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SCIENTIFIC REPORT OF EFSA

"Schmallenberg" virus: Analysis of the Epidemiological Data and Assessment of Impact [1]

European Food Safety Authority[2, 3]

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ABSTRACT

This scientific report provides an overall assessment of the impact of the infection on animal health, animal production and animal welfare of the provisionally named "Schmallenberg" virus (SBV) first detected in Germany. In Europe, 3745 holdings have been reported with SBV cases confirmed by laboratory testing across several Member States, mid May 2012. EFSA reviewed the epidemiological reports noting that SBV has been detected in cattle, sheep, goats and a bison. SBV antibodies have been detected in deer and no other species are known to be affected. EFSA also confirms that new studies support the initial assessment undertaken by the European Center for Disease Control and Prevention, that it is very unlikely that SBV poses a risk to humans. In terms of transmission routes, recent entomological investigations have identified SBV in field samples of biting midges of the *Culicoides obsoletus* group. Currently there is no evidence of any other route of transmission other than transplacental or vector borne routes. EFSA coordinated the collation of SBV epidemiological data during 2011-2012 in order to obtain comparable data for Europe. The maximum proportion of reported sheep holdings with SBV confirmed was 4% per country and 7.6% per region while for cattle less than 1.3 % of holdings were reported as SBV confirmed at both country and regional level. In order to assess the impact of SBV(spatial and temporal spread, proportion of affected holding and potential projection of arthrogryposis hydranencephaly syndrome cases) three models were used. In regions with SBV confirmed holdings, assuming a high prevalence of infection and post infection immunity, impact in the 2012-2013 calving and lambing season should be low. However, assuming SBV survived the winter of 2011, the models suggest that in unaffected regions with suitable temperatures for within herd transmission by vectors and high density of susceptible species (cattle and sheep) SBV infection is likely to spread. EFSA puts forward a number of recommendations to fill the knowledge gaps, these include but are not limited to: continuing serological investigations in affected regions and regions neighbouring affected areas, within herd and animal level impact investigation, monitoring putative vector population, setting SBV host vector transmission parameters, investigating other routes of transmission, host susceptibility, virulence and vulnerable period during

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gestation. Furthermore, the possible origins of the virus should be investigated as more information becomes available on the virus characteristics and infection epidemiology.

KEY WORDS

Schmallenberg virus (SBV), data collection, impact assessment, spread model

SUMMARY

This report by the European Food Safety Authority (EFSA) provides an overall assessment of the impact of the infection on animal health, animal production and animal welfare of the provisionally named "Schmallenberg" virus (SBV) together with a characterization of the pathogen that was first detected in Germany in 2011. In Europe mid May 2012, 3745 holdings have been reported with SBV cases confirmed by laboratory testing across eight[4] Member States.

The Authority reviewed the epidemiological reports noting that SBV has been detected in cattle, sheep, goats and a bison. SBV antibodies have been detected in deer and no other species are known to be affected. EFSA also confirms that new studies support the initial assessment undertaken by the European Center for Disease Control and Prevention, that it is very unlikely that SBV poses a risk to humans.

In terms of transmission routes, recent entomological investigations have identified SBV in field samples of biting midges of the *Culicoides obsoletus* group. Data from EU BT-NET for 2007-2011 indicates that the *Culicoides obsoletus* group is widespread in Europe. However this dataset is not representative for all countries in Europe, the sampling methods are not harmonized and there is some evidence of misidentification of the *Culicoides* species. Currently there is no evidence of any other route of transmission other than transplacental or vector borne routes.

EFSA coordinated the collation of SBV epidemiological data during 2011-2012 in order to obtain comparable data for Europe. The maximum proportion of reported sheep holdings with SBV confirmed was 4% per country and 7.6% per region while for cattle less than 1.3 % of holdings were reported as SBV confirmed at both country and regional level. The data collected indicates that the impact of SBV is greater in sheep holdings than cattle. This assessment of impact should be interpreted with caution however, since the case ascertainment are dependent on the disease being notifiable or not, the level of awareness of different stakeholders and the diagnostic capacity available in the Member State. No data is currently available on within herd impact.

The impact on animal welfare and animal production was not assessed due to lack of data. It is necessary to investigate the impact of SBV infection on return to service, milk yield and rates of dystocia

In order to assess the impact of SBV (spatial and temporal spread, proportion of affected holding and potential projection of arthrogryposis hydranencephaly syndrome cases) three models were used. The model considers a wide vulnerable period for both susceptible known species given that no information is yet available specifically for SBV. The geographical spread model was broadly able to capture the observed dynamics of SBV in Europe during 2011 in terms of duration of the transmission period and the number of infected holdings within a region. However, estimates for the within-region force of infection critically depend upon the level of under-ascertainment (due to lack of identification of affected holdings, vulnerable period used in the geographical spread model) of infected holdings, which sero-prevalence data suggest could be substantial. The probability of SBV surviving over the winter and subsequently spreading in 2012 is difficult to assess because of a lack of data. However, previous experience with BTV8 indicates that vector borne viruses can overwinter, if SBV overwinters the geographical spread model predicts that SBV is most likely to re-emerge between mid-April and the end of May 2012 and is likely to be of a similar size to the one occurred in 2011, though in regions previously unaffected (assuming post-infection immunity). From the prediction of the geographical spread model, the most likely affected areas for next season are expected to be at the south and east regions of the previously-affected areas.

The model of geographical and seasonal within holding transmission using bluetongue virus (BTV) parameters suggests virus transmission and spread becomes possible at temperatures around 15°C with

[4] Since completion of this report, Denmark has subsequently confirmed the presence of SBV through laboratory testing.

a temperature optimum between 18°C and 19°C. The analysis of the preceding 29 years daily temperatures suggests that most of Europe has a suitable climate for within holding vector borne transmission.

The projection model used to evaluate impact was based on the geographical spread model and reported affected holdings up to the month of March. The analysis of impact is limited to regions where calving and lambing data was available to EFSA. The model shows that further cases of arthrogryposis hydranencephaly syndrome (AHS) are likely to be very rare in lambs for the year 2012 after the month April, clearly predicting the observed pattern, since negligible number of affected sheep herds were reported in the month of April and May. However the projection model predicts that further cases in calves could be observed until July, consistent also with the observed pattern for this species, in which the newly reported affected holdings are mainly cattle holdings. The model predicts that the regions that have the highest infection and impact figures in cattle (and AHS cases) and those regions with the highest infection and impact figures in sheep (and AHS cases) are in general regions with large number of holdings (high livestock density).

In regions with SBV confirmed holdings, assuming a high prevalence of infection and post infection immunity, impact in the 2012-2013 calving and lambing season should be low. However, assuming SBV survived the winter of 2011, the models suggest that in unaffected regions or regions with low prevalence with suitable temperatures for within herd transmission by vectors and high density of susceptible species (cattle and sheep) SBV infection is likely to spread.

EFSA puts forward a number of recommendations to fill the knowledge gaps, these include but are not limited to: continuing serological investigations in affected regions and regions neighbouring affected areas, within herd and animal level impact investigation, monitoring putative vector population, setting SBV host vector transmission parameters, investigating other routes of transmission, host susceptibility, virulence and vulnerable period during gestation. Furthermore, the possible origins of the virus should be investigated as more information becomes available on the virus characteristics and infection epidemiology.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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 (SBV). 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, datasets at both individual and holding 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.

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.

CONTEXT OF THE SCIENTIFIC OUTPUT

This document proposes an overall assessment of the impact of SBV infection on animal health, animal production and animal welfare, and includes a characterisation of the pathogen, and as such responds to the ToR 4 of the request received from the European Commission. The document also provides an update of the epidemiological situation as reported by the EU member states (MS).

The assessment provides five outputs in relation to the impact of SBV in Europe to answer TOR 4:

- A review of the current knowledge on SBV
- A review of the potential routes of transmission and role of vectors in the spread of SBV
- An analysis of the epidemiological data available;
- A prediction of the geographical spread and an assessment of the potential geographical and seasonal within holding transmission;
- An assessment of the overall impact of SBV and a prediction of the possible future impact based on lambing and calving season data

ASSESSMENT

1. Introduction

1.1. Schmallenberg Virus

In November 2011, a previously unknown *Orthobunyavirus* was detected by metagenomic analysis at the Friedrich Loeffler-Institut Institute (FLI). The virus was provisionally named Schmallenberg Virus (SBV). Sequence information of the SBV genome shows that it belongs to the Simbu serogroup of the *Bunyaviridae* family, genus *Orthobunyavirus* (Hoffmann et al., 2012).

The *Orthobunyavirus* genus contains over 170 different viruses of veterinary and medical relevance. Based on a complementation fixation test for analysis of the nucleocapsid, 18 serogroups were distinguished within the Simbu serogroup. At least 25 viruses have been assigned to the Simbu serogroup and they are currently divided into seven species (Akabane, Manzanilla, Oropouche, Sathuperi, Shamonda, Shuni and Simbu viruses) that are defined by crossneutralization test and cross-heamagglutination-inhibition tests (Plyusnin et al 2012).

The genome of *Orthobunyavirus* viruses consists of three RNA segments, designated according to their size as L (large), M (medium) and S (small). The L segment encodes the viral RNA polymerase, the M segment encodes the precursor polyprotein which is cleaved into the two viral envelope glycoproteins (Gn and Gc) in addition to a non-structural protein (NSm), and the S segment encodes the viral nucleocapsid protein (N) and a non-structural protein (NSs) (Kobayashi et al., 2007).

Analysis of the RNA sequences of SBV can provide information on the identity of the virus as well as on its reassortant nature, which both relate to the question of its origin.

Preliminary sequence comparisons showed 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 with 97%, 71%, and 69% identity respectively (Hoffmann et al., 2012). The inconsistency between the different RNA segments was interpreted by the authors as not necessarily meaning that SBV is a reassortant but could also be due to the relatively low number of published sequences in the M and L segments for most of the Simbu serogroup viruses (Hoffmann et al., 2012).

As with other segmented viruses, reassortment can occur between different orthobunyaviruses if they co-infect one cell at the same time. The reported geographic distribution of some of the Simbu serogroup viruses is summarised in Table 1, the reports are from pathogen or antibody detection both in vectors and mammalian hosts. . Reassortment studies of the Simbu serogroup are limited. Antigenic and genetic comparisons of Akabane and Tinaroo viruses, both belonging to the Simbu serogroup, suggest that Tinaroo virus is a reassortant of the S and L segment of Akabane virus with the M segment of an unknown *Orthobunyavirus* (Kobayashi et al., 2007). Phylogenetic studies based on the M and S segment sequences of Akabane, Aino and Peaton viruses indicate that genetic reassortment has occurred among the ancestral viruses of three Simbu serogroup viruses (Yanase et al., 2003). Kobayashi et al. (2007) emphasise the importance of reassortment in field isolates of Akabane viruses.

In a subsequent sequencing study, the M segment of SBV showed high nucleotide sequence identity with Sathuperi (81.8-82.2%, depending on strain) and Douglas (81.7%) viruses, while the S and L segments of SBV showed a higher identity with Shamonda virus (96.4-96.7% and 89.5-94.1% respectively). This phylogenetic analysis suggests that SBV could be a reassortant of an M segment from Sathuperi virus and S and L segments of Shamonda virus (Yanase et al., 2012). The discrepancy between the results of this study and the one by Hoffmann et al. (2012) may be a consequence of the different viruses/sequences included in the phylogenetic analysis.

Further sequence data obtained at the FLI indicates that SBV is a member of the Sathuperi species and not a reassortant (Martin Beer, personal communication). Further phylogenetic analyses of SBV, using full-length sequences of several other members of the Simbu serogroup, are ongoing.

Table 1: Geographical distribution of Simbu serogroup viruses related to SBV

Simbu serogroup viruses	Geographical distribution	Reference
Aino	Australia, Japan, Korea	Lim et al., 2007; Yang et al., 2008; Yanase et al., 2012
Akabane	Australia, Bahrain, Cyprus, Indonesia, India, Israel, Japan, Jordan Kenya, Korea, Kuwait, Malaysia, Nepal, Oman, Pakistan, the Philippines, Taiwan, Thailand, Turkey, Saudi Arabia, Singapore, Syria, Sudan, Yemen,	Sellers and Herniman, 1981; Taylor and Mellor, 1994; Mohamed et al., 1996; Abu Elzein et al., 1998; Lee et al., 2002; Stram et al., 2004; Oem et al., 2012; Yanase et al., 2012
Douglas	Australia	Yanase et al., 2012
Shamonda	Japan, Nigeria	Yanase et al., 2005; Yanase et al., 2012
Sathuperi	India, Japan, Nigeria,	Yanase et al., 2004; Yanase et al., 2012

1.2. Susceptible species

SBV has been detected in cattle, sheep, goats, and in a bison (FLI, 2012). SBV specific antibodies have also been detected in seven samples from red deer or roe deer in North Rhine Westphalia, Germany (Martin Beer, personal communication) and in Moufflon and Alpacas. It is unknown whether other species are susceptible to SBV. Viruses of the Simbu serogroup have mostly been found in ruminant hosts.

The zoonotic Simbu serogroup viruses, like Oropouche virus, are not closely related to SBV, based on the available RNA sequences. There is no indication that humans can be infected with SBV. In a study carried out by Robert Koch Institute (RKI), samples from 60 sheep farmers in Germany with SBV cases on their farms tested negative for SBV and SBV specific antibodies. The National Institute of

Public Health and the Environment (RIVM) conducted a study in the Netherlands where a total of 301 persons were tested for antibodies against SBV by virus neutralization test. All sera tested negative. The study population consisted of 234 persons working or living on SBV infected farms and 67 veterinarians, all with known exposure to SBV infected herds. Of these, 229 persons had been directly exposed to newborn offspring or birthing material from SBV infected herds, and 150 persons reported exposure to biting insects. The European Centre for Disease Control and Prevention concluded that it is very unlikely that SBV poses a risk to humans (ECDC, 2012).

1.3. Clinical signs

Clinical signs of SBV infection in adult animals are either absent or non-specific. Main clinical signs observed in cattle are fever, loss of appetite, reduction in milk yield (up to 50%) and in some cases diarrhoea (Lievaart-Peterson, 2012), with a duration of approximately one week. In a preliminary infection study with three calves, transient fever and diarrhoea were observed, but the clinical signs subsided within a few days (Hoffmann et al., 2012). For adult sheep and goats, the majority of farmers did not see any clinical signs around the potential time of infection; some recalled to have observed mild diarrhoea and dullness in some animals. In addition, a proportion of non-pregnant ewes higher than normal was reported in some cases (Lievaart-Peterson et al., 2012).

SBV has been detected in malformed foetuses, stillborn or newborn lambs, calves and goat kids born at term. The most common malformations are arthrogryposis, torticollis, scoliosis, kyphosis, brachygnathia, and mild to severe hypoplasia of the central nervous system, leading to microcephaly, hydranencephaly, and cerebellar and spinal cord hypoplasia (van den Brom et al., 2012; Gariglinany 2012). Lung hypoplasia has also been observed in some affected lambs (Lievaart-Peterson et al., 2012).

In preliminary reports, congenital malformations in lambs ranged from mild to severe. In addition to congenital deformities, blind lambs with poor orientation and lambs unable to stand and suckle were born at affected farms (Lievaart-Peterson et al., 2012; van den Brom et al., 2012). Some ewes that gave birth to malformed lambs also gave birth to healthy lambs (van den Brom et al., 2012). Most SBV-affected lambs were born at term; several were stillborn but a few severely deformed lambs were born alive (van den Brom et al., 2012). There were also calves born at term without any external visible malformations that died within seven days of birth and tested positive for SBV by PCR. Some calves showed malaise but many died without any observable clinical signs. Hydranencephaly or histopathological lesions in the central nervous system were observed at necropsy in some, but not all, calves positive for SBV. Malformed calves tested negative by RT-PCR but positive by precolostral antibodies (F. Conraths personal communication).Thus, it seems like *in utero* infection with SBV can occur without leading to any of the congenital malformations described up-to-date. Nevertheless, although it seems unlikely due to the low vector activity at the time the calves were borne, it cannot be excluded that these PCR positive calves were infected following birth (ProMED-mail, 2012b).

As a consequence of the malformations in SBV affected lambs, many ewes suffered dystocia during parturition and some ewes died due to uterine perforation (van den Brom et al., 2012). During investigation of malformations in lambs at around 100 farms in the Netherlands, dystocia was reported to occur in approximately 65% of the deliveries and intervention during delivery was increasingly required (Lievaart-Peterson et al., 2012).

The welfare of dairy cows in relation to dystocia has been reviewed by EFSA (2009). Dystocia can have an effect on both the dam and the calf. The effect of dystocia on the dam welfare ranges from discomfort because of laceration of the vulva to paralysis of the obturator nerve and downer cow syndrome. Dystocia adversely affects milk, protein and fat yield, reproduction indexes, disease incidence, culling and cow deaths. Even mild dystocia has been shown to have an impact on calf health and survival. Welfare calf issues related to dystocia include a degree of anoxia, acidosis and severe injuries (e.g. broken ribs) and death.

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).

The neural and muscular lesions responsible for arthrogryposis in cattle are a consequence of infection between day 103 and day 174 of gestation while foetal infection between day 76 and 104 of gestation causes hydrancephaly (Kirkland et al., 1988). In some cases, varying degrees of encephalitis may occur in both acutely infected adult cattles and in newborn calves infected with some strains of Akabane virus (Uchida et al., 2000; Kono et al., 2008, Oem et al., 2012).

Out of the Simbu serogroup viruses that have been isolated in Australia, only the Akabane and Peaton viruses have been reported to cause congenital malformations in experimentally infected sheep (Parsonson et al., 1982, as cited by Akashi et al., 1997). If infection with Akabane virus occurs prior to pregnancy, a normal pregnancy is expected to occur. Congenital malformations in foetuses have been observed when the infection occurs during a vulnerable stage of the pregnancy. In pregnant sheep, the gestational period for the occurrence of foetal abnormalities has been shown to vary from day 30 to day 36 or 50 for Akabane virus (Hashinguchi et al., 1979; Parsonson et al., 1977 and 1981a). 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 Akabane virus between day 62 and day 96 of gestation resulted in foetal lesions. In pregnant goats, the critical period in the gestational cycle was estimated at about 40 days (Kurogi et al., 1977 a and b).

The vulnerable gestation period for the various susceptible species to SBV infection is not yet determined. Since the vulnerable gestation period for SBV infection is not yet determined it was decided to assume a worst case scenario of 28 to 56 for sheep and 62 to 173 for cattle for the purpose of this report.

Abortions in cattle have also been associated with Akabane virus (Inaba et al., 1975) and Aino virus (Tsuda et al., 2004; Uchinuno et al., 1998) but so far the effect of SBV infection on fertility is not known.

1.4. Viraemic period

Based on a preliminary experimental infection study , the viraemic period in cattle seems to be short. All 3 inoculated animals became infected and had positive PCR results between 2 and 5 days post-inoculation (dpi), with the lowest cycle threshold (Ct) values, about 21, occurring at 4 dpi. In all three infected animals, no virus could be detected in blood by PCR six days post infection (Hoffmann et al., 2012). The reported results have been confirmed in a second experimental infection with calves and sheep (Martin Beer, personal communication). The short duration of the viraemic period observed in preliminary studies of SBV is concordant with the viraemic period observed for Akabane virus (P. Kirkland personal communication).

1.5. Transmission routes

Horizontal animal to animal transmission has not been reported for Simbu serogroup viruses and so far no SBV infection has been detected in in-contact animals (Martin Beer, personal communication).

Transplacental transmission of SBV has been demonstrated. SBV can cross the placenta and infect the foetus, which may result in viraemic calves, lambs and goat kids being born. However, the risk of transmission from viraemic newborns is unknown.

Data regarding the role of semen on the transmission of SBV and other Simbu serogroup viruses is limited. Akabane virus could not be detected in semen collected from viraemic bulls experimentally infected (Parsonson et al. 1981a). Gard et al. (1989) used semen from bulls naturally infected with

simbu serogroup viruses to inoculate sheep, although some animals seroconverted, the possibility that these animals were infected naturally by vectors could not be excluded. Intra-uterine inoculation of Akabane virus in cattle at the time of artificial insemination did not result in clinical disease but most animals developed viraemia. Virus could not be recovered from nasal or vaginal swabs but was isolated from several tissues, including the reproductive tract and associated lymph nodes, brain and kidney. All pregnant cows that were allowed to go to term delivered healthy calves (Parsonson et al., 1981b). No virus could be isolated from bovine embryos collected from donor cows at 5, 6 and 7 days after insemination and exposed to Akabane virus following embryo collection, indicating that Akabane virus is unable to cross the zona pellucida and reach the embryonic cells. No difference was observed between the embryonic developments of embryos exposed to Akabane virus previous to implantation compared to unexposed control embryos (Singh et al., 1982).

All simbu serogroup viruses closely related with SBV are arthropod-borne viruses. Akabane virus was repeatedly isolated from unengorged field-collected females: from *C. brevitarsis* in Australia (Doherty *et al.*, 1972), from *C. imicola* and *C. milnei* in Zimbabwe (Blackburn & Searle, 1985) and from *C. oxystoma* in Japan (Kurogi *et al.*, 1987). Moreover, *C. sonorensis* from a Pirbright colony were susceptible to oral infection with Akabane virus (infection rate of 5.3% on 6 dpi at 25°C) and were able to transmit the virus through membrane (Jennings and Mellor, 1989). Thus, *Culicoides* can be considered proven vectors of Akabane virus (WHO, 1961).

Shamonda virus was first isolated from cattle blood in Nigeria in the 1960s (Causey *et al.*, 1972) and then from field populations of *Culicoides* in the 1970s. More recently, Shamonda virus was isolated from *Culicoides* biting midges and sentinel cattle in Japan (Yanase *et al.*, 2005).

Aino virus was first isolated from *Culex* mosquitoes, collected during a survey of Japanese encephalitis, in Japan in 1964 (Takahashi *et al.*, 1968). Although Aino virus was primary isolated from mosquitoes, attempts to demonstrate virus replication in mosquitoes have so far proved unsuccessful. Moreover, it is unlikely that the same virus could be biologically transmitted by two different families of hematophagous insects, due to the necessity of co-adaptation between virus and vector.

The transmission of these viruses was only comprehensively investigated for Akabane virus. It seems likely that Akabane virus was transmitted biologically by *Culicoides*, and that the rare virus isolations in mosquitoes were accidental. Akabane, Shamonda, Aino and Schmallenberg viruses are genetically closely related, and thus are probably all transmitted by *Culicoides*, as the Akabane virus. Indeed, the seasonality of SBV transmission reminds of a vector-borne disease and the current distribution of infected farms is similar to the BTV8 distribution observed in 2007.

Recent entomological investigations have identified SBV in field collected *Culicoides* from the Obsoletus Group in Denmark (Rasmussen *et al.* 2012) and from the Obsoletus Complex in Italy. Normally, the term “Obsoletus Complex” refers to sibling species *C. obsoletus* and *C. scoticus*, whereas the term “Obsoletus Group” refers to the morphologically close species *C. obsoletus*, *C. scoticus*, *C. chiopterus* and *C. dewulfi* (some authors exclude this latter species from the Obsoletus group).In Belgium, SBV was found in heads of *C. obsoletus* s.s. and *C. dewulfi*, (ProMed-mail, 2012a) proving that these species were able to develop a disseminated infection. These elements are concordant with the biological transmission of SBV by *Culicoides*. To definitively prove the ability of *Culicoides* to transmit SBV, vector competence studies are needed.

1.6. Immunity

Long lasting immunity was demonstrated in animals infected with Akabane virus (Taylor and Mellor, 1994). In areas endemic with Akabane virus, most adult animals would have acquired an active immunity sufficient to prevent the virus from reaching the foetus. The pathogenic effects of infection with Akabane virus is therefore only seen when the virus exceeds the limits of the endemic area and infects susceptible animals during a vulnerable stage of pregnancy. Such a situation is likely to occur at the edges of an endemic area especially after a dry period with absence of regular exposure to the

infection or after periods with high rainfalls with expanded vector activity (Kirkland et al., 1983) and due to the movement of either infected hosts or vectors (Taylor and Mellor, 1994).

Among the Simbu serogroup viruses, Akabane virus is the one with best knowledge on pathogenesis. At the moment, it is however uncertain if the analogy of SBV with Akabane is adequate. Preliminary studies showed that four animals that were re-infected with SBV following previous exposure did not develop viraemia (Martin Beer, personal communication).

1.7. Seroprevalence studies

The detection of SBV in the eight European affected countries has largely been dependent on the detection of malformed newborns or still births followed by confirmation of the virus presence by real time reverse transcription PCR. The congenital malformations observed in calves, lambs and goat kids are most likely the consequence of viral infection during a vulnerable period of the gestation. Since clinical signs resulting from infection of susceptible adults are often absent or mild, the estimation of past infection can only be achieved by serological investigation. A virus neutralization test (VNT) was developed at the Central Veterinary Institute (CVI) and FLI. An application for a commercial ELISA kit (less expensive and labor-intensive than the VNT) has been submitted to the competent authorities in April 2012 and an in house ELISA assay will be used for future surveys in the Netherlands. A limited number of preliminary seroprevalences studies have been carried out and made available in various countries in order to assess within herd and country seroprevalences (Table 2).

Table 2: Seroprevalence studies

France[a]	**Northern region**
Aisne	49 sheep tested by VNT, **71%** seropositive
Seine-Maritime	39 sheep tested by ELISA and VNT, **79.4**% seropositive
	Eastern region
Meurthe-et-Moselle	Farm with confirmed SBV, 30 cattle tested by VNT, **100%** seropositive (titres from 32 to > 256); 50 sheep on same premises tested, **86%** seropositive.
Moselle	Sheep farm with confirmed SBV, 100 sera tested by VNT, **32%** seropositive
	Central region
Cher	27 cattle tested by VNT, **74%** seropositive
Haute-Vienne	Sheep farm with confirmed SBV, 53 animals tested by VNT, **7.5%** seropositive
	47 sheep tested by ELISA and VNT, **14.9%** seropositive
Germany[b]	Random samples from the population (unknown number of herds); 60 cattle, 60 sheep and 60 goats sampled per federal state Preliminary results are in line with clinical case findings: gradient from north to south (high to low) and from West to East (high to low), indicating highest prevalence in Northwest of Germany. Cattle average 61.04% (CI 57.88-64.13) and above 85% in Hesse Lower Saxony and North Rhine Westphalia)
Netherlands[c]	Sample size of 1,100 randomly selected dairy cattle throughout the Netherlands ± **70%** seropositive Two sheep flocks (located in Southern and Eastern part of Netherlands) and two cattle herds (located in Northern and South-western part of Netherlands) that tested PCR-

	positive when malformed lambs and calves were born Dependent on herd size: Sera of 60 and 35 ewes were tested from 2 sheep flocks, Sera of 34 and 34 dairy cattle (> 2 years of age) were tested from 2 cattle herd Within herd: Sheep flocks: **70 – 95%** Dairy herds: **70 – 100%**
Spain[d]	The samples were from the province with the confirmed SBV case in a newborn lamb and the neighbouring province. Test used unknown. Five herds were tested. Sample sizes were relatively small, ranging from 4 to 70 adult animals per herd. The seroprevalence result of the single confirmed holding in Córdoba (70 animals) was 36,8%

(a) S. Zientara personal communication; (b) F. Conraths personal communication ; (c).Elbers et al 2012 ; (d) L. Romero Gonzalez personal communication

The seroprevalence study conducted in the Netherlands has been recently published (Elbers et al., 2012). The authors reported a high seroprevalence of antibodies against SBV in dairy cattle in the Netherlands in the winter of 2011–2012 of approximately 70%. The seroprevalence of antibodies against SBV in dairy cattle was significantly higher in the central-eastern part of the Netherlands than in the northern and southern parts of the country. No significant differences in age-specific mean prevalence of antibodies against SBV of cattle in the 3 regions were observed which might indicate that SBV probably arrived in 2011, and not earlier, to the area (Elbers et al., 2012). There was a high within-herd seroprevalence, indicating that most animals within an affected herd have been infected.

High seroprevalence both in between herds and within herd are consistent with results from studies in Akabane epidemics both in Australia and Japan where seroprevalence of up to 100% were observed.

2. Materials and Methods

2.1. Vectors: distribution and diversity

In order to explore the distribution and diversity of vectors in Europe the data collected for the EU BT-Net project (containing information from 2007 up to 2011) for each of the MS (those reporting to EU BT-Net) has been downloaded and collated.

A map containing the location of the traps available in EU BT-Net is produced; also information regarding the maximum number of *Culicoides* trapped in each location is displayed (the size of each circle is proportional to the maximum number of *Culicoides* trapped), in order to evaluate possible abundance of vectors in each region.

In order to explore diversity of *Culicoides* species in each region species reported in EU BT-Net is of interest. It is important to highlight that information on this regard was insufficient to evaluate diversity.

Other two maps are produced to explore the regions in which *C. imicola* and vectors of the Obsoletus Group were observed.

In order to study plausible seasonal variation monthly maps were produced with the maximum number of *Culicoides* trapped in each of the locations where vectors were trapped.

2.2. Assessment of Impact

For the purpose of this report impact is defined in the following way:

1. Geographical and Temporal Spread of SBV in Europe based on epidemiological reported data;

2. A prediction of potential geographical spread of SBV in the following season based on a geographical spread model that uses the epidemiological reported data to estimate the rate at which susceptible regions (NUTS2) become infected by infectious regions;

3. An assessment of the conditions that are needed to facilitate potential within holding spread based on a BTV within holding transmission model;

4. The proportion of affected holdings (holdings with at least one RT-PCR confirmed SBV animal) per region and at the country level;

5. A projection of potential AHS cases that could be observed for each species (cattle and sheep) based on the monthly lambing and calving percentages for each of the NUTS2 regions, the geographical spread model results and the within holding transmission model.

2.2.1. Geographical and temporal spread of SBV

2.2.1.1. Assessment based on reported data

The minimum dataset (EFSA, 2012a) provided by MS was analysed to obtain the number of holdings according to the status of the holding (SBV laboratory confirmed or not), the age class of the animals tested (adults or foetus/neonates), the type of test used (RT-PCR or serology), the species and the country reporting.

Temporal analysis was based upon the date when the first suspicion of SBV in the herd, according to the case definition, was reported to the veterinary services. Using this date the number of confirmed holdings per week of the years 2011 and 2012 for each of the affected countries was plotted, providing insight on the evolution over time. In addition a cumulative curve for each country was produced in order to evaluate country specific cumulative evolution over time of the number of affected holdings. The number of affected holdings per species were analysed in order to identify potential peaks for different species.

The potential period of viral circulation in Europe was estimated by back calculation using the first report date for the herd adjusted for the gestation period of the species reported and the vulnerable periods previously reported for other virus of the same group (the vulnerable periods used were 28-56 for sheep and 62-173 for cattle, see Section 1.3). Back calculations were performed using the minimum and maximum stages of vulnerability as well as a likely time drawn from within the likely period (minimum and maximum) considering equally likely to occur within the vulnerable period.

In the minimum dataset the location of the holding was recorded using the European NUTS regional classification. NUTS classification operates at four levels, 0 equates to the country, 1 to major socio-economic regions, 2 to basic regions for the application of regional policies and 3 to smaller regions[5]. The regions where at least one SBV confirmed holding was reported were mapped at the NUTS level reported by the MS. In addition the herds were reclassified at the NUTS 2 regional level. The NUTS 2 regions were classified according to the first month in which an SBV confirmed holding was reported and this was mapped to investigate the spatial spread for each species. Newly affected areas for each month were highlighted in order to differentiate them from previously infected areas.

2.2.1.2. Prediction of SBV geographical spread

The geographical spread of SBV was modelled at NUTS2-regions level, considering as epidemiological units the holdings within each NUTS2-region. Ample detail about the approach used can be found in Appendix A.

Data preparation

[5] the classification is available at http://epp.eurostat.ec.europa.eu/portal/page/portal/nuts_nomenclature/introduction

Demographic data for each NUTS2 region (number of cattle and sheep holdings) were based on data from the year 2007[6] . The centroids for each region were calculated and the geographic coordinates (latitude and longitude) of those centroids used to calculate the distance between the regions applying the Great Circle Method

Epidemiological data on confirmed holdings (holdings with confirmed AHS cases) were used to calculate vulnerable periods at holding level and, subsequently, *transmission periods* for transmission of SBV at regional level (NUTS2).

Risk periods for confirmed cattle holdings were calculated from the reporting date for the holding by subtracting the gestation period for cattle (set to 280 days) and adding the period of gestation at which the foetus possibly is at risk of developing AHS (vulnerable period, see Section 1.3).

Risk periods for confirmed sheep holdings were calculated in a similar manner, but with a the gestation period for sheep set to 150 days and the vulnerable period assumed for sheep (see Section 1.3)

Since the period of the gestation at which the foetus possibly is at risk of developing AHS for SBV is unknown, a wide vulnerable period (worst case scenario) was assumed, based on available information for other Simbu serogroup virus

The transmission period for each region was then assumed to be from the beginning of the earliest vulnerable period in cattle or sheep to the end of the latest vulnerable period in cattle or sheep.

In addition, the total number of cattle and sheep holdings reporting AHS cases in each region is calculated.

Modelling approach

Transmission between regions was modelled using a distance kernel-based approach, similar to that used previously for avian influenza (Boender et al. 2007; Truscott et al. 2007), foot-and-mouth disease (Chis-Ster & Ferguson 2007) and bluetongue (de Koeijer et al. 2011). In this case, the force of infection (rate at which susceptible regions become infected by an infectious region) for a region depends on i) the distance between region centroids, ii) the seasonal vector activity (obtained from Sanders et al. 2011), iii) the number of holdings with cattle or sheep in a region and iv) the infection status of each region (i.e. uninfected or infected).

Two different distance kernels (which describe how the force of infection depends on the distance between regions) were considered, one which depends on the density of the regions and another which ignores the density of the regions (Truscott et al. 2007). The force of infection assumes that cattle and sheep holdings are equally susceptible and infectious.

The mean duration of the transmission period for a region and its variability were estimated from the epidemiological data reported for each region.

Finally, the number of infected cattle and sheep holdings within a region was assumed to be negative binomial distributed with the means depending on the within-region force of infection for each species (cattle and sheep), the duration of the transmission period and the number of holdings of each species.

Simulating Geographical Spread in 2012

When investigating the potential for geographical spread in 2012 the model is initialised based on the epidemiological data for 2011, under the assumption that:

[6] http://epp.EUROSTAT.ec.europa.eu/portal/page/portal/statistics/search_database

- Regions infected in 2011 (i.e. those reporting cases so far) have experienced a complete outbreak with no subsequent spread in the region.
- However, they act as a source of infection for seeding outbreaks in 2012, with a given probability of SBV overwintering in each region; if they remain infected, they pose a risk until the end of June (this takes into account the gestation period and vulnerable gestation period for the species)

Potential geographical spread is simulated for both distance kernels used (see Appendix A.) and for a range of values for the probability of overwintering. In addition the uncertainty in the model parameters is incorporated by drawing parameters for each replicate from distributions based on the maximum likelihood estimates obtained previously (see Appendix A.).

Key assumptions

- The *transmission period* for each region (i.e. when SBV was circulating) is from the start of the earliest risk period within the region to the end of the latest risk period (based on species specific vulnerable periods) within the region.
- Cattle and sheep holdings are assumed to be equally susceptible and infectious.
- The force of infection between regions is assumed to depend on:
    - the distance between region centroids;
    - the number of cattle and sheep holdings in each region;
    - seasonal vector activity.
- Within each region the expected number of infected cattle or sheep holdings is given by the product of the within-region force of infection (assumed to be the same for all regions), the duration of the risk period for the region and the number of cattle or sheep holdings.
- When predicting spread in 2012, SBV is assumed to overwinter (with a given probability) in regions infected in 2011, which then acted as a source of infection for previously uninfected regions.
- All animals in NUTS2 regions develop life long immunity following SBV infection.

2.2.1.3. Potential geographical and seasonal within holding transmission

Vector borne disease transmission is largely driven by vector abundance, temperature and host densities. Assuming transmission of SBV is exclusively vector borne and that the vectors are species of *Culicoides*, the effect of temperature on key vector parameters (biting rate and survival rate) and virus development time in the vector is useful to estimate transmission intensity.

Due to limited information on the epidemiology of SBV, EFSA used a bluetongue virus (BTV) model to assess under which conditions SBV could spread into susceptible populations (EFSA, 2012a). The model, largely based on vector parameters for BTV, showed 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.

When focusing on within-holding transmission only (excluding between-holding transmission) the host abundance and spatial distribution can be ignored, given that the approach taken used a model developed for BTV. Both the spatial and the seasonal variation of the temperature at selected sites in Europe could be used to estimate and map the risk of potential vector borne virus transmission, in terms of time and space, given the virus is introduced in a specific holding.

The model used is an extension of the modeling approach carried out in (EFSA, 2012a), in this version, the variability between climate conditions from different years is accounted for and additional developments to assess within-holding transmission were implemented.

Key assumptions

- Transmission of SBV is exclusively vector-borne and the vectors all belong to *Culicoides spp*.
- Host abundance and spatial distribution are ignored, given that model focuses on within holding transmission.
- Infectious animal is assumed to be viraemic for four days.
- *Culicoides* spp. can survive 45 days at the maximum.
- BTV9 parameters (Table 9:) are used to model the within-holding transmission
- Within-holding transmission is modelled once an infectious animal has been introduced in the holding.

2.2.2. SBV: Affected Holdings and Projection of AHS Cases per Region

2.2.2.1. Assessment based on reported data

Data on the number of holdings for cattle, sheep and goats was obtained from the EUROSTAT Regional Agriculture Statistics database and the 2007[7] figures were selected as these were the most recent complete figures for all affected countries. A comparison between the total number of holdings per country and the reported SBV confirmed holdings per country is shown for each species (cattle, sheep and goats).

In order to study the intensity of SBV infection in the affected regions, the proportion of affected holding was calculated based on the number of reported SBV confirmed holdings and total number of holdings per NUTS 2 and mapped.

2.2.2.2. Projection of SBV – AHS Cases Based on Lambing and Calving Monthly Data

The relative potential impact of SBV based on AHS cases in newborns is calculated for each NUTS2 region predicted to become infected by the geographical spread model using a stochastic within-holding model.

Data preparation

Data on the monthly patterns of calving and lambing both within and beyond the area currently known to be infected was requested to the MS. The data received are displayed in Table 3.
Data provided at NUTS2 resolution were included in the projection assessment; data at coarser resolution were not used due to difficulties when matching this information with disease report data and the outputs of the prediction of SBV Geographical Spread (see Section 2.2.1.2).

Table 3: Spatio-temporal lambing and calving data received for this report.

Country	Type of data	Decision for use and rationale
Belgium	NUTS2 calving, NUTS1 lambing.	Used (calving data only).
Denmark	NUTS0, percentages. Stated that regional variation is minimal.	Used; assumed same monthly profile for each NUTS2 region.
Estonia	NUTS0/1/2 (all the same), percentages.	Used.
Finland*	NUTS3, percentages and numbers.	Used.
France*	NUTS3, percentages and numbers.	Used.
Italy	NUTS2 (calving only), NUTS0 (lambing), percentages.	Used (calving data only).
Latvia	NUTS0/1/2 (all the same), numbers.	Used.
Lithuania	NUTS0/1/2 (all the same), percentages.	Used.
Luxembourg	NUTS0/1/2 (all the same), calving only, percentages.	Used (calving data only).
Netherlands	NUTS2, percentages.	Used.
Norway	NUTS0, percentages. Stated that regional	Used; assumed same monthly profile

[7] http://epp.EUROSTAT.ec.europa.eu/portal/page/portal/statistics/search_database

	variation is minimal.	for each NUTS2 region.
Czech Republic	NUTS0, percentages.	Unused; resolution too coarse.
Ireland	NUTS0 percentages plus percentages for provinces.	Unused; resolution too coarse.
Spain	NUTS0, percentages.	Unused; resolution too coarse.
Sweden	NUTS0, percentages; NUTS3, numbers but without temporal distribution.	Unused; resolution too coarse or no temporal specification
United Kingdom	Mixed (NUTS0 numbers for cattle plus percentages for several classes of cattle and sheep holdings but without corresponding geographical data)	Unused; resolution too coarse or not specified geographically.

*NUTS2 data for France and Finland were generated by averaging the data provided at NUTS3 level, weighted according to the relative areas of the NUTS3 regions in each NUTS2 region.

The number of holdings and number of animals per NUTS2 region was obtained from EUROSTAT 2007 for all regions included in the analysis.

Simulation of SBV-infected holdings in each region

Only limited information was available on the distribution of holding sizes within each NUTS2 region. An exponential relationship was assumed (based on UK holding data used during previous modelling projects at Institute for Animal Health) and used to simulate holding sizes for each region.

The two main outputs from the model described in 2.2.1.2, for each NUTS2 region, are:

- an estimate of the period during which holdings in that region are at risk of infection, and
- the daily per-holding rate of infection.

The daily per-holding rate of infection was applied over the estimated *transmission period* to simulate the number of holdings within each NUTS2 region exposed to an SBV introduction event. This resulted in a number of infected holdings, along with a date of infection and holding size.

Modelling approach

A within-holding model for BTV transmission (section 2.2.2) was then used to simulate the time course of infections for each holding. This model was chosen as it has been previously extensively described (Gubbins et al., 2008 and Gubbins et al., 2012) and required just minor modifications to incorporate the SBV-specific available parameter estimates.

Calculation of impact

The probability that a host infection results in a AHS or other clinically-affected newborn animal was calculated from the calving and lambing data provided by the member-states.

The calving and lambing profiles supplied by each member state were used to infer the daily rate of conception per animal (with the duration of pregnancy in cattle and sheep taken as 280 and 150 days respectively for the purposes of this report) and from this a daily profile of the probability of an animal being in each day of gestation falling within the vulnerable period was produced. This was multiplied with the output of the within holding model to give the relative daily frequency of disease cases, which was then re-aggregated by month.

Each iteration of the within holding model results in a time series of the relative number of animals infected per calendar month.

The method used will significantly underestimate the absolute levels of infection /disease values due to the estimated force of infection based on the reported holdings with confirmed AHS cases, which is likely to be under-ascertained. The absolute impact estimates are therefore divided by the maximum total annual impact for the relevant host species for all regions used in the assessment, estimated by the model to give a relative impact value.

Key assumptions

- An exponential relationship was assumed to simulate holding sizes for each region.
- For each NUTS2 region, an estimate of the period during which holdings in that region are at risk of infection and the daily per-holding rate of infection was obtained as an output from the model described in Section 2.2.1.2.
- The model includes one host species (either cattle or sheep) and one vector (i.e. no distinction is made between different *Culicoides* spp. in their population dynamics or ability to transmit SBV). Since no data was available regarding mixed holdings (cattle and sheep), all holdings were assumed to be composed of only one species.
- The host population is assumed to be constant and is subdivided into susceptible (i.e. uninfected), infected and recovered classes. For the vector the adult female population is subdivided into the number of adult female midges that are susceptible (i.e. uninfected), exposed (i.e. infected, but not infectious) and infectious.
- The outbreak on a farm is assumed to be initiated by the introduction of 5 infectious vectors (Gubbins, 2008).
- Plausible distributions were obtained from the literature for each parameter.
    - Estimates for some parameters were related directly to SBV: duration of viraemia; and probability of transmission of host to vector.
    - Estimates for other parameters were related to *Culicoides* biting midges, the putative vectors of SBV: probability of transmission from vector to host; reciprocal of the time interval between blood meals; vector-to-host ratios; and vector mortality rate.
    - No information is available on the extrinsic incubation period for SBV and, hence, this was assumed to be the same as bluetongue virus (BTV).
- Explicit temperature dependence was included for the reciprocal of the time interval between blood meals (related to the biting rate), the vector mortality rate and the extrinsic incubation period.

3. Results

3.1. Vectors: Distribution and Diversity

The territory covered by UV-light traps in Europe is shown in Figure 1, the circle size indicates the frequency of reporting. Italy, the Netherlands and Spain are the countries for which more reports per trap are more frequently gathered.

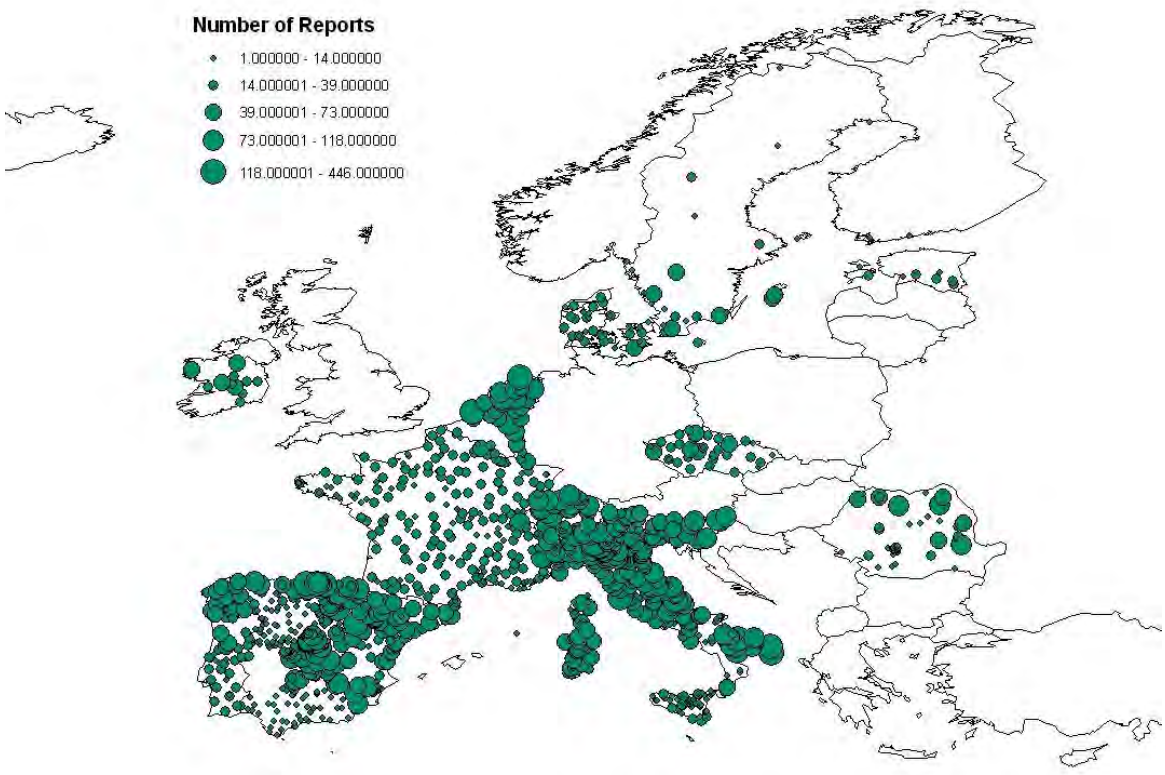


Figure 1: Location of each trap in each country (circle size depends on the number of reports)

Culicoides were found in the whole of Europe from southern Spain to northern Sweden and from western Ireland to eastern Estonia, without any clear gradient of abundance. Some sites of exceptional abundance are in Corsica, Sardinia, Northern Italy or Netherlands (Figure 2).

The distribution of *C. imicola* in western Mediterranean basin is presented in Figure 3. Although *C. imicola* was reported in the Netherlands, its presence is unlikely, and reporting of this species in the Netherlands might represent a reporting error.

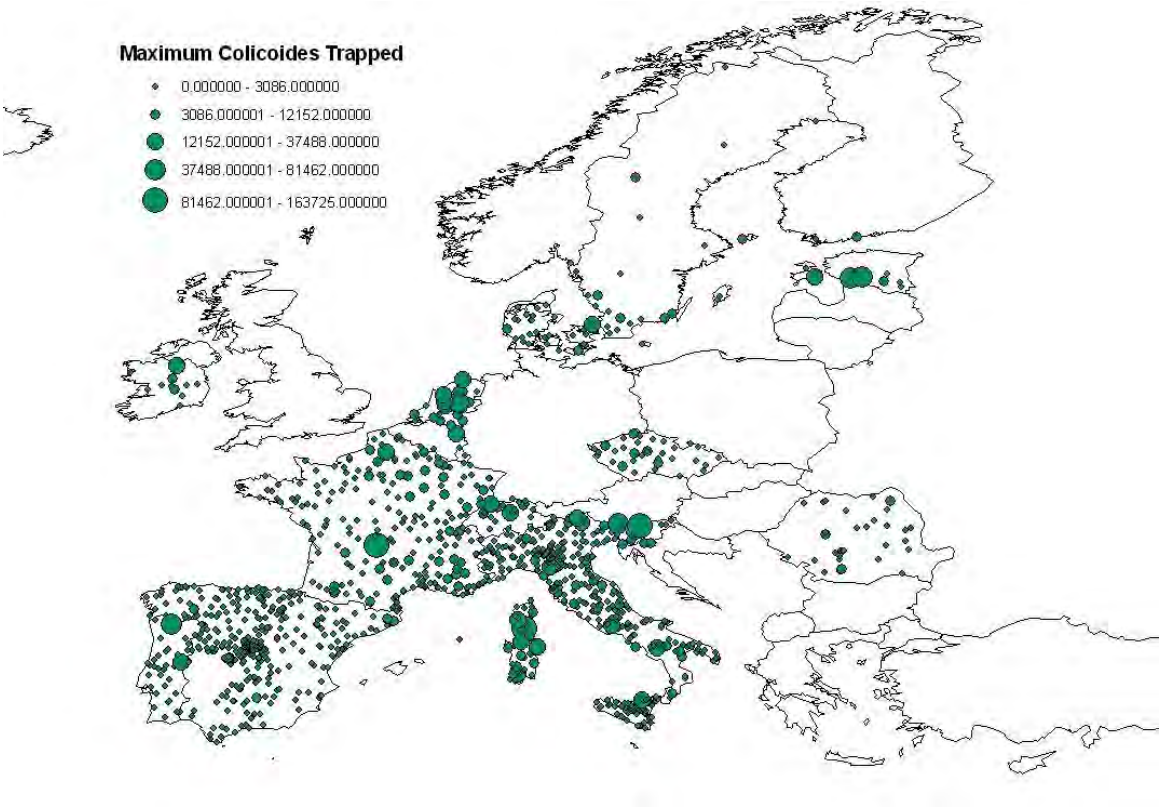


Figure 2: Maximum number of *Culicoides* trapped reported to EU BT-NET.

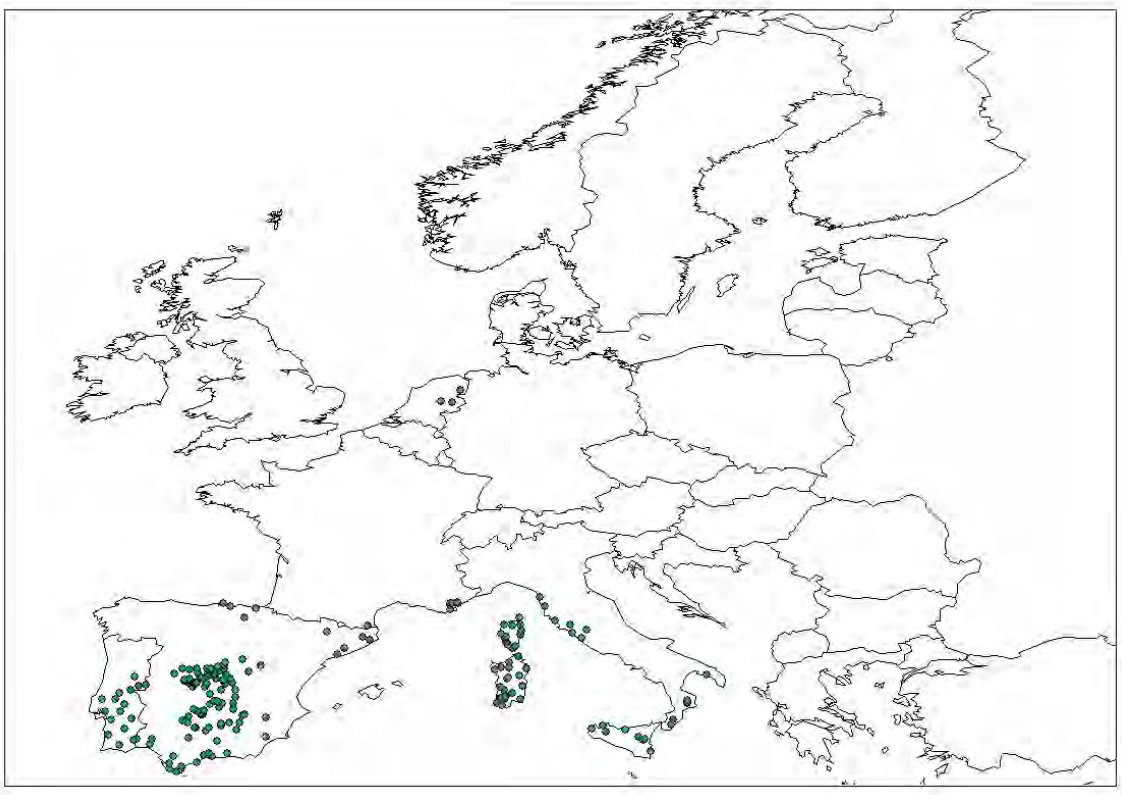


Figure 3: Locations where *C. imicola* were trapped and reported to EU BT-NET.

The Obsoletus Group on the other hand (regrouping *C. obsoletus*, *C. scoticus*, *C.chiopterus* and *C.dewulfi*) is common and widespread, found in the whole of Europe from southern Spain to Scandinavia (Figure 4) with the exception of extreme northern locations of Sweden or Norway (Nielsen *et al.* 2010). The apparent absence of the Obsoletus group in Italy (Figure 4) is due to a reporting issue and not an actual absence of the vector group in the region.

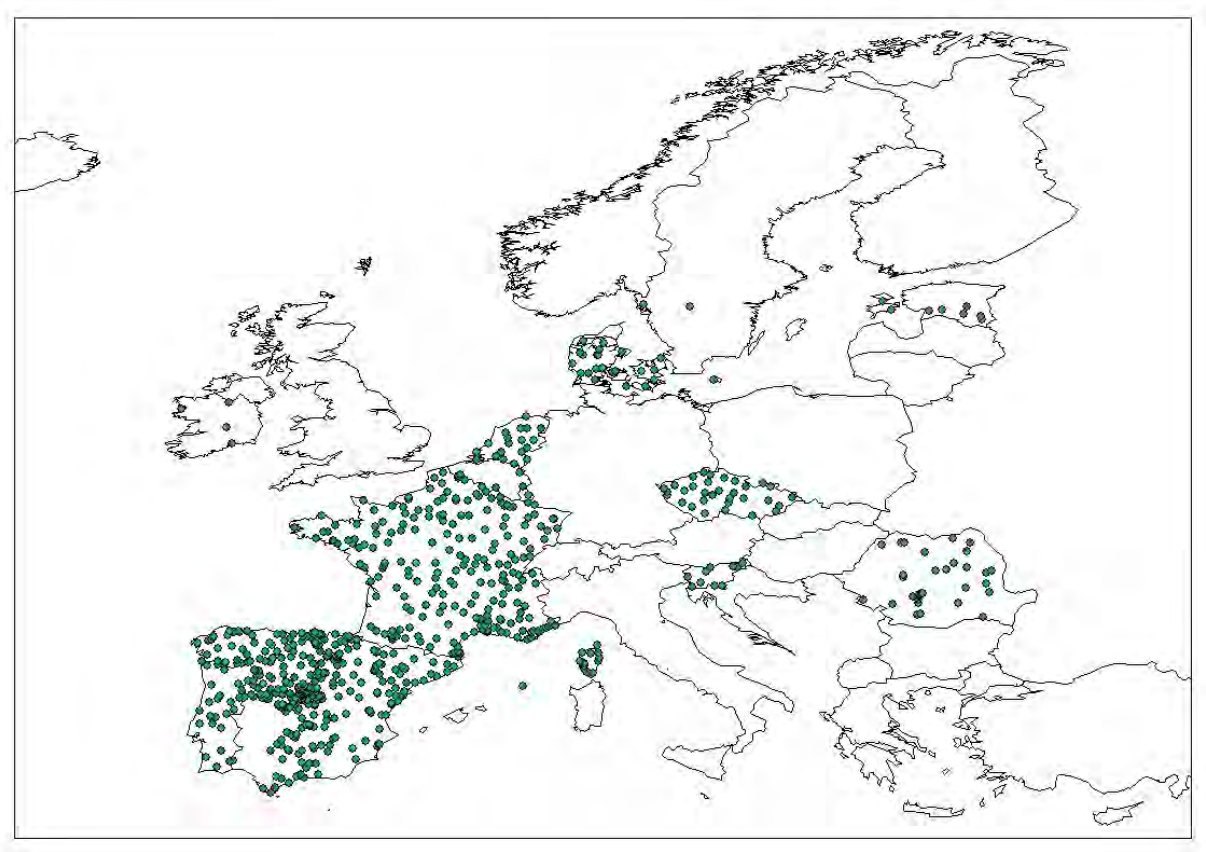


Figure 4: Locations where species of the Obsoletus Group were trapped and reported to EU BT-NET.

The maps in appendix D give an indication of the seasonal variations of *Culicoides* populations in Europe. *Culicoides* may be present throughout the year in the Mediterranean basin. In February, *Culicoides* were active in Portugal, Spain, the southern half of Italy and the West of France. In March, activity concerned a large part of Europe (up to the North of France), and, in April, up to the South of Scandinavia. First yearly report of *Culicoides* occurred in May in central Scandinavia and in July in Northern Scandinavia. *Culicoides* seemed to stop their activity in Northern Scandinavia in September. Populations were still active in November in coasts of Baltic and North Sea and rare in Netherlands in the month of December. France may still conserve active populations during December.

3.2. Assessment of the Impact

3.2.1. Geographical and Temporal Spread of SBV

3.2.1.1. Assessment Based on Reported Data

At present, eight Member States (Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Spain and United Kingdom) have confirmed cases of SBV (Table 4). All affected Member States have reported the number of confirmed herds following viral detection by PCR, virus neutralisation test or serological confirmation and France, Italy, Luxembourg, the Netherlands, Spain and United Kingdom, have also reported the number of suspect herds. For Belgium data was only available for the period up to the 21 March 2012.

Switzerland reported herds where malformed offspring were tested by RT-PCR and the dams by serological testing, all results were negative. Ireland reported surveillance testing of herds and all herds were negative. Estonia reported that there has been no suspect or confirmed herds in the country. Moreover Demark and Norway reported suspect herds, in all herds foetuses/neonates were tested by RT-PCR and the results were negative.

In Europe mid May 2012, 3745 holdings have been reported with SBV cases confirmed by laboratory testing. The majority of these confirmations come from holdings with foetuses and neonates with AHS type clinical signs and a positive result for RT-PCR. The number of confirmed acute cases in adults with viral RNA detection by PCR is limited to eight cases in Germany, most likely corresponding to infection during the period of viral circulation in summer/autumn 2011. In addition, as a serological test became available, adult animals were also tested. Generally these tests were performed on holdings where foetuses and neonates had already tested positive and the serology confirmed the SBV status of the holdings. However as in the case of Spain results of serological test in adults led to detection of viral circulation in a new region, where PCR test was negative. Investigations are ongoing to further assess the validity of this finding.

In the affected regions approximately the same number of sheep holdings and cattle numbers were reported while only 152 goat holdings were reported. However, about twice as many sheep holdings were found to have SBV confirmed cases compared to cattle holdings (Table 5).

Three countries Italy, Spain and Netherlands provided the extended dataset of individual animal results (Table 6). There are 23 reports of neonates being born without AHS clinical signs but testing positive by RT-PCR and for 926 foetuses and neonates with AHS type clinical signs the RT-PCR result was negative. This indicates that the laboratorial confirmation using RT-PCR may not reliably identify all SBV cases and from the figures it can be seen false negatives may occur more frequently in cattle. A high rate of false negatives for a test will result in an under estimation of the number of holdings and potentially regions affected by SBV

Table 4: Country level summary of minimum dataset reports (Countries with confirmed cases of SBV shaded grey)

Country	*Reported Holdings*	*Holdings SBV not confirmed*	*Holdings SBV confirmed*	*Foetus neonate RT-PCR test*	*Foetus neonate RT-PCR confirmed*	*Adults RT-PCR test*	*Adults RT-PCR confirmed*	*Adults serology tested*	*Adults serology confirmed*
Belgium	231	0	231	.	231	0	.	.	.
Denmark	38	38	0	38	0	0	.	0	.
France	3279	1836	1443	.	1443	0	.	.	.
Germany	1443	0	1443	.	1425	8	8	14	14
Ireland	56	56	0	56	0	1	0	.	.
Italy	6	4	2	6	1	5	0	5	2
Luxembourg	32	15	17	31	17	1	0	0	.
Netherlands	1634	1287	347	.	345	.	.	218	213
Norway	9	9	0	9	0	0	.	0	.
Spain	17	12	5	9	1	12	0	6	5
Sweden	19	19	0	18	0	0	.	11	0
Switzerland	5	5	0	5	0	0	.	.	.

Country	*Reported Holdings*	*Holdings SBV not confirmed*	*Holdings SBV confirmed*	*Foetus neonate RT-PCR test*	*Foetus neonate RT-PCR confirmed*	*Adults RT-PCR test*	*Adults RT-PCR confirmed*	*Adults serology tested*	*Adults serology confirmed*
United Kingdom	446	189	257	.	257	0	.	.	.
Total†	***7215***	***3470***	***3745***	††.	***3720***	***27***	***8***	***254***	***234***

† Calculated based on holding identification, if a holding reported cases in more than one species is considered as a single contribution

†† Foetus neonate RT-PCR test for some reporting countries the number of holdings with foetuses or neonates tested was not available only the number of holdings with laboratory confirmed SBV based on tissue from foetuses or neonates

Table 5: Species level summary of minimum dataset reports (Countries with confirmed SBV cases only)

Ruminant	*Reported Holdings*	*Holdings SBV not confirmed*	*Holdings SBV confirmed*	*Foetus neonate RT-PCR confirmed*	*Adults RT-PCR test*	*Adults RT-PCR confirmed*	*Adults serology tested*	*Adults serology confirmed*
Bison	1	0	1	1	.	.	.	.
Cattle	3448	2219	1229	1208	19	8	151	144
Goats	152	80	72	72	2	0	5	5
Sheep	3531	1063	2468	2463	6	0	88	86
	7132	***3362***	***3770***	***3744***	***27***	***8***	***244***	***235***

Table 6: Extended dataset – foetus and neonate SBV test results (reports of neonates being born without AHS clinical signs positive by RT-PCR shaded green and neonates with AHS type clinical signs negative by RT-PCR shaded blue

Country	*Species*	*AHS clinical signs*	*RT-PCR result*	*Number Neonates/foetuses*
Spain	Sheep	Y	POS	2
Italy	Cattle	N	NEG	1
		Y	NEG	1
	Goats	N	NEG	1
		Y	POS	1
	Sheep	Y	NEG	1
Netherlands	Cattle	N	NEG	208
		N	POS	6
		Y	NEG	700
		Y	POS	180
	Sheep	N	NEG	204
		N	POS	17
		Y	NEG	224
		Y	POS	107
				1653

Temporal Distribution: Reported Data

Analysis of reported holdings by week of first report and country is shown in Figure 5 for all species, and for cattle, sheep and goats separately. The graph combining all species shows an increase in the number of confirmed holdings up to the ninth week of the year 2012 followed by a steep decrease in the weeks 10 to 13. No decrease is observed after week 13. The analysis by species shows that the peak in cases between week 3 and week 9 is largely due to confirmed sheep holdings after week 9 the number of reported confirmed sheep holdings decreases and few confirmed sheep holdings are reported after week 14. This decrease is most probably linked to the end of the lambing season in affected countries. The continuation of reports of SBV confirmed holdings beyond week 13 is largely due to new cattle holdings. For cattle reports increase from week 4 and a peak is observed at week 16 but no clear decrease in confirmed holdings can be determined. A display of the cumulative numbers of confirmed holdings over time per country is presented in Figure 6.

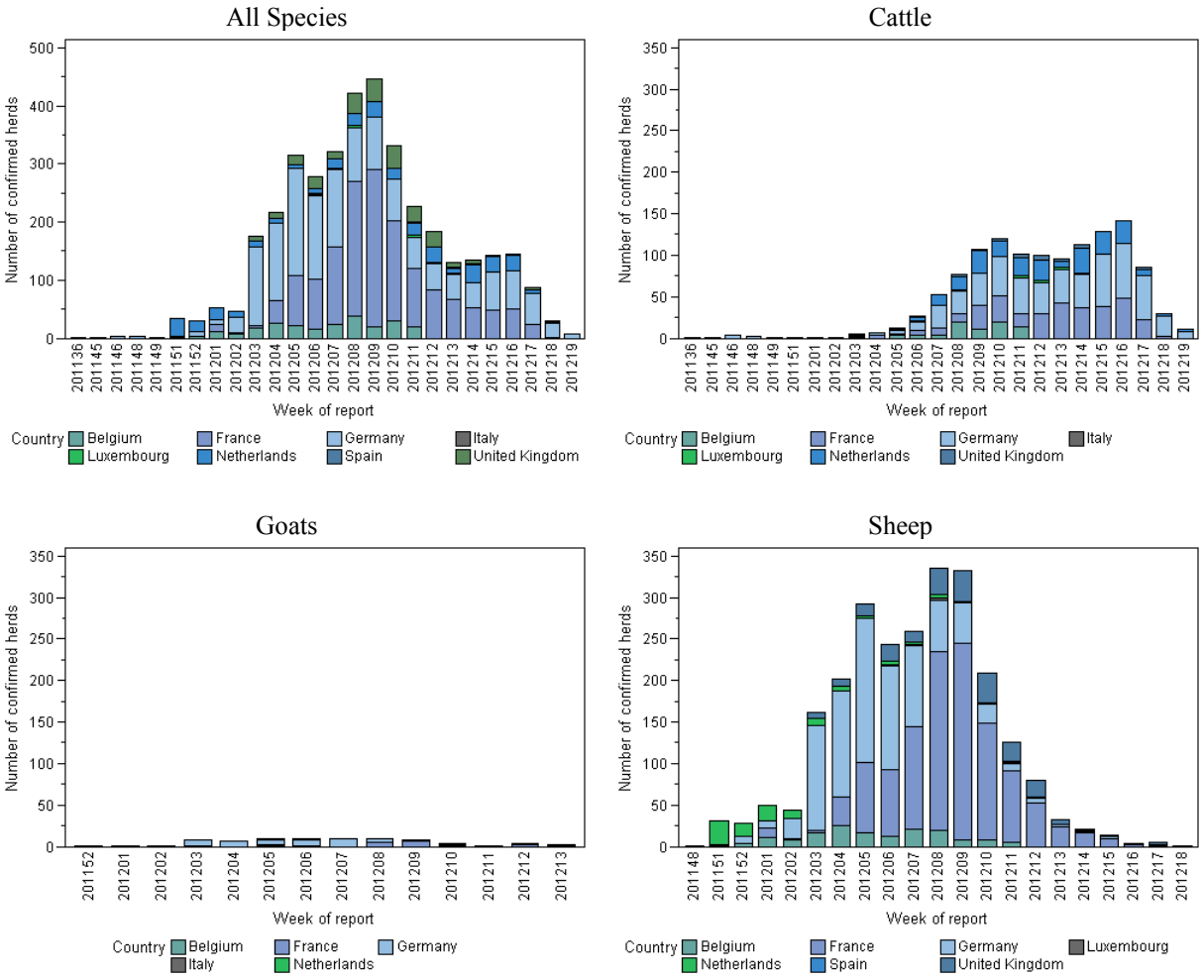


Figure 5: Week of first suspicion report for SBV confirmed holdings, with proportion in each country

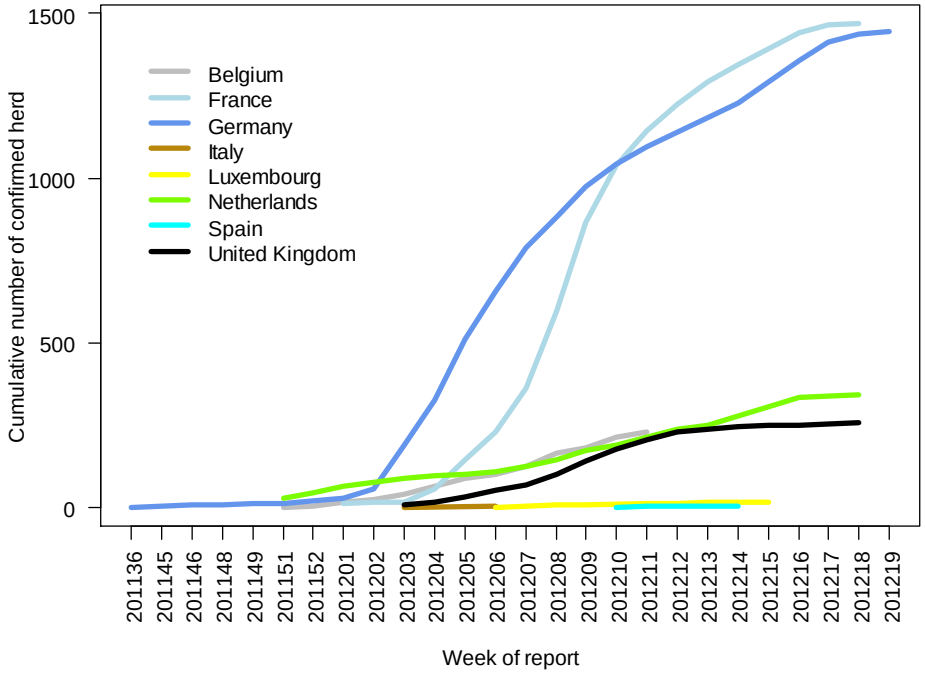


Figure 6: Cumulative confirmed holdings over time per country.

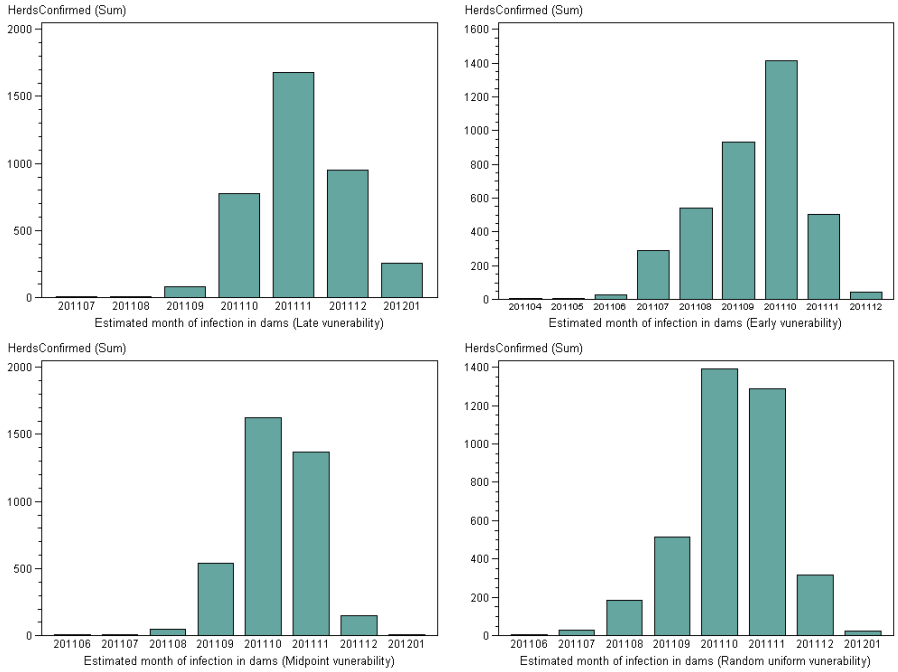


Figure 7: Estimation of month of infection dams considering gestation period and possible stage of vulnerability (sheep/goats 28-56 days cattle 62-173 days).

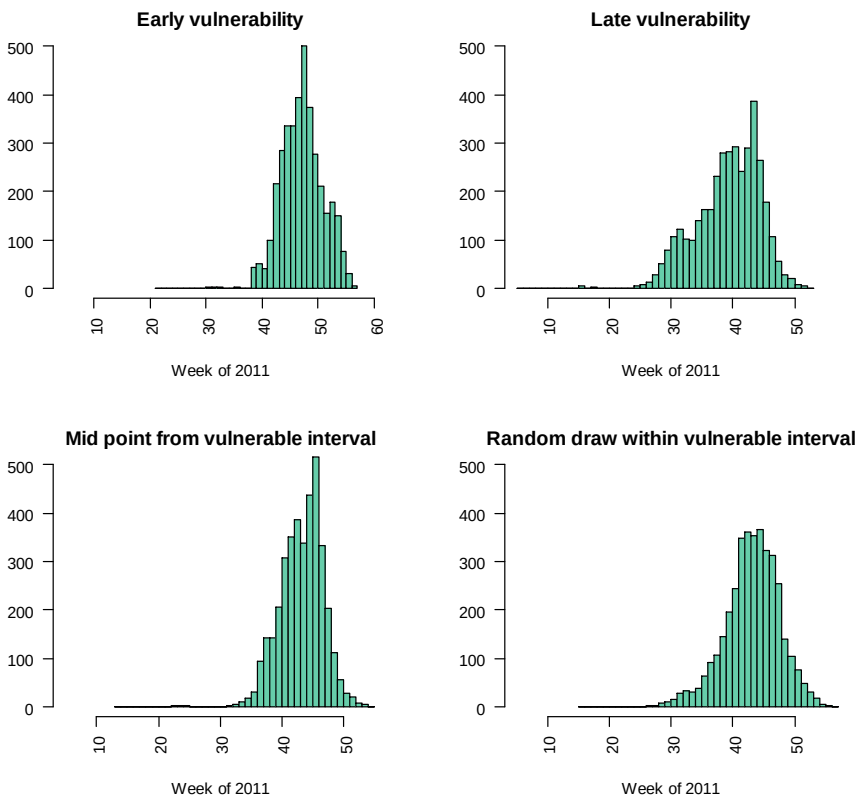


Figure 8: Estimation of week of infection dams considering gestation period and possible stage of vulnerability (sheep/goats 28-56days cattle 62-173 days).

The period of viral infection in dams, was calculated for SBV confirmed herds considering the duration of the gestation for each of the species (cattle, sheep and goats) and the vulnerable period (see section 1.3.). Figures 7 and 8 indicate that October and November 2011 was the most likely period for viral infection between weeks 40 and 50.

Spatial Spread: Reported Data

The regions with at least one SBV confirmed holding at the NUTS level reported by the MS are displayed in Figure 9 to Figure 11. The number of regions with confirmed SBV cases is highest for sheep, whilst fewer regions with confirmed SBV in goat holdings are reported. Currently regions with confirmed holdings for SBV are restricted to Western Europe.

Figure 12 to Figure 18 shows the spatial evolution of the SBV outbreak. Figure 12 shows the acute cases in adults reported for a single region in Germany in September 2011. In Figures 13 and 14 (November, December) the first AHS cases in foetuses and neonates in Germany and then Netherlands and Belgium are observed. In January 2012 (Figure 15) the SBV outbreak became more widely known and MS developed the laboratory capacity to test for SBV with RT-PCR, as a consequence newly affected regions are observed in France, Italy and the United Kingdom. In February and March (Figures 16 and 17) the new affected areas are in general neighbouring previously reported affected regions. In March the first confirmed holdings are reported in Spain, in one region SBV confirmed holdings are identified on the basis of serological results in adults rather than testing of foetuses or neonates with AHS clinical signs. Figure 18 shows the number of new regions with SBV holdings to be decreasing, with only one new region confirmed for SBV in April.

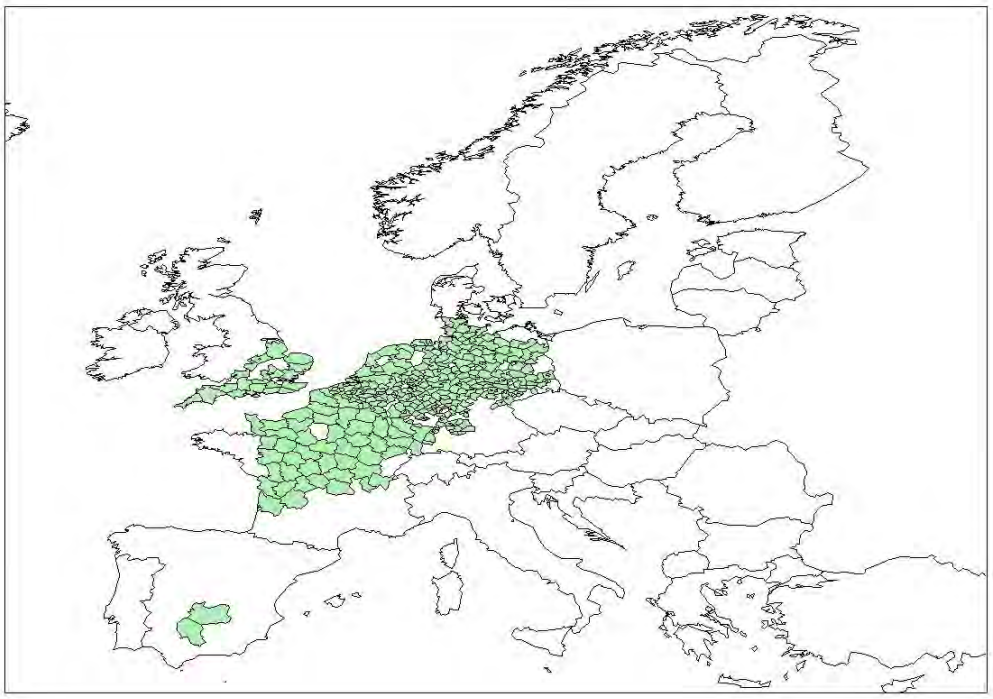


Figure 9: NUTS regions with at least one SBV confirmed holding – **Sheep**.

The regions where at least one SBV confirmed holding was reported were mapped at the NUTS level reported by the MS. Newly affected areas for each month were highlighted in order to differentiate them from previously infected areas. In Spain there were 2 NUTS regions with SBV viral circulation but only one was PCR test positive. Investigations are ongoing to further assess the validity of this finding.

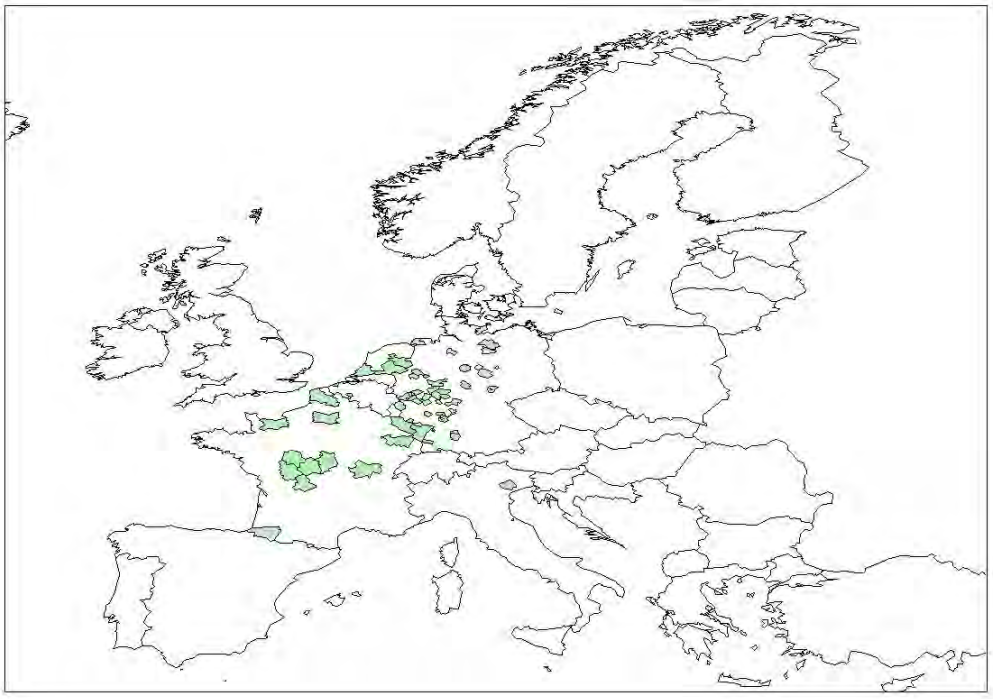


Figure 10: NUTS regions with at least one SBV confirmed holding – **Goats**

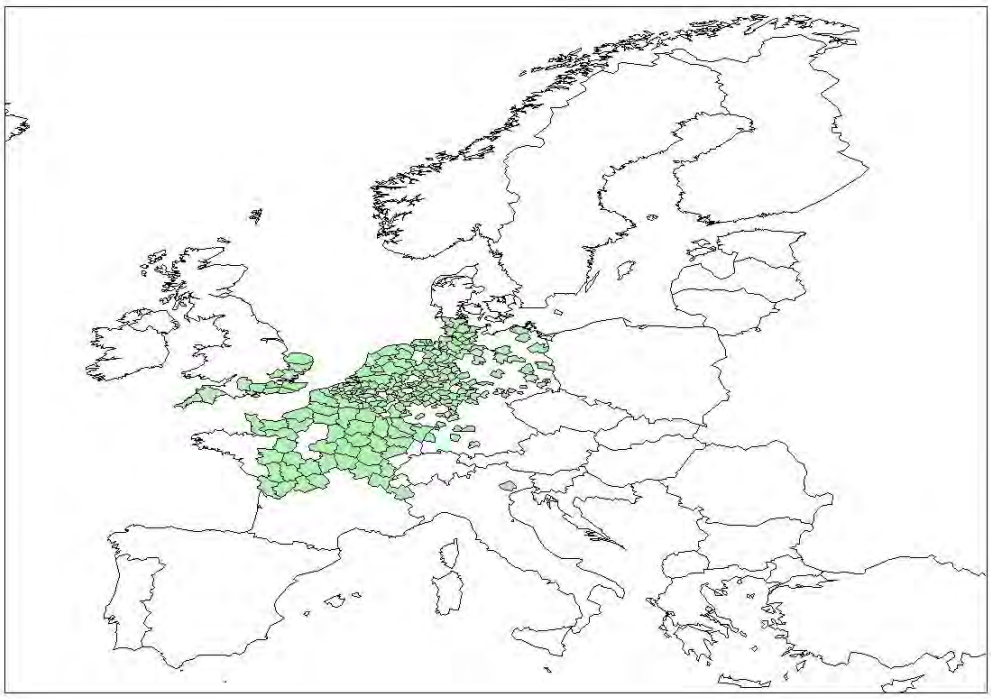


Figure 11: NUTS regions with at least one SBV confirmed holding – **Cattle**

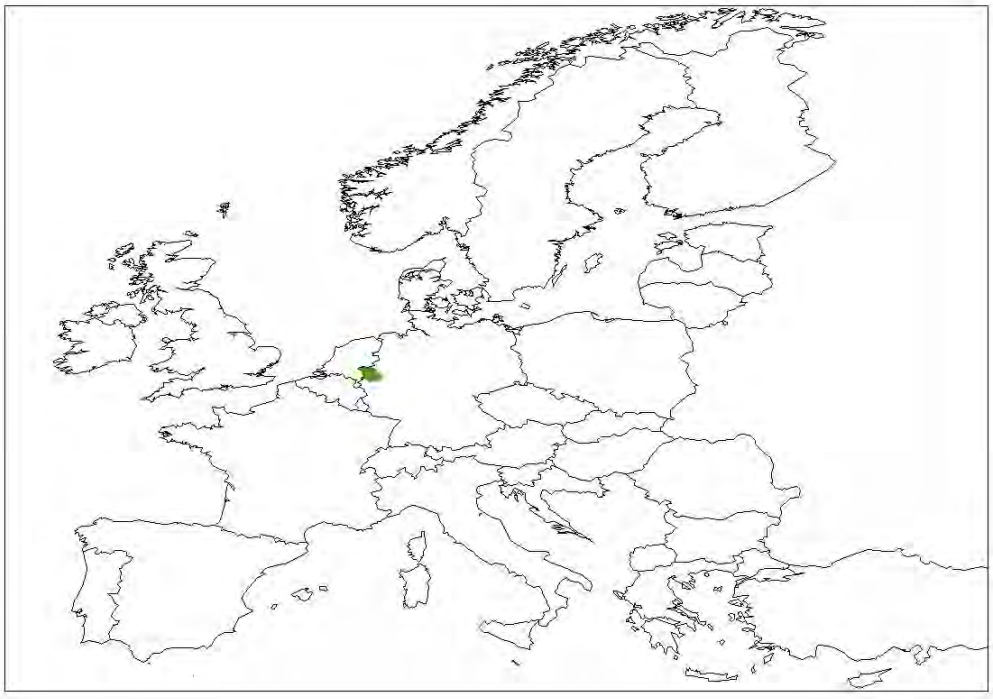


Figure 12: NUTS regions with at least one SBV confirmed holding – **September 2011.**

The herds were reclassified at the NUTS 2 regional level. The NUTS 2 regions were classified according to the first month in which an SBV confirmed holding was reported and this was mapped to investigate the spatial spread for each species. Newly affected areas for each month were highlighted in order to differentiate them from previously infected areas.

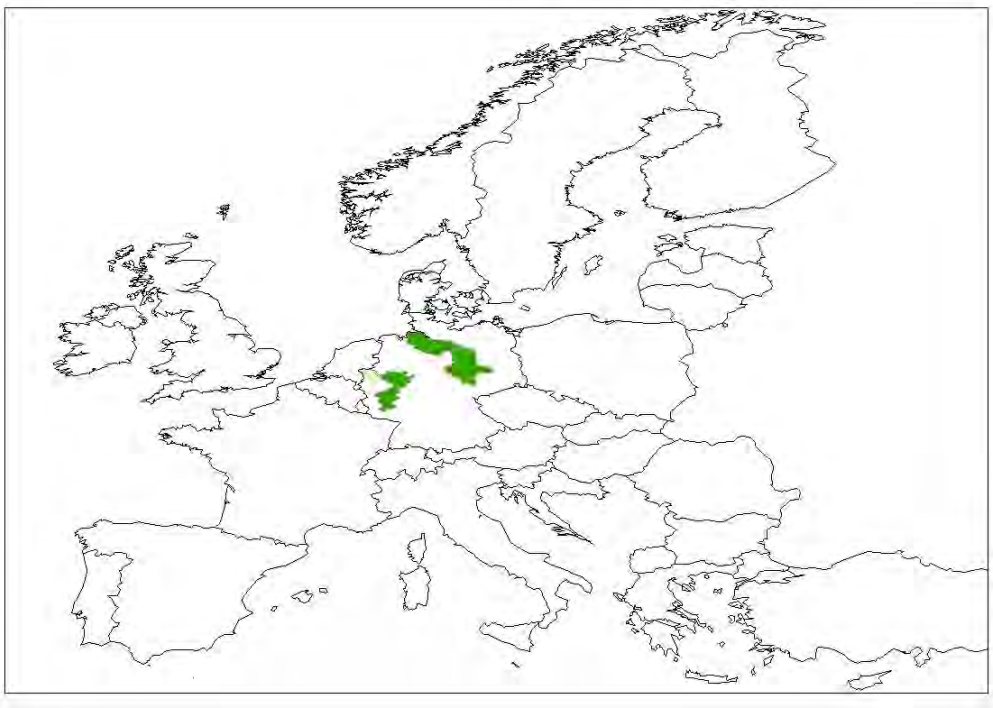


Figure 13: NUTS regions with at least one SBV confirmed holding – **November 2011**

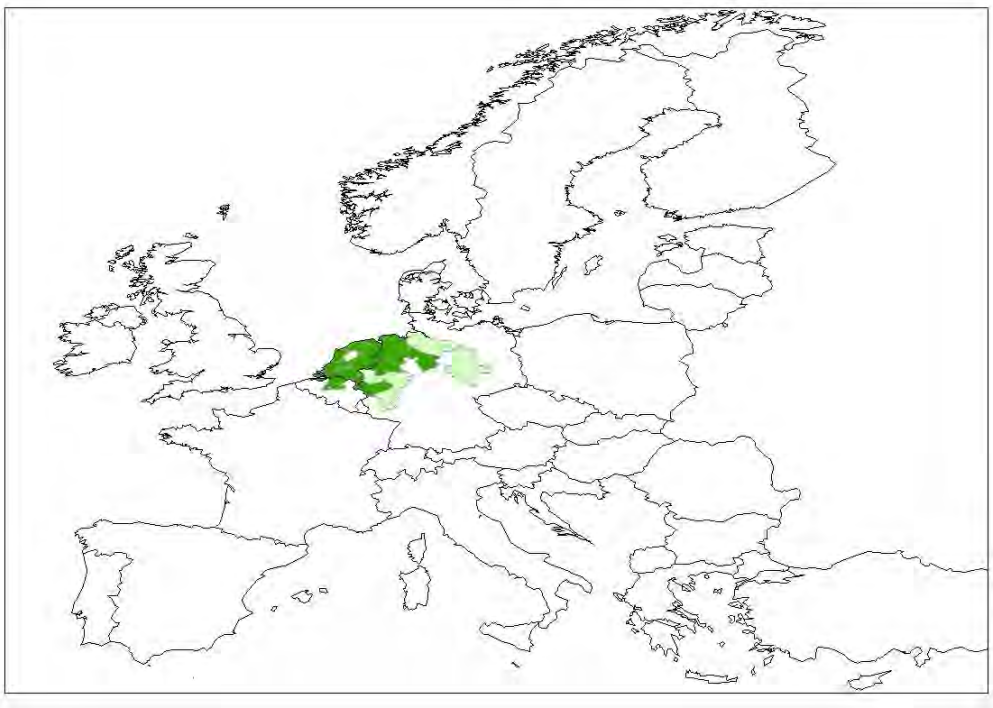


Figure 14: NUTS regions with at least one SBV confirmed holding – **December 2011**

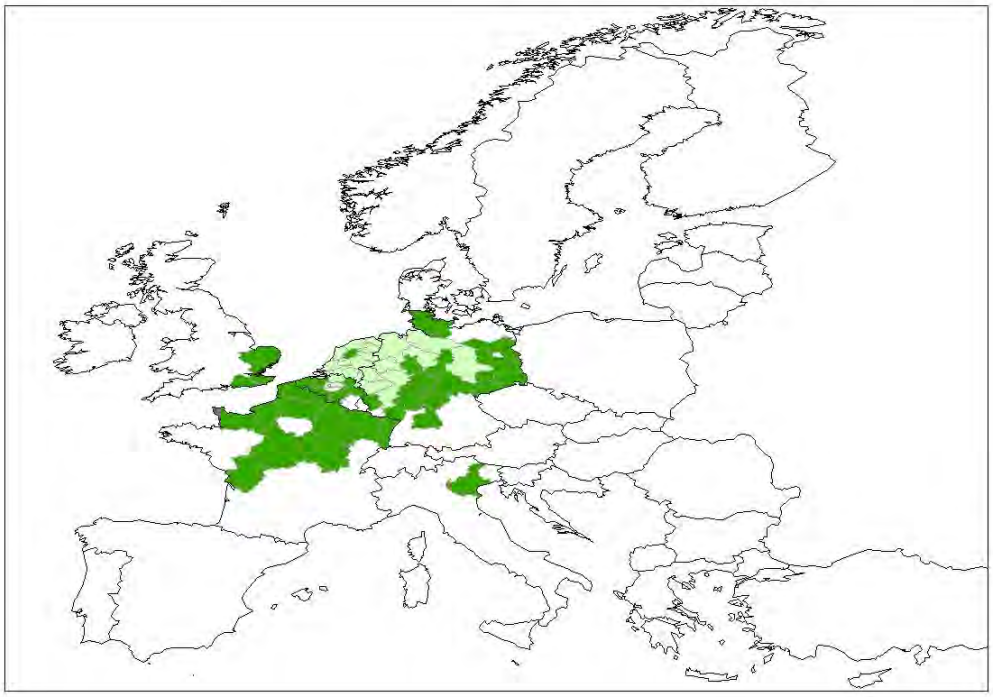


Figure 15: NUTS regions with at least one SBV confirmed holding – **January 2012**

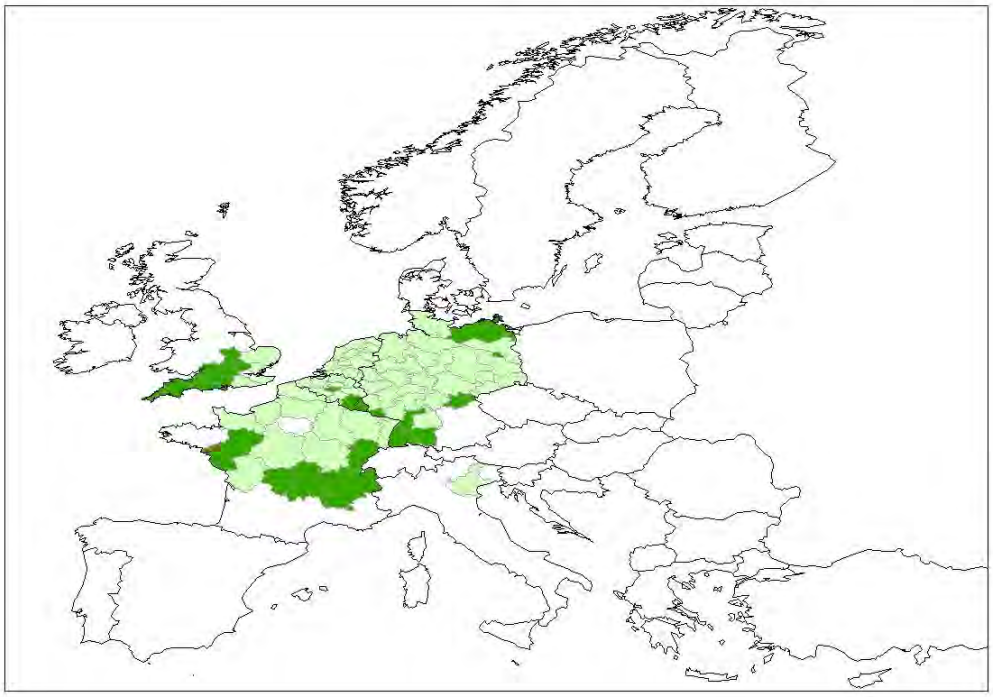


Figure 16: NUTS regions with at least one SBV confirmed holding – **February 2012**

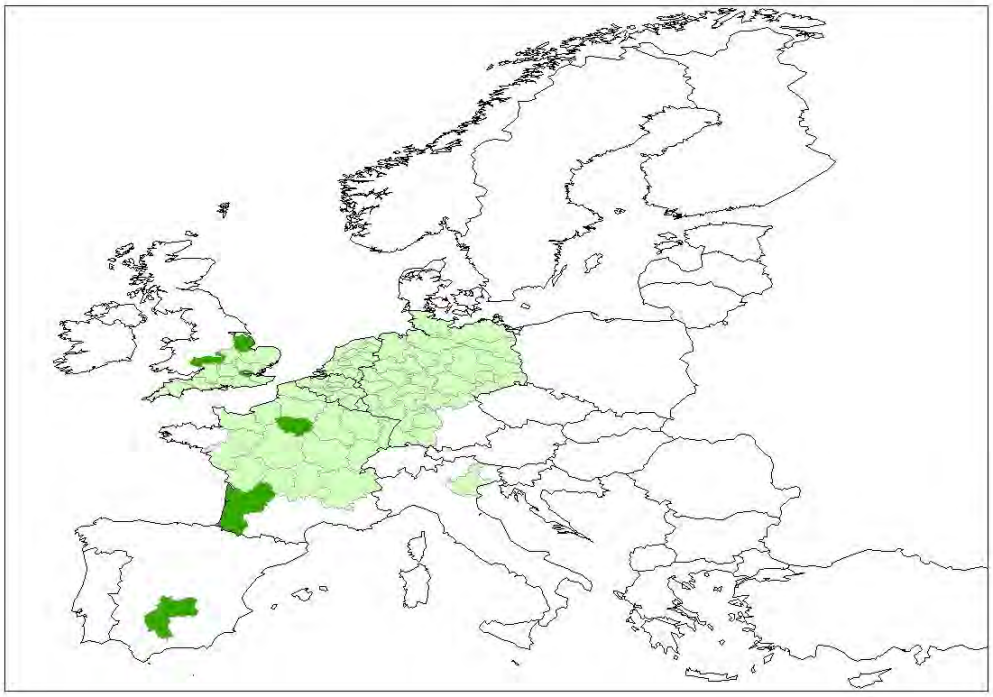


Figure 17: NUTS regions with at least one SBV confirmed holding – **March 2012** (there were 2 NUTS regions in Spain with viral circulation but only one was PCR test positive. Investigations are ongoing to further assess the validity of this finding).

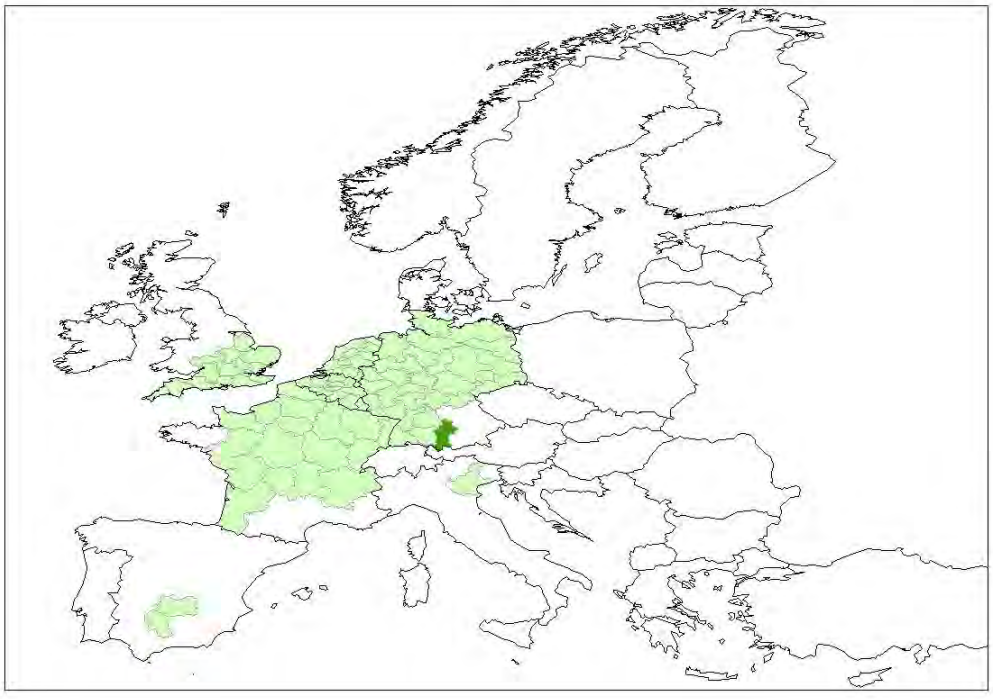


Figure 18: NUTS regions with at least one SBV confirmed holding – **April 2012** (there were 2 NUTS regions in Spain with SBV viral circulation but only one was PCR test positive. Investigations are ongoing to further assess the validity of this finding).

3.2.1.2. Prediction of SBV Geographical Spread

Parameter estimation

Maximum likelihood estimates and 95% confidence intervals are obtained for all the parameters of interest (Table 7). Comparing the Akaike Information Criterion (AIC) calculated for the two models, it is possible to conclude that the density-dependent kernel (AIC=1072.3) resulted in a better fit than the density-independent kernel (AIC=1260.7). Model predictions for both the animal density-dependent and the animal density-independent kernels (results not shown) are consistent with the observed time course for the number of regions in which SBV was assumed to be circulating, i.e. the observed data lie within the 2.5th and the 97.5th percentile estimated by the models (Figure 19). However, the density-dependent kernel provided a median number of affected regions which is higher and closer to the observed value (Figure 19).The results shown here are all from density dependent kernel.

The predicted times at which each region should have become infected are consistent with the assumed starting date of the transmission period for each region (results not shown), although the model tends to predict later infection times than the observed (predicted time courses in Figure 19).

The probability of a region becoming infected is quite high for most of the regions which reported AHS cases, except for the UK (Figure 20). There are, however, regions with a similar probability level of infection which do not become infected.

The fitted duration *of risk* distribution provides an adequate fit to the observed durations (Figure 21; χ^2=12.1, df=6; *P*=0.06). Similarly, the model for the number of infected cattle and sheep holdings is generally consistent with the observed number of infected holdings in most regions (Figure 22).

The impact of under-ascertainment of holdings on the estimates of the within-region force of infection is shown in Figure 23. Essentially, if the proportion of *infected* holdings *reporting* AHS cases decreases (either because of under-reporting or because the infection occurs outside the risk period), the estimated force of infection increases (Figure 23a,b).

The predicted sero-prevalence for a given proportion of infected holdings reporting AHS cases is shown in Figure 23c for cattle and Figure 23d for sheep.

Simulating geographical spread in 2012

The probability of SBV spreading in 2012 depends on the probability of SBV overwintering in a given region affected in 2011. It can be seen that when the probability of overwintering in a given region increases from 0.001 to 0.1, the probability for SBV of overwintering and spreading increases from around 0.01 to approximately 1 (see Figure 24).

Assuming that SBV does overwinter, however, the probability distribution of the number of regions that would be affected in 2012 is broadly similar to the within-region probability of overwintering (see Figure 25 and Figure 26).

According to the model outputs, when SBV does overwinter, it typically begins to circulate between mid-April and the end of May (i.e. days 100-150) (Figure 26). Then, the number of regions in which SBV is circulating increases, reaching a peak in September/October (i.e. days 275-300) (Figure 26). All the regions that were not affected before winter, are predicted to be at risk in 2012: In particular, the regions with the highest probability of being infected are at the south and the east of the areas that were affected before winter (Figure 27). The overall probability of a region becoming infected is low if the probability of SBV overwintering in that region is low, but the relative probabilities of a region becoming infected are similar (Figure 27).

Table 7: Maximum likelihood estimates (MLEs) and 95% confidence limits (CL) for parameters describing the geographical spread of Schmallenberg virus.

Parameter	Symbol	MLE	95% CL	
			lower	upper
transmission between regions				
density-dependent transmission:				
transmission parameter	β	8.8×10^{-9}	2.7×10^{-9}	2.8×10^{-8}
power	α	4.1	3.6	4.7
distance scaling	d_0	46.6	31.6	69.5
density-independent transmission:				
transmission parameter	β	1.3×10^{-9}	1.1×10^{-9}	1.7×10^{-9}
power	α	4.6	4.0	5.3
distance scaling	d_0	98.1	73.0	136.1
duration of risk (days)				
mean duration of risk	μ_D	154.3	148.4	160.3
standard deviation for duration of risk	σ_D	28.5	24.8	33.2
within-region transmission†				
force of infection for cattle holdings	λ_C	1.6×10^{-5}	1.3×10^{-5}	2.1×10^{-5}
dispersion parameter (cattle holdings)	k_C	0.9	0.6	1.2
force of infection for sheep holdings	λ_S	2.1×10^{-4}	1.6×10^{-4}	2.7×10^{-4}
dispersion parameter (sheep holdings)	k_S	0.8	0.6	1.0

† assumes complete ascertainment of infected holdings (see Figure 23)

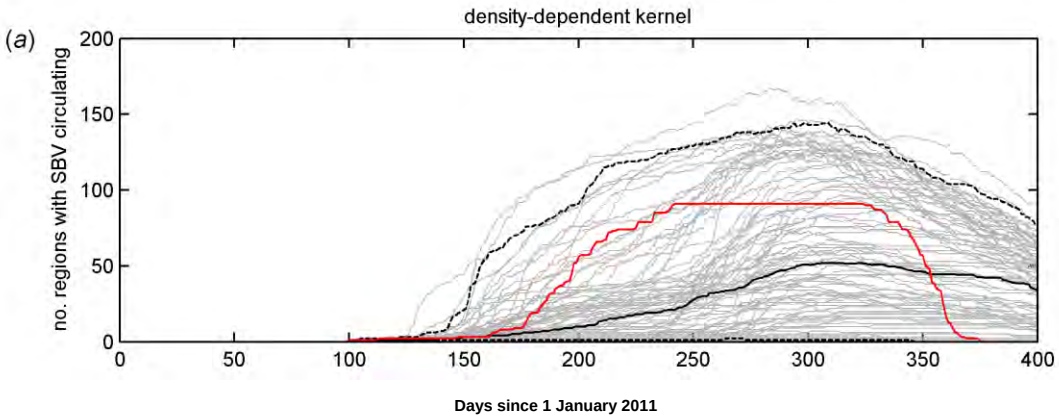


Figure 19: Predicted time course for the number of NUTS2 regions in which Schmallenberg virus was assumed to be circulating. Observed (red line) and predicted (solid black line: median; dashed black lines: 2.5th and 97.5th percentiles; grey lines: individual replicates) time course for the density-dependent kernel. Results are based on 100 replicates of the model using the maximum likelihood method to estimate the parameters (Table 7).

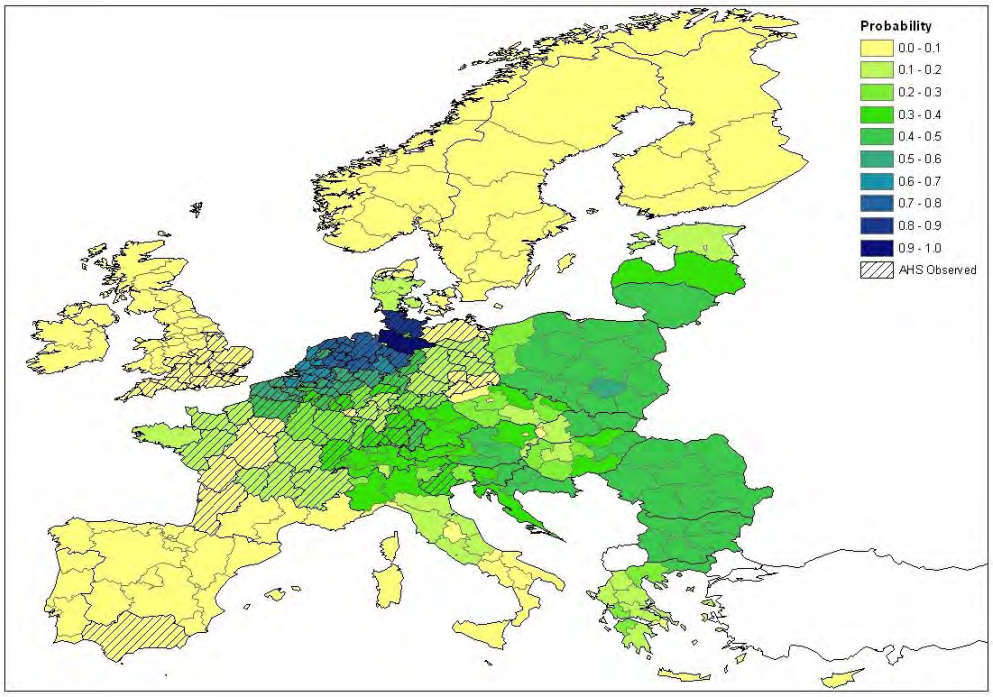


Figure 20: Predicted geographical spread of Schmallenberg virus in 2011 Dashed regions indicating the observed status (at least one cattle or sheep confirmed holding) and the colours indicating the proportion of model replicates for which that region became infected. Results are based on 100 replicates of the model using the maximum likelihood method to estimate the parameters (Table 7)**.** The holdings were reclassified at the NUTS 2 regional level.

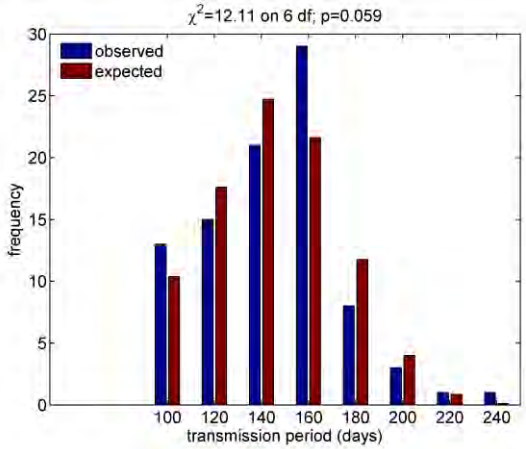


Figure 21: Observed (red bars) and expected (blue bars) duration of the transmission period for each region.

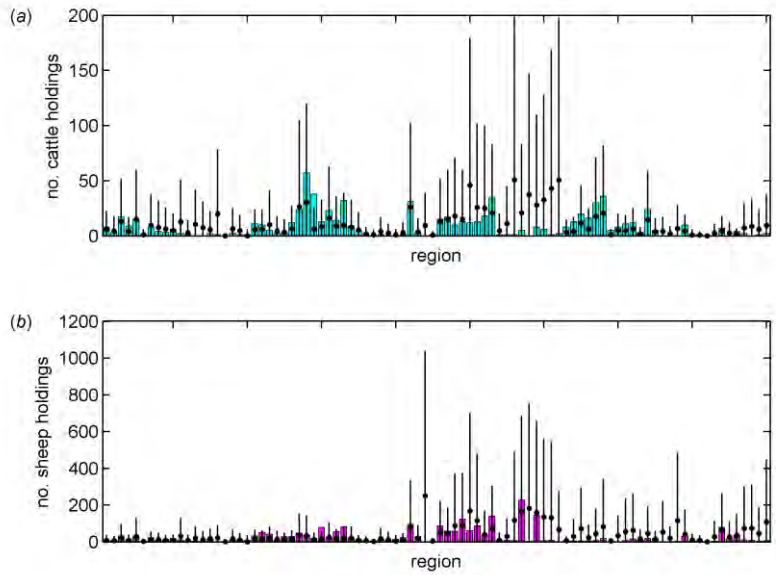


Figure 22: Observed (bars) and expected (mean (circles) and 2.5th and 97.5th percentiles (error bars) for the number of (a) cattle and (b) sheep holdings infected within a region. Affected regions are not labelled, but bars are ordered alphabetically by NUTS2 region code.

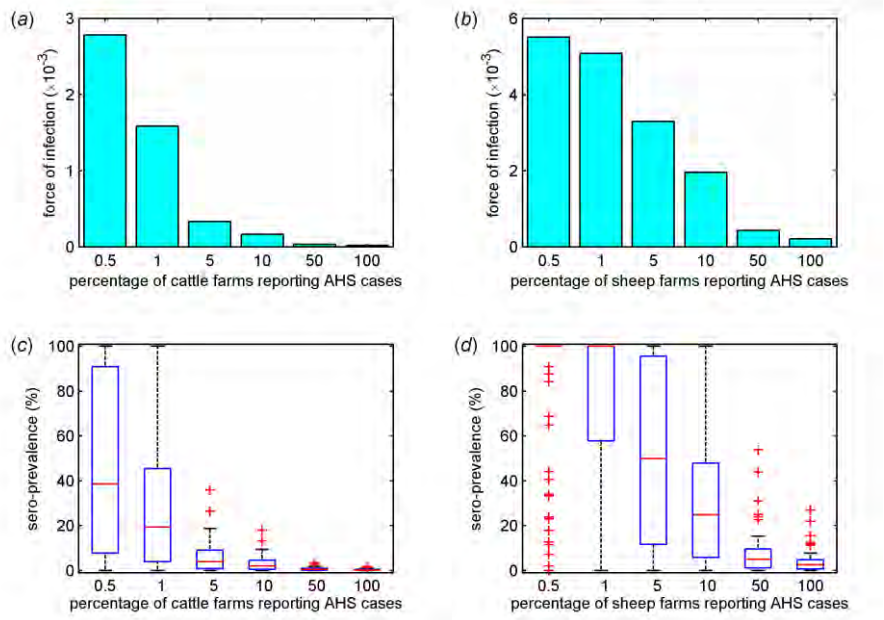


Figure 23: Impact of under-ascertainment of infected cattle and sheep holdings on estimates for the within-region force of infection for Schmallenberg virus. (*a*,*b*) Estimates for the within-region force of infection for (*a*) cattle or (*b*) sheep holdings assuming different values for the proportion of infected holdings reporting AHS cases. (*c*,*d*) Estimated sero-prevalence for (*c*) cattle and (*d*) sheep holdings in each region assuming a proportion of infected holdings report AHS cases.

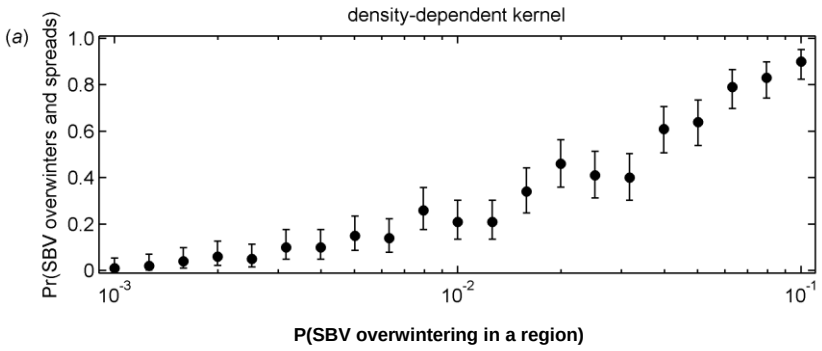


Figure 24: Probability that Schmallenberg virus overwinters and spreads in 2012. The circles represent the estimates and the error bars represent the 95% confidence interval and its dependence on the probability of SBV overwintering in a region. Results for each probability of overwintering are based on 100 replicates of the model.

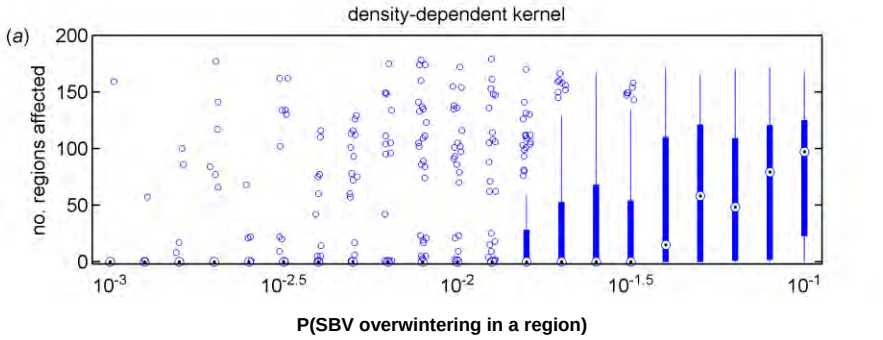


Figure 25: Predicted number of regions affected by Schmallenberg virus in 2012. Box-and-whisker plots show the median (target), interquartile range (blue bar), 1.5 times the interquartile range (whiskers) and any outliers (circles). Results for each probability of overwintering are based on 100 replicates of the model.

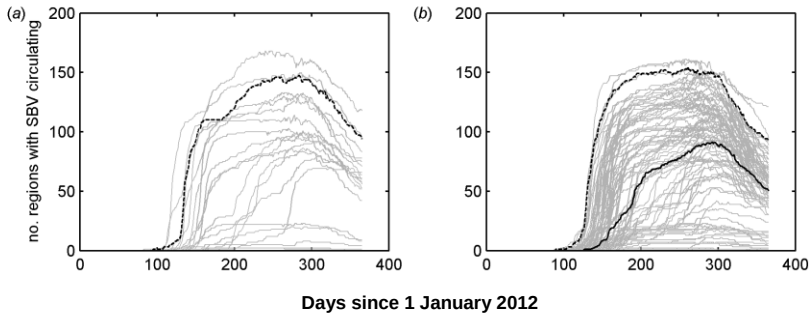
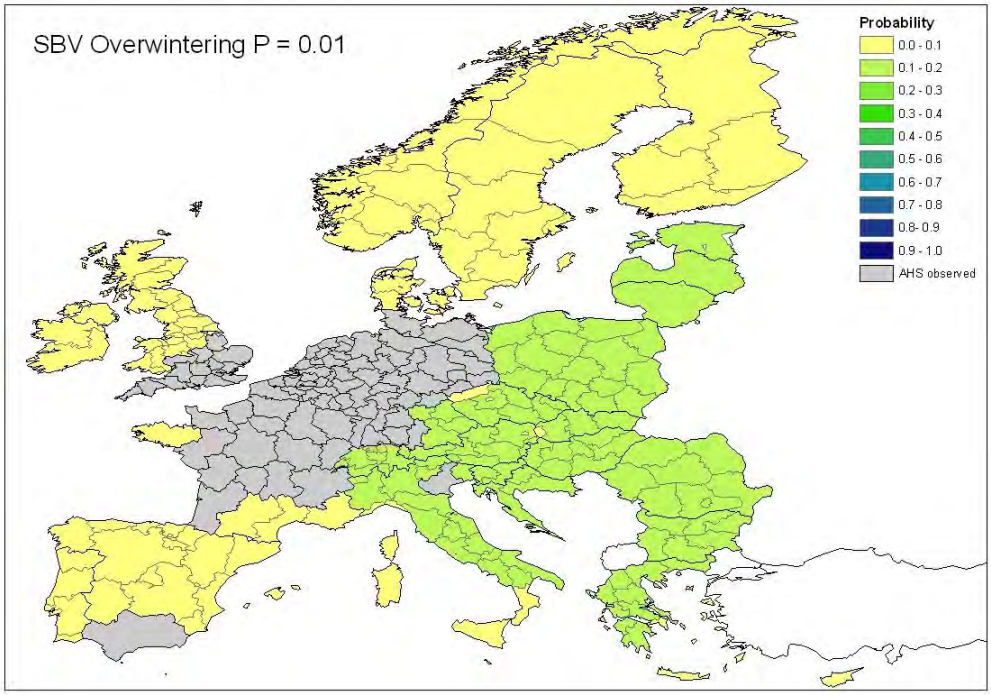
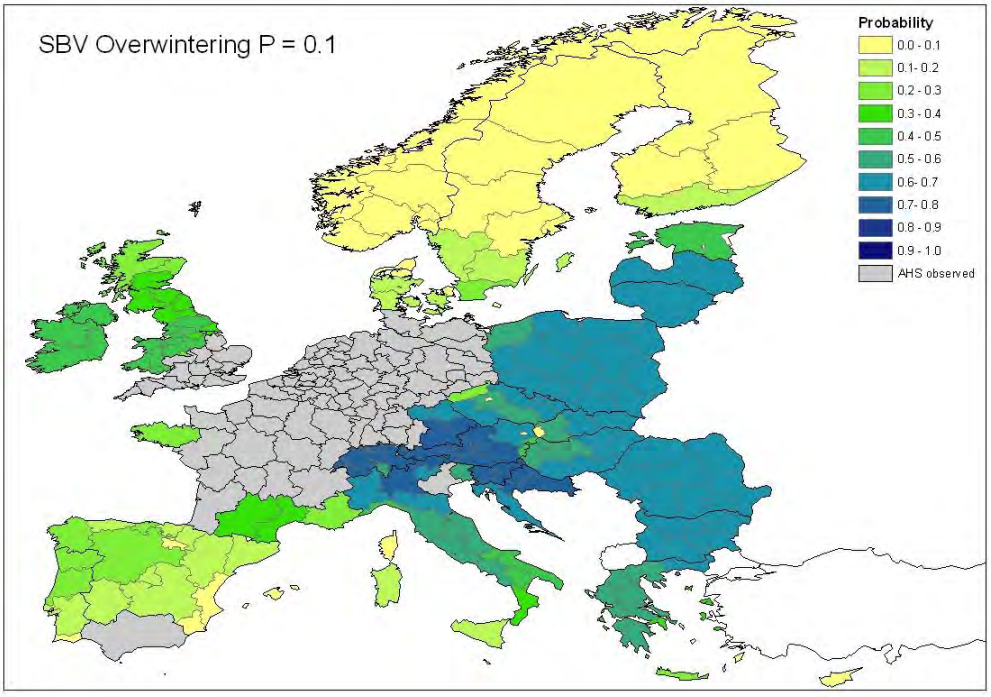


Figure 26: Predicted time course for the number of regions affected by Schmallenberg virus in 2012 assuming a probability of SBV overwintering in a region of (a) 0.01 or (b) 0.1. Each Figure shows the median (black line), 2.5th and 97.5th percentiles (dashed black lines) and individual replicates (grey lines).



a



b

Figure 27: Predicted geographical spread of Schmallenberg virus in 2012 assuming a density-dependent kernel and a probability of SBV overwintering in a region of either (a) 0.01 or (b) 0.1. Dashed regions indicating the observed status (at least one cattle or sheep confirmed holding) and the

colours indicating the proportion of model replicates for which that region became infected. The holdings were reclassified at the NUTS 2 regional level.

3.2.1.3. Potential Geographical and Seasonal Within holding Transmission

Temperatures too low for within holding transmission was estimated at around 15 ºC and below (see Appendix C.).The Figure 28 present the areas and seasons where $R_0 > 0$ at least one day every month. The analysis is based on daily calculation for the period 1983 – 2011, but only grid cells with 25 years or more temperature data are shown. In the period December-January the temperatures are too low for transmission of BTV9 and hence presumably also for SBV. During the late summer months only Scotland, Northwest Scandinavia and areas of high altitude do not allow transmission. This estimate of R_0 is independent of vector abundance. as long as vectors are present. Based on these historic temperatures alone areas with a risk of transmission cannot guarantee that animals are uninfected a given month.

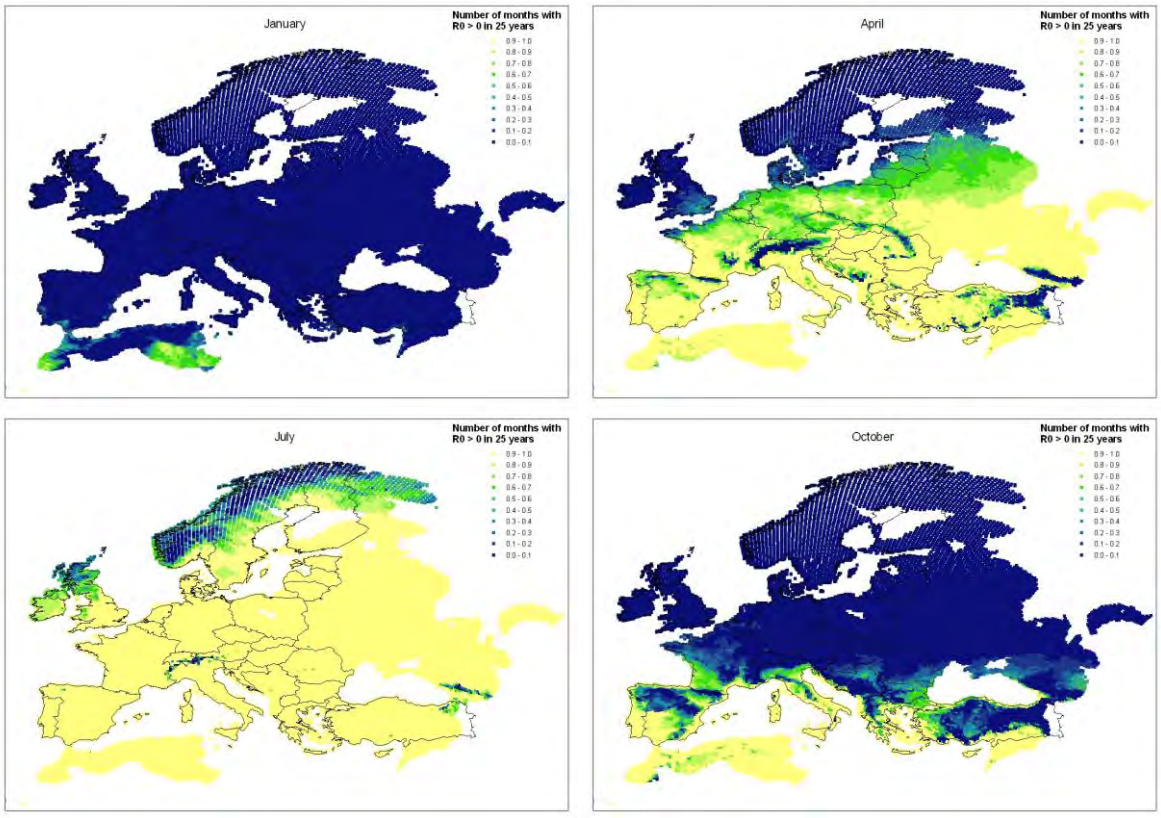


Figure 28: Areas and seasons where within holding transmission may take place at least one day per calendar month if an infectious host is introduced to the holding the particular month. The analysis was done for 25 to 29 years and the colours indicate for how many years the temperatures permitted transmission each of the 12 months, Yellow: 25 years out of 25 years, Blue: 0 years out of 25 years and White: no data available.

Large scale outbreaks require $R_0 > 1$. It is not possible to map the R_0 since the vector biting densities are largely unknown (results obtained from EU BT-Net data show lack of accuracy and comparability, thus not recommended to be used for this purpose) and might highly vary between months, regions of Europe and even between nearby holdings. Instead Figure 29 shows the densities of biting vectors needed to produce $R_0 > 1$ at the reported temperatures. Whenever this daily biting vector density is exceeded there is a risk that an introduction of SBV in a holding will spread to other animals in the holding.

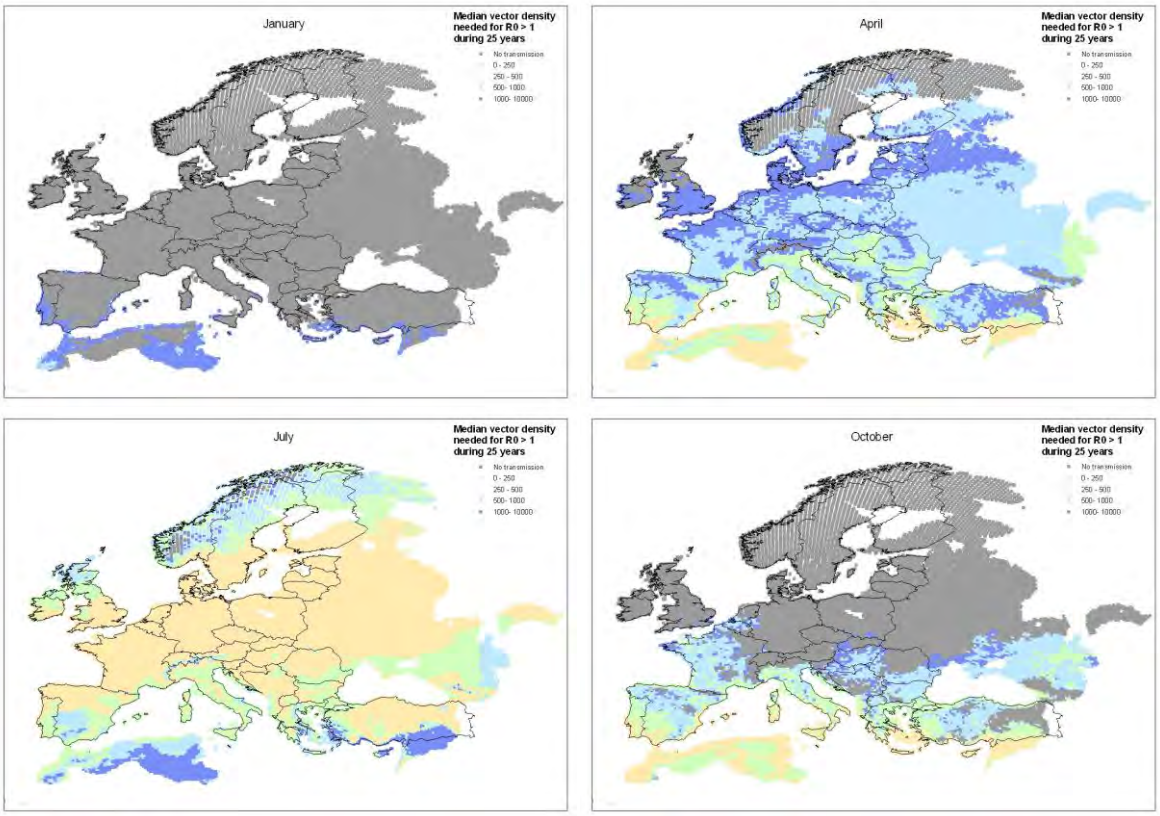


Figure 29: Areas and seasons where within holding transmission may exceed the important threshold value of 1 given the daily density of biting vectors indicated at the map. The analysis was done for 25 to 29 years and the data presented is the daily critical biting vector density for the median year. Grey areas indicate transmission was not possible in a median year, regardless of vector abundance. White areas indicate lack of data.

Temperate regions showed a clear annual pattern with the highest risk (lowest number of vectors required for R_0 to exceed 1) in July. The model estimated the optimum temperature for transmission to be between 18 and 19 ºC, and, because of this, on the southern European regions two peaks with high risk is observed: one peak in the cool spring and another peak in the cool autumn. However, this does not imply that the model suggests there are two annual transmission peaks in southern Europe: in fact, the actual transmission intensity will also be affected by the seasonality of vector abundance. The model only suggests that in southern Europe fewer vectors are needed in spring and autumn if compared to the warm summer.

Because of the low temperature optimum for BTV, and presumably for SBV, northern Europe, including parts of Scandinavia, appears to be well suited for virus transmission as long as *Culicoides* vectors are present, although the transmission season is shorter towards the north.

Resulting estimates are summarized in monthly means for each year at each grid point. Temperature varied between years and a minimum of 25 years was therefore used to predict risk for future years. Since Europe has experienced a warming trend in the past decades this may underestimate the true within holding risk, and therefore more pessimistic estimates based on the 10th percentile year are presented in the appendix (Figure 43).

3.2.2. SBV: Affected Holdings and Projection of AHS Cases per Region

3.2.2.1. Assessment Based on Reported Data

The number of confirmed holdings per country and species is shown in Figure 30. The largest proportion of the affected holdings in most countries are sheep holding except for Netherlands, .

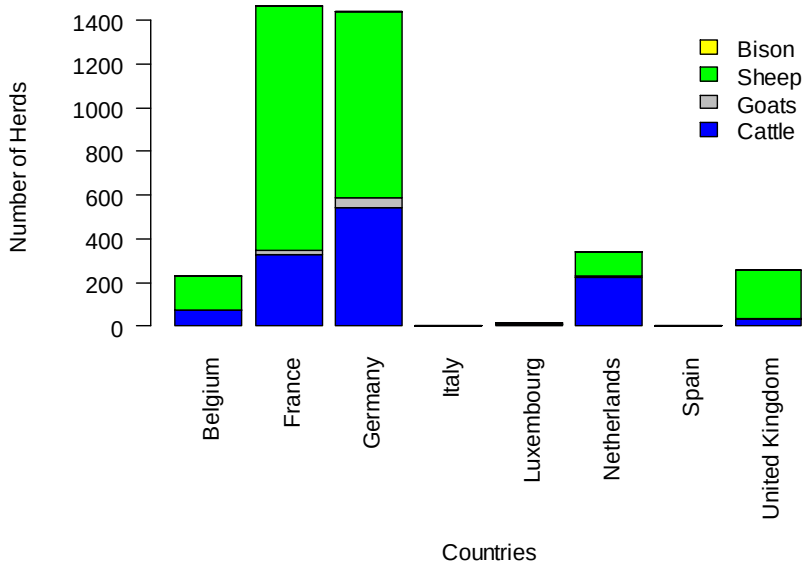


Figure 30: Total number of SBV confirmed holdings by country and species.

The comparative bar plots of the total number of holdings versus the total number of SBV confirmed holdings for each species are presented in Figure 31 to Figure 33. For all affected countries, the number of SBV confirmed holdings is low in comparison with the total number of holdings.

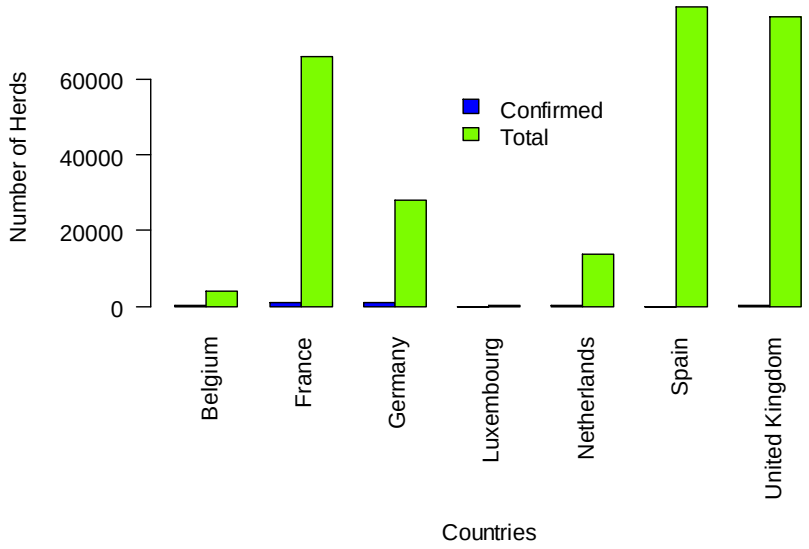


Figure 31: Total number of sheep SBV confirmed holdings by country versus total number of sheep holdings per country.

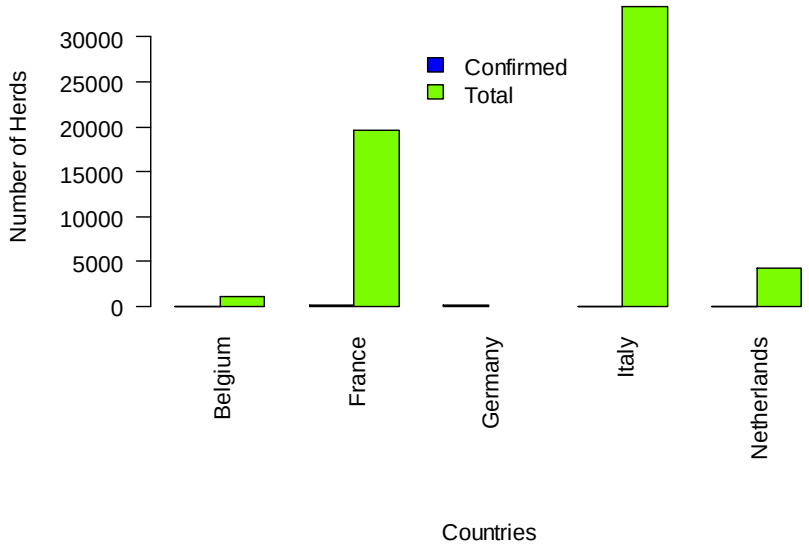


Figure 32: Total number of goats SBV confirmed holdings by country versus total number of goats holdings per country.

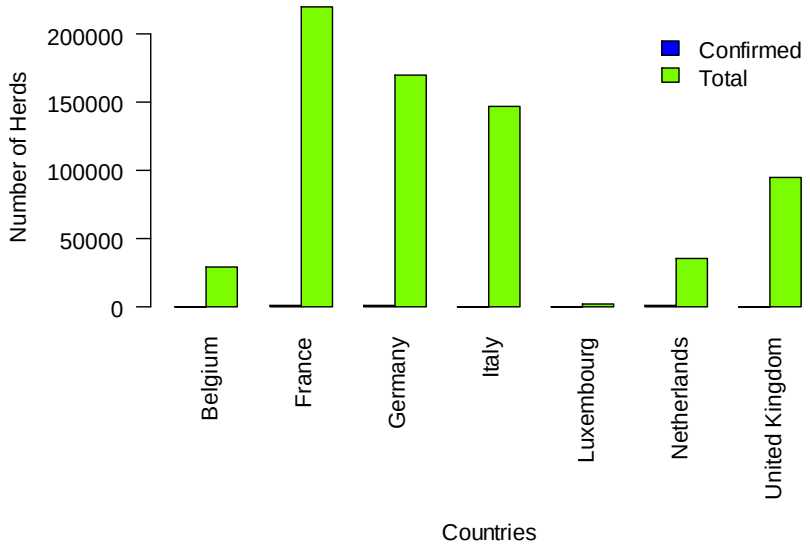


Figure 33: Total number of cattle SBV confirmed holdings by country versus total number of cattle holdings per country.

Table 8 below shows the ratio between SBV confirmed holding in sheep and cattle and the total number of holdings for the affected countries. This ratio was also calculated at NUTS 2 regional level and the results are shown in Figure 34 and 35, the maximum and minimum NUTS 2 region values are included in Table 8. The maximum number of holdings SBV confirmed per country was around 4% of sheep holdings in Belgium and per region in Germany (Nordrhein-Westfalen) 7.6% of sheep holdings were confirmed with SBV. For cattle at country level across Europe less than 1% of holdings were SBV confirmed, at the regional level in the Netherlands Flevoland showed 1.3% of cattle holdings being SBV confirmed.

The data indicates that the impact of SBV is greater in sheep holdings than cattle holdings but in no region or country does the number of affected holdings exceed 8%.

This analysis should be interpreted with caution as with a new disease under ascertainment in the early phase of the outbreak is expected and SBV is not notifiable in all reporting countries plus as described in section 3.2.1 the RT-PCR may result in false negatives especially in cattle. Additionally no reliable information was available on the number of foetuses or neonate exhibiting AHS clinical signs in the holdings with SBV confirmed, the reporting organisations were only able to report whether clinical signs had been observed for the holding as a whole.

Table 8: Proportion of cattle and sheep holdings confirmed with SBV

Ruminant	*Country*	*Total Holdings*	*Total SBV Confirmed Holdings*	*Percent Holdings Affected*	*Minimum Affected for NUTS 2 Region*	*Maximum Affected for NUTS 2 Region*
Sheep	Belgium	3890	155	3.98%	2.12%	6.21%
	Germany	28080	832	2.96%	0.25%	7.62%
	Spain	79120	5	0.01%	0.00%	0.07%
	France	66060	1122	1.70%	0.00%	6.73%
	Italy	75390	0	0.00%	0.00%	0.00%

Ruminant	*Country*	*Total Holdings*	*Total SBV Confirmed Holdings*	*Percent Holdings Affected*	*Minimum Affected for NUTS 2 Region*	*Maximum Affected for NUTS 2 Region*
	Luxembourg	220	6	2.73%	2.73%	2.73%
	Netherlands	13830	108	0.78%	0.00%	4.32%
	United Kingdom	76670	218	0.28%	0.06%	5.00%
Cattle	Belgium	28460	74	0.26%	0.11%	0.52%
	Germany	169700	541	0.32%	0.00%	0.97%
	Spain	124030	0	0.00%	0.00%	0.00%
	France	219970	328	0.15%	0.00%	0.80%
	Italy	147020	2	0.00%	0.00%	0.01%
	Luxembourg	1480	11	0.74%	0.74%	0.74%
	Netherlands	35260	233	0.66%	0.39%	1.32%
	United Kingdom	94650	36	0.04%	0.00%	0.92%

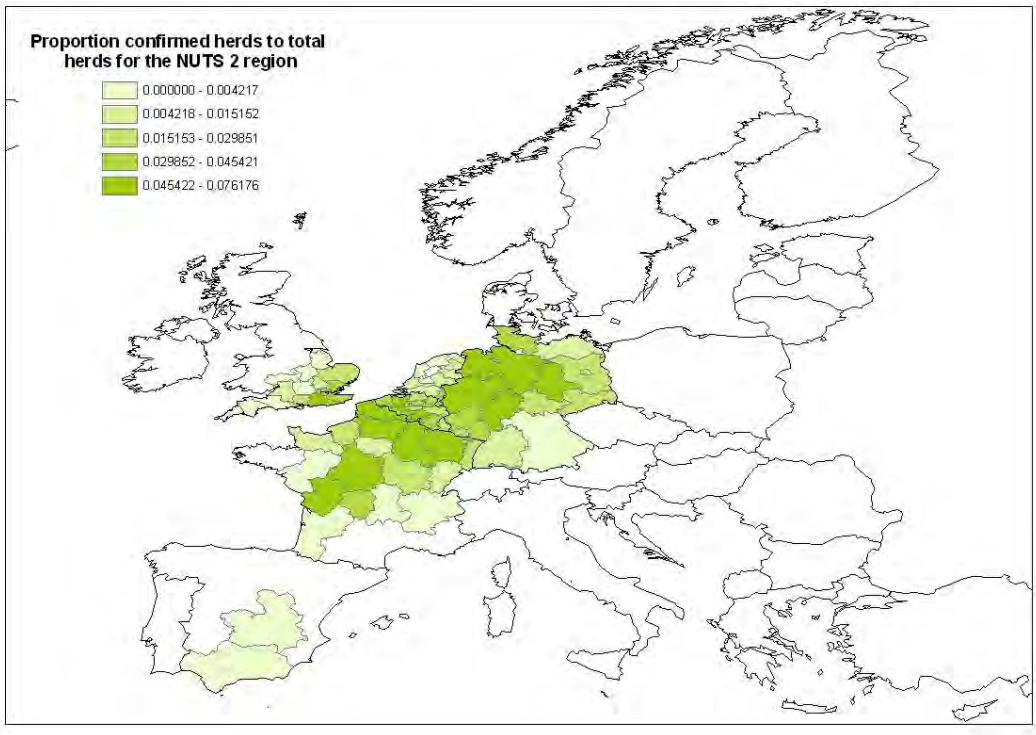


Figure 34: Proportion of confirmed herds for NUTS regions – **Sheep**

Due to lack of demographic data, the maps were made using NUTS2 level, resulting in larger shaded affected areas for some countries.

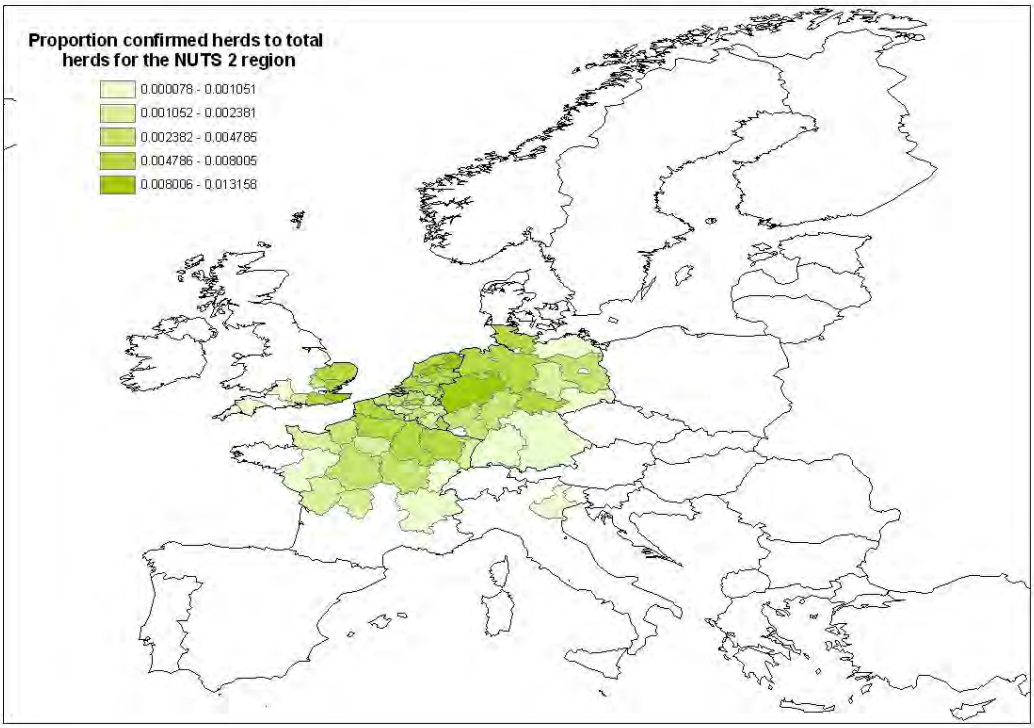


Figure 35: Proportion of confirmed herds for NUTS regions- **Cattle**

3.2.2.2. Projection of SBV – AHS cases based on Lambing and Calving Monthly Data

The estimated relative number of infected animals (cattle and sheep) for the regions that provided information regarding calving and lambing (see Table 3) is shown in Figures 36 and 37. The model requires the proportion of lambs or calves born each month (proportions calculated based on total births in a year) at regional level in order to predict the relative proportion of AHS cases (as defined in Section 2.3.2.5). Detailed information of this type was not available for all MS and as a consequence projections of the relative infection and impact are made for a limited number of regions and are therefore not representative for all countries in Europe.

The seasonal timing of infections is not substantially different for cattle and sheep (Figure 38 and Figure 39). Although the same parameter values are used in the within holding model for the two different host species, and thus the same monthly profile of infections would be expected on two identical holding sets infected at the same times, a different monthly profile would have been expected if the densities of the two hosts close to the geographical origin of the outbreak had differed substantially. For example, if sheep occurred at high densities in the earliest-infected areas then the observed monthly profile for sheep would be earlier than that for cattle.

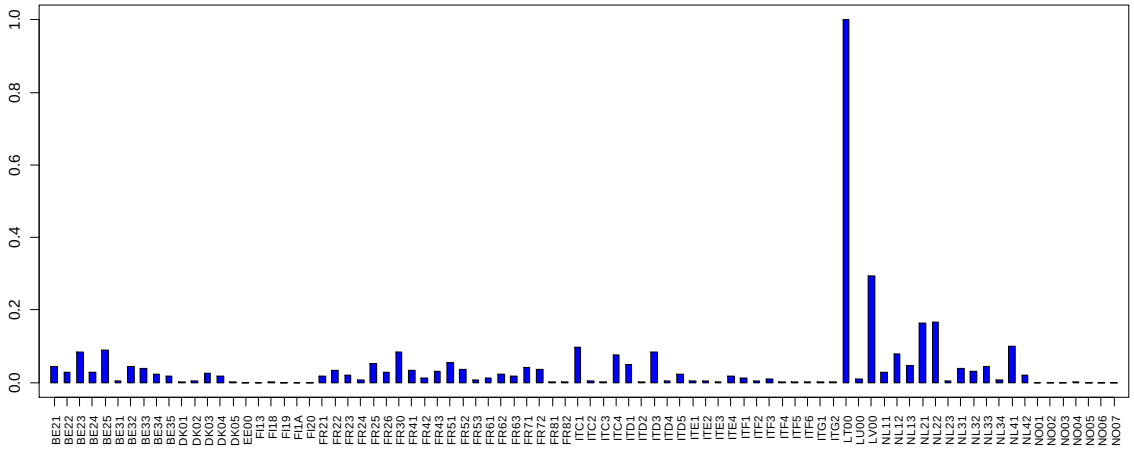


Figure 36: Total estimated impact (diseased calves born) by region, relative to maximum.- **cattle**

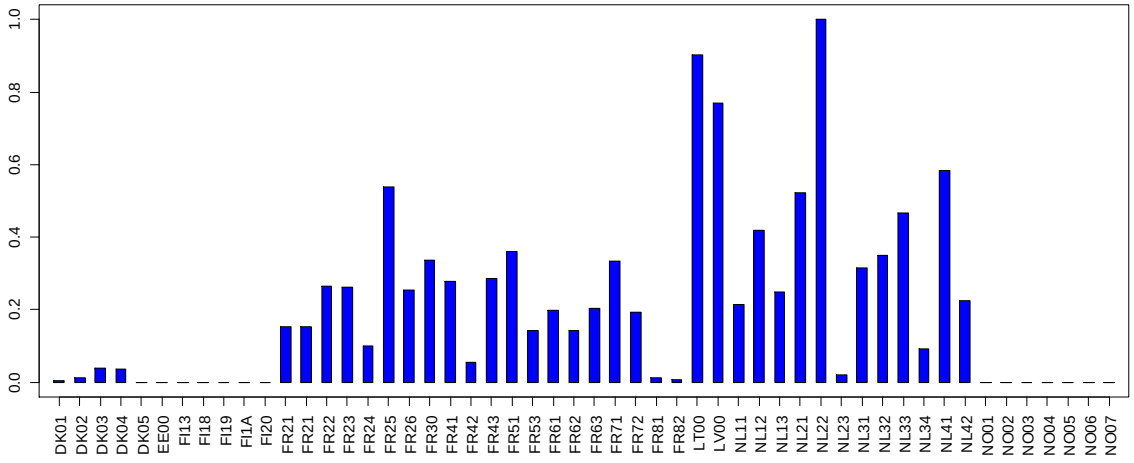


Figure 37: Total estimated impact (diseases lambs born) by region, relative to maximum.- **sheep**

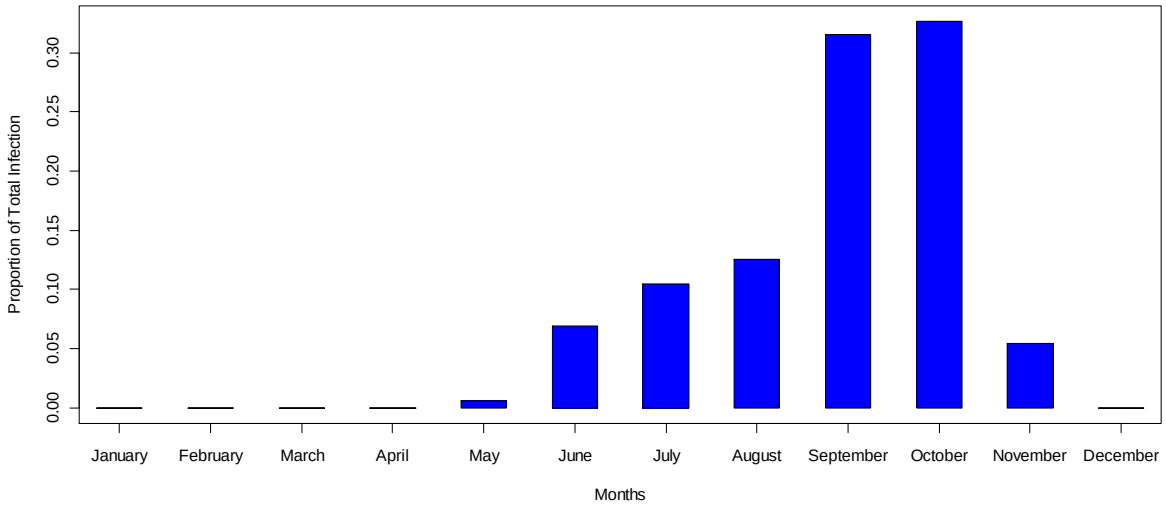


Figure 38: Predicted seasonal distribution infections over all regions - **cattle**

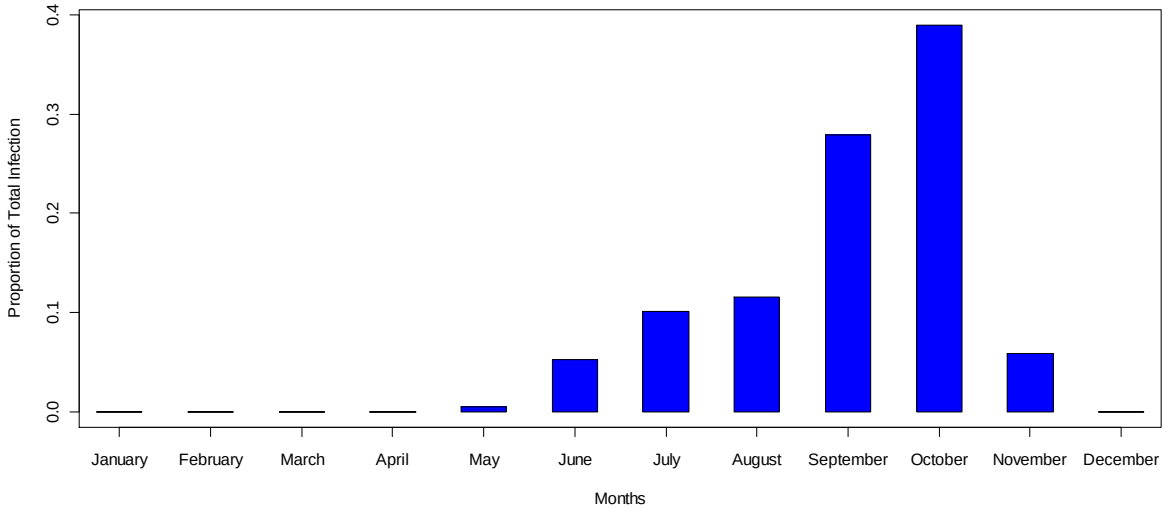


Figure 39: Predicted seasonal distribution of infections over all regions - **sheep**

Differences can be seen between the predicted temporal distribution of AHS cases in calves and sheep. These differences are a consequence of the different gestation periods in the different hosts, of the rate of geographical spread of the pathogen, of regional differences in host density and of regional differences in calving or lambing practice, as inferred from the expert opinions.

The predicted temporal disease profiles for the whole year 2012 suggest that no further cases of AHS are likely to be seen in lambs after the month April, while further cases in calves could be observed until July (Figure 40 and Figure 41). It should be highlighted that these findings are based on the regions for which data, valid to make the projection assessment of the SBV-AHS cases, was provided to EFSA hence the findings are not representative for all regions in Europe

The limited amount of geographical lambing and calving data available for this report limits the extent to which conclusions can be drawn regarding geographical variation.

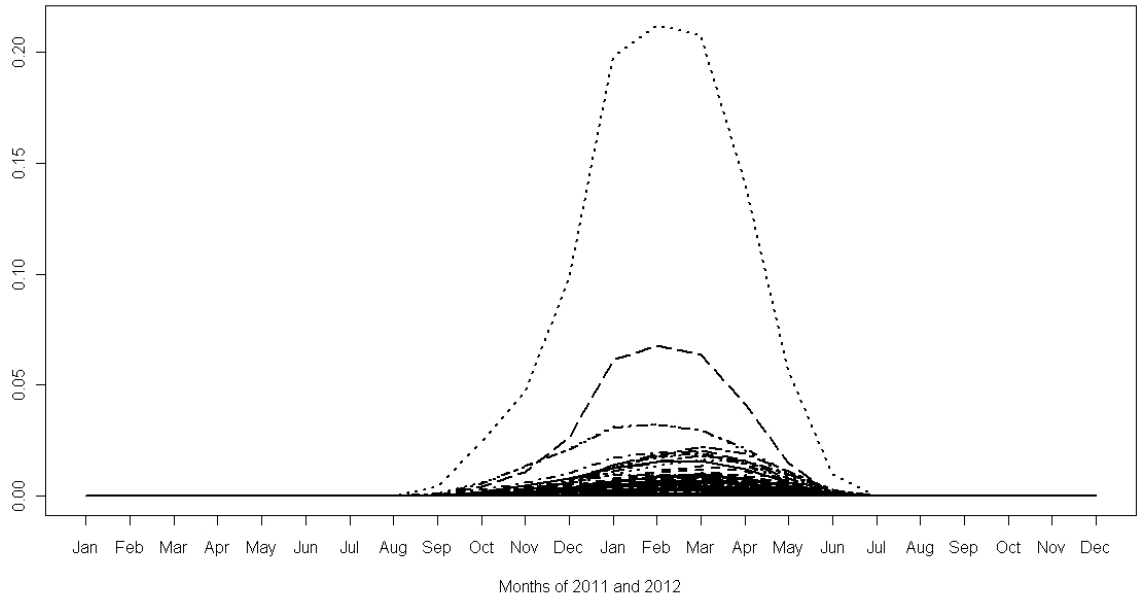


Figure 40: Predicted temporal distribution of AHS cases by region - **calves**

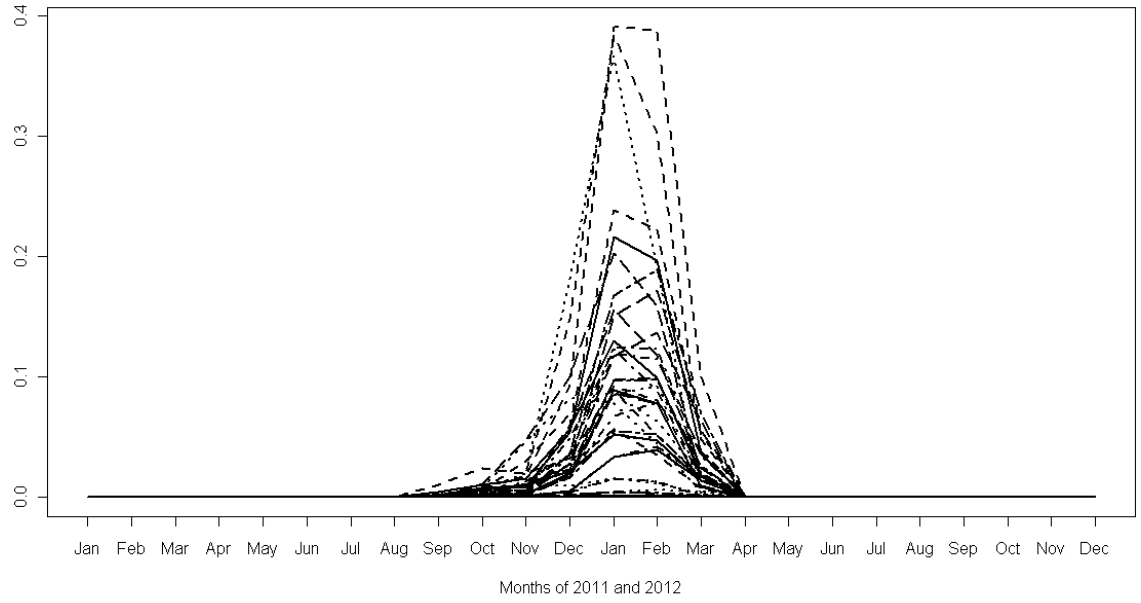


Figure 41: Predicted temporal distribution of AHS cases in by region - **lambs**

DISCUSSION

The fourth ToR of the EC mandate to EFSA requests an overall assessment of the impact of SBV infection on animal health, animal production and animal welfare together with a characterisation of the pathogen.

Regarding pathogen characterization, a narrative review of the available published literature on SBV was done including also some unpublished work that was brought to our attention. It is likely that

other work is under preparation and a further review of the information presented in this report will be essential.

Some discussion is ongoing regarding the origin of SBV and the possibility for this virus to be a reassortant from Sathuperi and Shamonda viruses (Yanase et al., 2012), which is regarded as a common feature in that group of viruses. However, the limited sequence information available about the M and L segments for most of the Simbu serogroup (Hoffmann et al., 2012) calls for further analysis to verify the phylogenenetic relationship of SBV with other related viruses.

Given that the affiliation of SBV to the Simbu serogroup is confirmed, and that Akabane virus is the most documented representative of the group, Akabane virus is used as a basis for most of the assumptions needed in the SBV assessment.

Further research is also needed on various aspects of the disease pathogenesis. The full range of susceptible species and the differences in their susceptibility is still unknown. Similarly, the duration of the viraemic period in affected animals is believed to be short but was not clearly established. The vulnerable period in the various species for the development of the different congenital defects observed is unknown; the estimated periods are however in accordance with the observed peaks of putative vector abundance.

Preliminary results are available regarding prevalence of infection mainly in areas where confirmed SBV cases were observed or areas neighbouring affected areas. The available results show a high percentage of seropositive animals in the confirmed herds and a high seroprevalence in affected regions. A gradient on the seroprevalence from north to south and west to east has also been observed but the results are still limited to a very small number of herds/animals and would need to be confirmed. Furthermore, results of seroprevalence studies must be interpreted with caution since validation of the available serological tests (VNT and ELISA) is not completed, and therefore test performance remains unknown. Comparison between different studies is complicated by different sampling strategies and laboratory protocols.

Questions regarding transmission routes are still unanswered but the temporal distribution of reported cases and the detection of SBV in different culicoides pools all seem to indicate that the most likely route of transmission is, as with all other viruses of the same group, vector borne.

After bluetongue emergence in the Mediterranean basin at the end of the 1990s, some member states started to monitor *Culicoides* populations. Later, bluetongue emerged in the North-West of Europe in 2006, and most of the European countries implemented a national system for the surveillance of *Culicoides* populations. Member states were invited by European regulations to share entomological data in a European database (EU BT-NET). This is probably a unique example of vector population monitoring at a continental scale during several years leading to an exceptional description of *Culicoides* diversity, population distribution and dynamics.

Some member states such as Belgium, Germany (2007 and 2008), United-Kingdom or Norway have also monitored *Culicoides* populations, but in absence of information about trap locations the result of the monitoring could not be mapped. Comparison between countries is difficult because of differences in: i) UV-light trap models ii) taxonomic level in *Culicoides* identification (at species of group level) and iii) trapping frequencies. Moreover, reporting is partial; the EU BT-NET system provides a maximum number of species to report of 14 and it is clear that these numbers of species do not reflect the actual diversity. Indeed, *Culicoides* fauna is composed by about 70 species in France (Venail *et al.* 2012), around 40 species were found in Greece (Patakakis *et al.* 2009), and 34 species in Sweden (Nielsen *et al.* 2010). These discrepancies with the data reported in BT-NET are primarily due to absence of discussion between partners involved in *Culicoides* surveillance to agree on: i) data to be shared and ii) level of identification available.

Culicoides diversity is contrasted especially between Mediterranean and non-Mediterranean regions. *Culicoides imicola* was the dominant species in the western Mediterranean basin while the Obsoletus Group was dominant in most of non-Mediterranean areas.

It is known that *Culicoides* dynamics depends on meteorological conditions. In non-Mediterranean Europe, *Culicoides* dynamics is usually bimodal with a population decline during summer and two peaks of abundances in spring and in autumn. The size of these peaks depends on meteorological conditions. This general pattern may be different from one year to another due to climatic variation among the years. For example, particularly wet summer may lead to unimodal abundance in regions where usually two peaks of abundance were previously observed. On the other hand, a single and a particularly high peak of abundance may be observed in place where favorable conditions occur in a short period of the year: mountain regions of northern locations. Moreover, 2 different species may exhibit different seasonal pattern under the same meteorological conditions. Indeed, in Corsica, the Obsoletus complex highlights an abundance peak in spring whereas *C. imicola* is present from July and most abundant in August (Balenghien *et al.* 2011). These two species do not have the same population dynamic, due to differences in optimal conditions for reproduction.

The assessment based on reported data results from data collected by EFSA referring to the period August 2011 to 10 May 2012. Uniform case definitions for the detection of infected adults and newborns were agreed to ensure comparability but the report levels are dependent of the disease regulatory framework (notifiable or not) in different countries, the level of awareness of different stakeholders and the diagnostic capability in place.

The date of the first report of confirmed herd based on confirmation of AHS case was 28 November 2011, if this was in fact the first case in lambs or a consequence of the lack of awareness about the new disease is difficult to determine. The temporal distribution of reported cases follows the lambing /calving season and it is not informative about the spread of infection that most likely occurred earlier on and was undetected since reporting of acute cases in adults was unlikely, only 8 holdings were reported from Germany in September 2011. Since the vulnerable stages of gestation in the various species are unknown there is great uncertainty of when infection occurred in the various regions of the EU.

The principal issue when attempting to investigate the geographical spread of SBV is that the epidemiological data do not provide direct information on when regions (or holdings) become infected. Rather, they provide the dates on which holdings in each NUTS2 region report AHS cases. From the reporting dates it is possible to infer a range of dates for which SBV must have been circulating in the NUTS2 region, but there is considerable scope for under-ascertainment, both of AHS cases and disease in adults, especially for a new disease such as that caused by SBV.

Under-ascertainment is an issue for any passive surveillance system however under-ascertainment at a regional level is partly mitigated by the methods used to reconstruct the transmission period (i.e. the time period when SBV was circulating) for each region. These methods cannot, however, account for holdings infected before or after the risk periods for holdings which report disease. Moreover, they require estimates for the stage of gestation at which infection with SBV at which AHS cases occur. These are not yet available for SBV, so a worst case scenario with a wide interval for the vulnerable period was used (see Section 1.3.).

It is very difficult to allow for under-ascertainment when analysing the number of infected cattle and sheep holdings within a region. Without additional data (for example, on sero-prevalence of holdings) it is not possible to infer the level of under-ascertainment and its impact can only be explored using a sensitivity analysis. Comparing the predicted sero-prevalence in each region with the range of sero-prevalences for SBV that have been reported for a small number of studies so far (Table 2) suggests that the proportion of infected cattle holdings reporting AHS cases is 0.5-1% (Figure 23c), while for infected sheep holdings it is 5-10% . This implies the within-region force of infection for cattle is

underestimated 100-fold, while that for sheep is underestimated 20-fold (Figure 23b) if complete ascertainment of cases is assumed.

The modelling approach adopted in the present study assumes that the parameters for transmission within and between regions are the same throughout Europe. However, it is likely that there will be regional heterogeneities in transmission as a consequence of environmental (in particular, temperature) or other factors. The model could and should be extended to explore the impact of these heterogeneities on the parameter estimates and model predictions.

In addition, the data were modelled at the level of NUTS2 regions rather than at the level of holdings. This was in part because of the available demographic and epidemiological data. In effect, this means we have adopted a metapopulation approach in which each region is treated as a patch (or subpopulation). This will clearly have implications for parameters describing transmission between regions, which may be quite different from those obtained if the model were applied at the holding level (cf. estimates obtained by de Koeijer et al. 2011, where a similar approach was applied to holding-level data for bluetongue virus in Europe, where transmission mechanisms are likely to be similar).

The critical parameter for determining the potential for spread in 2012 is the probability of overwintering. However, virtually nothing is known about mechanisms by which SBV may overwinter. Transmission from infected calves and lambs infected *in utero* could provide an important means of the virus surviving from one vector season to the next, but the probability of this occurring has not been quantified. Indeed, the most reliable indicator of whether or not there is a high probability of overwintering will be if and how SBV re-emerges in 2012 (e.g. as a single focus or as multiple foci).

The model used to investigate potential geographical and seasonal within holding transmission is based on historic temperatures. The interpretation of the risk is for practical purposes somewhat equivalent to the vector free periods identified in Europe during the BTV8 outbreak in 2006-09.

The maps of within holding spread produced include areas where spread between holdings might be unlikely. Therefore vector abundance exceeding the critical biting vector density does not necessarily mean that an increasing number of holdings will be affected, it merely suggest that an increasing number of animals in the affected holding are at risk of being infected. Existing or future national data on *Culicoides* biting rates at any geographical scale can be transformed into rough estimates of monthly epidemic risk using the maps in Figure 29. In general early spring and late autumn required a large number of biting vectors per host, but it should be noted that light traps collections from many European countries suggest that biting rates of more than a 1000 vectors per day are not unusual.

The model estimated the optimum temperature for transmission to be between 18 and 19 ºC, and because of this on the southern European regions two peaks with high risk is observed, one peak in the cool spring and another peak in the cool autumn. However this does not imply that the model suggests there are two annual transmission peaks in southern Europe since the actual transmission intensity will also be affected by the seasonality of vector abundance. The model only suggests that fewer vectors are needed in the spring and autumn in southern Europe compared to the warm summer.
Because of the low temperature optimum for BTV9 and presumably for SBV northern Europe including parts of Scandinavia appears to be well suited for virus transmission as long as *Culicoides* vectors are present, although the transmission season is shorter towards the north.

The assessment based on reported data is limited to the determination of proportion of confirmed SBV holdings in relation to the total number per holdings per species in the country. The highest proportion of affected holdings is observed in sheep in Belgium. The assessment of the proportions of reported affected holdings in term of the total number of holdings in the regions is less than 10 % for all affected regions. No data is available to allow for the determination of impact at herd level and future

retrospective studies of affected herds as well as case control studies are essential to have a insight on the within herd impact of SBV.

The impact on animal welfare and animal production was not assessed due to lack of data. It is necessary to investigate the impact of SBV infection on fertility (return to service), milk yield and rates of dystocia.

The approach taken to evaluate future impact (projection of SBV-AHS cases) has some limitations in addition to the assumptions detailed previously. It cannot be used to provide absolute estimates of the number of animals infected, given that the within-region force of infection (estimated in Section 3.2.1.2) is likely to be substantially underestimated.
In addition the model predicts that the regions that have the highest infection and impact figures in cattle (and AHS cases) and those regions with the highest infection and impact figures in sheep (and AHS cases) are in general regions with large number of holdings (high livestock density). This is a consequence of the geographical spread model predictions, which predicts the highest numbers of infected animals in the southern and eastern regions of Europe and the levels of infection depends on the livestock density.

It is important to note that the within holding model results in a low R_0 even though the preliminary seroprevalence studies suggests a high R_0 for some of the affected holdings. This indicates that there may be factors in the model that have not been accounted for, and they should be included in further assessments. If a large number of holdings are infected but R_0 values are low, a high proportion of outbreaks will contain only a single animal, which in turn means that the estimated number of infected animals per region is quite susceptible to the number of holdings in the region (having many hosts per holding becomes less important if most outbreaks die out while the number of cases is still small).

The estimates of the numbers of disease cases are subject to additional error due to lack of data on the probability of disease following SBV infection and in order to overcome this problem those for Akabane virus have been used.

Finally, underreporting is a likely issue in the case of a passive surveillance system such as the one used for SBV. However, if we assume that underreporting occurs at a constant rate we can use this to estimate the extent to which the overall impact of SBV on lambs and calves in the affected areas has been realised and the degree to which further cases are likely to be observed. Also, the assumption that holding size distributions in the UK are representative of those across the affected area may not be appropriate, thus it should be tested using the available data. Although, it should be highlighted that similar exponential patterns have been observed for Belgium and Germany.

CONCLUSIONS

The first detection of SBV occurred in Germany in 2011, the virus has now been identified as a member of the Simbu serogroup of the Orthobunyavirus genus. Analysis of the genetic sequence of SBV shows sequence similarities to a number of different Simbu serogroup viruses and suggests possible genetic reassortment.

Results from new studies confirm the initial assessment of the European Center for Disease Control and Prevention that it is very unlikely that SBV poses a risk to humans (ECDC, 2012).

Recent entomological investigations have identified SBV in samples of *Culicoides obsoletus* group. There is no evidence for any other transmission route apart from transplacental and vector borne routes.

Information gathered on vectors density distribution was collated by EU BT-NET after the bluetongue outbreak of 2007. Data indicates that the *Culicoides obsoletus* group is widespread in Europe. However not all countries in Europe reported information on *Culicoides*, the sampling methods are not harmonized and there is evidence of misidentification of *Culicoides* species.

SBV has been laboratory confirmed in holdings in eight[8] Member States. EFSA coordinated the collation of SBV epidemiological data during 2011-2012 in order to obtain comparable data for Europe. SBV has only been detected in ruminants (sheep, cattle, goats, bison), SBV antibodies were detected in deer no other species are known to be affected.

In Europe mid May 2012, 3745 holdings have been reported with SBV cases confirmed by laboratory testing. The maximum number of sheep holdings SBV confirmed was 4% per country and in a single region 7.6%. For cattle holdings at country level less than 1.3% of holdings were SBV confirmed. The data indicates that the impact of SBV is greater in sheep holdings than cattle. This assessment of impact should be interpreted with caution, since the case ascertainment is dependent on the disease being notifiable or not, the level of awareness of different stakeholders and the diagnostic capacity in the MS. No data is currently available on the within herd impact.

Only 8 holdings were confirmed based on viral detection in acute cases in adult animals in 2011, the remaining corresponds to detection in newborn and foetuses with AHS type clinical signs. The temporal distribution of AHS cases reports probably reflects the calving and lambing distribution. Adjustment according to the gestation and vulnerable period of the host shows that the likely period of infections for dams was between October and November 2011.

The impact on animal welfare and animal production was not assessed due to lack of data. It is necessary to investigate the impact of SBV infection on return to service, milk yield and rates of dystocia.

The geographical spread model is broadly able to capture the observed dynamics of SBV in Europe during 2011 in terms of geographical spread, duration of the transmission period and the number of infected holdings within a region. However, estimates for the within-region force of infection depend critically on the level of under-ascertainment of infected holdings, which sero-prevalence data suggest could be substantial.

The probability of SBV surviving over the winter and subsequently spreading in 2012 is difficult to assess because of lack of data. However, previous experience with BTV8 indicates that vector borne viruses can overwinter, if SBV overwinters the geographical spread model predicts that SBV is most likely to re-emerge between mid-April and the end of May and that any outbreak of SBV is likely to be of a similar size to the one occurred in 2011, though in regions previously unaffected (assuming

[8] Since completion of this report, Denmark has subsequently confirmed the presence of SBV through laboratory testing.

immunity in previously affected regions). From the prediction of the geographical spread model, the most likely affected areas for next season are expected to be to the south and east regions of the previously-affected areas.

The model of geographical and seasonal within holding transmission using BTV parameters suggests virus transmission and spread becomes possible at temperatures around 15° C with a temperature optimum between 18° C and 19° C. The analysis of the preceding 29 years daily temperatures suggests that most of Europe has a suitable climate for within holding vector borne transmission.

The projection model shows that further cases of AHS are likely to be very rare in lambs for the year 2012 after the month April, clearly predicting the observed pattern, since negligible number of affected sheep herds are reported in the month of April and May. However the model predicts that further cases in calves could be observed until July, consistent also with the observed pattern for this species, in which the newly reported affected holdings are mainly cattle holdings. It is important to note that the projection assessment is based on the regions that provided data (monthly calving and lambing percentages) and were suitable to conduct the assessment, thus might not be representative for all regions in Europe. The model predicts that the regions that have the highest infection and impact figures in cattle (and AHS cases) and those regions with the highest infection and impact figures in sheep (and AHS cases) are in general regions with large number of holdings (high livestock density).

In regions with SBV confirmed holdings, assuming a high prevalence of infection and post infection immunity, impact in the 2012-2013 calving and lambing season should be low. However, assuming SBV survived the winter of 2011, the models suggest that in unaffected regions or regions with low prevalence with suitable temperatures for within herd transmission by vectors and high density of susceptible species (cattle and sheep) SBV infection is likely to spread.

RECOMMENDATIONS

It is recommended that serological investigations are continued both in affected regions and regions neighbouring the known affected areas in order to determine the geographic spread of SBV infection and estimate seroprevalence. Such information would be useful to reduce under ascertainment and improve modelling predictions

No data is available regarding within herd impact. Information concerning the number of newborns and foetuses within a holding with arthrogryposis hydranencephaly syndrome (AHS) type clinical signs and other consequences of SBV infection such as loss of production is needed. This could be achieved by follow up monitoring of selected herds to properly evaluate the impact and magnitude of the spread of SBV infection.

Continued monitoring of EU ruminant adult population in affected regions and regions neighbouring the known affected areas is necessary in order to early detect infection with SBV. Monitoring of the putative vector populations (distribution, abundance and SBV detection) should be continued.

SBV was observed for the first time in September 2011. Its origin is still not known and should be investigated as more information becomes available on the virus characteristics and infection epidemiology. Retrospective seroprevalence studies are also essential in order to estimate the start of the outbreak.

The following knowledge gaps should be addressed:

- SBV vector competency and other vector host transmission parameters (eg. data on the extrinsic incubation period);
- Distribution, density and over wintering of Culicoides vectors;

- SBV host vector transmission parameters;
- Other routes of transmission;
- Host susceptibility, species range, virulence and vulnerable period during gestation;
- Development and duration of post infection immunity;
- Potential extensions of the geographical spread model.

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APPENDIXES

A. EPIDEMIOLOGICAL PARAMETERS FOR SCHMALLENBERG VIRUS

Parameters (point estimates and distributions) were derived from data in the published literature (Table 9). In some cases it was possible to obtain estimates related directly to SBV(duration of viraemia, probability of transmission of host to vector) or to *Culicoides* biting midges, the putative vectors of SBV (probability of transmission from vector to host, reciprocal of the time interval between blood meals, vector-to-host ratios, vector mortality rate). However, no information is available on the extrinsic incubation period for SBV and, hence, this was assumed to be the same as bluetongue virus (BTV).

Table 9: Point estimates and distributions for epidemiological parameters for the within-holding transmission of Schmallenberg virus (SBV).

Description	Symbol	Estimate	Distribution†	Comments
probability of transmission from infected female to offspring	p_V	-	Uniform(0,1)	-
probability of transmission from vector to host	b	0.78	Beta(7.38,2.13)	based on an analysis of data on the transmission of bluetongue virus to sheep by *C. sonorensis* presented in Baylis et al. (2008)
probability of transmission from host to vector	β	0.014	Beta(2.9,210.5)	based on analysis of Belgian data provided in ProMed report (archive number: 20120311.1066949); two pools out of 23 pools tested (each of 10 midges) were positive for SBV
ratio of vectors to cattle	m_C	-	Triangular(0,5000,1000)	based on a maximum host biting rate ($m_i a_i$) of 2500 bites per host per day (Gerry et al. 2001); cf. median holding size of 60 breeding cattle (census data) and light trap catches of up to 10000 midges per trap night (Meiswinkel et al. 2008)
ratio of vectors to sheep	m_S	-	Triangular(0,5000,1000)	cf. comment on ratio of vectors to cattle
reciprocal of the time interval between blood meals	a	-	-	depends on temperature: $a(T)=0.0002T(T\text{-}3.7)(41.9\text{-}T)^{1/2.7}$ (Mullens et al. 2004)

Description		Symbol	Estimate	Distribution†	Comments
duration of viraemia (cattle)	mean (days)	$1/r_C$	4	log N(1.4,0.4)	mean based on experimental infection of three calves with SBV (Hoffmann et al. 2012)
	no. stages	n_C	-	Uniform(1,20)	assumed range to reflect a range of possibilities from exponential distribution to (approximately) fixed duration of viraemia
duration of viraemia (sheep)	mean (days)	$1/r_S$	4	log N(1.4,0.4)	assumed to be the same as cattle
	no. stages	n_S	-	Uniform(1,20)	
Vulnerable period of gestation (cattle)					Since the vulnerable gestation period for cattle to SBV infection is not yet determined it was decided to assume a worst case scenario of 62 to 173 based on data available mainly for Akabane virus (Section1.3.)
Vulnerable period of gestation (sheep)					Since the vulnerable gestation period for sheep to SBV infection is not yet determined it was decided to assume a worst case scenario of 28 to 56 based on data available mainly for Akabane virus (Section1.3.).
virus replication rate above threshold		α	0.0189	N(0.0189,0.0035)	extrinsic incubation period assumed to follow a gamma distribution with reciprocal of the mean given by ν(T)=max(0,α(T-Tmin)) and scale parameter k; parameter estimates based on analysis of data for replication of bluetongue virus serotype 9 in C. sonorensis (Carpenter et al. 2011)
threshold temperature for virus replication		T_{min}	13.35	N(13.35,0.38)	
scale parameter for extrinsic incubation period		k	-	log N(2.63,0.76)	
vector mortality rate		μ	-	-	depends on temperature: μ(T)=0.009exp(0.16T) (Gerry & Mullens 2000); the equivalent daily survival probability is exp(-μ(T))
vector recruitment rate		ρ	-	-	for simplicity assumed to be equal to the vector mortality rate

† for the triangular distribution parameters are minimum, maximum and mode; log N indicates a log normal distribution

B. GEOGRAPHICAL SPREAD: METHODOLOGICAL DESCRIPTION

Modelling approach

Transmission between regions was modelled using a kernel-based approach, similar to that used previously for avian influenza (Boender et al. 2007; Truscott et al. 2007), foot-and-mouth disease (Chis-Ster & Ferguson 2007) and bluetongue (de Koeijer et al. 2011). In this case, the force of infection, λ, for region j on day t is given by,

$$\lambda_j(t) = \beta v(t)(C_j + S_j)\sum_{k \neq j} K(d_{jk})(C_k + S_k)I_k(t),$$

where β is the transmission parameter,

$$\log(v(t)) = b_0 + \sum_{n=1}^{2} a_n \sin\left(\frac{2n\pi}{365}t\right) + b_n \cos\left(\frac{2n\pi}{365}t\right),$$

is the seasonal vector activity (normalised so the maximum value is one; parameters were obtained from Sanders et al. 2011, their Table S1), C_j and S_j are the number of holdings with cattle or sheep in region j, respectively, and $I_k(t)$ is a variable indicating whether region k is uninfected (0) or infected (1) on day t. This formulation assumes that cattle and sheep holdings are equally susceptible and infectious.

Two formulations were considered for the distance kernel, $K(d_{jk})$ (where d_{jk} is the distance between the centroids of regions j and k): density-dependent and density-independent (cf. Truscott et al. 2007). For the density-dependent formulation, the kernel is given by,

$$K(d_{jk}) = k(d_{jk}),$$

while for the density-independent formulation it is given by,

$$K(d_{jk}) = \frac{k(d_{jk})}{\sum_{k \neq j} k(d_{jk})},$$

where,

$$k(d_{jk}) = \left(1 + \left(\frac{d_{jk}}{d_0}\right)^{\alpha}\right)^{-1},$$

and α and d_0 are parameters.

The duration of the transmission period for each region, T, was described using a zero-truncated Normal distribution with probability density function, $f(T|\mu_D,\sigma_D)$, where μ_D and σ_D are the mean and standard deviation, respectively.

Finally, the number of infected cattle and sheep holdings within a region (I_C and I_S) was described by a negative binomial distribution with probability density functions, $P(I_C|\mu_C,k_C)$ and $P(I_S|\mu_S,k_S)$, with means given by,

$$\mu_C = \lambda_C TC,$$
$$\mu_S = \lambda_S TS,$$

where λ_C and λ_S are the force of infection for cattle and sheep holdings within a region and dispersion parameters k_C and k_S.

Parameter estimation

Parameters in the model were estimated using maximum likelihood methods, with parameters for the three components (transmission between regions, duration of risk and number of infected holdings) estimated independently. The likelihood for transmission between holdings is given by,

$$L = \prod_{j \in U} \exp\left(-\sum_{t} \lambda_j(t) \right) \times \prod_{j \in I} \left\{ \exp\left(-\sum_{t=t_0}^{t_{\text{inf}}^{(j)}-1} \lambda_j(t) \right) \times \left[1 - \exp\left(-\lambda_j(t_{\text{inf}}^{(j)}) \right) \right] \right\},$$

where U is the set of regions which did not become infected, I is the set of regions which did become infected, t_0 is the start of the outbreak and t_{inf} is the time at which the region became infected. The first term is the contribution to the likelihood of regions which did not become infected, while the second term is the contribution to the likelihood of regions which did become infected. The likelihoods for the duration of transmission period and the number of infected holdings are simply the product of the appropriate probability density functions evaluated at the observed values for each infected region.

Model checking was carried out to assess goodness-of-fit. Transmission between regions was assessed by simulating 100 replicates of the model using the maximum likelihood estimates for the parameters and considering: (i) the observed and expected time courses for the number of regions in which SBV was assumed to be circulating; (ii) the observed and expected times at which the region became infected (i.e. the start of the transmission period); and (iii) the proportion of replicates for which each region became infected. The goodness-of-fit of the duration of transmission distribution to the observed data was assessed using a χ^2 test. The number of infected cattle and sheep holdings was assessed by determining whether the observed values lie within the 2.5th and 97.5th percentiles of the distribution for each region.

Because not all holdings will have become infected during their risk period for AHS cases, there is likely to be under-ascertainment of infected holdings. To assess the impact of under-ascertainment on the estimates for the within-region force of infection, the number of holdings reporting AHS cases for each region was divided by an assumed proportion of infected holdings reporting AHS cases (capped at the number of holdings in the region) and estimating the within-region force of infection for the inflated data.

C. POTENTIAL GEOGRAPHICAL AND SEASONAL WITHIN HOLDING TRANSMISSION

The potential number of secondary host infections, arising from the introduction of a single infectious host to a holding, was calculated using a deterministic transmission model.

This number of new infectious bites is used as proxy for the basic reproduction number (R_0). The model is a process-model, based on individually estimated parameters assumed to capture the transmission process and not on a statistical fit to the outbreak data.

An infectious host introduced in a holding is assumed to be viraemic for four days and hence able to infect biting *Culicoides* for four days. A model was built to calculate the number of new infected units (cattle) originating from these new infected vectors. Below the model steps are listed and commented:

- Firstly the probability of surviving 1 day, 2 days, 3 days, etc. is calculated using daily individual mean temperature and based on the relationship between temperature and survival of *Culicoides* (see Table 9). Although the available scientific literature suggests that *Culicoides* spp. can survive for long periods at low temperatures, it is here assumed that *Culicoides* spp.can survive to a maximum of 45 days.
- Secondly, the specific days the vectors would take a blood meal (biting days) is calculated for each vector cohort based on the relationship between egg development rate and temperature (see Table 9).
- Thirdly, the day when new bites would be infectious to hosts for each vector cohort is calculated based on the available data on the relationship between temperature and virus development time of BTV9 in laboratory strains of *Culicoides* (see Table 9).

Presently no data on development time of SBV in laboratory or in wild vectors have been published. Therefore, BTV9 parameters were used as proxy for SBV. Likewise, there are no data to estimate the proportion of vectors that becomes infected when biting an infectious host or, reversely, the proportion of hosts infected when bitten by an infectious vector. Therefore, these proportions were both assumed to be the same as the ones reported in scientific literature for analogous viruses (Table 9). For each daily cohort of vectors the model then calculates the number of infectious bites by summing up the daily number of biting vectors after passing the extrinsic incubation period up to 45 days. Only point estimates for the variables are used in the model.

Temperature data were provided to EFSA by JRC-MARS - Meteorological Data Base - EC - JRC. Spatially interpolated temperatures based on the existing network of meteorological stations were available in a 22823 cells for a 25×25 km regular climate grid. Only daily mean temperature data were available for the calculation, hence any impacts of high daytime temperatures or low night temperatures was ignored in the estimation of R_0. Likewise, since the temperature of resting sites of *Culicoides* is poorly known, any impact of microclimatic or indoor temperatures was ignored. Temperature data were provided for the period 1983 to 2011. R_0 is calculated on a daily basis for each grid, assuming an introduction of at least one infectious host per day since January 1st 1983.

The developed transmission model estimated R_0 in a vector cohort model driven by temperature (Figure 42). The cohort based model behaved differently than a model directly based on rates (Figure 42D). This is because the cohort based model calculated the R_0 by following each daily cohort of biting vectors. Hence R_0 was not a smooth function of temperature e.g. at 30 degrees the transmission intensity was very low because the survival rates of vectors was low. At 30 degrees the virus development time in the vector was too low for the virus to reach the salivary glands in time for the first blood meal following the infective blood meal. Therefore the vectors in this cohort could not deliver an infectious bite until the second blood meal following the infective blood meal, and at that time the vector cohort was almost extinct. However at 31 degrees the virus development time in the vectors was just fast enough for the virus to reach the salivary glands in time for the first blood meal

following the infective blood meal and when the cohort was much less reduced compared to the following blood meal. This resulted in an increased R_0 at 31 degrees compared to 30 degrees. The model is deterministic and in the real World this phenomenon is partly obscured by variation in virus development time between individual vectors in each cohort, however the biological phenomenon still exists. It is not possible to determine if a cohort based model is better reflection of reality than a rate based model. Both models predict an optimum temperature around 18-19^{o} C (Figure 42D). And for practical purposes and given the most common temperature range in Europe the two models differ little in the estimated R_0.

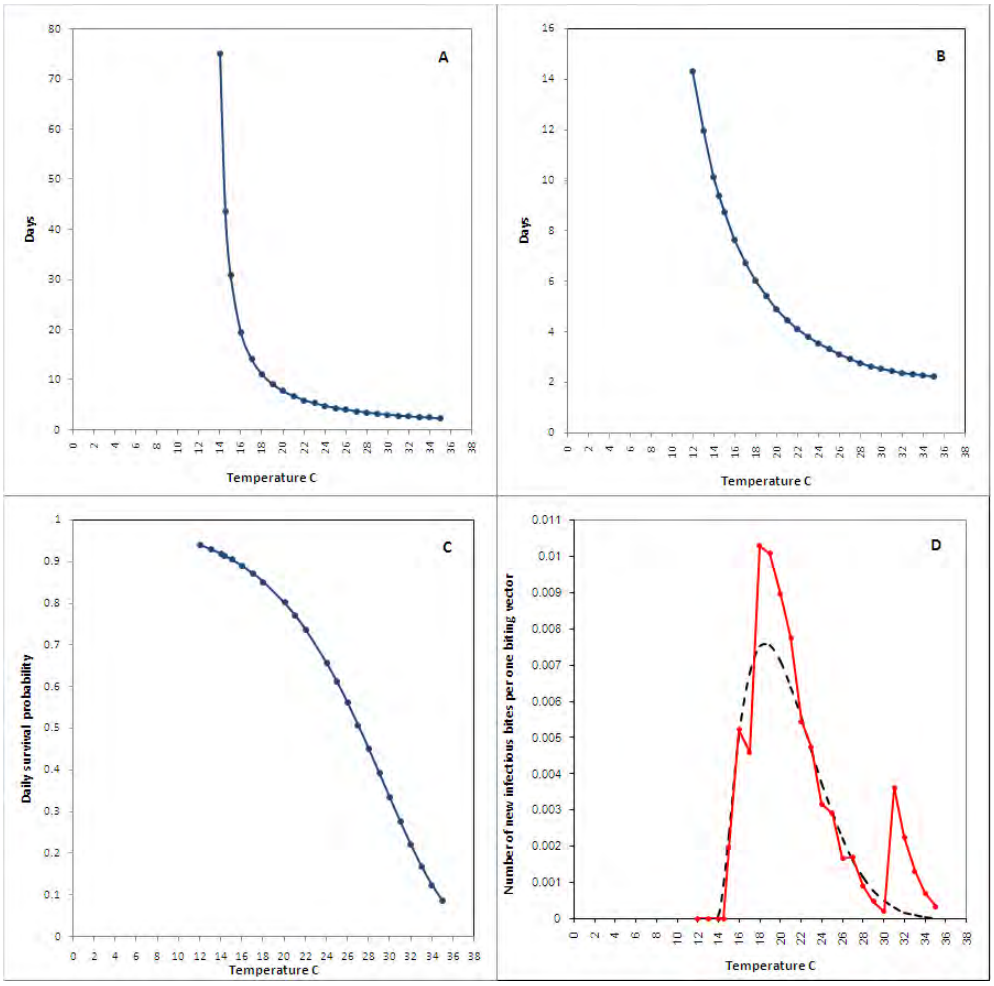


Figure 42: The model is driven by mean daily temperatures. Increasing temperatures increases the virus development rate in the vectors (A) reduces the interval between blood feeding (B), but also reduces the daily survival rates of the vectors (C). These counteracting effects of temperature result in a temperature optimum between 18 and 19º C (D). The effect of temperature on R0 may be calculated as a rate (blue dotted line in D) or as a cohort model as is used in the present analysis (red line in D).

The model assumed ruminant hosts were viraemic to vectors for 4 days and that 0.014% of vectors biting an infectious host would be infected (Table 9). We assumed that 78% of infectious vector would transmit virus to hosts (Baylis et al., 2008). The blood feeding preference for ruminants is set to 100%. Virus development in the vector may take place at temperatures above 13.3°C (Figure 28). However in order to complete the extrinsic incubation period in the vector within the 45 days chosen as the maximum lifespan of *Culicoides* for this analysis, the temperature had to be above 14.5°C. But because it was a cohort based model with specific vector biting days, it was not enough that virus development was completed within 45 days. To complete transmission a biting day resulting in an infective bite had to take place earlier than 45 days after the vector got infected and later than the extrinsic incubation

period in order for transmission to occur. With the selected parameter values this effectively resulted in a minimum temperature around 15°C.

Europe has experienced at warming trend in the past decades and the presented estimated medium daily densities of biting vectors needed to produce $R_0 > 1$ may thus underestimate the risk in the cooler parts of Europe. Therefore we also present the estimated daily densities of biting vectors needed to produce $R_0 > 1$ in the 10th percentile year. This is largely equivalent to the third most optimal year for transmission during the last 29 years, and thus produces a more pessimistic but not extreme risk based on the observed temperatures at each grid point (Figure 43). It should be noted that the 10th percentile is selected for each grid point and that it is not likely that all grid point in Europe will be a 10th percentile year during the same month.

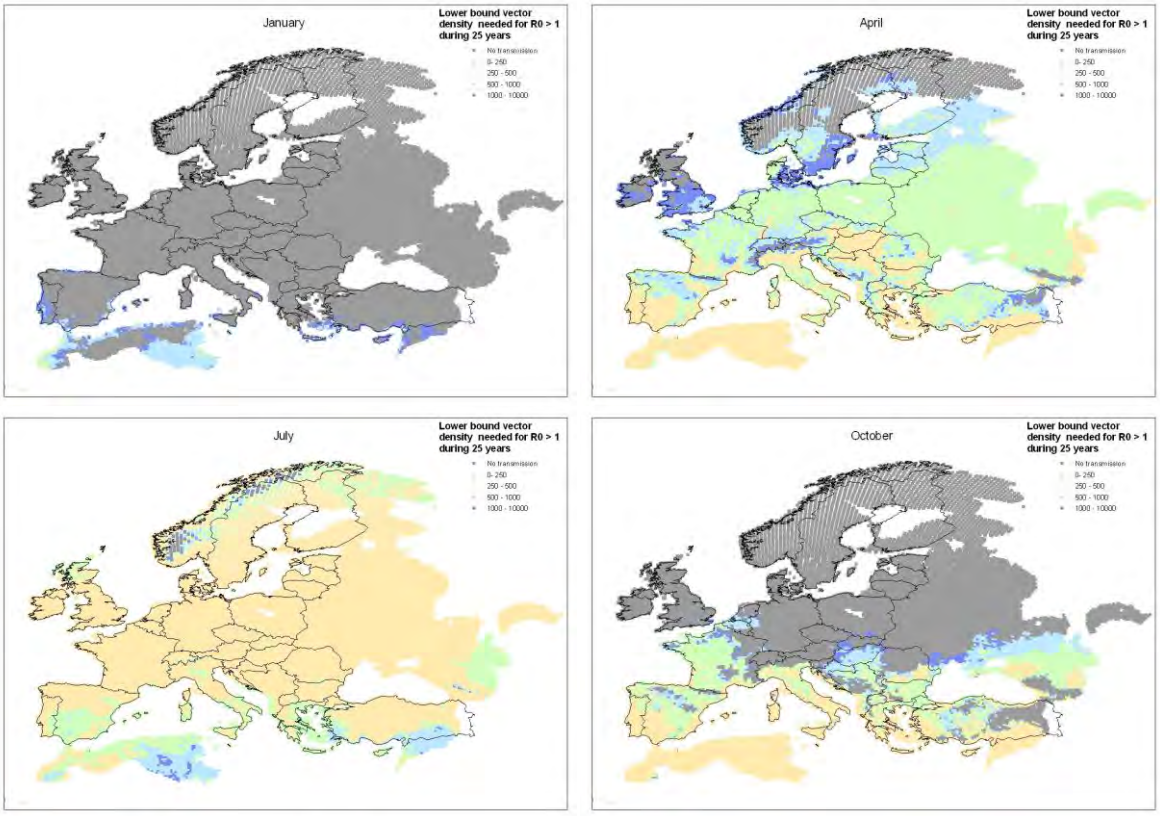


Figure 43: (Supplement to Figure 29). Areas and seasons where within holding transmission may exceed the important threshold value of 1 given the daily density of biting vector indicated at the map. The analysis was done for 29 years and the data presented is the daily critical biting vector density for the 10 percentile year. The 10 percentile year is used to account for the warming trend in Europe since 1983. Grey areas indicate transmission is not possible in a median year, regardless of vector abundance. White areas indicate lack of data.

The model calculated R_0 for each day. But it should be noted that the estimated R_0 for a given day refers to the day the index host become infectious to vectors. But since the cow is infectious for 4 days and vectors are allowed to live up to 45 days after being infected new secondary cattle may be infected up to 49 dates after the reported date. Hence the R_0 reported for e.g. September sums up new cases occurring in October or even November. Hence the R_0 refers to the risk associated with introducing an infectious host at a given date, or the risk associated with a host becoming infectious as a result of a bite from an introduced infectious vector.

D. PROJECTION OF SBV-AHS CASES BASED ON LAMBING AND CALVING

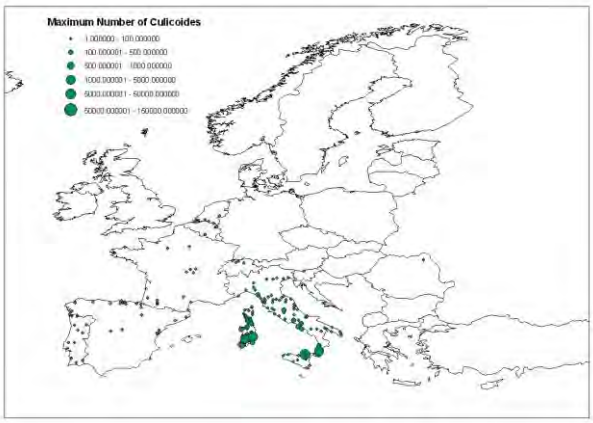
Parameter estimation

Parameters pertaining to *Culicoides* vectors (ratio of vectors to hosts, time intervals between blood meals, vector mortality rate) were retained. The duration of viraemia in cattle and sheep was set at 2-8 days based on the results described by Hoffman et al. (2012) and the disease-associated mortality rate for infected cattle and sheep was set at 0 based on the observed data (in which no serious clinical disease was observed in infected adult animals). In the absence of any data on other virus-specific parameters for SBV (extrinsic incubation period, probability of transmission) data on BTV were used (Table 9). "Infection" on a holding was assumed to be predominantly initiated by the introduction of *Culicoides* transported by the wind, and was therefore simulated assuming an introduction of five infectious *Culicoides* (i.e. with a fully-disseminated infection).

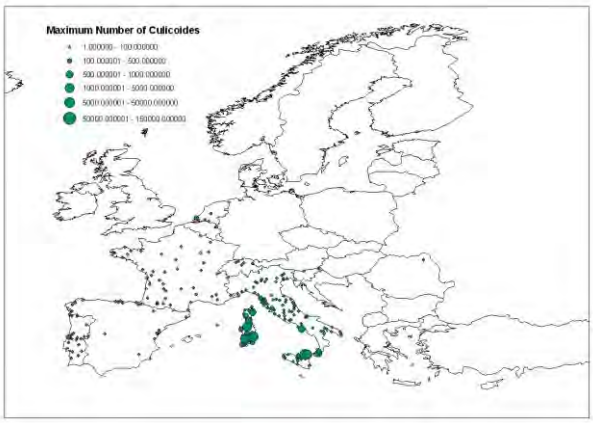
Temperature data, as provided to EFSA by JRC-MARS - Meteorological Data Base - EC – JRC, were used. A number of parameters of the transmission model are dependent on temperature, such as the extrinsic incubation period, the vector mortality, and the time interval between blood meals. Since no information on the physical location of the holdings was available, we calculated temperature-dependent parameters using the daily median temperature of the pixel closest to the centroid of the NUTS2 region.

E. VECTORS MONTHLY DISTRIBUTION

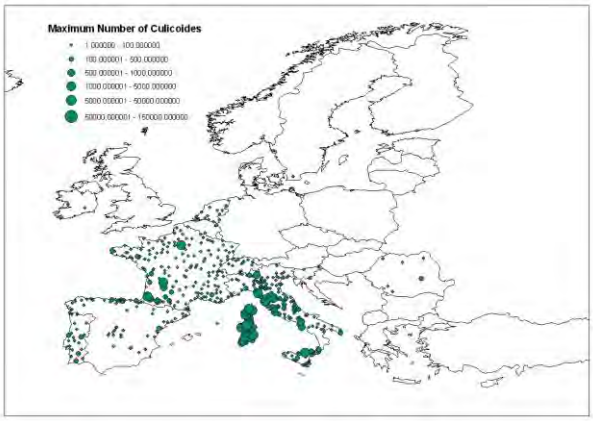
January



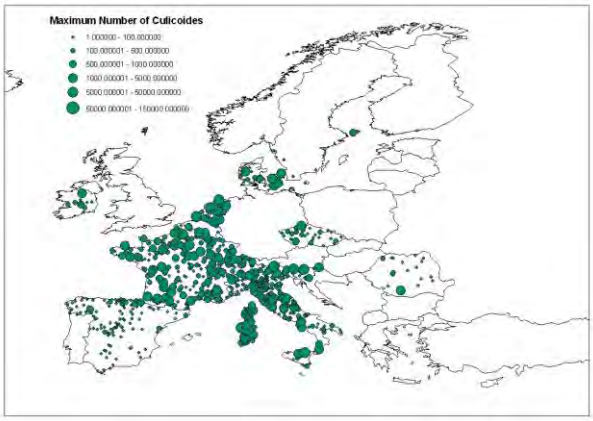
February



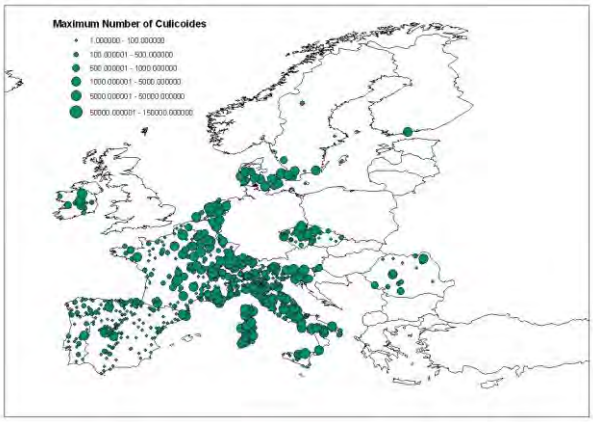
March



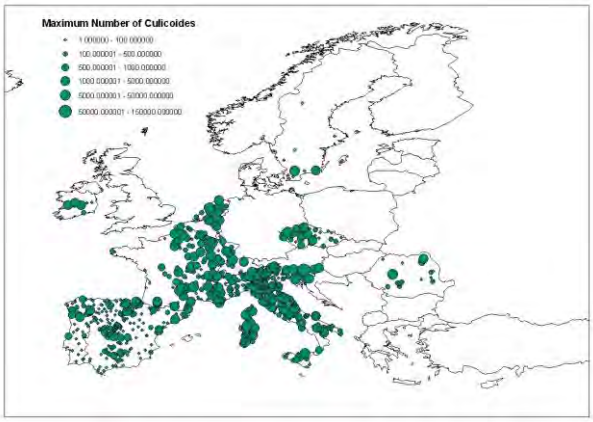
April



May



June



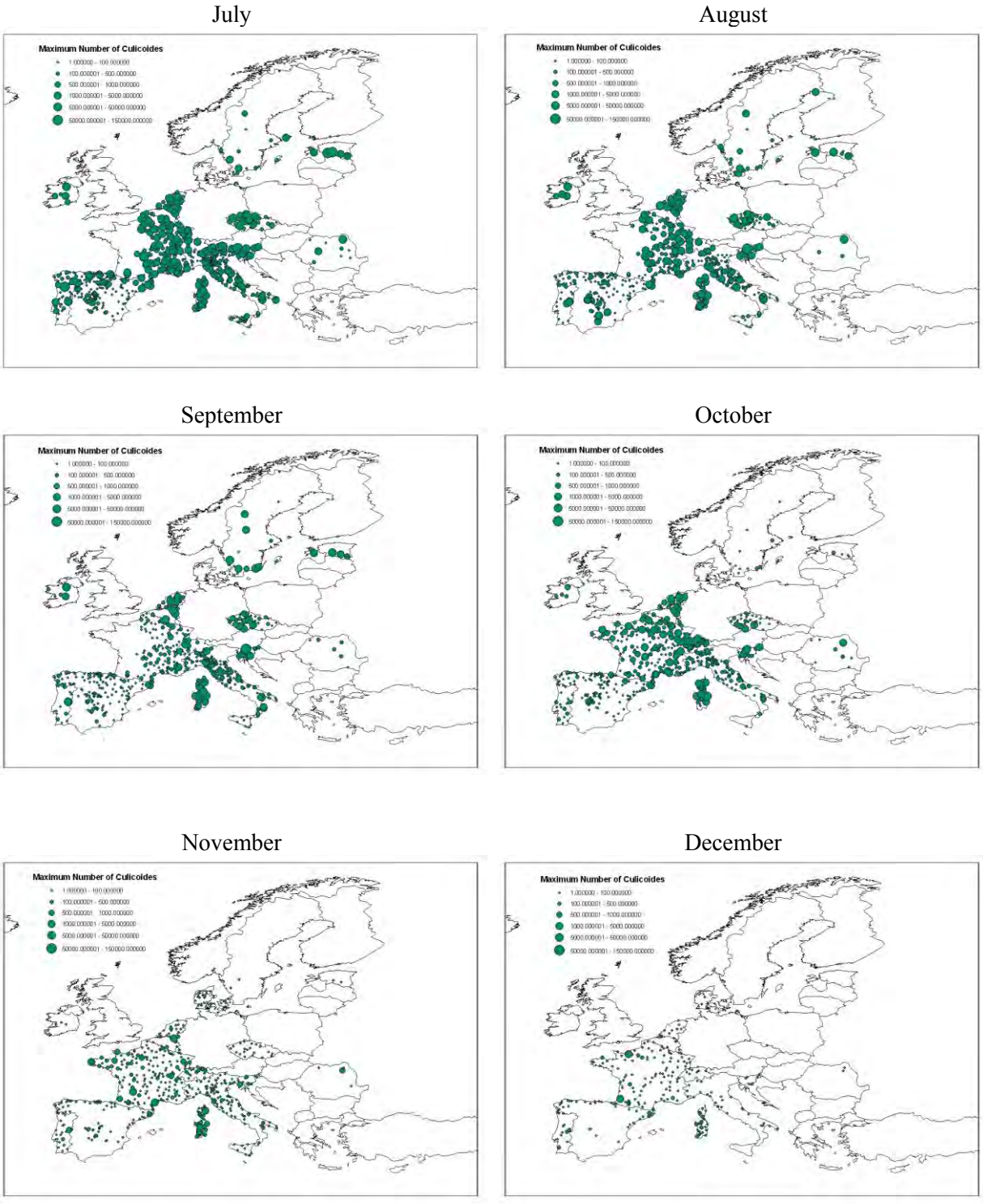


Figure 44: Maximum number of *Culicoides* trapped reported to EU BT-NET by month.

F. REPORTED DATA

Table 10: Country and species level summary of minimum dataset reports

Ruminant	*Country*	*Reported*	*Herds SBV not confirmed*	*Herds SBV confirmed*	*Foetus neonate RT-PCR test*	*Foetus neonate RT-PCR confirmed*	*Adults RT-PCR test*	*Adults RT-PCR confirmed*	*Adults serology tested*	*Adults serology confirmed*
Bison	Germany	1	0	1	1	1	.	.	.	.
Bison		***1***	***0***	***1***	***1***	***1***	***.***	***.***	***.***	***.***
Cattle	Belgium	74	0	74	.	74	0	.	.	.
	Denmark	20	20	0	20	0	0	.	0	.
	France	1460	1132	328	.	328	0	.	.	.
	Germany	545	0	545	.	527	8	8	14	14
	Ireland	44	44	0	44	0	1	0	.	.
	Italy	5	3	2	4	0	4	0	4	2
	Luxembourg	21	10	11	20	11	1	0	0	.
	Netherlands	1249	1016	233	.	232	.	.	132	128
	Norway	4	4	0	4	0	0	.	0	.
	Spain	8	8	0	3	0	6	0	1	0
	Sweden	9	9	0	8	0	0	.	5	0
	Switzerland	2	2	0	2	0	0	.	.	.
	United Kingdom	86	50	36	.	36	0	.	.	.
Cattle		***3527***	***2298***	***1229***		***1208***	***20***	***8***	***156***	***144***
Goats	Belgium	2	0	2	.	2	0	.	.	.
	Denmark	2	2	0	2	0	0	.	0	.

Ruminant	*Country*	*Reported*	*Herds SBV not confirmed*	*Herds SBV confirmed*	*Foetus neonate RT-PCR test*	*Foetus neonate RT-PCR confirmed*	*Adults RT-PCR test*	*Adults RT-PCR confirmed*	*Adults serology tested*	*Adults serology confirmed*
	France	64	47	17	.	17	0	.	.	.
	Germany	46	0	46	.	46	.	.	.	.
	Ireland	2	2	0	2	0	0	.	.	.
	Italy	1	0	1	1	1	1	0	1	1
	Luxembourg	1	1	0	1	0	0	.	0	.
	Netherlands	37	31	6	.	6	.	.	4	4
	Spain	1	1	0	0	.	1	0	0	.
	Switzerland	1	1	0	1	0	0	.	.	.
Goats		***157***	***85***	***72***		***72***	***2***	***0***	***5***	***5***
Sheep	Belgium	155	0	155	.	155	0	.	.	.
	Denmark	16	16	0	16	0	0	.	0	.
	France	1798	676	1122	.	1122	0	.	.	.
	Germany	851	0	851	.	851	.	.	.	.
	Ireland	10	10	0	10	0	0	.	.	.
	Italy	1	1	0	1	0	1	0	1	0
	Luxembourg	10	4	6	10	6	0	.	0	.
	Netherlands	348	240	108	.	107	.	.	82	81
	Norway	5	5	0	5	0	0	.	0	.
	Spain	8	3	5	6	1	5	0	5	5
	Sweden	10	10	0	10	0	0	.	6	0
	Switzerland	2	2	0	2	0	0	.	.	.

Ruminant	*Country*	*Reported*	*Herds SBV not confirmed*	*Herds SBV confirmed*	*Foetus neonate RT-PCR test*	*Foetus neonate RT-PCR confirmed*	*Adults RT-PCR test*	*Adults RT-PCR confirmed*	*Adults serology tested*	*Adults serology confirmed*
	United Kingdom	360	139	221	.	221	0	.	.	.
Sheep		***3574***	***1106***	***2468***		***2463***	***6***	***0***	***94***	***86***
Total		***7259***	***3489***	***3770***		***3744***	***28***	***8***	***255***	***235***

G. REGIONAL NUTS CODES

Table 11: Regional NUTS codes

Country	NUTS Code	Region Name
Belgium	BE10	Région De Bruxelles-Capitale / Brussels Hoofdstedelijk Gewest
Belgium	BE21	Prov. Antwerpen
Belgium	BE22	Prov. Limburg (B)
Belgium	BE23	Prov. Oost-Vlaanderen
Belgium	BE24	Prov. Vlaams-Brabant
Belgium	BE25	Prov. West-Vlaanderen
Belgium	BE31	Prov. Brabant Wallon
Belgium	BE32	Prov. Hainaut
Belgium	BE33	Prov. Liège
Belgium	BE34	Prov. Luxembourg (B)
Belgium	BE35	Prov. Namur
Germany	DE1	Baden-Württemberg
Germany	DE2	Bayern
Germany	DE3	Berlin
Germany	DE4	Brandenburg
Germany	DE5	Bremen
Germany	DE6	Hamburg
Germany	DE7	Hessen
Germany	DE8	Mecklenburg-Vorpommern
Germany	DE9	Niedersachsen
Germany	DEA	Nordrhein-Westfalen
Germany	DEB	Rheinland-Pfalz
Germany	DEC	Saarland
Germany	DED	Sachsen
Germany	DEE	Sachsen-Anhalt
Germany	DEF	Schleswig-Holstein
Germany	DEG	Thüringen
Denmark	DK01	Hovedstaden
Denmark	DK02	Sjælland
Denmark	DK03	Syddanmark
Denmark	DK04	Midtjylland
Denmark	DK05	Nordjylland
Spain	ES11	Galicia
Spain	ES12	Principado De Asturias
Spain	ES13	Cantabria
Spain	ES21	País Vasco
Spain	ES22	Comunidad Foral De Navarra

Spain	ES23	La Rioja
Spain	ES24	Aragón
Spain	ES30	Comunidad De Madrid
Spain	ES41	Castilla Y León
Spain	ES42	Castilla-La Mancha
Spain	ES43	Extremadura
Spain	ES51	Cataluña
Spain	ES52	Comunidad Valenciana
Spain	ES53	Illes Balears
Spain	ES61	Andalucía
Spain	ES62	Región De Murcia
Spain	ES63	Ciudad Autónoma De Ceuta
Spain	ES64	Ciudad Autónoma De Melilla
Spain	ES70	Canarias
Finland	FI13	Itä-Suomi
Finland	FI18	Etelä-Suomi
Finland	FI19	Länsi-Suomi
Finland	FI1A	Pohjois-Suomi
Finland	FI20	Åland
France	FR10	Île De France
France	FR21	Champagne-Ardenne
France	FR22	Picardie
France	FR23	Haute-Normandie
France	FR24	Centre
France	FR25	Basse-Normandie
France	FR26	Bourgogne
France	FR30	Nord - Pas-De-Calais
France	FR41	Lorraine
France	FR42	Alsace
France	FR43	Franche-Comté
France	FR51	Pays De La Loire
France	FR52	Bretagne
France	FR53	Poitou-Charentes
France	FR61	Aquitaine
France	FR62	Midi-Pyrénées
France	FR63	Limousin
France	FR71	Rhône-Alpes
France	FR72	Auvergne
France	FR81	Languedoc-Roussillon
France	FR82	Provence-Alpes-Côte D'Azur
France	FR83	Corse
France	FR91	Guadeloupe
France	FR92	Martinique

France	FR93	Guyane
France	FR94	Réunion
Italy	ITC1	Piemonte
Italy	ITC2	Valle D'Aosta/Vallée D'Aoste
Italy	ITC3	Liguria
Italy	ITC4	Lombardia
Italy	ITD1	Provincia Autonoma Bolzano/Bozen
Italy	ITD2	Provincia Autonoma Trento
Italy	ITD3	Veneto
Italy	ITD4	Friuli-Venezia Giulia
Italy	ITD5	Emilia-Romagna
Italy	ITE1	Toscana
Italy	ITE2	Umbria
Italy	ITE3	Marche
Italy	ITE4	Lazio
Italy	ITF1	Abruzzo
Italy	ITF2	Molise
Italy	ITF3	Campania
Italy	ITF4	Puglia
Italy	ITF5	Basilicata
Italy	ITF6	Calabria
Italy	ITG1	Sicilia
Italy	ITG2	Sardegna
Lithuania	LT00	Lietuva
Luxembourg	LU00	Luxembourg (Grand-Duché)
Latvia	LV00	Latvija
Netherlands	NL11	Groningen
Netherlands	NL12	Friesland (Nl)
Netherlands	NL13	Drenthe
Netherlands	NL21	Overijssel
Netherlands	NL22	Gelderland
Netherlands	NL23	Flevoland
Netherlands	NL31	Utrecht
Netherlands	NL32	Noord-Holland
Netherlands	NL33	Zuid-Holland
Netherlands	NL34	Zeeland
Netherlands	NL41	Noord-Brabant
Netherlands	NL42	Limburg (Nl)
Norway	NO01	Oslo Og Akershus
Norway	NO02	Hedmark Og Oppland
Norway	NO03	Sør-Østlandet
Norway	NO04	Agder Og Rogaland
Norway	NO05	Vestlandet

Norway	NO06	Trøndelag
Norway	NO07	Nord-Norge
United Kingdom	UKC1	Tees Valley And Durham
United Kingdom	UKC2	Northumberland And Tyne And Wear
United Kingdom	UKD1	Cumbria
United Kingdom	UKD2	Cheshire
United Kingdom	UKD3	Greater Manchester
United Kingdom	UKD4	Lancashire
United Kingdom	UKD5	Merseyside
United Kingdom	UKE1	East Yorkshire And Northern Lincolnshire
United Kingdom	UKE2	North Yorkshire
United Kingdom	UKE3	South Yorkshire
United Kingdom	UKE4	West Yorkshire
United Kingdom	UKF1	Derbyshire And Nottinghamshire
United Kingdom	UKF2	Leicestershire, Rutland And Northamptonshire
United Kingdom	UKF3	Lincolnshire
United Kingdom	UKG1	Herefordshire, Worcestershire And Warwickshire
United Kingdom	UKG2	Shropshire And Staffordshire
United Kingdom	UKG3	West Midlands
United Kingdom	UKH1	East Anglia
United Kingdom	UKH2	Bedfordshire And Hertfordshire
United Kingdom	UKH3	Essex
United Kingdom	UKI1	Inner London
United Kingdom	UKI2	Outer London
United Kingdom	UKJ1	Berkshire, Buckinghamshire And Oxfordshire
United Kingdom	UKJ2	Surrey, East And West Sussex
United Kingdom	UKJ3	Hampshire And Isle Of Wight
United Kingdom	UKJ4	Kent
United Kingdom	UKK1	Gloucestershire, Wiltshire And Bristol/Bath Area
United Kingdom	UKK2	Dorset And Somerset
United Kingdom	UKK3	Cornwall And Isles Of Scilly
United Kingdom	UKK4	Devon
United Kingdom	UKL1	West Wales And The Valleys
United Kingdom	UKL2	East Wales
United Kingdom	UKM2	Eastern Scotland
United Kingdom	UKM3	South Western Scotland
United Kingdom	UKM5	North Eastern Scotland
United Kingdom	UKM6	Highlands And Islands
United Kingdom	UKN0	Northern Ireland

H. MONTHLY LAMBING AND CALVING DATA

Table 12: Proportion of lambs born per country and per month over the year

Country	Region	NUTS code	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Source
Belgium	Flanders	BE	8%	40%	40%	10%	0%	0%	0%	0%	0%	0%	1%	1%	Expert estimation by Dr. Guido Bertels, DGZ Animal Health Service Flanders
Czech Republic	whole country	CZ	12%	19%	22%	25%	11%	3%	1%	1%	1%	1%	1%	4%	Central Database of animals
Denmark	whole country	DK	8%	13%	33%	29%	8%	1%	1%	2%	1%	1%	1%	2%	The Danish Knowledge Centre for Agriculture
Estonia	whole country	EE00	17%	17%	31%	20%	7%	2%	1%	1%	1%	1%	1%	1%	Estonian Agricultural Registers and Information Board
	Harjumaa		10%	21%	22%	27%	12%	5%	1%	0%	0%	0%	1%	1%	
	Hiiumaa		15%	19%	23%	23%	7%	2%	1%	1%	1%	0%	0%	8%	
	Ida-Virumaa		19%	14%	12%	22%	8%	7%	4%	1%	1%	9%	3%	0%	
	Jõgevamaa		11%	20%	25%	16%	11%	6%	0%	0%	0%	4%	1%	6%	
	Järvamaa		12%	12%	24%	33%	16%	1%	0%	0%	0%	2%	0%	0%	
	Läänemaa		21%	13%	21%	18%	16%	3%	2%	0%	4%	1%	0%	1%	
	Lääne-Virumaa		47%	4%	13%	17%	10%	0%	0%	1%	4%	4%	0%	0%	
	Põlvamaa		8%	9%	58%	16%	3%	1%	1%	1%	0%	0%	0%	3%	
	Pärnumaa		15%	12%	26%	28%	5%	1%	1%	3%	2%	5%	1%	1%	
	Raplamaa		16%	27%	26%	8%	11%	1%	0%	2%	1%	3%	3%	2%	
	Saaremaa		13%	19%	44%	16%	1%	1%	0%	1%	1%	0%	2%	2%	
	Tartumaa		7%	18%	35%	25%	12%	0%	0%	0%	0%	0%	1%	2%	
	Valgamaa		29%	13%	24%	25%	4%	1%	0%	0%	1%	1%	1%	1%	
	Viljandimaa		7%	18%	45%	22%	3%	3%	0%	1%	0%	0%	0%	1%	
	Võrumaa		9%	30%	32%	19%	4%	2%	1%	0%	1%	1%	1%	0%	
France	whole country	FR	13%	12%	11%	8%	5%	2%	1%	3%	6%	13%	14%	12%	GDS France
	Champagne-	FR21	11%	11%	16%	9%	0%	0%	0%	5%	5%	12%	19%	12%	

	Ardenne													
	Picardie	FR22	19%	0%	24%	0%	2%	2%	0%	0%	7%	7%	19%	19%	
	Haute-Normandie	FR23	8%	8%	3%	3%	0%	0%	0%	0%	3%	13%	31%	31%	
	Centre	FR24	9%	24%	24%	13%	9%	0%	0%	0%	6%	6%	6%	4%	
	Basse-Normandie	FR25	18%	18%	7%	7%	7%	1%	1%	1%	1%	6%	15%	18%	
	Bourgogne	FR26	16%	16%	17%	11%	4%	0%	0%	2%	3%	8%	14%	9%	
	Nord - Pas-De-Calais	FR30	15%	15%	15%	10%	10%	0%	0%	0%	10%	10%	0%	15%	
	Lorraine	FR41	9%	15%	14%	14%	6%	0%	0%	0%	4%	15%	15%	8%	
	Alsace	FR42	10%	10%	11%	11%	11%	0%	0%	0%	6%	16%	16%	10%	
	Franche-Comté	FR43	19%	21%	21%	3%	3%	0%	0%	0%	3%	5%	5%	19%	
	Pays De La Loire	FR51	17%	17%	17%	9%	2%	0%	0%	0%	5%	10%	10%	14%	
	Poitou-Charentes	FR53	17%	17%	17%	8%	8%	0%	0%	1%	6%	6%	7%	14%	
	Aquitaine	FR61	22%	13%	5%	5%	5%	0%	0%	0%	6%	15%	9%	22%	
	Midi-Pyrénées	FR62	7%	6%	6%	6%	8%	8%	2%	9%	12%	15%	12%	9%	
	Limousin	FR63	17%	17%	11%	11%	11%	0%	0%	6%	6%	6%	3%	13%	
	Rhône-Alpes	FR71	10%	10%	19%	17%	8%	1%	1%	4%	7%	6%	9%	7%	
	Auvergne	FR72	14%	14%	14%	8%	3%	4%	4%	5%	5%	14%	11%	5%	
	Languedoc-Roussillon	FR81	8%	11%	14%	14%	2%	0%	0%	0%	12%	15%	15%	8%	
	Provence-Alpes-Côte D'Azur	FR82	0%	20%	20%	6%	0%	0%	0%	5%	10%	15%	15%	10%	
Ireland	whole country	IE0	6%	24%	54%	14%	1%	0%	0%	0%	0%	0%	0%	0%	National farm survey/expert opinion
	Munster		7%	18%	60%	13%	3%	0%	0%	0%	0%	0%	0%	0%	
	Leinster		4%	26%	50%	18%	2%	0%	0%	0%	0%	0%	0%	0%	
	Connaught		9%	26%	61%	4%	0%	0%	0%	0%	0%	0%	0%	0%	
	Ulster		8%	15%	42%	34%	1%	1%	0%	0%	0%	0%	0%	0%	
Italy	whole country	IT	16%	20%	15%	10%	6%	3%	2%	3%	4%	10%	7%	5%	Estimated based on variation in flock sizes

														and requests for ear tags
Lithuania	whole country	LT00	12%	38%	30%	10%	0%	0%	0%	0%	0%	0%	2%	8%	State Enterprise "Agriculture Information and Rural Business Center
Latvia	whole country	LV00	21%	21%	24%	13%	6%	3%	1%	1%	1%	2%	2%	6%	Official data base according to Regulations 1760/2000 and 21/2004
Netherlands	whole country	NL	8%	15%	37%	22%	8%	3%	1%	1%	1%	0%	1%	1%	Not specified
	Groningen	NL11	6%	8%	43%	25%	8%	3%	1%	1%	1%	0%	2%	0%	
	Friesland	NL12	4%	8%	35%	30%	12%	5%	2%	0%	1%	1%	0%	1%	
	Drenthe	NL13	11%	15%	34%	19%	9%	3%	2%	1%	1%	1%	0%	1%	
	Overijssel	NL21	11%	21%	29%	20%	8%	4%	2%	1%	1%	1%	1%	1%	
	Gelderland	NL22	10%	19%	36%	18%	7%	3%	2%	1%	0%	0%	1%	1%	
	Flevoland	NL23	4%	10%	41%	19%	10%	6%	4%	0%	0%	1%	1%	4%	
	Utrecht	NL31	7%	13%	40%	24%	8%	2%	1%	0%	0%	0%	1%	2%	
	Noord-Holland	NL32	5%	7%	46%	27%	8%	2%	1%	0%	0%	0%	0%	1%	
	Zuid-Holland	NL33	6%	13%	42%	24%	8%	2%	1%	0%	0%	0%	0%	0%	
	Zeeland	NL34	11%	13%	40%	18%	7%	2%	1%	1%	2%	1%	1%	2%	
	Noord-Brabant	NL41	14%	20%	31%	17%	8%	2%	2%	1%	1%	1%	1%	2%	
	Limburg	NL42	13%	32%	30%	10%	4%	3%	2%	1%	0%	0%	1%	3%	
Norway	whole country	NO	0%	0%	1%	53%	45%	1%	0%	0%	0%	0%	0%	0%	Norwegian Sheep Health Services
Spain	whole country	ES	5%	5%	10%	10%	5%	10%	10%	5%	5%	5%	20%	10%	Technical-Economic report
Sweden	whole country	SE	10%	15%	25%	25%	10%	0%	0%	0%	0%	0%	0%	15%	Estimate by sheep farmers organisation
Switzerland	whole country	CH0	3%	35%	35%	3%	3%	3%	3%	3%	3%	3%	3	3	AGIS 2010 and estimation
United Kingdom	Lowland		10%	25%	25%	25%	5%	0%	0%	0%	0%	0%	5%	5%	Population numbers

	Upland		0%	5%	25%	50%	20%	0%	0%	0%	0%	0%	0%	0%	

Table 13: Proportion of calves born per country and per month over the year

Country	Region	NUTS code	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Source
Belgium	whole country	BE	8%	10%	13%	10%	9%	8%	6%	7%	7%	7%	7%	7%	Not specified
Belgium	Prov. Antwerpen	BE21	8%	8%	9%	7%	8%	8%	8%	9%	9%	8%	9%	8%	
Belgium	Prov. Limburg	BE22	8%	9%	11%	8%	8%	8%	7%	9%	8%	8%	9%	8%	
Belgium	Prov. Oost-Vlaanderen	BE23	8%	10%	12%	10%	10%	8%	7%	8%	7%	7%	7%	7%	
Belgium	Prov. Vlaams-Brabant	BE24	8%	10%	12%	11%	10%	8%	6%	7%	7%	7%	7%	7%	
Belgium	Prov. West-Vlaanderen	BE25	8%	11%	13%	10%	10%	8%	7%	7%	7%	6%	6%	7%	
Belgium	Prov. Brabant Wallon	BE31	9%	10%	12%	9%	9%	7%	6%	6%	8%	8%	8%	9%	
Belgium	Prov. Hainaut	BE32	9%	11%	12%	9%	9%	7%	6%	7%	7%	7%	8%	8%	
Belgium	Prov. Liège	BE33	8%	10%	12%	9%	9%	8%	7%	7%	8%	7%	8%	8%	
Belgium	Prov. Luxembourg	BE34	7%	9%	16%	14%	11%	8%	6%	5%	6%	6%	6%	7%	
Belgium	Prov. Namur	BE35	8%	10%	13%	10%	9%	7%	5%	5%	8%	8%	8%	8%	
Czech Republic	whole country	CZ	8%	9%	11%	10%	10%	9%	8%	7%	6%	6%	7%	7%	Central database of animals
Demnark	whole country	DK	8%	8%	9%	9%	9%	8%	8%	9%	7%	8%	8%	9%	The Danish Knowledge Centre for Agriculture
Estonia	whole country	EE00	8%	7%	10%	9%	8%	10%	10%	9%	7%	7%	7%	8%	Estonian Agricultural Registers and Information Board
	Harjumaa		7%	7%	11%	11%	10%	12%	9%	8%	6%	5%	6%	8%	
	Hiiuma		4%	5%	17%	22%	13%	10%	8%	6%	3%	4%	4%	4%	
	Ida-Virumaa		7%	9%	12%	12%	10%	11%	10%	7%	5%	5%	6%	6%	
	Jõgevamaa		10%	8%	9%	7%	7%	9%	11%	9%	7%	8%	7%	8%	
	Järvamaa		9%	7%	9%	8%	7%	10%	11%	9%	7%	8%	8%	7%	

	Läänemaa		7%	7%	13%	17%	9%	8%	8%	6%	6%	6%	7%	6%
	Lääne-Virumaa		8%	7%	11%	10%	9%	10%	10%	9%	6%	7%	6%	7%
	Põlvamaa		10%	7%	7%	5%	6%	9%	11%	10%	8%	9%	9%	9%
	Pärnumaa		7%	8%	12%	10%	10%	10%	10%	9%	6%	6%	6%	6%
	Raplamaa		7%	6%	11%	14%	10%	11%	11%	8%	6%	5%	6%	5%
	Saaremaa		7%	8%	13%	11%	10%	10%	9%	7%	6%	6%	6%	7%
	Tartumaa		9%	7%	9%	7%	8%	10%	11%	9%	7%	7%	8%	8%
	Valgamaa		7%	6%	12%	13%	9%	12%	10%	8%	6%	6%	5%	6%
	Viljandimaa		6%	7%	12%	11%	11%	12%	11%	8%	5%	6%	5%	6%
	Võrumaa		4%	5%	13%	11%	10%	12%	11%	9%	7%	5%	7%	6%
France	whole country	FR	9%	9%	11%	9%	7%	6%	6%	8%	10%	9%	9%	9%
	Champagne-Ardenne	FR21	8%	7%	8%	7%	5%	4%	4%	9%	12%	12%	12%	13%
	Picardie	FR22	7%	6%	8%	7%	7%	6%	6%	9%	12%	12%	11%	10%
	Haute-Normandie	FR23	7%	7%	10%	8%	7%	6%	6%	9%	11%	11%	9%	8%
	Centre	FR24	9%	9%	12%	9%	6%	5%	5%	6%	10%	9%	9%	10%
	Basse-Normandie	FR25	7%	7%	9%	9%	8%	7%	6%	9%	11%	10%	9%	8%
	Bourgogne	FR26	13%	12%	16%	10%	6%	4%	3%	3%	4%	5%	9%	15%
	Nord - Pas-De-Calais	FR30	8%	6%	7%	7%	6%	7%	7%	10%	11%	11%	11%	10%
	Lorraine	FR41	7%	6%	8%	7%	6%	5%	6%	9%	13%	12%	11%	10%
	Alsace	FR42	8%	7%	8%	7%	7%	7%	7%	9%	11%	10%	10%	9%
	Franche-Comté	FR43	8%	8%	9%	6%	6%	5%	5%	9%	13%	11%	10%	10%
	Pays De La Loire	FR51	6%	8%	11%	9%	7%	6%	7%	11%	11%	9%	8%	6%
	Bretagne	FR52	8%	8%	9%	8%	8%	8%	8%	9%	9%	9%	8%	8%
	Poitou-Charentes	FR53	8%	8%	11%	9%	7%	5%	5%	8%	12%	10%	9%	8%
	Aquitaine	FR61	8%	8%	11%	11%	10%	8%	7%	7%	7%	8%	7%	7%
	Midi-Pyrénées	FR62	8%	9%	12%	11%	9%	7%	6%	7%	8%	8%	7%	7%

	Limousin	FR63	8%	9%	15%	12%	8%	6%	5%	6%	9%	8%	7%	7%	
	Rhône-Alpes	FR71	7%	8%	9%	7%	7%	6%	6%	8%	11%	11%	10%	8%	
	Auvergne	FR72	11%	11%	13%	9%	6%	5%	4%	6%	8%	8%	9%	11%	
	Languedoc-Roussillon	FR81	13%	10%	13%	12%	8%	5%	4%	4%	5%	6%	8%	12%	
	Provence-Alpes-Côte D'Azur	FR82	8%	8%	11%	11%	7%	5%	4%	6%	10%	12%	9%	8%	
Ireland	whole country	IE0	7%	19%	22%	17%	11%	6%	3%	3%	3%	3%	3%	3%	Cattle registration scheme for calvings
Italy	whole country	IT	9%	8%	9%	8%	7%	7%	8%	8%	9%	9%	9%	9%	National cattle register
	Piemonte	ITC1	9%	8%	9%	9%	8%	7%	7%	8%	8%	8%	9%	9%	
	Valle D'Aosta	ITC2	13%	8%	7%	3%	2%	1%	1%	1%	1%	7%	32%	25%	
	Liguria	ITC3	8%	8%	10%	13%	13%	8%	7%	8%	7%	7%	6%	5%	
	Lombardia	ITC4	9%	7%	7%	6%	6%	6%	8%	9%	10%	10%	10%	10%	
	Abruzzo	ITF1	8%	7%	8%	11%	10%	9%	9%	8%	8%	8%	7%	7%	
	Molise	ITF2	9%	7%	9%	10%	9%	8%	9%	9%	8%	8%	7%	7%	
	Campania	ITF3	9%	8%	8%	9%	8%	9%	9%	10%	8%	8%	7%	7%	
	Puglia	ITF4	9%	7%	9%	9%	9%	10%	8%	9%	8%	8%	7%	7%	
	Basilicata	ITF5	7%	7%	11%	13%	13%	10%	7%	7%	7%	6%	6%	6%	
	Calabria	ITF6	9%	9%	12%	13%	12%	10%	7%	6%	6%	6%	5%	5%	
	Sicilia	ITG1	9%	9%	12%	12%	11%	8%	7%	6%	7%	7%	7%	7%	
	Sardegna	ITG2	11%	11%	13%	11%	9%	7%	6%	7%	7%	7%	6%	7%	
	Provincia Autonoma Bolzano	ITH1	9%	8%	8%	7%	6%	6%	9%	9%	9%	10%	10%	9%	
	Provincia Autonoma Trento	ITH2	9%	8%	7%	6%	5%	5%	6%	8%	10%	14%	12%	9%	
	Veneto	ITH3	10%	7%	7%	7%	6%	6%	7%	9%	9%	11%	10%	10%	
	Friuli-Venezia Giulia	ITH4	9%	7%	7%	7%	6%	7%	9%	9%	9%	10%	10%	10%	
	Emilia	ITH5	9%	7%	8%	7%	7%	7%	9%	9%	9%	10%	9%	9%	

	Romagna													
	Toscana	ITI1	8%	7%	9%	10%	10%	9%	9%	8%	8%	8%	7%	7%	
	Umbria	ITI2	8%	7%	9%	10%	9%	9%	9%	8%	8%	8%	7%	8%	
	Marche	ITI3	10%	7%	8%	10%	10%	9%	8%	8%	8%	8%	7%	7%	
	Lazio	ITI4	8%	8%	10%	11%	10%	9%	8%	9%	8%	7%	6%	6%	
Lithuania	whole country	LT00	7%	7%	14%	11%	10%	11%	10%	8%	2%	6%	6%	7%	Annual report on milk recording
Luxembourg	whole country	LU00	8%	8%	11%	9%	9%	7%	6%	7%	9%	8%	9%	9%	Official animal registration database
Latvia	whole country	LV00	7%	7%	13%	13%	11%	11%	9%	7%	5%	5%	5%	6%	Official data base according to Regulations 1760/2000 and 21/2004
Netherlands	whole country	NL	8%	7%	8%	7%	8%	8%	8%	10%	8%	8%	8%	8%	
	Groningen	NL11	7%	7%	8%	7%	8%	9%	9%	10%	9%	8%	8%	8%	
	Friesland	NL12	8%	7%	8%	6%	8%	8%	9%	10%	9%	9%	9%	9%	
	Drenthe	NL13	7%	7%	8%	7%	8%	8%	9%	10%	9%	8%	8%	8%	
	Overijssel	NL21	8%	7%	8%	7%	8%	8%	8%	9%	9%	8%	8%	9%	
	Gelderland	NL22	8%	7%	8%	7%	9%	8%	8%	9%	8%	8%	8%	8%	
	Flevoland	NL23	9%	7%	8%	6%	8%	8%	8%	9%	9%	9%	9%	9%	
	Utrecht	NL31	7%	7%	9%	7%	9%	9%	8%	10%	8%	8%	8%	8%	
	Noord-Holland	NL32	7%	7%	8%	7%	8%	8%	8%	10%	8%	9%	8%	8%	
	Zuid-Holland	NL33	8%	8%	9%	8%	8%	8%	8%	10%	8%	8%	8%	8%	
	Zeeland	NL34	8%	8%	9%	8%	8%	8%	8%	8%	8%	8%	8%	9%	
	Noord-Brabant	NL41	8%	7%	8%	6%	8%	8%	8%	10%	8%	8%	9%	8%	
	Limburg	NL42	8%	7%	8%	7%	9%	8%	8%	9%	8%	8%	8%	8%	
Norway	whole country	NO	5%	11%	25%	21%	13%	7%	5%	2%	2%	2%	3%	4%	Norwegian Cattle Health Services
Spain	whole country	ES	9%	9%	12%	11%	10%	8%	7%	7%	7%	8%	7%	7%	National Integrated System of Traceability

Sweden	whole country	SE	8%	9%	15%	12%	9%	7%	7%	7%	6%	6%	6%	7%	Central database
Switzerland	Aargau	CH033	9%	9%	9%	7%	7%	7%	8%	9%	9%	9%	8%	9%	Tierverkehrsdatenbank
	Appenzell Innerrhoden	CH054	8%	7%	7%	7%	6%	6%	7%	9%	13%	12%	10%	8%	
	Appenzell Ausserhoden	CH053	8%	7%	8%	7%	6%	6%	8%	10%	11%	11%	9%	8%	
	Bern	CH021	9%	9%	10%	7%	6%	6%	7%	8%	9%	10%	10%	9%	
	Basel-Landschaft	CH032	9%	8%	9%	7%	7%	7%	8%	9%	9%	9%	9%	9%	
	Basel-Stadt	CH031	10%	13%	9%	5%	7%	8%	6%	7%	7%	10%	9%	7%	
	Liechtenstein	LI000	9%	8%	7%	6%	7%	6%	8%	7%	9%	13%	10%	11%	
	Fribourg	CH022	10%	9%	9%	6%	5%	5%	6%	8%	11%	11%	10%	10%	
	Geneva	CH013	11%	9%	6%	5%	7%	1%	3%	7%	9%	15%	16%	11%	
	Glarus	CH051	9%	8%	8%	7%	4%	4%	5%	6%	9%	17%	14%	10%	
	Grisons	CH056	9%	5%	5%	4%	3%	2%	3%	8%	17%	20%	14%	10%	
	Jura	CH025	9%	7%	8%	7%	6%	6%	8%	9%	11%	9%	10%	9%	
	Lucerne	CH061	9%	9%	9%	7%	7%	7%	9%	9%	9%	9%	9%	8%	
	Neuchatel	CH024	8%	7%	10%	8%	7%	6%	9%	10%	9%	9%	9%	8%	
	Nidwalden	CH065	9%	9%	8%	6%	5%	5%	7%	9%	10%	11%	11%	10%	
	Obwalden	CH064	8%	8%	7%	6%	4%	4%	5%	9%	14%	14%	11%	10%	
	St.Gallen	CH055	8%	8%	8%	7%	6%	6%	8%	10%	10%	11%	9%	9%	
	Schaffhausen	CH052	8%	8%	9%	7%	8%	7%	8%	8%	9%	10%	8%	9%	
	Solothurn	CH023	9%	9%	9%	7%	7%	7%	8%	9%	9%	8%	9%	9%	
	Schwyz	CH063	9%	8%	8%	8%	6%	5%	7%	9%	10%	11%	10%	9%	
	Thurgau	CH057	9%	8%	9%	6%	7%	7%	8%	10%	10%	10%	9%	9%	
	Ticino	CH07	10%	8%	8%	8%	5%	3%	3%	4%	8%	15%	16%	12%	
	Uri	CH062	10%	8%	6%	5%	3%	2%	2%	3%	13%	20%	14%	13%	
	Vaud	CH011	9%	8%	9%	7%	5%	5%	5%	8%	10%	12%	11%	10%	
	Valais	CH012	10%	6%	5%	3%	2%	1%	2%	3%	8%	21%	24%	15%	
	Zug	CH066	8%	8%	9%	7%	7%	7%	8%	9%	10%	9%	9%	9%	

	Zurich	CH040	9%	9%	9%	7%	7%	7%	8%	9%	9%	9%	9%	9%	
United Kingdom	whole country	UK	6%	6%	12%	12%	12%	9%	7%	7%	8%	7%	7%	6%	Population numbers

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
Force of infection	The rate at which susceptible units become infected by infectious units
hydrocephalus	abnormal accumulation of fluid within the brain cavity of the skull
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)
Under ascertainment	refers to case ascertainment and uncertainties in the geographical model
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
overwintering	survival of the virus during period of low vector circulation (winter) in either host or vector

ABBREVIATIONS

AHS	arthrogryposis hydranencephaly syndrome
BTV	bluetongue virus serotype
CT	cycle threshold
CVI	Central Veterinary Institute
DCF	Data Collection Framework
DG SANCO	Direction générale de la santé et des consommateurs (Directorate-General for Health and Consumers)
DPI	Days post infection
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
ELISA	Enzyme-Linked ImmunoSorbent Assay
EU	European Union
FLI	Friedrich Loeffler Institut
MS	Member State
NUTS	Nomenclature of Territorial Units for Statistics
PCR	polymerase chain reaction
RKI	Robert Koch Institute
RT-PCR	reverse transcriptase PCR
SBV	Schmallenberg virus
SCoFCAH	Standing Committee on the Food Chain and Animal Health
ToR	Terms of Reference
VNT	Virus Neutralization test