

**QUESTIONS AND ANSWERS ON THE EC CONTROL MEASURES
FOR AVIAN INFLUENZA**

Communication from the European Communities

The following communication, received on 13 March 2006, is being circulated at the request of the Delegation of the European Communities.

Background

Numerous WTO Members have recently adopted precautionary measures restricting trade from the European Communities on grounds of outbreaks of Avian Influenza (AI). These restrictions reveal generally a lack of knowledge on how the European Communities deals with this disease, especially concerning the marketing conditions for live birds, meat and meat products, eggs and feathers, and animal feeding stuffs including processed poultry.

To overcome this situation, this document aims to explain the latest legislation adopted by the European Communities for the prevention of AI, including cooperation with third countries, international institutions and research centres.

This document has been structured in the form of questions and answers, with the aim that the interested reader can go directly to the point(s) of concern. Special emphasis has been laid down to explain the use of vaccination as a control measure.

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I. BACKGROUND

1. Poultry is listed in Annex I to the EC Treaty and one of the Community's tasks in the harmonized veterinary field is to improve the health status of poultry, thereby facilitating trade and ensuring the development of this sector. Furthermore, when defining and implementing Community policies and activities a high level of human health protection is to be ensured.

2. Concerning Avian Influenza (AI), most AI viruses are of low pathogenicity and do not cause serious disease in birds, but due to rapid virus mutation and possible re-assortment of the genetic material between different strains, the level of risks for animal and public health posed by the different strains is to some extent unpredictable. A consequence of the above is the existence of specific legislation aiming to control AI in the European Communities. This legislation takes into consideration the role of wild birds (ducks, geese and gulls in particular) that often carry these viruses without showing any symptoms and are considered to be the main "reservoir" of AI viruses in nature. From these birds, the low pathogenic viruses may spread to domestic poultry and some of these (notably those of the types H5 and H7), can mutate into highly pathogenic viruses causing the Highly Pathogenic AI (HPAI), a serious disease leading to epidemics in poultry and other birds. The recent Asian strain of the AI virus is an example of an HPAI virus which can also spread and cause disease in humans.

A. WHAT IS THE EC LEGISLATION ON AVIAN INFLUENZA?

3. EC legislation to control AI is laid down in Council Directive 92/40/EEC¹ although this Directive is being replaced by Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of AI and repealing Directive 92/40/EEC.² There are other actions for preventive hygienic measures at farm level, disease awareness amongst farmers and cooperation between operators in the poultry sector with a view to ensure that the strictest biosecurity measures are applied to prevent disease spread. According to this legislation:

- (a) all member States must have an AI contingency plan in place to ensure that the most appropriate measures are immediately implemented in the event of an outbreak;
- (b) all suspected cases of AI must be investigated and appropriate measures taken in case of confirmation of high pathogenic AI;
- (c) to limit the spread of the virus:
 - infected poultry must be killed in a humane way and disposed of safely;
 - feeding stuffs, contaminated equipment and manure must be destroyed or treated in order to inactivate the virus;
 - the veterinary authorities are required to immediately implement movement restrictions on the affected holdings and on all farms in a radius of at least 10 km around these holdings (the so called surveillance zone); and
 - if necessary, stamping-out measures can also be extended to poultry farms in the vicinity, or to holdings which have had high risk contact with infected farms.

¹ Council Directive 92/40/EEC of 19 May 1992 introducing Community measures for the control of AI (Official Journal L 167, 22 June 1992 p.:1).

² Official Journal L 10, 14 January 2006 pp.:16-65.

B. WHAT HAS BEEN THE SITUATION WITH REGARD TO THE AI OUTBREAKS CAUSED BY THE ASIAN STRAIN OF THE VIRUS?

4. Since 2003, the particularly virulent Asian strain of AI has caused the death or destruction of many million birds in South East Asia, and is still in circulation. In Central China, that is inhabited by a large population of different species of wild birds including migratory birds, several different species were found infected. At the end of July-beginning of August 2005, Russia and then Kazakhstan confirmed outbreaks in poultry farms of the Asian strain, while Mongolia detected this virus in wild birds. In Russia, the first outbreaks were all reported in Siberia, but since mid-October outbreaks have also been reported in the European part of the country. Since October, new cases of AI had been reported in Romania's Danube Delta region, a region where large numbers of migratory birds gather from different areas. Other cases have been reported in West Anatolia (Turkey), Croatia, Ukraine (Crimea), Germany, Italy, Greece, Austria and more recently in France. The situation with regard to AI is changing very rapidly and the European Communities regularly updates the situation on its website: http://europa.eu.int/comm/dgs/health_consumer/dyna/influenza/index.cfm

C. EC MEASURES TO REACT TO THE THREAT OF HPAI

5. The European Communities started intensive surveillance of domestic and wild birds already in 2003. An expert group reviewed the surveillance measures in place and recommended that all member States urgently review and intensify the surveillance programmes already planned for 2005/06 by increasing sampling of migratory waterfowl along the flyways that could pose a risk of disease introduction. In parallel, a fundamental review of the existing legislation on avian flu was proposed.

6. The expert group also recommended that member States introduce additional awareness programmes encouraging farmers to improve biosecurity measures, review and update the contingency plans for AI already in place according to EC legislation and ensure that existing measures and controls at EC external borders are fully applied as regards both commercial consignments and personal imports by individuals, particularly regarding pet birds. In the contingency plans, the need was highlighted to provide adequate protection for poultry workers at risk, as well as proper and reliable information on poultry products to consumers to prevent any lack of consumer confidence.

D. WHAT ARE THE MOST RECENT MEASURES TAKEN AGAINST AI IN THE EUROPEAN COMMUNITIES?

7. The European Communities follows the norms of the World Organization for Animal Health (OIE) and regularly reviews the situation in affected countries. This is done by the Standing Committee on the Food Chain and Animal Health (SCOFCAH). If appropriate, the European Communities establishes restrictions, which are updated in line with the latest epidemiological situation in the countries concerned. Import bans have been placed on live birds and risky poultry products such as fresh poultry meat and untreated feathers from all countries or regions which detected and confirmed outbreaks of the disease within their borders. As the Asian strain of the virus started to spread westwards from Asia in the second half of 2005, the European Communities stepped up preventive, surveillance and control measures. Tighter biosecurity measures (in continuous review as the situation evolves) were agreed. These included:

- (a) keeping poultry indoors in identified high risk areas;
- (b) banning the collection of birds at markets, shows and cultural events;
- (c) allowing member States to vaccinate zoo birds;

- (d) wild bird surveillance³; and
- (e) national testing programmes.⁴

These measures have already proven successful in detecting the virus in wild birds in several member States and in confining outbreaks in commercial flocks to a single incident.

II. WHY A NEW DIRECTIVE ON AVIAN INFLUENZA?

8. The new Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of Avian Influenza and repealing Directive 92/40/EEC⁵ is based on a proposal by the Commission that considered recent scientific knowledge on the risks of AI for animal and public health, new laboratory tests and vaccines as well as the lessons learnt during previous outbreaks. The Commission consulted:

- (a) the Scientific Committee on Animal Health and Animal Welfare;
- (b) the European Food Safety Authority (EFSA); and
- (c) the changes in the Terrestrial Animal Health Code and Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the OIE.

9. Council Directive 2005/94/EC updates all EC AI measures, to ensure that the most appropriate surveillance and prevention measures are in place and that the health risks, economic costs, and negative impact on society in the event of an outbreak are minimized. A key aspect of the Directive is the new focus on the surveillance and control of low pathogenic viruses, as a means of preventing a major AI outbreak.

10. In fact there is evidence that these HPAI strains originate from the low pathogenic avian viruses through mutation and moreover, wild birds often transmit the low pathogenic viruses to domestic flocks. As low pathogenic viruses cannot be eradicated from wild birds, the infection of domestic poultry can be best controlled and eradicated, therefore reducing the potential for a virus mutation into the highly pathogenic forms. In view of the above, particular provisions have been included concerning early detection of infection aiming at a quick reaction and the adoption of appropriate and proportionate control and eradication measures which include a system of active surveillance following general guidelines that may be adapted in the future at the light of further knowledge and developments in this field.

A. WHICH MEASURES ARE APPLIED IN CASE OF OUTBREAKS OF AVIAN INFLUENZA?

11. To prevent the spread of the disease, the affected poultry cannot be moved from farms where low pathogenic AI has been detected. Birds (from the affected farms) can be slaughtered normally or, alternatively, culled and destroyed ("stamping out"). The new AI Directive 2005/94/EC, also allows member States, under strictly controlled conditions, to carry out preventive vaccination and emergency vaccination against AI. National authorities must submit vaccination plans to the Commission for approval.

³ Wild bird hunting and other relevant organisations are now obliged to immediately notify national competent authorities of any abnormal mortality or significant disease outbreaks in wild birds. EC experts also drew up guidelines on testing wild birds for avian influenza.

⁴ In September 2005, member States backed a Commission Decision to provide €84 000 from the EC budget for the period of July 2005 to January 2006, and the amount will be further reviewed in early 2006.

⁵ OJ L 10, 14 January 2006, pp.:16 -65.

B. WHAT IS THE EC EXPERIENCE ON PREVENTIVE VACCINATION?

12. Following a major outbreak of HPAI (but not H5N1) in 1999-2000, a targeted preventive vaccination campaign using the DIVA strategy (see below) was developed and applied with turkeys, laying hens and poultry in certain high risk areas (transit of migratory birds) in the Po Valley region in Italy. The campaign was broadly successful in containing low pathogenic AI viruses to prevent them from mutating into highly pathogenic strains.

13. Since the major AI outbreak in the Netherlands, Belgium and Germany in 2003, successful special vaccination programmes were implemented to protect birds in zoos and approved centres in these countries. Other member States have recently started applying vaccination campaigns for zoo birds in response to the heightened risk of the H5N1 AI virus spreading to birds in the European Communities. Vaccination has also been authorised in the Netherlands and in France in the context of the current H5N1 outbreaks, under strict conditions.

C. WHAT IS THE DIVA STRATEGY?

14. DIVA stands for Differentiating between Infected and Vaccinated Animals. It is a specific vaccination strategy developed and applied in Italy since 2000, in regions where low pathogenic AI viruses frequently occur. DIVA consists of clear measures to distinguish between vaccinated birds and birds infected with AI that are indistinguishable in terms of antibodies. DIVA requires the use of appropriate vaccines and specific discriminatory tests which enable differentiation between vaccine and infectious antibodies. This is important:

- (a) to detect any AI outbreak in vaccinated birds; and also
- (b) for trade purposes as it enables restrictions on vaccinated poultry meat to be lifted once the flocks could be clearly shown to be free of infection.

15. The DIVA strategy has been accepted internationally as a good way to monitor and provide assurances on the health of vaccinated poultry and their products.

D. WHAT DOES THE NEW DIRECTIVE PROVIDE FOR VACCINATION?

16. The new AI Directive 2005/94/EC allows member States to carry out preventive vaccination and emergency vaccination against AI. National authorities must submit vaccination plans to the Commission for approval. The decision to use vaccination can be a useful tool where domestic birds are exposed to the virus from wild birds.

17. Preventive vaccination of individual birds may be used in a targeted way, for example a Commission Decision⁶ allows member States to vaccinate special categories of birds (e.g. zoo birds or rare species of birds) or to be used in certain categories of poultry in specific areas where low pathogenic AI viruses frequently recur. Preventive vaccination requires the adoption of particular surveillance and controls to prevent the possible persistence of disease in an endemic form in a poultry population.

18. Emergency vaccination may be used by member States when there is an outbreak of HPAI within or very close to their territory. It is a short term measure to contain an outbreak of AI in poultry or other captive birds or to stop it from spreading from other areas where there is a confirmed outbreak. Emergency vaccination cannot be applied unless a risk assessment demonstrates a

⁶ Commission Decision 2005/744/EC of 21 October 2005 laying down the requirements for the prevention of highly pathogenic avian influenza caused by influenza A virus of subtype H5N1 in susceptible birds kept in zoos in the member States (Official Journal L 279, 22 October 2005 pp.:75-78).

significant and immediate threat of AI spreading to the poultry and birds concerned, from another infected area.

19. The use of vaccination will always be strictly monitored and the EC rules require that vaccinated birds can be differentiated from infected birds (DIVA strategy - Differentiating between Infected and Vaccinated Animals) and that specific surveillance and control measures are in place. This is very important both for disease control and for trade purposes. In effect, restrictions on trade (both for the internal trade and to export) will be decided on a case-by-case basis.

1. What are the advantages of vaccinating birds against avian influenza?

- (a) Vaccination reduces the risk of birds becoming infected with the AI virus, and lowers the chances of the virus being introduced into a vaccinated holding, as a higher amount of the virus is needed before a vaccinated bird will become infected.
- (b) Vaccination also reduces the amount of the virus shed in the environment by a bird if it does become infected with avian flu, thereby helping to lower the risk of the disease spreading.
- (c) A properly vaccinated flock is less likely to have an outbreak of AI than a non-vaccinated flock, and if an outbreak of the disease does occur it is slower to spread and easier to contain and eradicate in a vaccinated flock.
- (d) Moreover, vaccination reduces the mortality levels of infected birds, making it useful for protecting valuable birds such as zoo birds.

2. What must a member State do prior to carrying out a vaccination campaign?

- (a) Before vaccinating any birds against AI, a member State must submit a detailed vaccination plan, including details on surveillance measures, to the Commission.
- (b) The Commission then reviews this plan, together with the Standing Committee on Food Safety and Animal Health. It may lay out further conditions, such as movement restrictions on live vaccinated birds, before authorising the vaccination campaign.
- (c) In the case of emergency vaccination, the member State may begin implementing the vaccination programme prior to authorisation from the Commission, provided that it issues a general ban on the movement of poultry and their product and other captive birds from the area of vaccination, and shows that vaccination will not have a negative effect on disease control.

E. WHAT SURVEILLANCE AND CONTROL MEASURES HAVE TO BE CARRIED OUT ON VACCINATED BIRDS?

20. Member States applying a vaccination plan must carry out intense surveillance on vaccinated poultry and captive birds, in line with the DIVA strategy to ensure that any outbreak of AI in the vaccinated birds is detected quickly, despite the fact that symptoms of the disease may be less obvious than in non-vaccinated birds. Different measures can be taken to monitor for the virus in vaccinated flocks:

- (a) "Sentinel" birds (non-vaccinated) placed in the flock with the vaccinated birds.

- (b) Regular testing (on swabs taken from vaccinated birds) to ensure that they have not become infected with the AI virus.
- (c) Movement restrictions are placed on live vaccinated birds and their hatching eggs, and these products cannot be traded or marketed.
- (d) The meat and products of vaccinated poultry can only be moved or traded if accompanied by a certificate to show that they have come from a healthy, virus-free bird.
- (e) Member States using vaccination as a preventive measure must also carry out blood tests that allow the differentiation between vaccinated and infected birds.

F. WHAT HAPPENS IF THERE IS AN OUTBREAK OF HPAI IN A VACCINATED FLOCK?

21. If there is outbreak of HPAI in vaccinated poultry, members States must apply the same eradication and control measures as are carried out when there is an outbreak in unvaccinated poultry:

- (a) all poultry on the infected holding must be culled;
- (b) their meat and products must be destroyed; and
- (c) thorough cleansing and disinfection must be carried out on the holding.

G. ARE THERE ANY REGIONALIZATION MEASURES IMPLEMENTED?

- (a) YES, first, a 3 km radius protection zone and 10 km radius surveillance zone must be set up around the site where the disease was detected;
- (b) SECONDLY, wider risk areas are marked to act as a buffer zone between the affected and non-affected part of the member State; and
- (c) THIRD, in these restricted areas severe movement restrictions, biosecurity measures and intense monitoring of holdings are implemented.

H. HOW CAN A TRADE PARTNER KNOW WHICH ARE THE INFECTED AND FREE ZONES?

22. EC member States immediately inform the Commission and other member States of any presence (or suspected presence) of AI, any AI confirmed in slaughterhouses, means of transport, border inspection posts and quarantine facilities for imports and the results of any surveillance for AI virus carried out in mammals. This information appears rapidly in a dedicated Webpage.⁷ Next to this, the Commission, in the course of a week, adopts a decision that is made public in the Official Journal of the European Communities (see in Annex I, 20 decisions adopted to date in the last six months). These decisions are also publicised in the press and notified, where appropriate, to the OIE.

23. From the above it follows that EC trading partners are informed of the affected areas by following the Official Journal of the European Communities, visiting the web page of the Commission or asking directly to the EC SPS Enquiry Point.⁸ The follow up of the situation can be

⁷ http://europa.eu.int/comm/dgs/health_consumer/dyna/influenza/index.cfm

See also page http://europa.eu.int/comm/health/ph_threats/com/Influenza/press_influenza_en.htm

⁸ Directorate-General for Health and Consumer Protection. Directorate D, Unit D/3 International Questions (multilateral). European Community' SPS Notification Authority and Enquiry Point: sps@cec.eu.int; juan.perez-lanzac@cec.eu.int; Fax +32/2 299 80 90.

easily done by visiting the pages of the Standing Committee on the Food Chain and Animal Health (SCFCAH section Animal health) in the Commission Web.⁹

I. CAN MEAT AND EGGS FROM VACCINATED BIRDS BE MARKETED?

24. Under EC legislation, only products from healthy animals may be marketed.¹⁰ Fresh meat, meat products and table eggs from vaccinated poultry can be traded. Meat has to be accompanied by a certificate verifying that they come from a virus-free poultry flock (see paragraph 20).

25. Vaccinated live poultry and birds, and their hatching eggs, cannot be traded within or from the European Communities, except under very limited circumstances. Eggs originating from holdings where poultry suspected of being infected with AI must be handled according to Regulation (EC) 852/2004¹¹ and Regulation (EC) 853/2004¹² under certain conditions.

26. The measures outlined in paragraphs 22 and 23 are in line with the OIE recommendations. Furthermore there are movement restrictions on live birds and hatching eggs in vaccinated zones. As a consequence, third country trading partners can apply a regionalised approach to EC exports of poultry and eggs.

J. WHAT ARE IMPLICATIONS OF VACCINATION IN THIRD COUNTRIES FOR EXPORTS TO THE EUROPEAN COMMUNITIES?

27. In terms of EC imports from third countries, live birds and hatching eggs from countries which have vaccinated against HPAI are banned. As general rule, fresh poultry meat is not authorized either from countries which have carried out vaccination programmes against HPAI in the previous 12 months.

28. However, the principle applied by the European Communities is that third countries which have animal health and food safety standards equal or equivalent to EC standards should be treated in a non-discriminatory fashion. Therefore, in line with this principle, special rules permitting imports of fresh poultry meat from a vaccination country might be adopted on a case-by-case basis on the condition that the third country in question can demonstrate that the animal health rules applied in its territory in relation to vaccination are equivalent to those applied by the European Communities. No third country where vaccination is applied has, to date, sought to export poultry or poultry products to the European Communities.

K. WHICH OTHER ACTIONS HAVE BEEN TAKEN?

29. At Community level, the human health risks posed by influenza viruses are primarily dealt with by other actions and legal acts concerning in particular:

- (a) the European Centre for Disease Prevention and Control (ECDC), established by Regulation (EC) No 851/2004¹³;

⁹ See pages http://europa.eu.int/comm/food/animal/diseases/controlmeasures/avian/index_en.htm
http://europa.eu.int/comm/food/committees/index_en.htm

¹⁰ Even if the meat is safe for humans.

¹¹ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (Official Journal L 139, 30 April 2004 pp.:1-55).

¹² Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (Official Journal L 139, 30 April 2004 pp.:55-205).

¹³ Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (Official Journal L 142, 30 April 2004 p.:1 -11).

- (b) the recommendations issued by the Commission on Community Influenza pandemic preparedness and response planning;
- (c) the European Union Early Warning and Response System; and
- (d) the establishment of the European Influenza Surveillance Scheme.

L. WHAT IS THE ROLE OF "REFERENCE LABORATORIES"?

30. Any suspicion of AI infection which may arise from clinical or laboratory investigations or any other reason set in motion immediate official investigations by the EC Reference Laboratories.¹⁴ As a result, immediate actions are foreseen as soon as the presence of infection is confirmed, including depopulation of the infected holdings and of those at risk of infection (see headings G and H).

M. HOW MANY METHODS OF DIAGNOSIS EXIST?

31. Only one. The legislation in place establishes provisions to ensure harmonised procedures and methods for the diagnosis, including the functioning of a Community reference laboratory as well as reference laboratories in member States.

N. WHICH STANDARDS ARE APPLIED FOR DEPOPULATION OF INFECTED FLOCKS?

32. Council Directive 93/119/EC¹⁵ sets out the minimum standards for the protection of animals at the time of slaughter or killing including for the purpose of disease control. Such rules apply fully to slaughter or killing.

O. WHICH STANDARDS ARE USED FOR CLEANSING AND DISINFECTION?

33. Disinfectants must comply with Directive 98/8/EC.¹⁶

P. WHAT HAPPENS IF AI IS DETECTED DURING IMPORTATION?

34. If AI is detected during importation in a quarantine facility or centre, as provided for in Commission Decision 2000/666/EC¹⁷, this should be reported to the Commission. This reporting in quarantine facilities excludes the procedure in Council Directive 82/894/EEC.¹⁸

III. WHAT HAPPENS WITH POULTRY BY-PRODUCTS?

35. 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

¹⁴ See more about the Reference Laboratories on our web page
http://europa.eu.int/comm/food/animal/diseases/laboratories/index_en.htm

¹⁵ Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing (Official Journal L 340, 31 December 1993 pp.:21-34).

¹⁶ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (Official Journal L 123, 24 April 1998 pp.:0001).

¹⁷ Commission Decision 2000/666/EC of 16 October 2000 laying down the animal health requirements and the veterinary certification for the import of birds, other than poultry and the conditions for quarantine (Official Journal L 278, 31 October 2000 pp.: 26-34).

¹⁸ Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the (Community Official Journal L 378, 31 December 1982 pp.:58-62).

presenting a risk to animal and public health are set by Regulation (EC) No 1774/2002¹⁹, which provide for a general framework for the disposal of animal by-products not intended for human consumption and animals killed in relation to disease outbreaks. Nevertheless, the new legislation provides for the adoption, by the committee procedure, of specific, additional or different measures where necessary to enhance further AI control measures.

A. HOW SAFE IS FEEDING STUFF MADE FROM POULTRY MEAT WASTE IN THE EUROPEAN COMMUNITIES?

36. Article 2.7.12.21 of the OIE Terrestrial Animal Health Code (TAHC) provides that products of poultry origin intended for use in animal feeding, regardless of the AI status of the country, zone or compartment of origin, may circulate on presentation of an international veterinary certificate attesting that: these commodities come from birds which have been kept in an AI free country, zone or compartment since they were hatched or for the past 21 days; or these commodities have been processed to ensure the destruction of AI virus and the necessary precautions were taken to avoid contact of the commodity with any source of AI virus. In the European Communities, pursuant to the Community legislation explained before, very intensive surveillance programmes for AI are in place to ensure that the most appropriate actions are immediately taken in poultry farms should the disease occur, and strict control conditions operate for the production of meat and bone meal from poultry meat waste and feather meal hydrolyzed for feed use.

See also paragraph 37 below.

B. HOW SAFE ARE FEATHERS AND DOWN (FROM POULTRY) FROM THE EUROPEAN COMMUNITIES?

37. Article 2.7.12.22 of the TAHC provides that regardless of the AI status of the country, zone or compartment of origin, these products may circulate on presentation of an international veterinary certificate attesting that: these commodities come from birds which have been kept in an AI free country, zone or compartment since they were hatched or for the past 21 days; or these commodities have been processed to ensure the destruction of AI virus and the necessary precautions were taken to avoid contact of the commodity with any source of AI virus.

38. In the European Communities, meat and bone meal from poultry meat waste as well as *hydrolyzed feather meal* are clearly identified and compulsory declarations set by law.²⁰ Any establishment producing these or any other feedstuff must be registered.²¹ Moreover, the technical conditions for production of both commodities are set also by law. In conclusion, existing legislation enables any EC member States to produce an international veterinary certificate providing sufficient guaranties about:

- (a) the identity of the commodities;
- (b) its origin (country, region and industrial plant in which has been produced);

¹⁹ Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (Official Journal L 273, 10 October 2002 pp.:1-95) and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (Official Journal L 139, 30 April 2004 pp.:55-205).

²⁰ Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC (Official Journal L 125, 23 May 1996 pp.:35-58).

²¹ Article 9 of Regulation No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (Official Journal L 35, 8 February 2005 pp.:1-22).

- (c) the processing conditions they have experienced to ensure the destruction of the AI virus; and
- (d) that necessary precautions have been taken to avoid contact of both commodities with any source of AI virus.

C. HOW WOULD THE LAW CHANGE IF NEW SCIENTIFIC DEVELOPMENTS OCCUR?

39. The new Council Directive allows further amendments to be made when necessary without delay in order to take account of developments in scientific and technical knowledge. Considering the unpredictability of influenza viruses, it ensures a swift procedure for a rapid adoption at Community level of additional or more specific measures to control any infection of poultry and other animal species whenever such measures are necessary.

D. CAN THE MEMBER STATES ADOPT OTHER MEASURES?

40. Yes, they can. The Directive sets out the minimum control measures to be applied in the event of an outbreak of AI in poultry or other captive birds. However, member States are free to take more stringent administrative and sanitary actions in the field covered by this Directive. In addition, this Directive should provide for member States' authorities to apply measures proportionate to the health risk posed by different disease situations.

IV. HUMAN HEALTH AND INFLUENZA

41. Influenza pandemic is the term used for a serious human influenza epidemic, more severe than the normal seasonal outbreaks. They are caused by a new virus emerging against which humans have reduced or no immunity, resulting in transmission and multiple outbreaks across the globe. Although pandemics are rare, scientists monitoring the evolution of influenza viruses consider that a virus capable of generating an influenza pandemic may arise in the coming years, and the World Health Organisation has issued similar warnings. The European Commission and EC member States are working continually on pandemic influenza planning and response measures in case of such an eventuality.

A. HAS ANY SAFETY ADVICE BEEN ISSUED AT EC LEVEL FOR POULTRY WORKERS AND OTHER PEOPLE IN CLOSE CONTACT WITH POULTRY?

42. Member States have issued national guidelines for poultry workers and other people who come into close contact with poultry infected with AI viruses. In general, the use of good hygiene practices (e.g. washing hands properly after contact with birds) and protective clothing and masks form the basis of recommendations.

43. The European Centre for Disease Prevention and Control (ECDC) has published guidelines for risk groups, such as cullers and people working and living on poultry farms in regions affected by the Asian strain.²² These guidelines can be viewed as a pre-emptive document, to be employed where there is an outbreak caused by this strain in the European Communities. The guidelines are based on 6 principles:

- (a) controlling the infection in birds;
- (b) minimizing the number of people possibly exposed to the virus;

²² The web address of the ECDC is <http://www.ecdc.eu.int/>
See also http://www.ecdc.eu.int/press/press_releases/PDF/060216_press_release.pdf

- (c) using personal protective equipment (e.g. gloves, masks) when directly involved in work with potentially infected animals;
- (d) using antiviral drugs in a proper and controlled manner, following a local risk assessment;
- (e) recommending seasonal influenza vaccination for people involved in culling infected poultry flocks, especially if seasonal influenza is circulating; and
- (f) surveying for infection among those potentially exposed.

B. WHAT IS THE PANDEMIC INFLUENZA PREPAREDNESS PLAN?

44. The EC preparedness plan identifies the key components needed to face up to pandemic influenza: the preparation and testing of national preparedness plans; surveillance and networking of national reference laboratories to identify the pandemic strain quickly; early notification of cases, outbreak assistance and coordination of responses of member States; and the adequate and timely supply of vaccines and anti-viral drugs. The plan revised WHO definitions of pandemic phases taking account of the opening of the European Centre for Disease Prevention and Control (ECDC). In particular, it sets out a proposed EC response for each phase of an influenza pandemic as defined by the WHO and clarifies the responsibilities of the EC member States, the Commission and the EC agencies in an influenza pandemic.

45. The influenza viruses are continuously changing, and every year the seasonal human influenza virus is different so vaccines have to be developed to respond to the new strains. The strain of virus that could cause a pandemic is unknown. From this it follows that it is not yet possible to create a vaccine against an unidentified virus. The Commission is focussing on ensuring that if a pandemic does occur, vaccine production capacities will be maximized so that doses can be made available in the shortest possible time and to as many people as possible.

C. WHAT IS THE ROLE OF THE EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC) IN PREPARING FOR PANDEMIC INFLUENZA?

46. The key responsibilities of the ECDC are to identify, assess and communicate current and emerging human health threats, including those caused by influenza viruses. It should analyze and assess, in real time, the human health risk related to latest developments on influenza. On the basis of its assessments, the ECDC should provide relevant and up-to-date scientific information, and timely advice, for effective outbreak management. Another important function allocated to the new agency is the technical operation and round-the-clock monitoring of the early warning and response system (EWRS), which is important for an effective and coordinated EC response to an outbreak.

D. WHAT IS THE EARLY WARNING AND RESPONSE SYSTEM?

47. The Early Warning and Response System (EWRS) is a telematic system linking the designated authorities in member States and the Commission. The system allows for immediate exchange of views on risk assessment and risk management crucial for timely public health action. Member States inform as soon as possible through the EWRS of any data they have of a public health threat that could have international consequences. The EWRS has already proven useful during a number of public health emergencies, including the Severe Acute respiratory Syndrome (SARS) outbreak in 2003.

E. HOW DOES THE EUROPEAN COMMUNITIES COOPERATE WITH ALL ITS TRADE PARTNERS?

48. The Commission has been working with member States and the WHO to help member States draw up and improve their own national preparedness plans so EC' member States now have pandemic preparedness plans in place. These were studied and assessed by the Commission, ECDC and WHO, and two workshops were held in March and October 2005 with member States, to address weaknesses and close gaps in the national plans. Work by the Commission and member States to keep improving and updating national plans as necessary is ongoing.²³

49. Pandemic simulation exercise: on 23-24 November, the Commission, member States, WHO, ECDC and the pharmaceutical industry took part in a command-post exercise on pandemic influenza. The exercise aimed to test communications, information exchange and coordination between member States, EC bodies and international organisations in a public health emergency. It also tested the inter-operability of national pandemic preparedness plans, and provided an opportunity to put into practice plans that had, up until then, only been on paper.

50. The international community has pledged a total amount of \$1.9 billion dollars to fight AI and prepare for a possible human influenza pandemic. To this the European Commission pledged €80 million (\$100 m) in aid grants from the Commission's External Relations budget and the European Development Fund and committed €20 million in research funds for AI from the EC 6th Research Framework Programme, for a total pledge of €100 million (\$122 million). Taken together with the €14 million (\$140 m) undertaken by the EC member States, the European Communities has in total pledged around €114 million (\$260 m).

51. Of the €80 million pledged by the European Commission to third countries, €30 million is destined for Asia, €5 million for Central Asia, €5 million for the EC's Eastern European neighbouring countries, €10 million for North Africa and the Middle East, and €30 million is earmarked for the African, Caribbean and Pacific Countries, subject to approval by the ACP countries. Separately, the European Commission is preparing to bring forward urgently €4 million in pre-accession aid to Turkey, foreseen for 2007, to tackle AI. Aid is also being provided under existing bilateral arrangements between the European Communities and its partners.

F. PROMOTING NETWORKS:

52. The Commission has also placed great emphasis on promoting various networks to bring key players together in addressing the threat of influenza. Networks of veterinary and human health laboratories are already in place in the European Communities, as is an EC-funded network known as the European Influenza Surveillance Scheme (EISS), which monitors seasonal influenza outbreaks each winter. The Commission is now working to establish improved co-operation between EISS, the ECDC and the Community Reference Laboratory for Avian Influenza, as well as other European and international organisations dealing with animal and human health, to ensure better preparation in case of a pandemic. This led, in September 2005, to the adoption of a Technical Guidance Document on procedures for communicating influenza A/H5 events in humans to member States, the ECDC and the Commission.

²³ See more in http://europa.eu.int/comm/health/ph_threats/com/Influenza/influenza_en.htm

G. USEFUL LINKS

European Centre for Disease Prevention and Control: <http://www.ecdc.eu.int>

WHO page on influenza: <http://www.who.int/csr/disease/influenza/en/>

World Organisation for Animal Health (OIE): <http://www.oie.int>

UN Food and Agriculture Organisation (FAO): <http://www.fao.org>

EC Website: http://europa.eu.int/comm/dgs/health_consumer/dyna/influenza/index.cfm

Annex I

List of Commission decisions, related to AI (adopted since October 2005)

1. 2005/726/EC: Commission Decision of 17 October 2005 amending Decision 2005/464/EC on the implementation of **survey programmes** for AI in poultry and wild birds to be carried out in the MS (Official Journal L 273, 19 October 2005 pp.:21 - 24)
2. 2005/731/EC: Commission Decision of 17 October 2005 laying down additional requirements for the surveillance of AI in **wild birds** (Official Journal L 274, 20 October 2005 pp.:93 - 94)
3. 2005/732/EC: Commission Decision of 17 October 2005 approving the programmes for the implementation of Member States' **surveys for avian influenza in poultry and wild birds** during 2005 and laying down reporting and eligibility rules for the Community financial contribution to the implementation costs of those programmes (Official Journal L 274, 20 October 2005 pp.:95 - 101)
4. 2005/734/EC: Commission Decision of 19 October 2005 laying down **biosecurity measures** to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an **early detection system** in areas at particular risk (Official Journal L 274, 20 October 2005 pp.:105 - 107)
5. 2005/744/EC: Commission Decision of 21 October 2005 laying down the requirements for the prevention of highly pathogenic avian influenza caused by influenza A virus of subtype H5N1 in susceptible **birds kept in zoos** in the MS (Official Journal L 279, 22 October 2005 pp.:75 - 78)
6. 2005/745/EC: Commission Decision of 21 October 2005 amending Decision 2005/734/EC laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by influenza A virus of subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an **early detection system** in areas at particular risk (Official Journal L 279, 22 October 2005 pp.:79 -80)
7. 2005/759/EC: Commission Decision of 27 October 2005 concerning certain protection measures in relation to highly pathogenic avian influenza in certain third countries and **the movement from third countries of birds accompanying their owners** (Official Journal L 285, 28 October 2005 pp.:52 – 59)
8. 2005/855/EC: Commission Decision of 30 November 2005 amending Decision 2005/734/EC laying down biosecurity measures to reduce the risk of transmission of highly pathogenic avian influenza caused by Influenza virus A subtype H5N1 from birds living in the wild to poultry and other captive birds and providing for an **early detection system** in areas at particular risk (Official Journal L 316, 2 December 2005 pp.:21- 22)
9. 2005/862/EC: Commission Decision of 30 November 2005 amending Decisions 2005/759/EC and 2005/760/EC relating to **measures to combat avian influenza in birds other than poultry** (Official Journal L 317, 3 December 2005 pp.:19 - 22)
10. 2005/926/EC: 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 (Official Journal L 337, 22 December 2005 PP.:60 - 70)

11. 2006/052/EC: Commission Decision of 30 January 2006 amending Decision 2005/731/EC laying down additional requirements for the **surveillance** of avian influenza in **wild birds** (Official Journal L 27, 1 February 2006 pp.:17- 18)
 12. 2006/086/EC: Commission Decision of 10 February 2006 concerning certain interim protection measures in relation to suspected cases of highly pathogenic avian influenza in wild birds in **Greece** (Official Journal L 40, 11 February 2006 pp.:26-31)
 13. 2006/090/EC: Commission Decision of 13 February 2006 concerning certain interim protection measures in relation to suspected cases of highly pathogenic avian influenza in wild birds in **Italy** (Official Journal L 42, 14 February 2006 pp.:46-51)
 14. 2006/094/EC: Commission Decision of 14 February 2006 concerning certain interim protection measures in relation to suspected cases of highly pathogenic avian influenza in wild birds in **Austria** (Official Journal L 44, 15 February 2006 pp.:25-30)
 15. 2006/104/EC: Commission Decision of 15 February 2006 concerning certain interim protection measures in relation to suspected cases of highly pathogenic avian influenza in wild birds in **Germany** (Official Journal L 46, 16 February 2006 pp.:53-58)
 16. 2006/105/EC: Commission Decision of 15 February 2006 concerning certain interim protection measures in relation to suspected cases of highly pathogenic avian influenza in wild birds in **Hungary** (Official Journal L 46, 16 February 2006 pp.:59-64)
 17. 2006/115/EC: Commission Decision of 17 February 2006 concerning certain protection measures in relation to highly pathogenic avian influenza in wild birds in the Community and repealing Decisions 2006/86/EC, 2006/90/EC, 2006/91/EC, 2006/94/EC, 2006/104/EC and 2006/105/EC (Official Journal L 48, 18 February 2006 pp.:28 - 34)
 18. 2006/135/EC: Commission Decision of 22 February 2006 concerning certain protection measures in relation to highly pathogenic avian influenza in poultry in the Community (Official Journal L 52, 23 February 2006 pp.:41 - 53)
 19. 2006/147/EC: Commission Decision of 24 February 2006 on introducing preventive vaccination against highly pathogenic avian influenza H5N1 and related provisions for movements in **the Netherlands** (Official Journal L 55, 25 February 2006 pp.:47 - 50)
 20. 2006/148/EC: Commission Decision of 24 February 2006 on introducing preventive vaccination against highly pathogenic avian influenza H5N1 and related provisions for movements in **France** (Official Journal L 55, 25 February 2006 pp.:51 - 57)
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