



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
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final

Draft

COMMISSION DECISION

of

on introducing preventive vaccination against highly pathogenic avian influenza and related provisions for movements in the Netherlands

(Memorandum from Mr. Markos KYPRIANOU)

Draft

COMMISSION DECISION

of

on introducing preventive vaccination against highly pathogenic avian influenza and related provisions for movements in the Netherlands

(Only the Dutch text is authentic)

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/EEC¹, and in particular, Article 57(2) thereof;

Whereas:

- (1) Avian influenza is an infectious viral disease in poultry and other birds, causing mortality and disturbances which can quickly take epizootic proportions liable to present a serious threat to animal health and under certain circumstances to human health and also to reduce the profitability of poultry farming.
- (2) The highly pathogenic avian influenza A virus of subtype H5N1 has been isolated from poultry and wild birds in certain parts of the Community and in third countries. The likelihood of the spread of that virus to poultry flocks, in particular by wild birds, is increasing within the Community.
- (3) Early detection systems and biosecurity measures to reduce the risk of transmission of avian influenza to poultry flocks are in place in the whole territory of the Netherlands.
- (4) In its scientific opinions on avian influenza with respect to animal health and welfare aspects, the role of wild birds in the spread of avian influenza and on vaccination of poultry, captive birds and zoo birds against avian influenza, the Animal Health and Welfare Panel of the European Food Safety Authority (EFSA) recommended that preventive vaccination can be considered, if a high risk of virus introduction is identified in particular in densely populated poultry areas.

¹ OJ L 10, 14.1.2006, p. 16.

- (5) In addition, EFSA states that during an avian influenza epidemic there is always a significant risk that hobby and pet birds are hidden and constitute an ongoing risk of infection. This eventuality should be considered, and instead of the mass culling of such birds, a policy of increased surveillance and biosecurity may be recommended. Quarantine and preventive vaccination may also be considered as options for these types of birds. However, such a practice should not jeopardise the strict biosecurity and other measures that should be in force in such areas aimed at eradicating any introduction of the virus. In particular, preventive vaccination may be applied in flocks in which the general flock management systems that are used preclude birds being permanently housed indoors or sufficiently protected against contacts with wild birds.
- (6) Commission Decision 2006/147/EC of 24 February 2006 on introducing preventive vaccination against highly pathogenic avian influenza H5N1 and related provisions for movements in the Netherlands² approved the plan for preventive vaccination against highly pathogenic avian influenza H5N1, as submitted by the Netherlands to the Commission on 21 February 2006, and the amendments thereto, including the continuation of that plan until 31 July 2007 ('the preventive vaccination plan'). It provides for certain measures to be applied in the Netherlands where preventive vaccination is carried out in certain poultry holdings at particular risk for the introduction of infection by that disease, including movement restrictions on vaccinated poultry.
- (7) Given the experience gained with preventive vaccination under field conditions during the implementation of the preventive vaccination plan, it is appropriate to continue this pilot project in order to obtain further insight into the development and levels of bird immunity under a controlled setting.
- (8) For that purpose, the Netherlands submitted on 29 June 2007 an updated preventive vaccination plan which is to be applied until 31 July 2009. The Commission examined that updated plan in collaboration with the Netherlands and considers that, subject to certain adaptations, it complies with the relevant Community animal health legislation. Accordingly, the updated preventive vaccination plan should be approved.
- (9) 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 products³ 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 Agency⁴ should be used.

² OJ L 55, 25.2.2006, p. 47. Decision as amended by Decision 2006/528/EC (OJ L 208, 29.7.2006, p. 39).

³ 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).

⁴ 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).

- (10) Where preventive vaccination is carried out in the Netherlands, monitoring of vaccinated and unvaccinated poultry flocks and movement restrictions for vaccinated birds should be implemented in order to prevent the eventual virus circulation in vaccinated flocks, if exposed to field virus.
- (11) In addition, certain restrictions should be placed on the movement of poultry and products thereof concerned by the preventive vaccination measures provided for in this Decision. Such restrictions should take into account the rules laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁵, Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁶ and Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption⁷.
- (12) In the interests of clarity of Community legislation, Decision 2006/147/EC should be repealed.
- (13) 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 certain measures to be applied in the Netherlands where preventive vaccination is carried out in certain poultry holdings at particular risk for introduction of avian influenza, including movement restrictions on vaccinated poultry and certain products derived thereof.

Article 2
Definitions

For the purpose of this Decision, the definitions laid down in Article 2 of Directive 2005/94/EC shall apply.

The following definitions shall also apply:

- (a) ‘backyard poultry’ means chickens, turkeys and other species belonging to the *Galliformes* order and ducks, geese and other species belonging to the *Anseriformes* order which are kept by their owners:

⁵ OJ L139, 30.4.2004, p. 1; corrected version (OJ L 226, 25.6.2004, p. 3).

⁶ OJ L 139, 30.4.2004, p. 55; corrected version (OJ L 226, 25.6.2004, p. 22). Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

⁷ OJ L 139, 30.4.2004, p. 206; corrected version (OJ L 226, 25.6.2004, p. 83) Regulation as last amended by Regulation (EC) No 1791/2006.

- (i) for their own consumption or use; or
 - (ii) as pets.
- (b) ‘organic’ and ‘free range layers’ means:
- (i) laying hens as defined in Article 2(2)(a) of Council Directive 1999/74/EC⁸; and
 - (ii) which have access to open runs.

Article 3

Approval of the vaccination programme

1. The plan for preventive vaccination against highly pathogenic avian influenza, as submitted by the Netherlands to the Commission on 29 June 2007, to be implemented until 31 July 2009, (‘the preventive vaccination plan’) is approved.
2. The Commission shall publish the preventive vaccination plan.

Article 4

Conditions for implementing the preventive vaccination plan

1. The Netherlands shall ensure that the preventive vaccination of backyard poultry and organic and free range layers is carried out in accordance with the preventive vaccination plan with an inactivated heterologous vaccine of avian influenza subtype H5 or with a bivalent inactivated heterologous vaccine containing both avian influenza subtypes H5 and H7 authorised by that Member State or the Community in accordance with Directive 2001/82/EC or Regulation No 726/2004.
2. The Netherlands shall ensure that intensive monitoring and surveillance, as set out in the preventive vaccination plan is carried out in the backyard poultry and flocks of organic or free range layers where preventive vaccination is carried out.
3. The Netherlands shall ensure that the preventive vaccination plan is implemented efficiently.

⁸ OJ L 203, 3.8.1999, p. 53.

Article 5

Restrictions on movements and dispatch of backyard poultry, including day-old chicks and hatching eggs derived from such poultry

1. The competent authority shall ensure that no poultry, including day-old chicks and hatching eggs, derived from such poultry and originating from backyard poultry holdings where vaccination is carried out, may be moved to other poultry holdings within the Netherlands or dispatched to another Member State.
2. By way of derogation from paragraph 1, and provided that they are individually identified, backyard poultry may be moved to other holdings of backyard poultry or temporarily gathered for shows and exhibitions:
 - (a) within the Netherlands;
 - (b) in another Member State following the agreement of the Member State of destination.

Any such movements or gatherings must be in accordance with the preventive vaccination plan, including the maintenance of records of such movements and gatherings.

Article 6

Restrictions on movements of organic and free range layers

The competent authority shall ensure that organic and free range layers from holdings where preventive vaccination is carried out are only moved:

- (a) to other holdings where preventive vaccination is carried out within the Netherlands;
- (b) to a slaughterhouse for immediate slaughter within the Netherlands; or
- (c) to a slaughterhouse in another Member State for immediate slaughter following the agreement of the Member State of destination.

Article 7

Health certification for intra-Community trade in poultry, day-old chicks and hatching eggs

1. The Netherlands shall ensure that health certificates for intra-Community trade in poultry, day-old chicks and hatching eggs from the Netherlands referred to in Articles 5 (2) and 6 (c) include the words:

"Poultry/day-old chicks/hatching eggs* in compliance with the rules laid down in Decision 2007/xxx/EC^A and vaccinated/derived from poultry vaccinated* against avian influenza on.....(date) with vaccine.....(name)."

^A Reference to this decision.

2. The Netherlands shall ensure that health certificates for intra-Community trade in poultry, day-old chicks and hatching eggs other than those referred to in paragraph (1) from the Netherlands include the words:

"The consignment consists of poultry/day-old chicks/hatching eggs* originating from holdings where no vaccination against avian influenza has been carried out."

* Keep as appropriate.

Article 8
Restrictions on the dispatch of table eggs

The competent authority shall ensure that table eggs that originate from and/or come from holdings where organic and free range layers are kept and in which preventive vaccination is carried out are only dispatched to other Member States subject to compliance with the following conditions:

- (a) the table eggs are derived from poultry which originate from holdings which have been regularly inspected and tested with negative results for highly pathogenic avian influenza in accordance with the preventive vaccination plan, with particular attention being paid to sentinel birds; and
- (b) the table eggs are directly transported:
 - (i) to a packing centre designated by the competent authority and that they are packed in disposable packaging or in containers, trays and other non-disposable equipment, which must be cleaned and disinfected before and after each use in accordance with the instructions and biosecurity measures required by the competent authority; or
 - (ii) to an establishment for the manufacture of egg products as set out in Chapter II of Section X of Annex III to Regulation (EC) No 853/2004 to be handled and treated in accordance with Chapter XI of Annex II to Regulation (EC) No 852/2004.

Article 9
Restrictions on the dispatch of meat, minced meat, meat preparations, mechanically separated meat and meat products derived from vaccinated organic and free range layers

1. The competent authority shall ensure that meat, minced meat, meat preparations, mechanically separated meat and meat products derived from vaccinated organic and free range layer flocks is only dispatched to other Member States subject to compliance with the following conditions:

- (a) it is derived from poultry which:
 - (i) originate from flocks which have been regularly inspected and tested with negative results for highly pathogenic avian influenza in accordance with the preventive vaccination plan with particular attention being paid to sentinel birds;
 - (ii) originate from flocks which have been clinically inspected by an official veterinarian within 48 hours before the time of loading, with particular attention being paid to sentinel birds;
 - (iii) are kept separated from other flocks which do not comply with the provisions of (i) and (ii) above; and
 - (b) it has been produced in accordance with Annex II and Sections II and III of Annex III to Regulation (EC) No 853/2004 and controlled in accordance with Sections I, II, III, and Chapters V and VII of Section IV of Annex I to Regulation (EC) No 854/2004.
2. The competent authority shall ensure that minced meat, meat preparations, mechanically separated meat and meat products containing meat derived from vaccinated organic and free range layer flocks is only dispatched to other Member States if such meat, preparations or products comply with paragraph 1 and are produced in accordance with Sections V and VI of Annex III to Regulation (EC) No 853/2004.

Article 10
Reports

The Netherlands 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.

Article 11
Repeal

Decision 2006/147/EC is repealed.

Article 12
Addresses

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission