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# Working document on

# Surveillance/monitoring and control measures

# for

# the pandemic (H1N1) 2009 influenza virus in pigs

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

## Content



# 1. Purpose

The purpose of this document is to provide guidance to the Member States on the appropriate measures to implement in case pigs are infected with the pandemic (H1N1) 2009 influenza virus ("the pandemic influenza virus"). The aim of this document is to promote a harmonised approach taking into consideration 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 the pandemic influenza virus is currently primarily a human disease.

# 2. Introduction

## 2.1. Status quo: Influenza virus infection of pigs

Influenza in pigs is caused by infection with influenza A viruses and is a contagious disease being endemic in many pig populations around the world. Influenza viruses which are found in pigs also occur in wild birds, poultry, horses and humans, but interspecies transmission is generally considered a rare event.

Influenza in pigs is usually a mild respiratory disease characterised by coughing, sneezing, nasal discharge and fever. The mortality is low and recovery is usually quick and uncomplicated, (within 10-14 days). Within the European pig population influenza A viruses of subtypes H1N1, H3N2 and H1N2 co-circulate widely. The pandemic influenza virus reported in humans has now been reported in pigs in Canada, Argentina, Australia, Singapore (pigs from Indonesia), Japan, Norway, UK (Northern Ireland), the Republic of Ireland and Iceland.

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 mainly 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.

It has been shown that pigs are susceptible to the pandemic influenza virus. However, there is no evidence, either from field observations or from the experimental studies that this virus behaves in a different way in pigs from other well known influenza viruses circulating in pigs. In pigs the pandemic influenza virus causes a mild infection of the respiratory tract, with some morbidity but generally leads to uneventful recovery. No "carrier" status is induced. The virus is only detected in the respiratory tract of infected pigs and does not appear to spread to

[1] As defined in the Terrestrial Animal Health Code 2009 of the World Animal Health Organization (OIE).

and replicate in other tissues (absence of detectable viraemia). **Influenza is not a food borne zoonoses and it does not spread to humans by meat or meat products.** Pork and pork products, 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.

Influenza viruses can be spread between pigs and pig farms by direct contact, short-distance aerosol transmission (air-borne disease) and fomite spread. Data on farm-to-farm windborne spread should not be extrapolated from other diseases such as FMD. Even in geographical areas of high pig density influenza does not spread very far or very rapidly by air**.**

Pre-existing immunity induced due to a previous influenza infection or following conventional influenza vaccination may not protect pigs against the infection with pandemic influenza virus, but it is not excluded that it may provide partial protection. Partial protection has been observed in some experimental studies with piglets having maternal antibodies but there have not been sufficient challenge studies to provide confidence in these findings.

Vaccines currently used in the EU or elsewhere to protect pigs against influenza may not be effective against the pandemic influenza virus.

It is expected that the pandemic influenza virus will continue to circulate and spread in the human population in countries around the world in the coming months, and this will increase in autumn and winter. Occasional transmission of pandemic influenza viruses from pigs to humans may theoretically occur. However, so far there is no evidence that pigs play a role in the epidemiology of the human pandemic.

Given the continued spread of this pandemic influenza virus in the human population, the risk of it entering pig farms in Europe will therefore increase in the next months.

### ***2.2. Status quo (legislation)***

No harmonised control rules are laid down in the EU legislation for influenza in swine. In fact, Council Directive 82/894/EEC on the notification of animal diseases lists the diseases of terrestrial animals that are subject to notification. Influenza in pigs is not listed there and therefore under EU legislation no legal obligation exists to notify and control the disease. Some Member States have existing or recently introduced national legislation on the obligation for notification of the disease and/or on control measures.

As regards the World Organisation for Animal Health (OIE), there is no obligation to notify influenza in pigs. 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"[2].

### ***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 in mammalian hosts is normally only seen in association with

[2] 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.

concurrent diseases. So far no significant changes in the behaviour of the pandemic influenza virus as compared with other influenza viruses circulating in pigs have been seen. The virus may also become pig adapted and less infective and less pathogenic in humans. The disease scenario for the future is expected to correspond to the current situation/knowledge of common influenza infection in pigs.

- The current situation/knowledge shows that there is no significant change in the behaviour of the pandemic influenza virus as compared with other influenza viruses circulating in pigs.
- There is no substantive data to suggest that past influenza viruses have increased in virulence in pigs and therefore there are no substantive data suggesting that the pandemic influenza virus is likely to develop increased virulence for swine.

However, in the event the pandemic influenza virus evolves and change its virulence leading to an increased transmissibility and pathogenicity in pigs or the disease causes a significant new public health threat, additional surveillance, protection and control measures may have to be taken. Hypothetically the following scenarios might occur:

- The virus might evolve and change its virulence leading to an increased transmissibility and pathogenicity in pigs. It is however important to note that, there is no substantive data to suggest that previously identified strains of influenza viruses have increased in virulence in mammalian species, especially in pigs and therefore there are no substantive data suggesting that the pandemic influenza virus is likely to develop increased virulence for people or other mammalian species.
- The disease might become endemic in the pig population in Europe and a more severe clinical picture with increased morbidity and mortality might be observed. Infected pigs may prove to be a significant source of infection for humans (increased zoonotic character). A sustained circulation of this virus in pigs may pose an additional risk for transmission to humans in close contact with infected pigs.
- Possible epizootics in pigs may hamper trade in pigs and pig 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 pig farms. The pig production sector should ensure that all pig workers are aware of the importance of properly applying biosecurity measures when entering pig farms. As the virus is now circulating in the human population, persons working with pigs should be aware of the risk of infecting pigs with the pandemic influenza virus, when they are themselves affected by influenza. In that case they should limit the risk of transmitting the virus to pigs by avoiding direct contact to pigs, ideally by not entering pig stables or by adopting adequate hygienic procedures. Therefore, the persons involved in pig production including veterinarians should take preventive measures in accordance with the recommendations issued by the competent public health authorities to further reduce the risk they might pose to the pigs which may include having themselves vaccinated against the pandemic influenza.

## 3. Surveillance/monitoring for pandemic influenza (H1N1) 2009 virus in pigs

### 3.1. Consideration for monitoring

Information is still missing with regard to the circulation of the pandemic influenza virus in EU pig populations. It is assumed that the pandemic influenza virus is not circulating on a large scale in pig farms in the EU at present; however this might occur in the future. To demonstrate that the pandemic influenza virus is not circulating in the EU Member States in which the virus has not been detected by conventional epidemiological methods (survey or cross-sectional studies) would require enormous resources. To put in place such studies would be disproportionate from a cost/benefit point of view and probably not feasible.

### 3.2. Objective of monitoring

The objective of monitoring should be the early/timely detection of the introduction/circulation of the pandemic influenza virus in pig holdings. The assumption should be that currently there is little circulation of this virus in pigs and that introduction into pig holdings would most probably occur by contact with infected humans.

The objective of continuous monitoring of influenza viruses in pigs is to determine genetic characteristics of influenza viruses detected in pigs, and in particular the pandemic influenza virus with a view to improve knowledge of the epidemiology and evolution of influenza viruses, to obtain insights into the public health risk of influenza viruses circulating in pigs, and for vaccine and diagnostics development.

### 3.3. Monitoring strategy

For early/timely detection**,** targeted risk-based monitoring is proposed as the method of choice.

Monitoring should be primarily targeted to farms where clinical signs consistent with influenza in swine have been identified. It may be difficult to achieve early detection because the clinical signs of the pandemic influenza can be very mild and can be confused with those caused by other respiratory infections. Where an epidemiological link to human cases has been clearly established and where an identified risk of human-to-pig transmission exists, vigilance at the farm should be increased and if appropriate it should be ensured that human contacts with influenza-like symptoms representing an epidemiological significant event are notified/reported promptly.

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

The value of the 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

Serology is not an option for surveillance because of the widespread circulation of influenza viruses of the "non-pandemic" H1N1 subtype, the H1N2 and H3N2 subtypes. The possibility of antibody cross reactions, either because the pigs have been naturally infected with these subtype(s) or because they have been vaccinated, can not be excluded. Therefore differential

diagnosis of the pandemic influenza virus remains an issue and can only be performed by molecular diagnostic techniques (PCR and genome sequencing).

Nasal swabs from pigs collected 2-3 days after the onset of the clinical signs are the sample of choice.

Surveillance strategies should have a clearly defined pathway to route the samples and make the testing protocol on the isolates available to a veterinary laboratory capable of identifying the pandemic influenza virus. Competent veterinary labs in the EU (i.e. AI NRL's) can be provided with newly developed testing protocols. It is important to ensure good cooperation with the human medical laboratories, however appropriate testing capacity should also be ensured in veterinary laboratories.

### *3.5 Mid-long term monitoring*

In a longer term, there is a need for comprehensive monitoring of influenza virus genotypes to follow the state of play and the emergence and evolution of possible virus re-assortants (virus monitoring) in pigs and other animal species, with the final aim to protect public health. For this purpose it is necessary that the laboratories involved in virus monitoring get sufficient samples for virus isolation. Further exchange of influenza isolates and sequencing data among laboratories for genetic characterisation should be ensured. Valuable experience in this regard has been made available through networks of expertise such as OFFLU[3] and research initiatives like ESNIP2[4].

For that, new more efficient diagnostic tools and sufficient laboratory capacity will be needed.

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

### *4.1. General consideration for taking actions*

The two main scenarios presented above will drive the type and intensity of the monitoring, protection and control measures to be taken.

The control measures to be taken on pig farms should be proportionate to the following factors:

i) the risk posed by pigs 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 surveillance/monitoring activities in place.

In addition, the measures to be taken on pig farms addressing human-to-pig transmission, pig-to-pig transmission and pig-to-human transmission should also take into account risk factors for humans that have been identified by the public health authorities.

[3] http://www.offlu.net/

[4] http://ec.europa.eu/research/health/infectious-diseases/emerging-epidemics/projects/109_en.html

In principle the following main control tools or control measures could be applied[5] in affected farms or regions:

- Stand still
- Quarantine/movement controls on the affected farms. Movement controls of live pigs on farms and in areas/regions
- Vaccination (if suitable vaccine available)
- Slaughter (Culling) of infected herds
- Increased bio security
- Awareness campaigns
- Protection measures for humans (will not be dealt in this paper)
- Do nothing

  Depending on the circumstances (see paragraphs 4.2. and 4.3.) these controls may be applied on a voluntary or compulsory basis

**From an animal disease control point of view:** Certain movement restrictions should be implemented for pigs showing signs of clinical respiratory illness. The main measure should be the movement controls of live animals to other farms. The farm 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. However, pigs that have recovered from the clinical symptoms can go to slaughter under the general hygienic provisions (Regulations (EC) No 853/2004 and 854/2004*).* This would depend also on the particular behaviour of the influenza strain (see paragraphs 4.2. and 4.3.) and the sustainability of the restrictions in proportion to the potential benefits to human and animal health. It should be noted that respiratory signs are not pathognomic for influenza and there could be a risk that disproportionate measures may be taken based on respiratory signs, only.

### ***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 to other farms.

**4.2.2.** Sustainable movement restrictions are recommended:

- Feasibility and effectiveness of movement controls largely depend on the type of farm. In general movement restrictions should only be put in place if these are practical and are considered likely to be effective and a feasible exit strategy is identified prior to imposition of restrictions.
- Quarantine/movement controls should in principle last for one week after the last clinical case.
- Healthy pigs can be routinely sent for slaughter for human consumption under the general hygienic provisions (Regulations (EC) No 853/2004 and 854/2004).

**4.2.3.** More stringent movement restrictions should not be put in place. Limited movements of pigs to other farms might be authorised following a risk assessment.

**4.2.4.** Culling is not recommended[6].

[5] Note that no ranking of measures is proposed.

**4.2.5.** To reduce the risk of disease transmission, the number of people entering an infected farm should be limited to an absolute minimum.

**4.2.6.** It should be assumed that there is a theoretical risk that the pandemic influenza virus may transmit between pigs and humans. Therefore, advice from the competent public health authorities should be taken into account when considering whether any additional measures are necessary to protect workers and others with close contact with suspect or infected pigs including the possible use of vaccination against the pandemic influenza.

### ***4.3. Control measures to be considered if significant changes in the severity of the disease in pigs or humans are observed***[7]

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

Movement restrictions should be always proportionate to the risk. An exit strategy for the movement restriction (lifting of the restrictions) should be drawn up in advance. Sustainability of movement restrictions remains an issue and laboratory testing before lifting the restrictions may be necessary.

Culling of pigs will not help in general 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 any case, culling of infected pigs during the clinical phase of the disease[8] should be carefully evaluated before implemented (zoonotic character and occupational exposure to be minimised).

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 one or more pigs 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 animals and carcasses

    - biosecurity (in particular restricting the entry of people into the farm)

    - limit occupational exposure

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[6] http://www.oie.int/eng/press/en_090611.htm

[7] A case definition of what constitutes a significant event has yet to be developed.

[8] This will be quite variable dependent on production type, husbandry practices on farm, structure of farm etc. It could be a wide window.

3. All the pigs in the various categories on the holding should be counted and a list should be compiled of the number of pigs already sick, dead or likely to be infected in each category.

Additional measures may be considered such as the establishment of a control zone and related measures. However, it should be noted that measures normally applied for exotic epidemic diseases (e.g. CSF or ASF) might be not appropriate or proportionate for influenza in pigs.

### ***4.4. Vaccination of pigs***

At this stage it is too early to envisage a role of vaccines in the prevention and control of the pandemic influenza virus in pigs under the different hypothetical scenarios. It is unlikely that this would be appropriate in the scenario described in paragraph 4.2.

Emergency vaccination against the pandemic influenza virus, once the vaccine is available**,** may be considered in all holdings within a potentially established control area/zone or in at-risk farms. It has to be kept in mind that the vaccine will be an inactivated vaccine. Two doses (two shots) with at least 2 weeks interval are needed and therefore it will last several weeks before the immunity is fully established. However, it should be considered that vaccine alone will not be sufficient to eradicate the virus.

Emergency vaccination in infected and affected farms is in general not recommended since the spread of the virus within the holding is much faster than the immune response to the vaccine.

If suitable vaccines for pigs are available, prophylactic/preventive vaccination may be carried out, to reduce the virus spread and virus load in an affected country or region if considered cost-effective.

Options:

- Compulsory vaccination in the control zone and epidemiologically linked farms
- Voluntary vaccination in the control zone and epidemiologically linked farm
- Voluntary vaccination in large infected farms containing several epidemiological units to reduce virus circulation and accelerate virus clearance

Where required by the epidemiological situation and in particular in an area with a high density of pigs, vaccination (compulsory or voluntary) might be extended also outside the control zone.

Voluntary vaccination may be recommended in at risk areas outside the control zone.