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Adopted: 14 December 2016

Urgent request on avian influenza

EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), More S, Bicot D, Bøtner A, Butterworth A, Calistri A, Depner K, Edwards S, Garin-Bastuji B, Good M, Gortázar Schmidt C, Michel V, Miranda MA, Saxmose Nielsen S, Raj M, Sihvonen L, Spooler H, Thulke HH, Velarde A, Willeberg P, Winckler P, Adlhoch C, Baldinelli F, Breed A, Brouwer A, Guillemain M, Harder T, Monne I, Roberts H, Cortinas Abrahantes J, Mosbach-Schulz O, Verdonck F, Morgado J and Stegeman A.

Abstract

H5N8 is currently causing an epizootic in Europe, infecting many poultry holdings as well as captive and wild bird species in more than ten countries. Given the clear clinical manifestation, passive surveillance is considered the most effective means of detecting infected wild and domestic birds. Testing samples from new species and non-previously reported areas is key to determine the geographic spread of H5N8 2016 in wild birds. Testing limited numbers of dead wild birds in previously-reported areas is useful when it is relevant to know whether the virus is still present in the area or not, e.g. before restrictive measures in poultry are to be lifted. To prevent introduction of H5N8 from wild birds into poultry, strict biosecurity implemented and maintained by the poultry farmers is the most important measure. Providing holding-specific biosecurity guidance is strongly recommended as it is expected to have a high impact on the achieved biosecurity level of the holding. This is preferably done during peace time to increase preparedness for future outbreaks. The location and size of control and in particular monitoring areas for poultry associated with positive wild bird findings are best based on knowledge of the wider habitat and flight distance of the affected wild bird species. It is recommended to increase awareness among poultry farmers in these established areas in order to enhance passive surveillance and to implement enhanced biosecurity measures including poultry confinement. There is no scientific evidence suggesting a different effectiveness of the protection measures on the introduction into poultry holdings and subsequent spread of H5N8 when applied to H5N8, H5N1 or other notifiable H5N8 viruses.

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Keywords: avian influenza, H5N8, outbreak, poultry, wild bird, captive bird

Requestor: European Commission

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

The European Commission has already requested¹ EFSA to provide a scientific opinion on avian influenza (AI), assessing the risks for virus introduction of highly pathogenic avian influenza (HPAI) H5N8 and possibly other HPAI viruses into the EU and the risks posed by these viruses to public and animal health. EFSA's work is in progress in relation to the risks posed by the H5N8 AIV to humans (TOR 2), in collaboration with ECDC and the EU Reference Laboratory for avian influenza in particular as regards the current evolving disease situation.

EFSA has been requested also to assess the suitability of preventive and control measures laid down in several Commission decisions that were adopted in 2006 during the HPAI H5N1 occurrence in the EU (TOR 2). These measures include early detection systems, biosecurity, movement restrictions, additional zoning for poultry and certain products in relation to infected wild birds, as well as surveillance and are laid down in Decisions 2005/734/EC, 2006/563/EC and 2010/367/EU. It should be assessed, if they should equally be applied to other subtypes or clades of HPAI viruses such as the H5N8 subtype when they are identified in poultry and/or wild birds. The measures laid down in Decision 2006/415/EC should be assessed as well.

The current occurrence of the HPAI H5N8 virus in wild birds and in poultry in several Member States makes management decisions in this respect even more urgent.

In view of the rapidly evolving disease situation, the European Commission asked EFSA to focus and prioritise on the above issues and to produce an urgent partial reply in relation to the measures cited above and their suitability for the current situation.

The European Commission would be grateful, if EFSA could deliver such response by the end of the year 2016.

1.2. Interpretation of the Terms of Reference

HPAI H5N8 virus has been isolated in poultry holdings, wild and captive birds in many Member States and in Switzerland between 28 October and 11 December 2016. This Statement provides a rapid and partial assessment of TOR2 from the mandate² previously received from the European Commission, focussing on the question whether the measures laid down in the four Decisions that are based on HPAI H5N1 findings in wild birds can be equally applied to manage the current HPAI H5N8 outbreaks.

A description of the detections in space and time as well as a list of affected wild bird species are provided in the first section of this Statement. The main genetic characteristics of the virus and the induced morbidity and mortality are analysed using the data available. The affected countries submitted data via the ADNS database and directly to EFSA, although it should be noted that this has been asked for at very short notice at a time when the countries were still focussing on managing the outbreaks. The dataset currently available upon establishment of the current report may hence not be fully comprehensive. A more complete data collection will be done after the end of the epizootic period to underpin the scientific opinion that will be finalised in 2017.

The characteristics of the circulating HPAI H5N8 virus and an analysis of what triggered virus detection in the field, are used to assess whether early detection in poultry and surveillance in poultry and wild birds could be applied similarly to HPAI H5N1 outbreaks, as described in the Decisions 2005/734/EC and 2010/367/EU, respectively. Based on this preliminary assessment, recommendations are provided that could help Member States in targeting surveillance for HPAI H5N8 in wild birds as an early warning for nearby poultry holdings, although more structured advice will be provided later in the full scientific opinion.

The analysis of similarities and differences in HPAI H5N8 and HPAI H5N1 transfer from wild birds to poultry is used to underpin the assessment of the biosecurity measures described in Decision

¹ (ARES (2015) 1422958) of 31/03/2015

² EFSA-Q-2015-00214

2005/734/EC: preventing direct and indirect contact between wild birds and poultry, ensuring separation between domestic ducks and geese from other poultry species and undertaking health checks in poultry flocks. In addition, an overview is provided on the main biosecurity measures applicable in a commercial poultry holding to reduce the risk of AI entry. It was considered that a holding consists of three zones: an open zone (e.g. residence, office), a professional zone (e.g. feed storage) and a production zone (e.g. animal facilities). A ranking of biosecurity measures is done per zone, taking into account feasibility, expected effectiveness and sustainable implementation. This information could be useful when providing guidance to commercial poultry holdings. A preliminary analysis on which measures could be applied in backyard holdings is also provided. However, a more detailed analysis and further practical guidance will be provided later in the scientific opinion.

Similarities and differences in phenotypic characteristics of the circulating HPAI H5N8 and HPAI H5N1 are also used to evaluate the implementation of protection measures: the establishment of control monitoring areas after HPAI H5N1 findings in wild birds (Decision 2006/563/EC), establishment of zones A and B after HPAI H5N1 findings in poultry (Decision 2006/415/EC) and the measures and prohibitions to be applied in these areas (both Decisions). Guidance is provided on which epidemiological data are necessary to analyse outbreaks. The derogations of these Decisions are not analysed, except the option to reduce the size of the control and monitoring zone (Article 4 of Decision 2006/563/EC).

Finally, the risk of the HPAI H5N8 to humans is briefly described based on the ECDC's recent rapid risk assessment and the outcome of the FLURISK model using the available data. Reference is also made to guidance documents describing protective clothing and prophylactic treatments.

2. Data and Methodologies

2.1. Data on the current HPAI H5N8 outbreaks in Europe

Data on the AI findings in wild birds, captive birds and poultry were extracted from ADNS for the period 1 October 2016 till 11 December 2016. The affected countries were asked to provide additional information on the infected wild bird species, holding characteristics and detection route. The timing of submission differed amongst countries: last update on 30/11/2016 (Denmark), 01/12/2016 (Austria, Germany), 02/12/2016 (Croatia, Italy, Netherlands, Sweden, Switzerland), 05/12/2016 (Finland, Hungary), 7/12/2016 (Poland) and 12/12/2016 (France). The majority of the data have been cross-referenced, but errors cannot be completely excluded given the short time period in which to generate this document.

2.2. Identification and ranking of biosecurity measures

A search has been done to identify additional biosecurity measures to those described in Decision 2005/734/EC (see section A4 of Appendix A), that could be applied on a commercial poultry holding located in a region where HPAI virus has been detected in poultry and/or wild birds. This means that AI virus exposure to the holding is assumed and hence increased implementation of biosecurity measures is required. Biosecurity guidance documents from several Member States and international organisations like OIE have been screened. Measures have been selected to cover the most important aspects of biosecurity and keeping their number limited to allow an effective and realistic implementation. Each measure is briefly described to achieve a common understanding and to prevent overlap between the measures.

Three biosecurity experts also ranked the measures for feasibility, sustainable implementation, effectiveness to prevent entry and effectiveness to prevent spread. For each parameter, the measures were ranked from highest to lowest importance within a given zone of the holding.

- Feasibility: proportion of the farmers willing to start implementing the given biosecurity measure
- Sustainable implementation: proportion of time when the farmer maintains the given biosecurity measure continuously during 30 days of high risk
- Effectiveness to reduce entry: reduction in the amount of virus coming from outside to the holding, able to reach poultry within the holding and to cause infection by implementing the given biosecurity measure

- Effectiveness to reduce spread: reduction in the amount of virus that can be transferred between poultry within the holding and be released outside of the holding by implementing the given biosecurity measure

The average of the individual rankings was calculated for each of the four parameters. Then, an overall average score was calculated. The measures are described per zone and they are ranked from high to low overall score (see sections 3.5.2.1 and 3.5.2.3).

3. Assessment

3.1. Overview of the AI outbreaks in Europe during October and November 2016

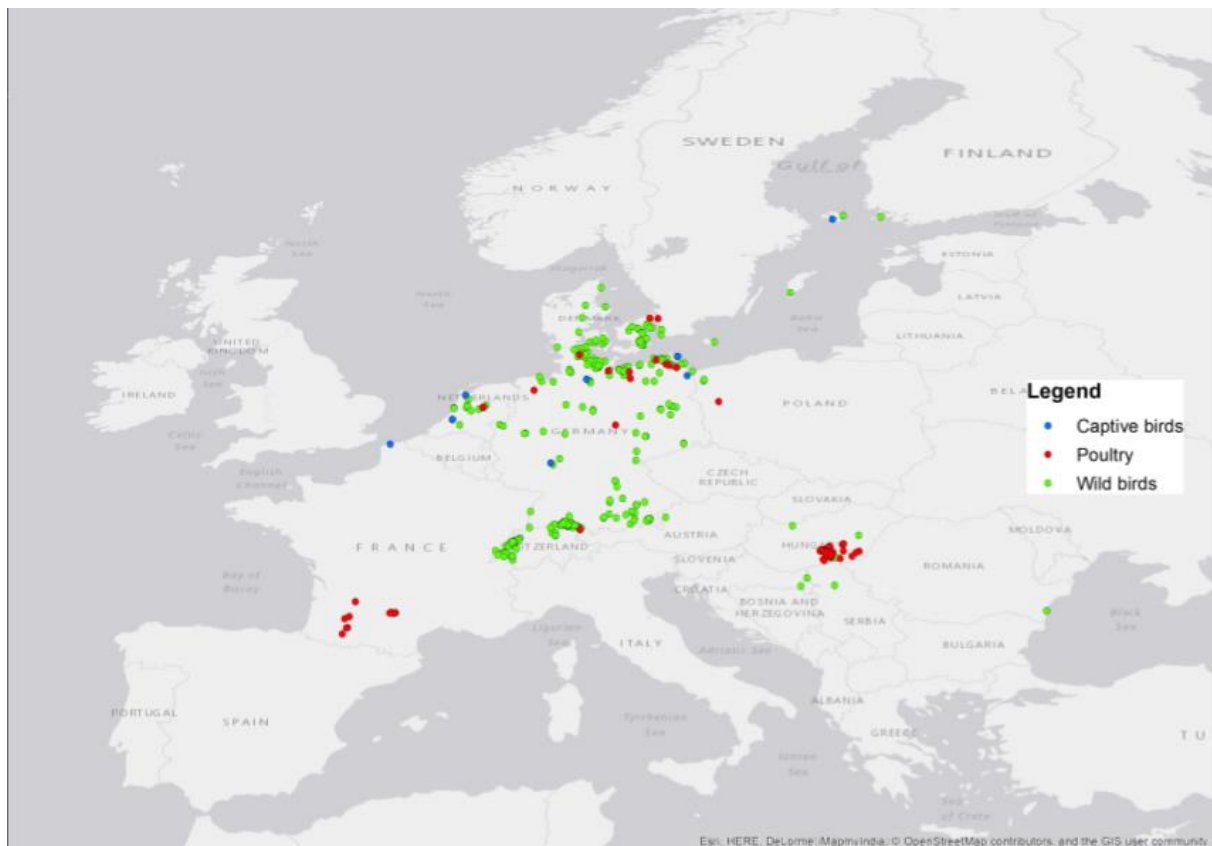


Figure 1: Overview of the reported HPAI H5N8 avian influenza cases in Europe between 20 October 2016 and 11 December 2016.

HPAI H5N8 in poultry

Overall, 163 poultry farms have been found to be infected by the currently circulating HPAI H5N8 virus by 11 December 2016 (Figure 1). The first confirmed case (03/11/2016) was a turkey holding in Hungary. One week later, infected holdings were also reported from Austria, Germany and additional farms in Hungary. The geographic extension of positive poultry holdings continued with confirmed cases in other Member States: Denmark (21/11/2016), The Netherlands (26/11/2016), Sweden (28/11/2016), France (01/12/2016) and Poland (03/12/2016). Several secondary outbreaks are reported in Hungary (106 out of 131 outbreaks) and France (5 out of 11 outbreaks). The number of affected duck farms was 81, of which 70 were in Hungary and 9 in France, whereas 40 outbreaks have been recorded in geese (of which 39 in Hungary), 4 in turkeys, 2 in laying hens, 1 in breeding chickens, 1 in broiler chickens, 1 in chicken (without specification), 1 in guinea fowl, and 18 in multiple or mixed species holdings. There is no species information from 13 holdings. Fifty-one holdings are reported by the Member State as commercial, 15 as backyard holdings (of which 10 are located in Germany) and no information is available on 97 holdings. From these data it seems that

domestic waterfowl are at higher risk of contracting the infection than gallinaceous poultry species, however, to estimate the relative risk necessary information on the number of poultry farms holding these species is presently not available.

HPAI H5N8 in wild birds

The first HPAI H5N8 infected wild bird was reported (27/10/2016) in Hungary, around one week before the first outbreak in a poultry holding in this country. A second HPAIV H5N8 infected wild bird was found in Poland on 12/11/2016. The next week, positive cases were reported by 5 additional Member States (Austria, Croatia, Denmark, Germany, The Netherlands) and Switzerland. Since then, HPAIV H5N8 infected wild birds have also been reported by Sweden, Romania, Finland, France and Serbia. Figure 1 represents the 593 cases reported until 11/12/2016. The numbers cannot be compared between countries and between regions within a country because the surveillance procedures and sensitivity are likely different. Furthermore, the reported numbers do not reflect the real numbers of wild birds that died because of HPAIV H5N8 but likely only a fraction thereof. Several mass mortality events involving 50 or more wild birds at specific locations have been reported, such as in Germany (e.g. Great Plön lake), Switzerland (Lake Constance), Poland (Zachodnio-Pomorskie) and the Netherlands (Gouwee). During active surveillance H5N8 was also found in the faeces of a wigeon in Friesland in the Netherlands (R. Fouchier, personal communication, 6 December 2016). Table 1 provides a list of HPAIV infected wild birds reported in ADNS or directly by Member States.

Table 1: List of wild and captured birds infected by HPAIV H5N8 in 2014-2015 and/or 2016 (reported by Member States or from other sources) (until 11/12/2016)

| Wild birds reported by MSs: | 2014-2015 | 2016 |
|---|-----------|------|
| Black-headed gull (<i>Chroicocephalus ridibundus</i>) | x | x |
| Common buzzard (<i>Buteo buteo</i>) | | x |
| Common coot (<i>Fulica atra</i>) | | x |
| Common eider (<i>Somateria mollissima</i>) | | x |
| Common goldeneye (<i>Bucephala clangula</i>) | | x |
| Common gull (<i>Larus canus</i>) | | x |
| Common magpie (<i>Pica pica</i>) | | x |
| Common moorhen (<i>Gallinula chloropus</i>) | | x |
| Common pochard (<i>Aythya ferina</i>) | | x |
| Carrion crow (<i>Corvus corone</i>) | | x |
| Eurasian curlew (<i>Numenius arquata</i>) | | x |
| Eurasian teal (<i>Anas crecca</i>) | x | x |
| Eurasian wigeon (<i>Anas penelope</i>) | x | x |
| Great black-backed gull (<i>Larus marinus</i>) | | x |
| Great crested grebe (<i>Podiceps cristatus</i>) | | x |
| Great cormorant (<i>Phalacrocorax carbo</i>) | | x |
| Green sandpiper (<i>Tringa ochropus</i>) | | x |
| Grey heron (<i>Ardea cinerea</i>) | | x |
| Herring gull (<i>Larus argentatus</i>) | | x |
| Hooded crow (<i>Corvus cornix</i>) | | x |
| Lesser black-backed gull (<i>Larus fuscus</i>) | | x |
| Little grebe (<i>Tachybaptus ruficollis</i>) | | x |
| Mallard (<i>Anas platyrhynchos</i>) | x | x |
| Merganser (<i>Mergus sp.</i>) | | x |
| Mute swan (<i>Cygnus olor</i>) | | x |
| Peregrine falcon (<i>Falco peregrinus</i>) | | x |
| Rails (<i>Rallidae</i>) | | x |
| Red-crested pochard (<i>Netta rufina</i>) | | x |
| Shelduck (<i>Tadorna tadorna</i>) | | x |
| Swans (<i>Cygnus spp.</i>) | x | x |
| Tufted duck (<i>Aythya fuligula</i>) | | x |
| White-tailed eagle (<i>Haliaeetus albicilla</i>) | | x |
| Whooper swan (<i>Cygnus cygnus</i>) | | x |
| Wild ducks | | x |
| Wild goose | | x |

HPAI H5N8 in captive birds

HPAI H5N8 outbreaks have been reported in captive birds on 8 different locations (4 in Germany, 2 in the Netherlands, 1 in France and 1 in Finland). Table 2 gives an overview of the affected captive bird species reported so far.

Table 2: List of captive birds infected by HPAIV H5N8 in 2014-2015 and/or 2016 (reported by Member States) (until 11/12/2016)

| Captive birds reported by MSs: | 2014-2015 | 2016 |
|--|-----------|------|
| Gadwall (<i>Anas strepera</i>) | | x |
| Eurasian Wigeon (<i>Anas penelope</i>) | x | x |
| Emu (<i>Dromaius novaehollandiae</i>) | | x |
| Great white pelican (<i>Pelecanus onocrotalus</i>) | | x |

Concurrent LPAI outbreaks in poultry and cases in wild birds

In addition to the HPAI H5N8 outbreaks, ten LPAI outbreaks have been confirmed since mid-October. Two of these LPAI outbreaks involved captive birds (H7N3 on 18/10/2016 and H5N2 on 18/11/2016, both in Germany). The other eight LPAI outbreaks were in poultry holdings: LPAI H5N2 on a turkey fattening holding in the Netherlands (27/10/2016), LPAI H5N1 and LPAI H5N3 in mixed species holdings in Italy (23/11 and 28/11/2016), five LPAI H5Ny outbreaks in German holdings.

The concurrent detection of non-HPAI H5 viruses in wild birds, captive birds and poultry while HPAI H5N8 is spreading in the same populations complicates situation assessment and decision-making regarding the implementation of appropriate restriction measures. Determination of the NA subtype (N8) does not necessarily help as also LPAIVs of subtype H5N8 are in circulation in wild bird populations or have been detected in poultry in France recently. In addition, the presence of concurrent or existing LPAIV infection may confuse the clinical picture of an HPAIV infection.

3.2. Characterization of the HPAI H5N8 viruses currently circulating in Europe

3.2.1. Genotypic characterization

Phylogenetic analysis

European HPAI H5N8 viruses from 2014 and 2016 are genetically distinguishable and are assigned to separate different phylogenetic clusters within the Gs/Gd lineage H5 clade 2.3.4.4. These clusters are derived from evolutionary analyses of the haemagglutinin (HA) gene sequences obtained from positive birds and uploaded to online repositories. In particular, phylogenetic analyses assign the 2016 viruses to clade 2.3.4.4 (Gochang1-like) while the 2014 viruses belonged to clade 2.3.4.4 (Buan2-like) (Lee et al., 2014).

Initial analyses of the HA gene generated from samples in the HPAI H5N82016 outbreak suggest the European viruses form two very closely related clusters that segregate by geographical origin; Northern Europe (Denmark, Germany, Netherlands, Poland, Sweden) and Central Europe (Croatia, Hungary,) possibly reflecting different introduction pathways via wild birds and separate circulation pools.

The phylogenetic distance between the 2016 Northern Europe and Central Europe clusters is sufficiently close to suggest that these are similar viruses of a common ancestor that have reached Europe via different geographical routes, whilst the 2014 and 2016 cluster differences on the HA gene suggest enough variation to possibly account for distinct phenotypic changes.

HPAI H5N8 viruses found in wild birds in June 2016 at Lake Uvs-Nur at the Russian-Mongolian border constitute the closest (but different) related sequences of the European viruses (Lee et al., 2017). Full genome sequences will be required to further elucidate spread pathways and possible genetic mixing with other AI viruses.

No adaptive mutations suggestive of increased risk for transmissibility to humans

Available HPAIV H5N8 2016 sequencing data (novel and GISAID) were matched with the CDC (Atlanta) H5N1 genetic changes inventory and the list of mutations required for H5N1 respiratory

droplet transmission in ferrets (Imai et al., 2012; Herfst et al., 2012) to identify genetic mutations that determine viral phenotypic characteristics that may signal adaptation to mammalian species or alter susceptibility to existing antivirals. This totals 118 mutations or combinations of mutations. A total of eight mutations/mutation combinations were observed, plus mixed motifs at three additional locations, in the H5N8 2016 viruses (EURL analysis). None of these mutations in isolation are considered to increase the zoonotic affinity of the virus which is still essentially an avian virus (ECDC, 2016). On the contrary, absence of a deletion in the NS1 at amino acid position 80-84 that is conserved among contemporary H5 viruses might decrease the zoonotic potential of the H5N8 virus.

3.2.2. Phenotypic characterization

Morbidity and mortality in poultry and wild birds

Clinical disease was reported in all infected poultry species, in most cases associated with high morbidity and high case fatality in birds. It should be noted that morbidity and mortality rates reported will depend on the time point following incursion when disease was detected and diagnosis confirmed. Thus, it is difficult to compare them between outbreaks. The currently circulating HPAIV H5N8 2016 invokes full-presentation as HPAI in chickens as demonstrated by intravenous pathogenicity indices³ (IVPI) close to 3.0 while the 2014/2015 viruses displayed IVPIs of about 2.5 to 2.8 although no direct comparisons using the same inoculation dose have been performed (EURL – Flulabnet).

For domestic ducks, the virulence of the contemporary European HPAI H5N8 appears higher than for viruses that were detected worldwide of clade 2.3.4.4 in 2014/2015. This is based on the apparent high mortality rate of domestic ducks reported from farms in southwestern France, in The Netherlands and in Hungary in 2016, compared to the low mortality rate of domestic ducks in farms in the U.K., Germany and The Netherlands which resulted from HPAI H5N8 viruses in 2014. However, it should be noted that cases of secondary infection are being reported in the absence of overt clinical disease. Experimental infection studies in domestic (Pekin) ducks are expected to give further insights into the virulence of clade 2.3.4.4/2016 viruses for anseriforme species.

Passive monitoring in wild birds recorded excess and regionally even mass mortality in several diving duck species (Tufted duck, Common pochard, Greater scaup). Gross pathology of carcasses of these birds revealed evidence of systemic infection with macroscopic lesions dominating in lung and liver tissues. Viral shedding at high titres from both oropharyngeal and cloacal excretions of these birds has been confirmed. Lethal courses of infection were also seen in other species of anseriform wild birds. These include mute swans, larger geese species (Canada, Greylag, and Bean geese). Very few cases of infected dabbling ducks were recorded so far although large numbers of European wigeons in the Netherlands tested positive recently. In addition, grebes and gull species were sporadically affected (Black-headed gull, Herring gull, Lesser black-backed gull; Greater Black Backed Gull) and also birds of prey, mainly Common buzzard but also White-tailed eagle. Longitudinally there seemed to be a shift in the species range after the incursion of 2016 HP H5N8 into wild birds in Central Europe: diving ducks were first to be seen affected, later the infection spread to swans, geese and species of grebes and finally ended up in scavenging predator species such as Herring gulls, Carrion crows, Common buzzards and White-tailed eagles.

For wild birds, the virulence of HPAIV H5N8 2016 appeared to be higher compared to HPAI H5N8 2014/2015. This is based, i. a., on the detection of H5N8 virus in faecal samples of apparently healthy Eurasian wigeons in the Netherlands in 2014/2015 in the absence of any observed mortality of Eurasian wigeons, compared to mortality of several dozens of Eurasian wigeons in the Netherlands in 2016 associated with H5N8 virus. The contrast between the high mortality of several species of wild water birds, particularly Tufted ducks, in several European countries in 2016, compared with the lack of such observations in 2014, also are supportive of an increased virulence of H5N8 2016 viruses.

³ 'highly pathogenic avian influenza (HPAI)' means an infection of poultry or other captive birds caused by:(a) avian influenza viruses of the subtypes H5 or H7 with genome sequences codifying for multiple basic amino acids at the cleavage site of the haemagglutinin molecule similar to that observed for other HPAI viruses, indicating that the haemagglutinin molecule can be cleaved by a host ubiquitous protease; or (b) avian influenza viruses with an intravenous pathogenicity index in six-week old chickens greater than 1.2 (Directive 2005/94/EC)

Although data from experimental infection studies in anseriforme and gallinaceous birds have not been reported yet, several differences between HPAIV H5N8 2016 on one hand and on the other hand HPAI H5N1 and HPAI H5N8 2014/2015 are notable:

1. Increased virulence for some anseriforme species, in particular Eurasian wigeons
2. Increased incidence of cases in wild bird populations
3. Increased number of incursions into poultry holdings and captive bird holdings

Experimental infection studies in key target species, analyses of full genome sequences and construction of reverse genetically modified viruses will be required to explore the molecular base of the apparently altered pathogenicity of the 2016 H5N8 viruses.

Preservation of HPAI viral infectivity in different matrices

Variation in the preservation between AI viruses in the environments relevant to the current epizootic is limited; therefore an extrapolation between historical studies carried out on HPAI H5N1 and other AI viruses to HPAI H5N8 is possible. This is required as there is currently little available experimental data for HPAI H5N8.

Viral infectivity in poultry faeces has been seen to persevere for up to 7 days at 20°C in conditions of high humidity out of direct sunlight (Webster et al., 1978 and Lue et al., 2003). At higher temperature and direct sunlight the infectivity will persist for significantly shorter periods (Songserm et al., 2006). At temperatures of 4°C in experimental conditions the infectivity can persist in faeces for up to 8 weeks (Kurmi et al., 2013). Several studies have shown that AI viruses can remain infectious in water for extended periods. Independent of the virus subtype, persistence of infectivity is negatively affected by increased temperature, salinity and presence of microbial flora for both HPAI and LPAI (Brown et al., 2007; Nielsen et al., 2013). In general, viruses were most stable at slightly basic pH (7.4-8.2), low temperatures (<17°C) and fresh to brackish salinities (Brown et al., 2009). For example at 4°C, the maximum resistance time varied between 18 and 176 days for 12 LPAI viruses of different H subtypes (Brown et al., 2009). Another study reported LPAI H5N1 persistence for 107 and 320 days in lake water at 10°C and 0°C, respectively (Nazir et al., 2010).

HPAIV H5N8 2014/2015 infectivity has been seen to persist for up to 4 days in chicken layer faeces and up to 2 days in broiler and turkey bedding (Hauck et al., 2016).

3.3. Early detection and surveillance of the currently circulating HPAI H5N8 viruses in poultry holdings

3.3.1. HPAI H5N8 early detection in poultry

At 11 December 2016, 163 poultry holdings have been reported to be infected with HPAI H5N8 2016. The vast majority of the primary outbreaks have been detected based on a clear clinical manifestation of the disease and a rapidly increasing mortality. Although reported mortality has been below 3% in a number of outbreaks, this will likely reflect early detection of the infection, not the inability of the infection to exceed 3% mortality rate in a week. In contrast to the previous H5N8 episode in 2014/15, domestic waterfowl also have a clear clinical manifestation of the infection and a high mortality rate as well. Given that many commercial farms have several flocks present, it is important to consider morbidity and mortality at the flock level, not at the farm level. Data regarding feed and water intake are not available yet as are data on egg production, however, given the rapid onset of the disease in the flocks, it is not likely that they will have had a relevant contribution to the detection. In conclusion, the early detection criteria described in Decision 2005/734/EC (see section A1 of Appendix A) could be applied in the current HPAI H5N8 outbreaks, in particular the increased mortality.

3.3.2. Annual AI surveillance programmes in poultry and wild birds

Decision 2010/367/EC (see section A2 of Appendix A) replaced Decision 2007/468/EC on the implementation of surveillance plans for poultry and wild birds in relation to detection of AI viruses in these two populations. The intent of the legislation was to provide information on circulating LPAI viruses in wild birds with the potential to enter poultry and mutate to HPAIV as well as the circulation of HPAI viruses in wild birds causing mortality, in particular, H5N1 HPAIV. Therefore the programmes

were designed to be risk based, and to complement the early detection systems for avian influenza in poultry. Wild birds are tested by PCR for the M gene with follow-up tests to confirm whether H5 and if so, if this is HPAI. At present the Annex II also provides the option to test for the Neuraminidase gene to rule out or confirm presence of N1. In the case of detecting N1, epidemiological follow-up is required and protection measures are put in place, in line with Decision 2006/563/EC. If N1 is not detected, no further action is required.

Surveillance in wild birds should focus on the passive detection of sick or dead wild birds. As the current H5N8 HPAI viruses circulating in the European Union are causing significant wild bird mortality events in species already named as target species for H5N1 HPAI, the effectiveness of the surveillance programme currently in place for H5N1 is expected to be similar for the currently circulating H5N8 viruses. Therefore, it is recommended that this article should apply to this and any other HPAI viruses which cause wild bird mortality events, including the requirement for follow-up as specified in Annex II (see section 3.6).

3.4. Surveillance of the currently circulating HPAI H5N8 viruses in wild birds

HPAI H5N1 surveillance in wild birds is described by Decision 2010/367/EU (see section A3 of Appendix A). Unlike HPAIV H5N1 (2.2 and 2. 3.2.1c clades), the HPAIV H5N8 2014 (2.3.4.4 clade) did not induce significant clinical disease in wild birds and was not associated with mass mortality events in wild birds. However, the current HPAI H5N8 2016 epizootic has once again shown significant levels of wild bird mortality. Therefore, passive surveillance of dead or moribund wild birds has utility for the detection of this ongoing HPAI H5N8 2016 epizootic.

When dead wild birds are identified and where there are multiple birds affected, then a subset of these carcasses should be sent for confirmative laboratory diagnosis. Besides testing for influenza virus, correct identification of the bird species involved is crucial to understand the epidemiology of the outbreak. If HPAI has been identified previously in the same species of wild bird in the same habitat range (see section 3.6.1) then these findings should be reported alongside a rough estimate of the number of birds affected, but no further laboratory analysis is needed. If the affected wild birds are of a novel species for that habitat range and geographically defined area then carcasses need to be tested for HPAIV H5N8.

Targeted active wild bird surveillance does not need be applied across the EU because it has negligible predictive value for HPAI outbreaks in poultry. Active surveillance of clinically healthy wild birds was a legislative requirement for Member States from 2006-2010 and resulted in 39 HPAIV positives from 246952 submissions. Since June 2010, there is no longer any requirement for Member States to test clinically healthy wild birds.

Where desirable, targeted active wild bird surveillance could nevertheless be undertaken on specific wild bird species which can be captured or hunted easily. This would be intended by epidemiological reasons to help better understand the course and spread of the epizootic. These intentions include understanding the differences between clinical manifestations in wild birds between the 2014 and 2016 HPAI H5N8 outbreaks as well as identifying species that may be involved in long distance virus transfer or that might serve as a reservoir for the virus.

3.5. Biosecurity measures reducing the risk of AI entry into a poultry holding

3.5.1. Minimal biosecurity measures to reduce risk of HPAI transmission from wild birds to poultry

There is very limited information available on the mechanisms of transmission of the currently circulating HPAI H5N8 virus from wild birds to poultry. In particular, the characterization of the viral excretion patterns in infected wild birds will be important. While HPAI H5N1/2006 was predominantly excreted with respiratory/oral secretions there is some evidence that HPAI H5N8/2016 might be excreted in high titres with faeces. Presence of high-titred virus in faeces may favour transmission among anseriforme wild birds and also to poultry.

Information was received from four Member States on 55 affected poultry holdings (6 backyards and 49 commercial) regarding outdoor access in a period of 10 days before suspicion of the corresponding HPAI H5N8 2016 outbreak. Outdoor access was possible the whole day in all (5/6) backyards and three commercial holdings, part of the day in 22 commercial holdings and 1 backyard and no outdoor access in 24 commercial holdings. More detailed analysis of these data in relation to housing orders and timing of outbreaks would be useful. Direct or indirect contact with wild birds is reported as the most likely source of infection (only info from 6 poultry holdings with primary infections in 4 different Member States), but detailed epidemiological investigations are still ongoing or the results are not yet available at the national level.

Based on the phenotypic characteristics of HPAI H5N8 2016 (see section 3.2.2), it is considered that the biosecurity measures described in Decision 2005/734/EC (see section A4 of Appendix A) have similar efficacy when implemented in the ongoing HPAI H5N8 outbreaks as for HPAIV H5N1: reducing the risk of HPAI transmission based on the listed risk factors, preventing direct and indirect contact between wild birds and poultry, separating domestic ducks and geese from other poultry and ensuring frequent animal health checks.

According to Ssematimba and colleagues (2013), the risk of HPAI H7N7 introduction into a poultry holding was determined by several characteristics of the holding:

- neighbourhood characteristics: landscape (e.g. location of other poultry and livestock establishments, wild bird concentrations and the distance from roads used to transport poultry, neighbouring fields where poultry manure is spread), density and type of adjacent poultry holdings, poultry-related transport on the road network
- contact structure: nature and frequency of farm visits (e.g. staff, veterinarian, egg collection, feed delivery, manure transport)
- biosecurity practices: measures implemented to reduce risk of AI entry into a poultry holding

It is important to make sure that farmers are familiar with these risk factors, as it will help them in the identification of possible risks and engage them in a strict implementation of adequate biosecurity measures. The sections below provide guidance on biosecurity measures that could be applied to reduce the risk of HPAI entry into poultry holdings, in particular during periods of high risk.

In case of an outbreak in a poultry holding, efficient measures to prevent AI spread outside the holding (biocontainment) are; prompt detection of infection, closure of the holding, immediate depopulation and cleansing/disinfection of the affected holding, as well as a temporary ban on restocking (see Mulatti et al., 2016). However, these measures are not further elaborated since the sections below focus on preventive actions in periods when AI virus exposure to the holding is assumed and hence increased implementation of biosecurity measures is required.

3.5.2. Biosecurity measures applicable in a commercial chicken holding

For this first analysis, the concept of a commercial poultry holding consisting of three zones⁴ is used:

- an open zone without activities related to poultry farming (e.g. residence, office) which is connected to the public road and separated from the professional and production zones of the holding
- a professional zone with poultry farming activities (e.g. storage feed and bedding) but without access of poultry and without storage of material that was in contact with poultry
- a production zone with farming activities (e.g. poultry production units) with access of poultry and storage of material that was in contact with poultry (e.g. manure, litter, eggs)

For this Statement, the main objective was to identify and describe a set of biosecurity measures that can be applied and is assumed to reduce the AI entry in a poultry holding during high risk periods. For the scientific opinion that will be delivered in 2017, an analysis will be performed to determine

⁴ schematic representations are for instance provided in the following French biosecurity document <http://www.itavi.asso.fr/content/plan-de-circulation-au-sein-de-mon-exploitation-circuit-long>; last accessed on 09 December 2016)

whether this three zone concept should be further developed or perhaps adapted to other existing concepts (e.g. 'clean' versus 'dirty' zones) to provide the best possible practical guidance to poultry farmers.

In high risk periods, it is recommended to restrict entry in the open zone by posing a sign indicating restricted entry at the entrance and to assure that clothing and footwear are clean (=free of organic material) before entry into the open zone. The text below describes the biosecurity measures applicable to the professional and production zones of a commercial chicken holding and the outcome of the ranking performed by three biosecurity experts (see methodology in section 2.2).

3.5.2.1 Description of biosecurity measures applicable in the professional zone

A professional zone (e.g. yard behind the farmer's residence, storage feed and clean bedding) is separated from the open zone (e.g. residence, office) and is free of poultry and materials that have been in contact with poultry.

The biosecurity measures are ordered from highest to lowest overall rank, considering equal weight for feasibility, sustainable implementation, effectiveness to reduce AIV entry, effectiveness to reduce AIV spread (see description of the used methodology in section 2.2).

Prevent access to mammals: rodent control should actively be implemented in the professional zone and access of other wild and domestic animals such as dogs or cats should be prevented by closing doors of the buildings and use of covering material. Baits and/or chemical pest control should always be used in accordance with the manufacturer's instructions.

Closed feed/bedding storage should be achieved in closed facilities or watertight feed bins to prevent access of animals (including wild birds and rodents).

Clean clothing and footwear: Clothing and footwear should always be clean (=free of organic material) before entry of the open zone. Appropriate foot hygiene measures can be applied (e.g. disposable overshoes).

Make environment unattractive to wild birds: prevent roosting and nesting of wild birds by making the open zone unattractive to them. For example, clean spilled feed, keep grass on the holding cut (wild birds eat grass seeds, forage in long grass), select trees and shrubs to minimise wild bird attraction, remove fallen fruit around the holding, use persuasive elements. Placing flashing or rotating lights at the entry points will deter wild birds from entering. Water drainage is implemented to prevent uncovered water accumulation. Ensure there are no hobby poultry flocks on the holding.

Biosafety training: Persons can enter the professional zone only after having participated in a general biosecurity training (e.g. via a course) adapted to poultry production and understanding the implications to animal health, human health and food safety. A holding-specific biosecurity plan should be available. The roles and responsibilities of the staff should be clearly defined/explained accordingly and professional visitors should be informed on the holding's layout and biosecurity plan before entering the professional zone.

Restricted access: Only staff and essential professional visitors (e.g. veterinarians, drivers, technicians, inspectors or catchers) can access the professional zone. Ideally, the borders of the professional zone are clearly marked with signs to remind staff and professional visitors to implement the necessary biosecurity measures.

Previous poultry contact:

- Staff can only enter the professional zone if they had no contact with poultry, poultry waste and/or a poultry processing material at another holding (including backyard) or wild birds (e.g. bird ringing or hunting) within the previous 72 hours. (footnote: 72 hours is used in practice but the scientific basis underpinning this time period is not clear)
- The farm should provide a visitor book to register. Professional visitors should record their visit and keep their own record of poultry holding visits.

Clean feed/bedding transport: Vehicles transporting feed or bedding have ideally only access to the professional zone and stop as close as possible to the place of destination (e.g. storage building) on a

paved ground surface. Cleaning of the wheels, wheel arches and footsteps/rests is implemented when entering/leaving the holding. Paths should be cleaned after passage of the vehicle. The frequency of these transports should be reduced as much as possible (e.g. one visit of large volume instead of two visits) and vehicles driving from one poultry holding to another should be prevented where possible. In cases where feed is supplied in a recipient (e.g. big bag), it is recommended to use new recipients.

Clean/disinfect poultry/waste transport: Vehicles transporting poultry, (hatching) eggs, or waste products (e.g. manure) should avoid passing the professional zone to reach the production zone. If that is not possible, cleaning and disinfection of the wheels, wheel arches and footsteps/rests is recommended when entering the holding. Paths should be cleaned and disinfected after passage. The frequency of these transports should be reduced as much as possible (e.g. one visit of large volume instead of two visits). Vehicles, crates and other materials that were in contact with poultry, eggs, carcasses or waste should not go from a poultry holding to another without cleaning and disinfection.

3.5.2.2 Ranking of biosecurity measures applicable in the professional zone

Preventing access of mammals to the professional zone is highly sustainable and has a high effectiveness in preventing AIV spread. Also making the professional zone unattractive to wild birds is highly sustainable. There are no clear differences between the biosecurity measures regarding effectiveness in prevention of AIV entry into the professional zone. Clean clothing and footwear have a high effectiveness in prevention of AIV spread. The experts noted that general biosecurity training is required when entering the professional (and production) zone but that holding-specific guidance will have the highest impact on the achieved biosecurity level. The overall ranking of the biosecurity measures applicable in the professional zone is provided in Figure B1, Appendix B.

3.5.2.3 Description of biosecurity measures applicable in the production zone

A production zone (e.g. animal production units) is physically separated from the open and professional zones and poultry and/or materials that have been in contact with poultry can be present.

The biosecurity measures are ordered from highest to lowest overall rank, considering equal weight for feasibility, sustainable implementation, effectiveness to reduce AIV entry, effectiveness to reduce AIV spread (see section 2.2).

Separation of poultry species: mixing of poultry species should be prevented by keeping each species and production type in a separate house. In particular mixing of ducks or geese with other poultry species should be prevented.

Make environment unattractive to wild birds: same as in professional zone.

Restricted access: Only staff and essential professional visitors (e.g. veterinarians, technicians, inspectors or catchers) can access the production zone. The borders of the production zone are physically separated (e.g. fence, barrier in hygiene lock) to enforce staff and professional visitors to implement the necessary biosecurity measures.

Prevent access to mammals: rodent control should actively be implemented both inside (without poultry access) and outside of the production zone and access of other domestic animals such as dogs or cats and wild animals such as fox, marten, badger should be prevented by closing doors of the buildings and use of covering material. Baits and/or chemical pest control should always be used in accordance with the manufacturer's instructions.

Hygiene lock to production unit: Clothing, footwear (capable of being washed or disinfected) should be changed, hands should be washed and disinfected and hair should be covered before and after entry of the production unit. Clothing and footwear should be production unit-specific. Persons can enter the production unit only when wearing personal protection equipment such as (disposable) coveralls or overalls, head covering and boots belonging to the holding. These should be cleaned and disinfected before/after use. Providing tools for scraping the soles of footwear will facilitate their cleaning. Place a hygiene line (a clear physical barrier, e.g. bench or low wall) is suggested, as a line is very easily crossed and therefore ignored) at the entrance of each poultry house: footwear and clothing have to remain at each side of this line in the hygiene lock.

Prevent direct wild bird contact: is assured by construction of bird proof roof and walls/fences when poultry are housed indoors. In case of outdoor housing, fences and/or nets can be used with a

maximum mesh diameter of 25 mm. Access of poultry to water bodies that could be visited by wild (water) birds should always be prevented.

Potable drinking water supplied to poultry (either in indoor or outdoor housing within the production zone) should be potable or comply to the national water quality standard. Poultry should not have access to surface water.

Flock management should be based on the 'all-in, all-out' principle, preferably at holding level. This means that all birds have a similar age and the houses will be emptied, cleaned (including removal of manure) and disinfected after each production cycle. Movement of feed between flocks should be avoided. Removal of carcasses, broken eggs and rejected eggs should be done at least daily.

Clean/disinfect poultry/waste transport: vehicles transporting poultry, hatching eggs, carcasses or waste (e.g. manure) should be empty (except for poultry and hatching egg delivery), clean and disinfected when entering the production zone. Cleaning and disinfection of the wheels, wheel arches and footsteps/rets is required when leaving the holding. Paths should be cleaned and disinfected after passage. Vehicles, crates and other materials that have been in contact with poultry, eggs, carcasses or waste should not go from one poultry holding to another holding without cleaning and disinfection. Ideally, these vehicles would not pass through the open and professional zones.

Prevention of direct contact with faecal droppings from flying wild birds is provided by construction of a roof and walls/fences when poultry are housed indoors. In case of outdoor housing, horizontal fabric (e.g. canvas) can be used.

Health monitoring starts by checking the health certificates for new poultry and/or hatching eggs when arriving at a holding. The place of origin should be documented and it is recommended to keep the number of suppliers as limited as possible. Quarantine should be implemented for new poultry and/or hatching eggs when arriving at a holding, in particular when new animals will be introduced in a flock. Monitoring of the poultry health status should be continued throughout the production cycle under the supervision of a veterinarian.

Previous poultry contact: same as in professional zone

Cleaning/disinfection equipment: Cleaning/disinfection equipment: any movable equipment should be cleaned and disinfected when entering and leaving a poultry production unit. All material should be kept specific per production unit (e.g. use colour codes), no equipment should be used on multiple farms. All other stationary equipment should be cleaned and disinfected after each production cycle.

Biosafety training: same as in professional zone

Protected waste storage: Storage of manure and used bedding should not be stored on the premises and immediately removed after a production cycle. Otherwise, it should be done in a way to prevent access of animals.

No feed/clean bedding transport: Vehicles transporting feed or bedding have no access to the production zone.

Carcass disposal: should be done in a vermin-proof structure, remote from the production units and close to the public road (accessible from outside the farm). It should be on a solid surface to allow proper cleaning and disinfection. Cooling is recommended as it facilitates longer storage and subsequently less frequent carcass transport because frequent carcass transport has a higher risk than keeping carcasses longer at a holding.

Filtration of incoming air: Filtration of incoming air can be achieved per production unit in some specific housing designs, via (e.g. HEPA) filters.

3.5.2.4 Ranking of biosecurity measures applicable in the production zone

Overall, separating poultry species, in particular ducks and geese from other poultry, is the most highly recommended measure in the production zone. It has a high feasibility and sustainability and has the highest rank for effectiveness to prevent spread in the production zone. Preventing direct wild bird contact via indoor housing or via fences and nets has the highest effectiveness to prevent entry whereas its feasibility depends on outdoor access of poultry. The main effect of this measure is preventing wild birds from landing where poultry is kept outdoors, resulting in a reduced probability of

wild bird defecation where poultry are present. However, faecal droppings from flying birds could reach poultry that are outside and are only protected via nets and fences, but the probability of wild bird defecation during flight is lower compared to its probability when a bird is on the ground or in the water. Poultry confinement is recommended in periods when there is an increased probability that a poultry holding is exposed to HPAIV. The start and duration of the confinement could be determined by HPAI surveillance in wild birds (see section 3.4), outbreaks in nearby poultry holdings and the season because the virus will persist longer in the environment in winter than in summer. Several Member States have decided to implement poultry confinement indoors. It is likely that HPAIV H5N8 exposure to poultry holdings will remain high for a long period, even beyond 12 weeks, because very high virus levels have been detected in faecal swabs of wild birds (quantitation cycle (Cq)-values of 20 or lower), the long virus tenacity during winter and the expected long duration of virus detections as has been seen in previous large HPAI epizootics.

Preventing direct contact with faecal droppings from flying wild birds by using a roof or canvas cover has the second highest effectiveness to prevent entry of AIV. If poultry cannot be confined in high risk periods, at least feeding and bedding should be provided under a roof or canvas cover to prevent contamination with faecal droppings from flying wild birds. Cleaning and disinfection of poultry and waste transports has a high effectiveness to prevent entry but its correct implementation is expected to decrease in time. The hygiene lock is important to prevent AIV entry in poultry production units, in particular via changing of cloths and footwear, washing/disinfecting hands and covering hair. However, the implementation of this measure has a low sustainability. Showering has only an added value if the walk-through principle is used. Cleaning and disinfection of equipment used in poultry production units and preventing access of mammals (rodents and pets) in the production units have both a high effectiveness to prevent AIV spread within the holding.

The overall ranking of the biosecurity measures applicable in the professional zone is provided in Figure B2, Appendix B. The experts indicated that it was difficult to rank the biosecurity measures applicable in the production zone because the implementation is often different in indoor versus outdoor conditions. Therefore, it might be useful to perform a separate ranking for indoor and outdoor production.

3.5.3. Biosecurity measures applicable in turkey and duck commercial holdings

3.5.3.1 Biosecurity in turkey holdings

Turkeys require frequent clean bedding during their production cycle to keep the bedding dry. This is the main differences in turkey production compared to chicken production, which is considered to affect the overall biosecurity level of a turkey holding. Straw has to be used which cannot be heat-treated, whereas other (heat-treatable) materials are used for other poultry species (e.g. plastic material for chickens). Therefore, there is a risk of introducing faeces-contaminated bedding. Furthermore, the bedding attracts wild birds and rodents.

Furthermore, turkeys are often kept in non-tightly closed buildings. In general, nets are used to prevent direct contact with wild birds, but production units are in most cases not wild bird proof (small birds can pass through small net pores and holes can be present).

Therefore, special attention is required in turkey holdings to prevent direct contact with wild birds and to prevent contamination of bedding by wild birds. A detailed analysis is required how the housing infrastructure can be adapted to reduce wild bird (and dust) access. Also the use of alternative bedding material has to be analysed.

3.5.3.2 Biosecurity in duck holdings

Foie gras production occurs in three phases:

- Pre-growing: 2 weeks, indoor, bedding can be heat treated
- Growing: 12 weeks, free-range, large flocks
- Fattening: 2 weeks, indoor, small flocks (because labour intensive)

The size of growing flocks varies widely, ranging from a few hundreds up to 20,000 birds, while the average capacity of fattening houses is around 1,000 birds. This means that at the end of the growing

phase, a large growing flock will be separated into many small fattening flocks, leading to intensive animal movements because the fattening houses are often at different locations. In addition, should a large flock become infected by HPAIV, it has the potential to contaminate a large number of other holdings. In several regions, there are not enough housing facilities available to keep the animals indoor during the growing phase. Keeping the animals in their natural environment is perceived as one of the (cultural) characteristics of the foie gras production. Preventing direct wild bird contact via nets and fences is often not feasible due to the large flock sizes, in particular during the long growing phase.

The production of broiler ducks is often done indoor and the animals remain at the same location during the production process. However, daily clean bedding is required.

Therefore, important biosecurity measures are reducing the frequency of animal transports and the number of different farms receiving animals from each other, clean and disinfect equipment and vehicles and have a storage for the bedding that does not allow for wild bird entrance.

3.5.4. Biosecurity measures applicable in backyard holdings

The experts checked the list of biosecurity measures applicable in commercial chicken holdings (see sections 3.5.2.1 and 3.5.2.3) and selected the measures that can be applied in backyard holdings, at least in periods of high risk to HPAIV exposure. The most important measures are preventing direct wild bird contact to poultry (as well as feed and bedding), providing potable drinking water (no surface water) and changing clothing and footwear, washing and disinfection of hands when entering and leaving the poultry facility. It is strongly recommended to keep poultry species separated, in particular ducks and geese from other poultry species, and prevention of direct contact of poultry with droppings from flying wild birds. Other feasible and relevant measures are keeping the environment clean, preventing the access of mammals (such as rodents and pets) to poultry, performing health monitoring of the flock and newly introduced poultry, cleaning and disinfection of any equipment, preventing any contact with commercial poultry holdings. Specific guidance to backyard holdings is to provide only commercial feed (no swill feeding).

3.6. Protection measures for poultry in relation to HPAI H5N8 findings in wild birds

3.6.1. Establishment of control and monitoring areas

Section A5.1 of Appendix A provides text fragments of the corresponding Decision 2006/563/EC).

There is currently no evidence in support of the claim that risks of incursions of HPAIV from infected wild birds into poultry holdings would depend on the subtype of HPAIV circulating in wild birds. Also, the immediate diagnostic and preventive measures that are to be implemented in poultry holdings are not influenced by the subtype of HPAIV. Therefore, a differentiated approach based on HPAIV subtypes as currently described in the legislation is not scientifically justified and, hence, it is recommended that control and monitoring areas should be established when an H5 or H7 HPAIV is detected in a wild bird population known to be capable of acting as maintenance reservoirs for HPAI, irrespective of which subtype it is.

A clear definition is required of what is considered "detection of HPAIV in a wild bird". Is it the detection of HPAIV (i) in a carcass of a dead wild bird, (ii) in swabs or other sample matrices (e.g. feathers) obtained from live captured or hunted wild birds, (iii) in faecal droppings sampled from the environment independently of the detected presence of the wild bird, or (iv) in other environmental matrices (e.g. surface water)? Considering that a large proportion of incursions is likely due to indirect contacts between wild bird habitats and poultry holdings, i.e. through contaminated fomites (shoes, vehicle tyres, equipment, bedding etc.), the presence of dead infected wild birds is not necessarily a prerequisite to prompt an incursion. Also, some HPAIV variants may express mild pathogenicity in some wild bird species such as mallards, but are still capable of inducing high pathogenicity in gallinaceous poultry. Thus, HPAIV may be circulating, even at higher prevalence, without causing overt mortality in wild bird populations. Yet, HPAI virus excreted from asymptotically infected wild birds may accumulate in the environment and increase risks of incursions of poultry holdings.

Consequently, it is recommended that detection of HPAIV in the environment independent of the presence of infected dead wild birds cannot be disregarded epidemiologically but should be reported.

The definition of the area for enhanced follow-up wild bird surveillance following detection of HPAIV in wild birds should be flexible and proportionate, depending on the suspected HPAIV prevalence in wild birds (e.g. 1 - scattered sporadic detection in 2014/2015 versus 2 - epizootic presence in 2016). The currently implemented zoning concept is still effective for scenario 1 but probably not in an epizootic situation as currently experienced. Therefore the area should be adapted e.g. to the habitats and home range size of the wild bird species present in the surroundings: for instance swans may well be resident at a single lake, whereas wintering ducks and geese generally commute between roosts and foraging areas used during daylight hours and during the night, separated from each other by several kilometres on average (further apart in geese than in ducks; Johnson et al., 2014), while gulls can have wide daily ranges. Time of the year should also be taken into account, since the commuting flights of wintering waterfowl do not exist when these birds are breeding and highly faithful to very small geographic areas. On top of these regular daily movements very large distances can be covered in a very short time by waterfowl during migrations. Finally, these birds are capable of crossing countries and large parts of continents during apparently erratic back and forth winter movements (Gourlay-Larour et al., 2012). Therefore, risk based analysis with ornithological input is required to underpin the delineation of very small areas.

In areas with HPAIV findings in wild birds as indicated above it is advised to increase awareness among poultry keepers towards the risk of introduction of HPAI from a wild bird reservoir. Given the rapidly increasing morbidity and mortality in most poultry types upon an HPAIV H5N8 2016 incursion, passive surveillance is likely to be much more effective than any kind of active surveillance for the purpose of early detection in a poultry flock. In contrast, when dealing with HPAI virus variants that do not result in a clear clinical manifestation in certain species (such as seen for H5N8 in e.g. domestic ducks in 2014), active surveillance in farms housing these species would help early detection.

3.6.2. Measures in the control and monitoring area

Section A5.2 of Appendix A provides text fragments of the corresponding Decision 2006/563/EC).

In addition to an increased awareness it is advised that farmers take actions to reduce the risk of introduction of HPAIV into their flocks. This includes strengthening of the biosecurity policy as indicated in section 3.5.

During an epizootic manifestation of HPAIV in wild birds, when seeking an overview of the epizootic situation it is advised to focus passive surveillance in wild birds on new species in an ornithologically defined area (see above) or findings in a new ornithologically defined area/habitats. It is not recommended to keep on testing dead birds from the same species and same or closely neighbouring regions, because it will likely only confirm what is already known whilst also placing pressure on existing diagnostic capacity. However, the latter testing is considered useful shortly before restrictive measures in poultry are to be lifted.

3.6.3. Prohibitions in the control area

Section A5.3 of Appendix A provides text fragments of the corresponding Decision 2006/563/EC).

Hunting disturbs wild birds. Preventing their forced movement might prevent accelerated spread of virus. In addition, risks of human contact with potentially infected hunted wild birds and contact with poultry through hunters visiting poultry holdings will be decreased.

Accordingly, other leisure activities on water (e.g. water sports, boat activity) might disturb potentially infected wild bird populations, and could also be restricted to prevent wild bird movements.

The use of live birds as decoys to attract the game for water-bird hunting constitutes another bridge of spread of HPAIV from wild bird habitats. Such live decoys should not be moved in/out of control areas. When kept on site without transport, they can be used as valuable sentinels (and were actually responsible for the first detection of H5N8 in northern France by the end of November 2016, Eurasian Wigeon (*Anas penelope*)).

3.6.4. Prohibitions in the monitoring area

Section A5.4 of Appendix A provides text fragments of the corresponding Decision 2006/563/EC.

The same argumentation on hunting as described in the previous section is relevant in the monitoring area.

3.7. Protection measures in relation to HPAIV H5N8 in poultry

3.7.1. Establishment of areas A and B

Decision 2006/415/EC only applies to HPAI viruses of the H5N1 strain (see section A6.1 of Appendix A). The intent of this Decision was to control the spread of virus to disease-free parts of the Community through the movement of poultry, other birds and products thereof. Two areas are required to be put in place where the restrictions apply: Part A, a high risk area comprising the 3km and 10km zones, and Part B, a low risk area, based on the geographical, ecological and epizootiological characteristics. These areas are only required for H5N1 HPAIV, but it would be sensible to apply the same zones to areas around premises where H5N8 HPAIV infection in poultry has been identified. Areas A and B are based on the transmission dynamics of H5N1 HPAIV and expert opinion to cover high risk and low risk spread regions from a contaminated area, into the local wild bird population or further spread into other poultry and captive birds, based on the presence of a poultry outbreak.

In previous instances where information is available, for example in the UK in 2007, an outbreak of H5N1 HPAI in poultry led to the implementation of such areas based on the ecological factors and on what was known of the behaviour of the birds at the site. Therefore, the zones were not simple concentric circles, but were geographically defined according to ornithological opinion (Defra, 2007). Wild bird passive surveillance (for birds found dead) and some active surveillance on site of wild bird faecal samples were carried out and no spill-over into the local wild birds was observed. The source of disease in this case was not believed to be wild birds, but the actions were taken in order to provide evidence to back this up.

As the wild bird species involved in the wild bird cases in Europe of H5N8 HPAI in 2016 and H5N1 HPAI in 2005-2007 are essentially from the same families of birds with similar behaviour and movement patterns (see section 3.2.2), it would be reasonable to suggest the establishment of areas A and B could apply to infections with any H5 or H7 HPAI viruses. The HPAIV H5N8, both in 2014/2015 and in 2016, has spread over a greater geographical area than HPAI H5N1 did. Therefore, the areas A and B will cover a larger surface in the ongoing HPAI H5N8 2016 epizootic compared to the HPAI H5N1 epizootic ten years ago.

3.7.2. Prohibitions in areas A and B

Section A6.2 of Appendix A provides text fragments of the corresponding Decision 2006/415/EC).

The variety of birds involved in the H5N8 HPAI wild bird cases to date has been striking both in the number of families involved and the similarity to H5N1 HPAIV wild bird cases (Artois et al., 2009) (see section 3.1). What is uncertain at present is whether any of those species show particular susceptibility, whilst others show no clinical signs. Until more evidence is available, it should be considered that any bird of these orders could be infected but may not all be clinically affected. Some of the poultry outbreaks in Europe have also had galliformes species (which would include chickens, turkeys and pheasants) showing relatively mild clinical signs although this may have been due to very early detection of the infection on the holding.

Poultry, hatching eggs, and day old chicks may only be moved to another Member State or third country under a specific licence, while the restrictions are in place. This is the same requirement as for any HPAI virus, the additional measures for H5N1 HPAIV is therefore related to the wider Part B. Meat, minced meat and mechanically separated meat from wild feathered game destined for human consumption can only move if marked and if either treated or produced in approved establishments. There is no restriction on the movement of meat and products from poultry from this area.

Therefore the same restrictions on the movement of live birds, hatching eggs and wild feathered game should be applied.

In terms of wild feathered game entering the food chain, there is only a very low public health risk associated with this virus (see section 3.8) and the sequence derived shows no affinity markers for human cells (see section 3.2.2). Therefore this is a less relevant issue for this particular viral event. Nevertheless, in the event of the product being diverted from the human food chain into animal feed, there would be considered a very low risk that it may give rise to another outbreak, which would have significant consequences for animal health. Therefore, the virus should be considered necessary primarily for the protection of animal health, rather than public health.

In terms of animal (avian) by-products, the currently circulating H5N8 virus is highly pathogenic and infected birds are likely to develop a systemic infection, as well as excrete virus through respiratory and cloacal excretions, therefore the products will carry a low risk of carrying infectious virus either in infected meat or contaminating products. Thermal processing should mitigate the risk in such products.

Bird fairs and gatherings can occur throughout the year and may involve mixed species. While these birds are often under owner care, there is no requirement for veterinary inspection of birds before entering gatherings and shows. An owner declaration may be required if birds are moving for trade purposes, but no veterinary inspection. Therefore these should not be allowed to move within any zone designated as part of disease control measures. It would be reasonable to apply the same measures around the outbreaks of H5N8 HPAIV in poultry.

3.7.3. Provision of information

Section A6.3 of Appendix A provides text fragments of the corresponding Decision 2006/415/EC).

There are not sufficient differences in the two viruses to expect different epidemiological evidence to be provided to the Commission and other Member States.

The epidemiological investigations should consider the timeline for entry of disease onto the premises based on production records. Details of the following are recommended (but not exclusively) any movements on or off of live birds, products, by-products, feed, veterinary medicines, visits made by staff or other professionals, source of water, the layout of the farm including an assessment of wild bird and wild mammals access (incl. rodents), biosecurity in place, recent trade to or from other Member States or third country trade partners.

3.8. Risk of HPAI H5N8 to humans

ECDC has assessed the risk of zoonotic transmission to the general public in EU/EEA countries to be very low, based on a review of the epidemiological, virological and environmental information relating to outbreaks of highly pathogenic avian influenza A virus subtype A(H5N8) in Europe up to 15 November 2016. The following paragraphs summarise the full review and conclusions, which can be found in the relevant ECDC Rapid Risk Assessment (ECDC, 2016). No human cases of A(H5N8) virus infection have been reported despite large numbers of people being occupationally exposed while managing the avian outbreaks of HPAIV A(H5N8) (Arriola et al., 2015). This contrasts with the risk of bird-to-human transmission of influenza A(H5N1) and is probably due to A(H5N8) receptor binding properties, with the A(H5N8) virus being better adapted to avian-like receptors than human-like receptors (Kaplan et al., 2016; Richard et al., 2015; Pulti-Penalzoza et al., 2015; Hanna et al., 2015). Although the sequence information available for recent isolates does not indicate increased affinity for humans, these viruses should be closely monitored for any adaptation⁵.

The relative likelihood of HPAIV H5N8 2016 making the species jump from poultry into humans has been assessed using the FLURISK model (De Nardi et al., 2014) and confirmed the ECDC risk assessment. The obtained relative likelihoods are around 2 log₁₀ scales lower for HPAI H5N8 2016 circulating in Europe compared to HPAI H5N1 clade 1 and clade 2 outbreaks in 2004 in South East Asia (Hill et al., 2015).

⁵ Department for Environment FaRAAPHA. Highly Pathogenic Avian Influenza H5N8 in Europe, Updated Outbreak Assessment number 3 2016 [26/11/2016]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/570883/hpai-europe-uoa-update3.pdf.

HPAI A(H5N8) viruses cluster in the same haemagglutinin (HA) clade 2.3.4.4 as A(H5N6) viruses from Asia – which have caused severe disease in humans in China. Given that the virus with the HA gene has evolved from the widely circulating A(H5N1) and clusters with A(H5N6) viruses, people in direct contact with or handling diseased birds or poultry and their carcasses (e.g. hunters, farmers, veterinarians and labourers involved in the culling and rendering) might be at risk of infection. Given this potential zoonotic risk, contingency plans for the control of avian influenza in poultry and birds are being implemented in collaboration with public health and occupational health authorities, to ensure that persons at risk are sufficiently protected from infection. Appropriate personal protective equipment, including respiratory protection, should be made available and used. People exposed at affected holdings or having direct contact with infected wild birds should be monitored for ten days in order to identify the possible emergence of related symptoms. Local health authorities may consider actively monitoring these groups and administering antiviral prophylaxis as recommended for persons with exposure to A(H5N1), dependent on the local risk assessment (i.e. intensity of exposure). Many EU Member States offer vaccination against seasonal influenza to persons exposed to poultry as a result of their occupation. Healthcare workers managing symptomatic exposed (or possible) cases should follow standard, contact and respiratory precautions, depending on the local risk assessment.

A workshop organised by ECDC with animal and public health experts involved in the HPAI A(H5N1) and A(H5N8) outbreaks in Europe in 2014/15, reviewed relevant national protocols available in EU/EEA countries, actions implemented and lessons learnt; a summary is available [here](#). Outcome of these discussions and current measures recommended by some EU countries have been published recently (Adlhoch et al., 2016).

Available guidance on protective measures

Although the risk of human infection is considered very low, most of the available national guidance documents recommend a number of risk mitigation measures to minimise exposure:

1. Provision of advice for the general population to avoid exposure to potentially infected birds by not touching dead wild birds, but to inform local veterinary authorities;
2. For local public and veterinary health authorities, to decrease the number of persons exposed to birds suspected or confirmed to have HPAI;
3. For persons exposed occupationally, to use appropriate personal protective equipment (PPE).

Reference to guidance documents describing prevention measures: see references provided in Appendix C.

4. Conclusions

- Passive surveillance is the most effective means of early detection of the current HPAI H5N8 2016 in wild birds as well as in poultry.
- Establishment of control and in particular monitoring areas for poultry associated with positive wild bird findings are best based on knowledge of the wider habitat and flight distance of the affected wild bird species.
- Testing samples from new species and non-previously reported areas is key to determine the geographic spread of HPAIV H5N8 2016 in wild birds. Testing limited numbers of dead wild birds in previously-reported areas is useful when it is relevant to know whether the virus is still present in the area or not, e.g. before restrictive measures in poultry are to be lifted.
- To prevent introduction of HPAIV H5N8 from wild birds into poultry holdings, strict biosecurity implemented and maintained by the poultry farmers is the most important measure.
- There is no scientific evidence suggesting a different effectiveness of the protection measures on the introduction into poultry holdings and subsequent spread of HPAIV when applied to H5N1 or H5N8 or other notifiable HPAI viruses.

5. Recommendations

- Upon detection of HPAIV in wild birds, it is recommended that control and in particular monitoring areas are established based on the ecological habitat and flight distance of the affected bird species.
- In the established control and monitoring area, it is recommended to increase awareness among poultry farmers in order to enhance passive surveillance and to implement enhanced biosecurity measures including poultry confinement.
- During an epizootic of HPAIV in wild birds, it is recommended to test samples from new species and non-previously reported areas.
- Providing holding-specific biosecurity guidance is strongly recommended as it is expected to have a high impact on the achieved biosecurity level. This is preferably done during peace time to increase preparedness for future outbreaks.

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Glossary and Abbreviations

Glossary:

| | |
|---|---|
| Backyard (or 'non-commercial) poultry holding | A farm where poultry and/or other captive birds are kept by their owners for their own consumption or use, or as pets. |
| Bedding | Bedding material before contact with poultry |
| Commercial poultry holding | A farm where poultry are kept for commercial purposes. The criteria are likely to differ between countries. |
| Litter | Bedding material during or after contact with poultry |
| Open zone of a holding | zone of a holding without activities related to poultry farming (e.g. residence, office) which is connected to the public road and physically separated from the professional and production zones of the holding |
| Production zone of a holding | zone of a holding with farming activities (e.g. poultry production units) with access of poultry and storage of material that was in contact with poultry (e.g. manure, litter, eggs) |
| Professional zone of a holding | zone of a holding with poultry farming activities (e.g. storage feed and bedding) but without access of poultry and without storage of material that was in contact with poultry |

Abbreviations

| | |
|------|--|
| AI | Avian influenza |
| AIV | Avian influenza virus |
| ECDC | European Centre for Disease Prevention and Control |
| EFSA | European Food Safety Agency |
| EU | European Union |
| EURL | European Reference Laboratory for Avian Influenza |
| HPAI | High pathogenic avian influenza |
| IVPI | Intravenous pathogenicity index |
| LPAI | Low pathogenic avian influenza |

Appendix A – Fragments from EC Decisions

A1. Early detection criteria (Decision 2005/734/EC, Article 2)

1. Member States shall introduce early detection systems in the areas of their territory that they have identified as being particularly at risk for the introduction of avian influenza, taking into account the criteria set out in Annex II to this Decision.
2. The early detection systems shall be aimed at a rapid reporting of any sign of avian influenza in poultry and other captive birds by the owners or keepers to the competent veterinary authority.
3. In particular in this context, the criteria set out in Annex II shall be taken into account.

ANNEX II, criteria to be considered for commercial poultry Holdings when applying the measure set out in Article 2:

- Drop in feed and water intake higher than 20 %,
- Drop in egg production higher than 5 % for more than two days,
- Mortality rate higher than 3 % in a week,
- Any clinical sign or post-mortem lesion suggesting avian influenza.

A2. Annual AI surveillance programmes in poultry and wild bird (Decision 2010/367/EU, Article 3)

The surveillance programmes for avian influenza in poultry and wild birds to be carried out by Member States, in accordance with Article 4(1) of Directive 2005/94/EC, shall comply with the guidelines set out in Annexes I and II to this Decision.

A3. HPAI surveillance in poultry and wild birds (Decision 2010/367/EU)

Article 1

Member States shall take the necessary measures to ensure that the competent authorities make appropriate arrangements with wild bird observation and ringing organisations, hunting and other relevant organisations in order to ensure that those organisations are required to notify the competent authorities without delay of any abnormal mortality or significant disease outbreaks occurring in wild birds and in particular wild water birds.

Article 2

1. Member States shall ensure that immediately following receipt by the competent authority of any notification, as provided for in Article 1, and whenever no clear cause of disease other than avian influenza is identified, the competent authority shall arrange for:

- (a) appropriate samples to be collected from dead birds and if possible from other birds which have been in contact with the dead birds;
- (b) those samples must be subjected to laboratory tests for the detection of the avian influenza virus.

2. Sampling and testing procedures shall be carried out in accordance with Chapters II to VIII of the Diagnostic Manual for avian influenza approved by Decision 2006/437/EC.

3. Member States shall inform the Commission without delay in the event of the laboratory tests provided for in paragraph 1(b) showing positive results for highly pathogenic avian influenza virus (HPAI).

Article 3

The surveillance programmes for avian influenza in poultry and wild birds to be carried out by Member States, in accordance with Article 4(1) of Directive 2005/94/EC, shall comply with the guidelines set out in Annexes I and II to this Decision.

Article 4

Without prejudice to the requirements provided for in Union legislation, the competent authority shall ensure that all positive and negative results of both serological and virological investigations for avian influenza obtained under the surveillance programmes for poultry and wild birds are reported every 6 months to the Commission. They shall be submitted via the Commission's online system each year by 31 July for the preceding 6 months (1 January to 30 June) and by 31 January for the preceding 6 months (1 July to 31 December).

A4. Biosecurity measures (Decision 2005/734/EC, Article 1)

1. Member States shall take appropriate and practicable measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza A virus subtype H5N1 (hereinafter 'avian influenza') from birds living in the wild to poultry and other captive birds, taking into account the criteria and risk factors set out in Annex I to this Decision.

2. Depending on the specific epidemiological situation, the measures of paragraph 1 shall be directed in particular at:

- (a) preventing direct and indirect contact between birds living in the wild, and in particular waterfowl, on the one hand and poultry and other birds, and in particular ducks and geese, on the other hand,
- (b) ensuring separation between domestic ducks and geese from other poultry.

3. Member States shall ensure that when animal health checks are undertaken on poultry holdings, they shall be done in a way to ensure compliance with the provisions of this Decision.

A5. Protection measures in relation to HPAI H5N1 in wild birds (Decision 2006/563/EC)A5.1. Establishment of control and monitoring areas

Article 3

1. The affected Member State shall establish around the area where the presence of HPAI caused by avian influenza A virus of subtype H5 is confirmed in wild birds and the neuraminidase type N1 is either suspected or confirmed:

- (a) a control area with a radius of at least three kilometres (the control area); and
- (b) a monitoring area with a radius of initially at least 10 kilometres, including the control area (the monitoring area).

5. If wild birds are suspected or confirmed to be infected with HPAI H5N1 in a protection or surveillance zone established pursuant to Article 11(1) of Decision 2006/416/EC (the protection or surveillance zones) due to such infection in poultry or other captive birds, the competent authority shall:

- (a) establish control and monitoring areas; and
- (b) undertake a risk assessment to consider whether the radius of the control and monitoring areas needs to be extended to overlap with the protection and surveillance zones.

The competent authority may apply the protection measures provided for in Article 5(b), (c) and (d), in any parts of the protection and surveillance zones that do not overlap with the control and monitoring areas when the risk assessment indicates that there is a risk of spread of HPAI H5N1 to poultry or other captive birds in those parts.

Article 4 (Derogations from measures provided for in Article 3(1))

1. By way of derogation from Article 3(1), the affected Member State may refrain from the establishment of control and monitoring areas on basis of the favourable results of a risk assessment by the competent authority. That assessment shall take into account geographical considerations, the ecology of the infected bird species and lead the competent authority to conclude that HPAI H5N1 is not present in the area in poultry or other captive birds or wild birds, or that the infected wild bird did not present a risk of spreading that virus to poultry or other captive birds or wild birds in the locality. In those circumstances the competent authority shall attempt, where necessary in liaison with the competent authorities of other Member States or third countries, to establish with the help of ornithological experts whether the wild birds are resident or migrating, such that an assessment can be made as to whether HPAI H5N1 exists in wild birds in other areas under their jurisdiction.

2. By way of derogation from Article 3(1) (a) and on the basis of favourable results to a risk assessment which has taken into account at least the criteria referred to in Article 3(2) and confirmed the existence of sufficient protection of the local poultry or other captive birds based on natural barriers or the absence of suitable habitats for wild birds presenting a risk of spreading HPAI H5N1 the control area may be:

- (a) amended to an area of sufficient size but in any event not less than of 1 km in radius; or
- (b) established as a band of 1 km in width from the banks of a river or the shores of a lake or coast for a length of at least 3 km. In this case and by way of derogation from Article 3(1)(b) the competent authority shall then also adapt the shape and the size of the monitoring area accordingly to separate the control area from the unaffected parts of the territory.

A5.2. Measures in the control and monitoring area

Article 5, Decision 2006/563/EC:

The affected Member State shall ensure that at least the following measures are applied in the control area:

- (a) the identification of all commercial poultry holdings and non-commercial holdings;
- (b) the implementation of the biosecurity measures laid down in Decision 2005/734/EC for poultry and other captive birds, including disinfection at the entrances and exits to premises where poultry or other captive birds are kept;
- (c) intensified official surveillance of wild bird populations, in particular water fowl, and further monitoring for dead or sick birds, if necessary with the co-operation of hunters and bird-watchers, and the reporting of dead bird findings to the competent authority and the removal, as far as possible, of carcasses of dead birds by personnel who have been specifically instructed on measures to protect themselves from infection with the virus and to prevent the spread of the virus to susceptible animals;
- (d) campaigns to inform the public and to increase disease awareness among owners of poultry or other captive birds, hunters, bird-watchers and those providing the services of water-related recreation;
- (e) periodic and documented visits to all commercial poultry holdings and targeted visits to non-commercial poultry holdings, prioritising those considered to be at greater risk, which must include:
 - (i) a clinical inspection of the poultry or other captive birds including, if necessary, the collection of samples for laboratory examination targeting poultry or other captive birds that had not been confined prior to the positive finding in a wild bird and in particular ducks and geese;
 - (ii) an assessment of the implementation of the biosecurity measures referred to in point (b). »

Article 7, Decision 2006/563/EC:

The affected Member State shall ensure that at least the measures provided for in 'measures in the control area' (a) to (d) are applied in the monitoring area.

Article 14, Decision 2006/563/EC:

Duration of the measures in the control and monitoring areas

1. If the neuraminidase type is confirmed as being different from N1, the measures provided for in Articles 5 to 8 shall no longer apply.
2. If the presence of HPAI H5N1 is confirmed in wild birds, the measures provided for in Articles 5 to 8 shall apply for as long as is necessary having regard to the geographical, limnological, administrative, ecological and epizootiological factors relating to avian influenza and for at least 21 days in the case of the control area and 30 days in the case of the monitoring area following the date of collection from wild birds of the samples on which a HPAI H5N1 virus was confirmed.

A5.3. Prohibitions in the control area

Article 6, Decision 2006/563/EC:

The affected Member State shall ensure that the following are prohibited in the control area:

- (a) the removal of poultry or other captive birds from the holding on which they are kept;
- (b) the assembly of poultry or other captive birds at fairs, markets, shows or other gatherings;
- (c) the transport through the control area of poultry or other captive birds, except transit through the control area by road or rail without unloading or stopping;
- (d) the dispatch of hatching eggs collected from holdings which on the date of collection were situated in the control area;
- (e) the dispatch from the control area of fresh meat, minced meat, meat preparations and meat products from poultry originating from the control area and wild feathered game taken from the wild in that area;
- (f) the transport or spread of unprocessed manure from holdings of poultry or other captive birds within the control area, except the transport for treatment in accordance with Regulation (EC) No 1774/2002;
- (g) the dispatch to other Member States and third countries of animal by-products of avian origin derived from poultry or other captive birds or wild feathered game originating from the control area;
- (h) the hunting of wild birds or otherwise taking them from the wild, unless authorised by the competent authority for specific purposes;
- (i) the release of game birds from captivity into the wild.

A5.4. Prohibitions in the monitoring area

Article 8, Decision 2006/563/EC:

The affected Member State shall ensure that the following are prohibited in the monitoring area:

- (a) the removal of poultry or other captive birds out of the monitoring area for the first 15 days following the date of establishment of that area;
- (b) the assembly of poultry or other captive birds at fairs, markets, shows or other gatherings;
- (c) the hunting of wild birds or otherwise taking them from the wild, unless authorised by the competent authority for specific purposes;
- (d) the release of game birds from captivity into the wild.

A6. Protection measures in relation to HPAI H5N1 in poultry (Decision 2006/415/EC)

A6.1 Establishment of areas A and B

Article 3, Decision 2006/415/EC:

1. The area listed in Part A of the Annex ('area A') is classified as the high risk area consisting of the protection and surveillance zones established in accordance with Article 16 of Directive 2005/94/EC.
2. The area listed in Part B of the Annex ('area B') is classified as the low risk area which may include all or parts of the further restricted zone established in accordance with Article 16 of Directive 2005/94/EC, and which shall separate area A from the disease free part of the affected Member State, if such part is identified, or from neighbouring countries.

Article 4, Decision 2006/415/EC:

1. Immediately following a suspected or confirmed outbreak of highly pathogenic avian influenza caused by highly pathogenic influenza A virus of subtype H5 suspected or confirmed to be of the neuraminidase type N1, the affected Member State shall establish:

- (a) area A, having regard to the legal requirements as set out in Article 16 of Directive 2005/94/EC;
- (b) area B having regard to geographical, administrative, ecological and epizootiological factors relating to avian influenza.

The affected Member State shall notify areas A and B to the Commission, to the other Member States and, as appropriate, to the public.

2. The Commission, in collaboration with the affected Member State, shall examine the areas established by the affected Member State and take the appropriate measures in relation to those areas pursuant to Article 9(3) and (4) of Directive 89/662/EEC and Article 10(3) or (4) of Directive 90/425/EEC.

3. If the neuraminidase type is confirmed as being different from N1, the affected Member State shall abolish the measures taken by it in relation to the areas concerned and notify the Commission and the other Member States.

The Commission, in collaboration with the affected Member State, shall take the appropriate measures pursuant to Article 9(3) or (4) of Directive 89/662/EEC and Article 10(3) or (4) of Directive 90/425/EEC.

4. If the presence of a highly pathogenic influenza A virus of the subtype H5N1 is confirmed in poultry, the affected Member States shall:

(a) notify the Commission and the other Member States;

(b) apply the measures provided for in Article 5:

(i) for at least 21 days in the case of the protection zone and 30 days in the case of the surveillance zone after the date of completion of the preliminary cleansing and disinfection on the holding where an outbreak is confirmed in accordance with Article 11(8) of Directive 2005/94/EC; and

(ii) as long as is necessary having regard to the geographical, administrative, ecological and epizootiological factors relating to avian influenza; or

(iii) until the date indicated for the affected Member State in the Annex;

(c) keep the Commission and the other Member States informed about any development with regard to areas A and B.

The Commission, in collaboration with the affected Member State, shall take the appropriate measures pursuant to Article 9(3) or (4) of Directive 89/662/EEC and Article 10(3) or (4) of Directive 90/425/EEC.

A6.2. Prohibitions in areas A and B

Article 5, Decision 2006/415/EC:

In addition to the restrictions on the movement of poultry, other captive birds, their hatching eggs and products derived from such birds laid down in Directive 2005/94/EC, for holdings in the protection, surveillance and further restricted zones, the affected Member State shall ensure that:

(a) no live poultry and other captive birds, except birds referred to in Article 2(c)(i) and (ii), and hatching eggs of poultry, other captive birds, except those from birds referred to in Article 2(c)(ii), and of wild feathered game birds are dispatched from area B to the remaining part of the territory of the affected Member State, if applicable, or to other Member States or to third countries;

(b) no products intended for human consumption derived from wild feathered game, are dispatched from areas A and B to the remaining part of the territory of the affected Member State, if applicable, or to other Member States and to third countries;

(c) no animal by-products derived entirely or partially from avian species from areas A and B and subject to the provisions of Regulation (EC) No 1774/2002 are transported between areas A and B or dispatched from those areas to the remaining part of the territory of the affected Member State, if applicable, or to other Member States or to third countries;

(d) no poultry or other captive birds are gathered at gatherings within area B such as fairs, markets or shows.

A6.3. Provision of information

Article 11, Decision 2006/415/EC:

All Member States shall immediately adopt and publish the measures necessary to comply with this Decision. They shall immediately inform the Commission thereof.

The affected Member State shall apply those measures as soon as it reasonably suspects the presence of highly pathogenic avian influenza virus of the subtype H5N1 in poultry.

The affected Member State shall regularly provide to the Commission and the other Member States the necessary information on the epidemiology of the disease and, where appropriate the additional control and surveillance measures and the awareness campaigns implemented.

Appendix B – Overall ranking of the biosecurity measures

Average ranking criteria for the Professional Zone

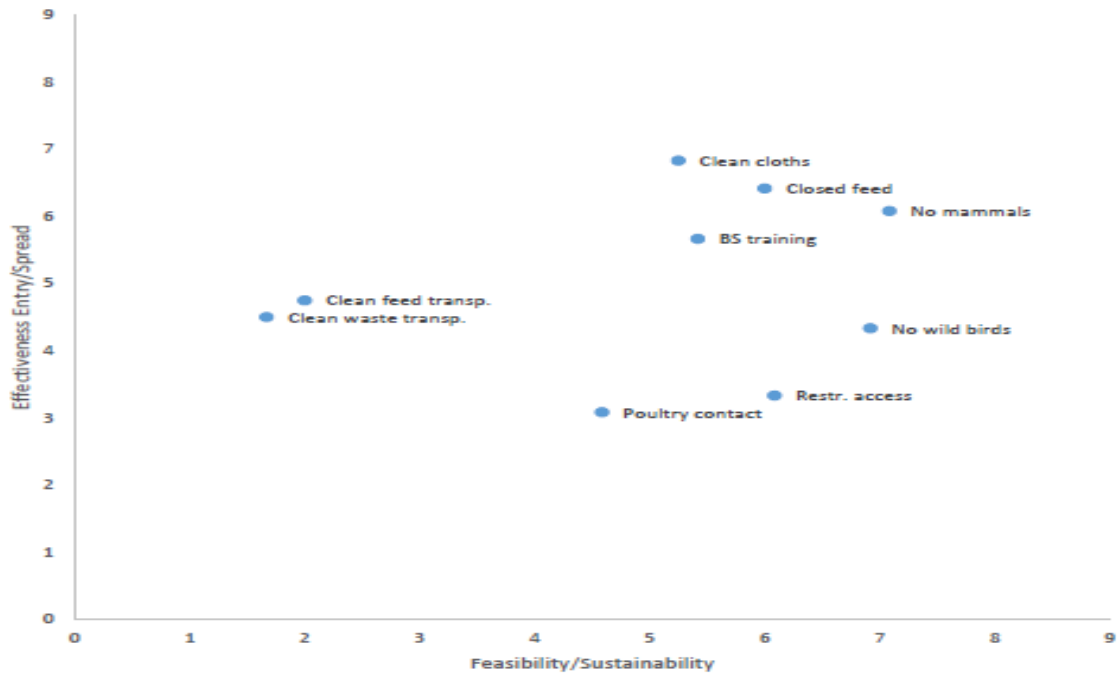


Figure B1: Average ranking of the biosecurity measures applicable in the professional zone of a commercial chicken holding

Average ranking criteria for the Production Zone

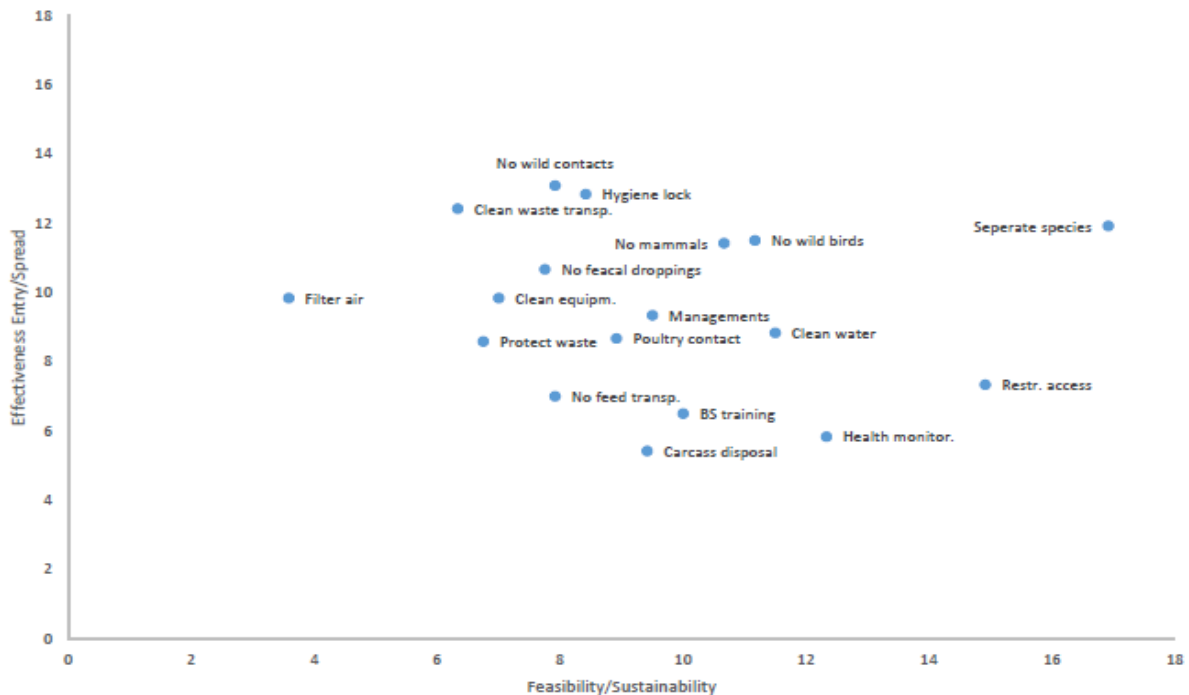


Figure B2: Average ranking of the biosecurity measures applicable in the production zone of a commercial chicken holding

Appendix C – Guidance documents describing prevention measures for humans

Adlhoch et al., 2016 Highly pathogenic avian influenza A(H5N8) outbreaks: protection and management of exposed people in Europe, 2014/15 and 2016 (Eurosurveillance)

Documents on avian influenza preparedness in EU/EEA countries:

http://ecdc.europa.eu/en/healthtopics/avian_influenza/preparedness-documents/Pages/default.aspx.

Links to the updated national preparedness plans in EU/EEA countries:

http://ecdc.europa.eu/en/healthtopics/pandemic_preparedness/national_pandemic_preparedness_plans/Pages/influenza_pandemic_preparedness_plans.aspx

A summary of the workshop:

http://ecdc.europa.eu/en/press/events/_layouts/forms/Event_DispatchForm.aspx?List=a8926334-8425-4aae-be6a-70f89f9d563c&ID=348.

Presentations available at:

<http://www.slideshare.net/tag/ECDC-avian-influenza-meeting-2015>