TECHNICAL REPORT

"Schmallenberg" virus: likely epidemiological scenarios and data needs[1]

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ABSTRACT

Following a request from the European Commission, the European Food Safety Authority (EFSA) issued a technical report on likely epidemiological scenarios in Europe in relation to a recently detected virus provisionally named "Schmallenberg" (SBV) virus (Simbu serogroup, Bunyaviridae family, genus *Orthobunyavirus*), found in ruminants. Clinical signs in adults are mainly mild or non-existent, but transient fever, loss of appetite, a reduction in milk yield and diarrhoea have been observed in association with the infection. The major clinical sign of SBV is congenital malformations in newborn animals similar to those observed in infections by Akabane virus. Germany, the Netherlands, Belgium, France and United Kingdom have reported confirmed cases. Due to limited information on the epidemiology of SBV, EFSA used a bluetongue virus (BTV8) model to assess whether SBV can spread into susceptible populations. BTV8 was chosen because: i) other Simbu serogroup viruses are primarily vector transmissible diseases as is BTV8, ii) BTV8 and SBV are circulating in the ruminant population iii) information is available regarding BTV8 in Europe whereas there has only been one case report for viruses of the Simbu serogroup in European Member States. The scenarios illustrate that whenever the number of vectors per host and the temperature are above a specific threshold, there is a possibility of disease epidemic in a susceptible population. In order to assess the situation in Europe and to refine the possible spread scenarios, knowledge of putative risk factors relevant for the disease transmission is necessary (including the immune status of the EU animal populations). EFSA proposes a coordinated data collection in all Member States in 2012 on the incidence and prevalence of the disease, number of malformed foetuses, as well as the presence of the virus in dams. Current knowledge suggests that it is unlikely that SBV can cause disease in humans; EFSA and ECDC are closely monitoring the situation in order to address public health concerns should these arise. EFSA will provide an overall assessment of the impact of SBV infection on animal health and welfare once further data become available from Member States.

Key words

Schmallenberg virus (SBV), Akabane virus, bluetongue virus (BTV8), genus Orthobunyavirus, epidemiological scenarios, data collection

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SUMMARY

Since autumn 2011, a previously unknown virus, provisionally named as "Schmallenberg" virus (SBV), has been reported in ruminants (cattle, sheep and goats) from Germany, The Netherlands, Belgium, the United Kingdom and France. In January 2012, the European Commission requested scientific assistance from EFSA under the provisions of Article 31 of Regulation (EC) No 178/2002. Among others, a preliminary analysis of the likely epidemiological scenarios that could be observed in the next months was requested, based on the existing knowledge of viruses of the Simbu virus serogroup and other vector borne epidemics in the region. This report provides likely epidemiological scenarios and data needed to improve the understanding of the disease spread and impact of SBV.

The report mainly focuses on animal health aspects. Current knowledge suggests that it is unlikely that SBV can cause disease in humans and as stated in the rapid risk assessment carried out by ECDC (ECDC, 2011). No additional information has since become available to invalidate this assessment. However, EFSA and ECDC are closely monitoring the situation in order to address public health concerns should these arise.

There is currently very limited knowledge specifically related to SBV. Available information on the SBV genome suggests that this virus is part of the Simbu serogroup of the Bunyaviridae family. SBV has been detected in ruminants. Main clinical signs observed in cattle are fever, loss of appetite, up to 50% reduction in milk yield and, in rare cases, severe diarrhoea, for approximately one week. SBV has also been detected in association with a variety of congenital abnormalities observed in stillborn or newborn lambs and calves.

In the absence of SBV specific knowledge regarding pathogenesis of SBV infection, an analogy was made with knowledge on Akabane virus, another representative of the of the Simbu serogroup. It is known that the pathogenic effects of infection with Akabane virus are only seen when the virus exceeds the geographical boundaries of the endemic area and infects susceptible animals in early stage of pregnancy. Such a situation is likely to occur at the edges of an endemic area and may be due to the movement of either infected hosts or infected vectors.

Without knowing the susceptibility to SBV in animal populations throughout the EU, and assuming that SBV induces a strong immunity similar to Akabane virus, three types of epidemiological situations can be envisaged: i) areas where a recent incursion might have occurred in populations not previously exposed to the pathogen, that is naïve populations, causing clinical disease in adult animals and, at a later date as consequence of infection of dams, malformation in foetuses; ii) areas where incursion occurred in the past and part of the ruminant population is immune and where congenital malformations are not observed or observed at a low level (mainly not reported); and iii) areas where no virus incursion occurred but a susceptible population is present. Surveillance data, as proposed in this report, should be collected by and shared between Member States in order to assess the immune status of animal populations, the impact of SBV infection, and further spread throughout EU. This should include data from serological surveillance also in areas where SBV has yet not been reported.

Due to limited information on the epidemiology of SBV, EFSA used a bluetongue virus (BTV8) model to assess under which conditions SBV could spread into susceptible populations. BTV8 was chosen because; i) BTV8 is an exclusively vector transmitted diseases as are other Simbu serogroup viruses ii) BTV8 and SBV are circulating in the ruminant population iii) information is available regarding BTV8 in Europe whereas there has only been one case report for viruses of the Simbu serogroup in Europe. Assuming that SBV is a non-direct transmissible, vector borne, infectious disease, that vector parameters for the spread of SBV are those for BTV8, and using indications on SBV viraemia given by a preliminary experimental infection in cattle, the hypothetical scenarios show that, depending on the temperature and the number of vectors, SBV might spread further in susceptible populations. Whenever the number of vectors per host and the temperature are above a specific threshold there is a possibility of a wider disease epidemic affecting more Member States. EFSA

proposes a coordinated data collection in all Member States in 2012 on the incidence and prevalence of the disease, number of malformed foetuses, as well as the presence of the virus in dams.

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BACKGROUND AS PROVIDED BY EUROPEAN COMMISSION

Over the last few weeks, exchanges of information from the Member States indicate that a recently detected virus circulated in the EU in the second semester of 2011 in domestic ruminants (cattle, sheep and goats) and in wild ruminants. The virus has been provisionally named "Schmallenberg" virus. The information available on the SBV virus genome suggests that this virus is part of the Simbu serogroup of the *Bunyaviridae* family, genus *Orthobunyavirus*, and that this virus causes non-specific clinical signs in cattle and congenital malformations, at the moment mainly in sheep and less frequently in goats.

The technical working group organised by the Commission services on 20 January 2012, in which EFSA participated, discussed the scientific assistance that the Commission and Member States may need in relation to this virus.

In particular, it was concluded that EFSA could assist the Commission and the Member States by means of the preparation of reports on the epidemiological situation based on the data gathered by the Member States.

Therefore, in the context of Article 31 of Regulation (EC) No 178/2002, EFSA has been asked to provide scientific assistance to the Commission.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested to deliver:

1. A preliminary analysis of the likely epidemiological scenarios that could be observed in the next months, based on the existing knowledge on viruses of the Simbu virus serogroup and other vector borne epidemics in the region. This preliminary analysis should be provided by 6 February 2012 to be able to share it with the Member States at the SCoFCAH meeting organised on 7 February 2012.

2. An analysis of the epidemiological data already available, taking also into account the expected seasonal pattern of virus circulation. This analysis should also include the information on the transmission routes for the virus. A first report should be produced by 31 March 2012, followed by regular updates on the epidemiological situation, every two months.

3. Guidance on data to be collected in Member States in order to optimise coordination to address this request. This may include the development of a case definition, data sets at both individual and herd level and minimum reporting guidance on epidemiological investigations to facilitate a future assessment of the impact of the infection and the risk of spread.

4. A report on the overall assessment of the impact of this infection on animal health, animal production and animal welfare together with a characterisation of the pathogen by 31 May 2012. This report will also need to be regularly updated but at a later stage.

At this stage there is no evidence that this virus is able to cause disease in humans, as indicated in the risk assessment carried out by the ECDC, however, EFSA and ECDC should maintain contact in order to address public health concerns, if any. EFSA will ensure full coordination and synergy when carrying out the tasks mentioned above with the Commission and the Member States' veterinary authorities.

The use of the EFSA Data Collection Framework (DCF) as a data exchange portal will be a valuable asset to collect information from Member States in a structured manner, with a view to its use for further risk assessment, but this will need to be coordinated with DG SANCO. This request should be kept under review with the aim of adapting it in the light of the evolution of the infection and the information that will become available in the coming weeks and months.

SCOPE

This report addresses ToR 1 and 3. Based on the limited information available, hypothetical epidemiological scenarios that may be observed in the next months are presented, assumptions and uncertainties discussed while data needs to improve the understanding of the disease spread and impact of the "Schmallenberg virus" (SVB) are highlighted.

The report focuses on animal health and welfare aspects since the first risk assessment carried out by ECDC indicated it is unlikely that this new virus can cause disease in humans (ECDC, 2011). However, EFSA and ECDC are closely monitoring the situation in order to address public health concerns, should these arise.

ASSESSMENT

1. Introduction

A previously unknown virus of the *Bunyaviridae* family, provisionally named "Schmallenberg" virus (SBV), has been reported as from November 2011 in ruminants (cattle, sheep and goats) in Germany and The Netherlands, followed by Belgium, the United Kingdom and France. Information on the situation before November 2011 is not available, due to absence of a test for direct or indirect detection of the virus.

Available information on the SBV genome suggests that this virus is part of the Simbu serogroup of the *Bunyaviridae* family, genus *Orthobunyavirus* (Hoffman et al., 2012). The genome of *Orthobunyavirus* viruses consists of three segments (S, M, and L) which encode for at least 5 proteins. Sequence comparisons show that the most similar sequences to SBV were from a Shamonda virus for the S segment, an Aino virus for the M segment and an Akabane virus for the L segment. As the phylogenetic analysis performed on the S segment confirmed highest genetic similarity to Shamonda virus within the Simbu serogroup (Hoffman et al., 2012), the designation of Shamonda-like virus has also been used for SBV.

Viruses of the Simbu group have mostly been reported from Asia, Australia, Africa and the Middle East. Akabane virus has been reported in cattle in Turkey (Taylor and Mellor, 1994). Based on serological evidence, authors conclude that the virus was present in some areas of the south Turkish coast in 1979 and 1980 but that it probably did not persist into 1981. According to Taylor and Mellor (1994), the failure of Akabane virus to persist in southern Turkey for more than two years indicated that this area was open to epidemic rather than endemic infection. Neutralizing antibodies of Akabane virus were detected in serum samples of sheep, goats and cattle from Cyprus from 1970 onwards (Sellers and Herniman, 1981).

Since other viruses of the Simbu serogroup are transmitted by insects (*Culicoides* midges and mosquitoes), it is likely that SBV virus is also transmitted by these insects but this has not been confirmed yet. A confirmation of the vector species that can transmit SBV and information on their distribution is needed. Without experimental infection studies to refute the hypothesis of direct transmission from animal to animal, direct transmission cannot be excluded.

Viruses of the Simbu group have mostly been found in ruminants. SBV has been detected in cattle, sheep, goats and in one bison (FLI, 2012). It is unknown whether other species are susceptible to SBV.

Clinical signs of SBV infection in adult animals are either absent or are non-specific. Main clinical signs observed in cattle are fever, loss of appetite, up to 50% reduction in milk yield and, in rare cases, severe diarrhoea, with a duration of approximately one week. These clinical signs were observed from August onwards, coinciding with the density peak of the putative vectors. Based on a preliminary experimental infection study, the viraemic stage in cattle seems to be short (viral detection was negative in all 3 infected animals 6 days post inoculation) and clinical signs subside within a few days (Hoffman et al., 2012).

SBV has been detected in malformed foetuses, stillborn or newborn lambs, calves and goat kids regularly born at term. The most common malformations are severe arthrogryposis, torticollis, brachygnathia, hydrocephalus and other severe brain malformations.

Altogether, the clinical picture to which SBV has been associated is very similar to that of infections with Akabane and Aino virus. The malformations induced by viruses of the Simbu serogroup are designated arthrogryposis hydranencephaly syndrome (AHS) (Coverdale et al., 1979; Inaba and Matumoto, 1981). In some cases, varying degrees of encephalitis may occur in both acute infections and newborns infected with Akabane Virus (Uchida et al., 2000; Kono et al., 2008).

Akabane virus is able to cross the ruminant placenta and should this happen in a specific stage of pregnancy, a variety of congenital abnormalities (AHS) are seen at parturition. In adult ruminants, Akabane infection appears to be subclinical or of light clinical manifestation. In endemic areas most adult animals would have acquired an active immunity sufficient to prevent the virus from reaching the developing foetus. The pathogenic effects of infection with Akabane virus are only seen when the virus exceeds the limits of the endemic area and infects susceptible animals in early stage of pregnancy. Such a situation is likely to occur at the edges of an endemic area and may be due to the movement of either infected hosts or infected vectors (Taylor and Mellor, 1994).

2. Epidemiological situation in Member states

The detection of SBV in 2011 has been associated with clinical signs in adult cattle, which were observed in summer and early autumn, and with congenital malformations in newborn animals, mainly lambs, starting from mid-December 2011.

Germany, the Netherlands, Belgium, France and United Kingdom are currently reporting suspected cases followed by confirmatory testing by reverse transcriptase quantitative PCR (RT-qPCR). A neutralization test and indirect immuno-fluorescence have been developed however, these assays are not appropriate for large scale sero-surveillance.

Various case definitions are being used by different Member states (MS) (Table 1). All affected MS are publishing reports for holdings where the virus has been confirmed for goats, sheep and cattle at a regional level (Table 2).

Table 1: Case definitions for suspicion of infection with SBV currently used in the affected Member States

MS	Adult animal	Offspring
DE	N/A	Increased occurrence of malformations of the arthrogryposis hydranencephaly syndrome (AHS) in calves and lambs.
NL	Acute diarrhoea, dip in milk production, fever or any other clinical suspicion notified by farmers who ask for exclusion of SBV (as cause of the clinical problems) by diagnostic testing of (blood) samples.	Any malformed calf, goat-kid or lamb.
BE	Cattle with high temperature, drop in milk production and diarrhoea.	Sheep, goats, cattle: abnormally high rate of stillbirths or abortions, birth defects such as malformations of the joints, hydrocephalus.
UK	N/A	Arthrogryposis or profound congenital nervous signs (obtundation ("dummy" presentation), blindness or marked paresis / paralysis) in a ruminant neonate or foetus and, in addition, for neonates and foetus from ruminant dams imported from mainland Europe in 2011, any stillbirth, weakness or disease with nervous signs.
FR		Within the known range of SBV cases, cattle, sheep or goat:

		(i) abortion or malformed newborn (arthrogryposis, shortening of the hamstrings, deformation of the jaw, hydranencephaly torticollis, etc.) or (ii) newborn with neurological disorders (flaccid paralysis, exaggerated movements, irritability, trouble feeding, ataxia, etc.). Outside the known range of SBV cases: second case (or more) of cattle, sheep or goat (i) abortion or malformed newborn, (arthrogryposis, shortening of the hamstrings, deformation of the jaw, hydranencephaly, stiff neck, etc.) or (ii) of newborns with neurological disorders (flaccid paralysis, exaggerated movements, irritability, trouble feeding, ataxia, etc.), occurring in the same farm during a quarter. Suspected case followed by confirmation by RT-qPCR

Table 2: Reported confirmed SBV cases (holdings where the virus has been confirmed as of February 03 2012)

	NL	**DE**	**BE**	**UK***	**FR***
Cattle	3	7	4	-	-
Sheep	85	263	75	11	50
Goat	5	10	1	-	-
Locations	All provinces except for province of Utrecht	North Rhine-Westphalia, Lower Saxony, Schleswig-Holstein, Rhineland-Palatinate Baden-Wuerttemberg, Brandenburg, Thuringia, Saxony-Anhalt, Hamburg, Bavaria	Most provinces with a greater density in north west Belgium	Norfolk, Suffolk, East Sussex, Essex and Kent	North of France: Aisne, Aube, Calvados, Haute-Marne, Meurthe-et-Moselle, Meuse, Moselle, Nord, Oise, Pas-de-Calais, Bas-Rhin, Seine-Maritime, Somme, Vosges

*BE data for Feb. 01 2012, UK data for Jan. 31 2012

The latest epidemiological information can be found on the relevant competent authority web sites (Table 3).

Table 3: URL links to SBV information in the MS,

DE	http://www.fli.bund.de/en/startseite/current-news/animal-disease-situation/new-orthobunyavirus-detected-in-cattle-in-germany.html
NL	http://www.government.nl/ministries/eleni/news/2012/01/24/schmallenberg-virus-found-in-two-calves.html
BE	in Dutch: http://www.favv.be/dierengezondheid/schmallenberg/ in French: http://www.favv.be/santeanimale/schmallenberg/default.asp in German : http://www.favv.be/tiergesundheit/schmallenberg/ .
UK	http://www.defra.gov.uk/animal-diseases/a-z/schmallenberg-virus/
FR	http://agriculture.gouv.fr/maladies-animales,11003

3. Possible period for detection of further cases of malformed ruminant foetuses

The number of cases being reported as suspect or confirmed may be biased. The numbers could be influenced by the level of awareness amongst farmers and veterinarians, by diagnostic capacity in the different Member States, as well as by seasons for calving and lambing. It is extremely difficult to come up with reliable science-based predictions of future cases due to limited specific knowledge about SBV. Predictions therefore rely on assumptions that SBV infections may lead to situations similar to those observed for other members of Simbu serogroup, namely Akabane virus, and spread of infection might occur only during the period when a sufficient number of vectors is available (vector season).

Assuming that SBV acts in their ruminant hosts in a similar way to other viruses of the genus *Orthobunyavirus*, in particular Akabane virus, of which the major animal health and welfare impacts consist in the development of malformations in foetuses and subsequent increase in dystocia. If infection occurs prior to pregnancy a normal pregnancy is expected to occur. Malformations in foetuses are observed when the infection occurs during a vulnerable stage of the pregnancy. In analogy to Akabane virus, the vulnerable stage of pregnancy may be between days 28 and 36 in sheep and between days 75 and 110 in cattle (FLI, 2012). In pregnant sheep, the gestational period for the occurrence of foetal abnormalities has been shown to vary from 30-36 days to 30-50 days (Hashinguchi et al., 1979; Parsonson et al., 1977 and 1981). This variation in the reported results has been ascribed to i) differences in the virulence of virus strains used, ii) differences in the passage level of the virus strain used, or iii) differences caused after growth of the virus in the arthropod vectors. Inoculation of pregnant cattle with virus between 62 and 96 days of gestation resulted in foetal lesions; in pregnant goats, the critical period in the gestational cycle was at about 40 days (Kurogi et al., 1977 a and b).

Considering these assumptions it could be expected that further cases resulting from infection by vectors during the period of vector activity, April to November, are still to be observed.

The lambing seasons varies considerably between different production systems and MS. For cattle the reproduction system in place depends on the production type. Considering an average gestation period of 150 and 280 days respectively for sheep/goats and cows it could be expected that the majority of the deformed lambs/kids would be born from December to February and the majority of deformed calves between March and May (Table 4).

Table 4: Expected period for detection of further cases based on infection time and gestation duration

Animal species	Infection April 2011	Infection August 2011	Infection October 2011
Lambs	August 2011	December 2011	February 2012
Calves	November 2011	March 2012	May 2012
Goat Kids	August 2011	December 2011	February 2012

4. Likely epidemiological scenarios

A preliminary analysis of the likely epidemiological scenarios that could be observed in the next months, based on the existing knowledge on viruses of the Simbu virus serogroup and other vector borne epidemics in the region is presented.

It is known that Akabane virus induces strong immunity in infected animals. Without knowledge about the immune status and the number of tested animals it is impossible to assess the true status of the population. Assuming that SBV induces strong immunity as does Akabane virus, there are three possible situations in relation to SBV infection status in different EU ruminant populations:

A: Areas where a recent incursion might have occurred in a naïve population causing clinical disease in adult animals and malformation in lambs and calves.

B: Areas where incursion occurred in the past and part of the ruminant population is immune and where congenital malformations are not observed or observed at a low level (mainly not reported).

C: Areas where no virus incursion has occurred and a susceptible population is present.

Assuming that the virus would persist (e.g. in infected offspring, in the vectors) in the areas where it is now present (reported or not) and that SBV is exclusively transmitted by vectors, viral circulation would restart in the vector season 2012.

4.1. Disease spread scenarios

To estimate how SBV could spread we need to know the disease specific threshold conditions. These conditions determine whether the infection will spread in a susceptible population (situation C) when it is introduced.

The threshold conditions that determine whether an infectious disease will spread in a susceptible population when introduced are characterized by the so called $\mathbf{R_0}$ (basic reproduction number). The concept of $\mathbf{R_0}$ (Ross, 1909), is defined such that if $\mathbf{R_0} < 1$, the modelled disease dies out, and if $\mathbf{R_0} > 1$, the disease spreads in the population.

The biological meaning of the reproductive number is the average number of secondary cases produced by one infected individual during the infected individual's entire infectious period when the disease is first introduced (Figure 1).

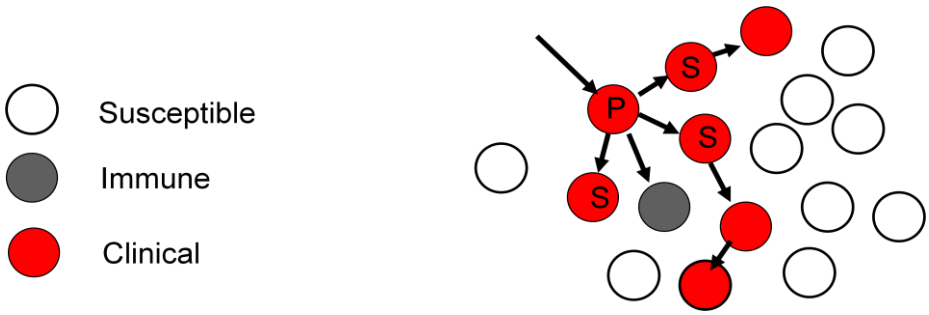

Figure 1: Transmission process and its relation with the basic reproductive number. P is referring to a primary case and S to a secondary case.

Let **r** be the average number of contacts per unit of time per individual, β be the probability of transmitting the infection per contact, and τ be the mean duration of the infectious period. Then the $\mathbf{R_0}$ can be estimated by:

$$R_0 = r \cdot \beta \cdot \tau$$

This formula can give insight into the transmission dynamics of infectious diseases for various relatively simple epidemiological models and $\mathbf{R_0}$ can be estimated from experimental data. However, as more heterogeneous structures or subgroups for the infected population are included in an epidemiological model and transmission of infection involves a vector, the calculation of $\mathbf{R_0}$ becomes more complicated, and it is difficult to find an explicit formula for $\mathbf{R_0}$.

4.1.1. Hypothetical SBV spread scenarios

SBV has been detected in association with clinical cases in ruminants. SBV is similar to viruses of the Simbu serogroup which are exclusively transmitted by mosquitoes and *Culicoides* biting midges.

The most important recent vector borne epidemic in Europe occurred during 2007-2009 with the incursion of bluetongue virus (BTV8). BTV8 is a non-direct transmissible vector borne infectious disease of ruminants transmitted by *Culicoides* biting midges. Considerable data regarding BTV 8 spread in Europe is available. Hence the preliminary modelling of the likely epidemiological scenarios that could be observed in the next months is mainly based on the data available for BTV8.

Rationale behind the use of BTV8 information and model to construct epidemiological scenarios:

- BTV8 is an exclusively vector transmissible disease as are Simbu group viruses
- BTV8 and SBV are circulating in the ruminant population
- Information is available regarding BTV8 in Europe whereas there has only been one case report for viruses of the Simbu group in Europe.

To provide hypothetical scenarios on how $\mathbf{R_0}$ is influenced by the temperature, the number of vectors per host and the duration of the viraemia, we used the model presented by Gubbins et al. (2008), which was developed to estimate the number of secondary cases of BTV8 in UK. We assumed that the transmission mode of SBV is similar to that of BTV8 and that similar vectors are involved in the transmission and spread. The parameters used in this scenario assessment are based on the information provided in Table 4. Further information about the assumptions made to estimate the number of secondary cases is described in the following section.

4.1.1.1. Hypothetical SBV spread scenarios – Modelling Assumptions

In order to generate possible epidemiological scenarios in relation to the spread of the virus, several modelling assumptions were made:

- The EU ruminant population is susceptible.
- SBV infection is assumed to be exclusively vector-transmitted and the transmission is similar to that of BTV8.
- Vectors are evenly distributed over the whole of Europe.

Parameters used in the model are assumed to be the same as those used for BTV 8 (Gubbins et al., 2008), except for the viraemia duration, taken from Hoffman et al. (2012). Furthermore, it was assumed that the viraemia duration was the same for both cattle and sheep, the proportion of bites for cattle and sheep were considered to be 0.5 for each species and no mortality in the ruminant hosts was considered (more details can be found in Table 5).

Table 5: Parameters in the transmission model. (adapted from Gubbins et al. 2008)

Description	Symbol	Estimate or range	Comments	References
Probability of transmission from vector to host	*b*	0.8–1.0	Used mid point (0.9)	O'Connell (2002)
Probability of transmission from host to vector	β	0.001–0.15	Used midpoint (0.0755)	Nunamaker et al. (1997), Gerry et al. (2001) and Carpenter et al. (2006)
Biting rate on species i	a_i	0.5		
Reciprocal of the time interval between blood meals	a	0–0.5	Depends on temperature: $a(T)=0.0002T(T-3.7)(41.9-T)^{1/2.7}$, Mullens et al. (2004)	Birley & Boorman (1982), Braverman et al. (1985), Mullens & Holbrook (1991) and Mullens et al. (2004)
Proportion of bites on cattle	φ	0.5		
Vector preference for cattle compared to sheep	σ	0–1	Vectors feed preferentially on cattle based on data for *C. imicola*. We have assumed that there is not a preference for cattle or sheep	Nevill (1979) and Braverman et al. (2003)
Ratio of vectors to cattle	m_C	0–250	Based on a maximum host biting rate ($m_i a_i$) of 2500 bites per host per day; cf. median holding size of 60 breeding cattle (census data) and light-trap catches of 0–5000 midges per trap day (P. S. Mellor 1993, unpublished data, from Pirbright, UK)	Gerry et al. (2001)
Ratio of vectors to sheep	m_S	0–250	See comments for vector to cattle ratio; cf. median holding size of 270 breeding ewes (census data) and light-trap catches of 0–5000 midges per trap day (P. S. Mellor 1993, unpublished data, from Pirbright, UK)	
Duration of viraemia (cattle)	V_C	1-6d	-	Hoffman et al. (2012)
Duration of viraemia (sheep)	V_S	1-6d	-	
Disease-induced mortality rate (cattle and sheep)	$d_S=d_C$	0	No observed mortality in sheep or cattle	
Vector recruitment rate	ρ	—	$\mathbf{R_0}$ does not include this parameter (see electronic supplementary material, appendix A)	
EIP mean no. stages	1/ν k	4–26 1–100	Depends on temperature: $\nu(T)=0.0003T(T-10.4)$, Mullens et al. (2004)	Gerry & Mullens (2000), Wittmann et al. (2002) and Mullens et al. (2004)
Vector mortality rate	μ	0.1–0.5	Depends on temperature: $\mu(T)=0.009\exp(0.16T)$, Gerry & Mullens (2000)	Birley & Boorman (1982), Braverman et al. (1985), Gerry & Mullens (2000) and Wittmann et al. (2002)

4.1.1.2. Hypothetical SBV spread scenarios - Results

The model output indicates that the spread of the disease would mainly depend on both temperature and number of vectors per host, assuming that SBV is exclusively vector-transmitted and transmission is similar to that of BTV8.

The longer the viraemia, the smaller the number of vectors per host that is necessary to obtain a $\mathbf{R_0}$ >1 ($\mathbf{R_0}$ > indicates that the disease would be expected to spread in a susceptible population) (Figure 2).

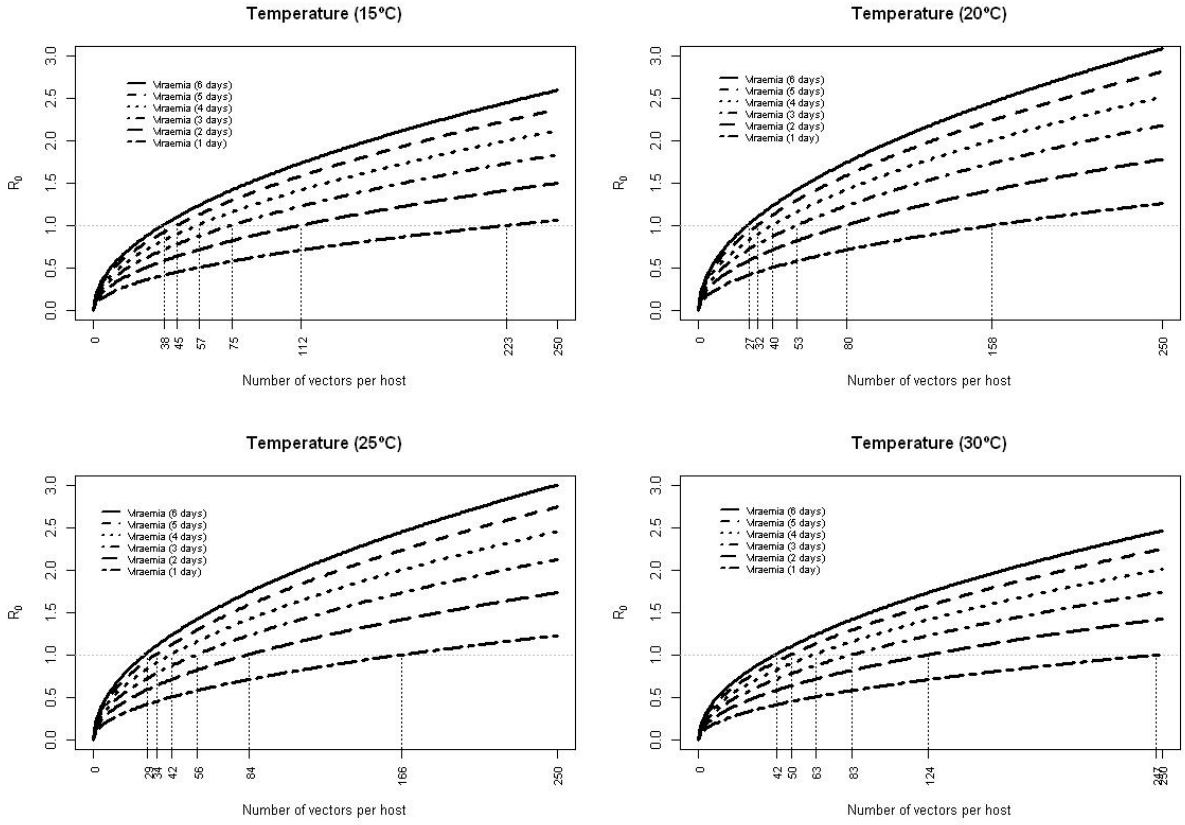

Figure 2: Estimation of the basic reproduction number ($\mathbf{R_0}$), based on different temperatures, number of vectors per host and duration of the viraemia. The X-axis displays the numbers of vectors per host that are needed for R0>1 (disease will spread in a susceptible population) for different viraemia durations.

The environmental temperature also plays an important role. A quadratic association is expected; the number of vectors per host needed for the disease to become epidemic will decrease if the temperature increases up to a certain threshold, which depends on the viraemia duration. Above the threshold, an increase of the number of vectors per host is needed for the disease to spread in a susceptible population (Figure 3).

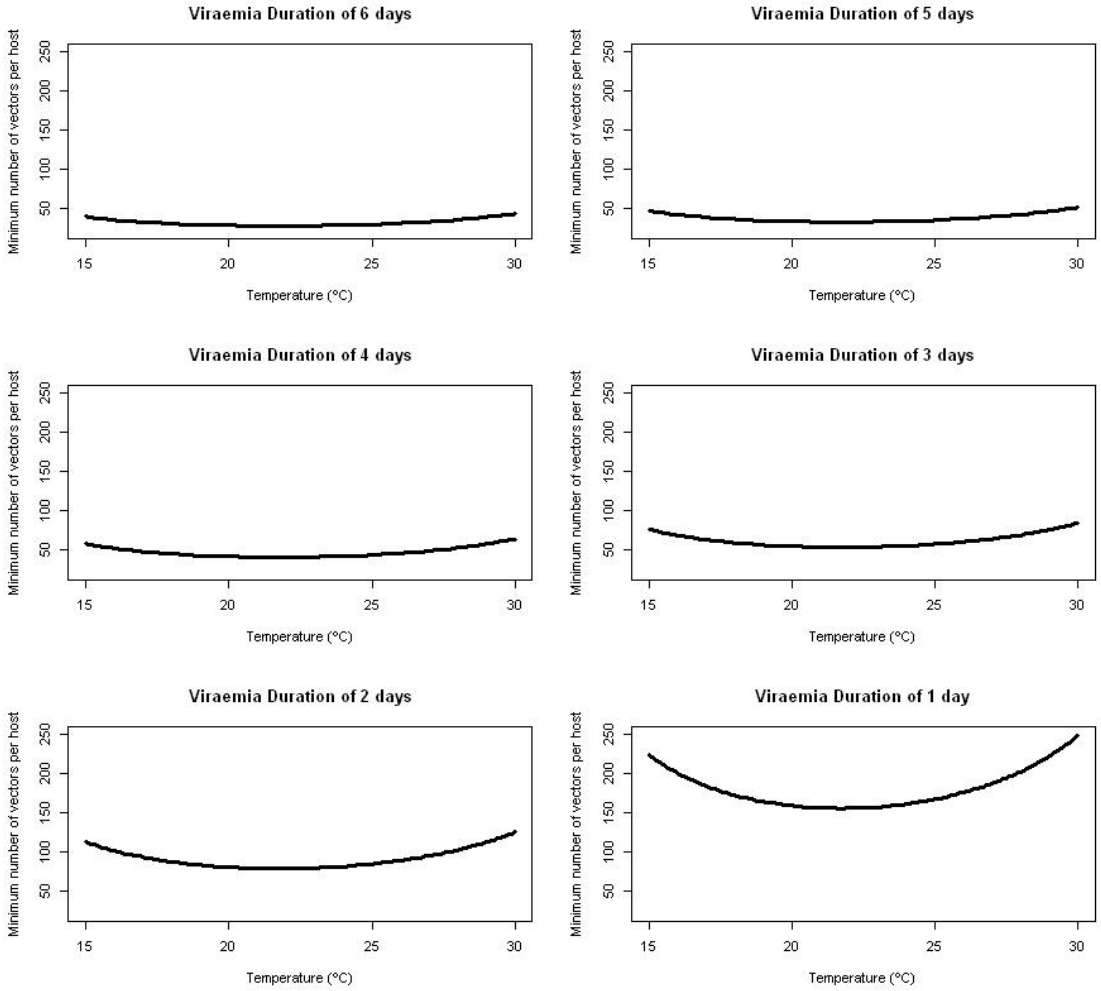

Figure 3: Relationship between temperature and minimum number of vectors per host needed to have R0 >1 for different viraemia durations.

As the temperature plays an important role in the prediction of possible disease spread, historical climate data (1950-2000) from http://www.worldclim.org/ was used to calculate the average temperature for the month of May. The month of May was selected in order to be able to reassess the scenarios when more information becomes available.

The latter was used to construct possible scenarios in terms of likelihood of spread of SBV in European areas for different assumed number of vectors per host ($n_1 < n_2 < n_3$). If the number of vectors per host is n_1 the spread of SBV in Europe is unlikely to be observed, considering the temperatures for the month of May (Figure 4). Whenever the number of vectors per host is n_3 or n_2 the spread of SBV would be likely indicating that the disease can spread to certain areas in Europe (Fig. 5 and 6).

Considering the historical average temperatures for May, for any of the number of vectors per host used, there will be areas in North Europe where the likelihood for spread could be considered negligible (Figure 5).

The spread model assumes a not previously exposed population which is therefore fully susceptible. These hypothetical scenarios illustrate possible situations in terms of likelihood of spread depending on the temperature and the number of vectors per host in order to facilitate the transmission from animals within a herd as well as animals between herds.

Figure 4: Scenario I for spread of SBV in Europe based on the average temperature in the month of May, considering n_1 vectors per host.

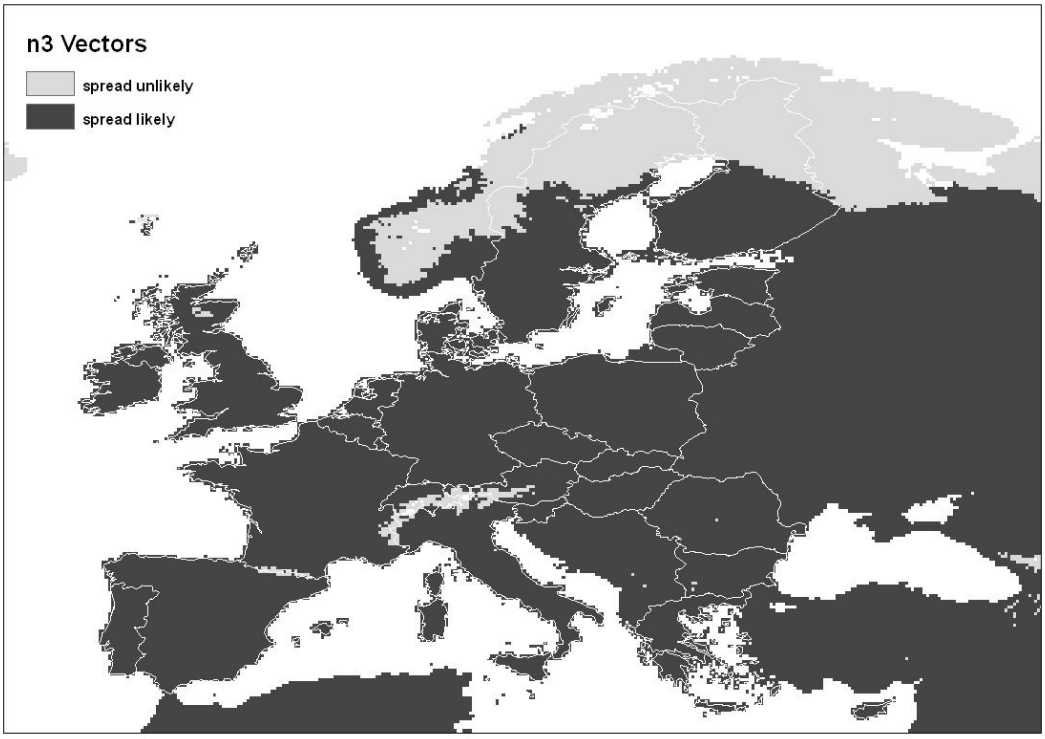

Figure 5: Scenario II for spread of SBV in Europe based on the average temperature in the month of May, considering n_3 vectors per host.

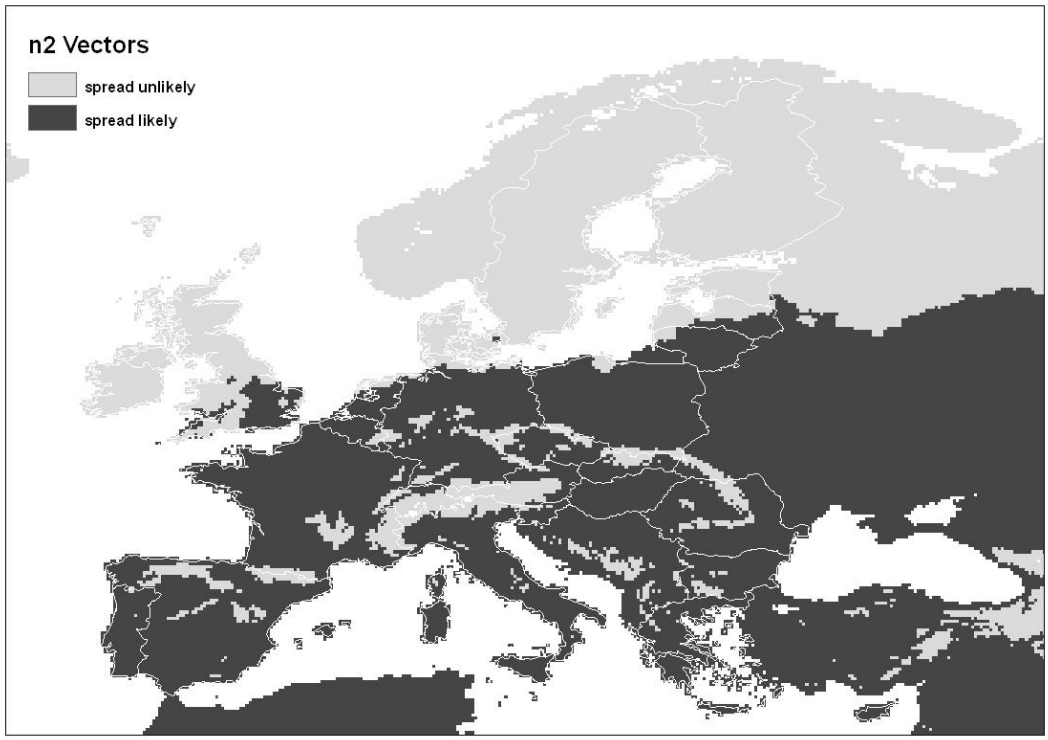

Figure 6: Scenario III for spread of SBV in Europe based on the average temperature in the month of May, considering n_2 vectors per host.

5. Uncertainties

Viraemia duration in naturally infected animals and the range of susceptible species is currently unknown. At this stage it is impossible to exclude other routes of transmission such as direct transmission and the epidemiological role of transplacental transmission on the spread of disease but we also do not know if SBV can be transmitted vertically (i.e. transmitted from parent to offspring) in the vector.

The importance of risk factors related to animal production and management such as exposure to vectors or gestation period at the time of infection are also not fully understood.

The current epidemiological situation is unclear for several reasons. Our knowledge on the geographical distribution of the disease is based on the reported cases, mainly of lambs, calves and kids showing malformations of the AHS type with laboratory confirmation of SBV infection by RT-qPCR.

It cannot be excluded that a much larger geographical area is affected due to under reporting. At a European level, notification is currently not obligatory in all MS. Case definitions, if available, vary between countries but are generally based on the identification of malformations in newborns or still born animals. Diagnostic confirmation is done by RT-qPCR, a test which is not completely validated. A first assay from the FLI-Institute was updated by a second test with an optimized performance; both assays are under further validation. However, the tests proved to be sensitive and specific as well as reproducible as repeatable in several laboratories and were used for the testing of several hundreds of samples including samples from the first animal experimental infection trials. Antibody detection is at the moment restricted to the virus neutralisation test and the indirect immune-fluorescence test (iIF) hence a high throughput antibody detection serological tool to be used in large scale surveys is not available. Therefore, at this point in time, the prevalence of infection cannot be estimated.

6. Data needs

In order to assess the situation in Europe and to refine the possible spread scenarios, knowledge of putative risk factors relevant for the disease transmission is necessary (including the immune status of the EU population).

This means that information about the factors that could influence the spread of the disease should be collected (including serological surveillance data in areas where SBV has yet not been reported), as well as information in relation to the possible animal health and welfare impact of the spread of the disease. In order to study impact, information on the incidence or prevalence of the disease in the population, number of malformed foetuses, as well as the presence of the virus in dams during the most likely period of foetal infection during gestation leading to the malformations observed should be recorded for the rest of the year 2012. This will allow to quantify the numbers of newborn malformed animals and its relation to the number of infected mothers during the gestation period. Details about data needs are described in appendix A.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

1. There is currently no knowledge of the susceptibility to SBV infection in animal populations throughout the EU. In analogy to Akabane virus that induces a strong immunity, three types of epidemiological situations could be identified, based on the infection status of animals with regards to SBV:

    a) Areas where a recent incursion might have occurred in a naïve population, causing non-specific clinical disease in adult animals and malformation in lambs, goat kids and calves.

    b) Areas where incursion occurred in the past and part of the ruminant population is immune and where congenital malformations are not observed or observed at a low level (mainly not reported).

    c) Areas where no virus incursion has yet occurred and a susceptible population is present.

    In order to assess the immune status of animal populations in all Member States, surveillance data at country level is required.

2. Due to limited information on the epidemiology of SBV, a bluetongue virus (BTV8) model was used to assess whether SBV can spread into susceptible populations. The hypothetical epidemiological scenarios when animal population across Europe are susceptible (as in situation 1c above) are based on the following assumptions:

    a) SBV infection is responsible for the clinical syndromes reported.

    b) SBV is a non-direct transmissible, vector-borne, infectious disease, only infecting ruminants.

    c) Vectors and vector parameters involved in the estimation of spread of SBV are those for BTV8.

    d) The parameters for viraemia duration of SBV are based on a preliminary experimental study on cattle.

    The results from the hypothetical scenarios show that depending on the temperature and the number of vectors, SBV might spread further in susceptible populations. Whenever the number of vectors per host and the temperature are above a specific threshold there is a possibility of disease epidemic.

3. The possibility of direct transmission (animal to animal) cannot be excluded at the moment although all virus of the Simbu serogroup are transmitted primarily by arthropod vectors.

4. A rapid risk assessment carried out by ECDC in 2011 concluded that it is unlikely that SBV can cause disease in humans. No further information is available to counter this conclusion.

RECOMMENDATIONS

1. Surveillance data, as proposed in Appendix A, should be collected and shared between Member states in order to assess the impact of SBV infection at EU level and its further spread. This should include data from serological surveillance also in areas where SBV has not been reported yet.

2. It is recommended that a harmonized case definition is used in all MS in order to facilitate data comparison and analysis at the European level.

3. Information is needed:

    a) Serodiagnostic tests (e.g. ELISA) to detect past exposure to SBV in animal populations in Member States

    b) Evaluation of immunity status, including an assessment of whether adult animals exposed to infection develop a strong and long-lasting immunity to SBV

    c) Transmission routes, including improved estimates of viraemia duration, vector competency and vertical transmission in vectors, as well as direct and transplacental transmission in ruminant hosts

4. It is recommended that close monitoring of possible public health impact is continued by ECDC and EFSA and the situation reassessed in light of any further scientific/epidemiological findings.

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APPENDIX

A. DATA COLLECTION

Notification at a European level is currently not obligatory but there is a need for harmonised case definitions and quantification of epidemiological parameters to allow for assessing impact and spread of this emerging disease in animals.

Population
The virus has been detected in cattle, sheep, goats and bison. The data should be reported for cattle, sheep or goats, other ruminant animals and closely related species.

Reporting period
First symptoms were reported in cattle in Germany in summer and early autumn 2011 (Hoffman et al, 2012). The reporting period is therefore defined as August 2011 to the date of transmission of data. A full epidemiological report of with numbers of observations starting from August 2011 should be transmitted. Upon receipt of an updated report from a country the previous report will be deprecated.

Case definitions:

Foetuses and neonates

Suspect case: Arthrogryposis hydranencephaly syndrome (AHS) in ruminants (stillbirths, premature births, mummified fetuses, and dysfunctions or deformities of foetuses or liveborn neonates including arthrogryposis, hydranencephaly, ataxia, paralysed limbs, muscle atrophy, joint malformations, torticollis, kyphosis, scoliosis, behavioural abnormalities and blindness)

Confirmed case: Confirmation of viral infection by RT-PCR, Viral isolation or other method of pathogen detection

Past Infection cases in dams

Suspect case: Ruminants with pregnancies resulting in AHS

Confirmed case: Confirmation of viral infection by ELISA or other method of indirect detection.

Adult animals

Confirmed case: Confirmation of viral infection by RT-PCR, Viral isolation, ELISA or other method of pathogen or indirect detection.

Herd case definition

Any herd with one of more of the case definitions above that is confirmed

Samples and Laboratory Methods

Pathogen detection: Pathogen detection is done by real-time RT-PCR or virus isolation.
Samples for pathogen detection in acute infection - serum or EDTA blood samples when clinical signs are observed (fever, drop in milk yield, diarrhoea).
Samples for pathogen detection in foetuses, abortions, stillbirths and malformed ruminants- brain plus supplementary samples of spleen and blood.

Indirect detection: Antibody detection by indirect immuno-fluorescence, virus neutralization test or other serological tests as they become available.
Samples for indirect detection - serum samples are recommended (EDTA blood samples are less suitable for the neutralization test)

Reporting guidelines minimum dataset
The following is a recommendation for the minimum dataset at herd/flock level to be reported based upon data currently being collected within the affected member states.

Unique herd identifier – Provide a code to uniquely identify the herd/flock within the reporting country. The code should be designed to ensure the individual farm remains anonymous but still allows the reported data to be linked with other EU level datasets e.g. Trade Control and Expert System.

Location – report the geographical location of the herd/flock
Countries should be encoded using the standard ISO-3166-1-alpha-2 coding system. Described in the COUNTRY catalogue.

Additional geographical detail about the region where the herd/flock is located can be specified using the Nomenclature of territorial units for statistics (NUTS) code (as described in NUTS catalogue). http://epp.eurostat.ec.europa.eu/portal/page/portal/nuts_nomenclature/introduction

The two catalogues (COUNTRY, NUTS) are published on the EFSA website http://www.efsa.europa.eu/en/efsajournal/pub/1457.htm in the standard sample description excel file for download.

Animal species – report the code and the text describing species of animal in the herd/flock selected from the catalogue below

Species catalogue

code	***name***
9281	Alpine chamois
11681	Barbary sheep
1601	Bison
14001	Buffalos
81	Camels
6581	Cattle (bovine animals)
1401	Deer
6761	Goats
14081	Lamas
11501	Mouflons
22101	Mountain goats
281	Reindeers
10061	Sheep
2861	Solipeds, domestic
6821	Water buffalos
10041	Wild boars

Production system – indicate whether the type of production on the farm is “controlled housing conditions and integrated production systems” as described the Appendix A Regulation (EC) 1244/2007 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain

products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:281:0012:0018:EN:PDF)

Animal Movements – indicate whether new animals were introduced to the farm in spring or summer of 2011

Date of first suspicious report – report the year, month and where available the day of the first report of a case according to the case definitions above within the herd/flock

Herd statistics – report the number of animals in the herd/flock for each of the categories in the table below. Where an observation has been made and there are no animals within that category report 0, where no observation has been made report NULL. Totals should be reported for the full reporting period from August 2011 to the data transmission date.

Element name	*Definition*	*Data type*	*Mand-atory*	*Catalogue*
herdID	Unique identifier for herd/flock	String(50)	Y	
country	Country where the herd/flock is located	String(2)	Y	COUNTRY
NUTScode	Code for region where farm is located using Nomenclature for Territorial Units for Statistics	String(5)		NUTS
NUTSregion	Text for region where farm is located using	String(250)		
speciesCode	Code for species of animal in herd/flock	String(5)	Y	SPECIES
speciesText	Text to describe the species of animal in the herd/flock	String(250)		
production	Indicate if the production is a controlled housing conditions and integrated production system	String(1)	Y	Y/N/U
animalMove	Indicate is new animals were introduced to the farm in spring or summer 2011	String(1)	Y	Y/N/U
firstReportY	Year of first suspicious report in herd/flock	integer (4)	Y	
firstReportM	Month of first suspicious report in herd/flock	integer (2)	Y	
firstReportD	Day of first suspicious report in herd/flock	integer (2)		
animals	Number of animals in herd/flock	Integer(6)	Y	
femaleBreed	Number females of breeding age in herd/flock	Integer(6)		
pregnant	Number of pregnant animals in herd/flock	Integer(6)		
liveBirths	Number of live births in herd/flock	Integer(6)		
stillBirths	Number of still births in herd/flock	Integer(6)		
abortions	Number of abortions in herd/flock	Integer(6)		
dystocia	Number of dystocic births in herd/flock	Integer(6)		
ahs	Number of births with arthrogryposis hydranencephaly syndrome	Integer(6)		
symptomatic	Number of symptomatic adult animals in herd/flock (fever, diarrhoea, losses in milk production)	Integer(6)		
deaths	Number of deaths in adult animals in herd/flock	Integer(6)		
adultsTestPD	Number of adult animals tested by pathogen detection methods in herd/flock	Integer(6)		
adultsTestPDPos	Number of positive adult animals tested by pathogen detection methods in herd/flock	Integer(6)		
adultsTestSero	Number of adult animals tested by indirect detection methods in herd/flock	Integer(6)		

adultsTestSeroPos	Number of positive adult animals tested by indirect detection methods in herd/flock	Integer(6)
offspringTestPD	Number of offspring tested by pathogen detection methods in herd/flock	Integer(6)
offspringTestPDPos	Number of positive offspring tested by pathogen detection methods in herd/flock	Integer(6)
offspringTestSero	Number of offspring tested by indirect detection methods in herd/flock	Integer(6)
offspringTestSeroPos	Number of positive offspring tested by indirect detection methods in herd/flock	Integer(6)
foodChain	Number of animals in herd/flock entering the food chain	Integer(6)
controlMeasure	Describe any control measures applied to the herd/flock	String(250)

Reporting guidelines extended dataset

To facilitate future epidemiological research including a better understanding of morbidity, the case fatality rate, incubation period and duration of symptoms, risk period for infection during pregnancy, role of transplacental transmission and other risk factors. The tables below for adult ruminants and offspring are proposed to support future research and risk assessments.

Congenital malformations and offspring from infected dams

Element name	***Definition***	***Data Type***	***Mand-atory***	***Controlled terminology***
herdID	Unique identifier for herd/flock for the reporting country	string (50)	Y	
country	Country where the farm is located	String(2)	Y	COUNTRY
NUTScode	Code for region where farm is located using Nomenclature for Territorial Units for Statistics	String(5)		NUTS
NUTSregion	Code Text for region where farm is located using Nomenclature for Territorial Units for Statistics	String(250)		
speciesCode	Code for species of animal	String(5)	Y	SPECIES
speciesText	Text to describe the species of animal	String(250)		
production	Indicate if the production is a controlled housing conditions and integrated production system	String(1)	Y	Y/N/U
animalID	Unique identifier for animal within the herd	string (50)	Y	
motherID	Unique identifier for the dam within the herd to link with the dams and acute adults table	string (50)	Y	

birthY	Year of birth	integer (4)	Y	
birthM	Month of birth	integer (2)	Y	
birthD	Day of birth	integer (2)		
sex	Sex of animal	string (1)		M/F/U
ahs	Indicate if the animal has arthrogryposis hydranencephaly syndrome	string (1)	Y	Y/N/U
arthrogryposis	Indicate if the animal has arthrogryposis	string (1)	Y	Y/N/U
hydranencephaly	Indicate if the animal has hydranencephaly	string (1)	Y	Y/N/U
ataxia	Indicate if the animal has ataxia or paralysed limbs	string (1)	Y	Y/N/U
spinalDefect	Indicate if the animal has torticollis, kyphosis, scoliosis	string (1)	Y	Y/N/U
neuroSigns	Indicate if the animal has neurological signs including behavioural abnormalities and blindness	string (1)	Y	Y/N/U
died	Indicate if the animal died	string (1)	Y	Y/N/U
sampleID	Identifer used for sample in testing laboratory	string (50)	Y	
labID	Identifier for laboratory performing test	string (50)		
sampleY	Year of sample	integer (4)	Y	
sampleM	Month of sample	integer (2)	Y	
sampleD	Day of sample	integer (2)		
tissueType	Code for type of tissue sampled	string(5)		SMPRT
testType	Code for type of test	string(5)	Y	PCR/IFAT/ELISA
result	Result of test	string(3)	Y	POS/NEG/EQU

Dams and acute adults

Element name	***Definition***	***Data Type***	***Mand-atory***	***Controlled terminology***
herdID	Unique identifier for herd for the farm	string (50)	Y	
country	Country where the farm is located	String(2)	Y	COUNTRY
NUTScode	Code for region where farm is located using Nomenclature for Territorial Units for Statistics	String(5)		
NUTSregion	Text for region where farm is located using	String(250)		NUTS
speciesCode	Code for species of animal	String(5)	Y	SPECIES
speciesText	Text to describe the species of animal	String(250)		
production	Indicate if the production is a controlled housing conditions and integrated production system	String(1)	Y	Y/N/U

animalID	Unique identifier for animal within the herd	string (50)	Y	
offspringID	Unique identifier for the offspring if reported in the cases congenital malformations table	string (50)	Y	
birthY	Year of birth	integer (4)	Y	
sex	Sex of animal	string (1)		M/F/U
fever	Indicate if the animal had fever	string (1)	Y	Y/N/U
diarrhoea	Indicate if the animal had diarrhoea	string (1)	Y	Y/N/U
neuroSigns	Indicate if the animal had neurological signs	string (1)	Y	Y/N/U
anorexia	Indicate if the animal had anorexia	string (1)	Y	Y/N/U
milkDrop	Indicate if the animal had a drop in milk production	string (1)	Y	Y/N/U
milkLoss	Percentage milk loss (if observed)	double		
durMilkLoss	Duration of milk loss (if observed) in days	integer (6)		
durSymptoms	Duration of symptoms (if observed) in days			
onsetY	Year of onset of symptoms (if observed)	integer (4)		
onsetM	Month of onset symptoms (if observed)	integer (2)		
onsetD	Day of onset onset symptoms (if observed)	integer (2)		
ahs	Indicate if the animal had offspring with arthrogyrposis hydranencephaly syndrome	string (1)		Y/N/U
stillBirth	Indicate if the animal had a still birth	string (1)		Y/N/U
abortion	Indicate if the animal had an abortion	string (1)		Y/N/U
returnToService	Indicate if the animal returned to service	string (1)		Y/N/U
dystocia	Indicate if the animal had a dystocic birth	string (1)		Y/N/U
liveBirth	Indicate if the animal had live offspring	string (1)		Y/N/U
offspring	Number of offspring (where live birth occurred)	integer (6)		
gestation	Number of days gestation	integer (6)		
died	Indicate if the animal died on farm	string (1)	Y	Y/N/U
sampleID	Identifer used for sample in testing laboratory	string (50)	Y	
labID	Identifier for laboratory performing test	string (50)		

sampleY	Year of sample	integer (4)	Y	
sampleM	Month of sample	integer (2)	Y	
sampleD	Day of sample	integer (2)		
tissueType	Code for type of tissue sampled	string(5)		SMPRT
testType	Code for type of test	string(5)	Y	PCR/IFAT/ELISA
result	Result of test	string(3)	Y	POS/NEG/EQU

Catalogue SMPRT

code	***name***
C0113	MILK OR MILK COMPONENT
C0185	BLOOD
C0199	BRAIN
CZ943	PERITONEAL FLUID
CZ801	FAECES
CZ861	FOETUS/STILL BIRTH
C0191	SPLEEN

GLOSSARY

arthrogryposis	also called multiple congenital contracture, characterized by bent limbs and joint contractures present at birth, fixing joints in abnormal positions and restricting their movement.
case definition	defines a case in surveillance. The case definition can be based on, for example, clinical signs, diagnostic testing, and animal or herd characteristics
hydrocephalus	abnormal accumulation of fluid within the brain cavity of the skull
naïve population	population not previously exposed to a defined pathogen, there is no immunological protection against the pathogen in the population
R_0	basic reproduction number: the average number of secondary cases produced by one infected animal during the infectious period
sensitivity	the proportion of infected animals that are correctly identified as positive based on specified diagnostic criteria. The higher sensitivity of a diagnostic test, the lower the number of false negatives (infected animals incorrectly identified as negative for an infection).
serosurveillance	serological surveillance for presence of antibodies to a pathogen in a unit, can identify previous exposure of a population to a pathogen.
specificity	the proportion of non-infected animals that are correctly identified as negative based on specified diagnostic criteria. The higher specificity of a diagnostic test, the lower the number of false positives (non-infected animals incorrectly identified as positive for an infection).
susceptible population	population at risk of becoming infected with a pathogen, there is no protective immunity against the pathogen in the population
torticollis	a lateral flexion of the neck (cervical spine)
unit	1. unit of measurement 2. epidemiological unit, e.g. animal, herd, holding, farm
vector	organism that carries and transmits an infectious pathogen from one host to another
vertical transmission	transmission of infectious pathogen from mother to offspring
viraemia	presence of virus in the blood

ABBREVIATIONS

AHS	arthrogryposis hydranencephaly syndrome
BTV8	bluetongue virus serotype 8
DCF	Data Collection Framework

DG SANCO	Direction générale de la santé et des consommateurs (Directorate-General for Health and Consumers)
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EIP	extrinsic incubation period: the time elapsed between that a vector acquires a pathogen and the same vector can transmit the infection to susceptible hosts
EU	European Union
MS	Member State
PCR	polymerase chain reaction
RT-PCR	reverse transcriptase PCR
SBV	Schmallenberg virus
SCoFCAH	Standing Committee on the Food Chain and Animal Health
ToR	Terms of Reference