



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.4.2005
COM(2005) 171 final

2005/0062 (CNS)
2005/0063 (CNS)

Proposal for a

COUNCIL DIRECTIVE

on Community measures for the control of Avian Influenza

Proposal for a

COUNCIL DECISION

amending Council Decision 90/424/EEC on expenditure in the veterinary field

(presented by the Commission)

{SEC(2005)549}

EXPLANATORY MEMORANDUM

1. Context of the proposal

- Grounds for and objectives of the proposal

The Commission envisages updating current Community measures on Avian Influenza (AI) laid down in Council Directive 92/40/EEC, with the objective to achieve better prevention and control of outbreaks and to reduce the health risks, the costs and losses and the negative impact to the whole of society due to this disease. The proposed changes in Community legislation on AI control should be made in parallel with amendments to Council Decision 90/424/EEC on Community expenditure in the veterinary field, to bring it in line with this proposal and ensure adequate financial support to the Member States (MSs) in relation to some of the newly envisaged control measures.

- General context

AI is a serious, highly contagious disease of poultry and other birds caused by different types of viruses included in the very large virus family called *Influenzaviridae*. AI viruses may also spread to other animals and humans, usually following direct contact with infected birds. In the human host, the disease may vary from mild conjunctivitis to serious disease, sometimes fatal; during the still ongoing AI epidemic in certain Asian countries, the case fatality rate in humans has been very high.

Due to continuous genetic changes of the disease agents and their possible “adaptation” to newly infected animal or human hosts, the risks posed by the different AI viruses to animal and public health is variable and to a large extent unpredictable. However, current knowledge indicates that the health risks posed by the so-called Low Pathogenic AI (LPAI) viruses - are inferior to the one posed by Highly Pathogenic AI (HPAI) viruses, which originate from a mutation of certain LPAI viruses, namely those of types H5 and H7, and which can cause a disease in poultry with a mortality rate as high as 90%.

As regards public health, data available indicate that HPAI viruses of types H5 and H7 have been responsible for the vast majority of the cases of AI reported in humans, and of all cases of human deaths due to AI viruses.

In general, domestic poultry populations are free from AI viruses. However, certain wild birds (particularly migratory waterfowl, such as ducks and geese) act as a permanent “reservoir” of LPAI viruses, from which they occasionally spread to domestic poultry. No measures are currently available or can be envisaged to stop or reduce virus circulation in wild birds living in nature; this means that there is a permanent risk of introduction of potentially very dangerous AI viruses from wild to domestic birds, and ultimately to other animals and humans.

For unclear reasons, an increase of AI outbreaks has occurred in recent years. Serious AI outbreaks (HPAI) have been recently reported in many different species of birds – including domestic poultry, kept under different husbandry

and management practices - in several different areas of the world, and across all continents. These outbreaks have caused the death or killing for disease control purposes of hundreds of millions of birds and very serious losses to the poultry industry worldwide. In connection with these outbreaks, several human cases of infection were also reported, some of them fatal.

In the EU, in the last five years, major outbreaks of HPAI have occurred in Italy (1999-2000) and the Netherlands, with secondary spread to Belgium and Germany (2003). These outbreaks had devastating consequences on the poultry sector and a negative impact on the society as a whole - particularly in the Netherlands, where several human cases of disease also occurred. This was despite the draconian control measures applied by the MSs including massive killing and destruction of poultry and other birds in the affected areas, which often went far beyond the minimum requirements of Directive 92/40/EEC.

After previous EU animal health crises, these outbreaks have prompted further criticisms in the MSs against massive slaughter of animals, due to animal welfare, ethical, social, economic and environmental reasons. The implementation of this measure has had a very negative impact on public opinion, and raised serious criticisms in particular in relation to special categories of birds, such as endangered species or breeds, or pets. The Court of Auditors has also often criticised the Commission due to the economic impact of massive slaughter on the Community budget.

Scientists deem that uncontrolled AI outbreaks, particularly those caused by certain virus types may, following transmission of the virus from birds or other animals into humans, eventually lead to the emergence of a virus fully adapted to humans and able to cause an Influenza pandemic, like the “Spanish flu” of 1917-1919. Such a pandemic could cause millions of human deaths and major socio-economic consequences all over the world.

Directive 92/40/EEC establishes compulsory disease control measures only in case of disease in poultry caused by HPAI. Lessons have been learnt during the recent epidemics. Outbreaks of AI caused by LPAI viruses of types H5 and H7, that subsequently mutated into HPAI viruses have caused devastating consequences. Once mutation has occurred, the virus is extremely difficult to control.

In view of the increased knowledge on the risks for human health posed by AI viruses, the opinions of the Scientific Committee (SC) and the most recent knowledge on the pathogenesis, the epidemiology and the distribution of AI, there is now a clear need to revise and update current legislation to reflect these new advances and experience and to improve disease control of both LPAI and HPAI in future. This will be of direct benefit to animal health and indirectly also human health.

- Existing provisions in the area of the proposal

Council Directive 92/40/EEC; Commission Decision 2002/649/EC; Commission Decision 2002/673/EC; By means of Commission Decision 2002/649/EC guidelines were laid down for EC-wide surveys for AI in poultry

and wild birds. By Commission Decisions 2002/673/EC and 2004/630/EC MSs' programmes for surveys in poultry and wild birds have been approved and are currently ongoing.

Decision 90/424/EEC on expenditure in the veterinary field establishes that MSs may receive a financial contribution from the Community for some of the measures implemented to control and eradicate AI (HPAI).

- Consistency with other policies

Since live poultry is listed in Annex I of 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 to ensure the development of this sector. Furthermore, a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities.

2. Consultation of interested parties and impact assessment

- Consultation of interested parties

Consultation with MSs in working groups and in electronic exchange on a draft proposal has taken place in July/October 2004.

In October 2004 European NGOs have been consulted on a draft proposal.

As a result of the consultation suggestions on improving of some Articles and Annexes of the draft proposal have been taken into account.

- Collection and use of expertise
 1. In 2000 the SC delivered an opinion on AI and recommended to amend the definition laid down in Directive 92/40/EEC so that disease control measures are also adopted in case of infection with AI virus strains of low pathogenicity.
 2. In 2003 another scientific opinion has been issued on the most recent diagnostic techniques and the use of vaccination against AI.
 3. The opinions of the SC are published on:

http://europa.eu.int/comm/food/fs/sc/scah/outcome_en.html.

The opinions have been considered in the drafting of the proposal.

- Impact assessment

The three policy options identified by the SC in its report of 2000 have been assessed and an impact assessment has been laid down¹.

The result can be summarised as follows:

Option 1: not to change the definition of AI and the control measures laid down in Directive 92/40/EEC, with a recommendation that MSs impose restrictions to limit the spread of LPAI:

To maintain the status quo would not reduce the risk for the Community of future HPAI outbreaks due to uncontrolled circulation of LPAI viruses in poultry farms. The simple recommendation to MSs to adopt national measures for LPAI control would not give sufficient guarantees for improved disease control and a reduction of the related health risks, taking also into account the resistance of operators against stricter control measures which may not be equally imposed to their competitors in other MSs. The implementation of national measures for LPAI surveillance and control by each individual MS may thus lead to serious disturbance to trade in poultry and poultry products and to unfair competition between poultry producers in a market where competition is very high.

Option 2: to change the current definition of AI to also include LPAI, thus establishing the same disease control measures for LPAI and HPAI:

To apply the current HPAI control measures also in case of LPAI would be disproportionate to the risks posed by LPAI to both animal and public health; this could also result in massive killings of animals - with a major negative impact on animal welfare - and very high costs for disease control, in circumstances where such massive killings and costs may not be justified nor sustainable. In the case of LPAI, the implementation of a compulsory and systematic stamping out policy, which would lead to massive killing and destruction of animals, does not appear necessary, although in certain cases it can still be a valid option, taking into account its costs and risks vs. its benefits. Furthermore, several other ancillary disease control measures that are necessary for HPAI, should be applied in a more flexible manner in the case of LPAI.

Option 3: to change the definition of AI to also include LPAI, but to foresee control measures taking into account the different type of virus and animal host involved:

The major benefit expected from option 3 would be to reduce the risk of HPAI outbreaks in poultry and other birds by means of a better control on LPAI, and by building on an approach that is proportionate to the risk posed by the two conditions. Furthermore, this approach would only be the one which would match the new Chapter of the O.I.E. Code, which is

¹ SEC(2005)549

expected to be finally adopted in May 2005 and this would prevent EC disease control measures having a negative impact on international trade.

3. Legal elements of the proposal

- Summary of the proposed action

Directive 92/40/EEC would be replaced by a new Directive updating the existing provisions, with the aim of ensuring a better control of AI, taking into account the need to reduce as much as possible the need for massive slaughter of birds.

In accordance with option 3, the following main changes would be introduced to current provisions on AI control:

1. Change in the definition of AI to extend the scope of the control measures also to those LPAI viruses which could potentially mutate into HPAI viruses, however it would make a distinction between the two conditions so that specific control measures can then be applied in relation to the different risks posed by these viruses.
2. Introduction of compulsory surveillance for LPAI in all MSs.
3. New and more flexible provisions on vaccination.
4. New and flexible provisions for the control of LPAI and HPAI in domestic birds other than poultry, such as those kept in zoos or endangered species.
5. New provisions to ensure co-operation between MSs veterinary and public health authorities in case of detection of AI, with the view of protecting human health.
6. Attribution to the Commission, through Comitology procedures, to adopt further and more specific AI control measures and to establish an AI vaccine bank.

- Legal basis

Article 37 of the Treaty establishing the European Community.

- Subsidiarity principle

The animal health measures laid down in this proposal falls under the exclusive regulatory competence of the Community. There are very few measures which are linked to public health, which are in line with the subsidiarity principle, as MSs are given the full responsibility for example to establish disease prevention measures for staff exposed to poultry infected or suspected to be infected with AI.

- Proportionality Principle

The proposal sets out the minimum measures to be applied in the event of an outbreak of AI in poultry and other birds. MSs are free to take more stringent administrative and sanitary action in the field covered by the proposed Directive. Furthermore, provisions are laid down to allow MSs authorities to apply measures proportionate to the different disease situations.

- Choice of instruments

The proposed instrument is a Directive.

Other means would not be adequate for the following reasons:

Experiences since 1964 with Community harmonized veterinary legislation have shown that a Directive gives sufficient flexibility for the MSs to apply legislation in the frame of their systems of legislation and administration. See also the comments on proportionality above.

4. Budget Implications

The budgetary implications of this proposal and of the associated proposal to amend Decision 90/424/EEC are indicated in the impact assessment and can be summarised as follows:

The annual additional cost for the Community budget related to the adoption and implementation of the measures indicated above would be 3-8 M€, that means ~5.5M€ on average. These costs should be largely balanced by the savings related to the reduced risks for future HPAI epidemics. Of course, it cannot be precisely indicated to what extent the new legislation would lead to a decrease in the number of future HPAI epidemics, the occurrence of which is still largely unpredictable and can never be totally excluded, given the nature of the risk in question. However, if these measures had been already in place and implemented in the EU in the last five years, one of the two major epidemics which have occurred in the Community would have been most likely prevented. Based on this, it may therefore be estimated that the implementation of the proposed measures could successfully prevent two major epidemics of HPAI in the next ten years.

The expenditure incurred by the MSs concerned for compensating farmers, for stamping out measures and for cleansing and disinfection (expenditure that are in principle eligible for a 50% Community co-financing in accordance with current provisions of Decision 90/424/EEC) in relation to the two major epidemics which recently occurred in the EU has been between 101 and 174 M€. It can therefore be estimated that at the current costs the prevention of two major epidemics would lead to savings for the Community budget of 100M€ or more over a ten year period. This would largely outweigh the additional costs foreseen for the new LPAI surveillance and control measures (~55 M€ in ten years).

Furthermore, thanks to the adoption of other control measures envisaged under the current proposal, including vaccination, other savings should result from the expected reduced size of future AI epidemics. It is, however, extremely difficult to

quantify these savings.

5. Additional Information

- Repeal of existing legislation

The adoption of the proposal will lead to the repeal of existing legislation.

- European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the EEA.

Proposal for a

COUNCIL DIRECTIVE

on Community measures for the control of Avian Influenza

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission²,

Having regard to the opinion of the European Parliament³,

Having regard to the opinion of the European Economic and Social Committee⁴,

Having regard to the opinion of the Committee of the Regions⁵,

Whereas:

- (1) Avian influenza is a serious, highly contagious disease of poultry and other birds caused by different types of influenza viruses. Those viruses may also spread to mammals, including pigs and humans.
- (2) Since live poultry is listed in Annex I of 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.
- (3) 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 influenza⁶, in order to ensure the protection of animal health and contribute to the development of the poultry sector.
- (4) 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.

² OJ C , , p. .

³ OJ C , , p. .

⁴ OJ C , , p. .

⁵ OJ C , , p. .

⁶ OJ L 167, 22.6.1992, p. 1. Directive as last amended by the 2003 Act of Accession.

- (5) 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 the changes in the Terrestrial Animal Health Code and the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organization for Animal Health (O.I.E.) on avian influenza.
- (6) 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.
- (7) The infection with certain strains of influenza viruses of avian origin may trigger outbreaks in domestic birds of epizootic proportions, causing mortality and disturbances of poultry on a scale, which can threaten in particular the profitability of poultry farming as a whole. Avian influenza viruses may also affect humans and may pose a serious risk to public health.
- (8) Current knowledge indicates that the health risks posed by the so-called low pathogenic avian influenza viruses are inferior to the one posed by highly pathogenic avian influenza viruses, which originate from a mutation of certain low pathogenic viruses.
- (9) Community legislation for the control of avian influenza should give the possibility for the 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.
- (10) With a view to preventing and anticipating the public health problems which may be posed by avian influenza, effective communication and close co-operation should be sought between the animal and public health services in the Member States, so that appropriate measures to safeguard human health can also be taken by the competent authorities, whenever necessary.
- (11) 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 measures which should include a system of active surveillance to be carried out by Member States. That surveillance should follow general guidelines which should be adapted in the light of further knowledge and developments in this field.
- (12) 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. Those measures 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.

- (13) In the case of detection of infection with low pathogenic avian influenza virus, or in the case of serological evidence of infection, where the presence of the virus cannot be confirmed by virus isolation tests, 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.
- (14) 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.
- (15) 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 disinfection of the infected premises, by establishing protection and surveillance zones around the outbreak and, if necessary, by vaccination.
- (16) 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.
- (17) Vaccination against avian influenza can be an effective tool to supplement disease control measures and to avoid massive killing and destruction of poultry and birds. Current knowledge suggests that vaccination may be useful not only in emergencies but also 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 protective vaccination.
- (18) Vaccinated poultry although protected against the clinical signs of disease, may become infected and may 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.
- (19) The Community and the Member States should also have the possibility to establish reserves of vaccine against avian influenza to be used in poultry and other birds in case of an emergency.
- (20) Provisions should be made 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 the Member States.
- (21) Provisions should be made to ensure the necessary level of preparation by the Member States to effectively tackle emergency situations caused by one or more outbreaks of avian influenza, in particular by drawing up contingency plans and setting up control centres. Such contingency plans should take account of the public health risk posed by avian influenza to poultry workers and other personnel.

- (22) 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 quarantine⁷, it 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 Community⁸, in cases of outbreaks in Member States would not be appropriate.
- (23) Cleansing and disinfection should be an integrated 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 market⁹.
- (24) 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 consumption¹⁰ 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. It is necessary to provide for the adoption by comitology of specific, additional or different measures where necessary to enhance further avian influenza control measures.
- (25) 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 origin¹¹ and Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs¹² may be applied under certain conditions to eggs originating from holdings where poultry suspected of being infected with avian influenza is kept.
- (26) 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 must be effective, proportionate and dissuasive.
- (27) 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.
- (28) Taking into account the unpredictability of influenza viruses, it is necessary 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, other birds or

⁷ 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).

⁸ 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).

⁹ OJ L 123, 24.4.1998, p. 1. Directive as last amended by Regulation (EC) No 1822/2003 (OJ L 284, 31.10.2003, p. 1).

¹⁰ OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 668/2004 (OJ L 112, 19.4.2004, p. 1).

¹¹ OJ L 226, 25.6.2004, p. 22.

¹² OJ L 139, 30.4.2004, p. 7.

other animals caused by any avian influenza viruses posing a serious threat to animal or public health, whenever such measures are necessary.

- (29) This Directive sets out the minimum control measures to be applied in the event of an outbreak of avian influenza in poultry and other 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 provides that Member States authorities may apply measures proportionate to the health risk posed by different disease situations.
- (30) In accordance with the principal of proportionality, it is necessary and appropriate for the achievement of the basic objective 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.
- (31) 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 Commission¹³.
- (32) In the interests of clarity and rationality of Community legislation, Directive 92/40/EEC should be repealed and replaced by this Directive.

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Directive sets out:
 - (a) certain preventative measures aimed at the surveillance and the early detection of avian influenza and increasing the level of awareness and preparation of the competent authorities and the farming community to the risks of that disease;
 - (b) the minimum control measures to be applied in the event of an outbreak of avian influenza in poultry and other birds and a possible spread of avian influenza viruses to mammals;
 - (c) other measures to be applied where a serious threat to animal or public health is identified in relation to any infection of birds or mammals caused by any influenza viruses of avian origin and to prevent the transmission of infection from those animals to humans.

¹³ OJ L 184, 17.7.1999, p. 23.

2. Member States shall remain free to take more stringent measures in the field covered by this Directive.

Article 2

Definitions of avian influenza, highly pathogenic avian influenza and low pathogenic avian influenza

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

1. “avian influenza” means an infection of poultry or other birds caused by any influenza A virus:
 - (a) of the subtypes H5 or H7; or
 - (b) with an intravenous pathogenicity index in six-week old chickens greater than 1.2;
2. “highly pathogenic avian influenza (HPAI)” means an infection of poultry or other birds caused by:
 - (a) avian influenza viruses of the subtypes H5 and H7 with a 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 birds caused by avian influenza viruses of subtypes H5 and H7 that does not come within the definition in point (2).

Article 3

Other Definitions

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

1. ‘poultry’ means all birds that are reared or kept in captivity for the production of meat, hatching eggs and eggs for consumption, the production of other commercial products, for restocking supplies of game or for breeding these categories of birds;
2. ‘wild bird’ means a free-living bird which is not kept on any holding as defined in point 5;
3. ‘other bird’ means any bird other than poultry that is kept in captivity for shows, races, exhibitions and competition, such as ornamental birds and racing pigeons, or for any reason other than those referred to in point 1;

4. 'officially registered rare breeds of poultry or other birds' means any poultry or other birds that the competent authority has officially recognised as such within their contingency plan provided for in Article 63;
5. 'holding' means any agricultural or other premises, such as hatcheries, circuses, zoos, pet bird shops, bird markets, and aviaries, where poultry or other birds are being bred or kept on a permanent or temporary basis, except:
 - (a) slaughterhouses, means of transport, quarantine facilities and centres, border inspection posts and laboratories; and
 - (b) living areas for humans on such premises for the purposes of the second subparagraph of Article 11(9), point (e) of Article 19, point (f) of Article 30, point (g) of Article 39 (5) and point (h) of Article 44 (1) unless poultry or other birds are kept on a permanent basis therein;
6. 'commercial poultry holding' means a holding where poultry is kept for commercial purposes;
7. 'non-commercial holding/pet bird holding' mean a holding where poultry or other birds are kept by their owners:
 - (a) for their own consumption of the poultry or other birds or their products; or
 - (b) as pets;
8. 'poultry compartment' or 'other birds compartment' means one or more poultry holdings or other birds holdings under a common biosecurity management system containing a poultry or other birds sub-population with a distinct health status with respect to avian influenza subjected to appropriate surveillance, control and biosecurity measures;
9. 'flock' means all poultry or other birds within a single production unit;
10. 'production unit' means a unit in a holding where the official veterinarian is satisfied that it 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 birds kept there,
11. 'ready-to-lay-poultry' means poultry prior to the laying stage;
12. 'hatching eggs' means eggs for incubation, laid by poultry;
13. 'day-old chicks' means all poultry less than 72 hours old, not yet fed; however, muscovy ducks (*Cairina moschata*) or their crosses may be fed;
14. 'diagnostic manual' means the diagnostic manual provided for in Article 51(1);
15. 'infected poultry' and 'infected other birds' means any poultry or other birds:
 - (a) in which the presence of avian influenza has been confirmed in accordance with the diagnostic manual; or

- (b) in the case of second and subsequent outbreaks of avian influenza, any poultry or other birds in which clinical signs, post-mortem lesions or reactions to laboratory tests carried out in laboratories approved in accordance with the first subparagraph of Article 51 (3) ('approved laboratory') are consistent with the diagnosis of avian influenza in accordance with the diagnostic manual;
16. 'poultry or other birds suspected of being infected' means any poultry or other 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. 'incubation period' means a maximum period of 21 days that takes place between the probable date of infection and the occurrence of clinical signs of avian influenza;
18. 'owner' means any natural or legal person who owns or keeps or who is otherwise responsible for poultry or other birds, whether or not for financial reward;
19. 'competent authority' means the authority of a Member State competent to carry out veterinary checks or administrative action in accordance with this Directive or any authority to which such competence has been delegated;
20. 'veterinary check' means any physical check and/or administrative formality carried out by the competent authority;
21. 'official veterinarian' means the veterinarian designated by the competent authority;
22. 'official surveillance' means the action of careful watching of a health situation concerning avian influenza by the competent authority which may lead to further investigations by it;
23. 'official supervision' means the actions taken by the competent authority to check and verify that a person is complying with or has complied with the instructions concerning avian influenza received from that authority;
24. 'killing' means any procedure other than slaughter causing the death of an animal or bird;
25. 'slaughter' means any procedure causing the death of an animal or bird by bleeding;
26. '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) the detailed rules provided for in Article 64(1) of this Directive;

27. 'Community vaccine bank' means appropriate premises designated in accordance with Article 59(1) of this Directive for the storage of Community reserves of avian influenza vaccines authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council¹⁴ and Regulation (EC) No 726/2004 of the European Parliament and of the Council¹⁵;
28. 'contact holding' means a holding where avian influenza could have been introduced as a result of its location, the movement of persons, poultry or other birds, vehicles or in any other way;
29. 'suspected outbreak' means a holding containing poultry or other birds where the competent authority suspects the presence of avian influenza;
30. 'outbreak' means a holding, where avian influenza has been confirmed by the competent authority;
31. '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 of Council Directive 64/432/EEC¹⁶, or the first outbreak in a different region of the same Member State;
32. 'differentiating infected from vaccinated animal (DIVA strategy)' means a vaccination strategy which enables the differentiation 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;
33. 'depopulation' means the removal of all poultry or other birds from a holding, a poultry compartment or other birds compartment, or a production unit;
34. 'mammal' means an animal of the class *Mammalia*;
35. 'carcasses' means poultry or other birds which have died or have been killed.

CHAPTER II

SURVEILLANCE, NOTIFICATIONS AND EPIDIOLOGICAL INQUIRIES

Article 4

Annual surveillance programmes

1. Member States shall ensure that surveillance programmes complying with Annex I are adopted each year in order to:

¹⁴ OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC.

¹⁵ OJ L 136, 30.4.2004, p. 1.

¹⁶ OJ 121, 29.7.1964, p. 1977. as last amended by Regulation (EC) No 1/2005 (OJ L 3, 5.1.2005, p. 1).

- (a) detect the prevalence of infections with avian influenza virus subtypes H5 and H7 in different species of poultry
 - (b) contribute to the knowledge on the threats posed by wildlife in relation to any influenza virus in birds of avian origin.
2. Member States shall submit the annual surveillance programmes to the Commission for approval by 15 June 2007 and thereafter by 15 June each year in accordance with the procedure referred to in Article 65(2).
3. Member States shall report to the Commission each year on the implementation of the annual surveillance programmes by 15 March of the year following implementation.

Article 5

Reporting and notifications

1. Member States shall provide for the immediate reporting to the competent authority of any cases of infected poultry, infected other birds or poultry or other birds suspected being infected.
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:
 - (a) any positive findings of avian influenza which are confirmed by the competent authority in slaughterhouses, means of transport, border inspection posts, and other places at Community borders and quarantine facilities or centers operating in accordance with Community legislation on imports of poultry or other birds;
 - (b) the results of any official surveillance for avian influenza carried out in poultry, other birds or other animals, including positive findings in wild birds; and
 - (c) any infection of poultry, other birds or other animals caused by any influenza virus of avian origin other than those referred to in point 1 of Article 2 which may pose a serious threat to animal or public health.

Article 6

Epidemiological inquiry

1. Member States shall ensure that epidemiological inquiries are carried out on the basis of questionnaires, established within the framework of the contingency plans provided for in Article 63.
2. The epidemiological inquiry shall deal with the following:
 - (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 on the holding, in the slaughterhouse or means of transport;
 - (c) the identification of any contact holding;
 - (d) the movements of poultry or other birds, persons, vehicles or any material or substance likely to have caused the spread of avian influenza virus.
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.

CHAPTER III

MEASURES TO BE APPLIED IN CASES OF SUSPECTED OUTBREAKS

Article 7

Measures to be applied on holdings

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 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 and other birds and all mammals of domestic species are counted or, if appropriate, estimated following their relevant category;
 - (b) a list is compiled of the approximate number of poultry and other 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 and deaths throughout the period of the suspected outbreak and shall be produced on request to the competent authority;
 - (c) poultry and other birds must be restricted to their living quarters or be confined in some other place where they can be isolated to prevent contacts with other poultry, other birds or wild birds;
 - (d) no poultry and other birds may enter or leave the holding ;

- (e) no carcasses, poultry or other birds meat including offal ('meat'), animal feed, utensils, materials, waste, droppings, poultry or other birds manure ('manure'), used litter or anything likely to transmit avian influenza may leave the holding without an authorisation from the competent authority;
 - (f) no eggs may leave the holding, with the exception of eggs including hatching eggs authorised by the competent authority to be sent directly to an establishment for the manufacture of egg products, as set out in Chapter II Section X of Annex III to Regulation (EC) No 853/2004 and to be handled and treated in accordance with Chapter IX of Annex II to Regulation (EC) No 852/2004; where the competent authority issues such an authorisation it shall be subject to the conditions set out in Annex III to this Directive;
 - (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 and other birds and of the holding itself in accordance with the instructions of the competent authority.
3. The competent authority shall ensure that an epidemiological inquiry is carried out in accordance with Article 6 ('the epidemiological inquiry').

Article 8

Derogations from certain measures to be applied on holdings

The competent authority may grant derogations from the measures provided for in points (c) to (f) of Article 7(2) 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.

Article 9

Duration of the measures to be applied on holdings

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 presence of avian influenza has been excluded by the competent authority.

Article 10

Additional measures based on the epidemiological inquiry

1. Based on the preliminary results of the 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. A temporary restriction may be introduced on the movements of poultry, other birds and eggs and the movement of vehicles related to the poultry sector in a large area or in the whole of the Member State.

That restriction may be extended to movements of mammals of domestic species, but shall not exceed 72 hours, unless justified by exceptional circumstances.

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

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

Samples shall be taken from the poultry or other birds when they are killed in order that the risk of a suspected outbreak can 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

MEASURES TO BE APPLIED IN CASES OF AN OUTBREAK OF HIGHLY PATHOGENIC AVIAN INFLUENZA (HPAI)

SECTION 1

MEASURES TO BE APPLIED ON HOLDINGS

Article 11

Measures to be applied by the competent authority

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 birds of the species in which HPAI has been confirmed 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 or killing and in accordance with Council Directive 93/119/EEC¹⁷.

That killing may be extended to other species of birds on the holding, on the basis of a risk assessment concerning further spread of avian influenza.
3. Poultry and other birds which have died or have been killed and hatching and table eggs on the holding shall be disposed of under official supervision.

¹⁷ OJ L 340, 31.12.1993, p. 21. Directive amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

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 hatching and table 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.

However, the competent authority may grant authorisations for table 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 and 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.

6. All substances and waste likely to be contaminated, such as poultry feed ('feed'), shall be destroyed or subjected to a treatment ensuring the destruction of the avian influenza virus, in accordance with the instructions of the official veterinarian.
7. Manure, slurry and bedding likely to be contaminated shall be treated in accordance with Article 49.
8. Following the disposal of carcasses, the buildings used for housing them, the equipment likely to be contaminated and the vehicles used for transporting the poultry or other birds, carcasses, meat, feed, manure, slurry, bedding and of any other material or substance likely to be contaminated shall be cleansed, disinfected or treated in accordance with Article 49.
9. Other domestic 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 52 (1) as soon as possible.

Article 12

Derogations from certain measures to be applied on holdings

1. Member States shall draw up detailed rules for granting derogations, as provided for in Articles 13 and 14, including alternative appropriate measures and conditions.

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 65(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/pet bird holding, a circus, a zoo, a pet bird shop, a wild life park, a fenced area where poultry or other birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other birds, provided that such derogations do not endanger disease control and basic Community interests.
2. The competent authority shall ensure that where a derogation is granted, as provided for in paragraph 1, the poultry and other birds concerned by the derogation:
 - (a) are kept completely isolated from other poultry or other birds and where appropriate from wild birds;
 - (b) must be subjected to further surveillance and testing in accordance with the diagnostic manual until the laboratory tests have indicated that they no longer pose a significant risk of further spread of HPAI; and
 - (c) are not to be 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.

SECTION 2
MEASURES TO BE APPLIED IN SEPARATE PRODUCTION UNITS AND CONTACT HOLDINGS

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 healthy poultry provided that such derogations do not endanger disease control measures and basic Community interests.

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 premises, is satisfied that they are completely independent of other production units in terms of location and day-to-day management of the poultry 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 shall 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 the poultry 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.

SECTION 3
PROTECTION AND SURVEILLANCE ZONES AND FURTHER RESTRICTED ZONES

Article 16

Establishment of protection and surveillance zones 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. When establishing protection and surveillance zones, as provided for in paragraph 1, the competent authority shall at least take account of the following criteria:
 - (a) the epidemiological inquiry;
 - (b) the geographical situation, particularly natural boundaries;
 - (c) the location and proximity of holdings;
 - (d) patterns of movements and trade in poultry and other birds and the availability of slaughterhouses;
 - (e) the facilities and personnel available to control any movement within the protection and surveillance zones of poultry and other birds, their carcasses, manure, bedding or used litter, in particular if the poultry or other birds to be killed and disposed of have to be moved from their holding of origin.
3. 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 2.
4. 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 in the protection and 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 the movements of poultry or other birds, meat, eggs, carcasses and feed;

- (b) owners are to provide the competent authority, on request, with any relevant information concerning the poultry or other birds and eggs entering or leaving the holding .
2. The competent authority shall ensure that all persons concerned are fully aware of the restrictions in place in the protection and surveillance zones.

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

SECTION 4

MEASURES TO BE APPLIED IN THE PROTECTION ZONE

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 holdings are visited by an official veterinarian within seven days of the date of the establishment of the protection zone for a clinical examination of the poultry and other birds; and, if necessary, the collection of samples for laboratory tests; a record of such visits and the findings thereof shall be kept;
- (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

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

- (a) poultry and other birds must be restricted to their living quarters or be confined in some other place where they can be isolated to prevent contacts with other poultry, other birds or wild birds;
- (b) carcasses are disposed of;
- (c) vehicles and equipment used for transporting live poultry or other birds and meat, feed, manure, slurry and bedding, and any other material or substances likely to be contaminated are cleansed, disinfected or treated as soon as possible after contamination, in accordance with Article 49;

- (d) all vehicles used by staff or other persons which enter or leave holdings and are likely to have become contaminated are cleansed, disinfected or treated immediately after contamination, in accordance with Article 49;
- (e) no poultry, other birds or other domestic animals may enter or leave a holding where poultry is kept without authorisation of the competent authority; this restriction shall not apply to animals which have access only to the living areas for humans on such holdings and when any contact with poultry or other birds can be excluded;
- (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 are kept by the owner in order to facilitate disease surveillance and control and must be made available upon request by the competent authority.

Article 20

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

The competent authority shall ensure that the removal or spreading of used litter or manure from holdings in protection zones are prohibited, unless authorised by it.

However, the movement of manure 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 the specific rules referred to in Article 64 (1).

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 birds are prohibited in protection zones.

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

Article 22

Prohibition on the movement and transport of poultry and other birds and eggs

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

However, that prohibition 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

By way of derogation from Article 22, the competent authority may authorise the direct transport of poultry for immediate slaughter, subject to the following conditions:

- (a) a clinical examination of the poultry on the holding of origin is carried out by the official veterinarian in order to prevent that any poultry, in which clinical signs of HPAI have been detected, is 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 to a slaughterhouse designated by the competent authority ('the designated slaughterhouse'), located within the protection or surveillance zone or in exceptional cases outside those zones;
- (d) the competent authority responsible for the designated slaughterhouse is informed before the dispatch of the poultry and that competent authority informs the competent authority responsible for the place of dispatch of the arrival of the poultry at the designated slaughterhouse;
- (e) at the designated slaughterhouse, 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 takes account of any signs relating to the presence of avian influenza during ante-mortem and post-mortem inspections carried out at the designated slaughterhouse;
- (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 Directive 2002/99/EC¹⁸, unless otherwise decided in accordance with the procedure referred to in Article 65(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

¹⁸ OJ L 18, 23.1.2003, p. 11.

- (ii) it is otherwise decided in accordance with the procedure referred to in Article 65(3).

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 to a holding or shed of that holding in the same Member State in which there is no other poultry, 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;
 - (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.

2. By way of derogation from Article 22, the competent authority may authorise the direct transport of day-old-chicks hatched from hatching eggs originating from holdings located outside the protection and surveillance zones to any other holding in the same Member State, 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 in 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 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 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;
- (d) the holding or shed of destination is placed under official surveillance following the arrival of the ready-to-lay poultry.

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 to a hatchery designated by the competent authority ('the designated hatchery'), preferably located within the protection or surveillance zone, subject to the following conditions:
 - (a) the parent flocks from which the hatching eggs are derived have been examined in accordance with the diagnostic manual with favourable results;
 - (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;
 - (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 table eggs 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.

Article 27

Derogation for the direct transport of poultry or other birds which have died

By way of derogation from Article 22, the competent authority may authorise the direct transport of poultry or other birds which have died provided that they are transported for disposing of.

Article 28

Cleansing and disinfecting of means of transport

1. The competent authority shall ensure that the vehicles and equipment used for the transport as provided for in Articles 23 to 27 or in the transport of meat are cleansed and disinfected as soon as possible following the transport, in accordance with Article 49.
2. The competent authority shall ensure that biosecurity measures are applied to prevent the spread of avian influenza by means of movements of vehicles to and from holdings located within the protection zone, particularly vehicles transporting feed.

Article 29

Duration of measures

1. The measures provided for in this Section shall be maintained at least 21 days following the date of completion of preliminary cleansing and disinfection on the infected holding in accordance with Article 49 and until all poultry and other birds on holdings located in the protection zone have undergone laboratory tests in order to detect the eventual presence of avian influenza 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 5

MEASURES TO BE APPLIED IN THE SURVEILLANCE ZONE

Article 30

Measures to be applied in the surveillance zone

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

- (a) a census of all poultry holdings is made as soon as possible;
- (b) the movement of poultry, ready-to-lay poultry, day-old chicks, hatching and table 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 hatching and table eggs to holdings, slaughterhouses or packing centres 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 point (a) of Article 23;
 - (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;
 - (iii) day-old-chicks:
 - to a holding or shed of such holding in the same Member State in which there is no other poultry provided that appropriate biosecurity measures are applied and the holding is placed under official surveillance following the transport, 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 in those zones 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 designated packing centre, provided that they are packed in disposable packaging by applying biosecurity measures in accordance with the instructions of the competent authority;
- (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 birds, carcasses, feed, manure, slurry and bedding, and any other material or substances likely to be contaminated, are cleansed and disinfected as soon as possible after contamination in accordance with Article 49;
- (f) no poultry, other birds or other domestic animals may enter or leave a holding where poultry is kept without authorisation of the competent authority; this restriction shall not apply to animals which have access only to the living areas for humans on such holdings and when any contact to poultry or other birds can be excluded;
- (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 or manure 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 the specific rules referred to in Article 64 (1);
- (i) fairs, markets, shows or other gatherings of poultry or other 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 at least 30 days following the date of completion of preliminary cleansing and disinfection on the infected holding in accordance with Article 49 and until laboratory tests in accordance with the diagnostic manual in order to detect the eventual presence of avian influenza have been carried out on holdings located within the surveillance zone.

SECTION 6
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 4 and 5 shall apply inside the further restricted zones provided for in Article 16 (3) ('the further restricted zones').
2. The competent authority may provide that preventative depopulation, either by slaughtering or killing of poultry or other birds, in accordance with Council Directive 93/119/EEC, is applied in holdings and areas at risk located in the 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, 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 65 (3).

SECTION 7
DEROGATIONS AND BIOSECURITY MEASURES

Article 33

Derogations

1. The competent authority may, based on a risk assessment, grant derogations from the measures provided in Sections 4 and 5 in cases of confirmation of HPAI in a hatchery.
2. The competent authority may grant derogations from the measures provided for in points (b) and (c) of Article 18, Article 22 and points (b), (c) and (f) of Article 30 in cases of an outbreak of HPAI in a non-commercial holding/pet bird holding, a circus, a zoo, a wild life park, a fenced area where poultry or other birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other birds.
3. By way of derogation from of Sections 4 and 5, in cases of outbreaks of HPAI the 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.

4. The derogations provided for in paragraphs 1, 2 and 3 shall only be granted provided that such derogations do not endanger disease control and basic Community interests.
5. Member States granting derogations provided for in paragraphs 1, 2 and 3 shall immediately inform the Commission thereof.
6. 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, 2 and 3, measures to prevent the spread of avian influenza may be adopted in accordance with the procedure referred to in Article 65 (3).

Article 34

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 4, 5 and 6, 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 specific poultry compartments and other 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 disposing 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 65 (3).

SECTION 8
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 certain premises other than holdings and in means of transport

Where there is suspicion or confirmation of the presence of HPAI in slaughterhouses, means of transport or border inspection posts, the competent authority shall immediately set in motion an investigation to confirm or exclude its presence in accordance with the diagnostic manual.

Article 36

Measures to be applied in slaughterhouses

1. The competent authority shall ensure, where HPAI is suspected or confirmed in a slaughterhouse, 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 the poultry is slaughtered, their meat shall be kept separately under official supervision until further investigations to confirm or exclude the presence of HPAI are completed, in addition to the investigations provided for in Article 35.

2. If HPAI is confirmed, the meat of the infected poultry or other birds and the meat likely to be contaminated shall be disposed of under official supervision.

Article 37

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

1. The competent authority shall ensure, where HPAI is suspected or confirmed in border inspection posts or means of transport, that, on the basis of a risk assessment, all poultry and other birds present in the border inspection post or in the means of transport are conveyed to an appropriate place to be killed or slaughtered as soon as possible under official supervision.

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

Where the poultry is slaughtered, their meat shall be kept separately under official supervision until further investigations to confirm or exclude the presence of HPAI are completed, in addition to the investigations provided for in Article 35.

2. If HPAI is confirmed, the carcasses of the infected poultry or other birds and the meat likely to be contaminated 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 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 in accordance with Article 49; in the case of border inspection posts, the prohibition on introduction may be extended to other animals;
- (b) the cleansing and disinfection of buildings, equipment and vehicles takes place under the supervision of the official veterinarian in accordance with Article 49;
- (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

MEASURES TO BE APPLIED IN CASES OF AN OUTBREAK OF LOW PATHOGENIC AVIAN INFLUENZA (LPAI)

SECTION 1

MEASURES TO BE APPLIED ON HOLDINGS

Article 39

Measures to be applied by the competent authority

1. Without prejudice to the measures provided to in points (a), (b), (c), (e), (g) and (h) of Article 7 (2), the competent authority shall ensure that in cases of outbreaks of LPAI, the measures provided for in paragraphs 2 to 6 of this Article are taken 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 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 birds on the holding based on 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 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/EEC and the competent authority shall decide that the poultry or other birds are:

- (a) killed as soon as possible, or
- (b) slaughtered in a designated slaughterhouse, provided that bio-security measures are applied.

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

- (a) carcasses, and
- (b) hatching eggs on the holding.

5. 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 wherever 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 placed under official surveillance and investigations are carried out in accordance with the diagnostic manual;
- (c) table eggs present on the holding and further produced in the holding before depopulation, as provided for in paragraph 2, are either transported to a designated packing centre, treated or disposed of;
- (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 are treated in accordance with Article 49;

- (f) after depopulation, the buildings used for housing the poultry and other 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 are cleansed, disinfected or treated in accordance with Article 49 as soon as possible;
 - (g) domestic animals, other than those which have only access to the living areas for humans do not enter or leave the holding without the authorisation of the competent authority;
 - (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 52(1), as soon as possible;
 - (i) the epidemiological inquiry is completed.
6. The competent authority may take additional precautionary measures to prevent the spread of LPAI, including specifying the destiny and treatment of the eggs and the treatments of the meat obtained provided that the procedure referred to in point (b) of paragraph 3 is followed.
7. Member States applying the measures provided for in paragraphs 2, 4 and 5 shall inform the Commission thereof.

Article 40

Derogations for certain premises

1. The competent authority may grant derogations from the measures provided for in Article 39(2) and point (b) of Article 39(4) in cases of an outbreak of LPAI in a non-commercial holding/pet bird holding, a circus, a zoo, a pet bird shop, a wild life park, a fenced area where poultry or other birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other birds, provided that such derogations do not endanger disease control and basic Community interests.
2. The competent authority shall ensure that where a derogation is granted, as provided for in paragraph 1, the poultry and other birds concerned by the derogation:
- (a) are kept completely isolated from other poultry or other birds and where appropriate from wild birds;
 - (b) must be subjected to further surveillance and testing in accordance with the diagnostic manual until the laboratory tests have indicated that they no longer pose a significant risk of further spread of LPAI; and
 - (c) are not to be 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, taking account of the animal health guarantees which may be obtained and shall provide for alternative appropriate measures.
- 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 65 (3).

SECTION 2

MEASURES TO BE APPLIED IN CASES OF OUTBREAK OF LPAI IN 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 and basic Community interests.
- 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 67(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 shall 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.

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 three kilometres 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 poultry holdings is made as soon as possible;
 - (b) laboratory tests are carried out on poultry holdings within a radius of at least one kilometre around the holding in accordance with the diagnostic manual.
 - (c) all movements of poultry and other birds, ready-to-lay poultry, day-old chicks and hatching and table eggs within the restricted zone are subjected 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 and other birds, ready-to-lay poultry, day-old chicks

and hatching and table eggs from the restricted zone are prohibited during the first 15 days following the establishment of the zone, unless the competent authority authorises the direct transport of:

- (i) poultry for slaughter to a slaughterhouse in the same Member State;
 - (ii) ready-to-lay poultry to a holding under official surveillance in the same Member State in which there is no other poultry; that holding shall be placed under official surveillance following the arrival of the ready-to-lay poultry;
 - (iii) day-old-chicks:
 - to a holding or shed of such holding in the same Member State in which there is no other poultry, provided that appropriate biosecurity measures are applied and the holding is placed under official surveillance following the transport; or
 - if hatched from hatching 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 in 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 by the application of biosecurity measures in accordance with the instructions of the competent authority;
- (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 birds, feed, manure, slurry and bedding and any other material or substances likely to be contaminated are cleansed and disinfected as soon as possible after contamination, in accordance with Article 49;
 - (h) no poultry, other 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 of domestic species which have only access to the living areas for humans on such holdings and when any contact to poultry or other birds can be excluded;
 - (i) 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;

- (j) the removal or spreading of used litter or manure is prohibited, unless authorised by the competent authority; the movement of manure 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 the specific rules referred to in Article 64 (1);
 - (k) fairs, markets, shows or other gatherings of poultry or other birds are prohibited, unless authorised by the competent authority;
 - (l) poultry or other birds for restocking of game are not be 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. Taking account of the measures referred to in paragraph 2, further measures may be adopted to prevent the spread of avian influenza in accordance with the procedure referred to in Article 65(3).

Article 45

Duration of measures

The measures provided for in this Section shall be maintained either:

- (a) at least 21 days following the date of completion of preliminary cleansing and disinfection of the infected holding in accordance with Article 49 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
- (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.

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 Article 43 and points (c), (d), (h) and (i) of Article 44 in cases of an outbreak of LPAI in a non-commercial holding/pet bird holding, a circus, a zoo, a pet bird shop, a wild life park, a fenced area where poultry or other birds are kept for scientific

purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other birds, provided that such derogations do not endanger disease control and basic Community interests.

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 65(3).

CHAPTER VI

MEASURES CONCERNING PUBLIC HEALTH AND ANIMALS OTHER THAN POULTRY OR OTHER BIRDS

Article 47

Public health measures

1. Member States shall ensure that in cases of outbreaks or confirmation of any other finding of influenza viruses of avian origin in poultry and other birds or mammals which may pose a risk to public health, the competent authority shall contact the relevant national public health authority as soon as possible in order to decide on the early adoption of appropriate precautionary measures aiming at the prevention of influenza infections in poultry workers and other persons at risk.
2. Where a risk to public health is identified, as referred to in paragraph 1, the Member State concerned shall immediately inform the Commission and the other Member States thereof.
3. The situation shall be reviewed in the framework of the Committee as soon as possible.
4. Additional animal health measures to prevent the spread of avian influenza from poultry, other birds or mammals to humans may be adopted in accordance with the procedure referred in Article 65 (3).

Article 48

Laboratory tests and other measures concerning pigs and other animals

1. The competent authority shall ensure that following an outbreak, laboratory tests are carried out on pigs present on the holding to confirm or exclude the presence of avian influenza.

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

2. Where the laboratory tests provided for in paragraph 1 confirm positive findings for avian influenza viruses in pigs, the competent authority may authorize 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 the 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, in particular during transport, and in accordance with Directive 93/119/EEC.
4. The competent authority may, following an outbreak or confirmation of a positive finding of avian influenza in pigs on a holding, and based on a risk assessment, apply the measures provided for in paragraphs 1, 2 and 3 to any other animals 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. Additional measures to prevent the spread of avian influenza in pigs and other animals, may be adopted in accordance with the procedure referred to in Article 65 (3)
7. Rules for the application of this Article may be adopted in accordance with the procedures referred to in Article 65 (2).

CHAPTER VII

CLEANSING, DISINFECTION AND RE-POPULATION

Article 49

Cleansing, disinfection and treatment

Member States shall ensure that:

- (a) the cleansing, disinfection and treatment of places, vehicles and any materials or substances 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) the disinfectants to be used and their concentrations are approved by the competent authority;

Article 50

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 poultry in a commercial poultry holding 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 49.
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 undergoes a weekly clinical examination carried out by the official veterinarian;
 - (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, 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. The re-population of poultry or other birds in non-commercial holding/pet bird holding, a circus, a zoo, a pet bird shop, a bird market, an aviary, a wild life park, or a fenced area where poultry or other birds are kept for scientific purposes or purposes related to the conservation of endangered species or officially registered rare breeds of poultry or other birds shall take place in accordance with the instructions of the competent authority.
5. The re-repopulation of poultry in contact holdings shall take place in accordance with the instructions of the competent authority.
6. Based on a risk assessment, the competent authority may order that the procedures provided for in paragraph 3 be applied to other holdings than commercial poultry holdings.

CHAPTER VIII

DIAGNOSTIC PROCEDURES, DIAGNOSTIC MANUAL AND REFERENCE LABORATORIES

Article 51

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 are carried out in accordance with the diagnostic manual in order to ensure uniform procedures for the diagnosis of avian influenza.

That manual shall be adopted in accordance with the procedure referred to Article 65 (2) within six months from the date of entry into force of this Directive. 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:
 - (i) to be observed by approved laboratories carrying out tests for the diagnosis of avian influenza; and
 - (ii) for the transport of samples;
 - (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 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 1 July 2006 and kept up-to-date.

Article 52

Reference laboratories

1. The laboratory set out in Annex VII shall be the Community reference laboratory for avian influenza ('the Community reference laboratory').

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

2. The laboratories listed in Part 1 of Annex VIII shall be the national reference laboratories for avian influenza ('the national reference laboratories').

Member States shall communicate to the Commission and other Member States any changes concerning their national reference laboratories as listed in Part 1 of that Annex .

3. Member States shall ensure that the national reference laboratories:
 - (a) carry out the functions and duties set out in Part 2 of 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.

CHAPTER IX

VACCINATION

SECTION 1

GENERAL PROHIBITION OF VACCINATION

Article 53

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 and Regulation No 726/2004 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 65(2).

SECTION 2

EMERGENCY VACCINATION

Article 54

Emergency vaccination in poultry or other birds

1. Member States may introduce emergency vaccination in poultry or other birds, in accordance with this Section, where there is an outbreak and a risk that avian influenza may spread.
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;
 - (c) the species and categories of poultry or other birds or, if appropriate, the poultry or other birds compartment to be vaccinated;
 - (d) the approximate number of poultry or other birds to be vaccinated;
 - (e) the summary of the vaccine characteristics;
 - (f) the envisaged duration of the emergency vaccination campaign;
 - (g) measures for movements of poultry or other birds and their products in accordance with the general requirements set out in Annex IX, except where the Member State concerned provides justification for measures differing from those general requirements;
 - (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 and other 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 and other birds.
3. Detailed rules for emergency vaccination may be established in accordance with the procedure referred to in Article 65 (2).

Article 55

Approval of emergency vaccination plans

1. The Commission shall immediately examine the emergency vaccination plan, as provided for in Article 54(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 65(3).

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

Article 56
Derogations

1. By way of derogation from Article 54, Member States may apply emergency vaccination around the outbreak before approval of the emergency vaccination plan, subject to the following conditions:
 - (a) the emergency vaccination plan and the decision to apply emergency vaccination are notified to the Commission before the commencement of the emergency vaccination;
 - (b) the Member State concerned applies the general requirements for movements of poultry and poultry products set out in Annex IX;
 - (c) the decision to apply emergency vaccination does not endanger disease control and basic Community interests.
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. Additional measures may be adopted in accordance with the procedure referred to in Article 65 (3).

SECTION 3
PROTECTIVE VACCINATION

Article 57
Protective vaccination in poultry or other birds

1. Member States may introduce protective vaccination in poultry or other birds, in accordance with this Section, where they deem that certain areas of their territory, certain characteristics of their poultry production or certain categories of poultry or other birds are at a particular high risk of the introduction and spread of avian influenza.
2. Where a Member State intends to introduce protective vaccination, as provided for in paragraph 1, it shall submit a protective 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 protective vaccination, including the disease history;
 - (b) the geographical area in which the protective vaccination is to be carried out and the number of holdings in that area;

- (c) the species and categories of poultry or other birds or, if appropriate, the poultry or other birds compartment to be vaccinated;
 - (d) the approximate number of poultry or other birds to be vaccinated;
 - (e) the summary of the vaccine characteristics;
 - (f) the envisaged duration of the protective vaccination campaign;
 - (g) the specific provisions on the movements of vaccinated poultry and other birds without prejudice to the measures provided for in Sections 4, 5 and 6 of Chapter IV and Section 3 of Chapter V;
 - (h) the record keeping and registration of the vaccinated poultry and other birds;
 - (i) the laboratory tests to be carried out in the holdings where protective vaccination is to be carried out and such tests in other holdings located in the vaccination area in order to monitor the epidemiological situation, the effectiveness of the protective vaccination campaign and the control of movements of vaccinated poultry and other birds.
3. Detailed rules for protective vaccination may be established in accordance with the procedure referred to in Article 65(2).

Article 58

Approval of protective vaccination plan

1. The Commission shall immediately examine the protective vaccination plan provided for in Article 57(2), together with the Member State concerned and shall review the situation in the Committee as soon as possible.
2. The protective vaccination plan shall be approved in accordance with the procedure referred to in Article 65(3).

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

SECTION 4 VACCINE BANKS

Article 59

Community vaccine bank

1. A Community vaccine bank may be established in accordance with the procedure referred in Article 65(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 65 (3), subject to detailed arrangements between the Commission and the third country concerned on the financial and technical co-operation to be adopted in accordance with that procedure.

Article 60

National vaccine banks

1. Member States may, within the framework of the contingency plan provided for in Article 63, 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 protective 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 61

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/EC¹⁹ and Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council²⁰.

Article 62

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 must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by

¹⁹ OJ L 38, 12.2.1998, p. 10.

²⁰ OJ L 165, 30.4.2004, p. 1.

31 December 2006 at the latest and shall notify it without delay of any subsequent amendment affecting them.

Article 63

Contingency plans

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 a precise indication of the number, location and census of all commercial poultry holdings and vaccine requirements, which each Member State concerned considers it needs in the event of emergency vaccination.
3. 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 65(2). Any subsequent amendments to that plan shall be adopted in accordance with the same procedure.

4. Member State shall update the contingency plan at least every five year and submit it to the Commission for approval in accordance with the procedure referred to in Article 65(2).
5. 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 centers, expert groups and real-time alert exercises, may be adopted in accordance with the procedure referred to in Article 65(2).

CHAPTER XI

IMPLEMENTING POWERS AND COMMITTEE PROCEDURE

Article 64

Implementing powers

1. Detailed rules necessary for the implementation of this Directive shall be adopted in accordance with the procedure referred to in Article 65(2) and 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 65(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 65(3).
 4. Without prejudice to the safeguard measures provided for in Article 9 of Council Directive 89/662/EEC²¹ or Article 10 of Council Directive 90/425/EEC²², 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 65(3).

Article 65

Committee procedure

1. The Commission shall be assisted by the Committee.
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 66

Repeals

Directive 92/40/EEC is repealed as from 31 December 2006. 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.

²¹ OJ L 395, 30.12.1989, p. 13. as amended by Directive 2004/41/EC (OJ L 157, 30.4.2004, p. 33).

²² OJ L 224, 18.8.1990, p. 29. as last amended by Directive 2002/33/EC (OJ L 315, 19.11.2002, p. 14).

Article 67
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 31 December 2006 shall continue to apply for the purpose of this Directive.

However, before 31 December 2006 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 65(2).

2. Pending the application of this Directive, further transitional provisions on the control of avian influenza may be adopted in accordance with the procedure referred to in Article 65(2).

Article 68
Transposition

1. Member States shall adopt and publish by 31 December 2006 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 January 2007.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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 69
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 70
Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

ANNEX I as referred to in Article 4(1)

REQUIREMENTS FOR ANNUAL SURVEILLANCE PROGRAMMES FOR AVIAN INFLUENZA IN POULTRY AND OTHER BIRDS

A. GENERAL REQUIREMENTS FOR SURVEYS IN POULTRY

1. Sampling shall cover the winter period as in many Member States a large slaughter of poultry, in particular turkeys and geese, takes place in December-January.
2. Testing of samples shall be carried out at the national reference laboratories for avian influenza in Member States or by other laboratories approved by the competent authorities and under the supervision of the national reference laboratory.
3. All results, both serological and virological, shall be sent to the Community reference laboratory for collation. The Community reference laboratory shall provide technical support and keep an enlarged stock of diagnostic reagents.
4. All avian influenza virus isolates shall be submitted to the Community reference laboratory. Viruses of subtypes H5 and H7 shall be subjected to the characterisation tests, in accordance with the diagnostic manual.
5. All positive findings shall be retrospectively tested at the holding and the conclusions of the test shall be reported to the Commission and the Community reference laboratory.
6. Specific protocols shall accompany the sending of material to the Community reference laboratory.
7. Collection of survey data shall be in accordance with the tables provided by the Community reference laboratory. In those tables the laboratory testing methods used shall be indicated.
8. Blood samples for serological tests shall be collected from all species of poultry, from at least 5 to 10 birds, except ducks and geese, per holding, and from the different sheds, if there is more than one shed on a holding.
9. Sampling shall be stratified throughout the whole Member State, so that samples can be considered as representative for the whole Member State, taking into account:
 - (a) the number of holdings to be sampled; that number shall be defined so as to ensure the identification of at least one infected holding if the prevalence of infected holdings is at least 5%, with a 95% confidence interval, in accordance with tables 1 and 2, and
 - (b) the number of birds sampled from each holding shall be defined so as to ensure 95% probability of identifying at least one positive bird if the prevalence of seropositive birds is $\geq 30\%$.

10. The sampling design shall also consider:
- (a) the types of production and their specific risks, such as free range, outdoor keeping, multi age layers, use of surface water, a relatively longer life span, and the presence of more than one species on the holding;
 - (b) the number of turkey holdings to be sampled, which shall be defined to ensure the identification of at least one infected holding if the prevalence of infected holdings is at least 5%, with a 99% confidence interval;
 - (c) where holdings producing ratites and quails are present in a Member State they shall be included in the annual surveillance programme;
 - (d) the time period; where appropriate, sampling shall be adapted to identified periods, during which the presence of other poultry hosts on a holding might pose a greater risk for disease introduction;
 - (e) Member States that must carry out sampling for Newcastle disease to maintain their status as Newcastle disease non-vaccinating countries (Commission Decision 94/327/EC²³) may utilise these samples from breeding flocks for the surveillance of H5/H7 antibodies.

Table 1: Number of holdings to be sampled of each poultry category (except turkey holdings)

Number of holdings per poultry category (except turkey holdings)	Number of holdings to be sampled
Up to 34	All
35-50	35
51-80	42
81-250	53
>250	60

²³ OJ L 146, 11.6.1994, p. 17.

Table 2: Number of turkey holdings to be sampled

Number of turkey holdings	Number of holdings to be sampled
Up to 46	All
47-60	47
61-100	59
101-350	80
>350	90

B. SPECIFIC REQUIREMENTS FOR DETECTION OF INFECTIONS WITH H5/H7 SUBTYPES OF AVIAN INFLUENZA IN DUCKS AND GEESE

1. Blood samples for serological testing shall be taken preferably from birds which are kept outside in fields.
2. From each selected holding 40-50 blood samples shall be taken for serological testing.

C. SPECIFIC REQUIREMENTS FOR DETECTION OF INFECTION IN WILD BIRDS

Survey design and implementation

1. In order to ensure a proper designing and implementation of sampling, the Member States shall ensure co-operation between veterinary authorities, wild life biologists, bird-watching and -ringing organisations and hunters.
2. Sampling shall focus on the wild birds migrating south during autumn and early winter.

Sampling procedures, storage and transport of samples

3. Cloacal swabs for virological tests shall be taken, particularly from those species with high susceptibility and increased contact with poultry, such as Mallard ducks.
4. The distribution between the different species shall, if possible, be as follows: 70% waterfowl; 20% shorebirds; 10% other free-living birds.
5. Swabs containing faeces, or carefully collected fresh faeces shall be taken from wild birds trapped, hunted and found freshly dead.
6. Pooling of up to five samples from the same species shall be possible.

7. Specific care shall be taken for the storage and transport of samples. If rapid transport within 48 hours to the laboratory, in transport medium at 4° Celsius, is not guaranteed, samples shall be stored and then transported in dry ice at -70° Celsius.

D. LABORATORY TESTING

Laboratory tests shall be carried out in accordance with the diagnostic manual. However, Member States wishing to adopt different tests, shall provide the relevant validation data to the Commission and the Community reference laboratory.

ANNEX II as referred to in Article 5(2)

NOTIFICATION OF DISEASE AND FURTHER EPIDEMIOLOGICAL INFORMATION TO BE PROVIDED BY THE 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 number of susceptible poultry or other birds in the slaughterhouse or means of transport;
 - (b) the number of dead poultry or other birds of each category in the slaughterhouse or means of transport;
 - (c) for each poultry or other bird category, the identified morbidity and the number of poultry in which avian influenza has been confirmed;
 - (d) the number of poultry or other birds killed or slaughtered in the slaughterhouse or means of transport;
 - (e) the number of poultry or other birds disposed of;

- (f) in case of a slaughterhouse, the distance from the nearest poultry or other bird holding;
 - (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 paragraph 1 and 2 must be forwarded within the time-limits laid down in the first paragraph of Article 4 of Directive 82/894/EEC.
4. The Member State concerned shall ensure that the information to be provided in accordance with paragraph 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 birds on the holding, slaughterhouse or means of transport were killed and their carcasses disposed of or slaughtered;
 - (b) any information relating to the possible origin of that disease 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 birds have been killed or slaughtered in contact holdings or in holdings containing poultry or other birds suspected of being infected with avian influenza virus, information on:
 - (i) the date of killing or slaughtering and the number of poultry or other 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 induced the suspicion that avian influenza is present in each suspected holding;
 - (iii) where poultry or other 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 case of confirmation of avian influenza in live poultry 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 finding to the Commission without delay and report on the measures taken.
6. The results of any surveillance for avian influenza carried out in poultry or other birds must be notified yearly to the Commission. However, the Commission and the

other Member States must be notified within 24 hours where a serious animal or public health threat is identified due to the surveillance.

7. Any positive result of laboratory tests for influenza viruses of avian origin other than those referred to in point 1 of Article 2, which have been carried out in poultry or other birds, must be notified yearly to the Commission. However, the Commission and the other Member States must be notified within 24 hours where a serious animal or public health threat is identified due to the testing.

ANNEX III as referred to in Articles 7(2) and 11(5)

AUTHORISATION TO REMOVE TABLE EGGS FROM A HOLDING IN ACCORDANCE WITH POINT (f) OF ARTICLE 7 (2) and ARTICLE 11 (5)

The competent authority may authorise the transport of eggs from a holding subject to the provisions of point (f) of Article 7(2) and Article 11(5) of this Directive to an establishment approved for the manufacture of egg products in accordance with the provisions of 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:
 - (a) comply with the requirements laid down in Section X of Annex III to Regulation (EC) No 853/2004;
 - (b) 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 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 1(b) 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 1(b) are transported in cleansed and disinfected vehicles.

ANNEX IV as referred to in Article 15(2) and Article 42 (2)

**MAIN CRITERIA AND RISK FACTORS FOR THE DECISION TO KILL POULTRY
IN CONTACT HOLDINGS OR HOLDINGS AT RISK**

The competent authority shall consider the following criteria when deciding whether to kill poultry in contact holdings or holdings at risk:

Criteria	Decision	
	For killing	Against killing
Clinical signs suggesting avian influenza in contact holdings	Yes	No
High susceptibility of predominant poultry species	Yes	No
Movement of poultry or other birds from the outbreak to contact holdings after the likely time of introduction of virus in the infected holding	Yes	No
Location of contact holdings in an area with a high density of poultry	Yes	No
Likely spreading of virus from the outbreak before application of eradication measures	Massive/unknown	Limited
Location of contact holdings within 500 meters ⁽¹⁾ from the outbreak	Yes	No
Proximity of contact holdings to more than one outbreak	Yes	No
Number of poultry or other birds in the outbreak and/or in contact holdings	High	Low

⁽¹⁾ In case with a very high density of poultry, a longer distance must be considered.

ANNEX V as referred to in Article 39(1)

**CRITERIA FOR THE DECISION FOR THE DESTINY OF EGGS AND
DEPOPULATION OF HOLDINGS IN RELATION TO LPAI**

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

- (a) species in question;
- (b) virus type and risk of its mutation;
- (c) density of holdings;
- (d) location of slaughterhouses and packing centres;
- (e) transport route;
- (f) evidence of spread;
- (g) public health risk, if any;
- (h) further treatments of the products in question;
- (i) socio-economic impact and other impacts.

ANNEX VI as referred to in Article 49

PRINCIPLES AND PROCEDURES FOR CLEANSING, DISINFECTION AND TREATMENT

1. The following general principles and procedures shall be applied for the cleaning, disinfection and treatment provided for in Article 49:
 - (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 officially approved by the competent authority to ensure destruction of avian influenza virus;
 - (c) the efficacy of disinfectants must be checked before use, as the efficacy of certain disinfectants is diminished by prolonged storage;
 - (d) the choice of disinfectants and of procedures for disinfection must be made taking into account the nature of the premises, 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 compartments likely to be contaminated must be included;
 - (i) following the 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;
 - (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 and other birds all necessary measures must be taken to avoid or minimise the dispersion of avian influenza virus; those measures must include *inter alia* 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) killed poultry or other birds must be sprayed with disinfectant;
 - (iii) if the killed poultry or other birds have to be removed from the holding for disposing of, covered and leak proof containers must be used;
 - (iv) as soon as the killed poultry or other 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 approved in accordance with Article 49;
 - (v) any tissue or blood spilled during the killing or slaughter or the post-mortem or gross contamination of buildings, yards, utensils etc. must be carefully collected and disposed of with the killed poultry or other birds;
 - (vi) the disinfectant must remain on the surface for at least 24 hours;
 - (b) final cleansing and disinfection:
 - (i) manure and used beddings 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 washed with water;
 - (iii) after washing with cold water, further spraying with disinfectant must be applied;
 - (iv) after seven days the premises 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 infective 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 plant for treatment of the manure 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 64(1). 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, in the case of holdings, where birds are kept in the open, the competent authority may establish specific procedures for cleansing and disinfection, taking into account the type of holding and the climatic conditions.

ANNEX VII as referred to in Article 52 (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 co-ordinate, 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 thorough knowledge of the preparation and use of the products of veterinary immunology used to eradicate and control avian influenza;
 - (b) to actively assist 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) prepare the programme and working documents for the Annual Meeting of National Reference Laboratories;
 - (e) assist in the conduction 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) keep under review the possible zoonotic impact arising from avian influenza viruses and collaborate with internationally recognized human influenza laboratories.

ANNEX VIII as referred to in Article 52(2)

**LIST OF NATIONAL REFERENCE LABORATORIES FOR AVIAN INFLUENZA
AND THEIR FUNCTIONS AND DUTIES**

1. The national reference laboratories for avian influenza are as follows:

Belgium &

Luxembourg: Centrum voor Onderzoek in Diergeneeskunde en Agrochemie (CODA)
Centre d'Etudes et de Recherches Vétérinaires et Agrochimiques, (CERVA)
Groeselenbergstraat 99/ 99, Rue Groeselenberg
B-1180 Brussel/Bruxelles

Czech

Republic: National Reference Laboratory for Newcastle Disease and highly pathogenic
Avian Influenza, Statni veterinarni ustav Praha
Sidlistni 136/24
165 03 Praha 6-Lysolaje

Denmark:

Statens Veterinære Serumlaboratorium
Hangøvej 2
DK-8200 Århus N.

Germany:

Friedrich-Löffler-Institut, Bundesforschungsanstalt für
Tiergesundheit (FLI) für
Boddenblick 5a
D-17493 Greifswald - Insel Riems

Estonia:

Estonian Veterinary and Food Laboratory, Tallinn laboratory
Väike-Paala 3
11415 Tallinn

Greece:

National Reference Laboratory, (NRL) Center of Veterinary
Institutes
80, 26th October Str
GR-54627 Thessaloniki

Spain:

Laboratorio Central de Veterinaria (L.C.V.)
Carretera de Algete, Km. 8
E-28110 Algete, Madrid

France:

Laboratoire d'Etudes de Recherches Avicoles et Porcines
B.P. 53, AFFSA Ploufragan (Agence Française de Sécurité
Sanitaire
des Aliments)
F-22440 Ploufragan

Ireland:	Poultry Virology, Veterinary Research Laboratory Abbotstown, Castleknock Dublin 15
Italy& San Marino:	Istituto Zooprofilattico Sperimentale delle Venezie (IZS-VE) Via Romea 14/A I-35020-Legnaro – Padova
Cyprus:	Veterinary Services, National Reference Laboratory for Newcastle Disease and Avian Influenza 1417 Nicosia
Latvia:	State Veterinary Medicine Diagnostic Centre (SVMDC) Lejupes str. 3 LV-1076 Riga
Lithuania:	National Veterinary Laboratory J.Kairiukscio 10 LT-2021 Vilnius
Hungary:	Central Veterinary Institute Tábornok u.2 149 Budapest
Malta:	Food and Veterinary Division Laboratory Civil Abattoir Albertown
Netherlands:	CIDC-Lelystad, Central Institute for Animal Disease Control, Lelystad Postbox 2004 NL-8203 AA Lelystad
Austria:	Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES) Veterinärmedizinische Untersuchungen Mödling, Robert Koch Gasse 17 A-2340 Mödling
Poland:	State Veterinary Institute in Puławy- Poultry Disease Department Al. Partyzantów 57 24-100 Puławy
Portugal:	Laboratório Nacional de Investigação Veterinária (LNIV) Estrada de Bemfica 701 P-1549-011 Lisboa

Slovenia:	National Veterinary Laboratory Gerbiceva 60 1000 Ljubljana
Slovakia:	State Veterinary Institute, Reference Laboratory for Newcastle Disease and Avian influenza Pod Dráhami 918 96086 Zvolen
Finland:	Eläinlääkintä ja elintarviketutkimuslaitos (EELA) Helsinki, Anstalten för veterinärmedicin och livsmedel Helsingfors PL 45 FIN-00581 Helsinki
Sweden:	Statens Veterinärmedicinska Anstalt Uppsala (SVA) S-75189 Uppsala
United Kingdom:	Veterinary Laboratory Agency (VLA) Weybridge Avian Virology, Woodham Lane New Haw, Addlestone Surrey KT 15 3NB Disease Surveillance and Investigation Department Veterinary Sciences Division Soney Road Belfast BT4 3SD

2. The functions and duties of the national reference laboratories

- (a) 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.
- (b) The national reference laboratories shall submit isolates of influenza virus of avian origin to the Community reference laboratory without delay for full characterisation:
 - (i) from all primary outbreaks of avian influenza;
 - (ii) in case of secondary outbreaks, from representative number of outbreaks;
 - (iii) in case of detection of influenza viruses other than those referred to in point 1 of Article 2 (a) in poultry, other birds or other animals, posing a serious threat to animal or public health.
- (c) The national reference laboratory in each Member State shall be responsible for co-ordinating the standards and diagnostic methods in each avian influenza diagnostic laboratory within that Member State. For that purpose:

- (i) they may provide diagnostic reagents to individual laboratories;
- (ii) they shall control the quality of all diagnostic reagents used in that Member State;
- (iii) they shall arrange comparative tests periodically;
- (iv) they shall hold isolates of avian influenza virus from outbreaks and of any other influenza viruses of avian origin detected in that Member State;
- (v) they shall collaborate with the national human influenza laboratories.

ANNEX IX as referred in point (g) of Article 54 (2) and point (b) of Article 56 (1)

GENERAL REQUIREMENTS ON MOVEMENTS OF POULTRY AND POULTRY PRODUCTS APPLICABLE IN RELATION TO EMERGENCY VACCINATION

1. Member States shall ensure that movement controls of poultry and birds vaccinated in accordance with Articles 54 and 56 and of their products are applied as set out in paragraphs 2 to 7.
2. For movements of live poultry, hatching and table eggs within the vaccination area the following provisions shall apply:
 - (a) hatching eggs shall:
 - (i) originate from a vaccinated or unvaccinated breeding flock which has been regularly examined, with favourable results, in accordance with the monitoring provided for in point (j) of Article 54(2);
 - (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 in disposable packaging or materials that can be effectively washed and disinfected;
 - (iv) be traced-back in the hatchery;
 - (b) day-old chicks shall:
 - (i) originate from hatching eggs satisfying the conditions set out in (a);
 - (ii) be transported in disposable packaging or materials that can be effectively washed and disinfected;
 - (iii) be placed in a poultry house or shed where:
 - no poultry has been kept for at least three weeks; and
 - cleansing and disinfection have been carried out in accordance with the instructions of the competent authority;
 - (c) ready-to-lay poultry shall:
 - (i) have been regularly vaccinated against avian influenza, if provided for in the vaccination programme;
 - (ii) have been regularly examined, with favourable results, in accordance with the monitoring provided for in point (j) of Article 54 (2);
 - (iii) be placed in a poultry house or shed where no poultry has been kept for at least three weeks, and where cleansing and disinfection has been carried out;

- (d) poultry for slaughter shall:
 - (i) be examined with favourable results before loading in accordance with the monitoring provided for in point (j) of Article 54 (2);
 - (ii) be sent directly to a slaughterhouse for immediate slaughter;
 - (iii) be transported in vehicles cleansed and disinfected under official supervision before and after each transport;
 - (e) table eggs shall:
 - (i) originate from a vaccinated or non-vaccinated layer flock which has been regularly examined, with favourable results, in accordance with the monitoring provided for in point (j) of Article 54 (2);
 - (ii) be sent directly to a packaging centre or a thermal-treatment plant;
 - (iii) be transported using disposable packaging material or materials that can be effectively washed and disinfected.
3. For movements of live poultry, hatching eggs and table eggs originating from outside the vaccination area into the vaccination area the following provisions shall apply:
- (a) hatching eggs shall:
 - (i) be transported directly to the hatchery of destination in disposable packaging or materials that can be effectively washed and disinfected;
 - (ii) be traced-back in the hatchery;
 - (b) day-old chicks shall:
 - (i) be transported in disposable packaging ;
 - (ii) be placed in a poultry house or shed where:
 - no poultry has been kept for at least three weeks; and
 - cleansing and disinfection have been carried out in accordance with the instructions of the competent authority;
 - (c) ready-to-lay poultry shall:
 - (i) be placed in a poultry house or shed where no poultry has been kept for at least three weeks, and cleansing and disinfection have been carried out;
 - (ii) be vaccinated at the farm of destination, if provided for in the vaccination programme;
 - (d) poultry for slaughter shall:
 - (i) be sent directly to a slaughterhouse for immediate slaughter;

- (ii) be transported in vehicles cleansed and disinfected under official supervision before and after each transport;
 - (e) table eggs shall:
 - (i) be sent directly to a packing centre or a thermal treatment plant;
 - (ii) be transported using disposable packaging or materials that can be effectively washed and disinfected.
4. For movements of live poultry, hatching and table eggs originating and coming from the vaccination area towards outside the vaccination area the following provisions shall apply:
- (a) hatching eggs shall:
 - (i) originate from a vaccinated or unvaccinated breeding flock which has been regularly examined, with favourable results, in accordance with the monitoring provided for in point (j) of Article 54(2) ;
 - (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 in disposable packaging or materials that can be effectively washed and disinfected;
 - (iv) be traced-back in the hatchery;
 - (b) day-old chicks shall:
 - (i) 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;
 - (ii) be transported in disposable packaging material,
 - (iii) be placed in a poultry house or shed where:
 - no poultry has been kept for at least three weeks; and
 - cleansing and disinfection have been carried out in accordance with the instructions of the competent authority;
 - (c) ready-to-lay poultry shall:
 - (i) not have been vaccinated;
 - (ii) have been regularly examined with favourable results, in accordance with the monitoring provided for in point (j) of Article 54(2);
 - (iii) be placed in a poultry-house or shed where no poultry has been kept for at least three weeks, and where cleansing and disinfection has been carried out;

- (d) poultry for slaughter shall:
 - (i) be examined before loading with favourable results, in accordance with the monitoring provided for in point (j) of Article 54(2)
 - (ii) be sent directly to a slaughterhouse for immediate slaughter;
 - (iii) be transported in vehicles cleansed and disinfected under official supervision before and after each transport;
 - (e) table eggs shall:
 - (i) originate from a vaccinated or non-vaccinated layer flock which has been regularly examined, with favourable results, in accordance with the monitoring provided for in point (j) of Article 54(2);
 - (ii) be sent directly to a packing centre or a thermal-treatment plant;
 - (iii) be transported using disposable packaging or packaging material which can be effectively washed and disinfected.
5. 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 heterologous subtype vaccine,
 - (ii) have been regularly inspected and tested with negative results in accordance with the provisions in the vaccination programme, in the framework of a DIVA strategy,
 - (iii) have been clinically inspected by an official veterinarian within 48 hours before loading; sentinel birds shall have been inspected with particular attention,
 - (iv) have been sent directly to a designated slaughterhouse for immediate slaughter;
 - (b) for meat obtained from non-vaccinated poultry, the poultry must undergo monitoring in accordance with the monitoring provided for in point (j) of Article 54(2).
6. The cleansing and disinfection referred to in this Annex shall be carried out in accordance with the instructions of the competent authority.
7. The testing requirements before loading as referred to in paragraphs (2), (3) und (4) shall be carried in accordance with the diagnostic manual.

ANNEX X as referred to in point 1 of Article 63

CRITERIA FOR CONTINGENCY PLANS

Contingency plans shall meet at least the following criteria:

1. The establishment of a crisis centre on a national level, which shall co-ordinate all control measures in the Member State.
2. A list shall be provided of local disease control centres with adequate facilities to co-ordinate the disease control measures at a 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 for human health posed by avian influenza.
4. Each local disease control centre must be able to contact rapidly persons and organisations which are directly or indirectly involved in an outbreak, s.
5. Equipment and materials shall be available to carry out the disease control measures properly.
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.
9. Provisions shall be in place in case vaccination against avian influenza shall be carried out containing different scenarios to be followed, a comprehensive vaccination plan, the indication of which populations of poultry and birds to be included into the scheme, the estimated quantity of vaccine required, the logistics of such a measure, in particular, the possible vaccine availability, the storage and distribution capacities and the availability of manpower for the administration of the vaccine
10. Provisions 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. Provisions shall be made for the recognition of officially registered rare breeds of poultry and birds.
12. Provisions shall be made for the identification of areas with a high density of poultry.

13. Provisions shall be in place for a close co-operation between the competent authorities of the veterinary, the public health and the environmental sector.
14. Provisions shall be made to ensure the legal powers necessary for the implementation of the contingency plans.

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 1 (3)	Article 1, second subparagraph
Article 2 (1)	Annex III, third subparagraph
Article 2 (2),(3)	-
Article 3 (1) to (14), (17), (18), (20), (22) to (33)	-
Article 3 (15)	Article 2 (a)
Article 3 (16)	Article 2 (b)
Article 3 (19)	Article 2 (d)-
Article 3 (21)	Article 2 (e)-
Article 4	-
Article 5 (1)	Article 3
Article 5 (2)	-
Article 6 (1)	-
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 8	-
Article 9	Article 4 (5)
Article 10	-
Article 11 (1)	
Article 11 (2) and (3)	Article 5 (1)(a)
Article 11 (4)	Article 5 (1)(d)
Article 11 (5)	Article 5 (1)(c)
Article 11 (6),(7)	Article 5 (1)(b)
Article 11 (8)	Article 5 (1)(e)
Article 11 (9) and (10)	-
Article 12	-
Article 13	-
Article 14	Article 6
Article 15	Article 8
Article 16 (1) and (2)	Article 9 (1)
Article 16 (3)	-
Article 16 (4)	Article 9 (6)
Article 17 (1)	Article 10
Article 17 (2)	Article 13
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 9 (2)(d) and (e)
Article 19 (e)	Article 9 (2)(f), first subparagraph
Article 19 (f),(g) and (h)	-
Article 20	Article 9 (2)(g)
Article 21	Article 9 (2)(h)
Article 22	Article 9 (2)(e)
Article 23	Article 9 (2)(f)(i)
Article 24	Article 9 (2)(f)(ii)
Article 25	-
Article 26 (1)	Article 9 (2)(f)(iii)
Article 26 (2)	-
Article 27	Article 9(2)(e)
Article 28	-
Article 29	Article 9 (3)
Article 30 (a)	Article 9 (4)(a)
Article 30 (b),(c)	Article 9 (4)(b),(c) and (d)
Article 30 (d),(e),(g) and (j)	-
Article 30 (f)	Article 9 (4)(b)
Article 30 (h)	Article 9 (4)(e)
Article 30 (i)	Article 9 (4)(f)
Article 31	Article 9 (5)
Article 32	-
Article 33	-
Article 34	-
Article 35	-
Article 36	-

Article 37	-
Article 38	-
Article 39	-
Article 40	-
Article 41	-
Article 42	-
Article 43	-
Article 44	-
Article 45	-
Article 46	-
Article 47	-
Article 48	-
Article 49	Article 11
Article 50	-
Article 51	-
Article 52 (1)	Article 15
Article 52 (2) and (3)	Article 14
Article 53	-
Article 54	Article 16 (a), first subparagraph
Article 55	Article 16 (a), first subparagraph
Article 56	Article 16 (a), second subparagraph
Article 57	-
Article 58	-
Article 59	-
Article 60	-
Article 61	Article 18

Article 62	-
Article 63	Article 17
Article 64 (1),(2) and (4)	-
Article 64 (3)	Article 20
Article 65	Article 21
Article 66	-
Article 67	-
Article 68	-Article 22
Article 69	-
Article 70	Article 23
Annex I	-
Annex II	-
Annex III	Annex I
Annex IV	-
Annex V	-
Annex VI	Annex II
Annex VII	Annex V
Annex VIII	Annex IV
Annex IX	-
Annex X	Annex VI
Annex XI	-

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Health and Consumers Protection

Activity: Food safety, animal health, animal welfare and plant health

TITLE OF ACTION: PROPOSAL FOR A COUNCIL DIRECTIVE ON COMMUNITY MEASURES FOR THE CONTROL OF AVIAN INFLUENZA

1. BUDGET LINE(S) + HEADING(S)

17 01: Administrative expenditure of health and consumer protection policy area

17 04 02: Other measures in the veterinary, animal welfare and public-health field

17 04 03: Emergency fund for veterinary complaints and other animal contaminations which are a risk to public health

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): 18,810 € million for commitment

2.2. Period of application:

Action is open ended

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million *(to three decimal places)*

	Year [2006]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Commitments	3.135	3.135	3.135	3.135	3.135	3.135	18.810
Payments	3.135	3.135	3.135	3.135	3.135	3.135	18.810

(b) Technical and administrative assistance and support expenditure *(see point 6.1.2)*

Commitments		0.000	0.000	0.000	0.000	0.000	0.000
Payments		0.000	0.000	0.000	0.000	0.000	0.000

Subtotal a+b							
Commitments	3.135	3.135	3.135	3.135	3.135	3.135	18.810
Payments	3.135	3.135	3.135	3.135	3.135	3.135	18.810

(c) Overall financial impact of human resources and other administrative expenditure
(see points 7.2 and 7.3)

Commitments/ payments	0.195	0.195	0.195	0.195	01195	01195	1.170
--------------------------	-------	-------	-------	-------	-------	-------	-------

TOTAL a+b+c							
Commitments	3.330	3.330	3.330	3.330	3.330	3.330	19.980
Payments	3.330	3.330	3.330	3.330	3.330	3.330	19.980

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:²⁴

Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp	Non-diff	NO	NO	NO	No 5 – 1a

4. LEGAL BASIS

Council Decision 90/424/EEC

²⁴ For further information, see separate explanatory note.

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention ²⁵

5.1.1. Objectives pursued

It is envisaged to update current Community legislation on avian influenza laid down in Council Directive 92/40/EEC, with the objective to achieve better prevention and control of outbreaks and to reduce the health risks, the costs and losses and the negative impact to the whole of society due to Avian Influenza.

Since live poultry is listed in Annex II of 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 to ensure the development of this sector. Furthermore, a high level of human health protection is to be ensured in the definition and implementation of all Community policies and activities.

Furthermore, thanks to the adoption of other disease control measures envisaged under the current proposal, including vaccination, other savings should result from the expected reduced size of future AI epidemics. It is, however, extremely difficult to quantify these savings.

Results would be achieved by means of surveillance and control measures targeted to the low pathogenic form of disease - to prevent virus mutation into its highly pathogenic form- by means of vaccination where appropriate and by other measures that take into account the most recent scientific knowledge on this disease, the lessons learned during recent outbreaks and the need to avoid massive killing and destruction of animals as much as possible. As mentioned already, these actions as such have no financial implications for the EU-budget.

However, in combination with Council Decision 90/424/EC the following actions, as it is already the case with existing avian influenza legislation, have financial consequences:

Objective 1: emergency fund eradication of the disease

Objective 2: surveillance

Objective 3: establishment of a vaccine bank

Objective 4: establishment of a Community Reference Laboratory for avian influenza

5.1.2. Measures taken in connection with ex ante evaluation

In view of the increased knowledge on the risks for human health posed by AI viruses, (which, particularly in the context of the ongoing outbreak in certain Asian countries, have prompted several actions by International organisations such the FAO, the WHO and the OIE), the opinions of the Scientific Committee and the most recent knowledge on the pathogenesis, the epidemiology and the distribution of AI, there is now a clear need to revise and update current legislation to reflect these new advances and experience and to improve disease control of both LPAI and HPAI in

²⁵ For further information, see separate explanatory note.

future. This will be of direct benefit to animal health and indirectly also human health.²⁶

5.1.3. *Measures taken following ex post evaluation*

Not applicable

5.2. Action envisaged and budget intervention arrangements

Not applicable

5.3. Methods of implementation

Not applicable

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1. *Financial intervention*

Commitments (in € million to three decimal places)

Breakdown	[2006]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Operational objective Nr 1	It is impossible to predict when and where there will be an outbreak of the disease and the relative costs.. The impact assessment annexed to the proposal has considered various scenarios from which it results that the new disease eradication measures should not lead to higher costs than the current ones.						
Operational objective Nr 2	1.500	1.500	1.500	1.500	1.500	1.500	9.000
Operational objective Nr 3	1.500	1.500	1.500	1.500	1.500	1.500	9.000
Operational objective Nr 4	0.135	0.135	0.135	0.135	0.135	0.135	0.810
TOTAL	3.135	3.135	3.135	3.135	3.135	3.135	18.810

²⁶ For minimum information requirements relating to new initiatives, see SEC 2000 (1051)

6.1.2. *Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)*

	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. years]	Total
1) Technical and administrative assistance							
a) Technical assistance offices							
b) Other technical and administrative assistance: - intra muros: - extra muros: <i>of which for construction and maintenance of computerised management systems</i>							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)²⁷

Commitments (in € million to three decimal places)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1...n)	Average unit cost	Total cost (total for years 1...n)
	1	2	3	4=(2X3)
<u>Action 1</u>				
- Measure 1				
- Measure 2				
<u>Action 2</u>				
- Measure 1				
- Measure 2				
- Measure 3				
etc.				
TOTAL COST				

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A	1	-	1	
	B	-	-	-	
	C	-	-	-	
Other human resources			-	-	
Total		1	-	1	

²⁷ For further information, see separate explanatory note.

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials	108,000	1 full time official per year
Temporary staff		
Other human resources (specify budget line)		
Total	108,000	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line	Amount €	Method of calculation
Overall allocation (Title A7)		
1701021101 – Missions	35,000	Based on 5 missions per year at an average of 7000 Euro per mission
1701021102 – Meetings	-	-
A07031 – Compulsory committees ¹	52,000	1 meeting of the Standing committee on Food Chain and Animal Health only on the subject of avian influenza
A07032 – Non-compulsory committees ¹	-	
A07040 – Conferences	-	-
A0705 – Studies and consultations	-	-
Other expenditure (specify)	-	-
Information systems (A-5001/A-4300)	-	-
Other expenditure - Part A (specify)	-	-
Total	87,000	

The amounts are total expenditure for twelve months.

¹ Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	195,000 €
II.	Duration of action	6 years
III.	Total cost of action (I x II)	1,170,000 €

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

The Commission will have at its disposal several ways to evaluate the impact of the proposal:

- the occurrence of future HPAI epidemics giving an overall indication on the effectiveness of the new measures,
- results of the surveillance programmes,
- control measures on LPAI outbreaks.

Already at this stage the Commission has the basic tools to monitor, such as the Standing Committee for the Food Chain and animal health and the network of Community and national reference laboratories.

8.2. Arrangements and schedule for the planned evaluation

As mentioned above, the Commission has at its disposal tools, such as the Standing Committee for the Food Chain and animal health and the network of Community and national reference laboratories; these instruments will allow

9. ANTI-FRAUD MEASURES

Not relevant

EXPLANATORY MEMORANDUM

1. Context of the proposal

- Grounds for and objectives of the proposal
 - The Commission envisages updating current procedures governing Community's financial contribution towards veterinary measures laid down in Council Decision 90/424/EEC²⁸ of 26 June 1990 on expenditure in the veterinary field.
 - The general objective is to better achieve the targets on specific veterinary measures on Avian Influenza.
- General context
 - The current proposal of the amendment of Decision 90/424/EEC is limited to avian influenza (AI).
 - By means of its proposal for a new Council Directive on Community measures for the control of Avian Influenza (*reference to the COM document*), the Commission envisages updating current measures laid down in Council Directive 92/40/EEC²⁹, with the objective to achieve better prevention and control of outbreaks and to reduce the health risks, the costs and losses and the negative impact to the whole of society due to Avian Influenza. This would be achieved by means of surveillance and control measures targeted to the low pathogenic form of disease - to prevent virus mutation into its highly pathogenic form - by means of vaccination where appropriate and by other measures that take into account the most recent scientific knowledge of this disease, the lessons learned during recent outbreaks and the need to avoid massive killing and destruction of animals as much as possible.
 - The proposed changes in Community legislation on AI control should be made in parallel with amendments to Council Decision 90/424/EEC on Community expenditure in the veterinary field to bring it in line with the new Directive and ensure adequate financial support to the MSs in relation to some of the newly envisaged AI control measures.

²⁸ OJ L 224, 18.8.1990, p. 19; Decision as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

²⁹ OJ L 167, 22.6.1992, p. 1.

- At present, Article 3 of Council Decision 90/424/EEC provides for a Community financial contribution (50%) to be granted to the MSs for some of the expenditure which they may incur when eradicating HPAI³⁰, namely for reimbursement to farmers who have had their birds slaughtered and destroyed to eradicate the disease, for cleansing and disinfection, and for the destruction of eggs, feedingstuff and other materials likely to be contaminated. In accordance with the same Article, The Community may also reimburse 100% of vaccine costs and 50 % of the costs incurred in carrying out that vaccination (at present only emergency vaccination but not preventive vaccination may be allowed in accordance with Directive 92/40/EEC).
- Consistency with other policies
 - A debate about the prevention of and response to sanitary crises is now underway. The Commission has already produced a preliminary study³¹ on a risk financing model for livestock epidemics in the EU and a complementary study is programmed for 2005. The Commission has also started a process of evaluation of the whole Community Animal Health Policy, which will include questions on the cost/effectiveness of the current financial instruments to cope with animal disease surveillance, control and eradication and on ways in which producers should be induced to take all appropriate measures to reduce the risk of disease introduction onto their farms. In this context major risk factors such as density of animal populations and on-farm biohazards will be considered, together with mitigating measures and consequences on the EU budget.
 - Based on the outcome of these studies and evaluation, alternatives to the current way Community financial support is granted to the Member States might be proposed. Nevertheless, it has been deemed appropriate to adopt the current proposal without waiting until the end of this process, taking into account the urgent need of revising current legislation on this major health risk.

2. Consultation of interested parties and impact assessment

- Consultation of interested parties
 - On the Draft Proposal for a new Council Directive on Community measures for the control of Avian Influenza, consultation with Member States in Commission Working Group and in electronic way has taken place in July/October 2004. In October 2004 European NGOs have been consulted on that Draft Proposal. As a result of the consultation, suggestions on improving of some Articles and Annexes of the Draft Proposal have been taken into account.

³⁰ Decision 90/424/EEC currently uses the very old terminology “avian plague” for HPAI.

³¹ http://europa.eu.int/comm/food/animal/diseases/financial/risk_financing_model_10-04_en.pdf.

Collection and use of expertise

- On AI: the newly envisaged measures have been taken into full account the opinions of the Scientific Committee on AI delivered in 2000 and 2003.
- Impact assessment
 - The policy options identified by the Scientific Committee, Section Animal Health and Welfare in its report of 2000 "Definition of Avian Influenza - Use of Vaccination against Avian Influenza" have been assessed. Three possible options for disease control have been examined and the option involving a change of the definition of AI to also include LPAI and to foresee control measures taking into account the different type of virus and animal has been considered most advantageous.
 - An impact assessment of the newly envisaged AI control measures and of the amendments proposed by means of this proposal to Council Decision 90/424/EEC has been produced (*reference to the SEC document*).

3. **Legal elements of the proposal**

- Summary of the proposed actions
 - The current proposal primary envisages the following changes to Decision 90/424/EEC:
 - to foresee a financial contribution (up to 50%) for the Member States surveillance programmes to be implemented annually.
 - to foresee a financial contribution (30%) to MSs, for the costs which they incurred in case of a stamping out policy being applied following LPAI outbreaks. The reduced contribution compared with HPAI outbreaks is justified by the fact that MSs should keep the option not to apply a stamping-out policy in case of LPAI, and a higher Community contribution might induce them not to make adequate use of this option. On the other hand, the Community co-financed surveillance programme should allow the detection of LPAI in a timely manner and thus the need for extensive stamping out should be reduced, with a positive impact also on MSs budgets.
 - as regards vaccination, Community financial support as specified above would continue to be granted only in case of emergency vaccination. In a similar manner, no changes would be introduced to existing provisions on co-financing of HPAI control measures.

Furthermore necessary adjustments and clarifications are foreseen.

- Legal basis
 - Treaty establishing the European Community, and in particular Article 37 thereof.
- Subsidiarity principle
 - The measures laid down in this proposal falls under the competence of the Community.
- Proportionality principle
 - The proposal sets out Community financial support to Member States of minimum measures to be applied in the event of an outbreak of Avian Influenza in poultry and other birds, and the minimum measures to allow a multi-annual effective and efficient approach for eradication, control and monitoring programmes for animal diseases and zoonoses.
- Choice of instruments
 - The proposed instrument is a Decision. This proposal concerns amendments to existing provisions on expenditure in the veterinary field that are laid down in a Council Decision. The legal instrument chosen to amend those provisions is therefore another Council Decision.

4. **Budget implications**

The current proposal would entail additional costs for the MSs and the Community budget, due to the measures being introduced for the surveillance and control of LPAI. The approximate costs for the Community budget can be anticipated as follows:

- (a) LPAI surveillance: 1-2 M€ per year. These figures take into account the costs of the programmes for AI surveillance which have been put in place in the MSs in 2003 and 2004. However, it is envisaged that in the future it might be appropriate to reinforce these programmes and this should lead to incremental costs;
- (b) LPAI control by means of stamping out: ~1-4 M€ per year. This figure is based on:
 - the results of the surveillance for Avian Influenza carried out in the MSs in 2003 and the preliminary data available on the LPAI surveillance carried out in 2004;
 - the average cost of any single AI outbreak for which a stamping out policy has been applied in the Community in recent years (~150,000 € per poultry farm); and
 - the costs for the EU budget of these outbreaks (30% of co-financing, that is 50,000€ per farm).

Assuming ~80-320 LPAI outbreaks per year in the whole EU, it is envisaged that it will be necessary to apply a stamping out policy on 20-80 LPAI infected farms each year, that is on 25% of the farms in which LPAI would be detected.

Furthermore, if the decision to establish an AI vaccine bank is finally taken, the establishment and maintenance of this bank would cost approximately 1-2 M€ per year. This figure has been estimated taking into account the costs of the existing Foot and Mouth Disease antigen bank for the formulation of vaccine. However, in this regard it must be underlined that:

- in accordance with already existing provisions of Article 7 of Decision 90/424/EEC, Community vaccine banks can already be financed by the Community budget;
- the newly envisaged Directive does not oblige the Community to set up an AI vaccine bank, but only establish the legal base for the Community to do so.

Therefore, the current proposal to amend Decision 90/424/EEC will not consider this particular aspect. As explained in the impact assessment accompanying the two Commission proposals on AI, the annual additional cost for the Community budget related to the adoption and implementation of the measures indicated above (including the possible establishment of a vaccine bank) would be ~3-8 M€, that means ~5-6 M€ on average.

However, it is expected that the above costs will be counterbalanced by the savings related to the reduced risks for future HPAI epidemics. Of course, it cannot be precisely indicated to what extent the proposed measures would lead to a decrease in the number of future HPAI epidemics, the occurrence of which is still largely unpredictable and can never be totally excluded, given the nature of the risk in question. However, if the envisaged measures had been already in place and implemented in the EU in the last five years, one of the two major epidemics which have occurred in the Community would most likely have been prevented. Based on this, it may therefore be estimated that the implementation of the proposed measures could successfully prevent two major epidemics of HPAI in the next ten years.

Proposal for a

COUNCIL DECISION

amending Council Decision 90/424/EEC on expenditure in the veterinary field

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission³²,

Having regard to the opinion of the European Parliament³³

Having regard to the opinion of the Economic and Social Committee³⁴

Whereas:

- (1) Avian influenza, previously called “avian plague”, is a very severe infection of birds that causes a very serious risk for animal health. Influenza virus of avian origin may also pose a risk for human health.
- (2) Decision 90/424/EEC³⁵ on expenditure in the veterinary field provides for the possibility of a financial contribution from the Community to the Member States for the eradication of certain animal diseases. Currently, this Decision foresees the possibility to grant such contribution for the eradication of avian influenza caused by the so-called “highly pathogenic” strains of virus.
- (3) During recent avian influenza epidemics, outbreaks of disease caused by low pathogenic avian influenza viruses subsequently mutated into highly pathogenic viruses causing devastating consequences and risks for public health. Once mutation has occurred, the virus is extremely difficult to control. Directive xxx on Community measures for the control of avian influenza establishes compulsory surveillance and control measures³⁶ also in relation with the low pathogenic viruses, so that outbreaks of highly pathogenic avian influenza can be prevented.
- (4) In the light of the adoption of Directive xxx it is appropriate to modify Decision 90/424/EEC so that Community financial assistance may also be granted for those

³² OJ C [...], [...], p. [...].

³³ OJ C [...], [...], p. [...].

³⁴ OJ C [...], [...], p. [...].

³⁵ OJ L 224, 18.8.1990, p. 19; Decision as last amended by Directive 2003/99/EC (OJ L 325, 12.12.2003, p. 1).

³⁶ OJ L [...], [...], p. [...] [...] see accompanying draft proposal.

eradication measures carried out by the Member States to combat avian influenza virus strains of low pathogenicity that may mutate into highly pathogenic strains.

- (5) The reference to Article 40 in Article 3(4) of Council Decision 90/424/EEC is erroneous as the procedure which is referred is mentioned in Article 41.

HAS ADOPTED THIS DECISION:

Article 1

Council Decision 90/424/EEC is amended as follows:

1. Article 3 is amended as follows:

- (a) in paragraph 1, the sixth indent is deleted;
- (b) in paragraph 2, the first indent is replaced by the following:
 - ‘the slaughter of animals of susceptible species which are affected or contaminated or suspected of being affected or contaminated, and their destruction, and, in the case of avian influenza, destruction of the eggs,’
- (c) paragraph 4 is replaced by the following:

‘If, in view of the development of the situation in the Community, it proves necessary to continue the measures provided for in paragraph 2, a new decision concerning the financial contribution by the Community, which might exceed the figure of 50% laid down in the first indent of paragraph 5, may be adopted in accordance with the procedure laid down in Article 41. When this decision is adopted, any measures which the Member State concerned must take in order to ensure the success of the action may be laid down, and in particular measures other than those mentioned in paragraph 2.’

2. The following Article 3a is inserted:

“Article 3a

- 1. This Article shall apply in the event of the occurrence of avian influenza in the territory of a Member State.
- 2. The Member State concerned shall obtain a financial contribution from the Community for the eradication of avian influenza if the minimum control measures provided for in Directive xxx have been fully and efficiently implemented in compliance with relevant Community legislation and, in the case of killing of animals of susceptible species which are affected or contaminated or suspected of being affected or contaminated, livestock owners have been compensated swiftly and adequately.

3. The financial contribution by the Community, divided if necessary into several tranches, must be:
 - in the case of highly pathogenic avian influenza 50% and in the case of low pathogenic avian influenza 30% of the following costs, incurred by the Member State in compensating livestock owners for the killing, the destruction of animals, the destruction of animal products, the cleaning and disinfection of holdings and equipment, the destruction of the contaminated feedingstuffs and for the destruction of contaminated equipment, where such equipment cannot be disinfected,
 - where emergency vaccination is decided upon in accordance with Article 55 of Directive xxx 100 % of the cost of supply of the vaccine and 50 % of the costs incurred in carrying out that vaccination.”

3. In the Annex, in Group 1, the following indent is added:

- ‘avian influenza .’

Article 2

This Decision is addressed to the Member States.

Done at Brussels

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Health and Consumers Protection

Activity: Food safety, animal health, animal welfare and plant health

TITLE OF ACTION: PROPOSAL FOR A COUNCIL DECISION AMENDING COUNCIL DECISION 90/424/EEC ON EXPENDITURE IN THE VETERINARY FIELD

1. BUDGET LINE(S) + HEADING(S)

17 04 01: Animal disease eradication and monitoring programmes and monitoring of the physical conditions of animals that could pose a public-health risk linked to an external factor

17 04 02: Other measures in the veterinary, animal welfare and public-health field

17 04 03: Emergency fund for veterinary complaints and other animal contaminations which are a risk to public health

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): 33 € million for commitment

2.2. Period of application:

Action is open ended

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

€ million *(to three decimal places)*

	Year [2006]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Commitments	5.5	5.5	5.5	5.5	5.5	5.5	33.0
Payments	5.5	5.5	5.5	5.5	5.5	5.5	33.0

(b) Technical and administrative assistance and support expenditure (see point 6.1.2)

Commitments		0.000	0.000	0.000	0.000	0.000	0.000
Payments		0.000	0.000	0.000	0.000	0.000	0.000

Subtotal a+b							
Commitments	5.5	5.5	5.5	5.5	5.5	5.5	33.0
Payments	5.5	5.5	5.5	5.5	5.5	5.5	33.0

(c) Overall financial impact of human resources and other administrative expenditure (see points 7.2 and 7.3)

Commitments/ payments	0.216	0.216	0.216	0.216	0.216	0.216	1.296
--------------------------	-------	-------	-------	-------	-------	-------	-------

TOTAL a+b+c							
Commitments	5.716	5.716	5.716	5.716	5.716	5.716	34.296
Payments	5.716	5.716	5.716	5.716	5.716	5.716	34.296

2.4. Compatibility with financial programming and financial perspective

Proposal is compatible with existing financial programming.

2.5. Financial impact on revenue:³⁷

Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

³⁷ For further information, see separate explanatory note.

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
Comp	Non-diff	YES	NO	NO	No 1a
Comp	Non-diff	YES	NO	NO	No 1a
Comp	Non-diff	NO	NO	NO	No 1a

4. LEGAL BASIS

Council Decision 90/424/EEC

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention ³⁸

5.1.1. Objectives pursued

Objective 1: EXTENSION of the surveillance programmes to avian influenza

Objective 2: EXTENSION of emergency measures (Article 3 of Decision 90/424/EEC) to low pathogenic avian influenza stamping out

Objective 3: POSSIBILITY to establish of an avian influenza vaccine bank

ONLY THE REALIZATION OF OBJECTIVE 2 LEADS TO AN ADDITIONAL DIRECT COST FOR THE EU-BUDGET. HOWEVER, THE STAMPING OUT OF LPAI COULD, COMPARED TO THE EXISTING SITUATION, LEAD TO AN OVERALL ECONOMY BECAUSE THE AIM IS TO PREVENT/REDUCE MUTATION FROM LPAI INTO HPAI.

5.1.1.1. Compulsory surveillance and control measures for LPAI.

Very often LPAI viruses do not cause any clinical signs in domestic poultry and therefore circulate unnoticed in the poultry population, due to direct or indirect contact between poultry farms or movements of poultry. Spread of LPAI viruses in domestic poultry is a major risk factor for their mutation into HPAI viruses, which then cause devastating disease outbreaks. The compulsory surveillance is needed so that disease control measures can be rapidly applied and mutation of LPAI into HPAI is prevented. The prevention of HPAI will protect the EU budget against high costs for its eradication.

³⁸ For further information, see separate explanatory note.

5.1.1.2. Possible establishment of an avian influenza vaccine bank

In some cases, it might be necessary to proceed to a rapid vaccination which again will protect the EU budget against high costs for its eradication.

5.1.2. *Measures taken in connection with ex ante evaluation*

AI is a serious, highly contagious disease of poultry and other birds caused by different types of viruses included in the very large virus family called Influenzaviridae. AI viruses may also spread to mammals, including humans, usually following direct contact with infected birds. In the human host, the disease may vary from mild conjunctivitis to serious disease, sometimes fatal; during the still ongoing AI epidemic in certain Asian countries, the case fatality rate in humans has been very high.

Due to continuous genetic changes of the disease agents and their possible “adaptation” to newly infected animal or human hosts, the risks posed by the different AI viruses to animal and public health is variable and to a large extent unpredictable. However, current knowledge indicates that the health risks posed by the so-called Low Pathogenic AI (LPAI) viruses - are inferior to the one posed by Highly Pathogenic AI (HPAI) viruses, which originate from a mutation of certain LPAI viruses, namely those of types H5 and H7, and which can cause a disease in poultry with a mortality rate as high as 90%.

As regards public health, data available indicate that HPAI viruses of types H5 and H7 have been responsible for the vast majority of the cases of AI reported in humans, and of all cases of human deaths due to AI viruses.

In general, domestic poultry populations are free from AI viruses. However, certain wild birds (particularly migratory waterfowl, such as ducks and geese) act as a permanent “reservoir” of LPAI viruses, from which they occasionally spread to domestic poultry. No measures are currently available or can be envisaged to stop or reduce virus circulation in wild birds living in nature; this means that there is a permanent risk of introduction of potentially very dangerous AI viruses from wild to domestic birds, and ultimately to other animals and humans.

For unclear reasons, an increase of AI outbreaks has occurred in recent years. Serious AI outbreaks (HPAI) have been recently reported in many different species of birds – including domestic poultry, kept under different husbandry and management practices - in several different areas of the world, and across all continents. These outbreaks have caused the death or killing for disease control purposes of hundreds of millions of birds and very serious losses to the poultry industry worldwide. In connection with these outbreaks, several human cases of infection were also reported, some of them fatal.

In the EU, in the last five years, major outbreaks of HPAI have occurred in Italy (1999-2000) and the Netherlands, with secondary spread to Belgium and Germany (2003). These outbreaks had devastating consequences on the poultry sector and a negative impact on the society as a whole - particularly in the Netherlands, where several human cases of disease also occurred. This was despite the draconian control measures applied by the Member States (MSs) including massive killing and

destruction of poultry and other birds in the affected areas, which often went far beyond the minimum requirements of Council Directive 92/40/EEC on Community control measures for the control of AI. These outbreaks have also entailed significant costs for the Community budget, in the framework of existing rules laid down in Council decision 90/424/EEC.

After previous EU animal health crises (classical swine fever, 1997-1998; foot and mouth disease, 2001) these outbreaks have prompted further criticisms in the MSs against massive slaughter of animals, due to animal welfare, ethical, social, economic and environmental reasons. The implementation of this measure has had a very negative impact on public opinion, and raised serious criticisms in particular in relation to special categories of birds, such as endangered species or breeds, or pets. The Court of Auditors has also often criticised the Commission due to the economic impact of massive slaughter on the Community budget.

Scientists deem that uncontrolled AI outbreaks, particularly those caused by certain virus types may, following transmission of the virus from birds or other animals into humans, eventually lead to the emergence of a virus fully adapted to humans and able to cause an Influenza pandemic, like the “Spanish flu” of 1917-1919. Such a pandemic could cause millions of human deaths and major socio-economic consequences all over the world.

Directive 92/40/EEC establishes compulsory disease control measures only in case of disease in poultry caused by HPAI. Lessons have been learnt during the recent epidemics. Outbreaks of AI caused by LPAI viruses of types H5 and H7, that subsequently mutated into HPAI viruses have caused devastating consequences. Once mutation has occurred, the virus is extremely difficult to control.

Council Decision 90/424/EEC provides for a Community financial contribution (50%) to be granted to the MSs for some of the expenditure which they may incur when eradicating HPAI (Decision 90/424/EEC currently uses the old terminology “avian plague” for HPAI), namely for reimbursement to farmers who have had their birds slaughtered and destroyed to eradicate the disease, for cleansing and disinfection, and for the destruction of eggs, feedingstuff and other materials likely to be contaminated. The Community may also reimburse 100% of vaccine costs.

In view of the increased knowledge on the risks for human health posed by AI viruses, the opinions of the Scientific Committee and the most recent knowledge on the pathogenesis, the epidemiology and the distribution of AI, there is now a clear need to revise and update current legislation to reflect these new advances and experience and to improve disease control of both LPAI and HPAI in future. This will be of direct benefit to animal health and indirectly also human health.

The current proposal envisages the following changes to Decision 90/424/EEC:

- to foresee a financial contribution (30%) to MSs, for the costs which they incurred in case of a stamping out policy being applied following LPAI outbreaks. The reduced contribution compared with HPAI outbreaks is justified by the fact that MSs should keep the option not to apply a stamping-out policy in case of LPAI, and a higher Community contribution might induce them not to make adequate use of this option. On the other hand, the Community co-

financed surveillance programme should allow the detection of LPAI in a timely manner and thus the need for extensive stamping out should be reduced, with a positive impact also on MSs budgets;

- to foresee a financial contribution (up to 50%) for the MSs surveillance programmes to be implemented annually in accordance with the first proposal (see also footnote 8).

The current proposal would therefore entail additional costs for the MSs and the Community budget, due to the measures being introduced for the surveillance and control of LPAI.

However, it is expected that the above costs will be counterbalanced by the savings related to the reduced risks for future HPAI epidemics. Of course, it cannot be precisely indicated to what extent the proposed measures would lead to a decrease in the number of future HPAI epidemics, the occurrence of which is still largely unpredictable and can never be totally excluded, given the nature of the risk in question. However, if the envisaged measures had been already in place and implemented in the EU in the last five years, one of the two major epidemics which have occurred in the Community would have been most likely prevented. Based on this, it may therefore be estimated that the implementation of the proposed measures could successfully prevent two major epidemics of HPAI in the next ten years.

The expenditure incurred by the MSs concerned for compensating farmers, for stamping out measures and for cleansing and disinfection (expenditure that are in principle eligible for a 50% Community co-financing in accordance with current provisions of Decision 90/424/EEC) in relation to the two major epidemics which recently occurred in the EU has been between 101 and 174 M€. It can therefore be estimated that at the current costs the prevention of two major epidemics would lead to savings for the Community budget of 100 M€ or more over a ten year period. This would largely outweigh the additional costs foreseen for the new LPAI surveillance and control measures (~50-60 M€ in ten years).

As seen above in this document, a decrease in the AI risk in poultry and other birds in the Community is bound to indirectly but significantly reduce the public health risks posed by AI viruses, including the one of an Influenza pandemic, since the circulation of AI viruses in domestic birds is the main source of the AI risk for humans. The implementation of regular surveillance would also have the positive effect that circulation of any AI virus in domestic poultry having a potential impact on public health could be rapidly detected, so allowing the adoption of any appropriate preventive measures, by both animal and public health authorities.

However, it is not possible to quantify more precisely the benefit of the proposed measures on public health.

As regards the prevention of an Influenza pandemic, this event may have its origin in any country in the world and may then spread into the Community due to human-to-human transmission of virus via movements of people. In this case, animal health control measures in place in the Community would have no effect in reducing that risk. However, the cost and the impact of an Influenza pandemic would be so serious that even a slight reduction of the overall risk stemming from the proposed measures

should not be disregarded in the overall cost/benefit evaluation of such measures. Furthermore, if such a catastrophic event originated in the EU in the absence of appropriate and scientifically updated Community legislation on animal health, the Community, as well as MSs, would be exposed to very serious criticisms, probably not inferior to the ones made in the past in relation to the emergence and spread of Bovine Spongiform Encephalopathy.

From all the data above, it emerges that both the Community as a whole and the MSs have a clear interest in the updating of Community policy on AI control, and to allocate appropriate resources for the prevention and control of disease.

5.1.3. Measures taken following ex post evaluation

Not applicable

5.2. Action envisaged and budget intervention arrangements

Not applicable

5.3. Methods of implementation

Not applicable

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

(The method of calculating the total amounts set out in the table below must be explained by the breakdown in Table 6.2.)

6.1.1. Financial intervention

Commitments (in € million to three decimal places)

Breakdown	[2006]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. Years]	Total
Operational objective Nr 1	1.500	1.500	1.500	1.500	1.500	1.500	9.000
Operational objective Nr 2	2.500	2.500	2.500	2.500	2.500	2.500	15.000
Operational objective Nr 3	1.500	1.500	1.500	1.500	1.500	1.500	9.000
TOTAL	5.500	5.500	5.500	5.500	5.500	5.500	33.000

6.1.2. *Technical and administrative assistance, support expenditure and IT expenditure (commitment appropriations)*

	[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5 and subs. years]	Total
1) Technical and administrative assistance							
a) Technical assistance offices							
b) Other technical and administrative assistance: - intra muros: - extra muros: <i>of which for construction and maintenance of computerised management systems</i>							
Subtotal 1							
2) Support expenditure							
a) Studies							
b) Meetings of experts							
c) Information and publications							
Subtotal 2							
TOTAL							

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)³⁹

Commitments (in € million to three decimal places)

Breakdown	Type of outputs (projects, files)	Number of outputs (total for years 1...n)	Average unit cost	Total cost (total for years 1...n)
	1	2	3	4=(2X3)
<u>Action 1</u>				
- Measure 1				
- Measure 2				
<u>Action 2</u>				
- Measure 1				
- Measure 2				
- Measure 3				
etc.				
TOTAL COST				

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A	2	-	2	
	B	-	-	-	
	C	-	-	-	
Other human resources			-	-	
Total		2	-	2	

³⁹ For further information, see separate explanatory note.

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials	216,000	1 full time official per year
Temporary staff		
Other human resources (specify budget line)		
Total	216,000	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Budget line	Amount €	Method of calculation
Overall allocation (Title A7)		
1701021101 – Missions		
1701021102 – Meetings		
A07031 – Compulsory committees ¹		
A07032 – Non-compulsory committees ¹		
A07040 – Conferences		
A0705 – Studies and consultations		
Other expenditure (specify)		
Information systems (A-5001/A-4300)		
Other expenditure - Part A (specify)		
Total		

The amounts are total expenditure for twelve months.

¹ Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	216,000 €
II.	Duration of action	6 years
III.	Total cost of action (I x II)	1,296,000 €

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

The Commission will have at its disposal several ways to evaluate the future impact of the proposals:

- from the occurrence of future HPAI epidemics on poultry, it will be evident whether the measures put in place have been effective to prevent and control those epidemics;

- from the results of the regular LPAI surveillance programmes, future programmes could be better modulated to ensure that the resources allocated are proportionate to the risks posed by LPAI; this would prevent under- or over-expenditure both for the Community and MSs in connection with surveillance;
- from the control measures applied by the MSs in relation to future LPAI outbreaks and related costs, it will be more clear what the real impact of the new financial measures introduced in relation to LPAI control will be.

The Commission has already in place the necessary basic tools to gather and analyse this information in the proper manner, such as the Standing Committee for the Food Chain and Animal Health, the inspectors of the Food and Veterinary Office and the network of Community and National Reference Laboratories, whose role will be confirmed and strengthened by the current proposal. However, in the future new scientific opinions could also be useful to assist the Commission for policy formulation and fine tuning of legislation, as well as for MSs when implementing disease control measures.

The Commission has also started a process of evaluation of the whole Community Animal Health Policy, which will include questions on the cost/effectiveness of the current financial instruments to cope with animal disease surveillance, control and eradication and on ways in which producers should be induced to take all appropriate measures to reduce the risk of disease introduction onto their farms. In this context major risk factors such as density of animal populations and on-farm biohazards will be considered, together with mitigating measures and consequences on the EU budget. Based on the outcome of these studies and evaluation, alternatives to the current way Community financial support is granted to the MSs might be proposed.

8.2. Arrangements and schedule for the planned evaluation

As mentioned above, the Commission has at its disposal tools, such as the Standing Committee for the Food Chain and animal health and the network of Community and national reference laboratories; these instruments will allow

9. ANTI-FRAUD MEASURES

Not relevant