

Exhibit EU-11

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

THE COUNCIL OF THE EUROPEAN UNION,

of poultry on a scale, which can threaten in particular the profitability of poultry farming as a whole.

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

(5) Community measures for the control of avian influenza were established by Council Directive 92/40/EEC of 19 May 1992 introducing Community measures for the control of avian influenza ⁽³⁾, in order to ensure the protection of animal health and contribute to the development of the poultry sector.

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament ⁽¹⁾,

(6) The measures laid down in Directive 92/40/EEC should be fundamentally reviewed in the light of recent scientific knowledge on the risks of avian influenza for animal and public health, development of new laboratory tests and vaccines and the lessons learnt during recent outbreaks of this disease in the Community as well as in third countries.

Having regard to the Opinion of the European Economic and Social Committee ⁽²⁾,

After consulting the Committee of the Regions,

Whereas:

(7) The new Community measures should also take account of the most recent opinions delivered by the Scientific Committee on Animal Health and Animal Welfare and by the European Food Safety Authority (EFSA) and the changes in the Terrestrial Animal Health Code and the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the International Office of Epizootics (O.I.E.) on avian influenza.

(1) Avian influenza is a serious, highly contagious disease of poultry and other captive birds caused by different types of influenza viruses. Those viruses may also spread to mammals, in particular pigs, and humans.

(2) Since poultry is covered by live animals listed in Annex I to the Treaty, one of the Community's tasks in the veterinary field is to improve the health status of poultry, thereby facilitating trade in poultry and poultry products and ensuring the development of this sector. Furthermore, a high level of human health protection is to be ensured when defining and implementing Community policies and activities.

(8) Certain influenza viruses of avian origin may in some circumstances affect humans and may then pose a serious risk to public health. The provisions of this Directive, which aim at fighting the disease in farmed animals, could indirectly contribute to preventing public health problems. However, it is, at this stage, chiefly for the Member States to tackle such problems.

(3) Influenza viruses include a large number of different virus strains. The level of risks posed by the different strains of influenza viruses for animal and public health is very variable and to some extent unpredictable, due to rapid virus mutation and possible re-assortment of the genetic material between different strains.

(9) At Community level, the human health risks posed by influenza viruses are primarily dealt with by other actions and legal acts. These concern in particular the European Centre for Disease Prevention and Control (hereinafter referred to as 'ECDC'), established by Regulation (EC) No 851/2004 of the European Parliament and of the Council ⁽⁴⁾, the recommendations issued by the Commission on Community Influenza pandemic preparedness and response planning, the European Union Early Warning and Response System and the establishment of the European Influenza Surveillance Scheme.

(4) The infection with certain strains of influenza viruses of avian origin may trigger outbreaks in domestic birds of epizootic proportions, causing mortality and disturbances

⁽¹⁾ Opinion delivered on 1 December 2005 (not yet published in the Official Journal).

⁽²⁾ Opinion delivered on 28 September 2005 (not yet published in the Official Journal).

⁽³⁾ OJ L 167, 22.6.1992, p. 1. Directive as last amended by the 2003 Act of Accession.

⁽⁴⁾ OJ L 142, 30.4.2004, p. 1.

- (10) It is appropriate, however, for the Commission to assess together with ECDC whether further public health or workers' health and safety measures, complementing the animal health provisions of this Directive are needed at Community level to address the risks posed by certain influenza viruses of avian origin to humans and in particular for workers in contact with infected animals and to present any necessary legislative proposals.
- (11) Current knowledge indicates that the health risks posed by the so-called low pathogenic avian influenza viruses are inferior to the risks posed by highly pathogenic avian influenza viruses, which originate from a mutation of certain low pathogenic viruses.
- (12) Community legislation for the control of avian influenza should enable Member States to adopt disease control measures in a proportionate and flexible manner, taking into account the various levels of risk posed by different virus strains, the likely social and economic impact of the measures in question on the agriculture sector and other sectors involved while at the same time ensuring that the measures taken for each specific disease scenario are the most appropriate.
- (13) In view of the potential of low pathogenic avian influenza viruses to mutate into highly pathogenic avian influenza viruses, provision should be made for the early detection of infection in poultry aimed at a quick reaction and the adoption of appropriate and proportionate control and eradication measures which should include a system of active surveillance to be carried out by Member States. Such surveillance should follow general guidelines to be adapted in the light of further knowledge and developments in this field.
- (14) Any suspicion of avian influenza infection which may arise from clinical or laboratory investigations or any other reason that leads to the suspicion of the presence of infection should set in motion immediate official investigations so that prompt and effective action can be taken, as appropriate. Such action should be reinforced as soon as the presence of infection is confirmed to include depopulation of the holdings infected and of those which are at risk of infection.
- (15) In the case of detection of infection with low pathogenic avian influenza virus, control measures may differ from those which should apply in the case of detection of highly pathogenic avian influenza virus, taking into account the different levels of risk posed by these two conditions.
- (16) Disease control measures and in particular the establishment of restriction zones should also be modulated taking into account the density of the poultry population as well as other risk factors in the area in which the infection has been detected.
- (17) If an outbreak occurs, it is also necessary to prevent any further spread of infection by carefully monitoring and restricting movements of poultry and the use of products liable to be contaminated, by tightening biosecurity measures at all levels of poultry production, by cleansing and disinfecting the infected holding, by establishing protection and surveillance zones around the outbreak and, if necessary, by vaccination.
- (18) Community measures for the control of highly pathogenic avian influenza should be based first on the depopulation of the infected flocks, in accordance with Community legislation on animal welfare.
- (19) Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing ⁽⁵⁾ sets out the minimum standards for the protection of animals at the time of slaughter or killing including for the purpose of disease control. Such rules apply fully to slaughter or killing pursuant to this Directive.
- (20) Vaccination against avian influenza can be an effective tool to supplement disease control measures and to avoid massive killing and destruction of poultry or other captive birds. Current knowledge suggests that vaccination may be useful not only as a short-term measure in emergencies but also as a long-term measure to prevent disease in situations of higher risk of introduction of avian influenza viruses from wild life or other sources. Provisions should therefore be established for both emergency and preventive vaccination.
- (21) Vaccinated poultry, although protected against the clinical signs of disease, may become infected and thus contribute to the further spread of the infection. Vaccination must therefore be accompanied by appropriate surveillance and restriction measures established at Community level. Therefore, the vaccination strategy should allow differentiation between infected and vaccinated animals. Products of vaccinated poultry, such as meat and table eggs, should be then placed on the market in accordance with the relevant Community legislation, including this Directive.

⁽⁵⁾ OJ L 340, 31.12.1993, p. 21. Directive as last amended by Council Regulation (EC) No 1/2005 (OJ L 3, 5.1.2005, p. 1).

- (22) It should also be made possible for the Community and the Member States to establish reserves of vaccine against avian influenza to be used in poultry or other captive birds in the case of an emergency.
- (23) Provisions should be adopted to ensure that harmonised procedures and methods are used for the diagnosis of avian influenza, including the functioning of a Community reference laboratory as well as reference laboratories in Member States.
- (24) Provisions should be adopted to ensure the necessary level of preparation by Member States effectively to tackle emergency situations caused by one or more outbreaks of avian influenza, in particular by drawing up contingency plans and setting up control centres.
- (25) If avian influenza is detected during importation in a quarantine facility or centre, as provided for in Commission Decision 2000/666/EC of 16 October 2000 laying down the animal health requirements and the veterinary certification for the import of birds, other than poultry and the conditions for quarantine ⁽⁶⁾, this should be reported to the Commission. However, reporting as provided for by Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community ⁽⁷⁾, in cases of outbreaks in Member States would not be appropriate.
- (26) Cleansing and disinfection should be an integral part of the Community control policy for avian influenza. Disinfectants should be used in compliance with Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ⁽⁸⁾.
- (27) Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption ⁽⁹⁾ lays down the rules on the collection, transport, storage, handling, processing and use or disposal of animal by-products including animals killed to eradicate epizootic diseases, to prevent them from presenting a risk to animal and public health. That Regulation and its implementing measures provide for a general framework for the disposal of dead animals. Provision should be made for the adoption, by the committee procedure, of specific, additional or different measures where necessary to enhance further avian influenza control measures.
- (28) 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 origin ⁽¹⁰⁾ and Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽¹¹⁾ may be applied under certain conditions to eggs originating from holdings where poultry suspected of being infected with avian influenza is kept.
- (29) Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (30) Provision should be made for the possibility for amendments to be made to the Annexes to this Directive when necessary without delay in order to take account of developments in scientific and technical knowledge.
- (31) Taking into account the unpredictability of influenza viruses, it is appropriate to ensure that a swift procedure is also in place for a rapid adoption at Community level of additional or more specific measures to control any infection of poultry and other animal species whenever such measures are necessary.
- (32) This Directive should set out the minimum control measures to be applied in the event of an outbreak of avian influenza in poultry or other captive birds. However, Member States are free to take more stringent administrative and sanitary action in the field covered by this Directive. In addition, this Directive should provide for Member States' authorities to apply measures proportionate to the health risk posed by different disease situations.
- (33) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objectives of ensuring the development of the poultry sector and contributing to the protection of animal health, to lay down rules on specific measures and minimum measures aimed at the prevention and control of avian influenza. This Directive does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.

⁽⁶⁾ OJ L 278, 31.10.2000, p. 26. Decision as last amended by Decision 2002/279/EC (OJ L 99, 16.4.2002, p. 17).

⁽⁷⁾ OJ L 378, 31.12.1982, p. 58. Directive as last amended by Commission Decision 2004/216/EC (OJ L 67, 5.3.2004, p. 27).

⁽⁸⁾ OJ L 123, 24.4.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

⁽⁹⁾ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 416/2005 (OJ L 66, 12.3.2005, p. 10).

⁽¹⁰⁾ OJ L 139, 30.4.2004, p. 55. Corrected version in OJ L 226, 25.6.2004, p. 22.

⁽¹¹⁾ OJ L 139, 30.4.2004, p. 1. Corrected version in OJ L 226, 25.6.2004, p. 3.

(34) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹²⁾.

(35) In the interests of clarity and rationality of Community legislation, Directive 92/40/EEC should be repealed and replaced by this Directive.

(36) The Council, in accordance with point 34 of the Inter-Institutional Agreement on better law making ⁽¹³⁾, encourages Member States to draw up, for themselves and in the interest of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures and to make them public.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Directive sets out:
 - (a) 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;
 - (b) the minimum control measures to be applied in the event of an outbreak of avian influenza in poultry or other captive birds and the early detection of possible spread of avian influenza viruses to mammals;
 - (c) other subsidiary measures to avoid the spread of influenza viruses of avian origin to other species.
2. Member States shall remain free to take more stringent measures in the field covered by this Directive.

Article 2

Definitions

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

1. 'avian influenza' means any of the influenza infections so described in Annex I(1);
2. 'highly pathogenic avian influenza (HPAI)' means any of the avian influenza infections so described in Annex I(2);
3. 'low pathogenic avian influenza (LPAI)' means any of the avian influenza infections so described in Annex I(3);
4. 'poultry' means all birds that are reared or kept in captivity for the production of meat or eggs for consumption, the production of other products, for restocking supplies of game birds or for the purposes of any breeding programme for the production of these categories of birds;
5. 'wild bird' means a free-living bird which is not kept on any holding as defined in point 8;
6. 'other captive bird' means any bird other than poultry that is kept in captivity for any reason other than those referred to in point 4 including those that are kept for shows, races, exhibitions, competitions, breeding or selling;
7. 'officially registered rare breeds of poultry or other captive birds' means any poultry or other captive birds that the competent authority has officially recognised as a rare breed within their contingency plan provided for in Article 62;
8. 'holding' means any agricultural or other premises, including hatcheries, circuses, zoos, pet bird shops, bird markets, and aviaries, where poultry or other captive birds are being bred or kept. However, this definition does not include slaughterhouses, means of transport, quarantine facilities and centres, border inspection posts and laboratories authorised by the competent authority to hold avian influenza virus;
9. 'commercial poultry holding' means a holding where poultry are kept for commercial purposes;

⁽¹²⁾ OJ L 184, 17.7.1999, p. 23.

⁽¹³⁾ OJ C 321, 31.12.2003, p. 1.

10. 'non-commercial holding' means a holding where poultry or other captive birds are kept by their owners:
 - (a) for their own consumption or use; or
 - (b) as pets;
11. 'poultry compartment' or 'other captive birds compartment' means a holding or holdings under a common biosecurity management system containing a poultry or other captive birds sub-population with a distinct health status with respect to avian influenza subjected to appropriate surveillance, control and biosecurity measures;
12. 'flock' means all poultry or other captive birds within a single production unit;
13. 'production unit' means a unit on a holding which the official veterinarian is satisfied is completely independent of any other unit in the same holding in terms of its location and day-to-day management of the poultry or other captive birds kept there;
14. 'day-old chicks' means all poultry less than 72 hours old, not yet fed, and muscovy ducks (*Cairina moschata*) or their crosses, less than 72 hours old, whether or not fed;
15. 'diagnostic manual' means the diagnostic manual provided for in Article 50(1);
16. 'poultry or other captive birds suspected of being infected' means any poultry or other captive birds exhibiting clinical signs or showing post-mortem lesions or reactions to laboratory tests which are such that the presence of avian influenza cannot be excluded;
17. 'owner' means any person or persons, either natural or legal having ownership of poultry or other captive birds, or charged with keeping such, whether or not for commercial purposes;
18. 'competent authority' means the authority of a Member State competent to carry out physical checks or administrative formalities in accordance with this Directive or any authority to which such competencies are delegated;
19. 'official veterinarian' means the veterinarian designated by the competent authority;
20. 'official surveillance' means the action of careful monitoring by the competent authority of the health status of poultry or other captive birds or mammals on a holding in relation to avian influenza;
21. 'official supervision' means the actions taken by the competent authority to verify that the requirements of this Directive and of any instructions from that authority as to how those requirements should be met are being, or have been, complied with;
22. 'killing' means any process other than slaughter causing the death of a mammal, poultry or other captive birds;
23. 'slaughter' means any process causing the death of a mammal or poultry by bleeding, for the purpose of human consumption;
24. 'disposing of' means the act of collecting, transporting, storing, handling, processing and using or disposing of animal by-products in accordance with:
 - (a) Regulation (EC) No 1774/2002; or
 - (b) rules to be adopted under the procedure referred to in Article 64(2);
25. 'Community vaccine bank' means appropriate premises designated in accordance with Article 58(1) for the storage of Community reserves of avian influenza vaccines;
26. 'contact holding' means a holding where avian influenza could have come from or have been introduced to as a result of its location, the movement of persons, poultry or other captive birds, vehicles or in any other way;
27. 'suspected outbreak' means a holding where the competent authority suspects the presence of avian influenza;
28. 'outbreak' means a holding where avian influenza has been confirmed by the competent authority;

29. 'primary outbreak' means an outbreak not epidemiologically linked with a previous outbreak in the same region of a Member State as defined in Article 2(2), point (p), of Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine⁽¹⁴⁾ or the first outbreak in a different region of the same Member State;

30. 'Differentiating Infected from Vaccinated Animal (DIVA) strategy' means a vaccination strategy which enables a differentiation to be made between vaccinated/infected and vaccinated/non-infected animals through the application of a diagnostic test designed to detect antibodies against the field virus and the use of non-vaccinated sentinel birds;

31. 'mammal' means an animal of the class Mammalia, except humans;

32. 'carcase' means poultry or other captive birds which have died or have been killed and are unfit for human consumption, or parts thereof.

CHAPTER II

PREVENTIVE BIOSECURITY, SURVEILLANCE, NOTIFICATIONS AND EPIDEMIOLOGICAL INQUIRIES

Article 3

Preventive biosecurity measures

Specific provisions concerning preventive biosecurity measures may be established in accordance with the procedure referred to in Article 64(2).

Article 4

Surveillance programmes

1. Member States shall carry out surveillance programmes in order to:

- (a) detect the prevalence of infections with avian influenza virus subtypes H5 and H7 in different species of poultry;
- (b) contribute, on the basis of a regularly updated risk assessment, to the knowledge on the threats posed by wild birds in relation to any influenza virus of avian origin in birds.

2. The surveillance programmes referred to in paragraph 1(a) shall comply with guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 64(2).

Article 5

Notification

1. Member States shall ensure that the suspected presence and presence of avian influenza are compulsorily and immediately notified to the competent authority.

2. In addition to the requirements provided for in Community legislation on notification of outbreaks of animal diseases, Member States shall notify the Commission in accordance with Annex II of any avian influenza confirmed by the competent authority in slaughterhouses, means of transport, border inspection posts and other places at Community borders and quarantine facilities or centres operating in accordance with Community legislation on imports of poultry or other captive birds.

3. Member States shall notify the results of any surveillance for avian influenza virus carried out in mammals.

Article 6

Epidemiological inquiry

1. Member States shall ensure that epidemiological inquiries are started on the basis of questionnaires, established within the framework of the contingency plans provided for in Article 62.

2. The epidemiological inquiry shall include the following at least:

- (a) the length of time during which avian influenza may have been present on the holding or other premises or means of transport;
- (b) the possible origin of avian influenza;
- (c) the identification of any contact holding;
- (d) the movements of poultry, other captive birds, persons, mammals, vehicles or any material or other means by which the avian influenza virus could have spread.

⁽¹⁴⁾ OJ L 21, 29.7.1964, p. 1977. Directive as last amended by Regulation (EC) No 1/2005 (OJ L 3, 5.1.2005, p. 1).

3. The competent authority shall take account of the epidemiological inquiry when:

- (a) deciding whether additional disease control measures, as provided for in this Directive need to be applied; and
- (b) granting derogations as provided for in this Directive.

4. If the epidemiological inquiry suggests that avian influenza may have spread from or to other Member States, the Commission and the other Member States concerned shall be immediately informed of the results of all findings of the inquiry.

confined in some other place on the same holding such that they do not have contact with other poultry or other captive birds on other holdings. All reasonable steps are taken to minimise their contact with wild birds;

(d) no poultry or other captive birds may enter or leave the holding;

(e) no carcasses of poultry or other captive birds, meat of poultry including offal ('poultry meat'), poultry feed ('feed'), utensils, materials, waste, droppings, poultry or other captive birds manure ('manure'), slurry, used litter or anything likely to transmit avian influenza may leave the holding without an authorisation from the competent authority, observing appropriate biosecurity measures such as to minimise any risk of the spread of avian influenza;

(f) no eggs may leave the holding;

(g) the movement of persons, mammals of domestic species, vehicles and equipment to or from the holding is subject to the conditions and authorisation of the competent authority;

(h) appropriate means of disinfection are used at the entrances and exits of buildings housing poultry or other captive birds and of the holding itself in accordance with the instructions of the competent authority.

CHAPTER III

SUSPECTED OUTBREAKS

Article 7

Measures to be applied on holdings where outbreaks are suspected

1. In the case of a suspected outbreak, the competent authority shall immediately set in motion an investigation to confirm or exclude the presence of avian influenza in accordance with the diagnostic manual and place the holding under official surveillance. The competent authority shall also ensure that the measures provided for in paragraphs 2 and 3 are complied with.

2. The competent authority shall ensure that the following measures are applied on the holding:

(a) poultry, other captive birds and all mammals of domestic species are counted or, if appropriate, their numbers estimated by the type of poultry or species of other captive bird;

(b) a list is compiled of the approximate number of poultry, other captive birds and all mammals of domestic species already sick, dead or likely to be infected in each category on the holding; that list shall be updated daily to take account of hatchings, births and deaths throughout the period of the suspected outbreak and shall be produced on request to the competent authority;

(c) all poultry and other captive birds are brought inside a building on their holding and kept there. Where this is impractical or if their welfare is compromised they are

3. The competent authority shall ensure that an epidemiological inquiry is carried out in accordance with Article 6 ('the epidemiological inquiry').

4. Notwithstanding paragraph 1, the competent authority may provide for the submission of samples in other cases. In such circumstances the competent authority may proceed without adopting some or all of the measures referred in paragraph 2.

Article 8

Derogations from certain measures to be applied on holdings where outbreaks are suspected

1. The competent authority may grant derogations from the measures provided for in Article 7(2) points (c) to (e) on the basis of a risk assessment and taking into account the precautions taken and the destination of the birds and products to be moved.

2. The competent authority may also grant derogations from the measures provided for in Article 7(2), point (h) in the case of other captive birds kept on non-commercial holdings.

3. With reference to Article 7(2) point (f), the competent authority may authorise the sending of eggs:

(a) directly 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; where the competent authority issues such an authorisation, the latter shall be subject to the conditions set out in Annex III to this Directive; or

(b) for disposal.

Article 9

Duration of the measures to be applied on holdings where outbreaks are suspected

The measures to be applied on holdings in cases of suspected outbreaks, as provided for in Article 7, shall continue to be applied until the competent authority is satisfied that the suspicion of avian influenza on the holding has been ruled out.

Article 10

Additional measures based on an epidemiological inquiry

1. Based on the preliminary results of an epidemiological inquiry, the competent authority may apply the measures provided for in paragraphs 2, 3 and 4 in particular if the holding is located in an area with a high density of poultry.

2. Temporary restrictions may be introduced on the movements of poultry, other captive birds and eggs and the movement of vehicles used by the poultry sector in a defined area or in the whole of the Member State.

Such restrictions may be extended to movements of mammals of domestic species, but in that case shall not exceed 72 hours, unless justified.

3. The measures provided for in Article 11 may be applied to the holding.

However, if conditions permit, application of those measures may be limited to the poultry or other captive birds suspected of being infected and their production units.

Samples shall be taken from the poultry or other captive birds if they are killed in order for the risk of a suspected outbreak to be confirmed or excluded, in accordance with the diagnostic manual.

4. A temporary control zone around the holding may be established and some or all of the measures provided for in Article 7(2) shall be applied as necessary to the holdings within that zone.

CHAPTER IV

HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

SECTION 1

Holdings, separate production units and contact holdings

Article 11

Measures to be applied on holdings where outbreaks are confirmed

1. In case of an outbreak of HPAI, the competent authority shall ensure that the measures provided for in Article 7(2) and (3) and paragraphs 2 to 10 of this Article are applied.

2. All poultry and other captive birds on the holding shall be killed without delay under official supervision. The killing shall be carried out in such a way as to avoid the risk of spread of avian influenza, in particular during transport.

However, Member States may grant derogations for certain species of poultry or other captive birds not to be killed, on the basis of an assessment of the risk of further spread of avian influenza.

The competent authority may take appropriate measures to limit any possible spread of avian influenza to any wild birds on the holding.

3. All carcasses and eggs on the holding shall be disposed of under official supervision.

4. Poultry already hatched from eggs collected from the holding during the period between the probable date of introduction of HPAI on the holding and the application of the measures provided for in Article 7(2), shall be placed under official supervision and investigations shall be carried out in accordance with the diagnostic manual.

5. Meat of poultry slaughtered and eggs collected from the holding during the period between the probable date of introduction of HPAI on the holding and the application of the measures provided for in Article 7(2) shall, wherever possible, be traced and disposed of under official supervision.

6. All substances and waste likely to be contaminated, such as feed, shall be destroyed or undergo a treatment ensuring the destruction of the avian influenza virus, in accordance with the instructions of the official veterinarian.

7. However, manure, slurry and bedding likely to be contaminated shall undergo one or more of the procedures provided for in Article 48.

8. Following the disposal of carcasses, the buildings used for housing them, pastures or land, the equipment likely to be contaminated and the vehicles used for transporting the poultry or other captive birds, carcasses, meat, feed, manure, slurry, bedding and any other material or substance likely to be contaminated shall undergo one or more of the procedures provided for in Article 48.

9. Other captive birds or mammals of domestic species shall not enter or leave the holding without the authorisation of the competent authority. That restriction shall not apply to mammals of domestic species which have access only to the living areas for humans.

10. In the case of a primary outbreak, the virus isolate shall be subjected to the laboratory procedure in accordance with the diagnostic manual to identify the genetic subtype.

That virus isolate shall be submitted to the Community reference laboratory, as provided for in Article 51(1) as soon as possible.

Article 12

Derogations

1. Member States shall draw up detailed rules for granting derogations, as provided for in Articles 11(2), 13 and 14, including alternative appropriate measures and conditions. Such derogations shall be based on a risk assessment carried out by the competent authority.

2. Member States shall immediately notify the Commission of any derogation granted in accordance with Article 13(1) and Article 14.

3. Where a derogation has been granted, as provided for in Article 13(1) and Article 14, the Commission shall immediately review the situation with the Member State concerned and in the Standing Committee on the Food Chain and Animal Health ('the Committee') as soon as possible.

4. Taking account of any derogation granted, as provided for in Article 13(1) and Article 14, measures to prevent the spread of avian influenza may be adopted in accordance with the procedure referred to in Article 64(3).

Article 13

Derogations concerning certain holdings

1. The competent authority may grant derogations from the measures provided for in the first subparagraph of Article 11(2) in cases of an outbreak of HPAI in a non-commercial holding, a circus, a zoo, a pet bird shop, a wild life park, a fenced area where poultry or other captive birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other captive birds, provided that such derogations do not endanger disease control.

2. The competent authority shall ensure that where a derogation is granted, as provided for in paragraph 1, the poultry and other captive birds concerned by the derogation:

(a) are brought inside a building on their holding and kept there. Where this is impractical or if their welfare is compromised they are confined in some other place on the same holding such that they do not have contact with other poultry or other captive birds on other holdings. All reasonable steps are taken to minimise their contact with wild birds;

(b) are subjected to further surveillance and testing in accordance with the diagnostic manual and are not moved until the laboratory tests have indicated that they no longer pose a significant risk of further spread of HPAI; and

(c) are not moved from their holding of origin, except for slaughter or to another holding:

(i) located in the same Member State, in accordance with the instructions of the competent authority; or

(ii) in another Member State, subject to the agreement of the Member State of destination.

3. The competent authority may grant derogations from the measures provided for in Article 11(5), for eggs to be sent directly 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.

Any such authorisations shall be subject to the conditions set out in Annex III to this Directive.

Article 14

Measures to be applied in cases of outbreaks of HPAI in separate production units

In cases of an outbreak of HPAI in a holding which consists of two or more separate production units, the competent authority may grant derogations from the measures provided for in the first subparagraph of Article 11(2) for production units containing poultry or other captive birds where no HPAI is suspected, provided that such derogations do not endanger disease control.

Such derogations shall only be granted in respect of two or more separate production units where the official veterinarian, taking account of the structure, size, operation, type of housing, feeding, water source, equipment, staff and visitors to the holding, is satisfied that they are completely independent of other production units in terms of location and day-to-day management of the poultry or other captive birds kept there.

Article 15

Measures to be applied in contact holdings

1. Based on the epidemiological inquiry, the competent authority shall decide if a holding is to be considered as a contact holding.

The competent authority shall ensure that the measures provided for in Article 7(2) are applied to contact holdings until the presence of HPAI has been excluded in accordance with the diagnostic manual.

2. Based on the epidemiological inquiry, the competent authority may apply the measures provided for in Article 11 to contact holdings and in particular if the contact holding is located in an area with a high density of poultry.

The main criteria to be considered for the application of the measures provided for in Article 11 in contact holdings are set out in Annex IV.

3. The competent authority shall ensure that samples are taken from poultry and other captive birds when they are killed in order to confirm or exclude the presence of HPAI virus in those contact holdings in accordance with the diagnostic manual.

4. The competent authority shall ensure that, on any holding where poultry or other captive birds are killed and disposed of and avian influenza is subsequently confirmed, the buildings and any equipment likely to be contaminated and the vehicles used for transporting the poultry, other captive birds, carcasses, meat, feed, manure, slurry, bedding and any other material or substance likely to be contaminated undergo one or more of the procedures provided for in Article 48.

SECTION 2

Protection, surveillance and further restricted zones

Article 16

Establishment of protection, surveillance and further restricted zones in cases of outbreaks of HPAI

1. Immediately following an outbreak of HPAI, the competent authority shall establish:

- (a) a protection zone with a radius of at least three kilometres around the holding;
- (b) a surveillance zone with a radius of at least 10 kilometres around the holding, including the protection zone.

2. If the outbreak of HPAI is confirmed in other captive birds in a non-commercial holding, circus, zoo, pet bird shop, wildlife park, a fenced area where other captive birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of other captive birds that do not contain poultry, the competent authority may, following a risk assessment, derogate to the extent necessary from the provisions of Sections 2 to 4 concerning the establishment of the protection and surveillance zones and the measures to be applied therein, provided that such derogations do not endanger disease control.

3. When establishing protection and surveillance zones, as provided for in paragraph 1, the competent authority shall take account of the following criteria at least:

- (a) the epidemiological inquiry;
- (b) the geographical situation, particularly natural boundaries;

- (c) the location and proximity of holdings and the estimated number of poultry;
- (d) patterns of movements and trade in poultry, other captive birds;
- (e) the facilities and personnel available to control any movement within the protection and surveillance zones of poultry or other captive birds, their carcasses, manure, bedding or used litter, in particular if the poultry or other captive birds to be killed and disposed of have to be moved from their holding of origin.

4. The competent authority may establish further restricted zones around or adjacent to the protection and surveillance zones, taking account of the criteria provided for in paragraph 3.

5. If a protection, surveillance or further restricted zone covers the territories of different Member States, the competent authorities of the Member States concerned shall collaborate to establish the zone.

Article 17

Measures to be applied both in the protection and in the surveillance zones

1. The competent authority shall ensure that the following measures are applied within the protection and surveillance zones:

- (a) arrangements are put in place which permit the tracing of anything likely to spread the avian influenza virus including poultry, other captive birds, meat, eggs, carcasses, feed, litter, people who have been in contact with the infected poultry or other captive birds or vehicles with a link to the poultry industry;
- (b) owners are to provide the competent authority, on request, with any relevant information concerning the poultry or other captive birds and eggs entering or leaving the holding.

2. The competent authority shall take all reasonable steps to ensure that all persons in the protection and surveillance zones affected by the restrictions concerned are fully aware of the restrictions in place.

That information may be conveyed through warning notices, media resources such as the press and television or any other appropriate means.

3. The competent authority may, where epidemiological information or other evidence indicates, implement a preventive eradication programme, including preventive slaughtering or killing of poultry or other captive birds, in holdings and areas at risk.

4. Member States applying the measures provided for in paragraph 3 shall immediately inform the Commission thereof, and the Commission shall review the situation with the Member States concerned and in the Committee as soon as possible.

SECTION 3

Measures to be applied in protection zones

Article 18

Census and visits by the official veterinarian and surveillance

The competent authority shall ensure that the following measures are applied in protection zones:

- (a) a census of all the holdings is made as soon as possible;
- (b) all commercial holdings are visited by an official veterinarian as soon as possible for a clinical examination of the poultry and other captive birds and, if necessary, the collection of samples for laboratory tests in accordance with the diagnostic manual; a record of such visits and the findings thereof shall be kept; non-commercial holdings are visited by an official veterinarian before the lifting of the protection zone;
- (c) additional surveillance is immediately implemented in accordance with the diagnostic manual in order to identify any further spread of avian influenza in the holdings located in the protection zone.

Article 19

Measures to be applied on holdings in protection zones

The competent authority shall ensure that the following measures are applied on holdings in protection zones:

- (a) all poultry and other captive birds are brought inside a building on their holding and kept there. Where this is impractical or if their welfare is compromised, they are confined in some other place on the same holding such that they do not have contact with other poultry or other captive birds on other holdings. All reasonable steps are taken to minimise their contact with wild birds;

- (b) carcasses are disposed of as soon as possible;
- (c) vehicles and equipment used for transporting live poultry or other captive birds, meat, feed, manure, slurry and bedding and any other material or substances likely to be contaminated, undergo without delay one or more of the procedures provided for in Article 48;
- (d) all parts of vehicles used by staff or other persons which enter or leave holdings and are likely to have become contaminated undergo without delay one or more of the procedures provided for in Article 48;
- (e) no poultry, other captive birds or domestic mammals may enter or leave a holding without authorisation of the competent authority. This restriction shall not apply to mammals which have access only to the living areas for humans in which they:
 - (i) have no contact with resident poultry or other captive birds, and
 - (ii) have no access to any cages or areas where such resident poultry or other captive birds are kept;
- (f) any increased morbidity or mortality or significant drop in production data in holdings is immediately reported to the competent authority, which shall carry out appropriate investigations in accordance with the diagnostic manual;
- (g) any person entering or leaving holdings observes appropriate biosecurity measures aimed at preventing the spread of avian influenza;
- (h) records of all persons visiting holdings, except dwellings, are kept by the owner in order to facilitate disease surveillance and control and must be made available upon request by the competent authority. Such records do not have to be kept where the visitors are to holdings such as zoos and wildlife parks where they have no access to the areas where the birds are kept.

Article 20

Prohibition on the removal or spreading of used litter, manure or slurry from holdings

The competent authority shall ensure that the removal or spreading of used litter, manure or slurry from holdings in

protection zones are prohibited, unless authorised by it. However, the movement of manure or slurry may be authorised from holdings under biosecurity measures to a designated plant for treatment or for intermediate storage for subsequent treatment to destroy the possible presence of avian influenza viruses in accordance with Regulation (EC) No 1774/2002 or with specific rules which may be adopted in accordance with the procedure referred to in Article 64(2).

Article 21

Fairs, markets or other gatherings and restocking of game

The competent authority shall ensure that fairs, markets, shows or other gatherings of poultry or other captive birds are prohibited in protection zones.

The competent authority shall ensure that poultry or other captive birds for restocking of game are not released in protection zones.

Article 22

Prohibition on the movement and transport of birds, eggs, poultry meat and carcasses

1. The competent authority shall ensure that within protection zones, the movement and transport from holdings on to roads, excluding private service roads of holdings, or by rail, of poultry, other captive birds, ready-to-lay poultry, day-old chicks, eggs and carcasses are prohibited.

2. The competent authority shall ensure that the transport of poultry meat from slaughterhouses, cutting plants and cold stores is prohibited unless it has been produced:

- (a) from poultry which has originated from outside the protection zones and has been stored and transported separately from the meat of poultry from within the protection zones; or
- (b) on a date at least 21 days before the estimated date of earliest infection on a holding in the protection zone and which since production has been stored and transported separately from such meat produced after that date.

3. However, the prohibitions in paragraphs 1 and 2 shall not apply to transit through the protection zone on roads or rail without unloading or stopping.

*Article 23***Derogations for the direct transport of poultry for immediate slaughter and the movement or treatment of poultry meat**

1. By way of derogation from Article 22, the competent authority may authorise the direct transport of poultry originating from a holding in the protection zone for immediate slaughter to a designated slaughterhouse subject to the following conditions:

- (a) a clinical examination of the poultry on the holding of origin is carried out by the official veterinarian within 24 hours of being sent for slaughter;
- (b) where appropriate, laboratory tests have been carried out on poultry on the holding of origin in accordance with the diagnostic manual, with favourable results;
- (c) the poultry are transported in vehicles sealed by the competent authority or under its supervision;
- (d) the competent authority responsible for the designated slaughterhouse is informed and agrees to receive the poultry and then confirms the slaughter to the competent authority of dispatch;
- (e) the poultry from the protection zone are kept separately from other poultry and are slaughtered separately or at different times from other poultry, preferably at the end of a working day; subsequent cleansing and disinfection shall be completed before other poultry are slaughtered;
- (f) the official veterinarian shall ensure that a detailed examination of the poultry is carried out at the designated slaughterhouse when the poultry arrive and after they are slaughtered;
- (g) the meat does not enter into intra-Community or international trade and bears the health mark for fresh meat provided for in Annex II to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption⁽¹⁵⁾, unless otherwise decided in accordance with the procedure referred to in Article 64(3) of this Directive;

(h) the meat is obtained, cut, transported and stored separately from meat intended for intra-Community and international trade and is used in such a way as to avoid it being introduced into meat products intended for intra-Community or international trade, unless:

- (i) it has undergone a treatment set out in Annex III to Directive 2002/99/EC; or
- (ii) it is otherwise decided in accordance with the procedure referred to in Article 64(3).

2. By way of derogation from Article 22, the competent authority may authorise the direct transport of poultry from outside the protection zone for immediate slaughter to a designated slaughterhouse within the protection zone and subsequent movement of the meat derived from such poultry providing that:

- (a) the competent authority responsible for the designated slaughterhouse is informed and agrees to receive the poultry and then confirms the slaughter to the competent authority of dispatch;
- (b) the poultry are kept separate from other poultry originating within the protection zone and are slaughtered separately or at different times from other poultry;
- (c) the poultry meat produced is cut, transported and stored separately from poultry meat obtained from other poultry originating in the protection zone;
- (d) the by-products are disposed of.

*Article 24***Derogations for the direct transport of day-old chicks**

1. By way of derogation from Article 22, the competent authority may authorise the direct transport of day-old chicks, originating from holdings within the protection zone to a holding or shed of that holding in the same Member State, preferably located outside the protection and the surveillance zones, subject to the following conditions:

- (a) they are transported in vehicles sealed by the competent authority or under its supervision;

⁽¹⁵⁾ OJ L 18, 23.1.2003, p. 11.

(b) appropriate biosecurity measures are applied during transport and at the holding of destination;

(c) the holding of destination is placed under official surveillance following the arrival of the day-old-chicks;

(d) if moved outside the protection or surveillance zone, the poultry shall remain on the holding of destination for at least 21 days.

2. By way of derogation from Article 22, the competent authority may authorise the direct transport of day-old chicks, hatched from eggs originating from holdings located outside the protection and surveillance zones, to any other holding in the same Member State, preferably located outside the protection and the surveillance zones, provided that the hatchery of dispatch can ensure by its logistics and by its hygienic working conditions that no contact has occurred between those eggs and any other hatching eggs or day-old chicks originating from poultry flocks within such zones and which are therefore of a different health status.

Article 25

Derogations for the direct transport of ready to lay poultry

By way of derogation from Article 22, the competent authority may authorise the direct transport of ready-to-lay poultry to a holding or shed of that holding preferably within the protection or the surveillance zone in which there is no other poultry, subject to the following conditions:

(a) a clinical examination of the poultry and other captive birds in the holding of origin and in particular of those to be moved is carried out by the official veterinarian;

(b) where appropriate, laboratory tests have been carried out on poultry in the holding of origin in accordance with the diagnostic manual with favourable results;

(c) the ready-to-lay poultry is transported in vehicles sealed by the competent authority or under its supervision;

(d) the holding or shed of destination is placed under official surveillance following the arrival of the ready-to-lay poultry;

(e) if moved outside the protection or surveillance zone, the poultry shall remain on the holding of destination for at least 21 days.

Article 26

Derogation for the direct transport of hatching and table eggs

1. By way of derogation from Article 22, the competent authority may authorise the direct transport of hatching eggs either from any holding to a hatchery located, in the protection zone and designated by the competent authority ('the designated hatchery') or, subject to the following conditions, from a holding located in the protection zone to any designated hatchery:

(a) the parent flocks from which the hatching eggs are derived have been examined in accordance with the diagnostic manual and avian influenza is not suspected on these holdings;

(b) the hatching eggs and their packaging are disinfected before dispatch and the tracing back of these eggs can be ensured;

(c) the hatching eggs are transported in vehicles sealed by the competent authority or under its supervision;

(d) biosecurity measures are applied in the designated hatchery in accordance with the instructions of the competent authority.

2. By way of derogation from Article 22, the competent authority may authorise the direct transport of eggs:

(a) to a packing centre designated by the competent authority ('the designated packing centre'), provided that they are packed in disposable packaging and that all biosecurity measures required by the competent authority are applied;

(b) 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; or

(c) for disposal.

*Article 27***Derogation for the direct transport of carcasses**

By way of derogation from Article 22, the competent authority may authorise the direct transport of carcasses provided that they are transported to be disposed of.

*Article 28***Cleansing and disinfecting of means of transport**

The competent authority shall ensure that the vehicles and equipment used for the transport as provided for in Articles 23 to 27 are cleansed and disinfected without delay by one or more of the procedures set down in Article 48 following the transport.

*Article 29***Duration of measures**

1. The measures provided for in this Section shall be maintained for at least 21 days following the date of completion of preliminary cleansing and disinfection on the infected holding by one or more of the procedures set down in Article 48 and until holdings located in the protection zone have been tested in accordance with the diagnostic manual.

2. When the measures referred to in this Section are no longer to be maintained, as provided for in paragraph 1 of this Article, the measures laid down in Article 30 shall apply in the former protection zone, until they are no longer to be applied as provided for in Article 31.

*SECTION 4***Measures to be applied in the surveillance zones***Article 30***Measures to be applied in the surveillance zones**

The competent authority shall ensure that the following measures are applied in surveillance zones:

- (a) a census of all commercial poultry holdings is made as soon as possible;
- (b) the movement of poultry, ready-to-lay poultry, day-old chicks, eggs within the surveillance zone is prohibited unless authorisation is granted by the competent authority, which ensures that appropriate biosecurity measures are applied to prevent the spread of avian

influenza; this prohibition shall not apply to transit thorough the surveillance zone on road or rail without unloading or stopping;

- (c) the movement of poultry, ready-to-lay poultry, day-old chicks and eggs to holdings, slaughterhouses, packing centres or an establishment for the manufacture of egg products located outside the surveillance zone is prohibited; however, the competent authority may authorise the direct transport of:

- (i) poultry for slaughter to a designated slaughterhouse, for the purpose of immediate slaughter subject to Article 23(1), points (a), (b) and (d);

The competent authority may authorise the direct transport of poultry from outside the protection and surveillance zones for immediate slaughter to a designated slaughterhouse within the surveillance zone and the subsequent movement of the meat derived from such poultry;

- (ii) ready-to-lay poultry to a holding in which there is no other poultry in the same Member State; that holding shall be placed under official surveillance following the arrival of the ready-to-lay poultry and the ready-to-lay poultry shall remain on the holding of destination for at least 21 days;

- (iii) day-old chicks:

to a holding or shed of such holding in the same Member State provided that appropriate biosecurity measures are applied and the holding is placed under official surveillance following the transport and day-old chicks shall remain on the holding of destination for at least 21 days, or

if hatched from hatching eggs originating from poultry holdings located outside the protection and surveillance zones, to any other holding, provided that the hatchery of dispatch can ensure by its logistics and biosecurity working conditions that no contact has occurred between these eggs and any other hatching eggs or day-old-chicks originating from poultry flocks within those zones and which are therefore of a different health status;

- (iv) hatching eggs to a designated hatchery located inside or outside the surveillance zone; the eggs and their packaging shall be disinfected before dispatch and the tracing back of these eggs must be ensured;

- (v) table eggs to a designated packing centre, provided that they are packed in disposable packaging and that all biosecurity measures required by the competent authority are applied;
- (vi) eggs 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 located inside or outside the surveillance zone;
- (vii) eggs for disposal;
- (d) any person entering or leaving holdings in the surveillance zone observes appropriate biosecurity measures aimed at preventing the spread of avian influenza;
- (e) vehicles and equipment used for transporting live poultry or other captive birds, carcasses, feed, manure, slurry and bedding and any other material or substances likely to be contaminated, are cleansed and disinfected without delay after contamination by one or more of the procedures provided for in Article 48;
- (f) no poultry, other captive birds or mammals of domestic species may enter or leave a holding where poultry is kept without authorisation of the competent authority. This restriction shall not apply to mammals which have access only to the living areas for humans in which they:
 - (i) have no contact with resident poultry or other captive birds, and
 - (ii) have no access to any cages or areas where such resident poultry or other captive birds are kept;
- (g) any increased morbidity or mortality or significant drop in production data in holdings is immediately reported to the competent authority, which shall carry out appropriate investigations in accordance with the diagnostic manual;
- (h) the removal or spreading of used litter, manure or slurry is prohibited unless authorised by the competent authority; the movement of manure may be authorised from a holding situated in the surveillance zone under biosecurity measures to a designated plant for treatment or for intermediate storage for subsequent treatment to destroy the

possible presence of avian influenza viruses, in accordance with Regulation (EC) No 1774/2002 or with specific rules which may be adopted in accordance with the procedure referred to in Article 64(2);

- (i) fairs, markets, shows or other gatherings of poultry or other captive birds are prohibited;
- (j) poultry for restocking of game are not released.

Article 31

Duration of measures

The measures provided for in this Section shall be maintained for at least 30 days following the date of completion of preliminary cleansing and disinfection on the infected holding in accordance with Article 48.

SECTION 5

Measures to be applied in further restricted zones

Article 32

Measures to be applied in further restricted zones

1. The competent authority may provide that some or all the measures provided for in Sections 3 and 4 shall apply inside the further restricted zones provided for in Article 16(4) ('the further restricted zones').
2. The competent authority may, where epidemiological information or other evidence indicates, implement a preventive eradication programme, including preventive slaughtering or killing of poultry or other captive birds, in holdings and areas at risk, according to the criteria of Annex IV, located in further restricted zones.

The restocking of those holdings shall take place in accordance with the instructions of the competent authority.

3. Member States applying the measures provided for in paragraphs 1 and 2 shall immediately inform the Commission thereof.

4. The Commission shall review the situation with the Member States concerned and in the Committee as soon as possible.

5. Without prejudice to decisions to be adopted pursuant to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽¹⁶⁾, further surveillance, biosecurity and control measures to prevent the spreading of avian influenza may be adopted in accordance with the procedure referred to in Article 64(3).

SECTION 6

Derogations and additional biosecurity measures

Article 33

Derogations

1. Member States shall define the detailed arrangements under which they may grant derogations provided for in Articles 16 and 23 to 27, including alternative appropriate measures and conditions. Such derogations shall be based on a risk assessment carried out by the competent authority.

2. The competent authority may, based on a risk assessment, grant derogations from the measures provided in Sections 3 and 4 in cases of confirmation of HPAI in a hatchery.

3. The competent authority may grant derogations from the measures provided for in Article 18, points (b) and (c), Article 22, and in Article 30, points (b), (c) and (f), in cases of an outbreak of HPAI in a non-commercial holding, a circus, a zoo, a wild life park, a fenced area where poultry or other captive birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other captive birds.

4. By way of derogation from Sections 3 and 4, in cases of outbreaks of HPAI Member States may, based on a risk assessment, introduce specific measures on movements of racing pigeons into, from and within the protection and surveillance zones.

5. The derogations provided for in paragraphs 1 to 4 shall only be granted provided that such derogations do not endanger disease control.

6. Member States granting derogations provided for in paragraphs 1 to 4 shall immediately inform the Commission thereof.

7. The Commission shall in all cases review the situation with the Member State concerned and in the Committee as soon as possible.

Taking account of any derogation granted, as provided for in paragraphs 1 to 4, measures to prevent the spread of avian influenza may be adopted in accordance with the procedure referred to in Article 64(3).

8. Any poultry (including day-old-chicks), other captive birds, hatching eggs, used litter, manure or slurry which come from a holding that has been granted a derogation under this Article, cannot be marketed outside the Member State concerned unless otherwise decided in accordance with the procedure referred in Article 64(3).

Article 34

Additional biosecurity measures

1. In order to prevent the spread of avian influenza, the competent authority may, in addition to the measures provided for in Sections 3, 4 and 5, order the implementation of additional biosecurity measures in holdings in the protection and surveillance zones and in the further restricted zones, as well as in poultry compartments and other captive birds compartments in the Member State concerned.

Those measures may include restrictions on movements of vehicles or persons for feed supply, egg collection, the transport to slaughterhouses of poultry, the collection for disposal of carcasses and other movements of personnel, veterinarians or persons supplying farm equipment.

2. Member States which adopt measures, as provided for in paragraph 1, shall immediately inform the Commission thereof.

3. The Commission shall review the situation with the Member State concerned and in the Committee as soon as possible.

4. Without prejudice to decisions to be adopted pursuant to Decision 90/424/EEC, further surveillance, biosecurity and control measures to prevent the spread of avian influenza may be adopted in accordance with the procedure referred to in Article 64(3).

⁽¹⁶⁾ OJ L 224, 18.8.1990, p. 19.

SECTION 7

Measures to be applied in cases of suspicion and confirmation of highly pathogenic Avian Influenza (HPAI) in certain premises other than holdings and in means of transport

Article 35

Investigation of suspected presence of HPAI in slaughterhouses and in means of transport

Where there is suspicion or confirmation of the presence of HPAI in slaughterhouses or means of transport, the competent authority shall immediately set in motion an investigation in the holding of origin of the poultry or other captive birds to confirm or exclude its presence in accordance with the diagnostic manual.

Article 36

Measures to be applied in slaughterhouses

1. Where HPAI is suspected or confirmed in a slaughterhouse, the competent authority shall ensure that, on the basis of a risk assessment, all poultry present in the slaughterhouse is either killed or slaughtered as soon as possible under official supervision.

Where such poultry is slaughtered, the poultry meat and any by-products derived from the poultry and poultry meat and by-products of any other poultry which may have been contaminated during the slaughter and production process, shall be kept separate and under official supervision until investigations in accordance with the diagnostic manual have been completed.

2. If HPAI is confirmed, the poultry meat and any by-products derived from the poultry and poultry meat and by-products of any other poultry which may have been contaminated during the slaughter and production process shall be disposed of as soon as possible under official supervision.

Article 37

Measures to be applied in border inspection posts or means of transport

1. Where HPAI is suspected or confirmed in border inspection posts or means of transport, the competent authority shall ensure that, on the basis of a risk assessment, all poultry and other captive birds present in the border inspection post or in the means of transport are killed, slaughtered or placed in isolation away from poultry or other captive birds and kept under official supervision until the inves-

tigation is completed in accordance with the diagnostic manual. The competent authority shall apply the measures provided for in Article 7 as appropriate.

The competent authority may authorise the movement of the poultry or other captive birds to another place where they are killed, slaughtered or placed into isolation.

The competent authority may decide not to kill or slaughter those poultry or other captive birds present in the border inspection post that have not been in contact with the poultry or other captive birds suspected of being infected.

2. Where poultry referred to in paragraph 1 is slaughtered, the poultry meat and any by-products derived from those poultry and poultry meat and by-products of any other poultry which may have been contaminated during the slaughter and production process, shall be kept separate and under official supervision until investigations in accordance with the diagnostic manual have been completed.

3. If HPAI is confirmed, the poultry meat and any by-products derived from those poultry and poultry meat and by-products of any other poultry which may have been contaminated during the slaughter and production process shall be disposed of as soon as possible under official supervision.

Article 38

Additional measures to be applied to slaughterhouses, border inspection posts or means of transport

The competent authority shall ensure that the following additional measures are applied where HPAI is suspected or confirmed in a slaughterhouse, border inspection post or means of transport:

- (a) no poultry or other captive birds are introduced into the slaughterhouse, the border inspection post or the means of transport until at least 24 hours after the cleansing and disinfection as provided for in point (b) are completed by one or more of the procedures set down in Article 48; in the case of border inspection posts, the prohibition on introduction may be extended to other animals;
- (b) the cleansing and disinfection of contaminated buildings, equipment and vehicles takes place in accordance with one or more of the procedures set down in Article 48 and under the official supervision of the official veterinarian;

- (c) an epidemiological inquiry is carried out;
- (d) the measures provided for in Article 7(2) are applied in the holding of origin of the infected poultry or carcasses and in contact holdings;
- (e) unless otherwise indicated by the epidemiological inquiry and the further investigations, as provided for in Article 35, the measures provided for in Article 11 are applied in the holding of origin;
- (f) the avian influenza virus isolate is subjected to the laboratory procedure in order to identify the subtype of the virus, in accordance with the diagnostic manual.

CHAPTER V

LOW PATHOGENIC AVIAN INFLUENZA (LPAI)

SECTION 1

Measures to be applied on holdings where outbreaks are confirmed

Article 39

Measures to be applied

1. In case of an outbreak of LPAI, the competent authority shall ensure that the measures provided for in points (a), (b), (c), (e), (g) and (h) of Article 7(2), Article 7(3) and paragraphs 2 to 5 of this Article are applied on the basis of a risk assessment and taking account of at least the criteria set out in Annex V.

2. The competent authority shall ensure that all poultry on the holding and all other captive birds of the species in which LPAI has been confirmed are depopulated under official supervision in such a way as to prevent the spread of avian influenza.

The depopulation may be extended to other captive birds on the holding based on the assessment of the risk that they pose as regards further spread of avian influenza and to other holdings that may be considered as contact holdings, based on the epidemiological inquiry.

Before depopulation, no poultry or other captive birds shall enter or leave the holding, unless authorised by the competent authority.

3. For the purpose of paragraph 2, the depopulation shall be carried out in accordance with Directive 93/119/EC and the

competent authority shall decide that the poultry or other captive birds are:

- (a) killed as soon as possible, or
- (b) slaughtered in a designated slaughterhouse in accordance with paragraph 4.

When depopulation is by slaughter in a designated slaughterhouse, the poultry shall be subjected to further surveillance and testing.

The poultry shall not be moved from the holding to the designated slaughterhouse until the competent authority, taking account, in particular, of the investigations and the laboratory tests directed at determining the extent of any excretion of the virus by the poultry carried out in accordance with the diagnostic manual and a risk assessment, is satisfied that the risk of further spread of LPAI is minimal.

4. Slaughter in a designated slaughterhouse in accordance with paragraph 3 may take place only provided that:

- (a) the poultry is sent directly from the holding to the designated slaughterhouse;
- (b) each consignment is sealed before dispatch by the official veterinarian responsible for the holding or under his supervision;
- (c) each consignment remains sealed throughout transport to the designated slaughterhouse;
- (d) further biosecurity measures prescribed by the competent authority are complied with;
- (e) the competent authority responsible for the designated slaughterhouse is informed and agrees to receive the poultry;
- (f) vehicles and equipment used for transporting live poultry and any other material or substances likely to be contaminated are cleansed and disinfected without delay after contamination, by one or more of the procedures set down in Article 48, and
- (g) the by-products of such poultry at the slaughterhouse are disposed of.

5. The competent authority shall ensure that the following are disposed of under official supervision:

(a) carcasses, and

(b) hatching eggs on the holding.

6. The competent authority shall ensure that the following measures are taken:

(a) hatching eggs collected from the holding during the period between the probable introduction of LPAI into the holding and the taking of the measures provided for in this Directive, are whenever possible traced and hatched under official surveillance;

(b) poultry already hatched from eggs collected from the holding during the period between the probable introduction of LPAI into the holding and the taking of the measures provided for in this Directive, are whenever possible placed under official surveillance and investigations are carried out in accordance with the diagnostic manual;

(c) eggs present on the holding and further produced on the holding before depopulation as provided for in paragraph 2, are transported provided that the risk of spread of LPAI is minimised:

(i) to a packing centre designated by the competent authority ('the designated packing centre'), provided that they are packed in disposable packaging and that all biosecurity measures required by the competent authority are applied;

(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; or

(iii) for disposal.

(d) any material or substance likely to be contaminated are either treated in accordance with the instructions of the official veterinarian or disposed of;

(e) manure, slurry and bedding likely to be contaminated undergo one or more of the procedures provided for in Article 48;

(f) after depopulation, the buildings used for housing the poultry or other captive birds, the equipment likely to be contaminated and the vehicles used for transporting carcasses, feed, manure, slurry, and bedding or any other material or substance likely to be contaminated undergoes without delay one or more of the procedures provided for in Article 48;

(g) mammals of domestic species do not enter or leave the holding without the authorisation of the competent authority. This restriction shall not apply to mammals which have access only to the living areas for humans in which they:

(i) have no contact with resident poultry or other captive birds, and

(ii) have no access to any cages or areas where such resident poultry or other captive birds are kept.

(h) in the case of a primary outbreak of LPAI, the virus isolate is subjected to the laboratory tests to identify the subtype of virus in accordance with the diagnostic manual; the virus isolate shall be submitted to the Community reference laboratory, as provided for in Article 51(1), as soon as possible.

7. Member States applying the measures provided for in paragraphs 2, 4 and 5 shall inform the Commission thereof.

Article 40

Derogations for certain holdings

1. The competent authority may grant derogations from the measures provided for in Article 39(2) and point (b) of Article 39(5) in cases of an outbreak of LPAI in a non commercial holding, a circus, a zoo, a pet bird shop, a wild life park, a fenced area where poultry or other captive birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other captive birds, provided that such derogations do not endanger disease control.

2. The competent authority shall ensure that where a derogation is granted, as provided for in paragraph 1, the poultry or other captive birds concerned by the derogation:

(a) are brought inside a building on their holding and kept there. Where this is impractical or if their welfare is compromised they are confined in some other place on the same holding such that they do not have contact with other poultry or other captive birds on other holdings. All reasonable steps are taken to minimise their contact with wild birds;

(b) are subjected to further surveillance and testing in accordance with the diagnostic manual and are not moved until the laboratory tests have indicated that they no longer pose a significant risk of further spread of LPAI; and

(c) are not moved from their holding of origin, except for slaughter or to another holding:

(i) located in the same Member State, in accordance with the instructions of the competent authority; or

(ii) in another Member State, subject to the agreement of the Member State of destination.

3. The competent authority may in cases of outbreaks of LPAI in hatcheries, based on a risk assessment, grant derogations from some or all of the measures provided for in Article 39.

4. Member States shall draw up detailed rules for applying the derogations provided for in paragraphs 1 and 3.

5. Member States shall immediately inform the Commission of any derogation granted in accordance with paragraphs 1 and 3.

6. The Commission shall review the situation with the Member State concerned and in the Committee as soon as possible.

7. Taking account of any derogation granted, as provided for in paragraph 1, measures to prevent the spread of avian influenza may be adopted in accordance with the procedure referred to in Article 64(3).

SECTION 2

Separate production units and contact holdings

Article 41

Measures to be applied in cases of outbreaks of LPAI in separate production units

1. In cases of an outbreak of LPAI in a holding which consists of two or more separate production units, the competent authority may grant derogations from the measures provided for in Article 39(2), for production units containing healthy poultry provided that such derogations do not endanger disease control.

2. Member States shall draw up detailed rules for applying the derogations provided for in paragraph 1, taking account of the animal health guarantees which may be obtained and shall provide for alternative appropriate measures.

3. Member States shall immediately inform the Commission of any derogations granted in accordance with paragraph 1.

4. The Commission shall review the situation with the Member State concerned and in the Committee as soon as possible.

5. Taking account of any derogation granted, as provided for in paragraph 1, measures to prevent the spread of avian influenza may be adopted in accordance with the procedure referred to in Article 64(3).

Article 42

Measures to be applied in contact holdings

1. Based on the epidemiological inquiry, the competent authority shall decide if a holding is to be considered as a contact holding.

The competent authority shall ensure that the measures provided for in Article 7(2) are applied to contact holdings until the presence of LPAI has been excluded in accordance with the diagnostic manual.

2. Based on the epidemiological inquiry, the competent authority may apply the measures provided for in Article 39 to contact holdings and in particular if the contact holding is located in an area with a high density of poultry.

The main criteria to be considered for the application of the measures provided for in Article 39 in contact holdings are set out in Annex IV.

3. The competent authority shall ensure that samples are taken from the poultry when they are killed in order to confirm or exclude the presence of the LPAI virus in those contact holdings in accordance with the diagnostic manual.

4. The competent authority shall ensure that, on any holding where poultry or other captive birds are slaughtered or killed and disposed of, and LPAI is subsequently confirmed, the buildings and any pastures used for housing them, farm yards and any equipment likely to be contaminated and the vehicles used for transporting the poultry, other captive birds, carcasses, meat, feed, manure, slurry, bedding and any other material or substance likely to be contaminated undergo one or more of the procedures provided for in Article 48.

SECTION 3

Establishment of restricted zones

Article 43

Establishment of restricted zones in cases of outbreaks of LPAI

Immediately following an outbreak of LPAI, the competent authority shall establish a restricted zone with a radius of at least one kilometre around the holding.

Article 44

Measures to be applied in the restricted zone

1. The competent authority shall ensure that the following measures are applied in the restricted zone:

- (a) a census of all commercial holdings is made as soon as possible;
- (b) laboratory tests are carried out on commercial poultry holdings within a radius of at least one kilometre around the holding in accordance with the diagnostic manual;
- (c) all movements of poultry, other captive birds, ready-to-lay poultry, day old chicks and eggs within or into the restricted zone are subject to authorisation and to other control measures deemed appropriate by the competent authority; this restriction shall not apply to the transit through the restricted zone on road or rail without unloading or stopping;
- (d) the movement of poultry, other captive birds, ready-to-lay poultry, day-old chicks and eggs from the restricted zone are prohibited unless the competent authority authorises the direct transport of:
 - (i) poultry for slaughter to a slaughterhouse in the same Member State;
 - (ii) live poultry to a holding or shed in the same Member State in which there is no other poultry. The live poultry shall remain there for 21 days and the holding shall be placed under official surveillance following their arrival;
 - (iii) day-old chicks:
 - to a holding or shed of such holding in the same Member State; the day old chicks shall remain there for 21 days and the holding shall be placed under official surveillance following their arrival; or
 - if hatched from eggs originating from poultry holdings located outside of the restricted zone to any other holding provided that the hatchery can ensure by its logistics and biosecurity working conditions that any contact is excluded with hatching eggs or day-old chicks originating from poultry flocks within the restricted zone and which are therefore of a different health status;
 - (iv) hatching eggs to a designated hatchery; the eggs and their packaging shall be disinfected before dispatch and the tracing back of these eggs must be ensured;
 - (v) table eggs to a packing centre provided that they are packed in disposable packaging and that all biosecurity measures required by the competent authority are applied;
 - (vi) eggs 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 located inside or outside the restricted zone;
 - (vii) eggs for disposal;
- (e) carcasses shall be disposed of;
- (f) any person entering or leaving holdings in the restricted zone observes appropriate biosecurity measures aimed at preventing the spread of avian influenza;

- (g) vehicles and equipment used for transporting live poultry or other captive birds, feed, manure, slurry and bedding and any other material or substances likely to be contaminated are cleansed and disinfected without delay after contamination, by one or more of the procedures set down in Article 48;
- (h) no poultry, other captive birds or mammals of domestic species may enter or leave a holding without authorisation of the competent authority. This restriction shall not apply to mammals which have access only to the living areas for humans in which they:
- (i) have no contact with resident poultry or other captive birds, and
- (ii) have no access to any cages or areas where such resident poultry or other captive birds are kept;
- (i) the removal or spreading of used litter, manure or slurry is prohibited, unless authorised by the competent authority; the movement of manure or slurry may be authorised from a holding situated in the restricted zone under biosecurity measures to a designated plant for treatment or for intermediate storage for subsequent treatment to destroy the possible presence of avian influenza viruses in accordance with Regulation (EC) No 1774/2002 or with specific rules which may be adopted in accordance with the procedure referred to in Article 64(2);
- (j) fairs, markets, shows or other gatherings of poultry or other captive birds are prohibited, unless authorised by the competent authority;
- (k) poultry or other captive birds for restocking of game are not released.
2. The competent authority may, based on a risk assessment, introduce further measures in addition to the measures provided for in this Section and shall inform the Commission thereof.
3. Further measures may be adopted to prevent the spread of avian influenza in accordance with the procedure referred to in Article 64(3).
- (a) at least 21 days following the date of completion of preliminary cleansing and disinfection of the infected holding by one or more of the procedures set down in Article 48, and until the competent authorities, based on the investigations and laboratory tests carried out in the restricted zone in accordance with the diagnostic manual and a risk assessment, consider that the risk of spread of LPAI is negligible;
- (b) at least 42 days following the date of confirmation of the outbreak and until the competent authorities, based on the investigations and laboratory tests carried out in the restricted zone in accordance with the diagnostic manual and a risk assessment, consider that the risk of spread of LPAI is negligible; or
- (c) for any other duration and under conditions to be established in accordance with the procedure referred to in Article 64(3).

Article 46

Derogations

1. Where LPAI is confirmed in a hatchery, the competent authority may, based on a risk assessment, derogate from some or all of the measures provided for in Articles 43 and 44.
2. The competent authority may grant derogations from the measures provided for in this Section in cases of an outbreak of LPAI in a non-commercial holding, a circus, a zoo, a pet bird shop, a wild life park, a fenced area where poultry or other captive birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other captive birds, provided that such derogations do not endanger disease control.
3. Member States granting the derogation provided for in paragraphs 1 and 2 shall immediately inform the Commission thereof.
4. The Commission shall review the situation with the Member State concerned and in the Committee as soon as possible.
5. Taking account of any derogation granted, as provided for in paragraphs 1 and 2, measures to prevent the spread of avian influenza may be adopted in accordance with the procedure referred to in Article 64(3).

Article 45

Duration of measures

The measures provided for in this Section shall be maintained:

CHAPTER VI

MEASURES AIMED AT AVOIDING THE SPREAD OF INFLUENZA VIRUSES OF AVIAN ORIGIN TO OTHER SPECIES*Article 47***Laboratory tests and other measures concerning pigs and other species**

1. The competent authority shall ensure that following confirmation of avian influenza on any holding, appropriate laboratory tests, in accordance with the diagnostic manual, are carried out on any pigs present on the holding to confirm or exclude that those pigs are, or have been, infected with the avian influenza virus.

No pigs shall be moved from the holding pending the results of those tests.

2. Where laboratory tests provided for in paragraph 1 confirm positive findings for avian influenza viruses in pigs, the competent authority may authorise the movement of those pigs to other pig holdings or to designated slaughterhouses, provided that subsequent appropriate tests have shown that the risk of spread of avian influenza is negligible.

3. The competent authority shall ensure that where laboratory tests provided for in paragraph 1 confirm a serious health threat, the pigs are killed as soon as possible under official supervision and in such a way as to prevent the spread of avian influenza virus, in particular during transport, and in accordance with Directive 93/119/EC.

4. The competent authority may, following confirmation of avian influenza on any holding, and based on a risk assessment, apply the measures provided for in paragraphs 1, 2 and 3 to any other mammals present on the holding and may extend those measures to contact holdings.

5. Member States shall inform the Commission within the framework of the Committee of the results of the tests and measures applied pursuant to paragraphs 1 to 4.

6. The competent authority may, following confirmation of avian influenza virus in pigs or any other mammals on any holding, undertake surveillance in accordance with the diagnostic manual to identify any further spread of avian influenza virus.

7. Additional measures to prevent the spread of influenza viruses of avian origin to other species, may be adopted in accordance with the procedure referred to in Article 64(3).

CHAPTER VII

CLEANSING, DISINFECTION AND RE-POPULATION*Article 48***Cleansing, disinfection and procedures for eliminating avian influenza virus**

Member States shall ensure that:

- (a) the cleansing, disinfection and treatment of holdings and any materials or substances therein which are contaminated or likely to be contaminated with avian influenza viruses are carried out under official supervision in accordance with:
 - (i) the instructions of the official veterinarian; and
 - (ii) the principles and procedures for cleansing, disinfecting and treatment set out in Annex VI;
- (b) any land or pastures used by poultry or other captive birds on a holding where avian influenza has been confirmed are not used by poultry or other captive birds until the competent authority is satisfied that any avian influenza virus present has been eliminated or inactivated;
- (c) the cleansing, disinfection and treatment of slaughterhouses, vehicles, trailers or any other means of transport, border inspection posts and any materials or substances therein which are contaminated or likely to be contaminated with avian influenza viruses are carried out under official supervision in accordance with the instructions of the official veterinarian;
- (d) any equipment, materials or substances therein which are contaminated or likely to be contaminated with avian influenza viruses and which cannot be effectively cleansed and disinfected or treated are destroyed;
- (e) the disinfectants to be used and their concentrations are authorised by the competent authority.

*Article 49***Re-population of holdings**

1. Member States shall ensure that paragraphs 2 to 6 of this Article are complied with, following the application of the measures provided for in Articles 11 and 39.

2. The re-population of commercial poultry holdings shall not take place for a period of 21 days following the date of completion of the final cleansing and disinfection as provided for in Article 48.

3. The following measures shall be performed during a period of 21 days following the date of the re-population of the commercial poultry holdings:

- (a) the poultry undergo at least one clinical examination carried out by the official veterinarian. That clinical examination, or if more than one is carried out, the final clinical examination, is undertaken as near as possible to the end of the 21 day period referred to above;
- (b) laboratory tests are carried out in accordance with the diagnostic manual;
- (c) poultry that die during the re-population phase are tested in accordance with the diagnostic manual;
- (d) any person entering or leaving the commercial poultry holding complies with appropriate biosecurity measures aimed at preventing the spread of avian influenza;
- (e) during the re-population phase no poultry leaves the commercial poultry holding without the authorisation of the competent authority;
- (f) the owner keeps a record on the production data, including morbidity and mortality data, which must be updated regularly;
- (g) any significant change in production data, as referred to in point (f), and other abnormalities are immediately reported to the competent authority.

4. Based on a risk assessment, the competent authority may order that the procedures provided for in paragraph 3 be applied to holdings other than commercial poultry holdings or other species on a commercial poultry holding.

5. The re-population of poultry in contact holdings shall take place in accordance with the instructions of the competent authority based on a risk assessment.

CHAPTER VIII

DIAGNOSTIC PROCEDURES, DIAGNOSTIC MANUAL AND REFERENCE LABORATORIES

Article 50

Diagnostic procedures and diagnostic manual

1. The Member States shall ensure that diagnostic procedures, sampling and laboratory testing to detect the presence of avian influenza in poultry or other captive birds or avian influenza virus in mammals are carried out in accordance with the diagnostic manual in order to ensure uniform procedures for its diagnosis.

That manual shall be adopted in accordance with the procedure referred to in Article 64(2) by 3 August 2006. Any subsequent amendment to the manual shall be adopted in accordance with the same procedure.

2. The diagnostic manual provided for in paragraph 1 shall establish at least the following:

- (a) minimum biosecurity requirements and quality standards to be observed by approved laboratories carrying out tests for the diagnosis of avian influenza;
- (b) criteria and procedures to be followed when clinical or post-mortem examinations are carried out to confirm or exclude the presence of avian influenza;
- (c) criteria and procedures to be followed for the collection of samples from poultry or other captive birds for laboratory tests to confirm or exclude the presence of avian influenza; including sampling methods for serological or virological screenings carried out in accordance with this Directive;
- (d) laboratory tests to be used for the diagnosis of avian influenza, including:
 - (i) tests for the differential diagnosis;
 - (ii) tests to distinguish HPAI and LPAI viruses;
 - (iii) suitable tests to distinguish between birds vaccinated and those infected with the field strain of avian influenza;

(iv) criteria for the evaluation of the results of the laboratory tests;

(e) laboratory techniques for the typing of avian influenza virus isolates.

3. Member States shall ensure that avian influenza viruses, their genome and antigens, and vaccines for research, diagnosis or manufacture of vaccine shall be manipulated or used only in places, establishments or laboratories approved by the competent authority where the appropriate biosecurity requirements are guaranteed.

The list of approved places, establishments or laboratories shall be transmitted to the Commission by 30 September 2007 and kept up-to-date.

Article 51

Reference laboratories

1. The laboratory named in Annex VII(1) shall be the Community reference laboratory for avian influenza (hereinafter referred to as 'the Community reference laboratory').

Without prejudice to Decision 90/424/EEC, the Community reference laboratory shall carry out the functions and duties listed in Annex VII(2).

2. Member States shall designate national reference laboratories and communicate to the Commission and other Member States the details thereof and any subsequent changes. The Commission shall publish and update the list of such national reference laboratories.

3. Member States shall ensure that the national reference laboratories:

- (a) carry out the functions and duties set out in Annex VIII;
- (b) are responsible for co-ordinating standards and methods of diagnosis in each Member State in accordance with Annex VIII and liaising with the Community reference laboratory.

4. The Community reference laboratory shall maintain close cooperation and contact with the OIE and FAO reference laboratory for avian influenza and, as appropriate, with other internationally recognised laboratories within the Community in order to ensure training, excellence and support to national reference laboratories in Member States and Third Countries.

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⁽¹⁷⁾ 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⁽¹⁸⁾ 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

⁽¹⁷⁾ 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).

⁽¹⁸⁾ OJ L 136, 30.4.2004, p. 1.

(c) where avian influenza has been confirmed in poultry or other captive birds in a nearby third country.

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 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 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.

CHAPTER X

COMMUNITY CONTROLS, PENALTIES AND CONTINGENCY PLANS

Article 60

Community controls

Commission experts may make on-the-spot checks in cooperation with the competent authority, in so far as it is necessary to ensure uniform application of this Directive in accordance with Commission Decision 98/139/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the Member States⁽¹⁹⁾ and Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁽²⁰⁾.

Article 61

Penalties

Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify the Commission of those provisions by the date specified in the first subparagraph of Article 67(1) and shall

notify it without delay of any subsequent amendment affecting them.

Article 62

Contingency plan

1. Member States shall draw up a contingency plan in accordance with Annex X specifying the national measures to be implemented in the event of an outbreak and submit that plan to the Commission for approval.

2. The contingency plan shall allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak. It shall give an indication of the number and location of all commercial poultry holdings. The contingency plan should give an indication of the maximum number of poultry, by species, that could be present on these commercial holdings. Member States should also estimate the amount of vaccine that would be needed in the event of emergency vaccination.

3. Provisions shall be in place for close cooperation between the competent authorities responsible for the different sectors, particularly those in charge of animal health, public health, environmental matters and health and safety of workers, in particular to ensure proper risk communication to farmers, workers in the poultry sector and the public.

4. The Commission shall examine the contingency plans in order to determine whether they permit the desired objective to be attained and shall suggest to the Member State concerned any amendments required, in particular to ensure that they are compatible with those of the other Member States.

The contingency plans shall be approved in accordance with the procedure referred to in Article 64(2). Any subsequent amendments to that plan shall be adopted in accordance with the same procedure.

5. Member State shall update the contingency plan at least every five years and submit it to the Commission for approval in accordance with the procedure referred to in Article 64(2).

6. In addition to the measures provided for paragraphs 1 to 4, further rules to ensure a rapid and efficient eradication of avian influenza, including provisions on disease control centres, expert groups and real-time alert exercises, may be adopted in accordance with the procedure referred to in Article 64(2).

⁽¹⁹⁾ OJ L 38, 12.2.1998, p. 10.

⁽²⁰⁾ OJ L 165, 30.4.2004, p. 1. Corrected version in OJ L 191, 28.5.2004, p. 1.

CHAPTER XI

IMPLEMENTING POWERS AND COMMITTEE PROCEDURE*Article 63***Implementing powers**

1. Detailed rules necessary for the implementation of this Directive shall be adopted in accordance with the procedure referred to in Article 64(2) and may include in particular specific rules concerning:

- (a) the disposal of carcasses, and
 - (b) the movement and treatment of feed, bedding, used litter, manure and slurry contaminated or suspected to be contaminated.
2. Any amendments to the annexes to take account of scientific and technical progress shall be decided in accordance with the procedure referred to in Article 64(2).

3. Detailed rules required by the epidemiological situation to supplement the minimum control measures provided for in this Directive shall be adopted in accordance with the procedure referred to in Article 64(3).

4. Without prejudice to the safeguard measures provided for in Article 9 of Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market⁽²¹⁾ or Article 10 of Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market⁽²²⁾, temporary emergency measures required due to a serious health threat caused by influenza viruses of avian origin other than those referred to in point 1 of Article 2, shall be adopted in accordance with the procedure referred to in Article 64(3).

*Article 64***Committee procedure**

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽²³⁾.

⁽²¹⁾ OJ L 395, 30.12.1989, p. 13. Directive as amended by Directive 2004/41/EC of the European Parliament and of the Council (OJ L 157, 30.4.2004, p. 33).

⁽²²⁾ OJ L 224, 18.8.1990, p. 29. Directive as last amended by Directive 2002/33/EC of the European Parliament and of the Council (OJ L 315, 19.11.2002, p. 14).

⁽²³⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 5(6) of that Decision shall be set at 15 days.

4. The Committee shall adopt its Rules of Procedure.

CHAPTER XII

TRANSITIONAL AND FINAL PROVISIONS*Article 65***Repeal**

Directive 92/40/EEC shall be repealed as from 1 July 2007. References to Directive 92/40/EEC shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex XI.

*Article 66***Transitional provisions**

1. Contingency plans for the control of avian influenza approved in accordance with Article 17(4) of Directive 92/40/EEC and in force at 1 July 2007 shall continue to apply for the purpose of this Directive.

However, by 30 September 2007 Member States shall submit to the Commission amendments to those contingency plans, to bring them in line with this Directive.

Those amended plans shall be approved in accordance with the procedure referred to in Article 64(2).

2. Pending the transposition of this Directive, further transitional provisions on the control of avian influenza may be adopted in accordance with the procedure referred to in Article 64(2).

*Article 67***Transposition**

1. Member States shall bring into force by 1 July 2007 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

When they are adopted by Member States, these measures shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 68***Entry into force**

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

*Article 69***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 20 December 2005.

For the Council

The President

M. BECKETT

ANNEX I

(referred to in Article 2)

Definition of avian influenza

1. 'avian influenza' means an infection of poultry or other captive birds caused by any influenza A virus:
 - (a) of the subtypes H5 or H7; or
 - (b) with an intravenous pathogenicity index (IVPI) in six-week old chickens greater than 1.2;

 2. 'highly pathogenic avian influenza (HPAI)' means an infection of poultry or other captive birds caused by:
 - (a) avian influenza viruses of the subtypes H5 or H7 with genome sequences codifying for multiple basic amino acids at the cleavage site of the haemagglutinin molecule similar to that observed for other HPAI viruses, indicating that the haemagglutinin molecule can be cleaved by a host ubiquitous protease; or
 - (b) avian influenza viruses with an intravenous pathogenicity index in six-week old chickens greater than 1.2;

 3. 'low pathogenic avian influenza (LPAI)' means an infection of poultry or other captive birds caused by avian influenza viruses of subtypes H5 or H7 that do not come within the definition in paragraph 2.
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ANNEX II

(referred to in Article 5(2))

Notification of disease and further epidemiological information to be provided by Member States

1. Within 24 hours of the confirmation of any primary outbreak or detection of avian influenza in a slaughterhouse or means of transport, the Member State concerned shall notify in accordance with the procedure referred to in Article 5 of Directive 82/894/EEC:
 - (a) the date of notification;
 - (b) the time of notification;
 - (c) the name of the Member State concerned;
 - (d) the name of the disease;
 - (e) the number of the outbreak or positive finding of avian influenza in a slaughterhouse or means of transport;
 - (f) the date on which the disease was first suspected;
 - (g) the date of confirmation;
 - (h) the methods used for confirmation;
 - (i) whether the disease has been confirmed in a holding, slaughterhouse or means of transport;
 - (j) the geographical location of the outbreak or positive finding of avian influenza in a slaughterhouse or means of transport;
 - (k) the disease control measures applied.

2. In the case of positive findings for avian influenza in slaughterhouses or means of transport, the Member State concerned must forward the following information in addition to the data referred to in paragraph 1:
 - (a) the estimated number, by category, of susceptible poultry or other captive birds in the slaughterhouse or means of transport;
 - (b) the estimated number, by category, of dead poultry or other captive birds in the slaughterhouse or means of transport;
 - (c) for each of the categories of poultry or other captive birds, the identified morbidity and the estimated number of poultry or other captive birds in which avian influenza has been confirmed;
 - (d) the estimated number of poultry or other captive birds killed or slaughtered in the slaughterhouse or means of transport;
 - (e) the estimated number of poultry or other captive birds disposed of;
 - (f) in the case of a slaughterhouse, the distance from the nearest commercial holding containing poultry or other captive birds;
 - (g) the location of the holding or holdings of origin of the infected poultry or carcasses.

3. In the case of secondary outbreaks, the information referred to in paragraphs 1 and 2 must be forwarded within the time-limits laid down in Article 4(1) of Directive 82/894/EEC.

4. The Member State concerned shall ensure that the information to be provided in accordance with paragraphs 1, 2 and 3, in relation to any outbreak or positive finding of avian influenza in a slaughterhouse or means of transport is followed as soon as possible by a written report to the Commission and the other Member States including at least:
 - (a) the date on which the poultry or other captive birds on the holding, slaughterhouse or means of transport were killed or slaughtered and their carcasses disposed of;
 - (b) any information relating to the possible origin of avian influenza or, if ascertained, its actual origin;
 - (c) information on the control system established to ensure that the measures in place for the control of animal movements are effectively implemented;
 - (d) in the case of detection of avian influenza in a slaughterhouse or means of transport, the genetic type of virus responsible;
 - (e) where poultry or other captive birds have been killed or slaughtered in contact holdings or in holdings containing poultry or other captive birds suspected of being infected with avian influenza virus, information on:
 - (i) the date of killing or slaughtering and the estimated number of poultry or other captive birds of each category killed or slaughtered in each holding;
 - (ii) the epidemiological link between the source of infection and each contact holding or the other reasons that have given rise to the suspicion that avian influenza is present;
 - (iii) where poultry or other captive birds in contact holdings have not been killed or slaughtered, information must be provided concerning the reasons for the decision not to kill or slaughter them.
 5. In the case of confirmation of avian influenza in live poultry, other captive birds or poultry products being imported or introduced at Community borders, in border inspection posts or in quarantine facilities or centres operating in accordance with Community legislation on imports, the competent authority must notify this confirmation to the Commission without delay and report on the measures taken.
 6. The Commission and the other Member States must be notified within 24 hours where a serious threat to health is identified as a result of any surveillance.
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ANNEX III

(referred to in Articles 8(3) and 13(3))

Authorisation to remove eggs from a holding in accordance with Article 8(3) and Article 13(3)

The competent authority may authorise the transport of eggs from a holding subject to the provisions of Article 8(3) and Article 13(3) of this Directive to an establishment approved for the manufacture of egg products in accordance with Regulation (EC) No 853/2004 ('the designated establishment'), subject to the following conditions:

1. in order to be allowed to be removed from the holding of origin, the eggs must be sent directly from the suspected holding to the designated establishment; each consignment must be sealed before dispatch by the official veterinarian responsible for the suspected holding or under his supervision and must remain sealed throughout transport to the designated establishment;
 2. the official veterinarian responsible for the holding of origin of the eggs shall inform the competent authority of the designated establishment of the intention to send the eggs to it;
 3. the competent authority responsible for the designated establishment shall ensure that:
 - (a) the eggs referred to in paragraph 1 are kept isolated from other eggs from the time they arrive until they are processed;
 - (b) the shells of such eggs are disposed of;
 - (c) the packaging used for the eggs is either destroyed or cleansed and disinfected in such a way as to destroy all avian influenza viruses;
 - (d) the eggs referred to in paragraph 1 are transported in cleansed and disinfected vehicles. Biosecurity measures are applied to staff and equipment and vehicles involved in the transport of the eggs.
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ANNEX IV

(referred to in Article 15(2), Article 32(2) and Article 42(2))

Main criteria and risk factors to be considered for the Decision to apply measures in contact holdings or holdings and areas at risk in the further restricted zones

Indicative criteria	
For depopulation	Against depopulation
Clinical signs suggesting avian influenza in contact holdings	No clinical signs suggesting avian influenza on the contact holdings and no epidemiological link
High susceptibility of predominant poultry species	Low susceptibility of predominant poultry species
Movement of poultry or other captive birds from holdings where avian influenza has been confirmed to contact holdings after the likely time of introduction of virus on to those infected holdings	No known movement of poultry or other captive birds from the holdings where avian influenza has been confirmed to contact holdings after the likely time of introduction of virus on to those infected holdings
Location of contact holdings in an area with a high density of poultry	Location of contact holdings in an area with a low density of poultry
Disease has been present for some time with likely spreading of virus from the holdings where avian influenza has been confirmed before application of eradication measures	Disease present but with limited spreading of virus from the holdings where avian influenza has been confirmed before application of eradication measures
Location of contact holdings within 500 metres ⁽¹⁾ of the holdings where avian influenza has been confirmed	Location of contact holdings more than 500 metres ⁽¹⁾ from the holdings where avian influenza has been confirmed
The contact holdings are linked to more than one holding where avian influenza has been confirmed	The contact holdings are not linked to holdings where avian influenza has been confirmed
The epidemic is not under control and the number of holdings where avian influenza has been confirmed is rising	The epidemic is under control

⁽¹⁾ In cases where poultry density is very high, a greater distance must be considered.

ANNEX V

(referred to in Article 39(1))

Criteria for the Decision to apply measures to holdings in relation to LPAI

When deciding on the movement of poultry or eggs and on depopulation of holdings in accordance with Article 39(1) the competent authority shall consider the following criteria at least:

- (a) species in question;
 - (b) number of holdings in the area around the holding of dispatch;
 - (c) location of designated slaughterhouses, hatcheries and packing centres;
 - (d) biosecurity measures applied in holdings, poultry or other captive bird compartments, during transport and during slaughter;
 - (e) transport route;
 - (f) evidence of spread;
 - (g) public health risk, if any;
 - (h) further treatments of the products in question;
 - (i) socio-economic and other impacts.
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ANNEX VI

(referred to in Article 48)

Principles and procedures for cleansing, disinfection and treatment of holdings

1. The following general principles and procedures shall be applied for the cleansing, disinfection and treatment provided for in Article 48:
 - (a) the cleansing and disinfection and, where necessary, the measures to destroy rodents and insects must be carried out under official supervision and in accordance with the instructions given by the official veterinarian;
 - (b) the disinfectants to be used and their concentrations must be authorised by the competent authority to ensure the destruction of avian influenza virus;
 - (c) disinfectants should either be used in accordance with the recommendations of the manufacturer where provided or in accordance with the instructions of the official veterinarian and/or the instructions of the competent authority, if any;
 - (d) the choice of disinfectants and of procedures for disinfection must be made taking into account the nature of the holdings, vehicles and objects which are to be treated;
 - (e) the conditions under which degreasing agents and disinfectants are used must ensure that their efficacy is not impaired; in particular, technical parameters indicated by the manufacturer, such as pressure, minimum temperature and required contact time must be observed;
 - (f) irrespective of the disinfectant used, the following general rules shall be applied:
 - (i) a thorough soaking of bedding and litter, as well as faecal matter, with the disinfectant;
 - (ii) washing and cleansing by careful brushing and scrubbing of the ground, floors, ramps and walls following the removal or dismantling, where possible, of equipment or installations otherwise impairing the effective cleansing and disinfection procedures;
 - (iii) then, further application of disinfectant for a minimum contact time as stipulated in the manufacturer's recommendations;
 - (g) where washing is carried out with liquids applied under pressure, re-contamination of the previously cleansed parts must be avoided;
 - (h) washing, disinfecting or destroying of equipment, installations, articles or anything likely to be contaminated must be envisaged;
 - (i) following disinfection procedures, re-contamination must be avoided;
 - (j) cleansing and disinfection as required in the framework of this Directive must be documented in the holding or vehicle register and, where official approval is required, be certified by the supervising official veterinarian or person under his supervision;
 - (k) cleansing and disinfection of vehicles used for transport and by staff.
2. Cleansing and disinfection of infected holdings shall be carried out in accordance with the following principles and procedures:
 - (a) preliminary cleansing and disinfection:
 - (i) during the killing of the poultry or other captive birds all necessary measures must be taken to avoid or minimise the dispersion of avian influenza virus; those measures must include the installation of temporary disinfection equipment, supply of protective clothing, showers, decontamination of used equipment, instruments and facilities and the interruption of power supply to the ventilation;

- (ii) carcasses of killed poultry or other captive birds must be sprayed with disinfectant;
 - (iii) any transport of carcasses of poultry or other captive birds which have to be removed from the holding for disposal shall be carried out in closed, leak proof vehicles or containers under official supervision in such a way as to prevent the spread of avian influenza virus;
 - (iv) as soon as the killed poultry or other captive birds have been removed to be disposed of, those parts of the holding in which they were housed and any parts of other buildings, yards etc. contaminated during the killing, or the post-mortem examination must be sprayed with disinfectants authorised in accordance with Article 48;
 - (v) any tissue or blood spilled during the killing or from the post-mortem examinations must be carefully collected and disposed of with the killed poultry or other captive birds;
 - (vi) the disinfectant must remain on the surface for at least 24 hours;
- (b) final cleansing and disinfection:
- (i) manure and used bedding must be removed and treated as provided in paragraph 3(a);
 - (ii) grease and dirt must be removed from all surfaces by the application of a degreasing agent, and the surfaces cleansed with water;
 - (iii) after washing with cold water, further spraying with disinfectant must be applied;
 - (iv) after seven days the holding must be treated with a degreasing agent, rinsed with water, sprayed with disinfectant and rinsed again with water.
3. Disinfection of contaminated bedding, manure and slurry shall be carried out in accordance with the following principles and procedures:
- (a) manure and used bedding shall either:
- (i) undergo a steam treatment at a temperature of at least 70 °C;
 - (ii) be destroyed by burning;
 - (iii) be buried deep enough to prevent access by wild birds and other animals; or
 - (iv) be stacked to heat, sprayed with disinfectant and left for at least 42 days;
- (b) slurry must be stored for at least 60 days after the last addition of infectious material, unless the competent authorities authorises a reduced storage period for slurry which has been effectively treated in accordance with the instructions of the official veterinarian so as to ensure the destruction of the virus.
- The competent authority may authorise the transportation of manure, litter and bedding likely to be contaminated to either an approved treatment plant where a treatment ensuring the destruction of any influenza virus is carried out, or for intermediate storage before destruction or treatment, in accordance with Regulation (EC) No 1774/2002 or with the specific rules referred to in Article 63(1) of this Directive. Such transport shall be carried out in closed, leak proof vehicles or containers under official supervision in such a way as to prevent the spread of avian influenza virus.
4. However, by way of derogation from paragraphs 1 and 2, the competent authority may establish specific procedures for cleansing and disinfection, taking into account the type of holding and the climatic conditions. The competent authority shall notify the Commission when this derogation is applied and provide them with details of the specific procedures.
5. Without prejudice to Article 48(b), if the competent authority is satisfied that any holding or part of any holding cannot, for any reason, be cleansed and disinfected, it may prohibit the entry of any person, vehicle, poultry, other captive bird or mammal of domestic species or any thing on to those holdings, or part of those holdings, and such prohibition shall remain in force for a minimum of 12 months.
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ANNEX VII

(referred to in Article 51(1))

Community reference laboratory for avian influenza

1. The Community reference laboratory for avian influenza is:

Veterinary Laboratories Agency (VLA), New Haw, Weybridge, Surrey KT 15 3NB, United Kingdom.

2. The functions and duties of the Community reference laboratory shall be:

- (a) to coordinate, in consultation with the Commission, the methods employed in the Member States for diagnosing avian influenza, specifically by:
- (i) typing, storing and supplying strains of avian influenza virus for serological tests and the preparation of antisera;
 - (ii) supplying standard sera and other reference reagents to the national reference laboratories in order to standardise the tests and reagents used in the Member States;
 - (iii) building up and retaining a collection of avian influenza virus strains and isolates;
 - (iv) organising periodical comparative tests of diagnostic procedures at Community level;
 - (v) collecting and collating data and information on the methods of diagnosis used and the results of tests carried out in the Community;
 - (vi) characterising isolates of avian influenza viruses by the most up-to-date methods available to allow greater understanding of the epidemiology of avian influenza and to gain an insight into the epidemiology of the virus and the emergence of highly pathogenic and potentially pathogenic strains;
 - (vii) keeping abreast of developments in avian influenza surveillance, epidemiology and prevention worldwide;
 - (viii) retaining expertise on avian influenza virus and other pertinent viruses to enable rapid differential diagnosis;
 - (ix) acquiring a knowledge of the preparation and use of the products of veterinary immunology used to control avian influenza;
- (b) to assist actively in the diagnosis of outbreaks in the Community by receiving isolates of influenza viruses of avian origin for confirmatory diagnosis, characterisation and epidemiological studies and to obtain virus isolates from primary outbreaks to be submitted from third countries authorised for the importation of live poultry and meat into the Community pursuant to the relevant Community legislation; on the virus isolates received, the Community reference laboratory shall in particular carry out the following:
- (i) nucleotide sequencing analysis to allow determination of the deduced amino acid sequence at the cleavage site of the haemagglutinin molecule;
 - (ii) determination of the intravenous pathogenicity index (IVPI);
 - (iii) antigenic typing;
 - (iv) phylogenetic analysis to assist in epidemiological investigations;
- (c) to facilitate the training or retraining of experts in laboratory diagnosis with a view to the harmonisation of techniques throughout the Community;
- (d) to prepare the programme and working documents for the Annual Meeting of National Reference Laboratories;

- (e) to assist in the conduct of avian influenza surveys in poultry and wild birds to be carried out in the Member States by supplying antigens in the framework of the programme and the approved testing procedures and prepare a summary report on the results of the surveys;
 - (f) to keep under review the possible zoonotic impact arising from avian influenza viruses and collaborate with internationally recognised human influenza laboratories;
 - (g) to develop, in consultation with the Commission, a crisis and contingency plan which shall include provision for the cooperation with the OIE and FAO reference laboratory for avian influenza and, as appropriate, with other internationally recognised laboratories within the Community.
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ANNEX VIII

(referred to in Article 51(3))

Function and duties of the national reference laboratories

1. The national reference laboratories shall be responsible for ensuring that in each Member State the laboratory testing to detect the presence of avian influenza and the identification of the genetic type of virus isolates are carried out in accordance with the diagnostic manual. For that purpose, they may make special agreements with the Community reference laboratory or with other national laboratories.
 2. The national reference laboratories shall submit isolates of influenza virus of avian origin to the Community reference laboratory without delay for full characterisation:
 - (a) from all primary outbreaks of avian influenza;
 - (b) in case of secondary outbreaks, from representative number of outbreaks;
 - (c) in case of detection of influenza viruses other than those referred to in Annex I(1) in poultry, other captive birds or mammals posing a serious threat to health.
 3. The national reference laboratory in each Member State shall be responsible for coordinating the standards and diagnostic methods in each avian influenza diagnostic laboratory within that Member State. For that purpose:
 - (a) it may provide individual laboratories with diagnostic reagents;
 - (b) it shall control the quality of all diagnostic reagents used in that Member State;
 - (c) it shall arrange comparative tests periodically;
 - (d) it shall hold isolates of avian influenza virus from outbreaks and of any other influenza viruses of avian origin detected in that Member State;
 - (e) it shall collaborate with the national human influenza laboratories.
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ANNEX IX

(referred in Article 55(1) point (b))

Requirements for movements of poultry or other captive birds and poultry products applicable in relation to emergency vaccination

1. Member States shall ensure that movement controls on poultry or other captive birds vaccinated in accordance with Article 55 and on their products are applied as set out in paragraphs 3 to 8 in accordance with the diagnostic manual.
2. Any vehicles or means of transport and equipment used for transporting live poultry or other captive birds, eggs or poultry meat within the context of this Annex shall undergo one or more of the cleansing, disinfection or treatment procedures provided for in Article 48 without delay after it has been used.
3. The following provisions shall apply to the movements of live poultry or other captive birds and eggs within the vaccination area:
 - (a) hatching eggs shall:
 - (i) originate from a vaccinated or unvaccinated breeding flock which has been examined, with favourable results, in accordance with the diagnostic manual;
 - (ii) have been disinfected before dispatch in accordance with a method approved by the competent authority;
 - (iii) be transported directly to the hatchery of destination;
 - (iv) be traceable within the hatchery;
 - (b) eggs shall originate from a vaccinated or non-vaccinated layer flock which has been examined, with favourable results, in accordance with the diagnostic manual and shall be transported to:
 - (i) a packing centre designated by the competent authority ('the designated packing centre'), provided that they are packed in disposable packaging and that all biosecurity measures required by the competent authority are applied, or
 - (ii) 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;
 - (c) day-old chicks shall:
 - (i) originate from hatching eggs satisfying the conditions set out in (a);
 - (ii) be placed in a poultry house or shed where there is no resident poultry;
 - (d) live poultry or other captive birds shall:
 - (i) have been vaccinated against avian influenza, if provided for in the vaccination programme;
 - (ii) have been examined, with favourable results, in accordance with the diagnostic manual;
 - (iii) be placed in a poultry house or shed where there is no resident poultry;
 - (e) poultry for slaughter shall:
 - (i) be examined with favourable results before loading in accordance with the diagnostic manual;
 - (ii) be sent directly to a designated slaughterhouse for immediate slaughter.

4. The following provisions shall apply to the movements of live poultry or other captive birds and eggs from holdings outside the vaccination area to holdings within the vaccination area:
- (a) hatching eggs shall:
 - (i) be transported directly to the hatchery of destination;
 - (ii) be traceable within the hatchery;
 - (b) eggs shall be transported to:
 - (i) a packing centre designated by the competent authority ('the designated packing centre'), provided that they are packed in disposable packaging and that all biosecurity measures required by the competent authority are applied, or
 - (ii) 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;
 - (c) day-old chicks shall be placed in a poultry house or shed where there is no resident poultry;
 - (d) live poultry or other captive birds shall:
 - (i) be placed in a poultry house or shed where there is no resident poultry;
 - (ii) be vaccinated at the farm of destination, if provided for in the vaccination programme;
 - (e) poultry for slaughter shall be sent directly to a designated slaughterhouse for immediate slaughter.
5. The following provisions shall apply to movements of live poultry or other captive birds, and eggs from holdings within the vaccination area to a holding outside the vaccination area:
- (a) hatching eggs shall:
 - (i) originate from a vaccinated or unvaccinated breeding flock which has been examined, with favourable results, in accordance with the diagnostic manual;
 - (ii) have been disinfected before dispatch in accordance with a method approved by the competent authority;
 - (iii) be transported directly to the hatchery of destination;
 - (iv) be traceable within the hatchery;
 - (b) eggs shall originate from a vaccinated or non-vaccinated layer flock which has been examined, with favourable results, in accordance with the monitoring diagnostic manual and shall be transported to:
 - (i) a packing centre designated by the competent authority ('the designated packing centre'), provided that they are packed in disposable packaging and that all biosecurity measures required by the competent authority are applied, or
 - (ii) 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;
 - (c) day-old chicks shall:
 - (i) not have been vaccinated;
 - (ii) originate from hatching eggs satisfying the conditions set out in point (a) of paragraph 2, point (a) of paragraph 3 or point (a) of paragraph 4;
 - (iii) be placed in a poultry house or shed where there is no resident poultry;

- (d) live poultry or other captive birds shall:
 - (i) not have been vaccinated;
 - (ii) have been examined with favourable results, in accordance with the diagnostic manual;
 - (iii) be placed in a poultry-house or shed where there is no resident poultry;
 - (e) poultry for slaughter shall:
 - (i) be examined before loading with favourable results, in accordance with the diagnostic manual;
 - (ii) be sent directly to a designated slaughterhouse for immediate slaughter.
6. For meat obtained from poultry kept within the vaccination area the following provisions shall apply:
- (a) for meat obtained from vaccinated poultry, the poultry shall:
 - (i) have been vaccinated with a vaccine that complies with a DIVA strategy;
 - (ii) have been inspected and tested with negative results in accordance with the diagnostic manual;
 - (iii) have been clinically inspected by an official veterinarian within 48 hours before loading and if appropriate any sentinel birds on the holding shall have been examined by the official veterinarian;
 - (iv) have been sent directly to a designated slaughterhouse for immediate slaughter;
 - (b) for any meat obtained from non-vaccinated poultry being sent for slaughter, the poultry shall undergo monitoring in accordance with the diagnostic manual.
7. The competent authority may authorise the movement of carcasses or eggs for disposal from holdings.
8. No further restrictions shall apply to movements of eggs packed and meat from poultry slaughtered in accordance with this Annex.
9. The movement of poultry (including day-old chicks) or other captive birds from the territory of the Member State is prohibited from the start of the emergency vaccination campaign until the emergency plan is approved under Article 54 and without prejudice to any further Community measures, unless it is authorised by the competent authority of the receiving Member State.
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ANNEX X

(referred to in Article 62(1))

Criteria for contingency plans

Contingency plans shall meet the following criteria at least:

1. The establishment of a crisis centre on a national level, which shall coordinate all control measures in the Member State.
 2. A list shall be provided of local disease control centres with adequate facilities to coordinate disease control measures at local level.
 3. Detailed information shall be given about the staff involved in control measures, their skills, their responsibilities and the instructions for staff, taking account of the need for personal protection and the potential risk to human health posed by avian influenza.
 4. Each local disease control centre must be able to contact rapidly persons and organisations directly or indirectly involved in an outbreak.
 5. Equipment and materials shall be available to carry out effectively the disease control measures.
 6. Detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination, including proposed means of disposal of carcasses.
 7. Training programmes shall be established to maintain and develop skills in field and administrative procedures.
 8. Diagnostic laboratories must have facilities for post-mortem examination, the necessary capacity for serology, histology etc. and must maintain the skills for rapid diagnosis. Arrangements must be made for rapid transportation of samples. The contingency plan shall also outline the testing capacity for the laboratory and the resources available to deal with an outbreak of disease.
 9. A vaccination plan dealing with a number of scenarios shall be produced which shall give an indication of which populations of poultry or other captive birds may be vaccinated, an estimate of the amount of vaccine required and its availability.
 10. Provision shall be made for the availability of data on registration of commercial poultry holdings on their territory, without prejudice to other relevant provisions established by Community legislation in this field.
 11. Provision shall be made for the recognition of officially registered rare breeds of poultry or other captive birds.
 12. Provision shall be made for the identification of areas with a high density of poultry.
 13. Provision shall be made to ensure the legal powers necessary for the implementation of the contingency plans.
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ANNEX XI

Correlation table

This Directive	Directive 92/40/EEC
Article 1(1)(a), (c)	—
Article 1(1)(b)	Article 1, first subparagraph
Article 1(2)	—
Article 2 point (1)	Annex III
Article 2 point (2)	Annex III, third subparagraph
Article 2 point (3)	
Article 2 points (4), to (15), (17), (20), (21) and (22) to (32)	—
Article 2, point (16)	Article 2(b)
Article 2, point (18)	Article 2(d)
Article 2, point (19)	Article 2(e)
Article 3	—
Article 4	—
Article 5(1)	Article 3
Article 5(2)	—
Article 5(3)	—
Article 6(1)	Article 4(2)(g)
Article 6(2)	Article 7(1)
Article 6(3) and (4)	—
Article 7(1)	Article 4(1)
Article 7(2)(a) and (b)	Article 4(2)(a)
Article 7(2)(c)	Article 4(2)(b)
Article 7(2)(d)	Article 4(2)(c)
Article 7(2)(e) and (g)	Article 4(2)(d)
Article 7(2)(f)	Article 4(2)(e)
Article 7(2)(h)	Article 4(2)(f)
Article 7(3)	Article 4(2)(g)
Article 7(4)	—
Article 8	—
Article 9	Article 4(5)
Article 10	—
Article 11(1)	Article 5(1), introductory wording
Article 11(2), first subparagraph	Article 5(1)(a)
Article 11(2), second and third subparagraphs	—

This Directive	Directive 92/40/EEC
Article 11(3)	Article 5(1)(a)
Article 11(4)	Article 5(1)(d)
Article 11(5)	Article 5(1)(c) and (d)
Article 11(6) and (7)	Article 5(1)(b)
Article 11(8)	Article 5(1)(e)
Article 11(9)	—
Article 11(10)	Annex III Chapter 3(3)
Article 12	—
Article 13	—
Article 14	Article 6
Article 15	Article 8
Article 16(1)	Article 9(1)
Article 16(2), (3) and (4)	—
Article 16(5)	Article 9(6)
Article 17(1)	Article 10
Article 17(2)	Article 13
Article 17(3), (4)	—
Article 18(a)	Article 9(2)(a)
Article 18(b)	Article 9(2)(b)
Article 18(c)	—
Article 19(a)	Article 9(2)(c)
Article 19(b), (c) and (d)	—
Article 19(e) first sentence	Article 9(2)(f), introductory wording
Article 19(e) second sentence, (f), (g) and (h)	—
Article 20	Article 9(2)(g)
Article 21	Article 9(2)(h)
Article 22(1) and (3)	Article 9(2)(e)
Article 22(2)	—
Article 23(1)	Article 9(2)(f)(i)
Article 23(2)	—
Article 24(1)	Article 9(2)(f)(ii)
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