A meeting of the OIE ad hoc Group on Schmallenberg virus (SBV) (hereafter the Group) was held at the OIE Headquarters from 10 to 11 October 2013.

1. Opening

Dr Bernard Vallat, Director General of the OIE, welcomed the participants of the Group as well as Delegations from Russia and Kazakhstan. He reminded that this meeting was an ad hoc Group meeting and as such, governed by the OIE Terms of References for ad hoc Groups. He emphasised that the members of an ad hoc Group should be nominated by the Director General of the OIE according to their internationally recognised expertise and the balance of their geographical origin. Therefore only the experts officially invited to participate to this Group could participate in the meeting. He reminded the members of the Group that they should fill in and sign a confidentiality undertaking and declaration of interest for this specific meeting.

Dr Vallat highlighted that, due to the importance of the meeting, he invited Dr Brückner, President of the Scientific Commission for Animal Diseases (Scientific Commission), from South Africa, to chair the Group and Dr Stuart MacDiarmid, Vice-President of the Terrestrial Animal Health Standards Commission (Code Commission), from New Zealand, to attend the meeting as an observer.

Delegations were invited to take opportunity of the presence of the international experts during the breaks of the Group meeting.

Dr Vallat reiterated the main topics of the agenda, to evaluate infection with SBV against the criteria in Article 1.2.2 of the Terrestrial Animal Health Code (Terrestrial Code) for possible inclusion on the OIE List of diseases and to update the OIE Technical Factsheet if necessary.

2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group was chaired by Dr Gideon Brückner. The OIE Scientific and Technical Department provided a rapporteur. The Group endorsed the proposed agenda.

The Agenda and list of participants are presented as Appendices I and II, respectively.

3. Background and update on vaccine availability and research findings regarding Schmallenberg virus

Dr Martin Beer presented the most recent findings on SBV infection. He highlighted that there was no evidence of introduction or spread of SBV before 2011 and that the wave of spread was very fast. He reiterated that the disease is not zoonotic and that in contrast to sheep, cattle foetuses are not the main target of SBV induced malformation. Results of studies conducted in Belgium and the Netherlands on sheep were expected to be available in the near future.

He emphasised that there is a real difference of the expression of the disease according to the species, notably between cattle and sheep. The wave of abortions and malformations reported in sheep (up to 60 % when the virus infects the herd at the most vulnerable stage of gestation) was never reported in cattle in which species the usual syndrome shows little malformation, even when pregnant cows were experimentally infected with SBV and SBV-RNA could be detected in the foetus.
Experimentally infected cattle could not be re-infected and neither contact nor oronasal infection was possible in naïve calves.

Dr Beer informed the Group that infection had been proven in winter time in an outdoor herd in North-East of Germany when the temperature was above 5 degrees Celsius and that therefore, it would be difficult to argue for a vector-free period in many European countries. According to the information available, Culicoides seem to transmit SBV substantially more efficiently than BTV.

Dr Beer highlighted that infectious SBV had been found in semen of some SBV seropositive bulls but that information on the possibility of transmission by artificial insemination was still lacking. PCR analysis also showed that discontinuous and intermittent shedding in semen is possible.

Following the presentation by Dr Beer, Dr Brückner invited comments from the members of the ad hoc Group.

The Group agreed that the question of the infectiousness of semen concerned only free countries. In infected countries, transmission by Culicoides is the relevant way.

The timing to obtain validation for the diagnostic tests and vaccines was highlighted. Dr Beer informed the Group that six laboratories in Western Europe were participating in their second ring test. He reminded the Group that the production of SBV vaccine was similar to the production of bluetongue virus vaccines and had helped to save time to produce SBV vaccine. Finally he clarified that the vaccine was not a DIVA one and it was not possible at this stage to distinguish vaccinated from naturally infected animals using serology.

The Group agreed that the literature was cautious on the zoonotic potential but considered that no evidence of human infection was proven despite a quick and widespread transmission of SBV in a highly human populated area. The Group emphasised that many articles that had been written at an early stage of the outbreak had raised questions which had since been answered.

The Group agreed that all viruses from the Simbu serogroup should be considered together, because of their similarity. The Group noted that literature had described some strains of Akabane virus that could have a greater impact than SBV.

According to the current knowledge, the Group agreed that once they become endemic, the impact of viruses of the Simbu serogroup rapidly becomes less significant, even in the case of the introduction of a new virus from this group.

The Group discussed the impact of SBV, the first virus of the Simbu serogroup to be introduced into Western Europe in an area highly populated with naïve ruminants.

4. **Assessment of Schmallenberg virus against the criteria provided in Chapter 1.2. of the Terrestrial Animal Health Code**

Dr MacDiarmid reminded the Group that only the criteria for inclusion of a disease in the List of the OIE described in Article 1.2.2. of the *Terrestrial Code* should be taken into consideration for listing/delisting any disease. He recalled that these criteria were adopted by the World Assembly of Delegates (World Assembly) in May 2011 and explained the process for their adoption to the Group.

The Group invited Dr Panin to share his thoughts on the proposal that Russia wanted to submit to the World Assembly to revise the criteria of Article 1.2.2.. Dr Panin indicated that one of the most important activities of the OIE is to ensure safe trade and that a consensus between importing and exporting countries was often difficult to reach. He also emphasised the long time that could be required to prove the absence of zoonotic potential. Therefore he proposed to introduce the concept of ‘waiting period’ in Article 1.2.2, during which an unknown/emerging disease would be listed by default by the OIE. This ‘waiting period’ for unknown/emerging diseases would give time (at least 5 years) to OIE Reference Centres to conduct studies and draft the disease profile. During the ‘waiting period’, importing countries could implement risk-based measures to protect themselves from the introduction of pathogen agent.

Dr Khairullin Berik Mukhitovich proposed to include a disease in the OIE List even when only a single criteria was fulfilled.
Dr Brückner took note of both suggestions and stated that once a formal proposal has been submitted by the Member Countries, it would be discussed by the Scientific and Code Commissions. However, he emphasised that for the purpose of this meeting, SBV could only be evaluated against the current version of the Terrestrial Code and if changes in the criteria for inclusion on the OIE List of Diseases were to be proposed following the meeting, they could not be taken into account prior to their adoption by the World Assembly. For this meeting, the Group would have to evaluate whether SBV fulfills the criteria to be listed according to the criteria already adopted and described in Terrestrial Code Chapter 1.2.

The Group evaluated infection with SBV against the criteria as follows:

1. **First criteria**: “International spread of the agent (via live animals or their products, vectors or fomites) has been proven.”

   The Group agreed that international spread of SBV has been proven to almost all countries in Western Europe (WAHID; EFSA, May 2013).

2. **Second criteria**: “at least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4.”

   Dr MacDiarmid emphasised that demonstration of a country’s freedom from a disease may be based on the surveillance criteria in Chapter 1.4. of the Terrestrial Code and pathogen specific surveillance may not be required.

   On this basis, several countries have claimed freedom from SBV.

3. **Third criteria**

   3a) “Natural transmission to humans has been proven, and human infection is associated with severe consequences”

   The Group recognised that a large number of people (many millions) have been exposed to SBV infected animals, including birth products, and vectors in the infected areas without any evidence of human infection being detected. They considered that this supported the absence of natural transmission to humans (ECDC, RKI and RIVM Joint Risk Assessment, 2012).

   3b) the disease has been shown to cause significant morbidity or mortality in domestic animals at the level of a country or a zone”

   Dr Reviriego provided the Group with extensive data from the first epizootic season of SBV in Europe. He mentioned that up to 99.76% of ruminants were seropositive but fewer than 4% of cattle holding and maximum 6.6% of sheep holdings reported clinical signs during the first epizootic season (EFSA, November 2012; Meroc E. et al., 2013; Veldhuis A.M.B. et al., 2013). The figures for the second season had not yet been published but already it was clear that these data would not contradict the conclusions reached after the first season.

   The Group challenged the definition of ‘significant morbidity’ and recognised that some OIE listed diseases could be questionable in terms of significant morbidity (e.g. infectious bovine rhinotracheitis). The Group noted that many non-listed diseases may have a higher morbidity and impact than SBV (e.g. Akabane virus, contagious ecthyma). However, the Group acknowledged that according to the WTO’s SPS agreement, a country free from a non-listed disease may impose sanitary measures to protect itself from the introduction of any disease for which it is free.

   Dr MacDiarmid reminded the Group that ‘morbidity’ means the expression of clinical signs, rather than the presence of infection.

   The Group could not reach a consensus but a majority considered that infection with SBV had no significant impact. The experts who did not share this position considered that the criteria of Article 1.2.2. should be revised before assessing the inclusion of SBV.
3c) the disease has been shown to, or scientific evidence indicates that it would, cause significant morbidity or mortality in wild animal populations.

The Group agreed that there was no scientific evidence indicating that SBV would have greater impact in wildlife than in domestic ruminants. Indeed, some studies (not published) would suggest that the impact would be rather less.

4) Fourth criteria: “A reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations.”

The Group agreed that diagnostic tools were available.

5) Fifth criteria: “The disease or infection is an emerging disease with evidence of zoonotic properties, rapid spread, or significant morbidity or mortality and a case definition is available to clearly identify cases and allow them to be distinguished from other diseases or infections.”

The majority of the group agreed that SBV is an emerging disease but without zoonotic potential.

In conclusion:

According to the scientific information available, the majority of the Group concluded that the infection with SBV did not meet the criteria to be included in the OIE List of disease. The Group agreed that future findings on SBV or changes in the criteria for inclusion in the OIE List of diseases may conduct to the reassessment of SBV.

5. Update of the OIE Technical Factsheet

The Group updated the OIE Technical Factsheet for SBV, which is presented as Appendix III.

6. Discussion with the Director General of the OIE

Dr Vallat referred to the Terms of Reference of the meeting and reminded the Group that the final decision on listing of SBV would be taken by the World Assembly in May 2014. Dr Vallat stated that should SBV not be listed by the World Assembly, the Scientific Commission could consider the removal of the factsheet from the OIE website.

On a question raised by Dr Panin, Dr Vallat highlighted the differences between serological surveys and criteria for listing a disease.

7. Finalisation and adoption of report

The Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report captured the discussions.

References


WAHID: www.oie.int/wahid
MEETING OF THE OIE AD HOC GROUP ON SCHMALLENBERG VIRUS
Paris, 10 – 11 October 2013

Terms of Reference

1. Assess Schmallenberg virus for possible inclusion in the OIE Listed Diseases against the criteria in the Terrestrial Animal Health Code, Chapter 1.2 for Listed Diseases.

2. Update the OIE Technical Factsheet, including information on potentially vaccine availability and advise if a new Code Chapter on that disease is relevant.

Agenda

1. Opening

2. Adoption of the agenda and appointment of chairperson and rapporteur

3. Background and update of vaccine availability and research findings regarding Schmallenberg virus

4. Assessment of Schmallenberg virus against the criteria provided in Chapter 1.2. of the Terrestrial Animal Health Code

5. Update the OIE Technical Factsheet

6. Discussion with the Director General of the OIE

7. Finalisation and adoption of the draft report
MEETING OF THE OIE AD HOC GROUP ON SCHMALLENBERG VIRUS
Paris, 10 – 11 October 2013

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Schmallenberg virus was discovered in November 2011 and epidemiological, immunological and virological investigations are on-going in several European countries. The information presented in this technical factsheet reflects the epidemiological observations and research done to date (October 2013), together with data extrapolated from genetically similar viruses of the same genus and serogroup.

**AETIOLOGY**

**Classification of the causative agent**

The “Schmallenberg virus” (SBV) is an enveloped, negative-sense, segmented, single-stranded RNA virus. It belongs to the *Bunyaviridae* family, within the *Orthobunyavirus* genus. The Schmallenberg virus is a member of the Simbu serogroup viruses, which includes Shamonda, Akabane, and Aino viruses. The Simbu viruses which are most related to SBV are Sathuperi and Douglas virus.

Field and laboratory studies indicate a causal relationship between SBV infection and the reported clinical signs.

**Resistance to physical and chemical action**

From extrapolation from the California serogroup of Orthobunyaviruses:

- **Temperature:** Infectivity lost (or significantly reduced) at 50–60°C for at least 30 minutes.
- **Chemicals/Disinfectants:** Susceptible to common disinfectants (1% sodium hypochlorite, 2% glutaraldehyde, 70% ethanol, formaldehyde)
- **Survival:** Does not survive outside the host or vector for long periods

**EPIDEMIOLOGY**

According to the epidemiological investigations, reinforced by what is already known about the genetically related Simbu serogroup viruses, SBV infection is mainly reported from ruminants. Serological and epidemiological studies indicate that it is not zoonotic. Transmission in animals is by insect vectors and then vertically in utero.

**Hosts**

- Confirmed by PCR or virus isolation:
  - Cattle, sheep, goats
  - Bison
  - Roe deer
  - Dog (a single case of PCR positive dog)
- Confirmed by serology only:
  - Red deer
  - Alpacas
  - Mouflons
  - Wild boar

**Transmission**

- Epidemiological investigations indicate insect vector transmission.
- Vectors: SBV genome was detected in several Culicoides species. To date, there is no evidence that mosquitoes play a role.
- Vertical transmission across the placenta is proven.
- SBV has been found in bovine semen. However, the potential for transmission by insemination is unknown.
- Direct transmission from animal to animal has been investigated but has not been proven.
Viraemia and incubation period

Experimental infection in cattle and sheep showed no clinical signs or mild symptoms at 3 to 5 days post-inoculation with an incubation period of between 1 and 4 days and viraemia lasting for 1 to 5 days.

Sources of virus

Material found to be positive in virus isolation (up to October 2013):
- Blood from affected adults and brain from infected foetus.

Material found PCR positive (up to October 2013):
- Organs and blood of infected foetus, placenta, amniotic fluid, meconium.
- Following an acute infection, SBV RNA can be detected up to several weeks in different tissues like semen, lymphatic organs, especially in mesenteric lymph nodes, spleen.

Occurrence

Some Orthobunyaviruses had previously been reported in Europe but viruses from the Simbu serogroup had never been isolated in Europe before 2011.

Schmallenberg virus was first detected in November 2011 in Germany from samples collected in summer/autumn 2011 from diseased (fever, reduced milk yield) dairy cattle. Similar clinical signs (including diarrhoea) were detected in dairy cows in the Netherlands where the presence of SBV was also confirmed in December 2011.

Since early December 2011, congenital malformations were reported in newborn lambs in the Netherlands, and SBV was detected in and isolated from the brain tissue. Up to now, The Netherlands, Belgium, Germany, United Kingdom, France, Luxembourg, Spain, Italy, Switzerland, Austria and Ireland have reported stillbirth and congenital malformations with PCR positive results. In addition, further spread of SBV to many other countries was reported.

For detailed information on the occurrence of this disease worldwide, see the OIE World Animal Health Information Database (WAHID) interface [http://www.oie.int/wahis/public.php?page=home].

DIAGNOSIS

Clinical diagnosis

Manifestation of clinical signs varies by species: bovine adults have shown a mild form of acute disease during the vector season, congenital malformations have affected more species of ruminants (to date: cattle, sheep, goat and bison). Some dairy sheep and cow farms have also reported diarrhoea.

- Adults (cattle)
  - Usually inapparent, but non-specific signs including the following:
    - Fever (>40°C)
    - Reduced milk yield
    - Diarrhoea
    - Individuals recover within a few days
    - Abortion

- Malformed animals and stillbirths (calves, lambs, kids)
  - Arthrogryposis/ Hydranencephaly
  - Brachygnathia inferior
  - Ankylosis
  - Torticollis
  - Scoliosis

The incidence of malformation varies depending on the stage of gestation at the time of infection and on the species. In some synchronised sheep flocks, the incidence can be high. However at the country level, the morbidity is not significant.

Lesions

In malformed newborn:

- Hydranencephaly
- Hypoplasia of the central nervous system
- Porencephaly
- Subcutaneous oedema (calves)

The clinical signs can be summarised as arthrogryposis and hydranencephaly syndrome (AG/HE)
**Differential diagnosis**

**For the acute infection of adults:**

The clinical signs are not specific. All possible causes of high fever, diarrhoea, milk reduction and abortion should be taken into account.

**For the malformation of calves, lambs and kids:**
- Other Orthobunyaviruses
- Bluetongue
- Pestiviruses
- Genetic factors
- Toxic substances

**Laboratory diagnosis**

**Samples**

Samples should be transported cooled or frozen

**From live animals for the detection of acute infection:**
- EDTA blood
- Serum
  - At least 2 ml, transported cooled

**From stillborns and malformed calves, lambs and kids:**
- **Virus detection:**
  - Tissue samples of brain (cerebrum and brainstem)
  - Amniotic fluid
  - From live newborn:
    - Amniotic fluid and placenta
    - (Meconium)
- **Antibody detection:**
  - Pericardial fluid
  - Blood(preferably pre-colostral)
- **Histopathology:**
  - Fixed central nervous system, including spinal cord

**Procedures**

**Identification of the agent**
- Real-time RT-PCR (Bilk et al., 2012); commercial PCR kits are available
- Cell culture isolation of the virus: insect cells (KC), hamster cells (BHK), monkey kidney cells (VERO)

**Serological tests on serum samples**
- ELISA: commercial kits available
- Indirect Immunofluorescence
- Neutralization test

For further information, reference material and advice, refer to Dr Martin Beer (Martin.Beer@fli.bund.de), Institute of Diagnostic Virology, Friedrich-Loeffler-Institut, Federal Research Institute for Animal Health, Greifswald-Insel Riems, Germany.

**Interpretation of the tests:**

Serological results (ELISA) for index cases should be confirmed by sero-neutralisation tests.

PCR-positive results for index cases should be confirmed by sequencing.
PREVENTION AND CONTROL

There is currently no specific treatment for Schmallenberg virus. Inactivated vaccines are commercially available in some countries.

Sanitary prophylaxis

Control of potential vectors during the vector-active season may decrease the transmission of virus. Rescheduling of breeding outside the vector season may decrease the number of foetal malformations.

REFERENCES AND OTHER INFORMATION

- ProMed Mail from Published Date: 2013-01-23 19:25:46: Subject: PRO/AH/EDR> Schmallenberg virus - Europe (07): (Germany) virus RNA bov semen ; Archive Number: 20130123.1511878


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The OIE will update this Technical Factsheet when relevant
# Additional Information

**MEAT**

**Relevant knowledge:** Only clinically healthy animals should be slaughtered. The viraemic period is very short. Transmission of the virus is by vectors.

**Risk of transmission to humans and animals:** Negligible

**MILK**

**Relevant knowledge:** Milk should only be collected from clinically healthy animals. The viraemic period is very short. Transmission of the virus is by vectors.

**Risk of transmission to humans and animals:** Negligible

**SEmen**

**Relevant knowledge:** Despite the very short viraemic period, SBV RNA could be detected in semen batches of SBV-infected bulls (Hoffmann et al, 2013 (a)). Furthermore, subcutaneous inoculation experiments proved the presence of infectious SBV in some of the PCR-positive bovine semen samples (Schulz, 2013 (b) submitted for publication).

**Risk of transmission to animals:** According to current knowledge, the risk is negligible for:
- semen batches collected before 31st of May 2011
- for semen batches from seronegative animals at least 28 days after semen collection.
- for semen batches tested for SBV-genome by an validated RNA-extraction method and RT-qPCR system.

**EMBRYOS**

**Relevant knowledge:** The viraemic period is very short. Embryos should be collected from clinically healthy animals. Akabane virus is classified under the category 4 (diseases or pathogenic agents for which studies have been done or are in progress that indicate that either no conclusions are yet possible with regard to the level of transmission risk; or the risk of transmission via embryo transfer might not be negligible even if the embryos are properly handled between collection and transfer).

**Recommendation:** Safety measures applicable to Akabane virus should thus be followed.

**Risk of transmission:** According to the current knowledge, the risk from sero-negative donor animals is negligible. Seropositive and PCR-negative donor animals at the day of insemination should be also considered with negligible risk.

**LIVE NON-PREGNANT ANIMALS**

**Relevant knowledge:** The viraemic period is very short. Mild clinical signs might occur. Transmission is by vectors.

**Risk of transmission:** Negligible for the following animals:
- PCR-negative after 7 days in a vector-free environment or,
- Seropositive and PCR-negative.

**LIVE PREGNANT ANIMALS**

**Relevant knowledge:** The virus can persist in the foetus; this may result in the birth of virus positive calves, lambs and kids.

**Risk of transmission:**
- Negligible for the offspring of animals held in a vector-protected environment tested with seronegative results after at least 28 days),
- Negligible for the offspring of animals seropositive before insemination,
- Undetermined for the offspring of all animals not covered by the previous bullets.