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Working document on
surveillance and control measures
for
the novel A/H1N1 influenza virus in pigs.

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

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1. Purpose

The purpose of this document is to provide guidance to the Member States on the appropriate measures to implement under different epidemiological scenarios promoting a harmonised approach for dealing with the situation as regards:

- a) surveillance /monitoring for novel influenza A(H1N1)¹ virus in the pig populations.
- b) the possible measures to be put in place if the novel influenza A(H1N1) enters EU pig farm(s).

The key principles to be taken into account for any kind of measure related to the novel virus to be implemented are **vigilance, proportionality and flexibility**.

It should be emphasised that the novel influenza A(H1N1) is primarily a human disease.

2. Introduction

2.1. Status quo (infection of pigs)

Swine influenza (SI) is caused by infection with influenza A viruses and is a contagious disease of pigs being endemic in many pig populations around the world. It is usually a mild respiratory disease characterized by coughing, sneezing, nasal discharge, fever. The mortality is low and recovery is usually quick and uncomplicated, (within 10-14 days). Within the European pig population the influenza A viruses subtypes H1N1, H3N2 and H1N2 co-circulate widely. The novel influenza A/H1N1 virus recently reported in humans has never been reported in pigs in Europe.

The novel influenza A(H1N1) virus ("the novel virus") is a new subtype of influenza A (H1N1) viruses causing disease in humans. The virus contains gene segments from pig, bird and human influenza viruses.

It could be shown experimentally that the pigs are susceptible to the novel virus. There is no evidence suggesting that this virus behaves in a different way from other well known influenza viruses of pigs. The disease in pigs is a mild infection of the respiratory tract, with some morbidity but generally leading to uneventful recovery. There is no "carrier" status in pigs for SI.

The novel virus was only detected in the respiratory tract of infected pigs and the virus did not appear to spread and replicate in other tissues (absence of detectable viraemia).

Influenza in pigs is considered an air-borne disease. However, data on farm-to-farm windborne spread should not be extrapolated from other diseases such as FMD. Even in high pig farms density areas SI does not spread very far or very rapidly by air.

¹ Note that following international consultation WHO is now calling this virus 'pandemic H1N1 2009'

SI is not a food borne zoonosis. The infection is not spread by meat or meat products.

Pre-existing immunity induced due to a previous SI infection or following conventional influenza vaccination may not protect pigs against the novel influenza virus but it is not excluded that it provides some partial protection. Partial protection has been observed in an experimental setup with piglets having maternal antibodies but not with sufficient challenge studies.

Vaccines currently used to protect pigs against SI may not be effective against the novel influenza virus.

Occasional transmission of Influenza viruses from pigs to humans and vice versa may occur.

Likely human-to-pig transmission of the novel virus has been reported only on two occasions in Canada and Argentina but the circumstances in which this transmission may have occurred are still not clear. No pig-to-human transmission has been reported so far. However, the role of pigs in the epidemiology or spread of the novel influenza virus has not been clarified.

It is expected that the novel influenza virus will continue to circulate and spread in the human population in Europe in the coming months, in particular in autumn and winter.

Given the continued spread of this novel 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 fact, Council Directive 82/894/EEC on the notification of animal diseases lists the diseases of terrestrial animals which are subject to notification. Swine Influenza is not listed there and therefore no strict legal obligations exist to notify and control the disease.

As regards OIE, there is no obligation for notification. However, Canada and Argentina notified two incidents (outbreaks) in pigs to the OIE, due to the emerging nature of the disease (new and emerging disease reporting).

Some Member States have national legislation on obligation for notification of the disease and/or on control measures.

2.3. Possible scenarios in the future

Two main possible scenarios are considered:

1- Mild/moderate disease in pigs

- This scenario corresponds to the current situation/knowledge. No significant change in the behaviour of the novel virus as compared with other swine influenza viruses.

2.- Significant changes in the severity of the disease caused by the novel virus in pigs or humans (several possibilities - worst case)

- The virus might evolve and change its virulence leading to an increased transmissibility. However, there is no substantive data to support increased virulence in influenza virus itself for mammalian species, especially in pigs.
- The disease might become endemic in the pig population in Europe. This is a distinct possibility and a more severe clinical picture with an increased morbidity and an increased mortality might be observed. However, increased disease severity with influenza in mammalian hosts it is normally seen in association with concurrent diseases.

- Infected pigs may turn out to be a possible and serious 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 epidemics in pigs may hamper trade with pigs and may cause major economic losses.

3. Surveillance/monitoring for novel influenza A(H1N1) virus in pigs

3.1. Consideration for surveillance

Information is still missing as regards the possible circulation of the virus in EU pig populations and spread of the novel virus from human to pig populations.

It is assumed that the novel virus is not circulating in swine farms in the EU at present, however this might occur in the future. To demonstrate that the novel virus is not circulating in the EU 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 even not feasible. However, there is a rationale for accepting the assumption that this virus is not currently circulating in EU pig population.

3.2. Objective of surveillance

The objective should be early/timely detection of virus introduction/circulation in the EU pig farm(s) assuming that currently there is no circulation of this virus in this population. However, if the novel virus circulated in pigs in a different scenario (see the worst case scenario) the objective and methodology of surveillance should be reviewed.

3.3. Surveillance strategy

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

Surveillance should be primarily targeted to farms where an epidemiological link to human cases has been clearly established and where an identified risk of human-to-pig transmission exists; it should also be assumed that there is a risk of transmission between pigs and humans. It may be difficult achieving early detection because of the clinical signs of the novel influenza can be confused with those caused by other respiratory infections; it should be ensured that human contacts with influenza like symptoms are timely notified/reported.

And surveillance may be secondarily targeted² to farms having an increased risk of virus detection such as those presenting influenza like illness in pigs that should be investigated in cases respiratory diseases caused by other agents have been ruled out.

3.4. Diagnostic

Serology is not an option for surveillance because of the widespread circulation of the “classic” H1N1 subtype, the H1N2 and H3N2 subtypes in the EU, and the possibility of cross reactions in pigs that have been naturally infected with these subtype(s) or that have been infected and/or vaccinated. Diagnosis of the novel virus remains an issue. It requires sophisticated diagnostic techniques.

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

² This targeting is likely to pose some difficulties

Surveillance strategies should have a clearly defined pathway to route the samples and make the testing protocol on the isolates available to the few laboratories capable to identify the novel virus. Competent veterinary labs in the EU (ie AI NRL's) can be provided with newly developed modifications to well established techniques thereby providing suitable testing capability. It is important to ensure good cooperation with the human medicine laboratories, however appropriate testing capacity should also be ensured in the veterinary laboratories.

3.5 Mid-long term surveillance/monitoring

In a longer term, there is a need for comprehensive surveillance on influenza virus genotypes in pigs to monitor the state of play and the emergence and evolution of possible virus re-assortants (virus monitoring), 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 isolates among laboratories for genetic characterization should be ensured.

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

4. Potential control measures in case of novel influenza A(H1N1) 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 surveillance, 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 novel 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 additional risk factors for humans that have been identified by the public health authorities.

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

- Stand still
- Quarantine
- Movement controls of live animals
- Vaccination (if suitable vaccine available)
- Slaughter (Culling) of infected herds
- Increased bio security
- Protection measures for humans (will not be dealt in this paper)

From an animal disease control point of view, certain movement restrictions should be implemented for farms or holdings with swine showing signs of clinical respiratory illness³. However, when a risk that the pigs in question are infected with the novel virus is identified, the main measure should be the movement controls of live animals. The farm should be placed under quarantine at least until seven days after the last clinical signs of disease have been observed.

Due to the zoonotic character the number of people entering the farm should be limited to an absolute minimum. Vaccination of these people against the homologous virus if such vaccine is available should be considered. A prohibition for people (other than the owner, veterinarian, workers, etc) to enter the farm should be put in force.

4.2. Control measures recommended if no significant change in the behaviour of the novel 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 farm and to other farms

4.2.2. Vaccination of people at risk because of their close contact with the suspected or affected pigs should be recommended if a human vaccine becomes available

4.2.3. Sustainable quarantine is recommended:

- Feasibility and effectiveness of quarantine largely depends on the type of farm;
- Quarantine should in principle last for one week after the last clinical case

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

4.2.5. Culling is not recommended⁴

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

Movement restrictions should be always proportionate to the risk. An exit strategy for the movement restriction (lifting of the restrictions) should be drawn 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 novel 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 disease⁵ should be carefully evaluated before implemented (zoonotic character and occupational exposure to be minimised).

³ Note that respiratory signs are not pathognomic for influenza. There could be a risk that disproportionate measures may be taken based on respiratory signs, only.

⁴ http://www.oie.int/eng/press/en_090611.htm

⁵ This will be quite variable dependent on production type, husbandry practices on farm, structure of farm etc. It could be a wide window

If appropriate, due to welfare or other economical reasons, recovered pigs can be regularly slaughtered, as this is normal praxis for the current SI viruses as there is no danger to spread the virus by meat or meat products.

If suitable vaccines for pigs are available, prophylactic vaccination should be carried out, to reduce the virus spread and virus load in an affected country or region.

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

1. Where a holding contains one or more pigs suspected of being infected with the novel virus, investigations to confirm or rule out the presence of the virus have to be initiated.
2. When the presence of novel virus cannot be ruled out, the holding should be placed under official surveillance and the following measures should be implemented until the presence of the novel virus has been ruled out or confirmed:
 - epidemiological enquiry
 - restrictions of movements (intra-farm)
 - restrictions of entry and exit of live animals and carcasses and animal products
 - biosecurity (in particular restricting the entry of people into the farm)
 - limit occupational exposure
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

Some additional measures may be explored in case of confirmation of the presence of novel A/H1N1 in pigs on a holding 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 SI.

4.4. Vaccination of pigs

Vaccination against the novel virus, once the vaccine is available, has to be considered in all holdings within the control zone as soon as possible. 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 the infected farm e.g. in production units which are not yet affected by the infection is in general not recommended since the spread of the virus within the holding is much faster than the immune response to the vaccine.

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 can be recommended in at risk areas outside the control zone.