAI outbreaks; and

² See: <https://www.efsa.europa.eu/en/topics/topic/avian-influenza>

- the potential difficulties that they could confront to coordinate a multi-regional epizootic of the disease.

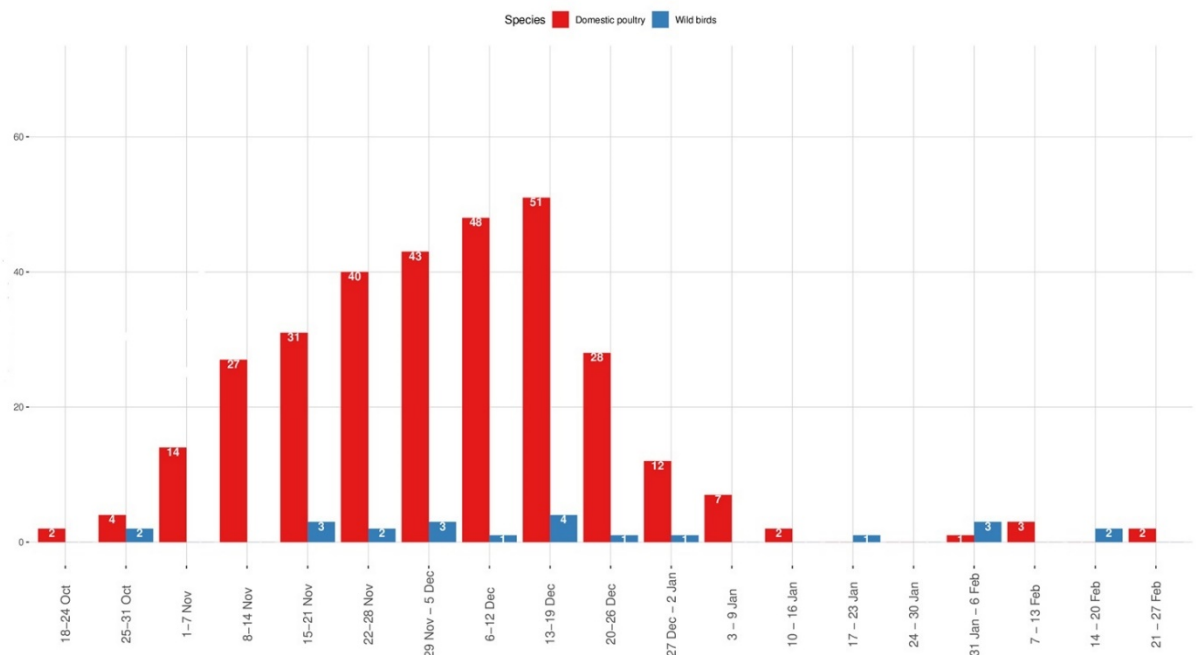
This audit has taken into account the measures undertaken by the Italian competent authorities to address those shortcomings.

4.4 HPAI IN ITALY IN 2021/22

Italy was only marginally affected by the 2020-2021 HPAI epizootic. The situation was significantly different during the 2021-2022 epizootic. Italy confirmed the first outbreak of HPAI caused by the H5N1 subtype strain on 19 October 2021 in a turkey establishment in the province of Verona (Veneto). Shortly afterwards, Italy notified the first cases of the disease confirmed in wild birds in Lombardy.

The epizootic followed a standard epidemic curve with a rapid and continuous increase in the number of outbreaks in poultry in Veneto (mainly) and in Lombardy until reaching its peak around mid-December. After that, the number of outbreaks began to decrease gradually, and the spread of the disease was nearly fully contained by mid-January 2022.

The following graph shows the temporal evolution of the number of HPAI outbreaks (in red) and cases (in blue) in poultry and wild birds, respectively, on a weekly basis between 18 October 2021 and the end of February 2022:

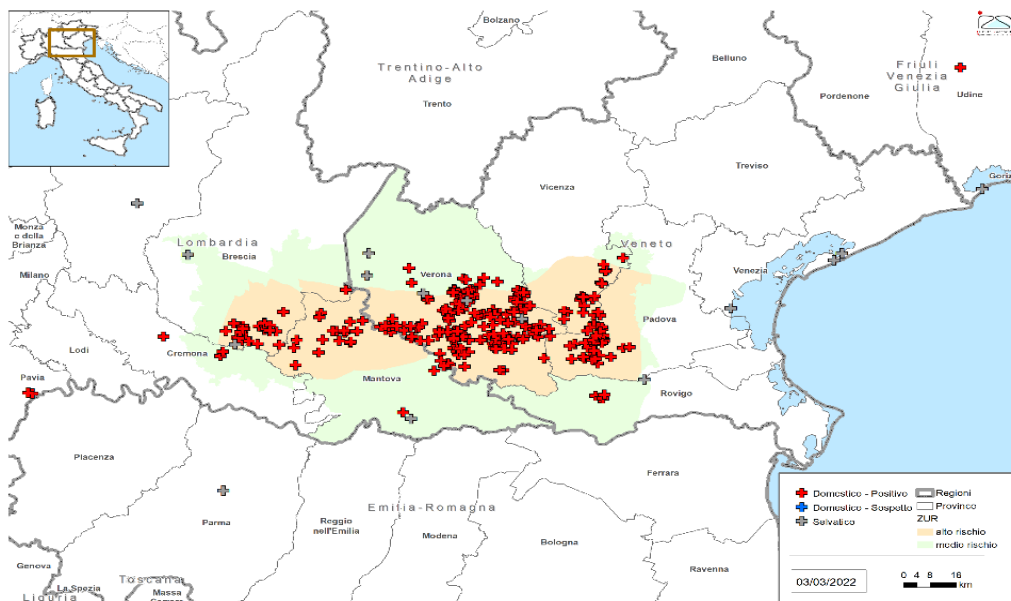


Out of the 315 outbreaks confirmed in poultry at the time of this audit, 248 were detected in Veneto and 60 in Lombardy. The epizootic commenced in Veneto in the province of Verona, where a high number of outbreaks happened for the first four weeks of the epizootic, many of them in establishments belonging to the same company (some 60%). After that, cases started to appear in the province of Padua (Veneto) in mid-November (some 20 cases until the end of

the month), and the epizootic spread in Lombardy during December, mainly in the provinces of Mantua and Brescia.

Unlike what had happened in previous HPAI epizootics the outbreaks not only affected establishments keeping turkeys (149 outbreaks, mostly in Veneto), but also broilers (76 outbreaks, 65 of which in Veneto) and layer hens (32 outbreaks in Veneto and 20 in Lombardy). The epizootic affected only a few backyard establishments, 13 in total and some in regions other than Veneto and Lombardy. The impact of the epizootic in the high-density production areas of both regions was considerable, for example, in Verona province, there were 179 outbreaks, affecting approximately 7.5 million poultry, whereas in Lombardy, where there were only 60 outbreaks, they affected some 4.5 million poultry.

The following map shows the geographical distribution of HPAI outbreaks confirmed in poultry during the 2021-2022 epizootic in the main affected areas of Veneto and Lombardy. The red crosses represent the confirmed outbreaks in poultry and the grey ones the cases detected in wild birds. The pale orange and green areas represent, respectively, the areas still considered at the time of this audit at high and middle risk of HPAI spread within the further restricted zone established by the competent authorities (see section 5.1.3.3):



Italy kept the Commission and the other Member States regularly informed of the evolution of the situation about HPAI through regular presentations made at the section on animal health and welfare of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). In addition, the webpage of the national reference centre for the epidemiology of avian influenza, which shares the same premises as the national reference laboratory (NRL) for the disease, provides regularly updated epidemiological information showing the evolution of the HPAI epizootics occurring in Italy:

<https://www.izsvenezie.com/reference-laboratories/avian-influenza-newcastle-disease/italy-update/>

5 FINDINGS AND CONCLUSIONS

Legal requirements

The Appendix to this report presents the legal requirements applicable since 21 April 2021 to the findings included in each chapter, as related to the provisions and measures specific for the control of HPAI that have been evaluated.

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 (EU) 2017/625.
- Specific animal welfare requirements related to animal depopulation in the event of an animal health crisis laid down in Council Regulation (EC) No 1099/2009.
- Specific requirements applying to disposal of animal by-products not intended for human consumption (ABP) in the event of a disease outbreak, which are laid down in Regulation (EC) No 1069/2009 of the European Parliament and of the Council and in Commission Regulation (EU) 142/2011.

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 HPAI – Handling of suspicion

1. The report of the previous audit provides a detailed description of the strengths of the surveillance system for early detection of HPAI in poultry that the competent authorities apply annually in the areas affected by the 2021-2022 epizootic. Following up from previous Commission audit findings the competent authorities approved a specific decree in March 2018 laying down the objectives and conditions that regions had to fulfil to receive economic support to reinforce their surveillance and preventive measures for HPAI. Both Veneto and Lombardy regions received significant financial support in that context in recent years.
2. In July 2019, the central competent authority and the RVS signed an agreement that detailed the concrete measures that the latter had to apply depending on the level of risk of introduction and transmission of the disease in parts of their territories. The agreement also set out criteria for the categorisation of zones at a high risk of HPAI introduction and rapid or standard spread (called, zones B and A respectively). That agreement includes specific measures to control and reduce the density of poultry in those zones and within establishments, e.g., it sets minimum distances between new establishments and existing ones, prohibits keeping several poultry species in the same establishment, and the opening of new establishments keeping poultry outdoors (only in zones B).

3. In December 2019 and April 2021, the central competent authority published additional orders that specifically highlighted the biosecurity measures that all poultry establishments had to apply and laid down criteria to determine in which parts of each region the RVS should prevent the authorisation of new establishments keeping poultry. On 2 October 2020 they published additional risk-mitigating measures to prevent the introduction of HPAI in poultry establishments (e.g., banning outdoor keeping of poultry) because of the high risk associated with the circulation of H5 HPAI virus subtypes in wild birds.
4. The audit team confirmed that the RVS in Veneto and in Lombardy had adapted in recent years their disease prevention and surveillance measures to the national provisions mentioned in the previous points. For example:
 - the RVS in Veneto published regional provisions on prevention, surveillance, and control of HPAI in May 2020. Since February 2021, it intensified official controls to verify compliance with national provisions on biosecurity. The provisions set out minimum frequencies for the inspections that the SVL had to carry out in poultry establishments. The RVS developed specific guidelines and inspection checklists with the support of a regional task force bringing together several experts in poultry production and health.
 - The RVS in Lombardy updated the level of risk of introduction and transmission of HPAI in different parts of their territory in December 2019 and introduced new legal provisions in July 2020 focused on biosecurity (including rules to verify them by the SVL) and to reduce the density of poultry. Those provisions introduced also a very detailed new multi-annual surveillance programme as well for avian influenza that adapted national surveillance requirements to the local circumstances.
5. The RVS in Lombardy intensified its awareness activities on HPAI to poultry keepers in early 2020 and in August 2021 because of the evolution of the epidemiological situation in Europe and the detection of circulation of an avian influenza virus in wild birds in their region. Both regions intensified awareness campaigns and advised on specific additional disease preventive practices, including a ban on keeping poultry outdoors in zones B and A, following provisions on that published by the central competent authority on 15 October 2021, after a case of low pathogenic avian influenza was confirmed in a neighbouring region a day before.
6. In relation to surveillance in wild birds, the national annual surveillance programme for HPAI lays down rules for the RVS and indicates that they should prioritise testing wild birds found dead, in particular of certain targeted species (in line with EFSA advice).
7. After the 2017-2018 epizootic, the central competent authority and the NRL decided to evaluate options to complement and improve that surveillance. The NRL made a detailed technical review of migratory routes involving the North of Italy, studied the possible impact of regional dynamics of wild bird movements and found practices that attracted

waterfowl and increased their presence in certain areas (e.g., private hunting grounds in certain wetlands). They also identified the weaknesses that could hinder the cooperation of the environmental authorities (e.g., shortage of personnel), of ornithologists (e.g., not counted on) and of the public (e.g., limited awareness) in the implementation of surveillance for HPAI in dead wild birds.

8. The NRL carried out as well specific monitoring activities in wild birds between November 2020 and February 2021 that confirmed the extensive circulation of several H5 subtypes of HPAI and of low pathogenic avian influenza in populations of wild ducks present in certain areas of Eastern Veneto. During the period of that study, there was hardly any outbreak in poultry in that part of Italy. That activity continued in 2021 until October, but since February they did not detect more HPAI virus circulation.
9. The RVS in both Veneto and Lombardy made efforts to improve the effectiveness of surveillance in wild birds for early detection of HPAI in line with Articles 4(a)(b) and 10(2) of, and Annex II (Section 4) to Regulation (EU) 2020/689, and during 2021 they implemented their surveillance according to the existing plan and to the national programme. For example, in 2019, Veneto reported nearly one third of the total number of wild birds tested in Italy (890 out of 2,720), the RVS in Lombardy added in 2018 an annual active component to their surveillance for HPAI in wild birds as they had very few wild birds found dead reported to the authorities.
10. In both regions, surveillance in wild birds found dead did not detect the circulation of the H5N1 HPAI virus subtype before the disease appeared in poultry farms (the first cases in wild birds were confirmed at the end of October in Lombardy, and in Veneto, the first cases in wild birds were confirmed during the second half of November). In total, by the end of January 2022 there were nine cases of HPAI confirmed in wild birds found dead in Veneto, and four in Lombardy.
11. The active surveillance component is sound and focuses mainly on hunted wild birds (starting in October, 11 targeted sites, especially on Brescia province due to the high density of poultry) and sampling of faeces from wild ducks in certain targeted areas (during spring and summer in some and every 15 days throughout the year in other).
12. The contribution of that active surveillance as an early warning system for HPAI was however limited. When it was discontinued in November, because of the wide restrictions applied in the affected territory related to the Covid-19 pandemic, it had detected only two cases of an H5 virus subtype through testing of hunted wild birds and one with testing of faeces of wild ducks.
13. Nonetheless, the detection of one of the cases mentioned above in August 2021, even if not confirmed as an HPAI subtype, triggered the RVS of Lombardy to start additional communication campaigns on HPAI (e.g., advice on stricter biosecurity measures, although not yet banning to keep poultry outdoors) and to widen active surveillance to more poultry species.

14. In Veneto, given the absence of reports on circulation of HPAI viruses in wild birds, the RVS did not introduce any additional HPAI preventive measure until the central competent authority published its order on 15 October, which was too late, as the first confirmed cases of the disease appeared immediately afterwards. They took some of those actions already as a reaction to the outbreaks, on 20 (e.g., additional surveillance in turkeys) and 25 October (e.g., banning repopulation of hunting areas with wild game and poultry fairs).
15. The inability of the surveillance to detect promptly the virus in wild birds (detection in wild birds happened after outbreaks in poultry establishments) contrasts with the fact that all competent authorities considered circulation of the virus in wild birds as the main cause for most of the initial outbreaks of the disease in both regions. The NRL confirmed this a posteriori by virus phylogenetic studies. That sub-optimal effectiveness cannot be considered in line with provisions laid down in Articles 26(2) and (4) and 27 of Regulation (EU) 2016/429, on the need to design and apply surveillance in a way that is appropriate and proportionate to the objectives pursued and to the risk factors involved in order to ensure the timely detection of the presence of the targeted disease.
16. Both RVS carry out annual inspection programmes on poultry establishments to verify compliance with national requirements on biosecurity, record keeping and early notification of suspicions of HPAI. The results of those inspections carried out between 2019 and 2021 showed an overall positive trend in the levels of compliance. In some of the SVL visited, the audit team saw that the results of the inspections in establishments keeping broilers showed a sub-optimal level of compliance with biosecurity requirements. According to the official veterinarians met, some of those establishments were new, and operators were not yet familiar with those disease preventive practices especially as broilers were not typically affected by HPAI in the past.
17. In all cases, official veterinarians had documented well their findings and issued recommendations to improve the level of compliance. According to CA the Covid-19 pandemic had a major impact in delaying both the application of improvements by the operators and the official follow-up of those activities.
18. During the 2021-22 epizootic, the number of HPAI outbreaks detected in broilers and in layer hens was unprecedented. For example, by 30 November 2021 there had been 121 confirmed outbreaks of HPAI in Italy (115 in Veneto), of which 27 and 10 had affected broilers and layer hens, respectively. One week later, of the 167 outbreaks confirmed (153 in Veneto), 45 and 15 had affected those two sectors, respectively. The outbreaks affecting those establishments kept increasing during the following weeks.
19. In the cases checked by the audit team, turkey producers notified suspect cases of HPAI quickly, in most cases timely. In contrast, the audit team saw examples of affected layer hen establishments where the operator had not notified the authorities despite experiencing mortality rates of four or five times the usual daily average for a few days, or of other significant deviations in other production parameters. That is not in line with

requirements laid down in Article 18(1)(a) and (c) of Regulation (EU) 2016/429.

20. According to the analysis provided by the national reference centre for the epidemiology of avian influenza, the H5N1 strain of HPAI responsible for the 2021-22 epizootic showed an atypical pattern in broilers, characterised by a long incubation period without showing apparent clinical signs, a sudden increase in mortality, or triggering an immunity reaction that could be detected quickly.
21. Those features contributed to a delay in the detection of HPAI, and many cases were only found by intensified surveillance introduced in response to other outbreaks in nearby establishments, or during pre-movement testing carried out before sending the animals to slaughter.
22. The audit team reviewed files related to suspect cases of HPAI; in most cases the SVL had acted timely (e.g., visiting the establishment, applying movement restrictions, and reinforcing biosecurity measures). During the investigation of suspect cases, official veterinarians usually took enough appropriate samples in accordance with the guidelines in the contingency plan for HPAI and sent them to the NRL or to the regional laboratory designated for that purpose in Lombardy. Both collection of the samples by staff of the SVL, and their analysis and confirmation by the NRL, were done timely within 24 hours.

5.1.1.2 Epidemiological enquiry – Additional control measures

23. During the first weeks of the 2021-2022 epizootic in Veneto, there was a specialised team of field epidemiologists from the national reference centre for the epidemiology of avian influenza in charge of performing epidemiological enquiries. In Lombardy, epidemiologists of the regional animal health laboratory provided similar support to the RVS and to the SVL involved in the epizootic. The audit team saw many examples of those enquiries. They were comprehensive and gathered all possible sources of information in line with Article 8(3) of Delegated Regulation (EU) 2020/687.
24. The main objective of this approach was to obtain harmonised and more elaborated results from the epidemiological enquiries and, thus, to facilitate the analysis of the situation and provide the local, regional, and national disease control centres with information that allowed them to adapt the disease control measures accordingly. That had been one of the undertakings given by the competent authorities in response to one of the recommendations of the previous audit report.
25. According to representatives of the field epidemiology teams and to SVL staff who performed those enquiries, the current model of epidemiological enquiry is too burdensome, and it requires gathering too much information, especially in the face of multiple outbreaks, and thus, it was not a suitable tool to inform quickly on the best possible measures mentioned above. That is not in line with general requirements laid down in Articles 5(1)(a) and 12(2) and (3) (read with point 5 in Chapter II of Annex II thereto) of Regulation (EU) 2017/625, for the competent authorities to have procedures and/or arrangements in place to ensure the effectiveness of official controls and other

official activities, to verify them, and to take corrective action and update them as appropriate when they identify shortcomings with their application.

26. Official veterinarians of the RVS and of the SVL are trained to perform those enquiries too. During November and December, in the face of increasing outbreaks and the impossibility for the field epidemiology teams to cope with that, they took over that responsibility partially, as part of mixed teams, or totally. Despite that, in numerous cases, the competent authorities given the workload generated from the other tasks related to the many outbreaks of the epizootic did not carry out an epidemiological enquiry at the time of suspicion or once the disease was confirmed. For example, by 7 December 2021, of the 153 cases confirmed in Veneto, in only 80 there had been an epidemiological enquiry, whereas in Lombardy, of the 11 cases confirmed, the enquiry had been already carried out in only five of them.
27. The shortcomings mentioned above did not allow the competent authorities to analyse quickly a sufficient number of records and information to ascertain quickly the likely spread of the disease and determine which preliminary disease control measures they had to take to prevent it. Thus, they could not fulfil the fundamental objectives of the epidemiological enquiries to inform decisions on application of control measures as provided for in Articles 55(1)(e) and (f), 56(a)(ii), 57(2)(e), 62(1) and 64(1)(f) and (2)(b) of Regulation (EU) 2016/429, and Articles 8(3), 9, 21(1)(c) and 23(a) of Delegated Regulation (EU) 2020/687.
28. The preliminary analysis of the information gathered by the epidemiological enquiries conducted by the NRL and by the Lombardy regional animal health laboratory, complemented with the results of the extensive phylogenetic analyses carried out by the NRL, attributed the evolution of the disease to several initial introductions of the infection by wild birds (e.g., at least seven different HPAI viruses introduced in poultry establishments), followed by local spread and facilitated by the proximity between establishments. Transmission was either airborne (e.g., forced ventilation and proximity, mainly in Veneto) or by human-mediated lateral spread (e.g., direct, and indirect contacts, some 98% of the outbreaks affecting establishments belonging to a few integrated companies).
29. In some cases, those analyses help to establish the very likely lateral spread of the disease between neighbouring provinces, e.g., between Verona and Padua, from the latter to Vicenza, and, to a lesser extent, between Mantua and Brescia. Their conclusions show that the transmission of the disease between Veneto and Lombardy was sporadic and probably happened only in a few cases between Verona and the provinces of Mantua and Cremona.

5.1.1.3 Handling of confirmation

30. The SVL and the RVS with the support of the NRL used well-adapted procedures to confirm the presence of HPAI in line with the relevant EU requirements and criteria. The NRL adapted their testing protocols to accelerate the confirmation of the disease when

the number of suspect cases and samples increased dramatically.

31. Upon confirmation, the SVL reinforced the preliminary movement restrictions in the affected establishments, and they applied additional disease control measures to accelerate the elimination of the infection and prevent the further spread of the disease.
32. In both regions, however, given the size and evolution of the epizootic, there were important delays (several days and even weeks) in the process of killing of poultry in infected establishments and, in removing the carcasses of killed or dead poultry and of other contaminated products (e.g., feed and litter) from affected establishments. The preliminary studies carried out by the national reference centre for the epidemiology of avian influenza seem to demonstrate that those delays contributed to the local spread of the disease. Those studies indicated as well that the risk of transmission was exacerbated by force ventilation, in particular between establishments keeping turkeys, that used it, and other situated nearby keeping mainly broilers and layer hens. These shortcomings are not in compliance with EU requirements laid down in Article 61(1)(b) and (c) of Regulation (EU) 2016/429 and Article 12(1) of Delegated Regulation (EU) 2020/687.

5.1.1.4 Contact (epidemiologically linked) establishments – Specific measures

33. In many cases, staff performing the epidemiological enquiry considered the outbreaks as primary cases infected by direct or indirect contact with wild birds. When they considered other hypotheses, the proximity to another affected establishment, close personal contacts (e.g., family, veterinary practitioners) and other indirect contacts (e.g., feed trucks servicing many farms) were the alternatives they chose more often.
34. Those enquiries took into account the monitoring period for HPAI set out in Annex II to Delegated Regulation (EU) 2020/687 preceding the detection of the disease in the affected establishments to identify possible contact establishments. According to data provided by the competent authorities, between Veneto and Lombardy they identified and investigated some 200 establishments potentially linked epidemiologically to confirmed cases. In those cases, they carried out the necessary investigations and, in the meantime, applied the required disease control measures on the traced establishments, e.g., movement quarantine, preventing indirect contact with other establishments.
35. The competent authorities confirmed HPAI in around 40 of those epidemiologically linked establishments, all but one in Veneto. Representatives of the RVS of Lombardy and of the main affected SVL in the region provided extensive proof of their investigations. They were able to confirm the epidemiological link only in one case.

Conclusions on early detection, handling of suspicion and confirmation of HPAI

36. The effective systems to raise and maintain public awareness and the good laboratory support helped the authorities to identify and confirm most cases of HPAI in poultry quickly. The delayed notification of suspect cases by certain operators is still a cause for concern as it may facilitate the spread of the disease in areas with a high density of

poultry.

37. Although the competent authorities have made considerable efforts to increase the sensitivity of surveillance for HPAI in wild birds, the tool however was not effective as an early warning system. That raises questions about the suitability of the design, the proper application, and the cost-effectiveness of that surveillance, as there is consensus among all relevant parties that the HPAI virus was circulating in wild birds in the affected areas before it was detected in poultry.
38. The competent authorities did not obtain timely the necessary information from the analysis of the epidemiological enquiries carried out in affected establishments to understand the likely spread of the disease, notably in areas with a high density of susceptible establishments exposed to a high level of environmental infection and frequency of contacts between them. Hence, they could not take the right decisions and adopt preliminary restrictions and additional control measures rapidly to contain the spread of the disease, as they had undertaken in response to a previous recommendation of the Commission services.
39. The detailed analysis of the epidemiological and virological information obtained from the 2021-2022 HPAI epizootic helped the authorities to confirm or identify the main risk factors present in the affected areas and in affected establishments that contributed to the spread of the disease. Thus, the authorities should have now sufficient information to tailor more effective risk-mitigating practices, to help preventing future similar epizootics.
40. The increasing delays in the killing and disposal of animals and of other products that may be contaminated, gradually undermined the effectiveness of other containment measures and was one of the main drivers of the further spread of the disease during the worst of the epizootic.

5.1.2 Diagnosis of HPAI

41. The NRL and the other two laboratories involved in laboratory diagnosis of HPAI in the main affected regions continue to participate in annual inter-laboratory comparison tests with consistently satisfactory results.
42. Once the epizootic was in full swing and the circulating virus strain was well-known, staff of the NRL took the decision to introduce a more suitable testing protocol that prioritised the direct confirmation of the specific circulating virus subtype, including its pathotyping, rather than applying several screening steps previously. The NRL provided convincing information about the validation process for that specific testing protocol that supports its reliability. That approach was also applied in the other branch of the NRL in Veneto. That alternative protocol translated into shorter turnaround times in confirming the presence of the H5N1 HPAI virus subtype in most of the cases investigated during the peak of the epizootic.

Conclusions on diagnosis of HPAI

43. The NRL and the other laboratories supporting its activities keep delivering high diagnostic standards and providing the competent authorities with reliable and rapid technical support for the detection and control of HPAI.

5.1.3 General measures in relation to protection and surveillance zones

5.1.3.1 Establishment of protection and surveillance zones

44. There was a very effective collaboration between all relevant competent authorities and advisory bodies to establish restricted zones around confirmed cases of HPAI in compliance with Article 60(b) of Regulation (EU) 2016/429 and Article 21 of Delegated Regulation (EU) 2020/687. Although there were delays of up to three days after official confirmation to issue the administrative orders setting out those zones, the SVL and the RVS applied the relevant restrictions immediately upon confirmation.
45. Representatives of the RVS and of the SVL established specific agreements and communication lines with all relevant public institutions and all industry stakeholders, even with the media, that operate effectively to apply those measures. The audit team saw several examples of communication issued by both RVS (e.g., the need for a derogation for any movement from a new restricted zone was enforced immediately in accordance with that official communication).
46. The SVL established restricted zones based on the minimum radius from the outbreak required by EU legislation (i.e., a 3 km one for the protection zone and a 10 km one for the surveillance zone) but they adapted that approach to the circumstances as the disease was evolving. Thus, in many cases, the overlap of areas due to the presence of several outbreaks ended up in larger merged protection and surveillance zones. The authorities correctly set the end date for the application of restrictions as the expiry date of the zones from the most recent outbreaks. That is in line with the provisions laid down in Article 64(1)(b), (h) and (i) and (2)(a) of Regulation (EU) 2016/429 and Article 21(2) of Delegated Regulation (EU) 2020/687 concerning the adaptation of the boundaries of the restricted zone with the aim of preventing the further spread of the disease.

5.1.3.2 Application of measures in protection and surveillance zones

47. The competent authorities in both regions made significant efforts to apply most of the relevant disease control measures in the restricted zone in accordance with Article 65 of Regulation (EU) 2016/429 and Article 22 of Delegated Regulation (EU) 2020/687. Application of some of those measures was more challenging after the situation deteriorated in November because of the number of cases confirmed and the many suspect cases notified daily.
48. In general, the competent authorities applied effective communication initiatives to inform all relevant parties within the restricted zones of the measures applicable in

accordance with Articles 22(3), (4) and (5), 25 and 40 of Delegated Regulation (EU) 2020/687 and to remind them of the importance of notifying immediately any suspect case of HPAI.

49. The SVL can make easily inventories of establishments keeping more than 50 poultry, as they are registered in the national database built for that purpose. The national reference centre for the epidemiology of avian influenza played a major role in that respect providing regularly updated data to the RVS and SVL on all establishments situated within restricted zones. However, performing inventories of smaller establishments was more difficult, as they are registered with the local authorities and that information is frequently not properly updated.
50. In general, the SVL in Veneto and Lombardy performed limited inventories of smaller establishments, although they obtained from the local authorities an approximate number of how many there could be in the established restricted zone, mainly in the protection zones (e.g., in some cases in Veneto, the SVL informed the audit team that there were on average some 30 or 35). Representatives of those services underlined that epidemiological evidence from the 2021-22 HPAI epizootic, including the analyses carried out by the NRL, confirms that those establishments played a negligible role in the dynamics and transmission of the disease in the affected areas and that they were right in focusing their control efforts on larger establishments (see section 4.4).
51. Once the number of outbreaks in the main affected areas became very high, some of the SVL in both regions could not carry out the quick official visits to all poultry establishments situated in the protection zones, as required by provisions laid down in Article 26(1) of Delegated Regulation (EU) 2020/687. The main reason for that was the temporary shortage of staff (see also 5.2.4).
52. The lack of checks in those establishments situated in protection zones, by definition at a high-risk of infection, precluded verification that they were applying proper biosecurity measures and implementing additional surveillance to identify the further spread of the disease from affected establishments quickly. This is not in line with the provisions laid down in Article 25(1)(b), (d) and (e) of Delegated Regulation (EU) 2020/687. Those limitations also applied to large establishments situated in some of those protection zones.
53. As an immediate reaction to the initial outbreaks of HPAI, the RVS in Veneto and Lombardy agreed with the national reference centre for the epidemiology of avian influenza and with the central competent authority to apply some preventive killing in establishments located within protection zones. However, this was not applied consistently nor in large scale. In Veneto, the authorities applied that measure in 11 cases within the first two weeks of the epizootic in October, whereas in Lombardy they did it in 16 establishments within the protection zones established for seven confirmed cases.
54. Representatives of the RVS of Lombardy underlined that in the cases where they had applied preventive killing, they could successfully prevent the spread of the disease to

the neighbouring area of the affected establishment. According to them, that was facilitated by delaying in parallel killing and disposal of poultry from the affected establishment, at least until the preventive killing of the neighbouring establishments had been finished.

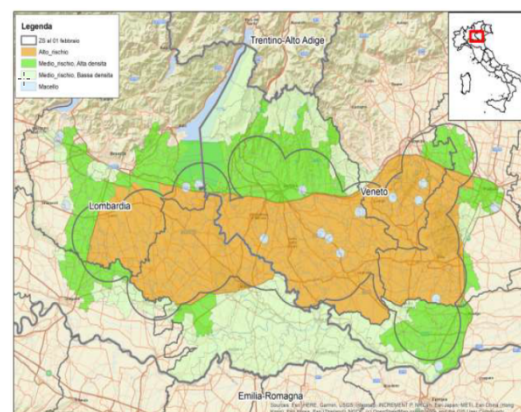
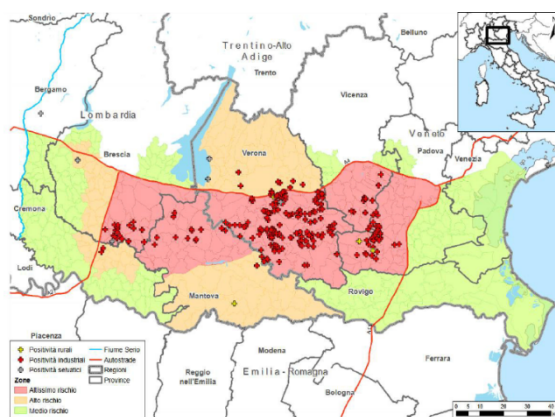
55. Once the number of affected establishments increased significantly and due to the limitations in the killing and carcass disposal capacities that affected both RVS at different moments, preventive killing was no longer feasible (see section 5.1.4.2). The authorities discussed with the industry the option of sending poultry from those establishments to slaughterhouses, as provided for in Article 22(2) of Regulation (EU) 2020/687. Both parties were convinced that reducing the density of poultry would facilitate the control and eradication of the disease, and both RVS applied this measure gradually and soundly. The measure contributed significantly to reduce the overall density of poultry in the zones B and A of both regions coming January 2022.
56. The impossibility to apply targeted preventive killing in protection zones in some of the high-risk affected areas did not allow the competent authorities to reduce the density of susceptible poultry as quickly within those zones as the epidemiological situation required. Considering that that was the preferred choice of the competent authorities based on their experience and the analysis of the situation, that cannot be considered fully in line with provisions of Article 61(1)(b) of Regulation (EU) 2016/429 and Article 22(2) of Regulation (EU) 2020/687.

5.1.3.3 *Further restricted zones*

57. During the first weeks of the epizootic in Veneto, none of the authorities considered necessary to establish further restricted zones around or adjacent to the protection and surveillance zones to apply additional restrictions and control measures within the high-risk zones B and A. That area had a very high density of establishments (e.g., there were 180 establishments only within the restricted zone set up in response to the first confirmed case) and of poultry, as all establishments were operating at their maximum capacity because of the proximity of Christmas.
58. The competent authorities were aware of the dense and frequent network of contacts occurring between many of those establishments, especially because most of them belong to the same few companies. The fast evolution of the disease confirmed that those circumstances were not properly considered in accordance with Article 64(2)(b) of Regulation (EU) 2016/429 and Article 21(1)(c) of Delegated Regulation (EU) 2020/687, when the authorities delimited the boundaries and size of the restricted zones to contain the spread of the disease and did not establish a further restricted zone immediately, precisely to prevent that.
59. On 5 November 2021, with 11 outbreaks already confirmed in Verona province and many other suspect cases under investigation), the national disease control centre decided to establish a first further restricted zone. Despite that, within the next two weeks the number of cases increased dramatically in Verona province, and the first cases were

confirmed in the neighbouring provinces of Padua (15 November), Brescia (16 November) and Mantua (19 November). On 22 November, the national disease control centre decided to expand the further restricted zone significantly, covering nearly the entire Verona province and the nearby areas, or the full territory, of other six neighbouring provinces.

60. The measures implemented in the context of the further restricted zone included intensified surveillance (e.g., testing of poultry before any movement was authorised), and restricting the repopulation of establishments keeping turkeys. On 22 November that measure covered the territory of the expanded zone. In areas of zones B and A contained in the further restricted zone, repopulation of establishments keeping other poultry species was only allowed after a careful risk assessment by the authorities.
61. Given the deterioration of the situation the following month, on 18 December the national disease control centre decided to expand the further restricted zone and introduced additional restrictions (see map below). In the central area of the zone (in red in the map on the left below), considered of very high risk, all repopulation was prohibited. In the orange area, the authorities could authorise repopulation exceptionally after a risk assessment; in the green area (considered of medium risk), that could happen according to an agreed timetable with the competent authorities.
62. At the end of January 2022, once the incidence of new outbreaks had diminished sharply and the density of poultry reduced dramatically, the national disease control centre decided to relax some of the restrictions within the further restricted zone. In the previous area considered of a very high risk (now orange in the relevant map on the right below), the competent authorities could allow repopulation of establishments after a risk assessment carried out by the national reference centre for the epidemiology of avian influenza. In the rest of the zone, now only differentiated according to the high (in dark green) or low (soft green) density of poultry, the repopulation was allowed under permission of the RVS and the SVL, respectively.
63. These two maps show the zone as established on 18 December 2021 and 2 February 2022, with the three colours showing the levels of risk, higher in the centre of the zone, in each of the areas considered within the zone (see an explanation in the points above):



64. The competent authorities carried out a risk assessment to inform their decision. For cases in the areas of higher risk, the RVS obtained the permission of the national disease control centre to grant derogations. After that and in all other cases where they granted a derogation, the RVS or the SVL granted them directly, but they communicated their decisions and the rationale behind to that centre.
65. The measures covered by the national order establishing the further restricted zone on 2 February 2022 were still in force at the time of this audit and repopulation was applied gradually and under full control of the competent authorities. The national reference centre for the epidemiology of avian influenza had evaluated which establishments within the zone could be restocked in Veneto (some 800 of a total of 1,748) and in Lombardy (some 310 of a total of 617).
66. By 28 February, the RVS and the relevant SVL of Veneto had authorised repopulation of 398 of those establishments, the majority keeping broilers (50% of the total that could be repopulated). The process was much slower for turkeys (in only 86 establishments of a total of 477 that could have done it). In those cases, official veterinarians had to carry out a verification of compliance with biosecurity rules unless that had been done the previous year.
67. The central competent authority informed timely the Commission and the other Member States of the establishment and adaptation of the further restricted zone as described above, which was in line with provisions laid down in Article 71(2) of Regulation (EU) 2016/429. Thus, the Commission could review the disease situation and those measures as required by paragraph 3 in the same Article and update regularly the Annex to Commission Implementing Decision (EU) 2021/641.

5.1.3.4 Derogations to measures applied in protection and surveillance zones

68. Both the RVS of Veneto and of Lombardy had a considerable number of requests for derogations for movements of poultry and its products from establishments situated in protection and surveillance zones, and in the further restricted zone. The RVS of Veneto handled some 600 requests between 25 October 2021 and 31 January 2022, and the RVS of Lombardy some 500 between 18 November and 31 December 2021. The audit team saw numerous examples of well-documented requests for those derogations, which in many cases were not granted. Overall, the competent authorities applied those measures in accordance with provisions laid down in Article 23 (point (a)) of Delegated Regulation (EU) 2020/687.
69. Staff of both RVS, and of the SVL more involved in handling those derogations, e.g., from Verona (responsible for some 400) and Brescia provinces; indicated that these tasks were a priority given the pressure from the operators and the need to reduce the size of the poultry population in the restricted zones sending quickly as many animals as possible for slaughter. They indicated that they were able to deal with all requests.
70. Most requests referred to moving poultry from protection and surveillance zones to the

closer slaughterhouses outside those zones and eggs for human consumption from the same zones (e.g., egg-packing centres and processing plants in the further restricted zone or in the free areas). There had been appropriate communication between the SVL of origin and the SVL of destination on the dispatch of consignments of those products originating in protection and surveillance zones.

71. The process to grant the derogations mentioned above required the favourable outcome of a risk assessment carried out and documented by the national reference centre for the epidemiology of avian influenza. In July 2021, the regions in the North of Italy, keeping some 80% of the poultry population in the country, had agreed with the central competent authority on a set of harmonised rules to deal with derogations in the event of HPAI outbreaks. The audit team checked in the SVL visited examples of the derogations they had granted. All of them kept appropriate documentation of the checks and tests they had carried out to verify compliance with the specific conditions provided for in Articles 28 to 31, 34, and 43, 44, 46, 47 and 50 of Delegated Regulation (EU) 2020/687 to grant those derogations.
72. The RVS of Lombardy granted a few derogations to move consignments of hatching eggs from surveillance zones to hatcheries situated in the further restricted zone or in the free areas, and the RVS of Veneto some for day-old-chicks to move from both protection and surveillance zones. These happened mostly towards the end of December 2021, from areas considered already of low risk. In those cases, when appropriate and as required by EU legislation, the SVL of origin had informed the SVL responsible for the establishment of destination to ensure that they could apply the required surveillance on that establishment.

Conclusions on general measures in relation to protection and surveillance zones

73. Although the competent authorities established restricted zones rapidly once they confirmed the presence of HPAI in poultry establishments, other shortcomings, such as the limited availability of means to apply animal depopulation and carcass disposal and the shortage of personnel to visit quickly high-risk establishments within those zones, undermined the quick application of measures to contain the disease and the prevention of its spread.
74. The competent authorities did not evaluate swiftly all relevant epidemiological criteria and establish immediately a further restricted zone in the area of Veneto where the epizootic began and which they considered of very high risk for the spread of HPAI. That delay undermined the effectiveness of the additional control measures they applied, which therefore were not sufficient to stop the spread of the disease before it reached epizootic proportions and expanded far beyond the initially affected area.
75. Once they established a further restricted zone, the competent authorities informed timely the Commission. That reinforces the transparency and reliability of the zoning policy applied in these situations in the EU.

76. The application of preventive killing to sufficiently reduce the poultry population in high-risk areas quickly and stop the spread of the disease was not possible due to resource constraints as all animal depopulation capacity was compromised by the numerous affected establishments. The impact of that shortcoming was partially mitigated by the decisive action of the competent authorities and the cooperation of the industry to send for slaughter as many poultry as possible from establishments situated within restricted zones.
77. The competent authorities granted derogations from prohibitions to move animals and products of animal origin from restricted zones correctly and transparently. They did not compromise the health status of the establishments and areas of destination of those commodities.

5.1.4 Animal depopulation for the purpose of disease control

5.1.4.1 Animal welfare considerations

78. The contract that the RVS of Lombardy had signed with the external service provider responsible for killing of animals and carcass disposal contains specific provisions requiring that company to ensure that their staff is properly and regularly trained to comply with animal welfare requirements at the time of killing animals.
79. Recommendation No 4 of the previous audit (on ensuring that the RVS effectively draw and use actions plans for the depopulation activities, which respect animal welfare requirements) still required further action from the competent authorities at the beginning of this audit. Both the RVS of Veneto and of Lombardy had upgraded the operational instructions and the guidance contained in their respective contingency plans, and they had updated the models of action plans to be used by staff of the SVL.
80. The audit team checked several examples of depopulation records during the on-the-spot visits in some SVL in both regions. In all cases their staff had verified and agreed with the external providers the application of one of the methods for poultry depopulation as recommended in the national contingency plan for HPAI, i.e., the use of high concentrations of carbon dioxide in containers or through whole-house gassing, and the use of Nitrogen. That was reflected in the action plans drawn for that purpose. According to some of those official veterinarians in charge of supervising depopulation activities, service providers were very experienced with the method applied and they did not detect any significant problem with the respect of requirements on animal welfare laid down in Regulation (EC) No 1099/2009.
81. Some of officials explained that the main difficulty they had confronted were the shortage of carbon dioxide (mainly in Veneto) and of Nitrogen (mainly in Lombardy) during the peak of the epizootic, because of the unprecedented high demand of those gasses for animal depopulation and the simultaneous constraints in their supply deriving from the Covid-19 pandemic.

82. The audit team saw evidence of observations regarding the methods of killing and their possible impact on animal welfare and the difficulties associated with their use, reflected in the reports prepared by responsible officials for the animal depopulation activities applied in some establishments, as required by Article 18 of Regulation (EC) No 1099/2009.

5.1.4.2 *Disposal of carcasses*

83. The authorities of Veneto and Lombardy, experienced difficulties to depopulate establishments due to the increasing amount of dead and killed poultry, and of other contaminated products, such as eggs, litter and feed. That situation worsened as the epizootic deteriorated. The additional spare capacity provided by the processing and incineration plants approved to handle category 1 and / or category 2 ABP in Veneto and in five neighbouring regions (equivalent to some 15-20% of their total capacity) turned out to be completely insufficient to cope with the size of the 2021-2022 HPAI epizootic. In the region of Veneto this was exacerbated by the inability of the competent authority to conclude a tender in order to appoint a depopulation and disposal provider despite funds being allocated by the central competent authority and this having been identified as a weakness already in previous Commission audits (see section 4.3).

84. Representatives of several SVL indicated that the service provided by the processing plants regarding means of transport, and associated personnel and equipment to load them did not match their needs by far. Some of them had hired specialised companies to do that, but as it had not been foreseen and prepared appropriately in peace time, it proved to be a significant challenge.

85. The means of transport available at short notice were often not suitable for safety reasons (e.g., not sufficiently leak-proof), and the staff involved did not have equipment to load the trucks. Other found difficulties to dispose of the material they had collected. During the Christmas period, still within the critical stage of the epizootic, there were important restrictions for those means of transport to circulate through major roads, which limited even more their availability and operational capacity. They added that all those shortcomings caused delays of up to a month in some cases to dispose of carcasses and of nearly two for other contaminated products, with delays of 15 to 20 days being very common during the peak of the epizootic.

86. Representatives of all authorities at central and regional level confirmed that they had not requested those companies to make available more collecting and processing capacity. To do so would have needed an agreement with those companies on specific conditions and financial arrangements, which they had not explored in peace time. National legislation gives the central competent authority another option, which is the declaration of a national emergency, entitling them to order those companies to provide the necessary support at short notice. However, they indicated that this was not possible during the HPAI epizootic because of the simultaneous emergency caused by the Covid-19 pandemic.

87. Representatives of the RVS of Veneto explained the many alternatives they had explored to accelerate disposal of carcasses which were still not enough for the quantities needed. They included transforming temporarily category 3 processing plants to category 2, using a large incinerator from a neighbouring province, using landfill sites, selecting specific areas for their burial, and applying temporary composting to poultry carcasses. Burial was only accepted for five establishments, while the temporary composting of poultry carcasses, after a careful evaluation by the national disease control centre, was authorised on 30 November for 11 establishments (requiring posterior processing of the resulting material). Other options (e.g., transforming temporarily category 3 processing plants to category 2, burial), were not successful, with operators objecting to change their usual business practices and the relevant competent authorities refusing to accept options like burial on environmental grounds. Those representatives conceded that they should have explored those alternatives in peace time, to know of those limitations beforehand and to negotiate feasible arrangements for the use of any of them.
88. By the end of November 2021, when there were more than 7,000 tonnes of carcasses accumulated in affected establishments in the region, the national disease control centre authorised the RVS of Veneto to use a category 2 biogas plant for their processing. They did that in accordance with a protocol developed *ad hoc* by that service, that demonstrated the inactivation of any remaining risk of HPAI with the process and had agreed the conditions for that exceptional activity with the relevant company. This option facilitated disposal of the amount mentioned above within approximately six weeks. Representatives of the RVS of Veneto conceded again that they should have been aware before the epizootic of that alternative to the use of the standard processing plants.
89. The shortcomings highlighted in the previous points are not in line with requirements of Articles 13(1)(a), 43(2)(c)(i) and (iii), and 61(1)(b) of Regulation (EU) 2016/429 on the responsibilities of the competent authorities to have access to adequate facilities and equipment and to have an effective organisation to be capable to take the necessary disease control measures, including disposal of animals that may be contaminated or contribute to the spread of the disease, in the event of an animal health crisis like the recent HPAI epizootic.
90. When there was collection and disposal of dead and killed poultry, staff of the relevant SVL regularly verified compliance with biosecurity aspects, transport documentation and reception and processing of the material at both ends of the disposal chain. Documenting that was part of the new operational instructions prepared by both RVS after the 2017-2018 HPAI epizootic in response to requirements from the central competent authority. The audit team saw documentation confirming that in some of the visited SVL. That was in line with provisions laid down in Article 22(3) and (4) of Delegated Regulation (EU) 2020/687.

Conclusions on animal depopulation for the purpose of disease control

91. The competent authorities took appropriate technical and supervisory measures to ensure the protection of animal welfare during depopulation of poultry establishments to control disease outbreaks. In doing that, they addressed an outstanding recommendation from the previous audit.
92. The competent authorities had not taken adequate administrative steps and made the necessary logistical arrangements to ensure sufficient capacity to collect and dispose safely of the carcasses of dead and killed poultry in establishments where the presence of HPAI was confirmed or as a preventive measure in areas affected by the disease. This was even more evident in the region of Veneto and caused significant delays in the depopulation of establishments and accumulation of carcasses, which significantly undermined the effectiveness of other measures to contain the spread of the disease.

5.1.5 Cleaning and disinfection

93. These activities were outsourced to external providers, but there was a point when they could not apply these measures within the expected deadlines, in particular in Veneto during the peak of the epizootic. Both the central competent authority and the regional authorities reacted quickly to address the situation and asked the Army to provide support, which they did immediately and effectively. The cases where the competent authorities had to postpone the application of cleaning and disinfection activities in affected establishments were not related to lack of resources for it, but a consequence of delays in removal of dead bodies or killed animals (see the previous section).
94. The audit team verified in the SVL and in the establishments visited, that official veterinarians had carried out appropriate official controls during those activities, and that they had documented them. The examples showed that the contaminated litter, was in many cases kept in the premises of affected establishments, stacked for at least 42 days to compost before being eventually disposed of safely.
95. The competent authorities provided guidance to their staff to verify compliance with relevant rules on cleaning and disinfection (e.g., between mid-November 2021 and 2 February 2022, the RVS of Veneto issued several orders and clarification notes providing instructions on how litter had to be managed in affected establishments).

Conclusions on cleaning and disinfection

96. The competent authorities ensured the adequate cleaning and disinfection of affected establishments except where the presence of contaminated materials precluded them to do so and caused delays. These activities contributed to the elimination of residual infection.

5.1.6 Lifting of restrictions

97. The competent authorities only started to lift most of the restrictions in protection and surveillance zones well advanced January 2022. Since early February 2022, they started to allow repopulation of certain establishments.
98. The SVL in cooperation with the relevant RVS and the national disease control centre was responsible of lifting restrictions in protection and surveillance zones. After verifying that the preliminary cleaning and disinfection had been carried out, they checked the number of establishments present in the zones and whether they were occupied or not, and with which species, and the surveillance activities that had been carried out in those zones recently.
99. At the time of lifting the restrictions, staff of the SVL had visited all registered establishments in protection zones, and many from the surveillance zones had been tested in the context of movements for slaughter or applications for other derogations. Thus, those cases were managed in accordance with provisions of Articles 39 and 55(1)(b) (referring to Article 41) of Delegated Regulation (EU) 2020/687.

Conclusions on lifting of restrictions

100. By the time of this audit, the authorities had taken a proportionate and risk-based approach to lifting some animal health restrictions in the main areas affected by the HPAI epizootic. Thus, that should contribute to prevent the further spread and recrudescence of the disease in those areas with a high density of susceptible poultry.
101. The checks applied for lifting restrictions, together with the fact that measures in the further restricted zone were still in force, provided guarantees that it was very unlikely that there was any remaining circulation of the HPAI virus.

5.1.7 Repopulation of affected holdings

102. At the time of this audit, the competent authorities have decided to postpone the authorisation to repopulate affected establishments until that activity is well underway within the further restricted zone in non-affected establishments.
103. The audit team was informed of the rules that will apply in those cases, including for example performance of an on-site visit, where staff of the SVL must check the suitability of the biosecurity measures and follow-up checks after introduction of new poultry, including clinical inspections and laboratory testing. Those measures are in line with provisions laid down in Article 61(3) of Regulation (EU) 2020/429 and Articles 57(1) and (2) and 59(5) of Regulation (EU) 2020/687.

Conclusions on repopulation of affected holdings

104. The rules available for the competent authorities to allow repopulation of establishments affected by outbreaks of HPAI are suitable to verify that there will not be any risk of residual infection in them and that general biosecurity measures to prevent reoccurrence of the disease are in place. No such repopulation had yet taken place at the time of the audit.

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

105. In recent years, the central competent authority has prompted several times the RVS to update their contingency plans and operational manuals in order to address the recommendations of the previous audit. The regional authorities updated their operational instructions to respect animal welfare at the time of killing animals for disease control purposes (see section 5.1.4.1). On the other hand, the audit team observed that the RVS of Veneto and of Lombardy, and their SVL, had kept different levels of update in their documentation and operational procedures to respond to animal health emergencies (e.g., in relation to preparedness for killing and disposal of carcasses).
106. The RVS of Veneto – and some of its SVL – had taken limited steps to update their regional operational manuals after the previous HPAI epizootic and after organising some simulation exercises in 2019. In contrast with that, they had already taken action to update many of those documents during February 2022, in reaction to the recent HPAI epizootic. The RVS of Lombardy had updated their operational manuals, and shared them with the SVL, in November 2020.
107. More than the existence of an updated operational manual, the main problems for the application of control measures by the SVL were structural (e.g., killing and disposal), and some operational shortcomings (e.g., lack of rapid analysis of epidemiological enquiries, availability of staff), as highlighted in other sections of this report. All services adapted quite quickly many of their procedures and administrative arrangements to those challenges (e.g., solving quickly *ad hoc* contracts with external service providers, organising additional surveillance and sampling programmes in restricted zones, developing tools to follow the evolution of those zones and adapt measures and deployment of human resources accordingly, etc.).
108. The central competent authority has a dedicated unit responsible for auditing the level of compliance of the RVS and SVL with their official control responsibilities in the sense of the provisions on internal audits laid down in Article 6 of Regulation (EU) 2017/625. The scope of those audits includes verifying the state of play of the animal health emergency preparedness systems put in place by those services in accordance with national rules on contingency planning. According to representatives of the central

competent authority, in 2020 that unit planned to audit the level of preparedness of the authorities of Veneto to respond to HPAI outbreaks. However, that had to be postponed due to the Covid-19 pandemic.

109. Representatives of both RVS provided evidence of the analysis and actions they took before the epizootic started. Those included contacts and discussions with the central competent authority (e.g., on the need for a national coordinated policy for killing and disposal and alternative policy options to reduce the density of poultry) and with the industry (e.g., on biosecurity and HPAI surveillance), and examples of how they had updated, or intended to do so, their operational manuals to respond to outbreaks of HPAI.

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

110. The database accessible to all competent authorities supported the selection and application of HPAI control measures effectively during the recent HPAI epizootic.
111. There are still some issues regarding availability of up-to-date information on the distribution of small poultry establishments keeping less than 50 animals that were active in the protection and surveillance zones established around HPAI outbreaks. Nevertheless, the number of outbreaks affecting this type of establishments during the 2021-2022 epizootic was very low (13 out of 315) and their willingness to notify suspect cases was very high.
112. Since 2018, the competent authorities have highlighted the importance of reducing the number of operating establishments, the density of poultry, and to avoid the proximity between establishments, particularly in high-density areas. The relevance of those risk factors in the dynamics of the recent HPAI epizootic was confirmed by epidemiological and phylogenetic studies as described elsewhere in this report. Both RVS provided the audit team with detailed information on the evolution of those population parameters in recent years.
113. The situation in Lombardy has improved slightly. Even if the number of establishments keeping layer hens has grown by 10% since 2018 (319 now), the total population in that sector has decreased by 20%. The number of establishments keeping turkeys and, mainly, the total poultry population, have decreased as well (the latter by more than 25%). In contrast with that, in Veneto both the number of establishments and the whole poultry population grew significantly between 2017 and 2021. That growth was manifest in the layer hens' sector (including pullets), with more than 130 new establishments (e.g., nearly a 50% increase in Verona province) and a 20% increase in the total population. And similarly in the broiler sector, with some 50 new establishments adding 3 million poultry to an already very high population in this sector (791 establishments, more than half of them in Verona province).
114. Most of the epidemiological enquiries, and the summaries presented by the RVS and SVL of their inspection programmes to verify compliance with biosecurity rules, underline the satisfactory levels of compliance observed. However, there are several

features of the recent epizootic that cast doubts on the accuracy of those conclusions: a) the assumption that introduction of the disease in poultry establishments through direct or indirect contact with wild birds played a major role in the epizootic, b) the fact that a significant number of establishments affected by the recent epizootic were affected by the previous one in 2017-2018, e.g., 8 out of the 27 affected in Brescia province, and c) the geographical distribution of the disease, with numerous clusters of outbreaks, and the phylogenetic and epidemiological evidence corroborating the likely lateral spread of the infection, including between some of the provinces and between establishments of the same companies.

115. According to the analysis of the competent authorities, local airborne spread played a significant role in transmitting the infection in areas with a very high density of establishments (e.g., facilitated by the proximity between establishments and by the use of force ventilation), together with the risk of environmental infection associated with wild birds. However, the industry had not adapted disease preventive measures properly to mitigate the impact of those critical risk factors, and the competent authorities had not adapted their verification activities to ensure that the measures applied by the industry were suitable for that purpose. Therefore, all that evidence had not been properly considered to guarantee that operators in the poultry industry can fulfil their responsibilities to minimise the risks of spread of HPAI applying appropriate biosecurity rules in line with the requirements laid down in Articles 10(1)(a)(iii), (b) and (c), (4) and (5), and 11(1)(b) of Regulation (EU) 2016/429.
116. The official controls, despite their extensive application and largely positive outcome, did not contribute sufficiently to correct the shortcomings related to biosecurity that likely facilitated the spread of the disease during the 2021-2022 epizootic. This is not in line with Article 5(1)(a) of Regulation (EU) 2017/625.

5.2.3 Operation of the national and local disease control centres – Information management tools and data analysis

117. The central competent authority via the operation of the national disease control centre is responsible of ensuring coordination of the implementation of the disease control measures applied by the RVS and the SVL in line with the national contingency plan for HPAI. They did that with the support of the national reference centre for the epidemiology of avian influenza and of the NRL. Both have access to state-of-the-art information management and analysis tools that allow them to provide regular advice to the national disease control centre and to the RVS, which they did, although with some important limitations (see sections 5.1.1.2 and 5.1.3.3).
118. The national disease control centre coordinated the application of control measures effectively. They provided good advice and took most of the decisions under its remit without delay, while maintaining constant communication with the regional authorities during the epizootic. The audit team could review the minutes of many of the meetings the centre held with the regional and local services, and with other stakeholders.

119. However, certain shortcomings, such as a) the lack of adequate epidemiological expertise to analyse the dynamics of the disease quickly, anticipate its evolution, and advice appropriately on actions to curtail its spread, b) the delays during the initial stages of the epizootic to decide on establishing a further restricted zone, and c) the incapability to find quickly adequate solutions to the problems experienced with application of animal depopulation, indicate that the operation of the national and regional disease control centres was not fully operational, which is not in line with Article 43(2)(a) and (d) of Regulation (EU) 2016/429.
120. The RVS set up their own control centres and provided regular support to the SVL where HPAI outbreaks were confirmed, which had their own operational local control centres. The audit team saw that the exchanges between the national, regional, and local centres were constant during the epizootic and were well documented. Overall, the coordinating activities of all disease control centres were in line with requirements on the application of the contingency plan for HPAI laid down in Article 43(2)(b) of Regulation (EU) 2016/429.

5.2.4 Availability of human resources – Responsibilities, instructions, and training

121. The SVL in Verona experienced a shortage of staff during the peak of the epizootic as the number of outbreaks increased dramatically. During that time, they received temporary support from the official veterinarians responsible for other areas of control in the SVL (e.g., for food safety). They got help as well from several private veterinary practitioners from the poultry industry, called upon temporarily for the occasion, and who carried out some other official activities where the risk of any conflict of interest was negligible. However, that was not enough, and that shortage caused delays in applying certain control measures (see for example section 5.1.3.2).
122. Neither the national nor the regional disease control centres reacted quickly enough to make available sufficient additional staff to attend the demands of that SVL during the worst weeks of the epizootic. That was not in line with requirements laid down in Articles 13(1)(a) and 43(2)(c)(iv) of Regulation (EU) 2016/429 on responsibilities of the competent authorities to have qualified personnel and an effective organisation to apply disease control measures effectively, and on application of the contingency plan for HPAI.

5.2.5 Availability of equipment and materials

123. After the publication of the Ministerial Decree in March 2018, the RVS had to make administrative arrangements to outsource animal depopulation activities to external service providers and ensure their rapid deployment in areas with a high density of poultry. In October 2019, the RVS of Lombardy signed a new contract to ensure access for the next five years to the services of a private contractor for that purpose, including carcass collection and disposal.
124. The regional authorities of Veneto had not yet addressed that issue in October 2021,

despite being granted more than two and half million euro for all activities by the Italian Government. That was in contradiction with the commitments they gave in response to one of the recommendations of the previous audit. This was due to a delay in the tender process, which they launched at the beginning of 2020 and was put on hold due to the Covid-19. That was still the case at the time of this audit.

125. During approximately the first month of the epizootic, the RVS and the SVL of Veneto used the service provider contracted by Lombardy for the application of animal depopulation. But this was no possible once the situation deteriorated in the latter region too, as the company was called in by the RVS of Lombardy to fulfil their exclusive contractual responsibilities.
126. The RVS of Veneto hired temporarily another company from Italy, the only other alternative in the country, but with the high number of outbreaks they had to handle, they explored other options from Holland and Germany. They signed a contract with a company from Holland that started to operate before the end of November but that was not sufficient to prevent the delays in killing poultry from affected establishments, as explained in Section 5.1.4.2.
127. The shortcomings described above are not in line with requirements of Articles 13(1)(a), 43(2)(c)(i) and (iii), and 61(1)(b) of Regulation (EU) 2016/429 on the responsibilities of the competent authorities to have access to adequate facilities and equipment and to have an effective organisation to be capable to take the necessary disease control measures, including the rapid killing of animals from affected establishments, in the event of an animal health crisis like the recent HPAI epizootic. They are not in line either with provisions on the application of the contingency plan for HPAI laid down in Article 43(2)(c)(iii), (v) and (vi) of the said Regulation to make available all appropriate materials and resources necessary for the rapid and efficient eradication of the disease.

5.2.6 Diagnostic capacity in case of an emergency

128. Both the NRL and the other laboratories involved in testing for HPAI had addressed the difficulties experienced during the 2017-2018 HPAI epizootic. During the recent epizootic, the NRL proved that they were able to guarantee availability of the necessary diagnostic services while meeting high quality standards, and even improving them to adapt to the epidemiological circumstances and accelerate detection of the disease. Their extensive use of genome sequencing and performance of phylogenetic analyses contributed significantly to the epidemiological analysis of the epizootic and to ascertain some of the main causes behind its evolution.

Conclusions on the application of the specific contingency plan

129. The competent authorities counted on well-developed and up-to-date contingency plans and operational manuals to respond to outbreaks of HPAI. However, some authorities responsible for some of the high-risk areas more affected by the 2021-2022 epizootic, had not taken adequate action to make sure that they could avail timely of adequate human,

technical and material resources to contain the disease rapidly and effectively. Those shortcomings were instrumental in facilitating the spread and long duration of the epizootic in those areas, and thus contributed to its high economic impact.

130. The absence of internal audits to check the compliance and suitability of the animal health emergency preparedness systems in the regions repeatedly affected by HPAI epizootics favoured the persistence of shortcomings in those systems, notably in Veneto. The existing shortcoming undermined the effectiveness of disease control and contributed to the size of the epizootic.
131. The disease control centres established at national, regional, and local level during the epizootic coordinated application of the main control measures in the affected areas effectively. However, they all failed to take certain important decisions at critical times, and thus, they did not prevent the spread of the disease effectively.
132. The competent authorities have repeatedly underlined the significant risk that the very high density of poultry represents for the areas affected by the 2021-2022 HPAI epizootic, but they have not acted accordingly to reduce it. Moreover, evidence confirms that that density has even increased in some of those areas. This, coupled with the sub-optimal application of biosecurity measures at times unsuitable to mitigate the prevailing risks of HPAI introduction and spread, raises concerns about their capability to prevent and control new HPAI epizootics.
133. The NRL increased and adapted appropriately its testing capacity and diagnostic strategy to cope with the 2021-2022 HPAI epizootic while ensuring the rapid detection and confirmation of the disease. That enabled the competent authorities to apply disease control measures quickly in areas with a high risk of disease spread.

5.3 OFFICIAL CONTROLS ON RESTRICTIONS AND DEROGATIONS THERETO RELATED TO INTRA-UNION TRADE OF POULTRY COMMODITIES

134. In all cases of suspicion of HPAI, the authorities forbid immediately the sale or movement of all birds and their products from the relevant establishment. This prohibition remained in force until the competent authorities ruled out the presence of the disease or, when it was confirmed, until they lifted the restrictions in the established restricted zone. The movement of day-old-chicks and hatching eggs from restricted zones to parts of Italy that could participate in intra-EU trade was only permitted in strict compliance with permitted derogations, including with provisions on quarantine, clinical inspection and testing carried out at the establishment of destination.

Conclusions on official controls on restrictions and derogations thereto related to intra-Union trade of poultry commodities

135. The competent authorities took the necessary measures and applied the required movement restrictions to prevent the spread of HPAI through intra-Union trade of

poultry and hatching eggs.

6 OVERALL CONCLUSIONS

The Italian competent authorities have not yet addressed satisfactorily some important structural and organisational shortcomings that undermined the capacity of the animal health emergency preparedness system, notably in Veneto and Lombardy, to respond rapidly and effectively to the 2021-2022 HPAI epizootic.

The Commission had highlighted those shortcomings in previous audits (in 2015 and 2019) and requested the competent authorities to resolve them as a priority. The delay in addressing those deficiencies, in particular in the Veneto region, had serious consequences as reiterated here below.

The areas of Veneto and Lombardy that were severely affected by the 2021-2022 epizootic have a high seasonal risk of introduction of HPAI via migratory wild birds. In addition, the poultry production sector in those areas is exposed to other intrinsic risk factors that may facilitate the rapid spread of the disease (e.g., high density of poultry establishments, intense network of frequent direct and indirect contacts). The competent authorities made significant efforts in recent years, including intensified official controls, to increase the levels of awareness and compliance with national rules on biosecurity in poultry establishments, but their effectiveness remains questionable.

Surveillance in wild birds was not effective to detect promptly the circulation of HPAI virus. This delayed the reinforcement of biosecurity measures to prevent its introduction in the poultry population, where that surveillance worked better, and the disease was usually confirmed quickly.

Despite previous experience and the strengths of the disease control system in those areas (e.g., experienced officials and production sector, availability of excellent technical and laboratory expertise, frequency of inspections in poultry establishments), the existing shortcomings favoured the epizootic to worsen rapidly.

The limited capacity to apply animal depopulation measures in affected establishments quickly and use preventive killing to reduce the infective pressure and the density of susceptible animals in the affected areas, in particular in Veneto alongside the risk factors mentioned above, favoured the widespread transmission of the disease, and delayed the eventual control of the epizootic.

The main cause precluding the control of the spread was the limited capacity to depopulate affected establishments quickly and to kill poultry preventively to reduce the infective pressure and the density of susceptible animals in the affected areas, in particular in Veneto. That, alongside the shortages of staff to perform epidemiological enquiries timely and the absence of capacity to dispose quickly of carcasses and contaminated material, favoured the widespread transmission of the disease, and delayed the eventual control of the epizootic.

The activities of the competent authorities, including of the national disease control centre, and the control measures applied became more effective only after the sharp reduction of the density of poultry in the main affected areas resulting from the many disease outbreaks and the policy to empty non-affected establishments. In this context the national disease control centre did not evaluate the epidemiological situation adequately from the beginning in order to take the necessary actions timely.

During the epizootic, the competent authorities managed properly the risks of transmission of the disease to other Member States through intra-EU trade.

7 CLOSING MEETING

On 11 March 2022, the audit team held a closing meeting with representatives of the competent authorities. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The representatives of the competent authorities did not indicate any disagreement with them and undertook to take immediate action to address the shortcomings identified by the audit team.

8 RECOMMENDATIONS

No.	Recommendation
1.	<p>To design and implement surveillance for early detection of HPAI in wild birds in a way that is appropriate and proportionate to the objectives pursued and to the risk factors involved to provide an early warning for the possible introduction of the disease in poultry so that operators can apply reinforced preventive measures without delay.</p> <p><i>Article 26(2) and (4), and 27 of Regulation (EU) 2016/429.</i></p> <p><i>Articles 4(a)(b) and 10(2) of, and Annex II (Section 4) to Delegated Regulation (EU) 2020/689.</i></p> <p><i>Based on conclusion 37 and associated finding 15.</i></p>
2.	<p>To ensure that operators fulfil their responsibilities to immediately notify the competent authority where there is any reason to suspect the presence in the poultry they keep of HPAI.</p> <p><i>Article 18(1)(a) and (c) of Regulation (EU) 2016/429.</i></p> <p><i>Based on conclusions 36 and associated finding 19.</i></p>

<p>3.</p>	<p>To make appropriate arrangements to accelerate the analysis of the results of epidemiological enquiries in case of suspicion and confirmation of HPAI so that the competent authorities can take well informed decisions on the application of temporary restrictions before the disease is confirmed, and on the establishment, boundaries, and prioritisation of disease control measures in restricted zones.</p> <p><i>Articles 55(1)(e) and (f), 56(a)(ii), 57(2)(e), 62(1) and 64(1)(f) and (2)(b) of Regulation (EU) 2016/429, and Articles 8(3), 9, 21(1)(c) and 23(a) of Delegated Regulation (EU) 2020/687 – on the contribution of epidemiological enquiries to inform which disease control measures to apply and where.</i></p> <p><i>Articles 5(1)(a) and 12(2) and (3) (read with point 5 in Chapter II of Annex II thereto) of Regulation (EU) 2017/625 – on procedures and/or arrangements to ensure the effectiveness of official controls and other official activities, to verify them, and to take corrective action and update them as appropriate when shortcomings with their application are identified.</i></p> <p><i>Article 43(2)(d)(iii) of Regulation (EU) 2016/429 – on the availability of operational expert groups as part of the contingency plan for HPAI.</i></p> <p><i>Based on conclusion 38, 74 and 131, and associated findings 25, 27, 58 and 119.</i></p>
<p>4.</p>	<p>To take appropriate action to improve the effectiveness of the biosecurity measures applied by operators of poultry establishments, by: a) evaluating their suitability to mitigate the prevailing risk factors involved in the areas where they are situated according to the local circumstances and practices, b) organising awareness and training initiatives tailored to the results of that evaluation, and c) applying official controls to verify their proper application. Thus, they will be able to prevent the introduction and minimise the spread of HPAI, in particular in areas with a high risk of incursion of the disease via migratory wild birds.</p> <p><i>Articles 10(1)(a)(iii), (b) and (c), (4) and (5), and 11(1)(b) of Regulation (EU) 2016/429 – on responsibilities on disease prevention and biosecurity.</i></p> <p><i>Articles 5(1)(a) of Regulation (EU) 2017/625 – on general obligations of the competent authorities to have procedures and/or arrangements in place to ensure the effectiveness of official controls.</i></p> <p><i>Based on conclusion 132 and associated findings 115 and 116.</i></p>

<p>5.</p>	<p>To take full consideration of all appropriate criteria that should be analysed in the context of a potential HPAI epizootic to decide quickly on the establishment of a further restricted zone to prevent the spread of the disease in areas where the risk of transmission is especially high.</p> <p><i>Articles 64(2)(b) and 71(2) and (3) of Regulation (EU) 2016/429, and Articles 21(1)(c) and 23(a) of Delegated Regulation (EU) 2020/687.</i></p> <p><i>Article 43(2)(a), (b) and (d)(i) and (ii) of Regulation (EU) 2016/429 – on the application of the contingency plan for HPAI</i></p> <p><i>Based on conclusions 38 and 74, and associated findings 25, 27 and 58.</i></p>
<p>6.</p>	<p>To render more functional the national and regional disease control centres for HPAI ensuring that they have access to adequate technical and epidemiological analysis expertise at all times so that they can: a) take well-informed rapid and effective decisions to control the disease as soon as primary cases are confirmed to prevent its spread, and b) assist the services responsible for controlling the disease to have access to all the necessary resources to do that effectively and without delay.</p> <p><i>Article 43(2)(a) and (d) of Regulation (EU) 2016/429 – on the application of the contingency plan for HPAI.</i></p> <p><i>Based on conclusions 38, 40, 73, 76, 92, 129 and 131, and associated findings 25, 27, 32, 56, 89, 119, 122 and 127.</i></p>
<p>7.</p>	<p>To make adequate arrangements to ensure that the competent authorities responsible for controlling outbreaks of HPAI have access to sufficient human resources to take all the necessary and appropriate measures, including visits to establishments situated within the restricted zone, to do that effectively and without unjustified delay.</p> <p><i>Articles 13(1)(a) and 43(2)(a), (b) and (c)(iv) of Regulation (EU) 2016/429 – on responsibilities of the competent authorities to have an effective organisation and a contingency plan for HPAI that allow them to have access to personnel.</i></p> <p><i>Articles 25(1)(b), (d) and (e), and 26(1) of Delegated Regulation (EU) 2020/687 – on visits to establishments in protection zones.</i></p> <p><i>Based on conclusions 73 and 129, and associated findings 51, 52 and 129.</i></p>

<p>8.</p>	<p>To take adequate administrative steps and make the necessary logistical arrangements to ensure sufficient capacity to apply killing of animals for disease control purposes and safe collection and disposal of the carcasses of dead and killed poultry and of other contaminated products in establishments where the presence of HPAI is confirmed and where preventive killing needs to be applied as a control measure.</p> <p><i>Articles 13(1)(a), 43(2)(c)(i) and (iii), and 61(1)(b) and (c) of Regulation (EU) 2016/429 – on the responsibilities of the competent authorities to have access to adequate facilities and equipment and to have an effective organisation to be capable to take the necessary disease control measures.</i></p> <p><i>Articles 12(1) and 22(2) of Delegated Regulation (EU) 2020/687 – on the disease control measures that the competent authority shall apply immediately upon confirmation of an outbreak of HPAI, and on preventive killing.</i></p> <p><i>Based on conclusions 40, 73, 76, 92 and 129, and associated findings 32, 56, 89 and 127.</i></p>
<p>9.</p>	<p>To carry out audits of the animal health emergency preparedness system in place in the regions repeatedly affected by HPAI epizootics in recent years to ascertain their compliance with national and EU requirements and their suitability and readiness to control outbreaks of the disease rapidly and effectively.</p> <p><i>Article 6 of Regulation (EU) 2017/625.</i></p> <p><i>Based on conclusions 37, 38, 40, 73, 76, 92, 129 and 130, and associated findings 15, 25, 27, 32, 51, 52, 56, 89, 108, 122 and 127.</i></p>

APPENDIX – SPECIFIC LEGAL REQUIREMENTS RELATED TO SPECIFIC PROVISIONS AND MEASURES

SPECIFIC CHAPTER IN THE REPORT	SPECIFIC PROVISIONS AND MEASURES	APPLICABLE LEGISLATION CORRESPONDING TO THE SPECIFIC PROVISIONS AND CONTROL MEASURES FOR HPAI AND TO RELATED REQUIREMENTS ON ANIMAL WELFARE AND ABP					
		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.1.1.1	Detection and notification of suspect cases – Handling of suspicion	<p><i>Art. 10, 11 and 13(2) – on responsibilities for animal health and biosecurity</i></p> <p><i>Art. 12(1)(b) and (c)(iii) – early detection</i></p> <p><i>Art. 18(1), 24 and 53(1) – operators’ responsibilities</i></p> <p><i>Art. 26, 54(1) and (2) – surveillance and investigation of suspects by competent authorities</i></p> <p><i>Art. 70(1) and (2) – HPAI in wild birds</i></p>	<p><i>Art. 5 – on obligations of operators</i></p> <p><i>Art. 6 – on investigation by the competent authorities</i></p> <p><i>Art. 62 to 67 – measures in the event of suspicion or confirmation of HPAI in wild birds (case investigation, determination of an infected zone and measures applied therein, awareness)</i></p>		<p><i>Art. 3(1)(a) – on general surveillance requirements</i></p> <p><i>Art. 4(1)(b)(i) and (ii) – on surveillance in wild birds</i></p> <p><i>Art. 7(2) – on the contribution of official controls and other official activities to surveillance</i></p> <p><i>Art. 9(1) and Annex I (points 1 and 3 in Section 1) – on case definitions – suspect case of HPAI</i></p>	<p><i>Art. 25 and 33 – on obligations of operators of poultry and captive birds on keeping of production performance and health records</i></p>	
5.1.1.2	Epidemiological enquiry – Preliminary control measures	<p><i>Art. 55(1), 56 and 59 – on preliminary control measures</i></p> <p><i>Art. 57 – on the epidemiological enquiry</i></p>	<p><i>Art. 7, 8 and 9 – on preliminary restriction measures, records analysis and temporary restricted zones</i></p> <p><i>Art. 12(3) and 17(1)</i></p>	<p><i>Art. 4, 5(1) and (2), and 6(3) – risks related to the spread of HPAI associated with transport of poultry</i></p>		<p><i>Art. 22, 33 and 34 – on record-keeping obligations of operators and transporters on the origin and destination of animals</i></p> <p><i>Art. 80 – on traceability of hatching eggs</i></p>	

¹ Commission Implementing Decision (EU) 2021/641 establishes at Union level the protection and surveillance zones to be set out by the Member States listed in the Annex thereto, following outbreaks of HPAI in poultry or other captive birds. It also establishes the duration of the measures to be applied in those zones in accordance with Article 39 and Article 55 of Delegated Regulation (EU) 2020/687, respectively. This Decision is applicable since 21 April 2021.

SPECIFIC CHAPTER IN THE REPORT	SPECIFIC PROVISIONS AND MEASURES	APPLICABLE LEGISLATION CORRESPONDING TO THE SPECIFIC PROVISIONS AND CONTROL MEASURES FOR HPAI AND TO RELATED REQUIREMENTS ON ANIMAL WELFARE AND ABP					
		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.1.1.3	Handling of confirmation – Derogations	Art. 58(1) and 60(a) – basis for confirmation of HPAI Art. 61(1) and (2) – on measures in affected establishments	Art. 11 – on official confirmation Art. 12 – on application of disease control measures in affected establishments Art. 13(1) to (3) and 15(3) – on derogations from killing of animals in affected establishments		Art. 9(2) and (3), and Annex I (points 2 and 3 in Section 1) – on case definitions – confirmed case of HPAI		
5.1.1.4	Contact (epidemiologically linked) establishments – Specific measures	Art. 62	Art. 17 (on their identification), and 18 and 19 (on the measures to be applied on them and products therefrom)				
5.1.2	Diagnosis of HPAI ²	Art. 17 Art. 54(2)(c)	Art. 3 and 6(2), and Annex I		Art. 6(1) – on the diagnostic methods to be used for surveillance		
5.1.3.1	Establishment of a restricted zone – protection and surveillance zones	Art. 60(b), 64 and 67	Art. 21(1) and (2) – establishment and adaptation of their boundaries				Art. 2(a) and 3(a)

² Regulation (EU) 2017/625 lays down the basic principles and general requirements for the designation and operation of official animal health laboratories and of NRLs in Article 5 (access to laboratory capacity), Article 34 and Annex III (methodological principles), Articles 37, and 40 to 42 (designation of laboratories, their accreditation and derogations thereto), Articles 38 and 39 (obligations of laboratories and of competent authorities), and Articles 100 and 101 (designation and responsibilities of NRLs).

SPECIFIC CHAPTER IN THE REPORT	SPECIFIC PROVISIONS AND MEASURES	APPLICABLE LEGISLATION CORRESPONDING TO THE SPECIFIC PROVISIONS AND CONTROL MEASURES FOR HPAI AND TO RELATED REQUIREMENTS ON ANIMAL WELFARE AND ABP					
		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.1.3.2	Application of measures in the restricted zone (protection and surveillance zones)	<p><i>Art. 65 and 66 – on general disease control measures</i></p> <p><i>Art. 71 – on additional disease control measures</i></p>	<p><i>Art. 22(1) – on the inventory of establishments keeping poultry</i></p> <p><i>Art. 22(2) – on preventive killing</i></p> <p><i>Art. 22(3) to (7), 24, 27(1) and (2) and 42 – on restrictions and conditions for movements and transport of animals, products of animal origin and ABP</i></p> <p><i>Art. 25 and 40 – on measures to be applied in protection and surveillance zones, respectively</i></p> <p><i>Art. 26 and 41 – on visits to establishments to be applied in protection and surveillance zones, respectively</i></p>				<i>Art. 2(a) and 3(a)</i>
5.1.3.3	Further restricted zones	<p><i>Art. 64(2) – on the establishment of additional restricted zones</i></p> <p><i>Art. 71 – on additional disease control measures</i></p>	<i>Art. 21(1)(c) – on their establishment and the measures to be applied therein</i>				<i>Art. 3a(a)</i>

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		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.1.3.4	Derogations to measures applied in protection and surveillance zones	Art. 65(1)(c), (d), (g), (h) and (i), (2)(b) and (3), and art. 66 – on disease control measures and operators’ obligations in restricted zones	<p><i>Art. 21(3) and 23 – on types of establishments, situations and cases where derogations can be applied</i></p> <p><i>Art. 27(3) and (4) – on exemptions to prohibitions of movements for certain products from protection zones</i></p> <p><i>Art. 28 and 43 – general conditions to grant derogations from prohibitions of movements of animals and products in protection and surveillance zones, respectively</i></p> <p><i>Art. 29 to 38, and Annexes VII (risk-mitigating treatments) and IX (marking of fresh meat) – specific conditions to grant derogations in protection zones</i></p> <p><i>Art. 44, 46, 47, 49(1)(b) and 50 to 54 – specific conditions to grant derogations in surveillance zones</i></p> <p><i>Art. 56 – on additional derogations from prohibition of movement of animals</i></p>				

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		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.1.4.1	Animal depopulation – Animal welfare considerations ³	<p><i>Art. 1(c) and 2(b)(i) – on the need to apply disease control measures taking into account animal welfare aspects (according to recital 7)</i></p> <p><i>Art. 61(1)(b) – on killing and disposal or slaughtering of animals from affected establishments</i></p>	<p><i>Art. 7(4), 9(4) and 22(2) – on preventive killing</i></p> <p><i>Art. 12(1)(a) and (2) – on killing of animals from affected establishments</i></p> <p><i>Art 37(1)(a) and 53(1)(a) – on killing of animals from a protection or surveillance zone in an ABP plant</i></p>				
5.1.4.2	Animal depopulation – Disposal of carcasses ⁴	<p><i>Art. 13(1)(a) – on availability of qualified personnel, financial resources and an effective organisation</i></p> <p><i>Art. 61(1)(b) – on killing and disposal of animals from affected establishments</i></p>	<p><i>Art. 7(5), 12(1)(c) and (2)(a), 22(3), (5) and (6) – on disposal of dead or killed animals, and of other ABP</i></p> <p><i>Art 37(1)(b) and 53(1)(b) – on disposal of animals from the restricted zone killed in an ABP plant</i></p> <p><i>Art 62(3)(a), 63(2)(a) and 64(2)(c) – on disposal of wild birds</i></p>				

³ In the spirit of recital (7) and Article 1(c) and 2(b)(i) of Regulation (EU) 2016/429, the animal welfare requirements related to animal depopulation in the event of an animal health crisis are laid down in Regulation (EC) No 1099/2009, in particular in its Article 18. Those requirements apply when control measures for HPAI include slaughter or killing of poultry or other captive birds for the purpose of disease control (as required by Article 61(1)(b) of Regulation (EU) 2016/429).

⁴ General legal requirements for safe collection, disposal and processing of ABP in the event of the onset of a category A disease are laid down in Regulation (EC) No 1069/2009, in particular in its Article 19(1)(e), and in Article 15(a) of, and Annex VI (Section I of Chapter III) to Regulation (EU) 142/2011. Specific disease control measures and restrictions applicable in those cases in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/687 complement those measures.

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		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.1.5	Cleaning and disinfection	<i>Art. 61(1)(f) and 65(1)(f) – in affected establishments and in restricted zones</i>	<i>Art. 15 and points A and B of Annex IV – on preliminary cleaning and disinfection Art. 16 – on derogations thereto (e.g., litter, bedding) Art. 57(1)(a) and (2), and points A and C of Annex IV – on final cleaning and disinfection</i>				
5.1.6	Lifting of restrictions	<i>Art. 68(1) – on maintaining and lifting disease control measures</i>	<i>Art. 39(1) and (3) and Annex X, and art. 55(1) and Annex XI – on rules to lift restrictions and other disease control measures in protection and surveillance zones, respectively</i>				<i>Art. 2(b), 3(b) and 3a(b)</i>
5.1.7	Repopulation of affected establishments	<i>Art. 61(3)</i>	<i>Art. 57 and points A and C of Annex IV, and art. 59 to 61 – on requirements to authorise repopulation</i>				
5.2.1	Contingency plan – Availability, drawing up, and regular updating	<i>Art. 43(1) and 45(1) – on drawing up and updating, and on verification of its functionality</i>	<i>Art. 4 – on implementation of disease control measures in accordance with the contingency plan for HPAI</i>				

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		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.2.2	Registration and approval of establishments – Areas with high density of poultry ⁵	<p><i>Art. 64(1) and (2) – on the establishment of a restricted zone</i></p> <p><i>Art. 84, 93, 94(1)(c) and (d), 96(1) and (2), 97, 98, 100, and 101(1) and (2) – on registration and approval of establishments</i></p> <p><i>Art. 99 – on procedures for granting approvals</i></p> <p><i>Art. 102 and 103 – on record-keeping obligations of operators, including hatcheries</i></p>	<p><i>Art. 8(1)(a) – inventory of poultry and captive birds in the event of suspicion of HPAI</i></p> <p><i>Art. 9(1)(a) and (b) – on analysis of information to establish a temporary restricted zone</i></p> <p><i>Art. 17(1) – on identification of linked establishments and other locations</i></p> <p><i>Art. 21(1) and (2), 22(1), 23, 25, 26(1), 39(1)(b), 40, 41, 55(1)(b), 59(2)(a), 63(1)(c) and 64(2)(a) – relevance of the inventory of establishments in the restricted zone</i></p>			<p><i>Art. 18 and 21 – on information to be kept by the authorities on registered and approved establishments keeping poultry and captive birds and of hatcheries</i></p>	

⁵ Besides Regulation (EU) 2016/429 and Delegated Regulation (EU) 2019/2235, additional requirements related to availability of data on registration of establishments keeping poultry – namely for those keeping breeding animals, layer 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

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		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.2.3	Operation of disease control centres – Information management tools and data analysis	<i>Art. 60(c) – on implementation of the contingency plan Art. 43(2)(a), (b) and (c)(i) and (v) – on matters covered by contingency plans</i>	<i>Art. 4 – on application of disease control measures in accordance with the contingency plan for HPAI Art. 66 – on the expert group in the event of a confirmed case in wild birds</i>				
5.2.4	Availability of human resources – Responsibilities, instructions and training	<i>Art. 13(1)(a) – on availability of qualified personnel and of an effective organisation Art. 14(1)(c)(i) and (ii) and (2) – on delegation of official activities Art. 43(2)(a), (b) and (c)(iv), (v) and (vi) – on matters covered by contingency plans</i>	<i>Art. 4 – on application of disease control measures in accordance with the contingency plan for HPAI</i>				
5.2.5	Availability of equipment and materials	<i>Art. 13(1)(a) – on availability of equipment Art. 43(2)(c)(iii), (v) and (vi) – on matters covered by contingency plans</i>	<i>Art. 4 – on application of disease control measures in accordance with the contingency plan for HPAI</i>				

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		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.2.6	Diagnostic capacity in case of an emergency ⁶	<p><i>Art. 13(1)(b) – on access to laboratories</i></p> <p><i>Art. 43(2)(c)(ii) – on matters covered by contingency plans</i></p> <p><i>Art. 61(1)(h) – on the laboratory examination of samples from affected establishments and other locations</i></p>	<p><i>Art. 4 – on application of disease control measures in accordance with the contingency plan for HPAI</i></p>				

⁶ Regulation (EU) 2017/625 lays down the basic principles and general requirements for the designation and operation of official animal health laboratories and of NRLs in Article 5 (access to laboratory capacity), Articles 37, and 40 to 42 (designation of laboratories, their accreditation and derogations thereto), Articles 38 and 39 (obligations of laboratories and of competent authorities), and Articles 100 and 101 (designation and responsibilities of NRLs).

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		Regulation (EU) 2016/429	Delegated Regulation (EU) 2020/687	Delegated Regulation (EU) 2020/688	Delegated Regulation (EU) 2020/689	Delegated Regulation (EU) 2019/2035	Decision (EU) 2021/641 ¹
5.3	Official controls on restrictions and derogations thereto related to intra-Union trade of poultry commodities	<p><i>Art. 100 – on suspension and withdrawal of approvals</i></p> <p><i>Art. 124(1), 125(1), 126 and 130 – general and specific animal health requirements for intra-Union trade of poultry</i></p> <p><i>Art. 157 and 159 – general animal health requirements for intra-Union trade of hatching eggs</i></p> <p><i>Art. 143, 145, 149(1), (2) and (3), 152 and 153 – on obligations and conditions for animal health certification for intra-Union trade of poultry</i></p> <p><i>Art. 161(1), 162(1) and 163(1) and (2) – on obligations and conditions for animal health certification for intra-Union trade of hatching eggs</i></p>	<p><i>See specific legislation related to application of measures in restricted zones and derogations thereto</i></p> <p><i>Art. 64(2)(b) – on prohibition of movements of wild birds and products thereof if an infected zone is determined where HPAI has been detected in wild birds</i></p>	<p><i>Art. 4, 5(1) and (2), and 6(3) – on the spread of HPAI associated with transport of poultry</i></p> <p><i>Art. 34(1)(a), (d), (f) and (g), and 35(1)(a) and (b) – animal health requirements for intra-Union trade of poultry</i></p> <p><i>Art. 36(1) and 38 – animal health requirements for intra-Union trade of day-old-chicks and hatching eggs</i></p> <p><i>Art. 80 and 82 – on certification for intra-Union trade of poultry and of day-old-chicks and hatching eggs</i></p> <p><i>Art. 91(1)(b), (c), (d) and (f), and (2)(c), (d), (e) and (f) – on responsibilities of the competent authorities for animal health certification</i></p> <p><i>Part 1 of Annex VIII (points 1(e) and 2(f)) – on information in animal health certificates</i></p>		<p><i>Art. 21(j) – on information to be kept by the authorities on restrictions on movements applied to approved establishments keeping poultry and captive birds, and to hatcheries</i></p>	

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2022-7586

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 2017/625	OJ L 95, 7.4.2017, p. 1–142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)Text with EEA relevance.
Reg. 2016/429	OJ L 84, 31.3.2016, p. 1–208	Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')
Reg. 2019/2035	OJ L 314, 5.12.2019, p. 115–169	Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs
Reg. 2020/687	OJ L 174, 3.6.2020, p. 64–139	Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases

Reg. 2020/688	OJ L 174, 3.6.2020, p. 140–210	Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs
Reg. 2020/689	OJ L 174, 3.6.2020, p. 211–340	Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases
Dec. 2021/641	OJ L 134, 20.4.2021, p. 166–260	Commission Implementing Decision (EU) 2021/641 of 16 April 2021 concerning emergency measures in relation to outbreaks of highly pathogenic avian influenza in certain Member States (notified under document C(2021) 2704)
Reg. 1099/2009	OJ L 303, 18.11.2009, p. 1-30	Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing
Reg. 1069/2009	OJ L 300, 14.11.2009, p. 1-33	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)
Reg. 142/2011	OJ L 54, 26.2.2011, p. 1-254	Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive