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DISCUSSION PAPER

**VACCINATION OF POULTRY AGAINST
HIGHLY PATHOGENIC AVIAN INFLUENZA H5N1
(DIVA STRATEGY)**

**This document does not necessarily represent
the views of the Commission services**

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Vaccination of poultry against Highly Pathogenic Avian Influenza H5N1 (DIVA¹ strategy)

1. Introduction

There are only limited experimental evidence and epidemiological data available on the use of vaccination of poultry and other captive birds against avian influenza, in particular against the “Asian strain” of Highly Pathogenic Avian Influenza H5N1 (hereby simply called HPAI H5N1) and this lack of theoretical and practical knowledge poses questions that may not have an answer.

However, the current epidemic of HPAI H5N1 and the transmission of this virus over long distances via migratory birds are unprecedented. Even if the magnitude of the risk that the migratory birds will pose to the EU in the near future is still unclear, there is growing evidence suggesting that the prevention and control of disease outbreaks in poultry and other captive birds will be a major challenge for the EU and for the whole world for many years to come. Annex I gives a picture of the current disease situation.

Despite the constraints that make it difficult to properly assess the risks and the benefits of using vaccination as an additional HPAI H5N1 prevention and control tool, it appears wise to explore this option in the EU, taking also into account the valuable experience gained in recent years in Italy, where following the major outbreak of HPAI of 1999/2000², a DIVA vaccination strategy has been developed and implemented in certain areas at risk of introduction of avian influenza viruses, which are located in the Po valley.

This document is aimed at providing guidance on the possible use of vaccination against HPAI H5N1 in domestic poultry or other captive birds in the current EU Member States in the period March - July 2006³. The opinions on avian influenza delivered by the Scientific Committee on Animal Health and Welfare in 2000 and 2003 and by the European Food Safety Authority in 2005⁴ are also fundamental documents to be consulted before taking decision on vaccination.

Vaccination should not be applied as an alternative to on-farm biosecurity measures, which are of fundamental importance for the prevention and control of avian influenza. However, it is recognised that one of the most important bio-security measures, namely keeping poultry indoors, may not be

¹ DIVA: Differentiating Infected from Vaccinated Animals, by means of “sentinel” non-vaccinated birds into a farm and by laboratory tests.

² That epidemic was caused by an H7N1 virus type.

³ Vaccination of special categories of birds such as zoo birds is already possible in accordance with Commission Decision 2005/744/EC.

⁴ These documents are available on the web sites of DG Health and consumer protection and EFSA.

easily applicable in certain categories of poultry or would compromise the status of “organic” or “free-ranging” poultry.

2. Legal framework for vaccination

The new Council Directive 2005/94/EC⁵ on the control of Avian Influenza allows the implementation not only of emergency vaccination following a disease outbreak (as the old Directive 92/40/EEC did) but also of preventive vaccination plans, which must be based on a risk assessment to be carried out by the Member States. Although Directive 2005/94/EC shall be only transposed and implemented by the Member States into national legislation by 1 July 2007, it entered into force on 3 February 2006. . Hence from this date, Member States have the possibility to submit their preventive or emergency vaccination plans to the Commission for approval on the basis of this new Directive and subsequent implementation, and apply vaccination using the broader framework that is foreseen in the new legislation, see also Annex II.

Directive 2005/94/EC also foresees that if veterinary vaccines are used, they should be authorised in accordance with the provisions of the Community pharmaceutical legislation (Directive of the European Parliament and of the Council 2001/82/EC⁶; Regulation (EC) No 726/2004 of the European Parliament and of the Council⁷).

As regards marketing authorisation procedures, in accordance with article 8 of Directive 2001/82/EC, the Member States may provisionally allow the use of currently available inactivated vaccines⁸ without a marketing authorization for placing on the market, after informing the Commission of the detailed conditions of use⁹.

In accordance with article 26 (3) of Directive 2001/82/EC, two Member States (UK, FR) granted a provisional marketing authorisations for inactivated avian influenza vaccine in the last months. That provisional authorisation is subjected to specific conditions and will be submitted to annual re-assessment. Consequently, in accordance with Article 7 of the said Directive, the other Member States may authorise the marketing or administration of vaccines for which provisional authorisation has been granted.

Marketing authorisation could also be granted provisionally at Community level in accordance with Article 39 (7) of Regulation N°726/2004.

5 OJ L 10, 14.1.2006, p 16.

6 OJ L311, 28.11.2001, p.1, as amended by Directive 2004/28/EC, OJ L136, 30.4.2004, p. 58.

7 OJ L136, 30.4.2004, p.1.

8 Representatives of the pharmaceutical industry have had the possibility to inform the Member States on the products currently available at a meeting held in Brussels on 10 January 2006.

9 On these bases, Italy has allowed the use of avian influenza vaccines in the Po valley.

3. General advantages and disadvantages of vaccination

Based on the information available on the control of and use of vaccines against Avian Influenza, the main pros and cons that are expected in relation to the use of vaccination for the prevention and control of HPAI H5N1 can be summarised as follows:

3.1. Advantages

- a) Vaccination reduces mortality and associated losses (this may be of major importance for very valuable birds, such as zoo birds);
- b) It reduces the risk of virus infection to individual birds and therefore reduce the risk of disease introduction into a vaccinated farm (a higher virus amount is necessary to cause infection of individual vaccinated birds).
- c) It reduces the amount of virus that is shed in the environment by an infected bird. As a consequence, in case the virus enters a vaccinated farm, there is less risk that the virus is spread to other farms. In a similar manner, also humans are less exposed to the risk.
- d) As a consequences of b) and c) above, primary outbreaks of disease are less likely to occur in a properly vaccinated population than in a non-vaccinated population and if they occur the disease is likely to be more easily contained and eradicated than in a non vaccinated population.

3.2. Disadvantages

- a) Vaccination is difficult/expensive to administer and requires a heavy organisation. Currently, in order to induce and maintain a good immunity, only vaccines to be administered by injection 1-3 times during the life span of a poultry bird are available.
- b) In certain species (in particular ducks and geese, but also turkeys) the immune response induced by vaccination is in general not fully satisfactory, the benefits indicated above are therefore inferior than in other birds (broilers, hens).
- c) It may “mask” the occurrence of disease in a farm and delay its detection; for this reason adequate clinical and laboratory surveillance in accordance with the DIVA principle are necessary. These measures are expensive and to a certain extent constitute restrictions to trade, as vaccinated poultry (and their products) must be subjected to special controls before being traded to ensure that the poultry (and their products) are not infected.
- d) If vaccination is not properly applied (or applied with low quality vaccines) and surveillance is not properly ensured, it may eventually lead to the persistence of disease at an endemic status in the vaccinated poultry population, as the virus would continue to circulate between not fully immune birds.
- e) It may induce a false sense of security and thus favourite relaxation of bio-security and surveillance measures by the poultry owner and so leading also to a potential risk for human health.

- f) Given the tendency of influenza viruses to mutate, it is appropriate to ensure that the vaccine strain matches the field virus. For the same purpose, it may also be necessary to properly update vaccine strain composition; however, poultry vaccines may not need annual update of their composition as human influenza vaccines.
- g) It may induce third countries to apply restrictions to trade on poultry and poultry products (meat, etc.). However, the OIE Terrestrial Animal Health Code, in relation to trade in live poultry, day-old live poultry and hatching-eggs (not poultry meat or eggs for consumption), only recommends that vaccination is performed in accordance with the guidelines for the surveillance of Avian Influenza and the relevant information is attached to the international veterinary certificate.

4. Cost/effectiveness of vaccination: some historical data

Because the current epidemic is unprecedented and there is very limited experience on vaccination of poultry against H5N1, it is extremely difficult to predict its cost/effectiveness. However, some data are available on the DIVA vaccination carried out in 4 Provinces of Northern Italy since December 2000, following the major epidemic of 1999/2000. The costs and losses of that epidemic have been estimated in 500 M€, including 110 M€ of compensation costs.

In the last 5 years, vaccination has been applied in meat producing turkeys and laying hens farms in Northern Italy as an additional tool to prevent introduction of Low Pathogenic Avian Influenza (LPAI) viruses from wild birds into poultry, to reduce circulation of these viruses in poultry and in this manner to prevent their possible mutation in HPAI viruses. Vaccination of 400-600 commercial poultry farms¹⁰ has had a cost of 2-4 M€ per year, including the cost of the vaccine doses, administration of vaccine and surveillance costs. The overall cost has been around 0.1 - 0.15 € per vaccinated bird.

Since vaccination has been applied, three LPAI outbreaks have occurred in poultry farms in Northern Italy, in both vaccinated and non vaccinated poultry farms. These outbreaks have been eradicated thanks to a stamping out policy combined with “controlled slaughter” of poultry. Outbreaks have occurred in both vaccinated and non-vaccinated farms, however, in at least two of these three outbreaks the positive effect of vaccination seems to be evident. None of these outbreaks has eventually led to an HPAI outbreak, however it is extremely difficult to establish to what extent this was due to vaccination, other disease control measures or other factors.

In accordance to Marangon et al¹¹, the Italian experience has shown that a DIVA vaccination strategy can be successfully used under certain circumstances both for emergency and prophylactic purposes, limiting financial losses generated by major epidemics.

¹⁰ the area of vaccination and number of vaccinated farms has changed during the vaccination campaign.

5. The preventive vaccination plans of the NL and France

At the end of February 2006, France and the Netherlands submitted preventive vaccination plans against HPAI H5N1 to the Commission for approval.

5.1 The French vaccination plan

The French plan approved by Commission Decision 2006/148/EC entails the vaccination of ducks and geese in the departments of Landes, Loire-Atlantique and Vendée, which are considered to be areas at high risk of HPAI H5N1. Vaccination has been deemed necessary for the ducks and geese in these regions as these birds cannot be easily put indoors. Vaccination has already started in one of the three departments. A total of 900 000 birds are expected to be vaccinated in the incoming weeks.

The French plan outlines the monitoring and control measures that will be taken in relation to the vaccinated birds. These include a pre-vaccination examination of flocks, monthly clinical surveillance of the holdings, the use of sentinel birds (i.e. unvaccinated control birds) to monitor for an avian influenza outbreak in the vaccinated flock. Farmers will be provided with warning criteria to help them in detecting any possible outbreak of avian influenza in the vaccinated birds.

Decision 2006/148/EC lays down further conditions, particularly in relation to the movement of vaccinated poultry. Vaccinated live poultry, their hatching eggs and day-old chicks cannot be exported or moved to another Member State or third country. Within France, vaccinated birds can only be moved to other vaccinated holdings, to holdings where there is complete separation of vaccinated and non-vaccinated birds, or to a slaughterhouse for immediate slaughter. Fresh meat and meat products from the vaccinated poultry can be marketed in the EU and dispatched to third countries, provided that it comes from holdings which have complied with all the above conditions, the flock from which it originates is inspected by a vet 48 hours prior to slaughter, and it meets all appropriate animal health rules. The Commission decision also requires that any packaging or means of transport used for vaccinated birds and their products is properly washed and disinfected.

5.2 The Dutch vaccination plan

The Dutch vaccination plan, which has been approved by Commission decision 2006/147/EC, applies to backyard (hobby) poultry and to free-range (organic) laying hens throughout the whole country. There are between 1-3 million hobby birds in the Netherlands, and around 5 million free-range laying hens. The vaccination will be provided on a voluntary basis, as an alternative to the requirement that these birds be kept indoors.

¹¹ Marangon and Capua, OIE Conference on Avian Influenza April 2005.

All bio-security measures, such as the feeding of poultry under cover, will still have to be applied, regardless of whether owners opt for vaccination or not. Detailed surveillance and control provisions are outlined in the Dutch plan. Monitoring for an outbreak of avian influenza in the vaccinated flock will be done using sentinel birds and serological tests, vaccinated poultry will be identified to distinguish them from non-vaccinated birds, records will be kept of all vaccinated holdings and bio-security measures will continue to be applied.

In accordance with Decision 2006/147/EC, vaccinated hobby poultry will only be allowed to be moved to other vaccinated backyard holdings in the Netherlands subject to permission from the authorities, while no movement of these birds to another Member State will be authorised. Meat and products from hobby poultry are not allowed to be commercially marketed anyway, so no additional provisions were needed for products from vaccinated hobby birds.

Vaccinated free-range laying hens may only be moved to other vaccinated holdings or directly to a slaughterhouse within the Netherlands, and may not be dispatched outside the country. Eggs from vaccinated laying hens can be marketed in the EU and dispatched to third countries provided that they are shown to come from a disease-free holding and must be packed in disposable packaging in an officially designated centre, in line with required bio-security measures. Fresh meat and meat products from the vaccinated laying hens can be put on the market provided that it comes from holdings which have complied with all criteria, the flock from which it originates is inspected by a vet 48 hours prior to slaughter, and it meets general animal health rules.

5.3 "Pilot projects"

When supporting the Commission's approval of the two vaccination plans, the Member States experts at the Standing Committee on the Food Chain and Animal Health highlighted that the French and the Dutch vaccination plans had to be considered as "pilot projects" that should allow the Community to gain more knowledge and experience on the use of vaccines.

The first results of the vaccination plans will be available in April-May 2006. The future vaccination policy of these two countries will be decided on the bases of the results obtained.

6. Setting the scenario

The vaccination scenarios that are described below are based on the following assumptions:

- a) Following the incursions of virus in several Member States in early 2006, there is a significant risk that further virus dissemination will take place in the coming weeks and months, either from the currently infected areas in Europe or from other geographical areas . There is now evidence that

the disease is widespread in several African countries, from which many birds will migrate in March and April towards Europe. The HPAI H5N1 already present in Europe or which might be introduced from Africa might affect wild bird populations living in wetlands and areas with a high density of wild birds. From the migratory and non-migratory birds above the disease might spread into domestic poultry and other captive birds. Backyard poultry farms and farms in which no clear separation of domestic birds with wild birds can be ensured are at higher risk. The disease might also enter the EU via other routes (legal or illegal trade, contiguity with a third country, etc).

- b) Prevention, surveillance and early-warning measures are already in place in the Member States in accordance with relevant legislation that would reduce the risk that the disease is introduced and spread in domestic poultry and other captive birds. However, intense surveillance in certain populations such as backyard poultry may be problematic and cumbersome.
- c) In case of introduction of disease into the populations indicated in b) above, the Member States will rapidly put in place a number of rigorous control and eradication measures, irrespective from vaccination, as provided in Council Directives 92/40/EEC and 2005/94/EC and national contingency plans to prevent the disease becoming established in domestic poultry populations and to ensure that a permanent wild birds / domestic birds cycle of infection is not established. Nevertheless, outbreaks of disease may lead to health risks for people directly exposed to infected poultry, major economic losses and require the adoption of draconian measures for their effective containment and eradication, including massive stamping-out of poultry and other captive birds. These measures may be difficult to implement as rapidly as desirable and may have a significant negative impact on poultry farmers and rural populations.

Given a), b) and c) above it is unlikely that the disease will become established in an endemic form in domestic bird populations in the EU in the next months, irrespective of vaccination. However, if properly applied and accompanied by a specific surveillance system, vaccination may contribute to reduce the risks and the overall negative impact of an outbreak.

7. Requirements for vaccination

The Member State wishing to implement vaccination against avian influenza must submit a plan that should give the following information and comply with the requirements below:

7.1 Disease Information

The Member State must give a clear description of its disease situation (or the neighbouring country or Member State, if this situation poses a threat). Results of previous surveillance in poultry and wild birds according to Commission Decisions 2005/732/EC¹² and its amendments (Commission Decisions 2005/464/EC¹³ and 2005/756/EC¹⁴) on intensified surveillance in wild birds specifically for H5N1 HPAI

¹² Commission Decision 2005/732/EC of 2005 implementing surveillance programmes

¹³ Commission Decision 2005

¹⁴

have to be taken into account in this description. Depending on this situation and the risk assessment of 6.2.below, it must be stated if emergency vaccination or preventive vaccination is envisaged.

7.2 Risk assessment

The Member State concerned must give a clear justification prior to introduce vaccination based on an assessment of risks for disease introduction in its poultry flocks. This shall take into account the risks factors and local conditions prevailing (such as structure of poultry keeping, husbandry practices such as percentage of free range holdings, susceptibility of different species, poultry density, proximity to wild bird wintering and resting sites and wetlands, possible contacts to wild birds etc.) It shall also explain why other biosecurity measures adopted at national and Community level are not deemed sufficient to protect poultry flocks.

7.3 Extension of vaccination area

The Member State must notify in which geographical area and type of holdings it intends to carry out vaccination. For this purpose clear maps with identification of administrative boundaries such as communes need to be provided. The number of holdings and approximate number of birds to be vaccinated must be indicated as well as the species of poultry (e.g. chicken, turkey, ducks, geese etc.) and the production categories (e.g. fattening birds, breeders, layers). All these holdings must be registered. If this is not yet the case for backyard flocks this must be done in case these shall be included in the vaccination programme. Identification of vaccinated animals should also be described.

7.4 Vaccination strategy

Vaccination shall be carried out in accordance with a DIVA strategy which shall allow a differentiation between vaccinated/infected and vaccinated/non-infected birds. It must be clearly described how this system can be implemented in the concerned species and production systems the Member State wishes to subject to vaccination. Details shall be provided in the section on surveillance. The duration of the vaccination campaign must be indicated.

74.1. Vaccine characteristics

Information on the vaccine(s) to be used must be submitted including the characteristics of the Master seed strain (subtype, LPAI, HPAI), the vaccine manufacturer, type of vaccine (inactivated, GMO, etc). It must be stated which provisions of pharmaceutical legislation market authorisation according to pharmaceutical legislation has been granted exists. Minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use in birds against H5 and/or H7 highly pathogenic avian influenza virus are set out in a document of the European Medicines Agency (EMA) of 16 February 2006 Doc.Ref.EMA/CVMP/IWP/46853/2006 of the Committee for Medicinal products for veterinary use (CVMP).

7.4.2. Vaccination scheme

The Member State must indicate the vaccination scheme to be applied to each species and production type to be vaccinated, the dose per bird, the age of the bird at vaccination, the frequency of vaccination and the intervals between (re)-vaccinations. Specific arrangements will be required if no all-in all out practise can be performed (e.g. birds to be added should have acquired sufficient immunity before moving into common sheds with birds already vaccinated).

7.4.3. Logistics of vaccination campaign

The Member State concerned must indicate the organisation of vaccine acquisition, vaccine storage, the distribution channels, maintenance of the cold chain, the application of vaccination by veterinarians, vaccinators etc and the destiny of unused vaccine doses. It must be guaranteed that all these steps are carried out under official supervision.

7.5 Surveillance and early reporting

7.5.1. Biosecurity and early detection systems:

Member States must ensure that heightened biosecurity measures and systems for early detection according to Commission Decision 2005/734/EC¹⁵ are in place in all holdings of the territory.

7.5.2. Accompanying surveillance

The Member State must clearly describe the surveillance measures to be implemented in case of preventive or emergency vaccination that should allow for an early detection of possible field virus circulation.

In the case of emergency and preventive vaccination all vaccinated flocks must be subjected to surveillance by laboratory tests. To this end sentinel birds (unvaccinated susceptible birds, that must be clearly identified to avoid substitution or mix-up) shall be placed in the holdings. It is recommended to use not less than 1% of the population and in any case a minimum of 100 birds. The laboratory tests to be carried out on these sentinel birds must be indicated in terms of sample size (to allow for detection of infection with satisfactory confidence levels) as well as the frequency of testing and the type of laboratory tests used. Severely diseased sentinel birds shall be humanely killed and dead birds shall be immediately submitted to laboratory investigation. In case of species that might not show clear clinical signs even in case of HPAI infections, the use of sentinels of a poultry species that show a higher susceptibility than the vaccinated one shall be considered instead. If suitable tests are available (discriminatory tests) laboratory testing shall be carried out on vaccinated birds. In the case of emergency vaccination the regular surveillance of poultry flocks shall also be intensified for non-vaccinated poultry flocks in the vaccination area. The frequency of testing and the laboratory tests used shall be adapted to the type of production, the species concerned and possible risk factors for introduction of infection (long living birds, very dense poultry area, multiple contacts within an integration...).

¹⁵ Commission Decision 2005/734/EC

7.6. Efficacy monitoring

Vaccinated birds shall be submitted to serological testing in order to evaluate the antibodies dynamics and assess the efficacy of vaccination in order to allow for adaptations of the ongoing vaccination scheme, if necessary, to achieve optimal protection.

7.7 Movement restrictions

Movement restrictions will differ for emergency vaccination programmes and preventive vaccination programmes depending on the actual risk of possible undetected field virus circulation. In case of movement of live poultry, day old poultry and hatching eggs this situation might often require laboratory testing before movement. In case of products derived from vaccinated poultry, such as meat and eggs compliance with the requirements of the surveillance accompanying the DIVA vaccination programme shall suffice.

7.7 Record keeping

Member States shall keep records for all poultry holdings (vaccinated and non-vaccinated), the holdings that are subjected to vaccination, the number of animal vaccinated, the number of holdings subjected to the surveillance programme and vaccine efficacy testing. All data in relation to vaccination logistics (vaccine storage, distribution as under 5.3.) have to be kept.

Poultry flock owners shall follow their legal obligation for record keeping. In addition owners of poultry hobby flocks shall keep a register of all movements of birds (acquisition, hatchings, deaths, movement to other keepers, slaughter for own consumption..).

7.8 Declaration by owner

Owner (keeper) must declare to adhere to reporting obligations as set out in Decision 2005/734/EC and to obey the movement restrictions laid down in the emergency or preventive vaccination plan. He must state that he has been informed about the eventual risks of vaccination as concerns masked infection, the clinical symptoms of AI infection in poultry and humans, the necessary bio-security measures to avoid introduction of field virus infection and the hygienic precautions for personnel.

8. Poultry populations at particular risk in the EU in which vaccination (DIVA strategy) against HPAI H5N1 could be envisaged

8.1 Preventive vaccination

Based on the pros and cons and the assumptions above, preventive vaccination could be envisaged in the following populations of domestic poultry:

- a) turkey, ducks, geese and laying hens farms located along major migratory flyways, in particular if in these farms an effective separation between the domestic poultry and wild birds cannot be ensured and if these farms are located in areas with a high density of poultry;

- b) backyard poultry farms located along major flyways or in the vicinity of areas with a high density of wild birds. Proper vaccination in these farms might have a significant impact to decrease the risk posed by the disease, taking into account that in many countries so far affected by HPAI H5N1, backyard flocks play a major role in the persistence of infection in an endemic form and that poultry-to-human transmission of virus has mainly occurred in people living in contact with backyard poultry. However, it would be at the same time a very challenging and demanding task, see also Annex III.

8.2 Emergency vaccination

Based on the pros and cons and the assumptions above, emergency vaccination following a disease outbreak could represent an alternative to pre-emptive culling in reducing the susceptibility of healthy flocks at risk by reducing the transmission rate. It could therefore be applied around or in the vicinity of an outbreak, giving priority to the poultry farms at higher risk described in 4.a) above. However, the size of the vaccination zone and the farms to be vaccinated cannot be identified *a priori*. The practicability of vaccination, the time interval necessary to obtain protective immunity and the resources available for such emergency vaccination must also be fully considered.

Both in case of preventive vaccination and emergency vaccination it will be of major importance:

- to establish an effective surveillance system in line with the DIVA strategy, which should take into account the experience gained in Italy;
- that poultry owners are properly informed on the pros and cons of vaccination, and on the measures and actions to be taken to prevent any spread of virus from their birds. Owners must be made aware that clinical signs of disease that would normally indicate the presence of infection may not be evident in vaccinated populations and that *inter alia* appropriate personal hygiene measures must be taken, in line with the guidelines issued by the ECDC to minimise the risk of humans acquiring HPAI H5N1 from exposure to infected birds.

In order to prevent any possible spread of disease which may occur in vaccinated flocks and may not be detected in a timely manner, the surveillance and control measures laid down in articles 3 to 9 of Commission Decision 2005/926/EC¹⁶ in relation to trade in vaccinated poultry and their products would be considered as an important reference by the Commission when assessing and eventually approving the vaccination plans submitted by the Member States. Before submission, the vaccination plan should be agreed between the animal health and public health authorities in the Member State.

¹⁶ Commission Decision of 21 December 2005 on introducing supplementary measures to control infections with low pathogenic avian influenza in Italy and repealing Decision 2004/666/EC

ANNEX I

The recent disease spread in Europe, Middle East and Africa

Following the spread of disease from south-east Asia to Mongolia, Russia, Kazakhstan, Romania, Turkey, Croatia and Ukraine in the second half of 2006 and a serious epidemic of disease in Turkey in January 2006, an unprecedented spread of HPAI H5N1 has occurred in Europe, Middle East and Africa last month.

In Europe, in February 2006 the virus has been detected in wild birds in 12 previously unaffected countries (Bulgaria, Greece, Italy, Slovenia, Austria, Hungary, Germany, France, Slovakia, Bosnia-Herzegovina, Switzerland and Sweden).

There is increasing evidence that virus dissemination in at least some of the countries above has been due to "cold winter" migration of birds from affected wetlands surrounding the Black Sea and the Caspian Sea. This spread of virus via wild birds has led to outbreaks of disease in poultry farms only in one case, so far (one outbreak in a turkey farm in France).

HPAI H5N1 has been most often detected in wild swans (*Cygnus olor*, *Cygnus cygnus*), that in at least some circumstances seem to have also played the role of virus disseminators.

In February 2006, the disease has also been reported for the first time in Iraq, Iran, Azerbaijan, Georgia, Nigeria, Egypt, Niger and Ethiopia. In many cases the disease has been reported in domestic poultry, only. Very few data are available on the occurrence of disease in wild life. Results of wild birds monitoring carried out in Africa under the auspices of FAO should be available in the next weeks.

ANNEX II
EMERGENCY AND PREVENTIVE VACCINATION AGAINST AVIAN INFLUENZA
IN DIRECTIVE 2005/94/EC

1. Emergency vaccination

A Member State may introduce emergency vaccination in poultry or other captive birds as a short term measure to contain an outbreak in poultry or other captive birds when a risk assessment indicates that there is a significant and immediate threat of avian influenza spreading within or into the Member State concerned and where an outbreak of the disease has been confirmed within that Member State, in a nearby Member State or in a nearby third country.

Where a Member State intends to introduce emergency vaccination it shall submit an emergency vaccination plan to the Commission for its approval.

The Commission shall immediately examine the emergency vaccination plan together with the Member State concerned and shall review the situation in the Committee as soon as possible. The emergency vaccination plan shall be approved in accordance with Regulatory Committee procedures (SCOFCAH).

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

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

- (a) the Commission is notified of the emergency vaccination plan and the decision to apply emergency vaccination before the commencement of the emergency vaccination;
- (b) the Member State concerned prohibits the movement of poultry or other captive birds and their products except under certain "basic" conditions on trade in vaccinated poultry and products from the vaccinated poultry that laid down in an Annex of the Directive (these conditions may be revised afterwards when the plan is approved by SCOFCAH procedure);
- (c) the decision to apply emergency vaccination does not endanger disease control.

When a Member State applies the derogation above, the disease situation and the emergency vaccination plan shall be reviewed in the Committee as soon as possible. The vaccination plan submitted could then be approved and further Community measures established.

2. Preventive vaccination

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

Where a Member State intends to introduce preventive vaccination, it shall submit a preventive vaccination plan to the Commission for its approval.

The Commission shall immediately examine the preventive vaccination plan together with the Member State concerned and shall review the situation in the Committee as soon as possible. The preventive vaccination plan shall be approved in accordance with Regulatory Committee procedures (SCOFCAH). The approval of the preventive vaccination plan may include measures restricting the movements of poultry or other captive birds and their products. Those measures may include restrictions concerning specific poultry compartments and other captive birds compartments and the establishment of restricted zones.

ANNEX III
SURVEILLANCE AND CONTROL OF AVIAN INFLUENZA H5N1
IN BACKYARD POULTRY FARMS - A VERY DIFFICULT AND DEMANDING TASK

Experience in Asia and eastern Europe suggests that HPAI H5N1 virus may be particularly difficult to control in areas with a high density of "backyard poultry". Furthermore, most human cases of disease have actually occurred in people living in close contact with backyard poultry.

In its opinion of September 2005, the EFSA has recognised that backyard poultry farms are often the link between wild birds and commercial poultry farms for the spread of Low Pathogenic Avian Influenza viruses. Once in commercial poultry farms, the disease may have devastating effects from an animal health point of view, in particular in those areas of the Community with a high density of farms. Once in these areas massive culling of both backyard and commercial poultry could be necessary. The experience suggests that this operation can be very demanding in terms of resources and having a major negative social impact, in particular when many backyard poultry owners are concerned.

The information accumulated in recent months suggests that wild birds and migratory birds play a significant role in the dissemination of HPAI H5N1 virus. To ensure a proper separation between backyard poultry and wild birds may be particularly problematic. Therefore, a proper strategy for the prevention, surveillance and control of disease in backyard poultry in the EU becomes essential to protect both animal and public health. This should be based on the following pillars:

1. Disease Information

It is crucial that backyard poultry farmers are informed on the bio-security measures to be taken in their farms to prevent contacts with other domestic or wild birds, the clinical signs of disease in their poultry and the hygienic measures and precautions to be taken in case of suspicion of disease to prevent a possible poultry-to-human spread of virus. Effective measures by the MSs are needed in passing this information to the local level.

2. Surveillance and early reporting

As poultry farmers and the owners of backyard poultry must be in position to rapidly report occurrence of clinical signs of disease to the competent authorities, they need to be informed of the local contact points for this. A system must also be in place for collection of carcasses of suspected poultry and for their rapid testing. As many of the owners may not currently have the knowledge to be able to act properly in they may need assistance in the local authorities eg information on killing birds correctly, disinfection etc.

3. Possible vaccination

This is particularly demanding in case of backyard poultry. Ideally, registration of all backyard farms should take place in the whole vaccination area. Vaccinated poultry should be individually identified, so that they can be differentiated from non-vaccinated ones. In addition farmers will have to keep dependable records and a post vaccination surveillance system will have to be put in place. Many owners may opt to slaughter the backyard birds rather than vaccinate them and this option should also be discussed with the owners.

Correct implementation of such measures will require that the owners are very well informed of what they must do and the implications for them of having the birds vaccinated. This should be done by the media at national, regional and local levels.

Before a decision to implement vaccination is taken, the Competent Authority should verify that all these elements are in place.