

**Veterinary Risk Analysis: Introduction of Bluetongue Virus into
Ireland from Bluetongue Restricted Areas in other Member States**

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1. Introduction

Assessing the risk of Bluetongue (BT) entry into Ireland is an ongoing process necessitated by an evolving disease pattern in affected Member States (MS), changes in animal movement regulations, and developments in scientific understanding of the epidemiology of the virus in domestic livestock. This risk analysis follows an assessment of the risk associated with introduction of the virus by various routes into Ireland from the UK published on the DAFF web site on (01/11/07). This update is necessary because of changes in animal movement regulations in response to new scientific data on how the virus can be transmitted in animals. Since the previous risk assessment, there have been no new developments in scientific knowledge on the accidental introduction of infected vectors by other means such as carriage on wind currents, in vehicles, containers, on plants, on non-susceptible species (horses, pets, people), or in hay or straw. Thus, these risk factors will not be addressed in this update.

2. Hazard Identification

2.1 Bluetongue Virus:

Bluetongue is an OIE listed viral disease of ruminants and camelids that has 24 known serotypes and occurs predominantly in warm temperate parts of the world. It may cause illness leading to loss of production or even death in sheep, deer, and cattle. Transmission is usually vector mediated (*Culicoides* midges) but may also be transmitted by the transplacental route (new scientific data on serotype 8), contaminated germplasm, or by iatrogenic means.

Ireland is one of the few EU Member States free of bluetongue at the present time. Furthermore, bluetongue has never been recorded on the island of Ireland. Introduction of the virus would have a negative impact on the farming sector in this country for several reasons:

- Direct losses of livestock – particularly with potentially high losses of sheep;
- Severe illness in infected sheep and cattle, including infertility, abortion and neonatal deaths, losses due to decreased production, lameness and other animal welfare implications;
- Bans on exports of live ruminants and germplasm that could cause long term economic losses;
- Movement restrictions that could stifle economic activity within and between restricted areas.

2.2 Bluetongue Epidemics in the EU:

Serosurveys indicated that many serotypes of BTV have been circulating for decades in Africa and the Middle East. Beginning in 1998 several serotypes extended their range northwards and westwards in to the Member States bordering the Mediterranean Sea. These serotypes included BT-1, BT-2, BT-4, BT-9, and BT-16 (Fig. 1). Initial spread was associated with an expansion of the range of the primary vector, *Culicoides imicola*. However, once in southern Europe, bluetongue viruses adapted to endemic midge species and the range of the virus increased further in the

Balkans, Italy, and the Iberian Peninsula (Purse *et al.*, 2005). At this point in time, northern Europe and Ireland were still outside the range of infection by these serotypes of BTV.

This situation changed in late summer 2006, when bluetongue virus serotype 8 (BT-8) first appeared in Belgium and the Netherlands and quickly spread to Luxembourg, Germany and northeastern France. The origin of the virus has never been determined. The virus over-wintered and reappeared as clinical infection in the same part of the EU in July 2007. It subsequently spread extensively and rapidly to adjacent areas and on September 22nd 2007, laboratory tests confirmed that BT 8 was present in a native-born rare breed bovine in Suffolk, UK (Figs 1, 2, 3). The farm had no history of livestock imports from Bluetongue affected countries in Europe. Subsequently, further cases were confirmed on different premises in Suffolk by laboratory testing and initially infected animals were culled. By the end of September Defra had confirmed that BT-8 was circulating between *Culicoides* vectors and livestock. The current situation (May 12th) is that a Protection Zone and a Surveillance Zone are in place (Fig. 4). Surveillance and epidemiological investigations are continuing and as of April 7th there were 125 infected premises in the UK with the most recent cases found as a result of on-going surveillance and pre-movement testing (Table. 1). The Vector Free Period (VFP) extended from the 20th of December to March 15th. Within the VFP, livestock could be moved out of the restricted areas under licence in compliance with Regulation 1266/2007, or could be moved to designated slaughterhouses in England or Wales. Susceptible livestock could also be moved from restricted areas in continental Europe in compliance with the Regulation.

As of 08/05/08 (SCoFCAH) there has been no evidence of BT-8 circulation in the 2008 season in any EU Member State (MS), although new cases have been confirmed in some areas, these are based on serological surveillance and the animals were likely infected in 2007. However, April 2008 was considerably colder than April 2007 and this may have delayed the emergence of vector populations this season. With the increase in vector populations in the UK over the coming months, and more favourable climatic conditions, it is highly likely that clinical cases will reappear as had occurred in continental Europe in 2007. Further spread of infection towards the west and north of England presents a clear hazard to Ireland in wind borne spread of infected vectors and also in the legal or illegal movement of livestock.

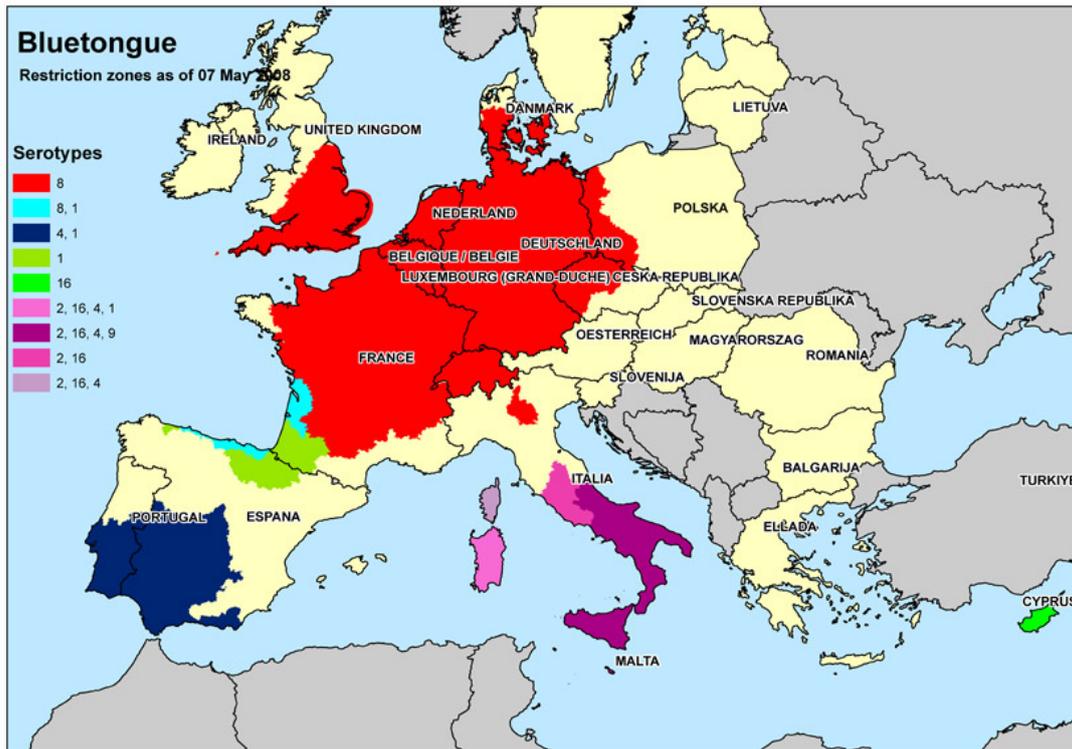


Figure 1: BT restriction zones in Europe as of May 7, 2008 (DG SANCO website)

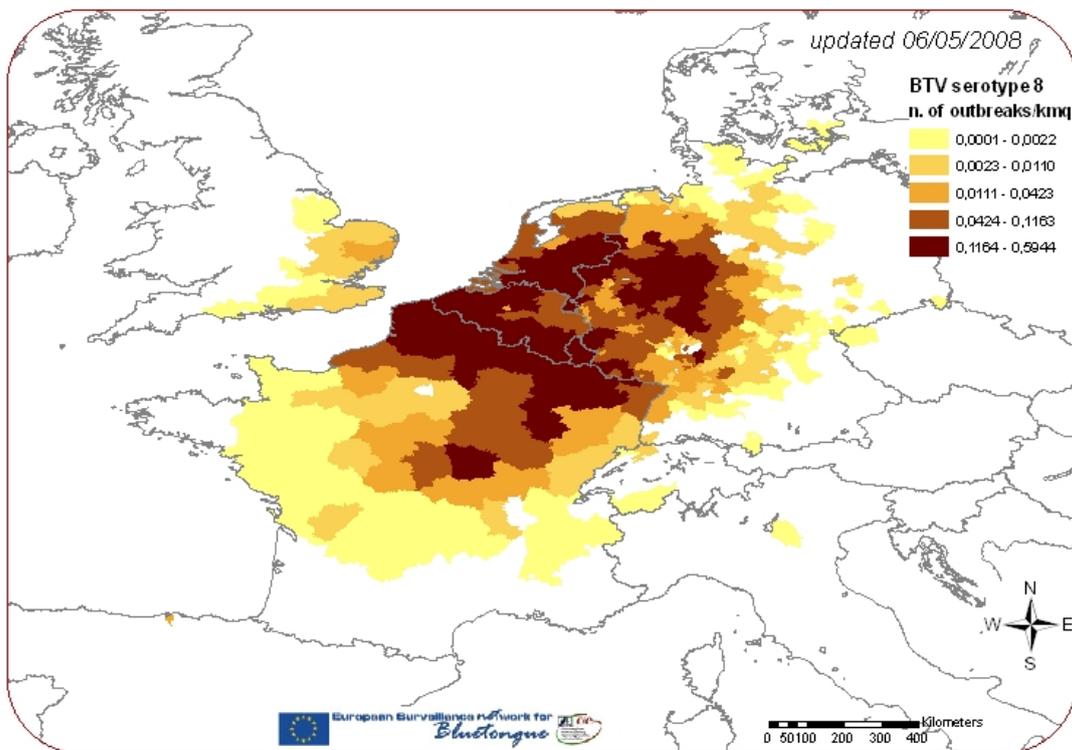


Figure 2: BT-8 outbreak density per square km on May 6 (EU-BT Net website)

From 01/05/2007 to 08/04/2008

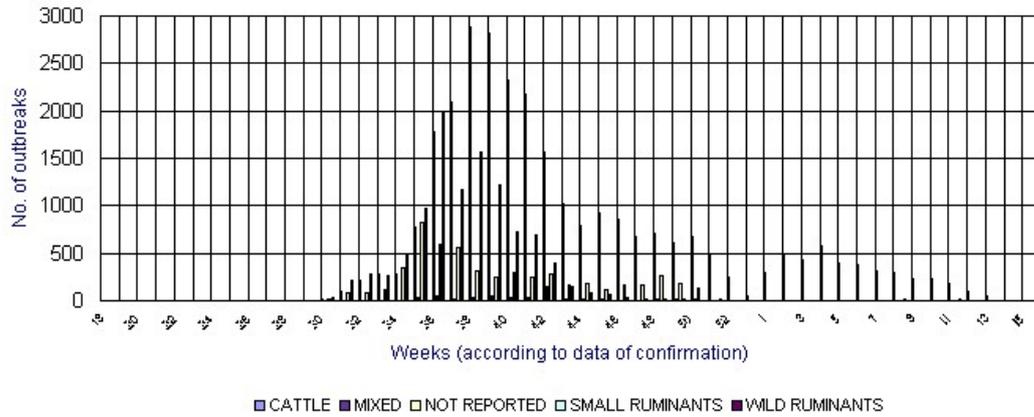


Figure 3: BT8 outbreak epidemic curve from May 2007 to April 2008 (from EU-BT Net website)

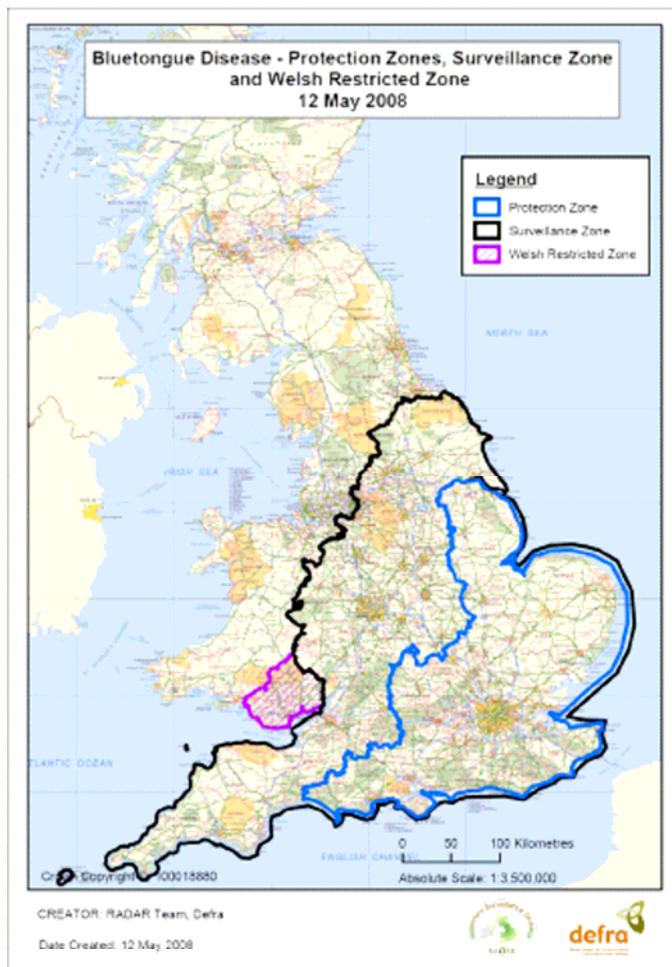


Fig. 4. BT restriction zones in the UK (from Defra)

Table 1: Review of the BT-8 and BT-1 epidemics in Europe on 7 April 2008

BT-8 Epidemic

In Europe, the number of confirmed outbreaks of BT- 8 between July 2007 and April 2008 is 57,542:

23,443 in Germany
19,323 in France
6,870 in Belgium (figure not updated since 31 December 2007)
6,442 in the Netherlands (figure not updated since 31 December 2007)
1,315 in Luxembourg (figure not updated since 31 December 2007)
125 in the United Kingdom
12 in Spain
7 in Switzerland
3 in Italy
2 in the Czech Republic
1 in Denmark

BT-1 epidemic

Three countries are currently affected:

Spain: 6,961 outbreaks have been notified between July 2007 and April 2008
Portugal: 158 outbreaks have been notified between July 2007 and April 2008
France: 5 outbreaks have been identified in the south-west of the country

Source: AFFSA website

2.3 Bluetongue Transmission

Vectors: Bluetongue virus is mainly transmitted by the feeding of adult female *Culicoides* (Diptera: Ceratopogonidae) midge species (OIE disease data). The midge species known to be competent vectors of BT-8 in other Member States are both numerous and widespread in Ireland based on DAFF funded surveillance carried out at 34 randomly selected trapping sites throughout the country, and sampled weekly since April 2007 (McCarthy *et al.*, 2008). *C. dewulfi*, a known BT-8 vector in the Netherlands, represented 40% of catches. This species is a particularly important vector as it breeds in cattle dung and as such is highly associated with livestock. This species, along with the midge species in the *Obsoletus* and *Pulicaris* complexes, are all important vectors, and in Ireland represent 90% of the midges trapped in 2007. Therefore, it is quite apparent that Ireland has several competent vector species and that these are widespread and are present in high numbers.

Contaminated Germplasm: A less common means of transmission is via semen from viraemic bulls and especially if there is also inflammation of the reproductive tract allowing leakage of blood cells into the semen (Osbourn 1994; Kitching 2006). Virus replication does not occur in the testes. It is thought that the virus is associated with the leaked blood cells, rather than the semen itself (C. Oura. Conference on BT 17 March 2008). Bluetongue transmission through embryo transfer from infected cattle or sheep is also very low if the embryos are washed to International Embryo Transfer Society (IETS) standards (Sutmoller and Wrathall 1997; Singh *et al.*, 1997).

Transplacental transmission: This mode of transmission from viraemic dam to foetus via the placenta was demonstrated in sheep using tissue culture virus at the Pirbright laboratory (Gibbs et al., 1979). In this experiment 8/10 lambs were shown to be viraemic for up to 145 days after infection of the dam. However, as similar data were not recorded from field infections, it was long assumed that this was not a significant route of transmission (OIE data sheet). However, observations from pregnant heifers imported into Northern Ireland during the VFP in 2008, and data presented to SCoFCAH (31/03/08) is now strong evidence that vertical transmission does occur with BT-8.

A group of 21 PCR-negative cattle were imported into Northern Ireland from the Netherlands on 11/01/08. The VFP commenced in the Netherlands on December 12th and the cattle had been tested twice prior to shipment. In eight animals, BT-8 ELISA titres were consistent with natural acquired immunity as determined by pre-and post-import testing. However, further testing 30 days post-import revealed one heifer was PCR positive but sero-negative. These results, confirmed by IAH Pirbright, were consistent with an early infection by BT-8 following importation. This would imply a non-vector mediated mode of transmission. Entomological surveillance in NI, including the farm in question, had shown that *Culicoides* were not active and ambient temperatures were also well below what is thought to be necessary for viral replication in vectors.

Subsequent investigation revealed that three calves (twins and a single calf) born in Northern Ireland to two of the sero-positive imported cows were both PCR and ELISA positive (PCR testing confirms the presence of viral RNA while ELISA testing identifies a host antibody response thus showing evidence of exposure to infection). This result strongly suggests that the calves were infected *in utero*. Furthermore, depending on the precise time of infection relative to the development of the immune system, *in utero* infection could result in a persistently infected animal, despite having circulating antibodies against the virus. As such, these could be a significant hazard by acting as a source of virus for vectors in the spring. In effect, the calves could act as a means for over-wintering of BTV, a mechanism that has never been fully elucidated.

As a result of these findings, further investigations of calves and/or lambs born from sero-positive/PCR negative dams were carried out in several Member States. Preliminary results of these investigations were reported at SCoFCAH on 30 April 2008 and published in the scientific literature (de Clercq et al., 2008).

Results so far show that in **Belgium** (de Clercq et al., 2008):

- 46 ewe/lamb pairs were sampled. All of the ewes were negative on PCR testing and 45 of the ewes were sero-positive. None of the lambs were positive on PCR testing. The lambs were sero-negative at birth, but became sero-positive after ingestion of colostrum. Thus, there is no evidence for trans-placental infection in sheep at this point in time.
- In cattle, 28 of 68 aborted fetuses were RT PCR positive (41%) and 4 of these were from dams that were PCR and ELISA positive. The conclusion is that trans-placental infection occurred.
- In cattle, of 109 newborn calves that died or were malformed, 11 were both PCR and ELISA positive (10%). Six of the dams that produced infected calves

were tested. Three were both PCR and ELISA positive while three were ELISA positive alone. This is further evidence for trans-placental infection.

- Of 90 cow/calf pairs sampled, 84 cows were sero-positive and 2 were sero-negative, 82 were PCR negative and 4 were PCR positive. Six (7%) of the calves were PCR positive (all were born to PCR negative, sero-positive dams). Trans-placental infection is likely in this case.
- Of 43 cow/calf pairs sampled before colostrum feeding, one pair was positive in both PCR and ELISA tests, while three PCR positive calves were produced by ELISA positive dams. This is further evidence for trans-placental infection.

Results from animals sampled from 20 farms in the **UK** during the VFP showed that one third of calves born to 54 sero-positive, PCR negative dams were positive on PCR testing. Thus, trans-placental infection has occurred in the UK. Testing of calves born to sero-positive imported cattle has shown no PCR positive calves to date.

On 21 April 2008 **Slovakia** reported 2 of 17 calves born to seropositive heifers from NL were PCR and virus positive at high titres. Two further calves died after birth and one had hydroanencephalus. The calves were sampled prior to colostrum feeding.

Results from the Netherlands confirm that BT-8 is found in newborn calves indicating trans-placental transmission.

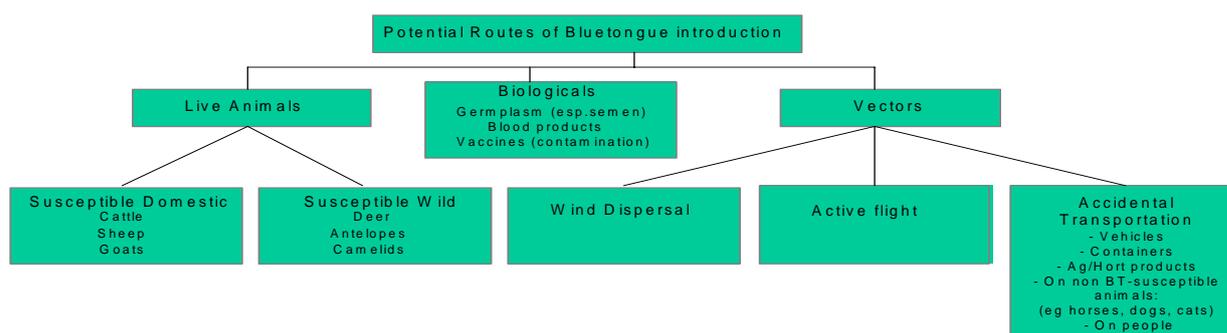
In summary, this evidence strongly indicates that there is transplacental transmission of BT-8 occurring in at least four MS and that infected calves can act as a means of over-wintering for the virus in Northern Europe. There is no evidence of transplacental transmission of BT-8 in sheep. There is also no evidence for trans-placental transmission with BT-1.

Iatrogenic or mechanical transmission: Oral infection of ruminants and African carnivores by the oral route has been documented for some other orbiviruses. It has been speculated that virus contaminated placentas and birth fluids could act as source of infection for adult cattle. It has been suggested that a cow from Scotland was infected by this route when exposed to infected calving heifers on a farm in Northern Ireland in January 2008. Limited data from the Netherlands also shows that contaminated colostrum could act as a source of infection for calves (van Rijn, Bluetongue working party meeting 30/04/08). Further research would be required to confirm or refute this mechanism of transmission. Likewise, it is conceivable that contaminated hypodermic needles could act a means of mechanical transmission. However, there is no empirical evidence to support this hypothesis. Furthermore, information from the Institute for Animal Health, Pirbright Laboratory (C. Oura, Conference on BT 170308) is that any potential risk from this means of transmission can be reduced by disinfecting needles between animals (e.g. those used for TB testing) using a mixture of citric acid and sodium dodecyl (lauryl) sulfate (SDS) anionic detergent. This means of transmission is not considered significant hazard for introduction of the virus into Ireland but would be considered as a means of spread following introduction by another route.

3. Release Assessment

3.1. Introduction of Bluetongue into Ireland

The following diagram represents the potential conceptual pathways or routes by which BT-8 could enter Ireland. This analysis focuses on the most significant potential route, which is the movement of infected live animals such as cattle and sheep. The second most likely route is wind-borne spread of infected vectors from a neighbouring MS such as the UK.



Ireland imports cattle and sheep for breeding or further production on average as follows:

	Continental Member States	GB	<i>Northern Ireland</i>	Total
Cattle	1,000	1,500	22,000	24,500
Sheep	0	500	4,250	4,750
Total	1,000	2,000	26,250	29,250

Table 2: Average number of ruminants destined for breeding or fattening imported annually

3.2. Importation of Infected Livestock:

Livestock imported into Ireland from restricted areas, and certified under Regulation 1266/2007 EC (Art. 8, Annex III) carry a **non-negligible** (see risk attributes in Annex I below) risk of introducing BTV to Ireland. Certification is based on such parameters as protection from vectors and results of laboratory tests (ELISA and/or PCR). The former may be mitigated somewhat by limiting animal movements to the Vector Free

Period, strategic shipment to avoid times of greatest vector activity, use of appropriate housing, and use of repellents or insecticides. Failure of laboratory tests through false negative results, variance in interpretation of results between laboratories or MS, or human error, could provide a means for BTV to be imported with infected livestock. This has already been documented in the EU by the movement of livestock subsequently found to be PCR positive by post-importation testing from restricted areas to the UK, Italy, Spain, Portugal, Poland, Slovakia and Romania.

3.3. Wind Borne Vectors:

The accidental arrival of infected wind borne vectors to Ireland from the UK is theoretically possible provided the wind trajectories and velocities are optimal, ambient temperatures are sufficient during transit for survival of infected parous female *Culicoides*, ambient climatic conditions suitable at landfall, and susceptible hosts present at landfall. As wind dispersal of *Culicoides* is greater over water than landmasses, the localization of the current outbreak in eastern and southern England would mitigate against dispersal as far as Ireland. Furthermore, from August 1st 2007 to the start of the VFP, there were few days when southeasterly winds flowed over Ireland from the UK, and for most of those the airflow was probably not strong enough to advect particles (such as infected midges) from the UK to Ireland (S. O'Reilly, Met Eireann). Since mid October, wind trajectory models have shown airflow from the UK towards Scandinavia and continental Europe and only rarely towards Ireland. Furthermore, modelling of wind trajectory paths originating in the outbreak area of Suffolk and Cambridgeshire have shown that wind from that area did not reach Ireland at any time during the BT-8 epidemic in the UK (Eoin Sherlock, Met Eireann). However, if the outbreak resumes in 2008 and propagates as quickly as it has in continental Europe in 2007, infection may spread further west towards Wales and north to Lancashire and Cumbria before it can be stopped by vaccination. In that case the level of risk to Ireland would increase significantly if climatic conditions are favourable for midges and wind trajectories are from the east or south east. This assessment applies to the current situation only and is an ongoing process that will be constantly reviewed and updated as necessary.

Bluetongue is not apparently circulating in eastern and southern England at the present time. Thus, infected midges are unlikely to be blown here at least until resumption of virus circulation later in the season. When and if, this recurs in the UK, then the probability of infected midges blowing to Ireland across the Irish Sea will depend on whether climatic variables are favourable to midge survival and viral development. Suboptimal ambient temperatures would lengthen the extrinsic incubation period for the virus, which combined with a decreased survival rate for parous females at lower temperatures, will greatly reduce the number of infective competent vectors. The risk of windborne introduction would be further reduced by the predominantly westerly flow of air over Ireland. In Spring and early Summer, easterly winds are more likely to be cool and dry and less favourable to *Culicoides* survival. Another factor that will mitigate against spread of infected midges to Ireland is the roll out of vaccine to UK farms (from 30/04/08) that will decrease the viral load in the national herd and flock.

4. Exposure Assessment

Spread of infection within Ireland would depend to a great extent on the means of virus introduction. For example, wind borne spread of infected *Culicoides* across the Irish Sea could result in multiple foci of infection whereas the importation of a single infected ruminant could result in a more localised outbreak of disease. Focusing on the latter scenario, spread of infection will depend on:

- Presence of a population of potential vector *Culicoides*,
- Climatic conditions favourable to midge survival and dispersal by wind,
- Susceptible livestock population.

As described above, Ireland has several potential *Culicoides* vector species among the *Obsoletus* and *Pulicaris* complexes, while *C. dewulfi* is particularly common at all sites monitored. Thus, from April through to October or November the only limitation on whether vector mediated transmission could occur in Ireland would be whether the ambient temperatures are sufficiently high to facilitate extrinsic incubation in the female *Culicoides*. The probability that climatic conditions will favour transmission will increase as the temperatures increase through May and June and continue favourable for replication into September. The final requirement for susceptible hosts is also fulfilled in that Ireland has high cattle (7 million) and sheep populations (4 million) coincident with the vector populations. The density of cattle and sheep populations is shown in **Annex II** below.

Thus, it would be expected that even with early detection of clinical cases, and deployment of vaccine, that an epidemic could propagate if climatic conditions favour vector survival and viral replication.

5. Consequences Assessment

Agriculture and livestock production in particular represents a significant proportion of the Irish economy. A summary of facts relating to Irish agriculture is shown below:

Key facts on Irish agriculture 2006 (DAFF):

Area: 6.9 m hectares

Area in agriculture: 4.3 m hectares

Agricultural land: 80% grassland, 11% rough grazing, 9% crops

132,700 farms

109,100 employed in agriculture

Exports of live ruminants

Ireland **exports** approximately 250,000 cattle every year. Most of these to other EU Member States and most of these are for further fattening. Calves go to the Netherlands, France and Belgium. Weanlings and stores go to Spain and Italy.

Finished animals and stores go to Northern Ireland, and some finished animals go to Great Britain.

Most of the sheep exported go for slaughter in Northern Ireland, with small numbers going to Great Britain.

Internal cattle movements

More than 5 million cattle movements take place annually **within Ireland (AHCS)**.

Production

The following are the figures for production in 2006 (Bord Bia):

	Production (tonnes)	Exports (tonnes)	Imports (tonnes)	Consumption (tonnes)
Beef	569,000	516,000	33,000	86,000
Sheep meat	71,500	54,000	3,000	20,500
	640,500	570,000	36,000	106,500

Table 3: Distribution of beef and sheep meat in Ireland 2006

90% of beef and 75% of sheep meat produced in Ireland is exported.

5.2 million tonnes of milk were produced in 2006. 80% of dairy products are exported.

The consequences of direct losses of livestock (illness in infected sheep and cattle, infertility, abortion and neonatal deaths, losses due to decreased production, lameness), welfare implications, bans on exports of live ruminants and germplasm to some destinations, and movement restrictions are likely to have severe economic impacts.

6. Risk Management

6.1. Importation of Bluetongue susceptible livestock:

6.1.1 EU rules

The importation of susceptible livestock from BT Restricted Zones in BT affected Member States is subject to regulations on intra-community trade. These include Commission Regulation No. 1266/2007 EC that came into effect on October 26th, 2007 and later amended by:

- Commission Regulation 289/2008 that requires each condition under which a consignment is certified to be stated in the accompanying health certificate
- Commission Regulation 384/2008 that sets down specific conditions for exempting pregnant animals from the exit ban provided for in Directive 2005/75/EC and

- Commission Regulation 394/2008 (EC), that provides further transitional provisions for exemption of certain animals from the exit ban provided for in the above Directive (see details below in paragraph **6.1.3**).

Note: Import of susceptible species from *BT-free Member States* or *BT-free Zones* in affected Member States is permitted under normal EU rules for intra-community trade in susceptible species provided that, if transiting BT restricted areas, that both the animals and the transportation are treated with insect repellent/insecticide and certified accordingly. As indicated in the risk analysis from 1/11/07 there is negligible risk of importing BT-8 from bluetongue-free MS or areas.

Susceptible animals imported into Ireland since November 1st, 2007 must be accompanied by a health certificate indicating compliance with the provisions in Commission Regulation 1266/2007/EC.

6.1.2 Slaughter animals (Arts 8.4 and 8.5)

Animals from a restricted area for immediate slaughter are exempt from movement restriction provided:

- There no cases of BT on the holding for at least 30 days prior to shipment;
- They are shipped under official supervision and slaughtered within 24 hours;
- The competent authority (CA) of origin notifies the CA of destination at least 48 hours prior;
- A channelling procedure may be required based on risk assessment for transport of animals to the place of slaughter.
- Information on the designated slaughterhouses will be public and notified on the BT Net system.

Risk assessment: The absence of clinical disease on the holding of origin, channelling of transport to designated slaughter houses, and slaughter in less than 24 hours should reduce the risk of transporting infected animals to a minimum. However the risk may be further reduced by ensuring that the animals and the means of transport are treated with insect repellent or insecticide before shipment and during transit. At the current time slaughter animals from BT Restricted Zones in Great Britain are only moving to designated plants in England or Wales. No slaughter animals are being imported into Ireland. Therefore the risk from the import of slaughter animals from BT Restricted Zones in Great Britain is currently **Negligible**.

6.1.3 Animals for breeding or production

Under Article 8 of the Regulation (as amended) there are seven alternative conditions (Annex III) for certification of breeding and production animals entering intra-community trade from Restricted Zones to free areas. Health certificates must indicate which of the rules apply to a particular consignment. Animals shipped under the provisions of this Regulation must be protected from vector attack during transportation.

The risk is assessed of importing BT infected livestock into Ireland during the remainder of 2008 under the provisions laid down in Regulation 1266/2007 EU, Annex III, and in the Transitional Measures (Commission Regulation 394/2008) under Article 9a provided for until **31 December 2008**. The net effect of these measures when applied to a MS availing of the transitional measures is to limit animals imported to:

- Fully vaccinated animals, (female animals must have been vaccinated before insemination/mating)
- Naturally immune animals, (female animals must have been demonstrated to be immune before insemination/mating) or
- Animals certified under conditions 1-4 that are less than 90 days of age, which have been in vector protected confinement since birth, and where PCR testing is to be carried out, the test has been carried out not earlier than 7 days before movement.

As of 07/05/08, Ireland, Northern Ireland, the UK, Sweden, Austria and Italy have been approved by the Commission to avail of this derogation.

6.1.4 Risk associated with movement conditions:

Condition 1: Under this condition non-pregnant animals may exit the restricted zone 60 days after the commencement of the seasonally VFP, or 60 days protected from vector attack, and subject to a negative PCR test carried out at least 7 days prior to shipment. In addition, the derogation under the transitional measures in effect until December 31st, 2008, limits the age of animals that can be moved under this provision to those less than 3 months, protected from vectors by confinement since birth, and with a negative PCR test on a sample taken not earlier than 7 days before shipment (ie within 7 days of shipment).

Risk assessment: These animals should pose a **Very Low** risk (see risk descriptors in **Annex I below**) of carrying BTV even though they may have been infected with the virus during the season of vector activity. The 60 day period of holding following the cessation of vector activity or in vector-proof housing, should be sufficient for immunity to develop and for clearance of virus from the blood. The carrying out of a PCR test at least 7 days before shipment should detect any animals that still have circulating virus. Thus the level of risk is dependent on stringent protection from vectors for the 60-day period and on the quality of the laboratory testing. RT-PCR has a high test sensitivity and specificity of about 99.5% but false positive or false negative results can infrequently occur. During 2007 and 2008, several Member States (Italy, Spain, UK, Portugal, Poland, Slovakia and Romania) have reported positive PCR results in animals that have tested negative prior to export from BT affected Member States. The risk can be mitigated against by post movement testing as carried out in Ireland. As no animals of susceptible species under 3 months of age are imported into Ireland, the derogation under the transitional measures will reduce the risk of importing susceptible animals to **Negligible**.

Condition 2: Under this condition animals should be kept protected from vector attack for 60 days until shipment. In addition, the derogation under the Transitional

Measures in effect until December 31st, 2008, limits the age of animals that can be moved under this provision to those less than 3 months and protected from vectors since birth.

Risk assessment: There is no requirement for either serology or PCR testing prior to shipment. Furthermore, the means of protection from vector attack is not defined and there is no requirement for shipment to be carried out in the vector free period. Thus, there could be a **High to Very High** risk associated with importing livestock certified under this condition of the Regulation. However, because Ireland does not import susceptible livestock under 3 months of age, the derogation provided in the Transitional Measures will prevent the importation of potentially infected animals. In this case, the risk can be reduced to **Negligible**.

Condition 3: Under this condition either animals have to be kept in a BT free area and shipped in the vector free period, or they have been protected from vectors for at least 28 days and have negative serology carried out at least 28 days following the start of the period of protection from vectors, or the start of the VFP. For female animals the certificate must state whether they are pregnant or may be pregnant. If the latter applies, they must have been protected from vectors for 28 days as stated and also have a negative serology test not earlier than 7 days before shipment. However, the derogation under the Transitional Measures in effect until December 31st, 2008, limits the age of animals that can be moved under this provision to those less than 3 months, protected from vectors since birth, and with a negative serology on a sample taken not earlier than 7 days before shipment.

Risk assessment: The 28 day period should be sufficient time for an animal exposed to BTV to have mounted an immune response. Thus, these animals would pose a **Negligible to Very Low** risk of carrying BTV provided there has been stringent protection from vectors and subject to the quality of the laboratory testing. Protecting females that may be pregnant against vector attack for 28 days and then testing prior to shipment should also ensure that they are free of BTV. Furthermore, the derogation under Article 9a means that in effect, no animals will be imported as the age is restricted to less than 3 months and the risk of importing BTV will be **Negligible**.

Condition 4: The conditions for shipment are similar to 3 above except that a negative PCR test result, instead of serology, is required at least 14 days after the start of the period of protection from vector attack, or start of the VFP. In addition, the derogation under the Transitional Measures in effect until December 31st, limits the age of animals that can be moved under this provision to those less than 3 months, protected from vectors since birth, and with a negative PCR on a sample taken not earlier than 7 days before shipment.

Risk assessment: These animals should pose a **Negligible to Very Low** risk of carrying BTV provided there has been stringent protection from vectors and subject to the quality of the laboratory testing as above. However, because Ireland does not import livestock under 3 months of age, the derogation

provided in the Transitional Measures will prevent the importation of potentially infected animals. The risk will therefore be **Negligible**.

Condition 5: This condition concerns **vaccinated animals** from a herd vaccinated as part of a vaccination programme. In addition under the amendment (Commission Regulation 384/2008)), health certificates for female animals must state that the animal is **not pregnant** or that it **may be pregnant**. If the latter applies, then the certificate must indicate the conditions under which they may leave a restricted area. Emergency vaccination commenced in various affected MS from March through May 2008. Such animals must be moved within the period of immunity and meet at least one of the following requirements: (1) Have been vaccinated at least 60 days prior to movement, (2) vaccinated with an **inactivated vaccine** for at least the number of days required to give immunity and tested negative by PCR at least 14 days before movement. The certificates for female animals must state that they were vaccinated and boosted with an inactivated vaccine and tested by PCR prior to insemination or mating. (3) If animals have been vaccinated previously, then revaccination must have occurred within the period covered by the previous vaccination. Female animals must have been vaccinated and boosted with an inactivated vaccine prior to insemination or mating. (4) Alternatively, the animals must have been kept since birth, or at least 60 days, free from vector attack (i.e. in a BTV free area or in the VFP) and vaccinated using an inactivated vaccine. Animals shipped under this condition will have a specific health certificate. In the case of female animals the certificate must state that mating or insemination occurred after the number of days necessary for immunity to develop.

Risk assessment: Inactivated (IA) vaccines are a relatively recent development in the control of bluetongue. The first campaigns using IA BT vaccines were against serotypes 2 and 4 in Italy, Spain, Portugal and France beginning in 2005 (Savini et al., 2008). These vaccines have been shown to be safe and efficacious in the field when used in cattle and sheep. As yet, the efficacy of the inactivated BT 8 vaccines is unknown as there has been insufficient time for testing. It is likely that the IA BT-8 vaccines will prove to be both safe and of high efficacy but it is also possible that efficacy will vary between vaccines produced by different manufacturers. Risk may be mitigated by post importation testing of vaccinated animals by PCR. In the case of female animals, the conditions stipulated should ensure that they are solidly immune before becoming pregnant. There should therefore be no risk that the foetus will become infected. The risk is therefore **Negligible to Very Low**. Safety and efficacy data from the 2008 BT-8 vaccination campaign in affected MS will likely reduce the risk to negligible in the coming months.

Condition 6: Animals originating in an area where one BT serotype is circulating and seropositive between 60 and 360 days prior to shipment. A new amendment to 6 (a) provides a second ELISA test not earlier than 7 days before movement. Alternatively, animals from this area that are seropositive at least 30 days prior to shipment but PCR negative less than 7 days before shipment. Animals shipped under this provision will have a specific health certificate. In the case of female animals, the certificate will state that these conditions were complied with prior to mating or insemination.

Risk assessment: Although these animals may be seropositive for BT-8, sufficient time should have elapsed in the first scenario for these animals to no longer be viraemic. As such, they should pose no risk for importation. In the second scenario, they are seropositive but no virus is detectable by PCR. Thus, non-pregnant animals in compliance with this condition should pose no risk. Pregnant animals should also have been demonstrated to be solidly immune prior to mating or insemination. Therefore there should be no risk of transplacental infection. Compliance with this condition carries **negligible risk** of importing infected livestock.

Condition 7: This condition is similar to 6 except that more than one serotype may occur in the area of origin. Thus, the serology must be serotype specific for the region. A new amendment to 7 (a) provides a second ELISA test not earlier than 7 days before movement. Animals shipped under this provision will have a specific health certificate. In the case of female animals, the certificate will state that these conditions were complied with prior to mating or insemination.

Risk assessment: Same as for condition 6.

6.2. Wind Borne Vectors

There is a **Medium to High Risk** that infected midges could be blown to Ireland from an adjacent affected part of the UK if climatic conditions are favourable. However, as this is a natural stochastic phenomenon not amenable to management, no action is required on the part of the competent authority other than to monitor climatic conditions on an ongoing basis.

7. Additional measures currently being carried out by DAFF

Post –import testing:

DAFF is currently conducting post-import testing of susceptible species imported from BT affected Member States. All animals imported from BT Restricted Zones in affected Member States since October 2006 have been serologically tested. In addition since 19 February 2008 all animals imported since November 2007 have also been tested by PCR (including retrospective sampling). From 19 February, all animals imported from Northern Ireland from 11 January 2008 have also been serologically and virologically tested.

From October 2006 to 4 April 2008 a total of 2875 imported animals (2620 cattle and 254 sheep) have been serologically tested. To date all results have been negative for antibodies to BT, with the exception of three consignments totalling 27 young bulls from Belgium in 2008, consisting of seropositive animals imported in compliance with the Regulation. Additional post importation testing confirmed that although they were seropositive, they were PCR negative. Thus, these animals pose a negligible risk of introducing BTV to Ireland.

From 19 February to 4 April 2008 a total of 1152 animals (1000 cattle and 152 sheep) have been PCR tested with negative results.

Ban on the import of female animals:

DAFF introduced a ban on the import of female cattle over 12 months, and female sheep over 6 months on 22 February (S.I. No. 46 of 2008), following the announcement by the authorities in Northern Ireland of new evidence of possible transplacental transmission in cattle on 15 February. This ban was rescinded and replaced by S.I. 133 of 2008, which requires imports to be in compliance with Commission Regulations 384/2008 and 394/2008.

8. Conclusion

Livestock imported from BT affected areas under certification based on Regulation 1266/2007/EC (Art. 8, Annex III) and its amendments (Regulations 289/2008, 384/2008 and 394/2008) carry a **negligible risk** of introducing BTV into Ireland. The reasons for this are:

- Under the provisions of the Regulation and the amendments, health certificates should only be issued to animals that have never been exposed to BTV (as determined by Vector Protection, movement in VFP, negative serology and/or PCR), or are solidly immune (through vaccination with inactivated vaccine, or through natural infection).
- Additional safeguards are in place to cover female animals to ensure that pregnant animals that may be carrying an infected foetus are not imported;
- And under the provisions of the derogation (Art. 9a), no animals over 3 months of age are imported while those less than 3 months are certified free of infection prior to movement.

Imports from BT-free MS or areas carry negligible risk of introducing BTV to Ireland.

9. Recommendations

Introduction of BTV infection to Ireland by legal importation of susceptible livestock under the current Regulations (as amended Commission Regulations 289/2008, 384/2008 and 394/2008 and including the implementation of the provisions of the transitional measures required by, and granted to, Ireland) carries a **Negligible to Very Low risk** of importing infected animals. Any residual risk can be minimised or eliminated by taking the following measures with susceptible livestock imported into Ireland from BT-affected MS for the remainder of 2008:

DAFF Measures

- 1) Continue testing all susceptible species by ELISA and PCR within one week of arrival at a farm of destination, then:
 - a) Slaughter PCR positives,
 - b) Retest ELISA positive, PCR negative, cases within 14 days.

On Farm of Destination

- 2) During the period of vector activity, and pending post-import test results:
 - a) Isolate and house all imported animals
 - b) All imported livestock are treated with an approved insecticide when leaving or transiting Restricted Zones. At the farm of destination, re-treat all susceptible species imports with an approved insecticide (www.bluetongue.ie) in accordance with manufacturers instructions to ensure two (2) months protection for cattle or one (1) month for sheep and goats. (Treatment may be discontinued if post-importation test results are negative).
 - c) Use insect repellents or insecticide strategically around animal housing to discourage entry of midges.
 - d) Remove potential midge breeding sites such as dung from areas around animal housing at frequent intervals (at least twice weekly).

10. Acknowledgements

This risk assessment was produced by Dr. Padraig Duignan, NDCC, with the assistance of Sally Gaynor and Billy McAteer, NDCC.

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Presentations to SCoFCAH on 31 March 2008, which can be accessed at:

http://ec.europa.eu/food/committees/regulatory/scfcab/animal_health/index_en.htm

Interim report on samples received at the Community Reference Laboratory (CRL) in Pirbright from Northern Ireland (NI) between 15/2/08 and 19/2/08

S.I. No. 46 of 2008, Diseases of Animals Act 1966 (Bluetongue) (Restriction on imports from Restricted Zones) Order 2008

EU BT-Net website (<http://eubtnet.izs.it/btnet/>)

DG SANCO website

(http://ec.europa.eu/food/animal/diseases/controlmeasures/bluetongue_en.htm)

Conference on Bluetongue Control: A new challenge for Europe. 17 and 18 March 2008. Brussels

Daily meteorological data and wind trajectories from S.O'Reilly and E. Sherlock, Met Éireann

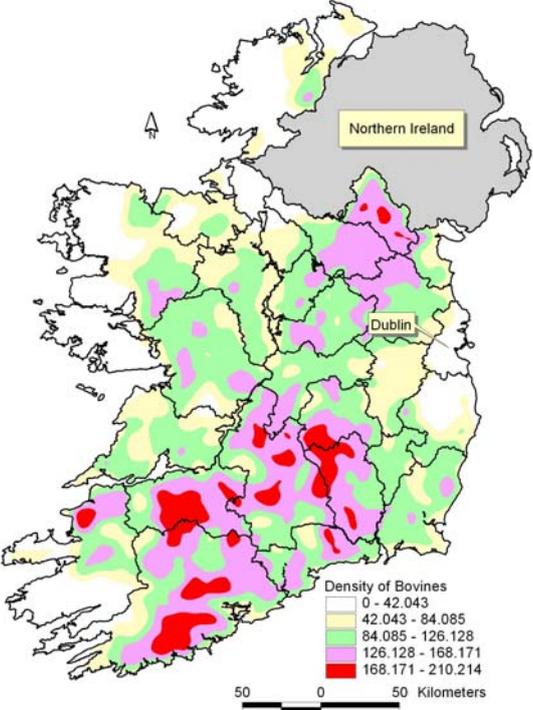
ANNEX I

Descriptors for critical attributes of risk¹

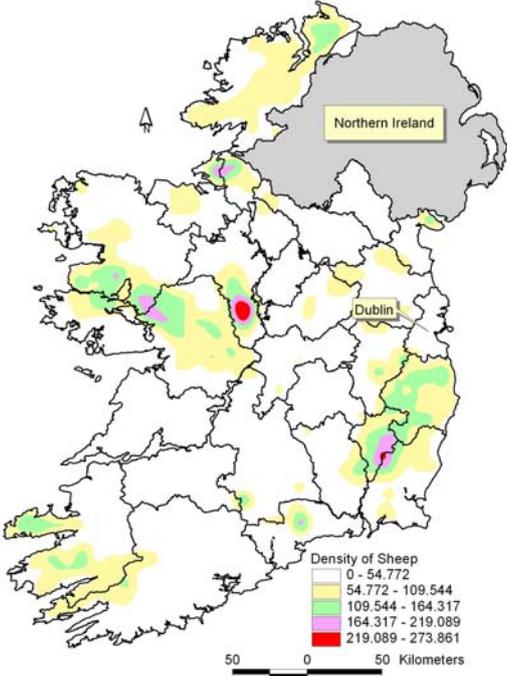
Risk Attributes	
Negligible	Not worth considering; insignificant
Non-negligible	Worth considering, significant
Risk Descriptors	
Very Low	Close to insignificant
Low	Less than average; coming below normal level
Medium	Around normal or average level
High	Extending above the normal level
Very High	Well above the normal or average level

¹From: Pearson, D. 2006. Risk analysis procedures. Biosecurity New Zealand, PP 29 of 103.

ANNEX II
Density of cattle and sheep



Density of bovines from AHCS 2007 (animals per km²)



Density of sheep from AHCS 2007 (animals per km²)

ANNEX III

Acronyms

AFSSA	French Food Safety Agency
AHCS	Animal Health Computer System
Bord Bia	Irish Food Board
BT	Bluetongue (disease)
BT-8	Bluetongue Serotype 8
BTV	Bluetongue Virus
CA	Competent Authority
DAFF	Department of Agriculture, Fisheries and Food
Defra	Department of Environment, Food and Rural Affairs (GB)
DG SANCO	EU Directorate General for Health and Consumers
ELISA	Enzyme-Linked Immunosorbent Assay
EU	European Union
EU BT-Net	European Union Surveillance System for Bluetongue
GB	Great Britain
IAH	Institute for Animal Health
IETS	International Embryo Transfer Society
MS	Member State
NDCC	National Disease Control Centre
NI	Northern Ireland
OIE	Office International des Epizooties (International Animal Health Organisation)
PCR	Polymerase Chain Reaction
RT-PCR	Reverse Transcriptase Polymerase Chain Reaction
SCoFCAH	Standing Committee on the Food Chain and Animal Health
SDS	Sodium Dodecyl (Lauryl) Sulfate
TB	Tuberculosis
UK	United Kingdom
VFP	Vector Free Period