Bluetongue monitoring and surveillance

in the Netherlands

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1. Introduction

Bluetongue (BT) is a non-contagious, insect-transmitted (only *Culicoides* species), viral disease of domestic and wild ruminants that does not affect humans. Since August 2006 bluetongue has been detected in the Netherlands, Belgium, western Germany and north-eastern France. The recent outbreak has highlighted the risks that many countries in Europe, not only in the Mediterranean area, may face in relation to BTV. In order to improve the understanding of the epidemiological situation and of the risks for the EU posed by this disease and to establish proportionate measures leading to a minimum disruption of trade it is necessary to enhance monitoring and surveillance for BT in the EU, in accordance with harmonised principles and guidelines¹.

The Terrestrial Animal Health Code of the OIE defines *monitoring* as the continuous investigation of a given population or subpopulation, and its environment, to detect changes in the prevalence of a disease or characteristics of a pathogenic agent. In this document, monitoring is used to refer to the actions and measures taken to assess the disease evolution in a BT restricted zone for the purpose of adaptation of Community and National legislation and in order to modulate restrictions on animal movements.

The Terrestrial Animal Health Code of the OIE defines *surveillance* as the investigation of a given population or subpopulation to detect the presence of a pathogenic agent or disease; the frequency and type of surveillance will be determined by the epidemiology of the pathogenic agent or disease, and the desired outputs. In this document, surveillance is used to refer to the actions and measures taken to demonstrate BTV absence in a non-restricted zone and early detect possible virus incursions into the zone for the purpose of adaptation of Community legislation.

1.1. Legal framework for Bluetongue surveillance and control

The Community legal framework on BT surveillance and control is laid down in Council Directive 2000/75/EC² and Commission Decision 2005/393/EC³. The two legal acts are in line with the recently reviewed chapter on BT of the Terrestrial Animal Health Code of the World Organisation for Animal Health (OIE). Depending on the basis of epidemiological, geographical, ecological or meteorological circumstances the competent authority may adapt or take further measures.

Decision 2005/393/EC as recently amended to incorporate the new restricted zones in Belgium, Germany, France, Luxembourg and the Netherlands provides for, among other ancillary measures, derogations from the restrictions to animal movements (especially domestic movements or intra-Community trade within restricted zones). Similar conditions can be applied for the movement of semen, ova and embryos.

In accordance to Community legislation, disease surveillance is of fundamental importance to assess the actual risk posed by animal movements and modulate trade restrictions accordingly. As a consequence of the increased threat posed by BT, there is an increasing need for a harmonised EU approach to monitoring and surveillance.

¹ Working document SANCO/10581/2006 rev 4, Working document on Bluetongue monitoring and surveillance in the EU

² Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue (OJ L 327, 22.12.2000, p. 74–83)

³ Commission Decision 2005/393/EC of 23 May 2005 on protection and surveillance zones in relation to bluetongue and conditions applying to movements from or through these zones (OJ L 130, 24.5.2005, p. 22–28). Decision as last amended by Decision 2006/650/EC (OJ L 267, 27.9.2006, p. 45-47)

1.2. Legal base for EU financial support to BT control, monitoring and surveillance

EU expenditure on BT is specifically foreseen under Article 3 and Article 24 of Council Decision 90/424/EEC⁴ on expenditure on the veterinary field.

 Article 3 of 90/424/EEC provides for the Community's financial contribution towards the emergency measures in the event of occurrence of BT in the territory of a MS. The MSs shall obtain a Community contribution for the eradication of the disease up to 50% of certain cost (compensation for slaughter, destruction of carcasses, disinfection...) incurred by the MS and up to 100% of the costs of the supply of vaccine doses and 50% of vaccination.

It also provides for a Community financial contribution where, on the outbreak, two or more MSs collaborate closely to control the epidemic particularly in carrying out an epidemiological survey and disease surveillance measures.

- Article 24 of 90/424/EEC provides for Community financial support to eradication and monitoring programmes that aim at progressively eliminating animal diseases (BT in endemic or high risk areas) that are endemic in certain areas of the Community.
- In addition, Article 19 of Council decision 90/424/EEC provides for Community financial support to technical and scientific measures. In this framework the Community can financially assist the MSs in undertaking the technical and scientific measures necessary for the development of Community veterinary legislation..
- The procedure of the Standing Committee on the Food Chain and Animal Health is mentioned for the financial decisions to be taken on the basis of article 3, 19 or 24 of Decision 90/424/EEC

1.3. Basic principles and tools of BT monitoring and surveillance in the Netherlands

1.3.1. Main objectives

The main objectives and principles of BT monitoring and surveillance can be summarised as follows:

- 1. Monitoring the dynamics of the disease in restricted (non-free) zones, as described in the annex of Decision 2005/393/EC.
- 2. Surveillance to confirm the absence of the disease or to early detect the entry of virus into free zones. Surveillance may have also the purpose to substantiate the country declaration of BTV-freedom in the framework of the OIE Code.
- 3. Gathering data for the assessment of the risk of entry and/or spread of virus into free or infected areas in order and to enhance disease prevention and implement appropriate control measures, including restrictions to animal movements accordingly. This data should include epidemiological, geographical and meteorological data, as well as information of the vector(s) in the areas.

1.3.2. Fundamental tools

BT monitoring and surveillance must be based on three fundamental tools:

- 1. Serological and virological surveillance on cattle
- 2. Entomological surveillance
- 3. Supplementary measures such as clinical surveillance (passive and active)

1.3.3. Geographical unit

• The epidemiological unit of concern for BT is neither the single animal nor the herd but a *geographical unit* that has to be defined taking into account mainly environmental characteristics.

⁴ Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field (OJ L 224, 18.8.1990, p. 19). Decision as last amended by Council Decision 2006/53 (OJ L 29, 2.2.2006, p. 37).

• For the purpose of bluetongue surveillance, the geographical unit will ideally be an area of approximately 45 x 45 km (approx. 2.000 Km²) unless specific environmental conditions justify a different size. In the Netherlands, the compartments, as defined for the use of the ADNS system will be used as geographical unit for surveillance purposes, these compartments do not exceed 3.000 km², except for compartment 1. This compartment will be divided in two subcompartments for this purpose. So, in total we will work with 21 compartments.



2. Monitoring BT in the Netherlands

2.1. Description

Monitoring consists of veterinary measures and strategies intended to provide information on BT situation in an infected, suspected or restricted zone. The purpose is to provide follow up information on the situation as regards the behaviour of the disease in a zone already subjected to restrictions in the movements of domestic animals susceptible to BT due to the risk attributed to this zone.

The objectives are:

- 1. to assess the circulation of the virus within the infected and restricted zones:
 - a. to better define the appropriate extent of the infected and restricted zones
 - b. to define the temporal and geographical distribution and progress of BTV
- 2. to gather information on the presence of:
 - a. vector species involved and their competence
 - b. quantitative estimation of vectors
 - c. identification of the vector-free season or periods with the lowest risk of viral transmission

2.2. Measures

2.2.1. Serological and virological monitoring

Serological monitoring of ruminants is aimed at assessing the circulation of BTV within the infected and restricted zones.

As a preliminary step, prior to setting the network of sentinel animals, to better define the appropriate extent of the infected and restricted zones a **cross-sectional serological study** will be performed this winter after Culicoïdes have stopped flying to gain additional information on the definition of the infected zone.

In the restricted zones and the zones where the circulation of the virus has been demonstrated it is necessary to differentiate newly infected animals from the seropositive animals due to past exposure to the virus. Therefore, **sentinel animals** will be established there.

a. Cross sectional study

The aim of the cross sectional study is to estimate the prevalence (with a certain precision) of infected cattle in the geographical (epidemiological) units.

For a reliable outcome of the study, the following scheme will be used:

The Netherlands will be divided in different parts where different prevalence's (% infected animals) are expected:

- Heavily infected compartments: expecting an a priori prevalence of 30% and with a 95% confidence and a 5% maximum allowable error in the prevalence estimate (meaning that the true prevalence in the field will be between (30%-5%=) 25% and 35% (= 30%+5%), we then need 330 samples per compartment.
- Medium infected compartments: expecting an a priori prevalence of 10% and with a 95% confidence and a 5% maximum allowable error in the prevalence estimate, we then need 870 samples per compartment
- Low infected compartments: expecting an a priori prevalence of 2% and with a 95% confidence and a 1% maximum allowable error in the prevalence estimate, we then need 1760 samples per compartment
- Uninfected compartments: since we do not expect to encounter infections in these compartments, it seems logical to base a sample size estimation on the following line of thinking : we want to detect a possible existence of infection at a prevalence of 0.1% with 95% confidence, we then need 2972 samples per compartment.

b. Sentinel network

In spring 2007, a sentinel network of bovine animals will be set up all over the territory of the Netherlands. Sentinel animals are guaranteed free from antibodies by means of a preliminary seronegative test, performed to the individual sentinel animals. Farms with a high rate of animal turnover will not be considered as sentinel.

The sentinel animals are selected in each geographical unit, preferably within an area of the geographical unit where, following a risk analysis considering entomological and ecological evaluations, the presence of the vector has been confirmed or habitats suitable for the vector's breeding are present. Moreover, the sites for the sentinel animals will be chosen carefully in order to maximise the chance of detecting BTV activity at the geographical unit for which the sentinel animal/site acts as a sampling point.

For surveillance purposes, it is necessary to perform monthly testing of the sentinel animals during the period of activity of the vector involved. Because there is no data available of the active period of the competent vector in the current outbreak, the sentinel animals will be tested at least monthly until December 2007.

Once a sentinel animal has seroconverted, it will not be tested again for surveillance purposes. The seroconverted sentinel animals will be virological examined in order to provide further information on the strain circulating. The compartment or a 20 km area where seroconversion has occurred is

considered infected and will not need to be monitored with sentinel animals any further in the season concerned.

Sample size

For each compartment a test program for 150 sentinel animals (cattle) will be identified (in order to detect a monthly incidence of seroconversion of 2% with a 95% confidence).

In compartments with a high prevalence, individual negative animals will be identified. In other, with a lower prevalence, it might be more practical to work with negative farms.

In the northern part of the Netherlands (if proven uninfected by the cross sectionel study), the possibility will be left open to collect blood at the slaughterhouse for serological testing.

Tests

The serological test for surveillance is the ELISA. In addition, samples from the seroconverted sentinel animals will be tested with PCR and virological methods to further confirm the serotype circulating in the zone.

2.2.2. Entomological investigation

The entomological surveillance is intended for two purposes:

- 1. to determine the population dynamics and over-wintering features of the *Culicoides* species in the Netherlands.
- 2. to define the geographical distribution and abundance of various *Culicoides* species in the Netherlands.

Entomological surveillance is based on "vector catching". For this purpose aspiration traps equipped with ultraviolet light will be used (South African "Onderstepoort-model"). Placing and maintaining the traps, as well as collection of midges and the information that accompany the samples will be carried out in accordance with the same pre-established protocols as were used in the "snapshot" in September 2006.

<u>Snapshot</u>

To get a quick overall view of the Culicoïdes population in the Netherlands a "snaphot" has been performed. In 104 quadrants of 20 x 20 km one Culicoïdes catch during one night has been made.

Contiuous entomolical surveillance

At least one trap is placed in each geographical unit. The traps will run throughout the night (from dusk to dawn) and operate at a rate of at least one night per week throughout the year. Midges are retrieved from each trap on the day following its operation. The traps will preferably be placed close to sentinel animals whenever possible.

In addition to the monitoring purposes, additional traps will be placed on farm/holding where virus transmission has been just confirmed to obtain additional information on the of *Culicoides* species responsible of BTV transmission).

Tests

Midges collected in the insect traps will be sent to the Plant Protection service of the Dutch Ministry of Agriculture, Nature and Food Quality. Here, trained personnel will count and identify the collected species of *Culicoïdes* and if necessary, select pools of *Culicoïdes* to send it to the Dutch reference lab (CIDC Lelystad) for virus detection.

2.2.2.1. Enhanced passive clinical surveillance

Bluetongue is a notifiable disease in the Netherlands. Clinical surveillance is intended to early detect the circulation of the virus. Clinical surveillance will be specially reinforced during the season of vector activity, and in particular at its beginning.

Passive surveillance is based on the reporting by the farmers to the veterinary authorities of clinical signs suggesting BT. In the Netherlands awareness campaigns for the farmers and veterinarians have already started in September 2006 and will continue throughout 2007.

2.2.2.2. Wildlife monitoring

In the south of the Netherlands 60 roe deer will be examined on bluetongue. Roe deer is the wild ruminant species that is the must abundant in the Netherlands. The south of the Netherlands seems to be the most infected zone. This monitoring is done to find out if wild ruminants are infected.

3. Development of milktest

In the Fall of 2006, research efforts are directed at developing an ELISA that uses individual milk samples as test medium instead of blood samples. Depending on the success of the development and validation of this test in time, we may be able to use this new milk-ELISA from the start of the sentinel network, or we have to use blood samples in the first sampling periods. The total costs will be \notin 60.000.

4. Concluding

This proposal is part of the harmonised BT monitoring and surveillance scheme in the EU (Working document SANCO/10581/2006 rev 4) and allows the full and secure implementation of the measures foreseen in Decision 2005/393/EC ensuring transparency among the MSs and also as regards Third Countries.

The setup of the surveillance and monitoring, including the operation of the traps, is based on the experiences and available data of the current outbreak of bluetongue, serotype 8. Protocols can be amended on the basis of the evidence obtained within the first years of implementation. All relevant results and findings are regularly presented in the Scofcah. If necessary, amendments will be presented for formal approval.

Annex I: Financial proposal

Cost concerning	Description	Amount	Costs per unit (€)	Total costs	Community funding requested
Cross sectional study	Blood sampling ¹	39.470	5	197.350	yes
	Elisa	39.470	4,90	193.403	yes
Identification of the sentinel animals	Blood sampling ²	5.000	10	50.000	yes
	Elisa	5.000	4,90	24.500	yes
Sentinel animals	Blood sampling ³	28.350	10	283.500	yes
	Elisa	28.350	4,90	138.915	yes
	PCR ^₄	100	26,60	2.660	yes
	Virus isolation ⁵	10	80,55	806	yes
Continuious entomological surveillance	Тгар	21	450	9.450	yes
	Catching Culicoïdes ⁶	1260	216	272.160	yes
	Determination Culicoïdes	1260	200	252.000	yes
Wildlife monitoring	Monitoring roe deer with PCR test	60	26,60	1.596	yes
Development milktest ⁷				75.000	yes
Snapshot ⁵	Catching Culicoïdes	104	432	44.928	
	Determination Culicoïdes	104	200	20.800	

¹ For the cross sectional study existing bloodstreams will be used, the cost of the sampling therefore is much lower then in the case of the sentinel animals. It is estimated that there will be 3 heavily infected compartments. 4 medium. 3 low and 10 non infected compartments.

 $^{^{2}}$ For the 21 compartments 3.150 sentinel animals (150 per compartment) must be identified. To find these animals it will be necessary to sample more animals (some of the animals will be positive, some animals will be replaces / slaughtered during the season). It is estimated that 5000 samples are necessary to find 3.150 sentinel animals.

³ The sentinel animals will be followed 9 months (from April, start of the vector season to December). So a total of 28.350 samples (9 months * 21 compartments * 150 animals) will be necessary. ⁴ In case of a positive Elisa a PCR test will be performed.

⁵ In case both tests are positive (Elisa and PCR) a virus isolation will be performed.

⁶ The vector program will start this year. The traps will be placed one night in each compartment during 60

weeks. ⁷ €40.000 (140 hours lab scientists, and 260 hours senior scientists), €2.000 (materials), €18.000 (collection of paired blood samples and milk samples and compensation farmers), €15.000 (unforeseen €5000 senior scientists and €10.000 lab scientists and senior scientists)

⁵ In the snapshot in 104 quadrants Culicoïdes catches were performed during one night. Because the traps were not placed permanently the costs for catching are higher than in case of permanent traps (continuous monitoring).

Total		1.567.068	