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Working document on
surveillance and control measures
for
the pandemic (H1N1) 2009influenza 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 provisional 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 the influenza pandemic (H1N1) 2009 virus in the pig populations.
- b) the possible measures to be put in place if the pandemic (H1N1) 2009 enters EU pig farm(s).

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

It should be emphasised that influenza pandemic (H1N1) 2009 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 influenza A viruses of subtypes H1N1, H3N2 and H1N2 co-circulate widely. The pandemic influenza A/H1N1 virus recently reported in humans has never been reported in pigs in Europe.

The influenza pandemic (H1N1) 2009 virus ("the pandemic virus") is a new strain of influenza A (H1N1) viruses causing disease in humans. The virus contains gene segments from pig, bird and human influenza viruses. This pandemic virus is indeed a public health issue for all worldwide but so far the role of animals has not been demonstrated in its epidemiology or spread.

It has been shown experimentally that pigs are susceptible to the pandemic 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 pandemic 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 virus can be spread 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 high pig farm density areas SI does not spread very far or very rapidly by air.

SI is not a food-borne zoonosis. There is no evidence for the pandemic virus spread to humans 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 pandemic influenza virus, but it is not excluded that it may provide 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 in the EU or elsewhere to protect pigs against SI may not be effective against the pandemic influenza virus.

Occasional transmission of influenza viruses from pigs to humans and vice versa may occur. The origin and nature of swine-like influenza viruses differ somewhat between Europe and North America. Swine origin influenza viruses also occur in wild birds, poultry, horses and humans, but interspecies transmission is considered a rare event. A new strain of influenza has been recently detected in two workers on a pig farm in Saskatchewan, Canada. This strain is a reassortment between a seasonal influenza strain and a swine influenza virus. It contains genes from current human seasonal influenza H1N1 and other genes from the North American triple reassortment swine influenza A viruses. Further epidemiological and virological investigations are underway in Canada. It should be emphasized that this event is not related to the current pandemic influenza.

Likely human-to-pig transmission of the pandemic virus has been reported only on two occasions in Alberta (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, there is not any evidence so far that pigs play a role in the epidemiology of the human pandemic or that the virus is being transmitted from pigs to humans.

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

Given the continued spread of this pandemic virus in the human population, the risk of it entering pig farms in Europe will therefore increase in the next months. Experience being gained in the Southern hemisphere will be valuable to better understand the risks.

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 that 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 the World Organization for Animal Health (OIE), there is no obligation to notify influenza in pigs. However, an emerging disease with significant morbidity or mortality, or zoonotic potential should be notified to the OIE. Canada and Argentina notified two incidents (outbreaks) in pigs due to its emerging nature.

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 hypothetical 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 pandemic virus as compared with other swine influenza viruses.

2.- Significant changes in the severity of the disease caused by the pandemic virus in pigs or humans¹ (several possibilities - worst case)

- The virus might evolve and change its virulence leading to an increased transmissibility. However, there is no substantive data to suggest that past influenza viruses have increased in virulence in mammalian species, especially in pigs and therefore there are no substantive data suggesting that the pandemic virus is likely to develop increased virulence for people or other mammalian species.
- 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, in the absence of significant genetic change to an existing strain of influenza, increased disease severity with influenza in mammalian hosts it is normally only seen in association with concurrent disease.
- Infected pigs may prove 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 pandemic influenza (H1N1) 2009 virus in pigs

3.1. Consideration for surveillance

Information is still missing with regard to the possible circulation of the pandemic virus in EU pig populations and spread of the pandemic virus from human to pig populations.

It is assumed that the pandemic virus is not circulating in pig farms in the EU at present; however this might occur in the future. To demonstrate that the pandemic 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 probably 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 the early/timely detection of the introduction/circulation of the pandemic virus in the EU pig population assuming that currently there is no circulation of this virus in this population. However, if the pandemic virus does circulate in pigs in a different

¹ This scenario might be split in two depending if the disease reveals to have become more severe for humans or for pigs.

scenario (see the worst case scenario) the objective and methodology of surveillance will need to be reviewed.

3.3. Surveillance strategy

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

At the early stages of the human pandemic, 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 pandemic influenza can be confused with those caused by other respiratory infections; it should be ensured that human contacts with influenza like symptoms representing an epidemiological significant event are timely notified/reported. The value of the surveillance strategies should be kept under review in line with the changing nature of the disease and the key principles of vigilance, proportionality and flexibility.

And surveillance may be secondarily targeted² to farms having an increased risk of virus detection such as those presenting influenza-like illness in pigs which should be investigated in cases where 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 influenza viruses of the "non-pandemic" 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 vaccinated. Differential diagnosis of the pandemic 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.

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 of identifying the pandemic virus. Competent veterinary laboratories in the EU (ie AI NRL's) can be provided with newly developed modifications to well established techniques thereby providing a 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 of influenza virus genotypes to monitor the state of play and the emergence and evolution of possible virus reassortants (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 isolates among laboratories for genetic characterization should be ensured. Valuable experience in this regard has been made available through networks of expertise such as OFFLU³ and research initiatives like ESNIP2⁴

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

² This targeting is likely to pose some difficulties

³ <http://www.offlu.net/>

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

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 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 pandemic 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 applied⁵ in affected farms or regions:

- Stand still
- Quarantine
- Movement controls of live animals (zoning)
- 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 (status quo)

From an animal disease control point of view, certain movement restrictions could be implemented for farms and holdings with pigs showing signs of clinical respiratory illness⁶. However, when a risk that the pigs in question are infected with the pandemic virus is identified (see point 3.3 above), the main measure should be the movement controls of live animals. If movement restrictions are put in place, the farm should be placed under quarantine at least until seven days after the last clinical signs of disease have been observed and it is determined that influenza is no longer considered a veterinary risk. This would depend also on the particular nature and behaviour of the influenza strain and the sustainability of the restrictions in proportion to the potential benefits to human and animal health.

Due to its zoonotic character the number of people entering the farm should be limited to an absolute minimum. Although the scope of this document is limited to measures in pigs, it is worth to mention that vaccination of 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 affected farm should be put in force.

⁵ Note that no ranking of measures is proposed.

⁶ 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 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 or premises 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/movement restrictions is recommended:

- Feasibility and effectiveness of quarantine largely depends on the type of farm. In general movement restrictions should only be put in place if a feasible exit strategy is identified prior to imposition of restrictions.
- Quarantine/movement restrictions should in principle last for one week after the last clinical case.
- Recovered pigs and healthy pigs can be routinely sent for slaughter for human consumption.

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 recommended⁷.

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 pandemic 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 disease⁸ should be carefully evaluated before implemented (zoonotic character and occupational exposure to be minimised).

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

If suitable vaccines for pigs are available, prophylactic vaccination may 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 pandemic virus on a holding may be envisaged such as:

⁷ http://www.oie.int/eng/press/en_090611.htm

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

1. Where a holding contains one or more pigs suspected of being infected with the pandemic virus, investigations to confirm or rule out the presence of the virus have to be initiated.
2. When the presence of pandemic 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 virus has been ruled out or confirmed:
 - epidemiological enquiry
 - restrictions of movements (intra-farm) as appropriate.
 - on-farm restrictions of entry and exit of live animals and fallen stock.
 - 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 pandemic 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

At this stage it is too early to envisage the role of vaccines in the prevention and control of the pandemic virus in pigs under the different hypothetical scenarios.

However, once the vaccine is available, vaccination against the pandemic virus, has to be considered in all holdings within the hypothetical control zone or in at-risk farms 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.