

**EUROPEAN COMMISSION HEALTH & CONSUMERS DIRECTORATE-GENERAL** Directorate D – Animal Health and Welfare Unit D1 – Animal Health and Standing Committees

SANCO/6133/2009-Rev.4

Version 03.11.2009

# Draft

# Working document on

# Surveillance, monitoring and control measures

for

# the pandemic (H1N1) 2009 influenza virus in poultry

This document does not necessarily represent the views of the Commission Services

### Content

- 1. Purpose of this document
- 2. Introduction
- 3. Surveillance/monitoring<sup>1</sup>
- 4. Control measures

# 1. Purpose

The purpose of this document is to provide guidance to the Member States on the appropriate measures to implement in case poultry are infected with the pandemic (H1N1) 2009 influenza virus hereafter the "pandemic influenza virus". The aim of this document is to promote a harmonised approach taking into considerations different epidemiological scenarios.

The key principles to be taken into account for any kind of measure are vigilance, proportionality and flexibility.

It should be emphasised that influenza associated with pandemic influenza virus is currently primarily a human disease.

# 2. Introduction

## 2.1. Infection of poultry/birds with influenza viruses - Status quo

## 2.1.1. Avian Influenza (AI)

Influenza viruses have shown to infect a great variety of birds of which migratory waterfowl are recognised as a natural reservoir. Occasionally these viruses also infect some mammalian species, such as humans, pigs, horses, cats, minks and marine animals.

In poultry influenza causes two distinct clinical forms: Highly Pathogenic Avian Influenza (HPAI) and Low Pathogenic Avian Influenza (LPAI). HPAI leads to serious disease in almost all poultry species resulting in very high mortality. Adult ducks may not always show clinical signs. HPAI is caused only by some viruses of the H5 and H7 subtypes which exhibit certain molecular characteristics that are at the basis of systemic infection and reason for the severity of the disease.

LPAI viruses belong to all H subtypes, but lack the molecular traits of HPAI viruses, thus causing only localised infection. It is generally recognised that LPAI viruses of the H5 and H7 subtype represent the progenitors of HPAI viruses as they may mutate and acquire the molecular traits of HPAI following introduction into poultry.

### 2.1.2. Pandemic influenza virus

The pandemic influenza virus is a new strain of influenza A (H1N1) viruses causing mainly disease in humans. The virus contains gene segments of influenza viruses predominately circulating in pigs, birds and humans. Infection with this pandemic influenza virus is primarily a public health concern worldwide and the role of animals has not been demonstrated in its epidemiology or spread.

<sup>&</sup>lt;sup>1</sup> As defined in the Terrestrial Animal Health Code 2009 of the World Animal Health Organization (OIE)

#### 2.1.3. Pandemic influenza virus in pigs

Infections with H1N1, H3N2 and H1N2 swine influenza (SI) viruses are enzootic in pigs in North America and Europe. Infection of domestic pigs with the pandemic influenza virus has been reported from several countries in different continents (including Canada, Argentina, Australia, Singapore (pigs from Indonesia), United Kingdom, Ireland, Norway and Iceland). In most instances virus transmission from infected humans to the pigs was considered the most likely source of infection of the pig. The susceptibility of pigs to the virus has also been documented through animal experiments. More information can be found in the Commission's website on Pandemic (H1N1) 2009 influenza in particular in the guidance document on surveillance and control of pandemic (H1N1) 2009 influenza in pigs (SANCO/6211/2009 Rev.7).

http://ec.europa.eu/food/animal/diseases/influenzaAH1N1/index\_en.htm

http://ec.europa.eu/food/animal/diseases/influenzaAH1N1/docs/wd\_surveillance\_and\_control\_of\_h1n1\_in\_pigs\_rev1\_140709\_en.pdf

#### 2.1.4. Pandemic influenza virus in turkeys

In August 2009, pandemic influenza virus was identified in two turkey breeder holdings in Chile. The clinical symptoms had started in mid July with a sudden drop in egg laying and altered egg shells. No increased mortality was observed. Normal egg production was again reached after 20 days of the infection. The symptoms were very much alike an infection with an LPAI virus.

This is the first detection of the pandemic influenza virus in a non-mammalian species.

By the time of the virus detection in turkeys there had been extensive human to human transmission of the pandemic influenza virus in Chile which makes occasional transmission from man to bird the most likely scenario. Some birds had been in contact with persons with respiratory disease.

Genetic sequencing of the HA gene from the pandemic influenza virus isolated from the turkeys showed 99.5% similarity to the Californian human strain and a 100% match to the human strain currently circulating in Chile. Mutations that might explain an increased capability of the virus to infect turkeys have not been detected, but work to further characterise the virus is needed.

The pandemic influenza virus has also been isolated in mid October from a turkey farm in Canada.

There is evidence of influenza viruses of different subtypes including the "non-pandemic" H1N1 influenza virus crossing the species barrier between turkeys and pigs with documented occurrence of infected turkeys and pigs on the same farm.

Recent attempts to experimentally infect turkeys with the pandemic influenza virus strain carried out in  $Europe^{2,3}$  and the USA<sup>4</sup> have been unsuccessful.

So far, natural infection of turkeys with the pandemic influenza virus is believed to have most likely occurred by airborne virus transmission from infected humans to turkeys.

 <sup>&</sup>lt;sup>2</sup> http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/docs/2009/23\_pig\_study\_h1n1\_brown.pdf
<sup>3</sup> Eurosurveillance, Volume 14, Issue 41, 15 October 2009.

http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19360

<sup>&</sup>lt;sup>4</sup>http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/docs/2009/22\_h1n1\_transmissibility\_studies\_s wayne.pdf

Thorough investigations of events of natural infection of turkeys/poultry with the pandemic influenza strain, in particular as regards the age of the birds, their immune status and concurrent infections will contribute to a better understanding of the epidemiology of the infection.

#### 2.1.5. Zoonotic implications and food safety

There is a theoretical possibility of turkey-to-human transmission but no turkey-to-human transmission has been reported so far.

At present there is no evidence that poultry play a role in the epidemiology of the pandemic influenza virus or that the virus is being transmitted from poultry to humans.

**Influenza is not a food borne zoonoses and it is not transmitted to humans by meat or meat products.** Poultry meat, poultry meat products and eggs, handled in accordance with good hygienic practices jointly recommended by the WHO, FAO, Codex Alimentarius Commission and the OIE, are not a source of infection from the virus.

#### 2.1.6. Short-term prospect

It is expected that the pandemic influenza virus will continue to circulate and spread in the human population in countries around the world. An increase in the numbers of human cases is anticipated during autumn and winter leading to a possibly higher risk of occasional virus introduction into poultry holdings. However, it should also be considered that poultry appears to be less susceptible to infection with the pandemic influenza virus than pigs.

#### 2.2. Legislation – (Status quo)

Council Directive 2005/94/EC lays down control measures for infections of poultry and other captive birds with HPAI viruses of any subtype and LPAI viruses of the H5 and H7 subtypes as the latter have the potential to mutate to HPAI viruses. Current Community rules are proportionate to the risks posed by the two categories of viruses and allow for flexibility of implementation based on risk assessment.

The AI definition does not include the pandemic influenza strain and it is therefore not subject to notification of animal diseases according to Directive 82/894/EEC.

However, Directive 2005/94/EC will apply for surveillance and in case AI is suspected in poultry, require official investigation and appropriate measures to be applied on the holding until the presence of an influenza virus falling under the AI definition is ruled out through laboratory analysis.

Likewise, the AI definition of the World Organisation for Animal Health (OIE) does not include the pandemic influenza virus and there is no obligation to notify its detection in poultry or birds. However, the OIE has recommended that veterinary authorities rapidly report the initial occurrences of the disease in animals to the OIE by using the qualification of "emerging disease".<sup>5</sup>

#### 2.3. Possible scenarios in the future

It is important to note that irrespective of any possible changes in the genome of the virus increased disease severity may be seen in association with concurrent diseases.

<sup>&</sup>lt;sup>5</sup> The Terrestrial Code of the OIE lays down rules on notification in Chapter 1.1:

http://www.oie.int/eng/normes/mcode/en\_chapitre\_1.1.2.htm and on criteria for listing diseases in Chapter 1.2.: http://www.oie.int/eng/normes/mcode/en\_chapitre\_1.1.1.htm.

Two main hypothetical scenarios are considered:

#### 2.3.1. Mild/moderate disease in poultry

• This scenario would correspond to the current situation with the pandemic influenza virus rarely infecting poultry and causing mild clinical symptoms similar to those seen with LPAI virus.

2.3.2. Significant changes in the severity of the disease caused by the pandemic influenza virus in poultry or humans<sup>6</sup> (several possibilities - worst case scenario)

- The virus might evolve and change its virulence leading to an increased severity of the disease in poultry/birds. However, to date the pandemic influenza virus isolated from humans has remained relatively stable without signs of significant 'drifting' (undergoing slight genetic changes) or 'shifting' (undergoing substantial genetic changes). Up to now only viruses of the H5 and H7 subtypes have shown to mutate to highly pathogenic viruses when introduced to poultry. There are no substantive data indicating that the pandemic influenza virus is likely to develop increased virulence for birds, humans or mammalian species.
- The disease might become endemic in the poultry population in Europe and a more severe clinical picture with increased morbidity and mortality might be observed. Infected poultry may prove to be a significant source of infection for humans (increased zoonotic character). A sustained circulation of this virus in poultry may pose an additional risk for transmission to humans that are in close contact with infected birds.
- Potential serious epidemics in poultry may hamper trade with poultry and poultry products and may cause major economic losses.

### 2.4. Prevention, vigilance and awareness

Biosecurity is crucial to prevent the introduction of any infectious disease agent into poultry holdings. The poultry sector should ensure that all poultry workers are aware of the importance of properly applying biosecurity measures when entering poultry farms. As the virus is now circulating in the human population, persons working with poultry should be aware of the risk of infecting poultry with the pandemic influenza virus, when they are themselves affected by influenza. In that case they should limit risk of transmitting the virus to poultry by avoiding direct contact to poultry, ideally by not entering poultry stables or by adopting adequate hygienic procedures. Therefore, the persons involved in poultry production including veterinarians should in accordance with the recommendations issued by the competent public health authorities take preventive measures to further reduce the risk they might pose to poultry which may include having themselves vaccinated against pandemic influenza.

The poultry sector should be vigilant for signs of infection in poultry. It should be noted that in particular turkeys and quails have shown to be more prone to become infected with the pandemic influenza than other poultry species therefore requiring special attention.

# 3. Surveillance/monitoring for pandemic influenza virus in poultry 3.1. Considerations for surveillance/monitoring

<sup>&</sup>lt;sup>6</sup> This scenario might be split in two depending, if the disease reveals to have become more severe for humans or for poultry/birds.

Compulsory active surveillance for AI in poultry has been carried out in Member States since 2003. Its objective is to protect animal health of poultry by detecting circulation of LPAI of the H5 and H7 subtype before these viruses have the possibility to potentially mutate to HPAI. The surveys are carried out by serological testing. Positive results have to be followed up by virus detection methods.

Passive surveillance data (i.e. monitoring for changes in production data such as slightly increased mortality, egg drop, reduced water and feed intake etc.) suggesting presence of AI virus have to be further investigated according to the Directive 2005/94/EC in order to confirm or rule out virus presence. The pandemic influenza virus appears to behave like an LPAI virus. It should therefore, in principle, be detected by the current passive surveillance in place.

This suggests that an adaptation of the current active surveillance scheme in poultry is not needed.

Based on the existing knowledge and experience the assumption should therefore be that currently there is no circulation of the pandemic influenza virus in poultry and that introduction into poultry holdings would most probably occur by contact with infected humans.

#### 3.2. Objective of monitoring

The objective of current monitoring of the AI health status in poultry is the early/timely detection of the introduction/circulation of avian influenza viruses as defined in Directive 2005/94/EC. In case of suspicion for AI, the required diagnostic procedures should allow detection of pandemic influenza virus.

#### 3.3. Monitoring strategy

A risk-based approach should be followed with monitoring primarily targeted to poultry holdings where an epidemiological link to human cases has been clearly established and where an identified risk of human-to-poultry transmission exists. Vigilance at such holdings should be increased.

If infection with the pandemic influenza strain is detected in pigs (or other animals) present on a holding where also poultry is kept, consideration should be given to testing poultry to determine if they have become infected.

The value of monitoring strategies should be kept under review in line with the changing nature of the disease and the key principles of vigilance, proportionality and flexibility.

#### 3.4. Diagnosis

For serological investigations in poultry the haemagglutination inhibition (HI) test is the gold standard; it is used to detect serological reactions to H5/H7. Pre-screening tests e.g. ELISA or AGID will detect any antibodies to influenza A virus. Positive serological reactions to H1 will need to be followed-up by virus detection methods.

For virus detection methods a modified real time RT-PCR (RRT PCR) is available to detect influenza A virus including the pandemic influenza strain with an additional RRT-PCR being used to confirm positives as pandemic influenza virus. Positive results should be confirmed by virus isolation in embryonated fowls' eggs.

Competent veterinary laboratories such as the national laboratories for AI can be provided with newly developed testing protocols and diagnostic advice by the Community Reference laboratory for AI. Timely sharing of epidemiological information, virus sequences and virus isolates is important to identify possible changes to the genetic characteristics of the pandemic influenza virus.

### 3.5. Mid-long term virus monitoring in the context of research

The monitoring of the virus characteristics, virus mutations and the emergence of virus reassortants is crucial and should be subject of ongoing research. Good cooperation between veterinary and human medical laboratories should therefore be ensured to build enable comprehensive monitoring of influenza virus genotypes occurring in humans and animals. Further exchange of virus isolates and sequences data among laboratories for genetic characterization should be ensured. Valuable experience in this regard has been made available through networks of expertise such as OFFLU<sup>7</sup> and research initiatives under a specific call for avian and human influenza<sup>8</sup>: Framework 6 (FP6) Projects<sup>9</sup>,FP7 Projects<sup>10</sup>, and 'Preparedness and capacity building for emerging epidemics'<sup>11</sup>, swine focussed projects like ESNIP2<sup>12</sup> and influenza network enhancing projects such as Flulabnet.

# 4. Potential control measures in case of pandemic influenza (H1N1) 2009 outbreak(s) or infection in poultry

## 4.1. General consideration for taking further actions

The two main scenarios presented above (2.3.1. and 2.3.2.) will drive the type and intensity of the surveillance, protection and control measures to be taken.

As outlined in section 2.2., EU legislation to control outbreaks of AI is laid down in Council Directive 2005/94/EC and specifies the control measures to be taken on poultry holdings according to the subtype and pathogenicity of the virus.

Control measures to be put in place should be proportionate to the following factors:

i) the risk posed by poultry in the transmission of the pandemic influenza virus to humans, if any, compared to the role played by human-to-human transmission, and

ii) the severity of disease in animals and humans.

Information on these main factors will be provided by the monitoring activities in place.

Control measures in poultry may also address the specific situation of the pandemic influenza virus considering actual or potential human-to-poultry transmission, poultry-to-poultry transmission and poultry-to-human transmission and take into account risk factors for humans that have been identified by the public health authorities.

In principle the following main control measures could be applied<sup>13</sup> in infected holdings or regions:

- Stand still
- Quarantine/Movement controls on the suspected / infected flocks
- Slaughter (Culling) of infected flocks
- Increased biosecurity
- Epidemiological investigations tracing

<sup>&</sup>lt;sup>7</sup> http://www.offlu.net/

<sup>&</sup>lt;sup>8</sup> http://ec.europa.eu/research/health/poverty-diseases/doc/influenza-research\_en.pdf

<sup>&</sup>lt;sup>9</sup> http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/fp6projects\_en.html

<sup>&</sup>lt;sup>10</sup> http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/projects/l-preparedness\_en.html

<sup>&</sup>lt;sup>11</sup> http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/fp7projects\_en.html

<sup>&</sup>lt;sup>12</sup> http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/projects/109\_en.html

<sup>&</sup>lt;sup>13</sup> Note that no ranking of measures is proposed.

- Movement controls of live poultry on farms and in areas/regions
- Vaccination (if suitable vaccine available)
- Protection measures for humans (will not be dealt with in this paper)
- Awareness campaigns
- Do nothing

From an animal disease control point of view the main measure should be aimed at preventing virus spread to other animal holdings by the control of movement of live animals to other farms. The farm quarantine/movement controls should be in place until at least seven days after the last clinical signs of disease have been observed in the epidemiological unit and influenza is no longer considered a veterinary risk.

Sustainable movement restrictions are recommended. Feasibility, sustainability and effectiveness of quarantine/movement controls largely depend on the type of holding. In general movement restrictions should only be put in place, if a feasible exit strategy is identified prior to the imposition of restrictions.

Measures to be implemented in relation to the pandemic influenza virus will also depend on the particular nature and behaviour of the virus strain, the sustainability of the restrictions in proportion to the potential benefits to human and animal health and from a cost-effectiveness point of view.

# 4.2. Control measures recommended if no significant change in the behaviour of the pandemic influenza virus is observed (mild/moderate disease)

Only a limited number of measures should be taken to ensure proportionality:

**4.2.1.** Biosecurity should be enhanced to avoid further virus spread within the affected holding or premises and to other holdings.

**4.2.2.** The means of applying quarantine/movement controls will need to be assessed. Healthy poultry and poultry that have recovered from the clinical symptoms can go to slaughter under the general hygienic provisions (Regulations (EC) No 853/2004 and 854/2004).

**4.2.3.** Movements of other poultry (ready to lay pullets, fattening turkeys, day-old chicks.) to other holdings (e.g. empty sheds) could be permitted under biosecurity measures including for transport in such a way as to prevent the spread of the virus similar to the provisions of Directive 2005/94/EC relating to LPAI.

**4.2.4.** Movements of hatching eggs to a hatchery should be allowed under biosecurity measures including for transport in such a way as to prevent the spread of the virus similar to the provisions of Directive 2005/94/EC relating to LPAI.

**4.2.5.** Movements of table eggs to packaging centres should be permitted provided biosecurity measures including the use of new or cleaned and disinfected packaging material are applied.

**4.2.6.** More stringent movement restrictions should not be put in place.

**4.2.7.** Culling is not recommended.

**4.2.8.** To reduce the risk of disease transmission, the number of people entering the infected holdings should be limited to an absolute minimum and only by strictly applying the necessary hygienic measures.

**4.2.9.** It should be assumed that there is a theoretical risk that the pandemic influenza virus may transmit between poultry and humans. Therefore, advice from public health authorities should be taken into account when considering whether additional measures are necessary to

protect workers and others with close contact with suspect or infected poultry, including the possible use of vaccination.

# 4.3. Control measures recommended, if significant changes in the severity of the disease in poultry or humans are observed

# Any guidance in this section will be kept under review to reflect the nature of any change in the severity of disease.

Theoretically, if the pandemic influenza virus would substantially increase its virulence for poultry and fulfil the pathogenicity criteria for HPAI virus laid down in the Directive 2005/94/EC, the control measures of the Directive apply.

Culling of poultry will not help to guard against public or animal health risks presented by this pandemic influenza virus and such action may be inappropriate. However, this measure should be carefully evaluated under the circumstance of increased disease severity.

In case culling of infected poultry during the clinical phase of the disease is performed, this should be carried out carefully taken into account the zoonotic character and occupational exposure.

To complement the measures taken in case of changes on the disease severity, further measures in case of suspicion of the presence of the pandemic influenza virus on a holding may be envisaged such as:

- 1. Where a holding contains poultry suspected of being infected with the pandemic influenza virus investigations to confirm or rule out the presence of the virus must be initiated.
- 2. When the presence of pandemic influenza virus cannot be ruled out, the holding should be placed under official surveillance if this is warranted by the public health risk that the virus represents. The following measures should be implemented until the presence of the pandemic influenza virus has been ruled out or confirmed:
  - epidemiological enquiry
  - restrictions of movements (intra-farm) if appropriate
  - on-farm restrictions of entry and exit of live poultry and carcasses
  - biosecurity (in particular restricting the entry of people into the farm) limit occupational exposure

#### 4.4. Vaccination of poultry

At this stage it appears too early to envisage the possible role of vaccines in the prevention and control of the pandemic influenza virus in poultry. In contrast to the situation in pigs, vaccination of poultry against influenza viruses is not routinely applied. Vaccination against AI viruses covered by the definition in Directive 2005/94/EC is subject to Commission approval.