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Working Document

Schmallenberg Virus

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Guidance Document on the Priority Actions to be Undertaken in the EU in the Next Months

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

Document agreed at the
SCoFCAH Meeting of 7 February 2012

Content

1. Purpose of this document

The purpose of this document is to summarise the current state of play of the Schmallenberg virus (SBV) infection in the EU, to identify priority issues and to provide guidance to the Member State's competent authorities and stakeholders on certain actions.

This document addresses the following issues:

1. Understanding the epidemiology of the infection and its impact (the current stage of the epidemic, the distribution of the vectors, susceptible species, the source of the infection, possible risks posed by different commodities).
2. Human health impact: the ECDC assessment.
3. Characterisation of the pathogen.
4. Current diagnostic tools and availability of serological tests.
5. Monitoring and reporting procedures for suspected cases and epidemiological investigations.
6. Possible evolution of the epidemiological situation in the next vector activity season and which control measures could be applied.
7. Usefulness and timeline for developing a vaccine.
8. Investigation and scientific studies.
9. OIE standards and trade concerns.
10. Next steps.

2. Background information

A previously unknown virus of the *Bunyaviridae* family has been reported as from November 2011 in ruminants (cattle, sheep and goats) in Germany, the Netherlands, Belgium, the United Kingdom and France. Its detection has been associated with transient clinical signs of disease in adult cattle (fever, diarrhoea, reduced milk yield, etc.), which were observed in summer and early autumn, and with congenital malformations in newborn animals, mainly lambs, observed in early winter. Typical deformities in lambs have included crooked necks, hydrocephalus and stiff joints. Most were born dead while infected live lambs did not survive.

There is no evidence that the Schmallenberg virus could cause illness in humans. The European Centre for Disease Prevention and Control (ECDC) performed a preliminary assessment, on 22 December 2011, on the zoonotic risks of SBV which indicates that "it is

unlikely that this new orthobunyavirus can cause disease in human but it cannot be excluded at this stage". The document is available here:

http://ecdc.europa.eu/en/publications/Publications/231112_TER_Risk_assessment_Schmallenberg_virus.pdf

During the Standing Committee on the Food Chain and Animal Health (SCoFCAH), on 11 January 2012 and the Working Party of Chief Veterinary Officers of the 27 EU Member States (held in the Council under the Danish Presidency together with the Commission on 25 January 2012), the representatives from Germany, the Netherlands, Belgium, the United Kingdom and France presented the epidemiological situation on this disease in each country as well as recent scientific data on the pathogen itself. Until 7 February 2012, cases of disease were reported by Germany (314 cases in cattle, sheep and goats), in 93 farms in the Netherlands (in cattle, sheep and goats), in 88 farms in Belgium (in sheep and cattle), 11 farms in the United Kingdom and 66 farms in France (in sheep only).

The information available on the Schmallenberg virus genome suggests that this virus is part of the Simbu serogroup of the *Bunyaviridae* family, genus *Orthobunyavirus*. Viruses of the Simbu serogroup are mostly found in ruminants in Asia, Australia, Africa and the Middle East (Israel). Simbu serogroup viruses are primarily transmitted by insect vectors (midges, mosquitoes) with no direct transmission from animal to animal. Viruses of the Simbu serogroup have not been previously isolated in Europe. According to literature, they are only rarely associated with clinical symptoms. They have the potential to induce congenital defects, such as the ones caused by the Akabane virus, which has been reported in Australia Japan, Cyprus (neutralising antibodies found for the first time in 1970), Turkey and Israel. Potential to cause congenital damage in ruminants may be attributed to other members of the Simbu serogroup. None of the infections and diseases caused by the viruses of the Simbu serogroup are included in the OIE list of diseases or subjected to OIE standards on trade.

The route of transmission used by several viruses of the Simbu serogroup (vectors) implies that transmission during winter is limited, if any, and horizontal (animal-to-animal) transmission of virus by means of meat or other similar products do not (or is very unlikely to) occur. Vertical transmission for SBV is suspected given the infections of foetuses.

The SBV can be identified through PCR testing, seroneutralisation test and indirect immunofluorescence; these serological tests do not allow for large scale serosurveillance and no timeline is available for obtaining a test suitable for mass serosurveillance. The shortness of the viremic period was demonstrated (4-6 days post-exposure) which can make the identification of the pathogen in adult live animals more problematic. The virus is present for longer time in infected foetuses and can be detected in malformed newborns. No vaccines are currently available. As it has been observed for Akabane virus, it was observed that an infection in a naïve population could cause significant number of abortions or congenital malformations leading to perinatal death; however, considering the behaviour of viruses similar to SBV, it can be assumed that the second breeding cycle would be almost normal given the immunity acquired by the population. Population immunity can possibly be acquired naturally against SBV, which would imply, that the clinical consequences of the disease would tend to disappear spontaneously.

Data recently gathered in the Netherlands suggest that SBV has been one of the minor causes of abortions in bovine animals in the country (101 sera of cows which had aborted in September and October 2011 were tested by RT-PCR for SBV and 2 of the samples tested were positive).

In the framework of the EU disease passive and active surveillance activities for endemic and also emerging diseases, several EU Member States that detected abnormalities have spontaneously implemented a suspicion-reporting procedure for abortions, stillbirths or congenital malformations in ruminants; this allows collecting data to better understand the pathogenesis and epidemiology of this infection. The situation could change during the vector activity period.

The EU does not apply any trade restrictions in relation to the SBV virus as well as any other *Orthobunyavirus* on live animals, their meat, milk or animal by-products.

No restrictions on trade in live ruminants or their products originating from the affected areas have been introduced in the EU after the detection of the SBV, as no trade restrictions have been considered appropriate, at least at this stage, taking also into account that it is winter time and that according to the information available the viremic period in infected cattle is very short (4-6 days post-exposure).

The SCoFCAH agreed on 11 January 2012 on a statement on this infection. The document is available here:

http://ec.europa.eu/food/animal/diseases/schmallenberg_virus/docs/sv_statement_11012012_en.pdf

The Working Party of Chief Veterinary Officers of the 27 EU Member States met in Council under the Danish Presidency and agreed on an information note prepared by the Commission addressing several aspects of the SBV infection with respect to trade. The note is available here:
http://ec.europa.eu/food/animal/diseases/schmallenberg_virus/docs/information_1818_note_240112_en.pdf

3. Specific Issues

1. Understanding the epidemiology of the infection and its impact (the current stage of the epidemic, the distribution of the vectors, susceptible species, the source of the infection, risk posed by different commodities).

Orthobunyaviruses are mainly transmitted by mosquitoes (*Culicidae*) or midges (*Culicoides*). Some data on distribution of *Culicoides* vectors in the Member States is available from surveillance on Bluetongue (see an overview of the seasonally vector free period here: http://ec.europa.eu/food/animal/diseases/controlmeasures/bluetongue_en.htm#svfp).

The susceptible species to SBV, as reported by Member States, are ruminants (cattle, sheep, goats and bison). Other species had been previously reported to be susceptible to the Simbu serogroup (pigs, buffalo, camels, deer goats, horses and dogs), but no report links these species to SBV yet.

An assessment of the impact of SBV on animal health, public health and animal production is needed, in particular on both the economic aspects (losses in agricultural production) and on trade (trade consequences of any measure taken at EU level).

Data is needed, notably:

1. Updated information on vector distribution, as well as a confirmation on the vectors that can transmit SBV.

2. Confirmation on the susceptible species (through natural infection).
3. Identification of the current stage of the epidemic (peak, decline, etc.) in order to better understand the potential further spread of the disease.
4. Epidemiological data on herd incidence, prevalence, morbidity, mortality, case-fatality rate, incubation period, risk period for foetal infection during pregnancy; routes of transmission.

EFSA has been asked to provide guidance on the further data to be collected. The EFSA Data Collection Framework (DCF) will be used for this purpose. It is therefore desirable that liaison between Member States, experts and EFSA is ensured and that data be gathered in a manner that enables risk assessment. At the same time, this process should respect the data confidentiality rules within the context of the EFSA mandate.

The data transmitted to EFSA should be preferably be in line with the "Reporting guidelines minimum dataset" presented in the Appendix on data collection of the EFSA Technical Report "Schmallenberg virus: likely epidemiological scenarios and data needs".

EFSA will work together with Member States to ensure that the epidemiological data can be used to maximum effect through the provision of guidance. Periodical reports will be shared on the status and analysis of the data collected. Once the data have been collected, EFSA will provide an overall assessment of the impact of SBV infection on animal health, animal production and animal welfare together with a review on what is known about the virus (http://www.efsa.europa.eu/en/press/news/120131.htm).

2. Human health impact: the ECDC assessment.

The impact assessment considers that "it is unlikely that this new orthobunyavirus can cause disease in human but it cannot be excluded at this stage". Current public health data confirms this situation. In addition there is no evidence that people in close contact with infected animals (e.g. farmers, and veterinarians) have shown any signs of illness that could be related to the virus.

At the meeting of the Working Group on Schmallenberg Virus of 20 January 2012, the ECDC confirmed that their assessment is still valid. The Epidemiological Update made on 25 January 2012 by ECDC does not bring any changes to the previous statements.

It is recommended that the animal and human health services continue collaborating closely to ensure rapid detection of any change in the epidemiology in humans and animals, particularly with respect to people in close contact with ruminants. A harmonised human case definition has been proposed to ensure a consistent approach in the EU. A conference call coordinated by ECDC took place on 31 January 2012 to examine strengthening surveillance. It was agreed that there were no basis for requesting EU wide human surveillance plan because the national human surveillance schemes were considered appropriate.

ECDC will continue to liaise with the Member States, the European Commission and EFSA on SBV.

3. Characterisation of the pathogen.

Currently the infection is being identified through RT-PCR. Its genetic sequence is similar to the sequences of Shamonda, Aino, Akabane, that are members of the Simbu serogroup. The clinical picture in adult cattle appears to be diarrhoea, reduced milk production and fever; in sheep, cattle and goats it produces abortions, stillbirths and neonatal malformations.

A clearer picture of the pathology of the disease in the affected species, including quantification of the clinical disorders and gravity, supported by diagnostic tools is required; this should be coupled with information on the pathogenesis and the routes of transmission.

The Shamonda, Aino and Akabane viruses are known to cause subclinical infections in a large proportion of the infected animals, in particular in non-naïve populations. It would be of major importance to understand if SBV behaves in the same manner.

4. Current diagnostic tools and availability of serological tests.

Virus neutralisation test and the indirect immunofluorescence assay have already been developed, but these serological tests cannot be automated for screening significant number of samples. RT-PCR can detect the pathogen itself but the shortness of the viremic period limits its usefulness for detecting the virus in live animals.

Serological tests (e.g. ELISA) may need to be developed before undertaking a large scale screening of samples before starting any form of surveillance, if needed.

It is recommended that Member States proactively seek supply of the necessary reference materials enabling operational diagnostic capabilities to sustain laboratory and epidemiological investigations.

5. Monitoring and reporting procedures for suspected cases and epidemiological investigations.

The current reporting of suspicions (abortions, stillbirths or congenital malformations) followed by confirmatory PCR testing has been used by several Member States to detect the infection. Most recent figures on suspicion reporting without infection confirmation indicate a high level of awareness and vigilance.

There is no rationale for setting-up any EU-wide notification obligations at this stage. Due to the inadequacy of diagnostic tools and to the current epidemiological situation, there are no bases for setting up nation-wide active surveillance schemes.

It is recommended that each Member State activate its veterinary vigilance procedures for ensuring that each suspected case be identified and reported by the farmer and field veterinarians to the veterinary authority. Investigations should be triggered by the occurrence of perinatal clinical signs (perinatal deaths and congenital malformations like crooked necks, hydrocephalus, scoliosis, arthrogryposis, and stiff joints). Suspicions should be tested for differential diagnosis with SBV considering the prevailing epidemiological circumstances and the coexistence of other diseases cursing with similar clinical signs and reproductive disorders (brucellosis, clamydiosis, Q-fever, etc). Findings need to be reported at EU level.

In order to ensure adequate reporting, it is recommended that Member States ensure adequate information be provided to farmers, private veterinarians and that the veterinary laboratories have the necessary diagnostic capabilities for detecting SBV.

In the framework of EFSA activities, a national procedure for data collection, verification and submission of data related to SBV investigations should be put in place. This procedure should take into account the data structure recommended by EFSA.

The current epidemiological situation does not indicate that it is worth to thoroughly embark the veterinary services in the investigation of clinical signs in adult animals (fever, diarrhoea,

reduced milk yield, etc.) which are non-specific. The approach could change in the next vector activity season.

6. Possible evolution of the epidemiological situation in the next vector activity season and which control measures could be applied.

It is expected that, in the following months, further reports on lambing and calving problems will be received. The situation is expected to evolve with the start of the next vector activity season which would see a broader area affected by SBV.

Depending on the epidemic stage currently in progress, the evolution of the infection could vary. There is no information on when SBV was first introduced in the EU. A retrospective investigation based on samples collected by Member States in the context of different surveillance activities may provide the data required to trace back to the first circulation of the SBV in a territory.

If we assume that movements of live animals can play a major role on SBV spread, then factors such as vector and the animal movements from affected farms during past summer and autumn need to be taken into consideration; possibly this could have already led to a still undetected further geographical spread of infection.

Data on viruses of the Simbu serogroup indicates that milk, meat and meat products as well as by-products are not a mean of transmission of the pathogen.

An estimate of the possible evolution of the infection considering its impact and an assessment on further EU control measures for live animals, if any, are required. It is also possible that the seasonality of the infection cycle would not even entail a second epidemic circulation next year. This is supported by the shortness of the viremic period (estimated currently in 6 days or less) and the natural immunity that is expected to be quickly acquired by the herds.

7. Usefulness and timeline for developing a vaccine.

No vaccine currently exists for SBV. Vaccination could be an option for controlling the disease. At the same time, the susceptible populations seem to develop quickly natural immunity against virus similar to SBV. Notwithstanding the absence of data demonstrating that vaccination against SBV will produce a protective immunity, it should be noted that for a similar virus like Akabane, a vaccine exists, but it's not necessarily used for economic consideration and immunisation of animals can be achieved by moving the youngsters into endemic areas before they are made pregnant.

An assessment on whether vaccination could be a suitable, feasible, affordable and proportionate control option is required. Issues on safety of vaccines either live attenuated or inactivated remain to be further assessed. The time required for marketing the vaccine needs to be considered before embarking on production initiatives.

8. Investigation and scientific studies.

DG SANCO will explore further ways of promoting joint research initiatives with cooperation of DG RTD on SBV. Some initiatives such as EMPERIE and other ongoing project are already active and have contributed to the identification of this virus.

The Commission is currently working together with the Member States to identify which studies would be useful to assist defining EU policies and legislation addressing SBV. A meeting of experts for coordinating scientific studies is planned for mid February 2012. These projects could be undertaken and co-financed under the framework of the EU expenditure in the veterinary field.

9. OIE standards and trade concerns

None of the infections and diseases caused by the viruses of the Simbu serogroup are included in the list of diseases subjected to international notification or standards on trade established by the OIE.

The affected EU Member States have, however, in full transparency notified the OIE the occurrence of the Schmallenberg virus in their territory, under the notification procedure for emerging diseases.

The EU does not apply any trade restrictions in relation to the Schmallenberg virus as well as any other Orthobunyavirus on live animals, their meat, milk or animal by-products.

The data currently available, although incomplete, suggests that the SBV infection would not meet the requirements for being listed (Chapter 1.2. of the OIE Terrestrial Animal Health Code) mainly because neither morbidity nor mortality appear to be significant.

Therefore, the data available suggest that SBV infection does not deserve a different approach from diseases like Akabane. Hence, the EU considers that restrictive measures against EU exports of ruminants (cattle, sheep and goats) and their products are not justified.

This approach is supported by the recommendations unanimously adopted by the 4th meeting of the Regional Steering Committee for Europe of the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs) which took place in Brussels on January 26-27 2012: "*In the context of the current epidemiological knowledge regarding infection with Schmallenberg virus in Europe, trade restrictions not be imposed to countries notifying the disease, and monitoring of the infection be continued and enhanced, as well as research and cooperation*".

Regardless of the lack of evidence justifying trade barriers, several third countries have applied a ban to imports of ruminants and ruminants' products (live ruminants, meat, by-products, semen and embryos) from the affected Member States. An increasing number of third countries are requesting clarification on the current situation.

10. Next steps.

It is desirable that the initiatives taken by both risk managers and risk assessors are coordinated. This will result in a better understanding of this infection allowing for scientific based, proportionate and effective responses to the risks in view of the possible adoption of further actions. Broadening the number of research centres into this effort, maximising synergies through concerted research programmes, avoiding duplications and overlapping would assist in obtaining more quickly the answers needed.

EFSA will collect data on SBV through the DCF. It is requested that involved Member States provide the required data in the format defined by EFSA.

4. References

1. ANSES (France) : http://www.anses.fr/PMEC00CB01.htm
2. DEFRA (United Kingdom): http://www.defra.gov.uk/animal-diseases/a-z/schmallenberg-virus/
3. ECDC assessment: http://ecdc.europa.eu/en/publications/Publications/231112_TER_Risk_assessment_Schmallenberg_virus.pdf
4. EFSA Technical Report "Schmallenberg virus: likely epidemiological scenarios and data needs". Appendix on data collection, Reporting guidelines minimum dataset. http://www.efsa.europa.eu/en/supporting/doc/241e.pdf
5. FAVV- AFSCA (Belgium): http://www.favv.be/santeanimale/schmallenberg/
6. FLI (Germany) - Schmallenberg Viruspage: http://www.fli.bund.de/en/startseite/current-news/animal-disease-situation/new-orthobunyavirus-detected-in-cattle-in-germany.html
7. Hoffmann B, Scheuch M, Höper D, Jungblut R, Holsteg M, Schirrmeier H, et al. Novel orthobunyavirus in cattle, Europe, 2011. Emerg Infect Dis Volume 18, Number 3—March 2012. Accessed on *01/02/2012*. http://dx.doi.org/10.3201/eid1803.111905
8. OIE Listing Criteria, Chapter 1.2. of the OIE Terrestrial Animal Health Code: http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.1.2.htm
9. OIE Notification by Belgium: http://web.oie.int/wahis/public.php?page=single_report&pop=1&reportid=11485
10. OIE Notification by France: http://web.oie.int/wahis/public.php?page=single_report&pop=1&reportid=11568
11. OIE Notification by Germany: http://web.oie.int/wahis/public.php?page=single_report&pop=1&reportid=11514
12. OIE Notification by the Netherlands: http://web.oie.int/wahis/public.php?page=single_report&pop=1&reportid=11447
13. OIE Notification by the United Kingdom: http://web.oie.int/wahis/public.php?page=single_report&pop=1&reportid=11539
14. RIVM (the Netherlands) – Risk Profile: http://www.rivm.nl/dsresource?objectid=rivmp:60483&type=org&disposition=inline
15. SCoFCAH statement: http://ec.europa.eu/food/animal/diseases/schmallenberg_virus/docs/sv_statement_11012012_en.pdf
16. VWA (the Netherlands): http://www.vwa.nl/onderwerpen/dierziekten/dossier/schmallenbergvirus
17. Working Party of Chief Veterinary Officers, information note: http://ec.europa.eu/food/animal/diseases/schmallenberg_virus/index_en.htm