COMMISSION DECISION

of 3 November 2008

concerning preventive vaccination against low pathogenic avian influenza in mallard ducks in Portugal and certain measures restricting the movements of such poultry and their products

(notified under document number C(2008) 6348)

(Only the Portuguese text is authentic)

(2008/838/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 [1], and in particular Article 57(2) thereof,

Whereas:

(1) Directive 2005/94/EC sets out certain preventive measures relating to the surveillance and the early detection of avian influenza and increasing the level of the competent authorities' and the farming community's awareness of, and preparation for, the risks of that disease.

(2) Since September 2007, outbreaks of low pathogenic avian influenza have occurred in certain poultry holdings in the central-western part of Portugal, in particular in holdings that keep poultry intended for re-stocking supplies of game.

(3) Portugal has taken measures in accordance with Directive 2005/94/EC to control the spread of that disease.

(4) A risk assessment carried out by Portugal identified that holdings keeping mallard ducks (*Anas platyrhynchos*) intended for re-stocking supplies of game (mallard ducks) could pose a significant and immediate threat of spreading avian influenza within Portugal or into other Member States. Portugal decided therefore to introduce emergency vaccination in order to contain the outbreak.

(5) Commission Decision 2008/285/EC [2] approved the emergency vaccination plan submitted by Portugal. That Decision also provided for certain measures to be applied in a holding where vaccinated mallard ducks are kept and in unvaccinated poultry holdings, including movement restrictions on vaccinated mallard ducks, their hatching eggs and mallard ducks hatched from such eggs in accordance with the approved vaccination plan.

(6) The implementation of the emergency vaccination plan applied by Portugal has been completed by 31 July 2008.

(7) In accordance with Article 8 of Decision 2008/285/EC, Portugal has submitted a report on the implementation of the emergency vaccination plan and has reported to the Standing Committee on the Food Chain and Animal Health.

(8) On the basis of the information provided by Portugal, it appears that the outbreak has been successfully contained.

(9) Based on a further risk assessment, Portugal deems that on the holding the high value mallard breeding ducks are still exposed to the potential risk of avian influenza infection, in particular by possible indirect contact with wild birds. Portugal has therefore decided to continue vaccination against avian influenza as a long-term measure by implementing a preventive vaccination plan on the holding at risk in the region of Lisboa e Vale do Tejo, Ribatejo Norte, Vila Nova da Barquinha that keeps such mallard ducks.

(10) Portugal has by letter dated 10 September 2008 submitted a preventive vaccination plan to the Commission for approval.

(11) According to that preventive vaccination plan, Portugal intends to introduce preventive vaccination which is to be applied until 31 July 2009.

(12) In its scientific opinions on the use of vaccination to control avian influenza issued by the European Food Safety Authority in 2005 [3], 2007 [4] and 2008 [5], the Animal Health and Welfare Panel stated that emergency and preventive vaccination against avian influenza is a valuable tool to complement the control measures for that disease.

[1] OJ L 10, 14.1.2006, p. 16.
[2] OJ L 92, 3.4.2008, p. 37.

[3] *The EFSA Journal* (2005) 266, 1-21, Scientific Opinion on Animal health and welfare aspects of avian influenza.
[4] *The EFSA Journal* (2007) 489, Scientific Opinion on Vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds.
[5] *The EFSA Journal* (2008) 715, 1-161, Scientific Opinion on Animal health and welfare aspects of avian influenza and the risks of its introduction into the EU poultry holdings.

(13) In addition, the Commission has examined the preventive vaccination plan submitted by Portugal, and is satisfied that it conforms with relevant Community legislation. In view of the epidemiological situation as regards low pathogenic avian influenza in Portugal, the type of holding to be vaccinated and the limited scope of the vaccination plan, it is appropriate to approve that preventive vaccination plan. The implementation of that preventive vaccination plan will also provide with further practical experience and knowledge on the efficacy of vaccine in mallard ducks.

(14) For the purposes of the preventive vaccination plan to be carried out by Portugal, 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 ([1]) or Regulation (EC) 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 ([2]) should be used.

(15) In addition, surveillance and laboratory testing in the holding keeping the vaccinated mallard ducks and in unvaccinated poultry holdings should be carried out as set out in the preventive vaccination plan.

(16) It is also appropriate to introduce certain restrictions on the movement of vaccinated mallard ducks, their hatching eggs and mallard ducks derived from vaccinated poultry in accordance with the preventive vaccination plan. Due to the small number of mallard ducks present on the holding where preventive vaccination is to be carried out, as well as for reasons of traceability and logistics, vaccinated birds should not be moved from that holding.

(17) In relation to trade in poultry intended for restocking supplies of game, additional measures have been taken by Portugal pursuant to Commission Decision 2006/605/EC of 6 September 2006 on certain protection measures in relation to intra-Community trade in poultry intended for restocking of wild game supplies ([3]).

(18) In order to reduce the economic impact on the holding concerned, certain derogations from movement restrictions for mallard ducks derived from vaccinated mallard ducks should be provided for, since such movements do not pose a specific risk for spread of disease and provided that official surveillance is carried out and that the specific animal health requirements for intra-Community trade are complied with.

(19) The preventive vaccination plan should be approved so that it can be implemented until 31 July 2009.

(20) Decision 2008/285/EC should be repealed as it has become obsolete after 31 July 2008.

(21) 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

1. This Decision lays down certain measures to be applied in Portugal where preventive vaccination of mallard ducks (*Anas platyrhynchos*) intended for re-stocking supplies of game (mallard ducks) is carried out in a holding, which is exposed to the risk of avian influenza. Those measures include certain restrictions on the movement within and dispatch from Portugal of the vaccinated mallard ducks, their hatching eggs and mallard ducks derived thereof.

2. This Decision shall apply without prejudice to the protection measures to be taken by Portugal in accordance with Directive 2005/94/EC and Decision 2006/605/EC.

Article 2

Approval of the preventive vaccination plan

1. The plan for preventive vaccination against low pathogenic avian influenza in Portugal, as submitted by Portugal to the Commission on 10 September 2008, to be implemented on a holding in the region of Lisboa e Vale do Tejo, Ribatejo Norte, Vila Nova da Barquinha until 31 July 2009 (the preventive vaccination plan) is approved.

2. The Commission shall publish the preventive vaccination plan.

Article 3

Conditions for implementing the preventive vaccination plan

1. Portugal shall ensure that the mallard ducks are vaccinated in accordance with the preventive vaccination plan with a bivalent inactivated heterologous vaccine containing both avian influenza subtypes H5 and H7 authorised by that Member State in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.

2. Portugal shall ensure that surveillance and laboratory testing of the holding keeping the vaccinated mallard ducks and in unvaccinated poultry holdings, as set out in the preventive vaccination plan, is carried out.

([1]) OJ L 311, 28.11.2001, p. 1.
([2]) OJ L 136, 30.4.2004, p. 1.
([3]) OJ L 246, 8.9.2006, p. 12.

3. Portugal shall ensure that the preventive vaccination plan is implemented efficiently.

Article 4

Marking and restrictions on the movement and dispatch and disposal of vaccinated mallard ducks

The competent authority shall ensure that vaccinated mallard ducks on the holding referred to in Article 2(1) are:

(a) marked individually;

(b) not moved to other poultry holdings within Portugal or dispatched to other Member States.

After their reproductive period, such ducks shall be killed humanely on the holding referred to in Article 2(1) and their carcases safely disposed of.

Article 5

Restrictions on the movement and dispatch of hatching eggs originating from the holding referred to in Article 2(1)

The competent authority shall ensure that hatching eggs originating from mallard ducks on the holding referred to in Article 2(1) may only be moved to a hatchery within Portugal and not dispatched to other Member States.

Article 6

Restrictions on the movement and dispatch of mallard ducks derived from vaccinated mallard ducks

1. The competent authority shall ensure that mallard ducks derived from vaccinated mallard ducks may only be moved after hatching to a holding located in a surrounding area established in Portugal in relation to the holding referred to in Article 2(1) as set out in the preventive vaccination plan.

2. By way of derogation from paragraph 1 and provided that the mallard ducks derived from vaccinated mallard ducks are more than four month old, they may be:

(a) released into the wild in Portugal; or

(b) dispatched to other Member States provided that:

(i) the results of the surveillance and laboratory tests as set out in the preventive vaccination plan, are favourable; and

(ii) the conditions for dispatch of poultry for re-stocking supplies of wild game laid down in Decision 2006/605/EC are met.

Article 7

Health certification for intra-Community trade in mallard ducks derived from vaccinated mallard ducks

Portugal shall ensure that health certificates for intra-Community trade in poultry intended for re-stocking supplies of game referred to in Article 6(2)(b) include the following sentence:

'The animal health conditions of this consignment are in accordance with Decision 2008/838/EC (*).

(*) OJ L 299, 8.11.2008, p. 40.'.

Article 8

Reports

Portugal shall submit to the Commission a report on the implementation of the preventive vaccination plan within one month from the date of application of this Decision and give quarterly reports at the Standing Committee on the Food Chain and Animal Health thereafter.

Article 9

Repeal

Decision 2008/285/EC shall be repealed.

Article 10

Applicability

This Decision shall apply until 31 July 2009.

Article 11

Addressees

This Decision is addressed to the Portuguese Republic.

Done at Brussels, 3 November 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission