

COMMISSION IMPLEMENTING DECISION (EU) 2015/892**of 9 June 2015****concerning the approval of a plan for preventive vaccination against low pathogenic avian influenza in a holding keeping mallard ducks in Portugal and certain measures restricting the movements of such poultry and their products***(notified under document C(2015) 3745)***(Only the Portuguese text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 provides that Member States are to ensure that vaccination against avian influenza is prohibited on their territory, except where emergency vaccination or preventive vaccination is carried out pursuant to the conditions laid down in the relevant sections of Chapter IX of that Directive.
- (2) Section 3 of Chapter IX of Directive 2005/94/EC provides that Member States may introduce preventive vaccination in poultry or other captive birds as a long-term measure to control that disease where, on the basis of a risk assessment, they deem that certain parts of their territory, types of poultry husbandry or certain categories of poultry or other captive birds are exposed to the risk of avian influenza.
- (3) In accordance with Article 52(1)(c) of that Directive, only vaccines authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council ⁽²⁾ or Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽³⁾ are to be used for vaccination of poultry or other captive birds against avian influenza.
- (4) Low pathogenic avian influenza has been eradicated in Portugal. However, according to the results of a risk assessment, high value mallard breeding ducks kept in one holding located in Vila Nova da Barquinha in the region of Lisboa e Vale do Tejo, Ribatejo Norte, are still exposed to the potential risk of avian influenza infection, due to possible indirect contact with wild birds.
- (5) Therefore, Portugal submitted to the Commission for approval successive plans for preventive vaccination against low pathogenic avian influenza, the most recent of which was approved by Commission Implementing Decision 2013/651/EU ⁽⁴⁾ and implemented by Portugal until 31 July 2014.
- (6) As provided for by that Implementing Decision, Portugal submitted a report on the implementation of that plan to the Standing Committee on Plants, Animals, Food and Feed. That report demonstrated that virus circulation was successfully prevented in the vaccinated mallard flocks as well as in poultry holdings located in the surrounding area.
- (7) Scientific opinions of the European Food Safety Authority in 2005 ⁽⁵⁾, 2007 ⁽⁶⁾ and 2008 ⁽⁷⁾ have confirmed that preventive vaccination is a valuable tool to complement control measures for avian influenza.

⁽¹⁾ OJ L 10, 14.1.2006, p. 16.

⁽²⁾ 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 (OJ L 311, 28.11.2001, p. 1).

⁽³⁾ 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 (OJ L 136, 30.4.2004, p. 1).

⁽⁴⁾ Commission Implementing Decision 2013/651/EU of 8 November 2013 approving a preventive vaccination plan against low pathogenic avian influenza in a holding keeping mallard ducks in Portugal and certain provisions for their movements and products thereof (OJ L 302, 13.11.2013, p. 53).

⁽⁵⁾ Scientific Opinion on Animal health and welfare aspects of Avian Influenza (The EFSA Journal (2005) 266, 1-21).

⁽⁶⁾ Scientific Opinion on Vaccination against avian influenza of H5 and H7 subtypes in domestic poultry and captive birds (The EFSA Journal (2007) 489).

⁽⁷⁾ Scientific Opinion on Animal health and welfare aspects of avian influenza and the risks of its introduction into the EU poultry holdings (The EFSA Journal (2008) 715, 1-161).

- (8) On 1 February 2015, Portugal submitted a new plan for preventive vaccination against low pathogenic avian influenza to the Commission for approval. That plan is to be applied until 31 December 2020 ('the preventive vaccination plan').
- (9) Considering the epidemiological situation as regards low pathogenic avian influenza in Portugal, the risk associated with the type of holding concerned and the limited scope of the preventive vaccination plan, that plan should be approved and implemented until 31 December 2020.
- (10) In addition, in order to detect a potential silent virus circulation in vaccinated mallard ducks, surveillance and laboratory testing in the holding keeping the vaccinated mallard ducks and unvaccinated sentinel ducks should be carried out as set out in the preventive vaccination plan.
- (11) It is also appropriate to introduce certain restrictions on the movement and dispatch of vaccinated mallard ducks, their hatching eggs and mallard ducks derived from such ducks 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 mallard ducks should not be moved from that holding, but killed after the end of their reproductive cycle in accordance with Article 18 of Council Regulation (EC) No 1099/2009 ⁽¹⁾ and safely disposed of in accordance with the requirements set out in Commission Regulation (EU) No 142/2011 ⁽²⁾.
- (12) Portugal has taken additional measures pursuant to Commission Decision 2006/605/EC ⁽³⁾ for trade in poultry intended for restocking supplies of game.
- (13) To reduce the economic impact on the holding concerned, certain derogations from movement restrictions for mallard ducks derived from vaccinated parent mallard ducks should be allowed provided that such movements do not increase the risk for the spread of avian influenza and provided that official surveillance is carried out and that the specific animal health requirements for trade within the Union are complied with.
- (14) In order for the Commission and other Member States to monitor the implementation of the preventive vaccination plan by Portugal, it is appropriate for Portugal to provide regular updates to the Standing Committee on Plants, Animals, Food and Feed.
- (15) Given that the plan should be approved for several years, Portugal might need to make certain adjustments to the preventive vaccination plan, such as the number of mallards to be vaccinated or the type of vaccine to be used, as well as a premature ending of vaccination. The present Decision should therefore foresee an obligation for Portugal to inform the Commission of such planned adjustments to which the Commission may either agree to without a necessary reapproval of the plan or for which a new approval procedure should be required.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter and scope

1. This Decision lays down certain measures to be applied in Portugal in one holding in the municipality of Vila Nova da Barquinha, region of Lisboa e Vale do Tejo, Ribatejo Norte, where preventive vaccination of mallard ducks (*Anas platyrhynchos*) intended for restocking supplies of game ('mallard ducks') is carried out and which is exposed to the risk of the introduction of the avian influenza virus.

⁽¹⁾ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (OJ L 303, 18.11.2009, p. 1).

⁽²⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

⁽³⁾ 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 (OJ L 246, 8.9.2006, p. 12).

Those measures include:

- (a) certain restrictions on the movement within and dispatch from Portugal of the vaccinated mallard ducks, their hatching eggs and mallard ducks derived therefrom;
- (b) the disposal of vaccinated mallard ducks.

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 plan for preventive vaccination

1. The plan for preventive vaccination against low pathogenic avian influenza in Portugal, as submitted by Portugal to the Commission on 1 February 2015, to be implemented on the holding referred to in Article 1(1) until 31 December 2020 ('the preventive vaccination plan') is approved.
2. The Commission shall publish the preventive vaccination plan on its website.

Article 3

Conditions for implementing the preventive vaccination plan

1. Portugal shall ensure that the preventive vaccination plan is implemented by using a monovalent inactivated vaccine containing the avian influenza subtype H5 authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004.
2. Portugal shall ensure that the preventive vaccination plan is implemented as notified.

Article 4

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

Portugal shall ensure that vaccinated mallard ducks on the holding referred to in Article 1(1) are:

- (a) marked individually;
- (b) not moved to other poultry holdings within Portugal;
- (c) not dispatched from Portugal.

After their reproductive period, those mallard ducks shall be killed on the holding referred to in Article 1(1) of this Decision in accordance with the requirements of Article 18 of Regulation (EC) No 1099/2009, and their carcasses shall be safely disposed of in accordance with the requirements of Regulation (EU) No 142/2011.

Article 5

Restrictions on the movement and dispatch of hatching eggs derived from mallard ducks on the holding referred to in Article 1(1)

Portugal shall ensure that hatching eggs derived from mallard ducks on the holding referred to in Article 1(1):

- (a) are only moved to a hatchery in Portugal;
- (b) are not dispatched from Portugal.

*Article 6***Restrictions on the movement and dispatch of mallard ducks derived from vaccinated mallard ducks**

1. Portugal shall ensure that mallard ducks derived from the vaccinated parent mallard ducks are only moved after hatching from the holding referred to in Article 1(1) to a holding located in a surrounding area as established and identified by Portugal in the preventive vaccination plan.
2. By way of derogation from paragraph 1, mallard ducks derived from vaccinated parent mallard ducks and provided they are older than four months may be:
 - (a) released into the wild in Portugal; or
 - (b) dispatched from Portugal provided that:
 - (i) the results of the surveillance and laboratory tests as set out in the preventive vaccination plan, are favourable;
 - (ii) the conditions for dispatch of poultry for restocking supplies of wild game laid down in Decision 2006/605/EC are met.

*Article 7***Health certification for trade within the Union in mallard ducks derived from vaccinated parent mallard ducks**

Portugal shall ensure that health certificates for intra-Union trade in poultry intended for restocking supplies of game accompanying the mallard ducks dispatched pursuant to Article 6(2)(b) include the following sentence:

'The animal health conditions of this consignment are in accordance with Commission Implementing Decision (EU) 2015/892 (*).

(*) OJ L 146, 11.6.2015, p. 11.'

*Article 8***Reports and information**

1. Portugal shall submit to the Commission a report on the implementation of the preventive vaccination plan within one month from the date of notification of this Decision and report annually thereafter at the meeting of the Standing Committee on Plants, Animals, Food and Feed.
2. Portugal shall inform the Commission of the following:
 - (a) planned amendments to the preventive vaccination plan whose approval is provided for in Article 2;
 - (b) the date of ending of preventive vaccination on the holding referred to in Article 1(1).
3. The Commission must examine the amendments proposed by Portugal and shall:
 - (a) either agree to the proposed amendments to the preventive plan approved according to Article 2;
 - (b) or foresee a new approval procedure for the amended preventive vaccination plan.

*Article 9***Applicability**

This Decision shall apply until 31 December 2020.

Article 10

Addressee

This Decision is addressed to the Portuguese Republic.

Done at Brussels, 9 June 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission
