

COMMISSION DECISION

of 28 August 2007

concerning measures to prevent the spread of highly pathogenic avian influenza to other captive birds kept in zoos and approved bodies, institutes or centres in the Member States*(notified under document number C(2007) 3987)***(Text with EEA relevance)**

(2007/598/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC⁽¹⁾, and in particular the first paragraph of Article 22 thereof,

Having regard to Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC⁽²⁾, and in particular Articles 56(3), 57(2) and 63(3) thereof,

Whereas:

- (1) Directive 2005/94/EC sets out certain preventive measures relating to the surveillance and the early detection of avian influenza and the minimum control measures to be applied in the event of an outbreak of that disease in poultry or other captive birds.
- (2) Directive 2005/94/EC also lays down rules for the introduction of preventive vaccination against avian influenza of poultry and other captive birds, such as other captive birds kept in zoos and approved bodies, institutes or centres, and provides for detailed rules thereof to be established by the Commission. That Directive also provides for the submission by the Member States to the Commission for approval of their preventive vaccination plans for poultry or other captive birds.
- (3) Commission Decision 2006/474/EC of 6 July 2006 concerning measures to prevent the spread of highly pathogenic avian influenza caused by influenza A virus

of subtype H5N1 to birds kept in zoos and approved bodies, institutes and centres in the Member States and repealing Decision 2005/744/EC⁽³⁾ lays down rules to prevent the spread of avian influenza caused by highly pathogenic influenza A virus of subtype H5N1 from birds living in the wild to birds kept in zoos and approved bodies, institutes or centres. It also lays down rules for the vaccination of birds kept in zoos and approved bodies, institutes or centres and provides for detailed rules for the submission by the Member States to the Commission of their vaccination plans.

- (4) For the purposes of such preventive vaccination, only vaccines authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products⁽⁴⁾ or Regulation No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency⁽⁵⁾ should be used.
- (5) Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos⁽⁶⁾ defines zoos which are covered by that Directive. In the interests of consistency of Community legislation, that definition should be taken into account for the purposes of this Decision.
- (6) Pursuant to Decision 2006/474/EC, the Commission has approved 17 preventive vaccination plans against avian influenza for birds kept in zoos submitted by Member States. Vaccination plans have been implemented by 14 Member States. In general no adverse reactions in almost 45 000 vaccinated birds have been observed and most bird species have produced a significant immune response following two administrations of the vaccines.

⁽³⁾ OJ L 187, 8.7.2006, p. 37.

⁽⁴⁾ OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

⁽⁵⁾ OJ L 136, 30.4.2004, p. 1. Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).

⁽⁶⁾ OJ L 94, 9.4.1999, p. 24.

⁽¹⁾ OJ L 268, 14.9.1992, p. 54. Directive as last amended by Commission Decision 2007/265/EC (OJ L 114, 1.5.2007, p. 17).

⁽²⁾ OJ L 10, 14.1.2006, p. 16.

- (7) In addition, experience gained during the latest vaccination campaign and the opinions of the Scientific Panel on Animal Health and Animal Welfare of the European Food Safety Authority of 1 February 2007 on preventive vaccination of zoo birds against avian influenza of H5 and H7 subtypes and of 11 May 2007 on vaccination in domestic poultry and captive birds, demonstrate that it is appropriate to extend the scope of the preventive vaccination plans to any highly pathogenic avian influenza of the H5 and H7 subtypes, thereby taking into account the risks posed by wild migratory birds proceeding from areas where avian influenza cases in wild birds or outbreaks in poultry occur and in the event an outbreak in poultry occurs in the same Member State, a neighbouring Member State or a third country that is liable to endanger the health status of birds kept in zoos and approved bodies, institutes or centres.
- (8) Furthermore the administrative requirements for approval and implementation of preventive vaccination plans should be amended, provided they do not endanger disease control. Accordingly, requirements which ease the administrative burden should be taken into account in the present Decision.
- (9) It is further appropriate to consider certain preventive vaccination plans that have been approved pursuant to Decision 2006/474/EC as approved for the purposes of the present Decision. Accordingly, such plans should be listed in Annex III to the present Decision.
- (10) Since the date of adoption of Decision 2006/474/EC, certain Member States have submitted preventive vaccination plans for approval in accordance with the requirements of that Decision. Those Member States have been informed of the requirements set out in the present Decision. As those plans also comply with the requirements of the present Decision, they should be approved and listed in Annex III hereto.
- (11) For the sake of clarity it is appropriate to repeal Decision 2006/474/EC and replace it by this Decision.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

This Decision lays down detailed rules:

- (a) to be applied in order to prevent the spread of highly pathogenic avian influenza virus from birds living in the wild or from outbreaks in poultry or other captive birds, to other captive birds kept in zoos and approved bodies, institutes or centres;
- (b) for the preventive vaccination of other captive birds kept in zoos and approved bodies, institutes or centres.

Article 2

Definitions

For the purposes of this Decision, the following definitions shall apply:

- (a) the definitions in Article 2 of Directive 2005/94/EC;
- (b) the definition of zoos in Article 2 of Directive 1999/22/EC;
- (c) the definition of approved bodies, institutes or centres in Article 2(1)(c) of Directive 92/65/EEC.

Article 3

Measures to reduce the risk of transmission of highly pathogenic avian influenza

1. Member States shall take appropriate and practicable measures to reduce the risk of transmission of highly pathogenic avian influenza from birds living in the wild to other captive birds kept in zoos and approved bodies, institutes or centres, taking into account the criteria and risk factors set out in Annex I.

2. Paragraph 1 shall also apply in the event of an outbreak in poultry in the same Member State, a neighbouring Member State or a third country that is liable to endanger the health status of other captive birds kept in zoos and approved bodies, institutes or centres.

3. Depending on the specific epidemiological situation, the measures referred to in paragraph 1 shall, in particular, be directed at preventing direct and indirect contact between birds living in the wild, especially waterfowl, and other captive birds kept in zoos and approved bodies, institutes or centres.

Article 4

Preventive vaccination plans

Preventive vaccination plans in respect of other captive birds kept in zoos and approved bodies, institutes or centres, submitted in accordance with Article 56(2) of Directive 2005/94/EC shall comply with the requirements set out in Annex II to this Decision.

Article 5

Approval of preventive vaccination plans

1. The preventive vaccination plans submitted in accordance with Article 56(2) of Directive 2005/94/EC and listed in Part I of Annex III to this Decision are hereby approved.

2. The Commission shall publish the approved preventive vaccination plans referred to in paragraph 1.

Article 6

Availability and information concerning preventive vaccination plans

1. Member States shall, before preventive vaccination is introduced, compile the exact address and location of the zoos and approved bodies, institutes or centres, where vaccination it is to be carried out by allocating approval or registration numbers, as appropriate, and shall keep that information updated.

2. Member States shall submit to the Commission and the other Member States each year, by 30 March at the latest, or upon specific request by the Commission, a report on the implementation of the approved preventive vaccination plans for the preceding year using the reporting model as set out in Annex IV.

That report shall be submitted in the framework of the Standing Committee on the Food Chain and Animal Health.

3. Member States shall inform the Commission of the following:

- (a) planned amendments to their approved preventive vaccination plans;
- (b) the date of cessation of preventive vaccination of other captive birds kept in zoos and approved bodies, institutes or centres.

Article 7

Repeal

Decision 2006/474/EC is repealed.

Article 8

Transitional provision

The preventive vaccination plans approved pursuant to Decision 2006/474/EC and listed in Part II of Annex III to this Decision shall be considered as being approved for the purposes of the present Decision.

Article 9

Compliance by Member States

Member States shall take the necessary measures to comply with this Decision. They shall immediately inform the Commission thereof.

Article 10

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 28 August 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Criteria and risk factors to be considered when applying the measures set out in Article 3 in zoos and approved bodies, institutes or centres

1. Location of zoos and approved bodies, institutes or centres along migratory flyways of birds, in particular if proceeding from countries where outbreaks of highly pathogenic avian influenza have occurred, taking into account the serotype detected and the likelihood of wild birds having been affected.
 2. Distance of zoos and approved bodies, institutes or centres from wetlands and water areas such as ponds, swamps, lakes or rivers where migratory waterfowl may gather.
 3. Location of zoos and approved bodies, institutes or centres in areas of a high density of migratory birds, particularly waterfowl.
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ANNEX II

Requirements for the use of preventive vaccination as referred to in Article 4

1.	Extent of the vaccination to be carried out	The vaccination against avian influenza shall only be carried out in birds kept in zoos and approved bodies, institutes or centres. The competent authority shall keep lists of zoos, approved bodies, institutes or centres for a period of at least five years from the date of such vaccination.
2.	Bird species to be vaccinated	The competent authority shall be notified of a list of birds to be vaccinated together with the individual identification and keep it for at least five years from the date of the vaccination.
3.	Duration of vaccination	<p>(a) All birds to be vaccinated in zoos and approved bodies institutes or centres shall be vaccinated as quickly as possible.</p> <p>(b) Offspring, newly introduced birds and birds for which an insufficient immune response has been demonstrated must also be vaccinated.</p> <p>(c) Annual re-vaccination is recommended to maintain bird immunity.</p>
4.	Specific requirements for movements of birds	<p>(a) Vaccinated birds kept in approved bodies, institutes or centres including zoos approved in accordance with Directive 92/65/EEC where vaccination is carried out may be moved to approved bodies, institutes or centres in other Member States provided that they meet the requirements set out in this Decision and are accompanied by a health certificate as laid down in Part 3 of Annex E to Directive 92/65/EEC, where under point II.5. the following must be certified:</p> <p>'Birds conform to Decision 2007/598/EC were vaccinated against avian influenza on ... (date) with vaccine ... (name).'</p> <p>(b) Vaccinated birds kept in zoos that are not approved in accordance with Directive 92/65/EEC where vaccination is carried out may be moved to other Member States after authorisation by the Member State of destination provided that they meet the requirements set out in this Decision and are accompanied by a health certificate as laid down in Part 1 of Annex E to Directive 92/65/EEC to which the following words shall be added at the end of point II.3.2.:</p> <p>'Birds conform to Decision 2007/598/EC and vaccinated against avian influenza on ... (date) with vaccine ... (name).'</p> <p>(c) When vaccination of birds kept in zoos, approved bodies, institutes or centres is not longer applied, the conditions for movements laid down in points (a) and (b) shall be maintained for a period of 12 months from the date of the vaccination of the last bird.</p>
5.	Special identification and special registration of the vaccinated birds	Vaccinated birds must be individually identifiable and the identity records of these birds must be clearly annotated accordingly. An indelible identification of the other captive birds indicating that they have been vaccinated shall be applied at the time of vaccination wherever possible.
6.	Execution of the vaccination campaign	<p>(a) Vaccination shall be carried out under the supervision of a veterinarian and necessary measures must be in place to avoid possible spread of virus.</p> <p>(b) A written record on the number of vaccinated birds and the number of vaccine doses used shall be communicated to the competent authority after vaccination is carried out and thereafter on a monthly basis, if further birds as referred to in point 3(b) are vaccinated.</p> <p>(c) Wherever possible blood samples from 10 % of the birds shall be taken prior to and at least 30 days from the date of each vaccination for serological testing for avian influenza. A record of the test results must be kept for at least five years from the date of vaccination.</p>
7.	Vaccine to be used	The inactivated vaccine to be used shall be suitably formulated and be effective against highly pathogenic avian influenza virus of subtype H5 or H7 or both. It shall be used in accordance with the instructions of the manufacturer and/or the veterinary authorities.

ANNEX III

Lists of approved preventive vaccination plans for birds kept in zoos and approved bodies, institutes or centres

Part I:

Preventive vaccination plans approved by this Decision and *referred to in Article 5(1)*

Code	Member State	Date of submission of plan
BE	Belgium	22 March 2007
ES	Spain	27 June 2007
FR	France	4 January 2007
SE	Sweden	7 March 2007
UK	United Kingdom	27 June 2007

Part II:

Preventive vaccination plans approved under Decision 2006/474/EC and *referred to in Article 8 of the present Decision*

Code	Member State	Date of submission
CZ	Czech Republic	21 March 2006
DK	Denmark	20 February 2006
DE	Germany	31 March 2006
EE	Estonia	6 March 2006
IE	Ireland	6 March 2006
IT	Italy	6 March 2006
LV	Latvia	28 February 2006
LT	Lithuania	6 March 2006
HU	Hungary	1 March 2006
NL	The Netherlands	16 November 2005
AT	Austria	21 April 2006
PT	Portugal	29 November 2005

ANNEX IV

Reporting model for the implementation of the approved preventive vaccination plans referred to in article 6(2)

General information						
Country	Zoo	Vaccine	Route (specify if different in different species)	Weight — Dose regime used (Actual/estimated/average weight of species)	Vaccine interval	Interval from last vaccination to post-vaccination blood collection

HI serum antibody titre							
English name/ local name	<i>Latin name</i>	Taxonomic Order	Individual identification	Vaccine Dose (ml)	Pre-vacc	Post-1st vacc	Post-2nd vacc

Adverse Individual effects		Mortality	
Local	general	Direct (catching/handling)	Delayed (specify cause of death)

Information required from the Laboratory				
Virus strain of vaccine	Antigens (virus strains) used in HI test	Cut-off or end-titre point used as a measure of vaccine efficacy	Reference serum used	(reference to) Methodology