

Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC

CHAPTER IX

VACCINATION

SECTION 1

General prohibition of vaccination

Article 52

Manufacture, sale and use of avian influenza vaccines

- 1 Member States shall ensure that:
 - a vaccination against avian influenza is prohibited on their territory, except as provided for in Sections 2 and 3;
 - b the handling, manufacture, storage, supply, distribution and sale of avian influenza vaccines on their territory are carried out under official supervision;
 - c 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 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⁾ are used.
- 2 Rules relating to the conditions of supply and storage of stocks of avian influenza vaccines in the Community may be adopted in accordance with the procedure referred to in Article 64(2).

SECTION 2

Emergency vaccination

Article 53

Emergency vaccination in poultry or other captive birds

- 1 A Member state may introduce emergency vaccination in poultry or other captive birds as a short term measure to contain an outbreak when a risk assessment indicates there is a significant and immediate threat of avian influenza spreading within or into the Member State concerned in accordance with this Section where there is one or more of the following:
 - a an outbreak within that Member State;
 - b an outbreak in a nearby Member State; or
 - c where avian influenza has been confirmed in poultry or other captive birds in a nearby third country.

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2 Where a Member State intends to introduce emergency vaccination, as provided for in paragraph 1, it shall submit an emergency vaccination plan to the Commission for its approval.

That plan shall be in accordance with a DIVA strategy and contain at least the following information:

- a the disease situation which has led to the application for emergency vaccination;
- b the geographical area in which emergency vaccination is to be carried out and the number of holdings in that area and the number of holdings to be vaccinated if different;
- c the species and categories of poultry or other captive birds or, if appropriate, the poultry or other captive birds compartment to be vaccinated;
- d the approximate number of poultry or other captive birds to be vaccinated;
- e the summary of the vaccine characteristics;
- f the envisaged duration of the emergency vaccination campaign;
- g the specific provisions on the movements of vaccinated poultry or other captive birds which shall be without prejudice to the measures provided for in Sections 3, 4 and 5 of Chapter IV and Section 3 of Chapter V;
- h the criteria for deciding if emergency vaccination is to be applied in contact holdings;
- i the record keeping and registration of the vaccinated poultry or other captive birds;
- j clinical and laboratory tests to be carried out in the holdings where emergency vaccination is to be carried out and in other holdings located in the emergency vaccination area in order to monitor the epidemiological situation, the effectiveness of the emergency vaccination campaign and the control of movements of vaccinated poultry or other captive birds.

3 Detailed rules for emergency vaccination may be established in accordance with the procedure referred to in Article 64(2).

Article 54

Approval of emergency vaccination plans

1 The Commission shall immediately examine the emergency vaccination plan, as provided for in Article 53(2), together with the Member State concerned and shall review the situation in the Committee as soon as possible.

2 The emergency vaccination plan shall be approved in accordance with the procedure referred to in Article 64(3).

The approval of the emergency vaccination plan may include measures restricting the movements of poultry or other captive birds and their products. Those measures may include restrictions concerning specific poultry compartments and other captive birds compartments and the establishment of restricted zones.

Article 55

Derogations

1 By way of derogation from Article 54, Member States may apply emergency vaccination before approval of the emergency vaccination plan, subject to the following conditions:

- a the Commission is notified of the emergency vaccination plan and the decision to apply emergency vaccination before the commencement of the emergency vaccination;
 - b the Member State concerned prohibits the movement of poultry or other captive birds and their products except under the conditions provided for in Annex IX;
 - c the decision to apply emergency vaccination does not endanger disease control.
- 2 When a Member State applies the derogation provided for in paragraph 1, the disease situation and the emergency vaccination plan shall be reviewed in the Committee as soon as possible.
- 3 The measures applied may be approved or changed in accordance with the procedure referred to in Article 64(3).

SECTION 3

Preventive vaccination

Article 56

Preventive vaccination in poultry or other captive birds

1 Member States may introduce preventive vaccination in poultry or other captive birds as a long term measure in accordance with this Section where they deem that on the basis of a risk assessment certain areas of their territory, type of poultry husbandry or certain categories of poultry or other captive birds or the poultry or other captive birds compartments are exposed to the risk of avian influenza.

2 Where a Member State intends to introduce preventive vaccination, as provided for in paragraph 1, it shall submit a preventive vaccination plan to the Commission for its approval.

That plan shall be in accordance with a DIVA strategy and contain at least the following information:

- a a clear description of the reasons for the preventive vaccination, including the disease history;
- b the area, type of poultry husbandry or certain categories of poultry or other captive birds or the poultry or other captive birds compartments in which the preventive vaccination is to be carried out and the number of holdings in that area and the number and type of holdings to be vaccinated if different;
- c the species and categories of poultry or other captive birds or, if appropriate, the poultry or other captive birds compartment to be vaccinated;
- d the approximate number of poultry or other captive birds to be vaccinated;
- e a summary of the vaccine characteristics;
- f the envisaged duration of the preventive vaccination campaign;
- g the specific provisions on the movements of vaccinated poultry or other captive birds which shall be without prejudice to the measures provided for in Sections 3, 4 and 5 of Chapter IV and Section 3 of Chapter V;
- h the record keeping and registration of the vaccinated poultry or other captive birds;
- i the laboratory tests to be carried out in accordance with the Diagnostic Manual in the holdings where preventive vaccination is to be carried out at the same time as surveillance and testing in an appropriate number of other holdings located in the vaccination area or the poultry or other captive birds compartments in order to monitor

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the epidemiological situation, the effectiveness of the preventive vaccination campaign and the control of movements of vaccinated poultry or other captive birds.

3 Detailed rules for preventive vaccination may be established in accordance with the procedure referred to in Article 64(2).

Article 57

Approval of preventive vaccination plan

1 The Commission shall immediately examine the preventive vaccination plan provided for in Article 56(2), together with the Member State concerned and shall review the situation in the Committee as soon as possible.

2 The preventive vaccination plan shall be approved in accordance with the procedure referred to in Article 64(3).

The approval of the preventive vaccination plan may include measures restricting the movements of poultry or other captive birds and their products. Those measures may include restrictions concerning specific poultry compartments and other captive birds compartments and the establishment of restricted zones.

SECTION 4

Vaccine banks

Article 58

Community vaccine bank

1 A Community vaccine bank for the storage of Community reserves of avian influenza vaccines authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may be established in accordance with the procedure referred to in Article 64(2).

2 Member States shall have access to the Community vaccine bank on request to the Commission.

3 Where it is in the interest of the Community, the Commission may supply vaccines to third countries.

Without prejudice to agreements concluded between the Community and third countries, the access of third countries to the Community vaccine bank shall be authorised in accordance with the procedure referred to in Article 64(3), subject to detailed arrangements between the Commission and the third country concerned on the financial and technical cooperation to be adopted in accordance with that procedure.

Article 59

National vaccine banks

1 Member States may, within the framework of the contingency plan provided for in Article 62, establish or maintain a national vaccine bank for storage of reserves of avian

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influenza vaccines authorised in accordance with Article 5 to Article 15 of Directive 2001/82/EC, to be used for emergency or preventive vaccination.

2 Member States maintaining a national vaccine bank shall inform the Commission of the quantities and types of the stored vaccines.

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- (1) [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](#)).
- (2) [OJ L 136, 30.4.2004, p. 1](#).