Annex 12B

CHAPTER 10.4.  
  
**INFECTION WITH HIGH PATHOGENICITY AVIAN INFLUENZA VIRUSES**

Article 10.4.1.

**General provisions**

1) ~~The objective of this chapter is to mitigate animal and public health risks posed by avian influenza viruses, and prevent their international spread. The chapter focuses on high pathogenicity avian influenza viruses, which cause the~~ *~~listed disease~~* ~~of concern. However, since they have the ability to mutate into high pathogenicity viruses, low pathogenicity avian influenza viruses of H5 and H7 subtypes should be included in any~~ *~~surveillance~~* ~~and control programmes for high pathogenicity viruses. This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of~~ *~~infection~~* ~~with avian influenza viruses in the absence of clinical signs.~~

This chapter deals with the *listed disease*, *infection* with high pathogenicity avian influenza viruses.

~~For the purposes of the~~ *~~Terrestrial Code~~*~~, avian influenza is defined as an~~ *~~infection~~* ~~of~~ *~~poultry~~* ~~caused by any influenza A virus of the H5 or H7 subtypes or by any influenza A virus with an intravenous pathogenicity index (IVPI) greater than 1.2 (or as an alternative at least 75% mortality) as described below. These viruses are divided into high pathogenicity avian influenza viruses and low pathogenicity avian influenza viruses:~~

*~~a)~~* ~~high pathogenicity avian influenza viruses have an IVPI in six-week-old chickens greater than 1.2 or, as an alternative, cause at least 75% mortality in four-to eight-week-old chickens infected intravenously. H5 and H7 viruses which do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as high pathogenicity avian influenza virus;~~

*~~b)~~* ~~low pathogenicity avian influenza viruses are all influenza A viruses of H5 and H7 subtypes that are not high pathogenicity avian influenza viruses.~~

2) For the purposes of the *Terrestrial Code*:

*a)* High pathogenicity avian influenza means an *infection* of *poultry* by any influenza A virus ~~with an intravenous~~ that has been determined as high pathogenicity ~~index (IVPI):~~ in accordance with the *Terrestrial Manual*.

~~‒~~ ~~in six-week-old chickens greater than 1.2 or, as an alternative, causes at least 75% mortality in four-to eight-week-old chickens infected intravenously. Viruses of H5 and H7 subtypes that do not have an IVPI of greater than 1.2 or cause less than 75% mortality in an intravenous lethality test should be sequenced to determine whether multiple basic amino acids are present at the cleavage site of the haemagglutinin molecule (HA0); if the amino acid motif is similar to that observed for other high pathogenicity avian influenza isolates, the isolate being tested should be considered as a high pathogenicity avian influenza virus.~~

*b)* ~~The following defines the~~ An occurrence of *infection* with a high pathogenicity avian influenza virus~~:~~ is defined by the isolation and identification of the virus ~~as such~~ or the detection of specific viral ribonucleic acid ~~has been detected~~, in one or more samples from *poultry* ~~or a product derived from~~ *~~poultry~~*.

Annex 12B (contd)

~~3)~~ *~~Poultry~~* ~~is defined as ‘all domesticated birds, including backyard~~ *~~poultry~~*~~, used for the production of~~ *~~meat~~* ~~or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds, as well as fighting cocks used for any purpose’.~~

~~Birds that are kept in captivity for any reason other than those reasons referred to in the preceding paragraph, including those that are kept for shows, races, exhibitions, competitions or for breeding or selling these categories of birds as well as pet birds, are not considered to be~~ *~~poultry~~*~~.~~

*~~c)~~* *~~Poultry~~* ~~means all domesticated birds used for the production of~~ *~~meat~~* ~~or eggs for human consumption, for the production of other commercial products, or for breeding of these categories of birds, as well as fighting cocks used for any purpose. All birds used for restocking supplies of game are considered~~ *~~poultry~~*~~. If birds are kept in a single household and their products are only used in the same household, these birds are not considered~~ *~~poultry~~*~~.~~

*~~d)~~* ~~Birds that are kept in captivity for any reason other than those referred to in the preceding paragraph, including those that are kept for shows, races racing, exhibitions, zoological collections, competitions or for, breeding or selling these categories of birds, as well as pet birds, are not considered~~ *~~poultry~~*~~.~~

*~~e~~c)* ~~the~~ The *incubation period* at the *flock-*level for high pathogenicity avian influenza ~~shall be~~ is 14 days.

3) ~~In accordance with Chapter 1.1., a sudden and unexpected change in the distribution, host range, or increase in incidence or virulence of, or morbidity or mortality caused by avian influenza viruses is notifiable to the OIE, as well as zoonotic avian influenza viruses. Occurrences of influenza A viruses of high pathogenicity in birds other than~~ *~~poultry~~*~~, including~~ *~~wild~~* ~~birds, are notifiable. Six-monthly reports on the presence of avian influenza viruses in a country or~~ *~~zone~~* ~~should include low pathogenicity viruses of H5 and H7 subtypes.~~

Although the objective of this chapter is to mitigate animal and public health risks posed by *infection* with high pathogenicity avian influenza viruses, other influenza A viruses of avian host origin (i.e. low pathogenicity avian influenza viruses) may have the potential to exert a negative impact on animal and public health. A sudden and unexpected increase in virulence of low pathogenicity avian influenza viruses in *poultry* is notifiable as an *emerging disease* in accordance with Article 1.1.4. *Infection* of domestic and *captive wild* birds with low pathogenicity avian influenza viruses having proven natural transmission to humans associated with severe consequences, and ~~is also notifiable as an~~ *~~emerging disease~~* ~~with public health impact in accordance with Article 1.1.4. Occurrences of~~ *infection* of birds other than *poultry,* including *wild* birds, with ~~avian~~ influenza A viruses of high pathogenicity ~~in birds other than~~ *~~poultry~~*~~, including~~ *~~wild~~* ~~birds~~, are notifiable in accordance with Article 1.3.6.

4) A *notification* of *infection* of birds other than *poultry,* including *wild* birds, with ~~avian~~ influenza A viruses of high pathogenicity ~~in birds other than~~ *~~poultry~~*~~, including~~ *~~wild~~* ~~birds~~, or of *infection* of *poultry* or *captive wild* birds with low pathogenicity avian influenza viruses ~~in~~ *~~poultry~~* ~~(as described in point 2) c))~~ does not affect the high pathogenicity avian influenza status of the country or *zone*. A Member Country should not impose bans on the trade ~~in~~ *~~poultry~~* ~~and~~ of *poultry* *commodities* in response to such *notifications*, or to other information on the presence of any influenza A virus in birds ~~other than~~ *~~poultry~~*~~, including~~ *~~wild~~* ~~birds~~.

~~For the purposes of the~~ *~~Terrestrial Code~~*~~, the~~ *~~incubation period~~* ~~for avian influenza shall be 21 days.~~

~~5)~~ ~~This chapter deals not only with the occurrence of clinical signs caused by avian influenza, but also with the presence of~~ *~~infection~~* ~~with avian influenza viruses in the absence of clinical signs.~~

5) This chapter includes *monitoring* considerations for low pathogenicity avian influenza viruses because some, especially H5 and H7 subtypes, have the potential to mutate into high pathogenicity avian influenza viruses.

Annex 12B (contd)

~~6)~~ ~~Antibodies against H5 or H7 subtype, which have been detected in~~ *~~poultry~~* ~~and are not a consequence of~~ *~~vaccination~~*~~, should be immediately investigated. In the case of isolated serological positive results,~~ *~~infection~~* ~~with avian influenza viruses may be ruled out on the basis of a thorough epidemiological and~~ *~~laboratory~~* ~~investigation that does not demonstrate further evidence of such an~~ *~~infection~~*~~.~~

~~7)~~ ~~For the purposes of the Terrestrial Code, ‘avian influenza free establishment’ means an establishment in which the poultry have shown no evidence of infection with avian influenza viruses, based on surveillance in accordance with Articles 10.4.27. to 10.4.33.~~

~~8)~~ *~~Infection~~* ~~with influenza A viruses of high pathogenicity in birds other than~~ *~~poultry~~*~~, including~~ *~~wild~~* ~~birds, should be notified according to Article 1.1.3. However, a Member Country should not impose bans on the trade in~~ *~~poultry~~* ~~and~~ *~~poultry commodities~~* ~~in response to such a~~ *~~notification~~*~~, or other information on the presence of any influenza A virus in birds other than~~ *~~poultry~~*~~, including~~ *~~wild~~* ~~birds.~~

~~4~~6) The use of *vaccination* against ~~high pathogenicity~~ avian influenza ~~in~~ *~~poultry~~* may be recommended under ~~specified~~ specific conditions~~, while not affecting the status of a free country or~~ *~~zone~~*. ~~if the~~ Any vaccine ~~complies~~ used should comply with the standards described in the *Terrestrial Manual*. *Vaccination* will not affect the high pathogenicity avian influenza status of a free country or *zone* if *surveillance* supports the absence of *infection*, in accordance with Article 10.4.22., in particular point 2. *Vaccination* ~~is an effective complementary control tool that~~ can be used as an effective complementary control tool when a *stamping-out policy* alone is not sufficient. ~~The decision whether~~ Whether to vaccinate or not ~~is to~~ should be ~~made~~ decided by the *Veterinary ~~Authorities~~* *Authority* ~~based on~~ on the basis of the avian influenza situation as well as the ability of the *Veterinary Services* to ~~execute~~ implement the ~~proper~~ *vaccination* strategy, as described in Chapter 4.~~17~~18. ~~Any vaccine used should comply with the standards described in the~~ *~~Terrestrial Manual~~*~~.~~

~~59~~7) Standards for diagnostic tests and vaccines, including pathogenicity testing, are described in the *Terrestrial Manual*. ~~Any vaccine used should comply with the standards described in the Terrestrial Manual.~~

Article 10.4.1bis.

**Safe commodities**

When authorising ~~import~~ importation or transit of the following *commodities*, *Veterinary Authorities* should not require any conditions related to high pathogenicity avian influenza~~-related conditions~~, regardless of the high pathogenicity avian influenza status of the *exporting country* or *zone*:

1) heat-treated *poultry* *meat* *products* in a hermetically sealed container with ~~a~~ an F0~~-~~value of 3~~.00~~ or above;

2) extruded dry pet food and ~~poultry-based~~ coated ingredients after extrusion;

3) rendered *meat* and bone meal, blood meal, feather meal, and *poultry* oil;

4) washed and steam-dried feathers and down from *poultry* and other birds ~~processed by washing and steam-drying~~.

Other *commodities* of *poultry* and other birds can be traded safely if in accordance with the relevant articles of this chapter.

~~Article 10.4.2.~~

**~~Determination of the avian influenza status of a country, zone or compartment~~**

~~The avian influenza status of a country, a~~ *~~zone~~* ~~or a~~ *~~compartment~~* ~~can be determined on the basis of the following criteria:~~

~~1)~~ ~~avian influenza is notifiable in the whole country, an ongoing avian influenza awareness programme is in place, and all notified suspect occurrences of avian influenza are subjected to field and, where applicable,~~ *~~laboratory~~* ~~investigations;~~

Annex 12B (contd)

~~2)~~ ~~appropriate~~ *~~surveillance~~* ~~is in place to demonstrate the presence of~~ *~~infection~~* ~~in the absence of clinical signs in~~ *~~poultry~~*~~, and the~~ *~~risk~~* ~~posed by birds other than~~ *~~poultry~~*~~; this may be achieved through an avian influenza~~ *~~surveillance~~* ~~programme in accordance with Articles 10.4.27. to 10.4.33.;~~

~~3)~~ ~~consideration of all epidemiological factors for avian influenza occurrence and their historical perspective.~~

~~Article 10.4.3.~~

**~~Country, zone or compartment free from avian influenza~~**

~~A country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~may be considered free from avian influenza when it has been shown that in~~*~~fection~~* ~~with avian influenza viruses in~~ *~~poultry~~* ~~has not been present in the country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~for the past 12 months, based on~~ *~~surveillance~~* ~~in accordance with Articles 10.4.27. to 10.4.33.~~

~~If~~ *~~infection~~* ~~has occurred in~~ *~~poultry~~* ~~in a previously free country,~~ *~~zone~~* ~~or~~ *~~compartment~~*~~, avian influenza free status can be regained:~~

~~1)~~ ~~In the case of~~ *~~infections~~* ~~with high pathogenicity avian influenza viruses, three months after a~~ *~~stamping-out policy~~* ~~(including~~ *~~disinfection~~* ~~of all affected~~ *~~establishments~~*~~) is applied, providing that~~ *~~surveillance~~* ~~in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.~~

~~2)~~ ~~In the case of~~ *~~infections~~* ~~with low pathogenicity avian influenza viruses,~~ *~~poultry~~* ~~may be kept for~~ *~~slaughter~~* ~~for human consumption subject to conditions specified in Article 10.4.19. or a~~ *~~stamping-out policy~~* ~~may be applied; in either case, three months after the~~ *~~disinfection~~* ~~of all affected~~ *~~establishments~~*~~, providing that~~ *~~surveillance~~* ~~in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.~~

Article 10.4.2~~34~~.

**Country~~,~~ or zone ~~or compartment~~ free from ~~infection with~~ high pathogenicity avian influenza ~~viruses in poultry~~**

A country~~,~~ or *zone* ~~or~~ *~~compartment~~* may be considered free from *~~infection~~* ~~with~~ high pathogenicity avian influenza ~~viruses in~~ *~~poultry~~* when:

‒ *infection* with high pathogenicity avian influenza viruses ~~in~~ *~~poultry~~* is a *notifiable disease* in the entire country;

‒ an ongoing awareness programme is in place to encourage reporting of suspicions of high pathogenicity avian influenza;

‒ ~~an ongoing avian influenza~~ *~~surveillance~~* ~~is implemented to monitor the general situation of H5 and H7 low pathogenicity avian influenza viruses in~~ *~~poultry~~* ~~and an awareness programme is in place related to~~ *~~biosecurity~~* ~~and management of H5 and H7 low pathogenicity avian influenza viruses;~~

absence of *infection* with high pathogenicity avian influenza viruses, based on *surveillance*, in accordance with Chapter 1.4. and Articles 10.4.20. to 10.4.22ter., has been demonstrated in the country or *zone* for the past 12 months;

‒~~1)~~ ~~based on~~ *~~surveillance~~* ~~in accordance with Chapter 1.4. and Articles 10.4.27. to 10.4.33., it has been shown demonstrated that~~ *~~infection~~* ~~with high pathogenicity avian influenza viruses in~~ *~~poultry~~* ~~as defined in Article 10.4.1.~~~~has not been present occurred in the country, or~~ *~~zone~~* ~~or compartment~~~~for the past 12 months; Although its status with respect to low pathogenicity avian influenza viruses may be unknown; or~~

an awareness programme is in place related to *biosecurity* and management of avian influenza viruses;

‒ ~~bird~~ *commodities* are imported in accordance with Articles 10.4.~~5~~3. to 10.4.~~23~~17bis.

~~The~~ *~~s~~Surveillance* should ~~may need to~~ be adapted to parts of the country or existing *zones* ~~or~~ *~~compartment~~* depending on historical or geographical factors, industry structure, population data~~,~~ ~~or~~ and proximity to recent *outbreaks* or the use of *vaccination*.

~~If~~ *~~infection~~* ~~has occurred in~~ *~~poultry~~* ~~in a previously free country,~~ *~~zone~~* ~~or compartment, the free status can be regained three months after a~~ *~~stamping-out policy~~* ~~(including~~ *~~disinfection~~* ~~of all affected~~ *~~establishments~~*~~) is applied, providing that~~ *~~surveillance~~* ~~in accordance with Articles 10.4.27. to 10.4.33. has been carried out during that three-month period.~~

Annex 12B (contd)

Article 10.4.~~3~~2bis.

**Compartment free from high pathogenicity avian influenza**

The establishment of a *compartment* free from high pathogenicity avian influenza should ~~follow~~ be in accordance with ~~the~~ relevant requirements of this chapter and the principles described in Chapters 4.~~3~~4. and 4.~~4~~5.

Article 10.4.~~3~~2ter.

**Establishment of a containment zone within a country or zone free from high pathogenicity avian influenza**

In the event of ~~an~~ *outbreak~~s~~s* of high pathogenicity avian influenza within a previously free country or *zone*, a *containment* *zone*, which includes all epidemiologically linked *outbreaks*, may be established for the purpose~~s~~ of minimising the impact on the rest of the country or *zone*.

In addition to the requirements for the establishment of a *containment zone* outlined in Article 4.~~3~~4.7., the *surveillance* programme should take into account the density of *poultry* production, types of *poultry*, local management practices (including inter-premises movement patterns of *poultry*, people and equipment), relevant *biosecurity*, ~~and~~ the presence and potential role of birds other than *poultry*, including *wild* birds, and the proximity of *poultry* *establishment*s to ~~perennial~~ permanent and seasonal water bodies.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. It may be reinstated, irrespective of the provisions of Article 10.4.~~3~~2quater., once the *containment zone* is clearly established. It should be demonstrated that *commodities* for *international trade* ~~either~~ have originated from outside the *containment zone* or comply with the relevant articles of this chapter.

Article 10.4.~~3~~2quater.

**Recovery of free status**

If *infection* with high pathogenicity avian influenza virus has occurred in *poultry* in a previously free country or *zone*, the free status ~~can~~ may be regained after a minimum period of 28 days (i.e. two *flock*-level *incubation periods*) after a *stamping-out policy* has been completed (i.e. after the *disinfection* of the last affected *establishment*), provided that *surveillance* in accordance with Articles 10.4.~~27~~20. to 10.4.~~33~~22ter., in particular point 3 of Article 10.4.~~30~~22., has been carried out during that period and has demonstrated the absence of *infection*.

If a *stamping-out policy* is not implemented, Article 10.4.~~3~~2. applies.

Article 10.4.~~5~~3.

**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**

For live poultry (other than day-old poultry)

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the *poultry* showed no clinical signs of avian influenza on the day of shipment;

2) *~~a)~~* the *poultry* ~~were kept in~~originated from ~~an avian influenza free~~ a country, *zone* or *compartment* free from high pathogenicity avian influenza ~~since they were hatched or for at least the past 21 days~~;

*~~b~~*3) the *poultry* originated from a *flock* ~~free from~~ *~~infection~~* ~~with any H5 or H7~~ that was monitored for avian influenza ~~A~~ viruses and was found to be negative;

Annex 12B (contd)

~~3~~4) the *poultry* are transported in new or appropriately ~~sanitized~~ sanitised *containers*.

If the *poultry* have been vaccinated against avian influenza viruses, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ ~~mentioned~~ stated in the *international veterinary certificate*.

Article 10.4.~~6~~4.

**Recommendations for the importation of live birds other than poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) on the day of shipment, the birds showed no clinical signs of *~~infection~~* ~~with a virus which would be considered~~ avian influenza ~~in~~ *~~poultry~~*;

2) the birds ~~were~~ had been kept in isolation facilities approved by the *Veterinary Services* since they were hatched or for at least ~~21~~ 28 days (i.e. two *flock*-level *incubation periods*) prior to shipment and showed no clinical signs of *~~infection~~* ~~with a virus which would be considered~~ avian influenza ~~in~~ *~~poultry~~* during the isolation period;

3) a statistically ~~valid~~ appropriate sample of the birds~~, selected in accordance with the provisions of Article 10.4.29.,~~ was subjected, with negative results, to a diagnostic test for avian influenza ~~A viruses~~ within 14 days prior to shipment ~~for H5 and H7 to demonstrate freedom from~~ *~~infection~~* ~~with a virus which would be considered avaina influenza in~~ *~~poultry~~*;

4) the birds are transported in new or appropriately ~~sanitized~~ sanitised *containers*.

If the birds have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ ~~mentioned~~ stated in the *international veterinary certificate*.

~~Article 10.4.7.~~

**~~Recommendations for importation from a country, zone or compartment free from avian influenza~~**

~~For day-old live poultry~~

*~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that:~~

~~1)~~ ~~the~~ *~~poultry~~* ~~were kept in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~since they were hatched;~~

~~2)~~ ~~the~~ *~~poultry~~* ~~were derived from parent~~ *~~flocks~~* ~~which had been kept in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~for at least 21 days prior to and at the time of the collection of the eggs;~~

~~3)~~ ~~the~~ *~~poultry~~* ~~are transported in new or appropriately sanitized~~ *~~containers~~*~~.~~

~~If the~~ *~~poultry~~* ~~or the parent~~ *~~flocks~~* ~~have been vaccinated against avian influenza, the nature of the vaccine used and the date of~~ *~~vaccination~~* ~~should be attached to the~~ *~~certificate.~~*

Article 10.4.~~8~~5.

**Recommendations for importation from a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza ~~viruses in poultry~~**

For day-old live poultry

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

Annex 12B (contd)

1) the day-old live *poultry* ~~were~~ had been kept in a country, *zone* or *compartment* free from *~~infection~~* ~~with~~ high pathogenicity avian influenza since they were hatched;

~~2)~~ and

*a)* the day-old live *poultry* were derived from parent *flocks* ~~free from~~ *~~infection~~* ~~with any H5 or H7~~ that were monitored for avian influenza ~~A~~ viruses and were found to be negative~~which had been kept in an avian influenza free~~ *~~establishment~~* ~~for at least 21 days prior to and~~at the time of ~~the~~ collection of the eggs from which the day-old *poultry* hatched; or

*b)* the day-old live *poultry* that hatched from eggs that ~~have~~ had had their surfaces ~~sanitized~~ sanitised in accordance with point 4 d)of Article 6.5.5.;

AND

2~~3~~) the day-old live *poultry* ~~are~~ were transported in new or appropriately ~~sanitized~~ sanitised *containers*.

If the day-old live *poultry* or the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ ~~mentioned~~ stated in the *international veterinary certificate*.

Article 10.4.~~9~~6.

**Recommendations for the importation of day-old live birds other than poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) on the day of shipment, the birds showed no clinical signs of *~~infection~~* ~~with a virus which would be considered~~ avian influenza ~~in~~ *~~poultry~~*;

2) the birds were hatched and kept in isolation facilities approved by the *Veterinary Services*;

3) a statistically appropriate sample of the parent *flock* birds were subjected, with negative results, to a diagnostic test for avian influenza ~~A viruses~~ at the time of ~~the~~ collection of the eggs ~~for H5 and H7 to demonstrate freedom from~~ *~~infection~~* ~~with a virus which would be considered avian influenza in~~ *~~poultry~~*;

4) the birds ~~are~~ were transported in new or appropriately ~~sanitized~~ sanitised *containers*.

If the birds or parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ ~~mentioned~~ stated in the *international veterinary certificate*.

~~Article 10.4.10.~~

**~~Recommendations for importation from a country, zone or compartment free from avian influenza~~**

~~For hatching eggs of poultry~~

*~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that:~~

~~1)~~ ~~the eggs came from an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~*~~;~~

~~2)~~ ~~the eggs were derived from parent~~ *~~flocks~~* ~~which had been kept in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~for at least 21 days prior to and at the time of the collection of the eggs;~~

~~3)~~ ~~the eggs are transported in new or appropriately sanitized packaging materials.~~

Annex 12B (contd)

~~If the parent~~ *~~flocks~~* ~~have been vaccinated against avian influenza, the nature of the vaccine used and the date of~~ *~~vaccination~~* ~~should be attached to the~~ *~~certificate~~*~~.~~

Article 10.4.~~11~~7.

**Recommendations for importation from a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza ~~viruses in poultry~~**

For hatching eggs of poultry

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the hatching eggs came from a country, *zone* or *compartment* free from *~~infection~~* ~~with~~ high pathogenicity avian influenza ~~viruses in~~ *~~poultry~~*;

2) *a)* the hatching eggs were derived from parent *flocks* ~~free from~~ *~~infection~~* ~~with any H5 or H7~~ that were monitored for avian influenza ~~A~~ viruses and were found to be negative ~~which had been kept in an avian influenza free~~ *~~establishment~~* ~~for at least 21 days prior to and~~ at the time of ~~the~~ collection of the hatching eggs; or

*b*~~3~~) the hatching eggs have had their surfaces ~~sanitized~~ sanitised ~~(~~in accordance with ~~Chapter 6.5.~~ point 4 d) of Article 6.5.5.~~)~~;

3~~4~~) the hatching eggs are transported in new or appropriately ~~sanitized~~ sanitised packaging materials and *containers*.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ ~~mentioned~~ stated in the *international veterinary certificate*.

Article 10.4.~~12~~8.

**Recommendations for the importation of hatching eggs from birds other than poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) a statistically ~~valid~~ appropriate sample of the parent *flock* birds ~~from the parent~~ *~~flock~~* ~~birds were~~ was subjected, with negative results, to a diagnostic test for avian influenza ~~A viruses~~ ~~seven~~ 14 days prior to and at the time of ~~the~~ collection of the hatching eggs ~~for H5 and H7~~ ~~to demonstrate freedom from~~ *~~infection~~* ~~with a virus which would be considered avian influenza in~~ *~~poultry~~*;

2) the hatching eggs have had their surfaces ~~sanitized~~ sanitised ~~(~~in accordance with point 4 d)of Article 6.5.5. ~~Chapter 6.5.~~;

3) the hatching eggs are transported in new or appropriately ~~sanitized~~ sanitised packaging materials and *containers*.

If the parent *flocks* have been vaccinated against avian influenza, the nature of the vaccine used and the date of *vaccination* should be ~~attached to~~ ~~mentioned~~ stated in the *international veterinary certificate*.

Article 10.4.9.

**Recommendations for importation from a country, zone or compartment free from high pathogenicity avian influenza**

For poultry semen

Annex 12B (contd)

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor *poultry*:

1) showed no clinical signs of avian influenza on the day of semen collection;

2) were kept in a country, *zone* or *compartment* free from high pathogenicity avian influenza.

Article 10.4.10.

**Recommendations for the importation of semen from birds other than poultry**

Regardless of the high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the donor birds:

1) were kept in isolation facilities approved by the *Veterinary Services* for at least 28 days (i.e. two *flock*-level *incubation periods*) prior to semen collection;

2) showed no clinical signs of avian influenza during the isolation period;

3) were subjected, with negative results, to a diagnostic test for avian influenza within 14 days prior to semen collection.

~~Article 10.4.13.~~

**~~Recommendations for importation from a country, zone or compartment free from avian influenza~~**

~~For eggs for human consumption~~

*~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that:~~

~~1)~~ ~~the eggs were produced and packed in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~*~~;~~

~~2)~~ ~~the eggs are transported in new or appropriately sanitized packaging materials.~~

Article 10.4.~~14~~11.

**Recommendations for importation from a country, zone or compartment free from ~~infection with~~ high pathogenicity avian influenza ~~viruses in poultry~~**

For eggs for human consumption

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the eggs for human consumption were produced and packed in a country, *zone* or *compartment* free from *~~infection~~* ~~with~~ high pathogenicity avian influenza ~~viruses in~~ *~~poultry~~*;

~~2)~~ ~~the eggs have had their surfaces sanitized (in accordance with Chapter 6.5.) ;~~

2~~3~~) the eggs for human consumption ~~are~~ were transported in new or appropriately ~~sanitized~~ sanitised packaging materials and *containers*.

Article 10.4.~~15~~12.

**Recommendations for the importation of egg products ~~of~~ from poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

Annex 12B (contd)

1) the *~~commodity~~* egg products ~~is~~ are derived from eggs which meet the requirements of Article~~s 10.4.13. or~~ 10.4.~~14~~11.; or

2) the *~~commodity~~* egg products ~~has~~ have been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza viruses, in accordance with Article 10.4.~~25~~18.;

AND

3) the necessary precautions were taken to avoid contact of the *~~commodity~~* egg products with any source of high pathogenicity avian influenza viruses.

~~Article 10.4.16.~~

**~~Recommend8ations for importation from a country, zone or compartment free from avian influenza~~**

~~For poultry semen~~

*~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that the donor~~ *~~poultry~~*~~:~~

~~1)~~ ~~showed no clinical sign of avian influenza on the day of semen collection;~~

~~2)~~ ~~were kept in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~for at least 21 days prior to and at the time of semen collection.~~

~~Article 10.4.17.~~

**~~Recommendations for the importation from a country, zone or compartment free from~~ ~~infection with~~ ~~high pathogenicity avian influenza~~ ~~viruses in poultry~~**

~~For poultry semen~~

*~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that the donor~~ *~~poultry~~*~~:~~

~~1)~~ ~~showed no clinical signs of~~ ~~infection with high pathogenicity~~ avian influenza ~~viruses in~~ *~~poultry~~* ~~on the day of semen collection;~~

~~2)~~ ~~were kept in a country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~free from~~ *~~infection~~* ~~with~~ ~~high pathogenicity avian influenza~~ ~~viruses in~~ *~~poultry~~* ~~for at least 21 days prior to and at the time of semen collection~~.

~~Article 10.4.18.~~

**~~Recommendations for the importation of semen of birds other than poultry~~**

~~Regardless of the~~ ~~avian influenza~~ ~~status of the country of origin,~~ *~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that the donor birds:~~

~~1)~~ ~~were kept in isolation approved by the~~ *~~Veterinary Services~~* ~~for at least~~ ~~21~~ ~~28 days prior to semen collection;~~

~~2)~~ ~~showed no clinical signs of~~ *~~infection~~* ~~with a virus which would be considered avian influenza in~~ *~~poultry~~* ~~during the isolation period;~~

~~3)~~ ~~were tested within 14 days prior to semen collection and shown to be free from~~ *~~infection~~* ~~with a virus which would be considered avian influenza in~~ *~~poultry~~*~~.~~

Annex 12B (contd)

Article 10.4.~~19~~13.

**Recommendations for importation from a country, zone or compartment ~~free from avian influenza or~~ free from ~~infection with~~ high pathogenicity avian influenza ~~viruses in poultry~~**

For fresh meat of poultry

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *fresh meat* comes from *poultry*:

1) which ~~have been kept in~~ originated from a country, *zone* or *compartment* free from *~~infection~~* ~~with~~ high pathogenicity avian influenza ~~viruses in~~ *~~poultry~~* ~~since they were hatched or for at least the past 21 days~~;

2) which ~~have been~~ were slaughtered in an approved *slaughterhouse/abattoir* in a country, *zone* or *compartment* free from *~~infection~~* ~~with~~ high pathogenicity avian influenza ~~viruses in~~ *~~poultry~~* and ~~have been~~ were subjected to ante- and post-mortem inspections in accordance with Chapter 6.3., ~~and have been found free of any signs suggestive of avian influenza~~ with ~~favorable~~ favourable results.

Article 10.4.~~20~~14.

**Recommendations for the importation of meat products ~~of~~ from poultry**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) the *~~commodity~~ meat products* from *poultry* ~~is~~ are derived from *fresh meat* which meets the requirements of Article 10.4.~~19~~13.; or

2) the *~~commodity~~ meat products* from *poultry* ~~has~~ have been processed to ensure the ~~destruction~~ inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.~~26~~19.;

AND

3) the necessary precautions were taken to avoid contact of the *~~commodity~~ meat products* from *poultry* with any source of high pathogenicity avian influenza viruses.

Article 10.4.~~21~~15.

**Recommendations for the importation of poultry products not listed in Article 10.4.1bis. and intended for use in animal feeding, or for agricultural or industrial use**

Regardless of the high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international* *veterinary certificate* attesting that:

1) these *commodities* ~~were processed in a country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~free from high pathogenicity avian influenza and~~ were obtained from *poultry* which originated in a country, *zone* or *compartment* free from high pathogenicity avian influenza and that the necessary precautions were taken to avoid contamination during processing with any source of high pathogenicity avian influenza viruses;

OR

2) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses using:

*a)* moist heat treatment for 30 minutes at 56°C; or

*b)* heat treatment where the internal temperature throughout the product ~~reaches~~ reached at least 74°C; or

*c)* any equivalent treatment that has been demonstrated to inactivate avian influenza viruses;

Annex 12B (contd)

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

~~Article 10.4.21.~~

**~~Recommendations for the importation of products of poultry origin, other than feather meal and poultry meal, intended for use in animal feeding, or for agricultural or industrial use~~**

~~Regardless of the avian influenza status of the country of origin,~~ *~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that:~~

~~1)~~ ~~these~~ *~~commodities~~* ~~were processed in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~from~~ *~~poultry~~* ~~which were kept in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~from the time they were hatched until the time of~~ *~~slaughter~~* ~~or for at least the 21 days preceding~~ *~~slaughter~~*~~; or~~

~~2)~~ ~~these~~ *~~commodities~~* ~~have been processed to ensure the destruction of avian influenza virus using;~~

*~~a)~~* ~~moist heat treatment for 30 minutes at 56°C; or~~

*~~b)~~* ~~any equivalent treatment which has been demonstrated to inactivate avian influenza virus;~~

~~AND~~

~~3)~~ ~~the necessary precautions were taken to avoid contact of the~~ *~~commodity~~* ~~with any source of avian influenza virus.~~

Article 10.4.~~22~~16.

**Recommendations for the importation of feathers and down ~~of~~ from poultry not listed in Article 10.4.1bis.**

~~Regardless of the avian influenza status of the country of origin,~~ *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* originated from *poultry* as described in Article 10.4.~~19~~13. and were processed in a~~n avian influenza free~~ a country, *zone* or *compartment* free from high pathogenicity avian influenza; or

2) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses using one of the following:

*a)* ~~washed and steam dried at 100°C for 30 minutes;~~

*~~b)~~* fumigation with formalin (10% formaldehyde) for 8 hours;

*b~~c~~)* irradiation with a dose of 20 kGy;

*c~~d~~)* any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;

AND

3) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

Annex 12B (contd)

Article 10.4.~~23~~17.

**Recommendations for the importation of feathers and down of birds other than poultry not listed in Article 10.4.1bis.**

Regardless of the ~~avian influenza~~ high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

1) these *commodities* have been processed to ensure the ~~destruction~~ inactivation of ~~any virus which would be considered~~ high pathogenicity avian influenza viruses ~~in~~ *~~poultry~~* using one of the following:

*a)* ~~washed and steam dried at 100°C for 30 minutes;~~

*~~b)~~* fumigation with formalin (10% formaldehyde) for 8 hours;

*b~~c~~)* irradiation with a dose of 20 kGy;

*c~~d~~)* any equivalent treatment which has been demonstrated to inactivate avian influenza viruses;

2) the necessary precautions were taken to avoid contact of the *commodity* with any source of ~~viruses which would be considered~~ high pathogenicity avian influenza viruses ~~in~~ *~~poultry~~*.

Article 10.4.17bis.

**Recommendations for the importation of ~~scientific~~ collection specimens, skins and trophies of birds other than poultry**

Regardless of the high pathogenicity avian influenza status of the country of origin, *Veterinary Authorities* should require the presentation of an *international* *veterinary certificate* attesting that:

1) these *commodities* have been processed to ensure the inactivation of high pathogenicity avian influenza viruses in accordance with Article 10.4.19bis.;

AND

2) the necessary precautions were taken to avoid contact of the *commodity* with any source of high pathogenicity avian influenza viruses.

~~Article 10.4.24.~~

**~~Recommendations for the importation of feather meal and poultry meal~~**

~~Regardless of the avian influenza status of the country of origin,~~ *~~Veterinary Authorities~~* ~~should require the presentation of an~~ *~~international veterinary certificate~~* ~~attesting that:~~

~~1)~~ ~~these~~ *~~commodities~~* ~~were processed in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~from~~ *~~poultry~~* ~~which were kept in an avian influenza free country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~from the time they were hatched until the time of~~ *~~slaughter~~* ~~or for at least the 21 days preceding~~ *~~slaughter~~*~~; or~~

~~2)~~ ~~these~~ *~~commodities~~* ~~have been processed either:~~

*~~a)~~* ~~with moist heat at a minimum temperature of 118ºC for minimum of 40 minutes; or~~

*~~b)~~* ~~with a continuous hydrolysing process under at least 3.79 bar of pressure with steam at a minimum temperature of 122ºC for a minimum of 15 minutes; or~~

*~~c)~~* ~~with an alternative rendering process that ensures that the internal temperature throughout the product reaches at least 74ºC;~~

~~AND~~

Annex 12B (contd)

~~3)~~ ~~the necessary precautions were taken to avoid contact of the~~ *~~commodity~~* ~~with any source of avian influenza viruses.~~

Article 10.4.~~25~~18.

**Procedures for the inactivation of high pathogenicity avian influenza viruses in ~~eggs and~~ egg products from poultry**

The following ~~times for industry standard temperatures~~ time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses present in ~~eggs and~~ egg products:

|  | **Core temperature (°C)** | **Time** |
| --- | --- | --- |
| Whole egg | 60 | 188 seconds |
| Whole egg blends | 60 | 188 seconds |
| Whole egg blends | 61.1 | 94 seconds |
| Liquid egg white | 55.6 | 870 seconds |
| Liquid egg white | 56.7 | 232 seconds |
| Plain or pure egg yolk | 60 | 288 seconds |
| 10% salted yolk | 62.2 | 138 seconds |
| Dried egg white | 67 | 20 hours |
| Dried egg white | 54.4 | 50.4 hours |
| Dried egg white | 51.7 | 73.2 hours |

~~The listed temperatures~~ These time/temperature combinations are indicative of a range that achieves a 7-log10 ~~kill~~ reduction of avian influenza virus infectivity. These are ~~listed as~~ examples ~~in~~ for a variety of egg products~~,~~ but, when supported by ~~scientifically~~ ~~documented~~ scientific evidence, ~~variances~~ variations ~~from~~ of these ~~times and temperatures~~ time/temperature combinations may be used, and they may be used for ~~additional~~ other egg products, ~~may also be~~ ~~suitable~~ ~~when~~ if they achieve equivalent inactivation of the virus.

Article 10.4.~~26~~19.

**Procedures for the inactivation of high pathogenicity avian influenza viruses in meat products from poultry**

The following ~~times for industry standard temperatures~~ time/temperature combinations are suitable for the inactivation of high pathogenicity avian influenza viruses in *meat products*.

|  | **Core temperature (°C)** | **Time** |
| --- | --- | --- |
| ~~Poultry meat~~  Meat products from poultry | 60.0 | 507 seconds |
| 65.0 | 42 seconds |
| 70.0 | 3.5 seconds |
| 73.9 | 0.51 second |

~~The listed temperatures~~ These time/temperature combinations are indicative of a range that achieves a 7-log10 ~~kill~~ reduction of avian influenza virus infectivity. ~~Where scientifically documented~~ When supported by scientific evidence, ~~variances from~~ variations of these ~~times and temperatures~~ time/temperature combinations may ~~also~~ be ~~suitable~~ used ~~when~~ if they achieve ~~the~~ equivalent inactivation of the virus.

Annex 12B (contd)

Article 10.4.~~26~~19bis.

**Procedures for the inactivation of high pathogenicity avian influenza viruses in ~~scientific~~ collection specimens and in skins and trophies**

For the inactivation of high pathogenicity avian influenza viruses in ~~scientific~~ collection specimens and in skins and trophies, one of the following procedures should be used:

1) boiling in water for an appropriate time ~~so as~~ to ensure that any ~~matter~~ material other than bone, claws or beaks is removed; or

2) soaking, with agitation, in a 4% (w/v) solution of washing soda (sodium carbonate- Na2CO3) maintained at pH 11.5 or above for at least 48 hours; or

3) soaking, with agitation, in a formic acid solution (100 kg salt [NaCl] and 12 kg formic acid per 1,000 litres water) maintained below pH 3.0 for at least 48 hours; wetting and dressing agents may be added; or

4) in the case of raw hides, ~~treating~~ treatment for at least 28 days with salt (NaCl) containing 2% washing soda (sodium carbonate-Na2CO3); or

5) treatment with 1% formalin for a minimum of six days; or

6) any equivalent treatment which has been demonstrated to inactivate the virus.

Article 10.4.~~27~~20.

**~~Introduction to~~ Principles of surveillance ~~of high pathogenicity~~ for avian influenza**

~~Articles 10.4.27. to 10.4.33. define the principles and provide a guide on the~~ *~~surveillance~~* ~~for avian influenza~~ ~~complementary to Chapter 1.4.,~~ ~~Article 10.4.20. defines the~~ The following principles ~~and Articles 10.4.21., 10.4.22., 10.4.22bis. and 10.4.22ter. provide guidance on avian influenza~~ *~~surveillance~~* ~~for the entire country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~and~~ are complementary to Chapter 1.4. ~~applicable to~~ ~~These principles~~ and should be applied by Member Countries seeking to determine their high pathogenicity avian influenza status.~~.;~~ *~~Surveillance~~* ~~is~~ ~~they~~

These principles are also necessary to support *vaccination* programmes, to monitor ~~general situation of H5 and H7~~ low pathogenicity avian influenza viruses, especially H5 and H7, in *poultry* and ~~for~~ to ~~monitoring~~ ~~monitor~~ detect high pathogenicity avian influenza in *wild* birds. ~~This may be for the entire country,~~ *~~zone~~* ~~or~~ *~~compartment~~*~~.~~ ~~Guidance for Member Countries seeking free status following an~~ *~~outbreak~~* ~~and for the maintenance of avian influenza status is also provided.~~

~~The presence of influenza A viruses in~~ *~~wild~~* ~~birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A in~~ *~~wild~~* ~~birds. However, the definition of avian influenza in this chapter refers to the~~ *~~infection~~* ~~in~~ *~~poultry~~* ~~only, and Articles 10.4.27. to 10.4.33. were developed under this definition.~~

The impact and epidemiology of avian influenza differ widely ~~in~~ among different regions of the world and therefore it is impossible to provide ~~specific~~ detailed recommendations for all situations. *~~Surveillance~~* ~~strategies employed for demonstrating freedom from avian influenza at an acceptable level of confidence should be adapted to the local situation.~~ Variables such as the frequency of contacts ~~of~~ between *poultry* ~~with~~ and *wild* birds, different *biosecurity* levels and production systems, and the commingling of different susceptible species including domestic waterfowl, may require ~~specific~~ different *surveillance* strategies to address each ~~specific~~ situation. Furthermore, domestic waterfowls typically do not show clinical signs and have longer infective periods than gallinaceous *poultry*. It is therefore incumbent upon the Member Country to provide scientific data that explain~~s~~ the epidemiology of avian influenza in the region ~~concerned~~ of concern and also ~~demonstrates~~ to demonstrate how all the risk factors ~~are managed~~ have been taken into account. ~~There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of~~ *~~infection~~* ~~with avian influenza viruses is assured at an acceptable level of confidence.~~ Member Countries have flexibility to provide a science-based approach to demonstrate absence of *infection* with high pathogenicity avian influenza viruses at an appropriate level of confidence, as described in Chapter 1.4.

Annex 12B (contd)

There is an increased recognition of the value of the application of sequencing technologies and phylogenetic analyses to determine routes of introduction, transmission pathways and epidemiological patterns of *infection*. When avian influenza viruses are detected, Member Countries should apply these technologies, when possible, to enhance the evidence used to develop specific *surveillance* strategies and control activities.

*A monitoring* system for low pathogenicity avian influenza viruses in *poultry* should be in place for the following reasons:

1) *~~Surveillance~~* ~~of~~ Some H5 and H7 low pathogenicity avian influenza viruses ~~in~~ *~~poultry~~* ~~is relevant as they might~~ have the potential to mutate into high pathogenicity avian influenza viruses~~. There is~~ and currently ~~no scientific evidence~~ it is not possible to predict ~~if~~ whether and when this mutation ~~might~~ will occur. *~~Outbreaks~~* ~~of low pathogenicity viruses can be managed at~~ *~~establishment~~* ~~level however spread to other~~ *~~poultry~~**~~establishments~~* ~~increases the risk of virus mutation, if it is not detected and managed. Therefore, a system should be in place to detect clusters of infected~~ *~~poultry~~**~~establishments~~* ~~where H5 and H7 low pathogenicity viruses spread between~~ *~~poultry~~**~~establishments~~*~~.~~

2) The detection of sudden and unexpected increases in virulence of low pathogenicity avian influenza viruses in *poultry*, in order to fulfil notification obligations of an *emerging disease* in accordance with Article 1.1.4.

3) The detection, in domestic and *captive wild* birds, of low pathogenicity avian influenza viruses that have been proven to be transmitted naturally to humans with severe consequences~~,~~ is notifiable ~~as in order to fulfil notification obligations of an~~ *~~emerging disease~~*~~,~~ in accordance with Article 1.1.~~4~~3.

*~~Surveillance~~* ~~for avian influenza should be in the form of a continuing programme designed to establish that the country,~~ *~~zone~~* ~~or~~ *~~compartment~~*~~, for which application is made, is free from~~ *~~infection~~* ~~with avian influenza viruses.~~

~~In cases where potential public health implications are suspected, reporting to the appropriate public health authorities is essential.~~

Article 10.4.~~28~~21.

**~~General conditions and methods for surveillance~~ Surveillance for early warning of high pathogenicity avian influenza**

1) An ongoing *~~S~~surveillance* programmefor avian influenza should be in ~~the form of a continuing programme~~ place and be designed to detect the presence of *infection* with high pathogenicity avian influenza viruses in the country or *zone* in a timely manner. ~~A~~ *~~surveillance~~* ~~system in accordance with Chapter 1.4. should be under the responsibility of the~~ *~~Veterinary Authority~~*~~. In particular:~~

*~~a)~~* ~~a formal and ongoing system for detecting and investigating~~ *~~outbreaks~~* ~~of~~ *~~disease~~* ~~or~~ *~~infection~~* ~~with avian influenza viruses should be in place;~~

*~~b)~~* ~~a procedure should be in place for the rapid collection and transport of samples from suspect cases of avian influenza to a~~ *~~laboratory~~* ~~for avian influenza diagnosis;~~

*~~c)~~* ~~a system for recording, managing and analysing diagnostic and~~ *~~surveillance~~* ~~data should be in place.~~

2) The high pathogenicity avian influenza *surveillance* programme should include the following~~:~~.

*a)* ~~include an~~ An *early warning system* for reporting suspected *cases*, in accordance with Article 1.4.5. throughout the production, marketing and processing chain ~~for reporting~~ ~~suspicious~~ ~~suspected~~ *~~cases~~*. Farmers and workers~~,~~ who have day-to-day contact with *poultry*, as well as diagnosticians, should report promptly any suspicion of ~~high pathogenicity~~ avian influenza to the *Veterinary Authority*. ~~They should be supported directly or indirectly (e.g. through private~~ *~~veterinarians~~* ~~or~~ *~~veterinary para-professionals~~*~~) by government information programmes and the~~ *~~Veterinary Authority~~*~~.~~ All suspected *cases* of high pathogenicity avian influenza should be investigated immediately~~.~~ ~~As~~ ~~Given that suspicion cannot always be resolved by epidemiological and clinical investigation~~ ~~alone,~~ and samples should be taken and submitted to a *laboratory* for appropriate tests. ~~This requires that sampling kits and other equipment are available for those responsible for~~ *~~surveillance~~*~~. Personnel responsible for~~ *~~surveillance~~* ~~should be able to call for assistance from a team with expertise in avian influenza diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential~~;

Annex 12B (contd)

*b)* ~~implement~~ Implementation, ~~when~~ as relevant, of regular and frequent clinical inspection, ~~and~~ or serological and virological testing, of high-risk groups of *animals*, such as those adjacent to a~~n~~ country or *zone* infected with high pathogenicity avian influenza ~~infected country or~~ *~~zone~~*, places where birds and *poultry* of different origins are mixed, such as live bird markets, and *poultry* in close proximity to waterfowl or other potential sources of influenza A viruses. This activity is particularly applicable to domestic waterfowl, where detection of high pathogenicity avian influenza via clinical suspicion can be of low sensitivity~~;~~.

*c)* ~~ensure that~~ Immediate investigation of the presence of antibodies against influenza A viruses~~, which~~ that have been detected in *poultry* and are not a consequence of *vaccination*~~, be immediately investigated~~. In the case of single or isolated serological positive results, *infection* with high pathogenicity avian influenza viruses may be ruled out on the basis of a thorough epidemiological and *laboratory* investigation that does not demonstrate further evidence of such an *infection*.

~~An effective~~ *~~surveillance~~* ~~system will periodically identify suspicious cases that require follow-up and investigation to confirm or exclude that the cause of the condition is influenza A viruses. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably.~~ ~~Documentation for freedom from~~ *~~infection~~* ~~with avian influenza viruses should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of~~ *~~laboratory~~* ~~testing and the control measures to which the~~ *~~animals~~* ~~concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).~~

~~Article 10.4.29.~~

**~~Surveillance strategies~~**

~~1.~~ ~~Introduction~~

~~The target population for~~ *~~surveillance~~* ~~aimed at identification of~~ *~~disease~~* ~~and~~ *~~infection~~* ~~should cover all the susceptible~~ *~~poultry~~* ~~species within the country,~~ *~~zone~~* ~~or~~ *~~compartment~~*~~. Active and passive~~ *~~surveillance~~* ~~for avian influenza should be ongoing with the frequency of active~~ *~~surveillance~~* ~~being appropriate to the epidemiological situation in the country.~~ *~~Surveillance~~* ~~should be composed of random and targeted approaches using molecular, virological, serological and clinical methods.~~

~~The strategy employed may be based on randomised sampling requiring~~ *~~surveillance~~* ~~consistent with demonstrating the absence of~~ *~~infection~~* ~~with avian influenza viruses at an acceptable level of confidence. Random~~ *~~surveillance~~* ~~is conducted using serological tests. Positive serological results should be followed up with molecular or virological methods.~~

~~Targeted~~ *~~surveillance~~* ~~(e.g. based on the increased likelihood of~~ *~~infection~~* ~~in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the avian influenza status of high risk populations.~~

~~A Member Country should justify the~~ *~~surveillance~~* ~~strategy chosen as adequate to detect the presence of~~ *~~infection~~* ~~with avian influenza viruses in accordance with Chapter 1.4. and the prevailing epidemiological situation, including~~ *~~cases~~* ~~of high pathogenicity influenza A detected in any birds. It may, for example, be appropriate to target clinical~~ *~~surveillance~~* ~~at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).~~

~~If a Member Country wishes to declare freedom from~~ *~~infection~~* ~~with avian influenza viruses in a specific~~ *~~zone~~* ~~or~~ *~~compartment~~*~~, the design of the survey and the basis for the sampling process would need to be aimed at the population within the~~ *~~zone~~* ~~or~~ *~~compartment~~*~~.~~

~~For random surveys, the design of the sampling strategy should incorporate epidemiologically appropriate design prevalence. The sample size selected for testing should be large enough to detect~~ *~~infection~~* ~~if it were to occur at a predetermined minimum rate. The sample size and expected~~ *~~disease~~* ~~prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of~~ *~~surveillance~~* ~~and the epidemiological situation, in accordance with Chapter 1.4. Selection of the design prevalence in particular should be clearly based on the prevailing or historical epidemiological situation.~~

Annex 12B (contd)

~~Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the~~ *~~vaccination~~* ~~and~~ *~~infection~~* ~~history and the different species in the target population.~~

~~Irrespective of the testing system employed,~~ *~~surveillance~~* ~~system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of~~ *~~infection~~* ~~or not. This should involve both supplementary tests and follow-up investigation to collect diagnostic material from the original sampling unit as well as~~ *~~flocks~~* ~~which may be epidemiologically linked to it.~~

~~The principles involved in~~ *~~surveillance~~* ~~for~~ *~~disease~~* ~~and~~ *~~infection~~* ~~are technically well defined. The design of~~ *~~surveillance~~* ~~programmes to prove the absence of~~ *~~infection~~* ~~with, or circulation of, avian influenza viruses should be carefully followed to avoid producing results that are either insufficiently reliable, or excessively costly and logistically complicated. The design of any~~ *~~surveillance~~* ~~programme, therefore, requires inputs from professionals competent and experienced in this field.~~

~~2.~~ ~~Clinical surveillance~~

~~Clinical~~ *~~surveillance~~* ~~aims at the detection of clinical signs of avian influenza at the~~ *~~flock~~* ~~level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening,~~ *~~surveillance~~* ~~based on clinical inspection should not be underrated. Monitoring of production parameters, such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory~~ *~~disease~~* ~~or a drop in egg production, is important for the early detection of~~ *~~infection~~* ~~with avian influenza viruses. In some cases, the only indication of~~ *~~infection~~* ~~with low pathogenicity avian influenza virus may be a drop in feed consumption or egg production.~~

~~Clinical~~ *~~surveillance~~* ~~and~~ *~~laboratory~~* ~~testing should always be applied in series to clarify the status of avian influenza suspects detected by either of these complementary diagnostic approaches.~~ *~~Laboratory~~* ~~testing may confirm clinical suspicion, while clinical~~ *~~surveillance~~* ~~may contribute to confirmation of positive serology. Any sampling unit within which suspicious~~ *~~animals~~* ~~are detected should have restrictions imposed upon it until avian influenza~~ *~~infection~~* ~~is ruled out.~~

~~Identification of suspect~~ *~~flocks~~* ~~is vital to the identification of sources of avian influenza viruses and to enable the molecular, antigenic and other biological characteristics of the virus to be determined. It is essential that avian influenza virus isolates are sent regularly to the regional Reference Laboratory for genetic and antigenic characterisation.~~

~~3.~~ ~~Virological surveillance~~

~~Virological~~ *~~surveillance~~* ~~should be conducted:~~

*~~a)~~* ~~to monitor at risk populations;~~

*~~b)~~* ~~to confirm clinically suspect cases;~~

*~~c)~~* ~~to follow up positive serological results;~~

*~~d)~~* ~~to test ‘normal’ daily mortality, to ensure early detection of~~ *~~infection~~* ~~in the face of~~ *~~vaccination~~* ~~or in~~ *~~establishments~~* ~~epidemiologically linked to an~~ *~~outbreak~~*~~.~~

~~4.~~ ~~Serological surveillance~~

~~Serological~~ *~~surveillance~~* ~~aims at the detection of antibodies against avian influenza virus. Positive avian influenza viruses antibody test results can have four possible causes:~~

*~~a)~~* ~~natural~~ *~~infection~~* ~~with avian influenza viruses;~~

*~~b)~~* *~~vaccination~~* ~~against avian influenza;~~

Annex 12B (contd)

*~~c)~~* ~~maternal antibodies derived from a vaccinated or infected parent~~ *~~flock~~* ~~are usually found in the yolk and can persist in progeny for up to four weeks;~~

*~~d)~~* ~~lack of specificity of the test.~~

~~It may be possible to use serum collected for other survey purposes for avian influenza~~ *~~surveillance~~*~~. However, the principles of survey design described in these recommendations and the requirement for a statistically valid survey for the presence of avian influenza viruses should not be compromised.~~

~~The discovery of clusters of seropositive~~ *~~flocks~~* ~~may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or~~ *~~infection~~*~~. As clustering may signal~~ *~~infection~~*~~, the investigation of all instances should be incorporated in the survey design. Clustering of positive~~ *~~flocks~~* ~~is always epidemiologically significant and therefore should be investigated.~~

~~If~~ *~~vaccination~~* ~~cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to~~ *~~infection~~* ~~or~~ *~~vaccination~~* ~~should be employed.~~

~~The results of random or targeted serological surveys are important in providing reliable evidence that no~~ *~~infection~~* ~~with avian influenza viruses is present in a country,~~ *~~zone~~* ~~or~~ *~~compartment~~*~~. It is therefore essential that the survey be thoroughly documented.~~

~~5.~~ ~~Virological and serological surveillance in vaccinated populations~~

~~The~~ *~~surveillance~~* ~~strategy is dependent on the type of vaccine used. The protection against influenza A virus is haemagglutinin subtype specific. Therefore, two broad~~ *~~vaccination~~* ~~strategies exist: 1) inactivated whole viruses, and 2) haemagglutinin expression-based vaccines.~~

~~In the case of vaccinated populations, the~~ *~~surveillance~~* ~~strategy should be based on virological or serological methods and clinical~~ *~~surveillance~~*~~. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, virus antibody free birds and clearly and permanently identified. Sentinel birds should be used only if no appropriate~~ *~~laboratory~~* ~~procedures are available. The interpretation of serological results in the presence of~~ *~~vaccination~~* ~~is described in Article 10.4.33.~~

Article 10.4.~~30~~22.

**Surveillance for demonstrating ~~Documentation of~~ freedom from ~~avian influenza or freedom from infection with~~ infection with high pathogenicity avian influenza ~~viruses in poultry~~**

1. ~~Additional surveillance requirements for Member Countries declaring freedom of the country, zone or compartment from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry~~

~~In addition to the general conditions described in above mentioned articles, a~~ A Member Country declaring freedom of the entire country, ~~or~~ a *zone* or a *compartment* from ~~avian influenza or from~~ *~~infection~~* ~~with~~ high pathogenicity avian influenza ~~viruses~~ in *poultry* should provide evidence ~~for the existence~~ of an effective *surveillance* programme.

Transparency in the application of different methodologies is essential to ensure consistency in decision-making, ease of understanding, fairness and rationality. The assumptions made, the uncertainties, and the effect of these on the interpretation of the results, should be documented.

The ~~strategy and~~ design of the *surveillance* programme will depend on the ~~prevailing~~ epidemiological circumstances and it should be planned and implemented ~~according to general conditions and methods described in~~ in accordance with this chapter and ~~in~~ Article 1.4.6~~, to demonstrate absence of~~ *~~infection~~* ~~with avian influenza viruses or with high pathogenicity avian influenza viruses, during the preceding 12 months in susceptible~~ *~~poultry~~* ~~populations (vaccinated and non-vaccinated)~~. This requires the availability of demographic data on the *poultry* population and the support of a *laboratory* able to undertake identification of *infection* with avian influenza viruses through virus detection and antibody tests.

The *surveillance* programme should demonstrate absence of *infection* with high pathogenicity avian influenza viruses during the preceding 12 months in susceptible *poultry* populations (vaccinated and non-vaccinated).

Annex 12B (contd)

The design of the sampling strategy should include an epidemiologically appropriate design prevalence. The design prevalence and desired level of confidence in the results will determine the sample size. The Member Country should justify the choice of design prevalence and confidence level used on the basis of the stated objectives of the *surveillance* and the epidemiological situation.

~~This~~ *~~surveillance~~* ~~may be targeted to~~ *~~poultry~~* ~~population at~~ The sampling strategy may be risk-based if scientific evidence is available, and provided, for the quantification of risk factors. ~~s~~Specific risks could include those linked to the types of production, possible direct or indirect contact with *wild* birds, multi-age *flocks*, local trade patterns including live bird markets, use of possibly contaminated surface water, ~~and~~ the presence of more than one species ~~on~~ at the ~~holding~~ *establishment* and poor *biosecurity* ~~measures~~ in place. ~~It should include the monitoring of high pathogenicity avian influenza virus in~~ *~~wild~~* ~~birds and of H5 and H7 low pathogenicity avian influenza virus in poultry, in order to adapt the biosecurity and possible control measures.~~

Data from different *surveillance* activities can be included to increase the sensitivity of the *surveillance* system ~~estimates and hence the confidence in freedom from disease~~. If this is to be done, ~~a probabilistic approach is required to combine~~ data from structured (e.g. surveys and active *surveillance*) and non-structured (e.g. passive *surveillance*) sources should be combined~~. It is necessary to quantify~~ and the sensitivity of each activity should be quantified~~,~~ in order to be able to quantify the sensitivity of the overall *surveillance* system ~~and estimate the probability of disease freedom~~.

The *surveillance* programme should include *surveillance* for high pathogenicity avian influenza viruses in birds other than *poultry,* including *wild* birds and *monitoring* of low pathogenicity avian influenza viruses in *poultry*, in order to ensure that *biosecurity* and control measures are fit for purpose.

Documentation ~~for~~ of freedom from *infection* with high pathogenicity avian influenza should provide details of the *poultry* population, the occurrence of suspected *cases* and how they were investigated and dealt with. This should include the results of *laboratory* testing and the *biosecurity* and control measures to which the animalsconcerned were subjected during the investigation.

2. Additional requirements for countries, zones or compartments that ~~practice~~ practise vaccination

*Vaccination* to prevent the transmission of high pathogenicity avian influenza virus may be part of a diseasecontrol programme. The level of *flock* immunity required to prevent transmission depends on the *flock* size, composition (e.g. species) and density of the susceptible *poultry* population. ~~It is therefore impossible to be prescriptive.~~ Based on the epidemiology of avian influenza in the country, *zone* or *compartment*, ~~it may be that~~ a decision ~~is~~ may be reached to vaccinate only certain species or other *poultry subpopulations*.

In all vaccinated *flocks* ~~there is a need to perform virological and serological~~ tests should be performed to ensure the absence of virus circulation. ~~The use of sentinel~~ *~~poultry~~* ~~may provide further confidence of in the absence of virus circulation.~~ The tests ~~have to~~ should be repeated ~~at least~~ ~~every six months or at shorter intervals~~ at a frequency~~, according~~ that is proportionate to the *risk* in the country, *zone* or *compartment*. The use of sentinel *poultry* may provide further confidence ~~of~~ in the absence of virus circulation.

~~Evidence to show the effectiveness of the~~ *~~vaccination~~* ~~programme should also be provided.~~

Member Countries seeking the demonstration of freedom from high pathogenicity avian influenza in vaccinated population should refer to the ~~C~~chapter ~~2.3.4. paragraph C 4~~ on ~~A~~avian ~~I~~influenza (*infection* with avian influenza viruses) ~~of~~ in the *Terrestrial Manual*~~, including virus or serological DIVA approaches~~.

Evidence to show the effectiveness of the *vaccination* programme should also be provided.

3. Additional requirements for recovery of free status

In addition to the conditions described in the point above, a Member Country declaring that it has regained country, *zone* or *compartment* freedom after an *outbreak* of high pathogenicity avian influenza in *poultry* should show evidence of an active *surveillance* programme, depending on the epidemiological circumstances of the *outbreak*,to demonstrate the absence of the *infection*. This will require *surveillance* incorporating virus detection and antibody tests. ~~The use of sentinel birds may facilitate the interpretation of~~ *~~surveillance~~* ~~results.~~ The Member Country should report the results of an active *surveillance* programme in which the susceptible *poultry* population undergoes regular clinical examination and active *surveillance* planned and implemented according to the general conditions and methods described in these recommendations. The *surveillance* samples should be representative of *poultry* *populations* at risk. The use of sentinel birds may facilitate the interpretation of *surveillance* results.

Annex 12B (contd)

*Populations* under this *surveillance* programme should include:

~~1~~*a)* *establishments* in the proximity of the *outbreaks*;

~~2~~*b)* *establishments* epidemiologically linked to the *outbreaks*;

~~3~~*c)* ~~animals moved from or~~ *poultry* used to re-populate affected *establishments*;

~~4~~*d)* any *establishments* where ~~contiguous culling~~ preventive depopulation has been carried out~~;~~.

Article 10.4.~~30~~22bis.

**Surveillance of wild bird populations**

~~The presence of high pathogenicity avian influenza viruses in~~ *~~wild~~* ~~birds creates a particular problem. In essence, no Member Country can declare itself free from influenza A viruses in~~ *~~wild~~* ~~birds. However, the definition of high pathogenicity avian influenza in this chapter refers to the~~ *~~infection~~* ~~in~~ *~~poultry~~* ~~only, and Articles 10.4.27. to 10.4.33. were developed under this definition.~~

Passive *surveillance,* ~~(~~i.e. sampling of birds found dead,~~)~~ is an appropriate method of *surveillance* in *wild* birds ~~as~~ because *infection* with high pathogenicity avian influenza ~~is usually~~ can be associated with mortality in some species. Mortality events, or clusters of birds found dead should be reported to the local *Veterinary Authorities* and investigated, including through the collection and submission of samples to a *laboratory* for appropriate tests.

Active *surveillance,* i.e. sampling of live ~~in~~ *wild* birds, ~~usually has lower sensitivity for detection of high pathogenicity avian influenza, but~~ may be necessary for detection of some strains of high pathogenicity avian influenza viruses that produce *infection* without mortality in *wild* birds. Furthermore, it increases knowledge of the ecology and evolution of avian influenza viruses.

*Surveillance* in *wild* birds should be targeted towards times of year, species~~,~~ and locations ~~and times of year~~ in which *infection* is more likely.

*Surveillance* in *wild* birds should be enhanced by raising awareness, ~~raising~~ and by active searching and *monitoring* for dead or moribund *wild* birds when high pathogenicity avian influenza has been detected in the region. The movements of migratory water birds, in particular ducks, geese and swans, should be taken into account as a potential pathway for introduction of virus to uninfected areas.

Article 10.4.~~30~~22ter.

**Monitoring of ~~H5 and H7~~ low pathogenicity avian influenza in poultry populations**

*Outbreaks* of low pathogenicity avian influenza viruses can be managed at the *establishment* level; however, spread to other *poultry* *establishments* increases the risk of virus mutation, particularly if it is not detected and managed. Therefore, a *monitoring* system ~~that includes awareness and reporting~~ should be in place.

*Monitoring* the presence and types of ~~H5 and H7~~ low pathogenicity avian influenza viruses can be achieved through ~~the~~ a combination of clinical investigation~~s~~ ~~where~~ when *infection* is suspected ~~through~~ because of changes in production ~~indicators~~ parameters, such as reductions in egg production or *feed* and water intake, and active serological and virological *surveillance*, which can be supported by the information obtained by the *surveillance* system for high pathogenicity avian influenza.

Serological and virological *monitoring* should aim at detecting clusters of infected *flocks* to identify spread between *establishments*. Epidemiological follow-up (tracing forward and back) of serologically positive *flocks* should be carried out to determine ~~if~~ whether there is clustering of infected *flocks* regardless of whether the seropositive birds are still present ~~on~~ at the *establishment* or whether active virus *infection* has been detected. Hence, *monitoring* of low pathogenicity avian influenza will also enhance early detection of high pathogenicity avian influenza.

Annex 12B (contd)

~~Article 10.4.31.~~

**~~Additional surveillance requirements for countries, zones or compartments declaring that they have regained freedom from avian influenza or from infection with high pathogenicity avian influenza viruses in poultry following an outbreak~~**

~~In addition to the general conditions described in the above-mentioned articles, a Member Country declaring that it has regained country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~freedom from avian influenza or from~~ *~~infection~~* ~~with high pathogenicity avian influenza viruses in~~ *~~poultry~~* ~~should show evidence of an active~~ *~~surveillance~~* ~~programme depending on the epidemiological circumstances of the~~ *~~outbreak~~* ~~to demonstrate the absence of the~~ *~~infection~~*~~. This will require~~ *~~surveillance~~* ~~incorporating virus detection and antibody tests. The use of sentinel birds may facilitate the interpretation of~~ *~~surveillance~~* ~~results.~~

~~A Member Country declaring freedom of country,~~ *~~zone~~* ~~or~~ *~~compartment~~* ~~after an~~ *~~outbreak~~* ~~of avian influenza should report the results of an active~~ *~~surveillance~~* ~~programme in which the susceptible~~ *~~poultry~~* ~~population undergoes regular clinical examination and active~~ *~~surveillance~~* ~~planned and implemented according to the general conditions and methods described in these recommendations. The~~ *~~surveillance~~* ~~should at least give the confidence that can be given by a randomised representative sample of the populations at risk.~~

~~Article 10.4.32.~~

**~~Additional sSurveillance~~ ~~requirements for the avian influenza free establishments~~**

~~The declaration of avian influenza free~~ *~~establishments~~* ~~requires the demonstration of absence of~~ *~~infection~~* ~~with avian influenza viruses. Birds in these~~ *~~establishments~~* ~~should be randomly tested using virus detection or isolation tests, and serological methods, following the general conditions of these recommendations. The frequency of testing should be based on the~~ *~~risk~~* ~~of~~ *~~infection~~* ~~and at a maximum interval of 21 28 days.~~

~~Article 10.4.33.~~

**~~The use and interpretation of serological and virus detection tests~~**

*~~Poultry~~* ~~infected with avian influenza virus produce antibodies against haemagglutinin (HA), neuraminidase (NA), nonstructural proteins (NSPs), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins is not covered in this chapter. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct and blocking ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI), ELISA and neutralisation (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies against the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.~~

~~The HI and NI tests can be used to subtype influenza A viruses into 16 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of influenza A viruses.~~

*~~Poultry~~* ~~can be vaccinated with a variety of influenza A vaccines including inactivated whole virus vaccines, and haemagglutinin expression-based vaccines. Antibodies against the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.~~

~~Influenza A virus~~ *~~infection~~* ~~of unvaccinated birds including sentinels is detected by antibodies against the NP/M, subtype specific HA or NA proteins, or NSP.~~ *~~Poultry~~* ~~vaccinated with inactivated whole virus vaccines containing a virus of the same H sub-type but with a different neuraminidase may be tested for field exposure by applying serological tests directed to the detection of antibodies against the NA of the field virus. For example, birds vaccinated with H7N3 in the face of a H7N1 epidemic may be differentiated from infected birds (DIVA) by detection of subtype specific NA antibodies of the N1 protein of the field virus. Alternatively, in the absence of DIVA, inactivated vaccines may induce low titres of antibodies against NSP and the titre in infected birds would be markedly higher. Encouraging results have been obtained experimentally with this system, but it has not yet been validated in the field. In~~ *~~poultry~~* ~~vaccinated with haemagglutinin expression-based vaccines, antibodies are detected against the specific HA, but not any of the other viral proteins.~~ *~~Infection~~* ~~is evident by antibodies against the NP/M or NSP, or the specific NA protein of the field virus.~~

Annex 12B (contd)

~~All~~ *~~flocks~~* ~~with seropositive results should be investigated. Epidemiological and supplementary~~ *~~laboratory~~* ~~investigation results should document the status of avian influenza~~ *~~infection~~* ~~for each positive~~ *~~flock~~*~~.~~

~~A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.~~

~~Information should be provided on the performance characteristics and validation of tests used.~~

~~1.~~ ~~Procedure in case of positive test results if vaccination is used~~

~~In case of vaccinated populations, one has to exclude the likelihood that positive test results are indicative of virus circulation. To this end, the following procedure should be followed in the investigation of positive serological test results derived from~~ *~~surveillance~~* ~~conducted on vaccinated~~ *~~poultry~~*~~. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated, and the results should be collated in the final report.~~

~~Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated~~ *~~animals~~*~~.~~

*~~a)~~* ~~Inactivated whole virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If~~ *~~poultry~~* ~~in the population have antibodies against NP/M and were vaccinated with inactivated whole virus vaccine, the following strategies should be applied:~~

*~~i)~~* ~~sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating influenza A virus~~ *~~infection~~*~~, specific HI tests should be performed to identify H5 or H7 virus~~ *~~infection~~*~~;~~

*~~ii)~~* ~~if vaccinated with inactivated whole virus vaccine containing homologous NA to field virus, the presence of antibodies against NSP could be indicative of~~ *~~infection~~*~~. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins;~~

*~~iii)~~* ~~if vaccinated with inactivated whole virus vaccine containing heterologous NA to field virus, presence of antibodies against the field virus NA or NSP would be indicative of~~ *~~infection~~*~~. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.~~

*~~b)~~* ~~Haemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect avian influenza~~ *~~infection~~*~~. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of~~ *~~infection~~*~~. Sampling should be initiated to exclude the presence of avian influenza virus by either virus isolation or detection of virus specific genomic material or proteins.~~

~~2.~~ ~~Procedure in case of test results indicative of infection with avian influenza viruses~~

~~The detection of antibodies indicative of an~~ *~~infection~~* ~~with avian influenza virus in unvaccinated~~ *~~poultry~~* ~~should result in the initiation of epidemiological and virological investigations to determine if the~~ *~~infections~~* ~~are due to low and high pathogenicity viruses.~~

~~Virological testing should be initiated in all antibody-positive and at risk populations. The samples should be evaluated for the presence of avian influenza virus, by virus isolation and identification, or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting~~ *~~infection~~* ~~by avian influenza virus. All influenza A virus isolates should be tested to determine HA and NA subtypes, and~~ *~~in vivo~~* ~~tested in chickens or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as high or low pathogenicity avian influenza viruses or other influenza A viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and~~ *~~in vivo~~* ~~testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as high or low pathogenicity avian influenza viruses. The use of antigen detection systems, because of low sensitivity, should be limited to screening clinical field~~ *~~cases~~* ~~for~~ *~~infection~~* ~~by influenza A virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.~~

Annex 12B (contd)

*~~Laboratory~~* ~~results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:~~

*~~a)~~* ~~characterisation of the existing production systems;~~

*~~b)~~* ~~results of clinical~~ *~~surveillance~~* ~~of the suspects and their cohorts;~~

*~~c)~~* ~~quantification of~~ *~~vaccinations~~* ~~performed on the affected sites;~~

*~~d)~~* ~~sanitary protocol and history of the affected~~ *~~establishments~~*~~;~~

*~~e)~~* ~~control of animal identification and movements;~~

*~~f)~~* ~~other parameters of regional significance in historic avian influenza virus transmission.~~

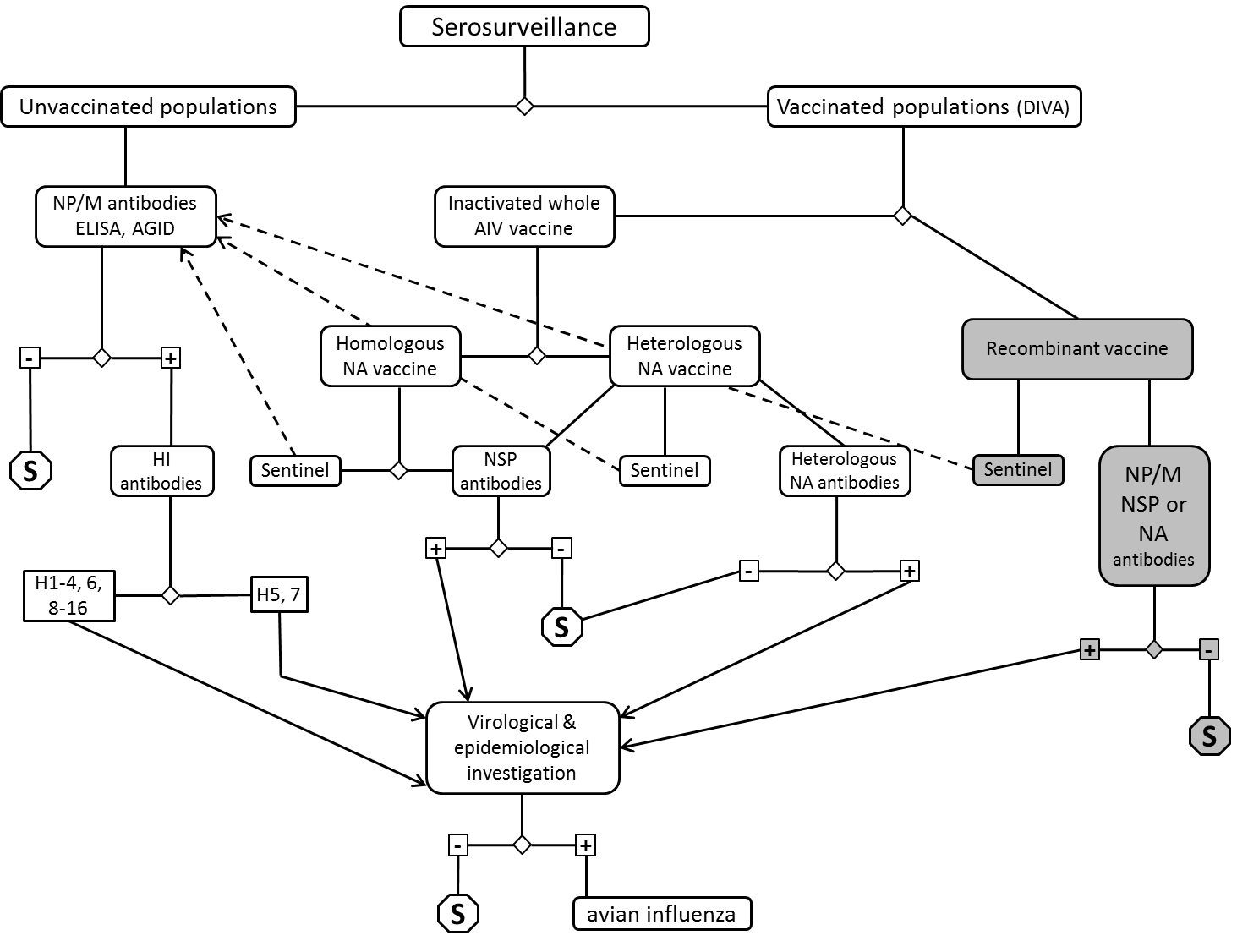
~~The entire investigative process should be documented as standard operating procedure within the epidemiological~~ *~~surveillance~~* ~~programme.~~

~~Figures 1 and 2 indicate the tests which are recommended for use in the investigation of~~ *~~poultry flocks~~*~~.~~

|  |
| --- |
| ~~Key abbreviations and acronyms:~~ |
| ~~AGID Agar gel immunodiffusion~~ |
| ~~DIVA Differentiating infected from vaccinated animals~~ |
| ~~ELISA Enzyme-linked immunosorbent assay~~ |
| ~~HA Haemagglutinin~~ |
| ~~HI Haemagglutination inhibition~~ |
| ~~NA Neuraminidase~~ |
| ~~NP/M Nucleoprotein and matrix protein~~ |
| ~~NSP Nonstructural protein~~ |
| ~~S No evidence of avian influenza virus~~ |

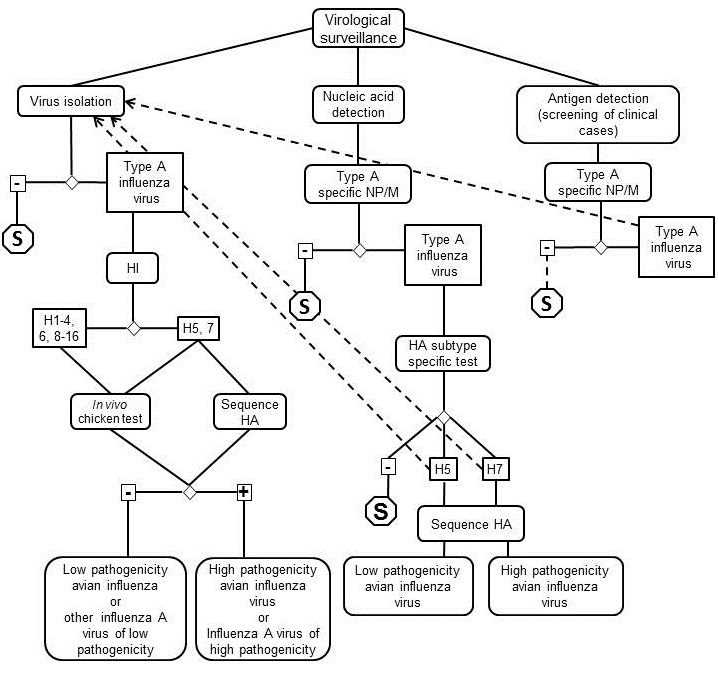
Annex 12B (contd)

***~~Fig. 1.~~*** *~~Schematic representation of laboratory tests for determining evidence of avian influenza infection through or following serological surveys~~*

~~~~

Annex 12B (contd)

***~~Fig. 2.~~*** *~~Schematic representation of laboratory tests for determining evidence of avian influenza infection using virological methods~~*

***~~~~***

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_