

EUROPEAN COMMISSION HEALTH & CONSUMERS DIRECTORATE-GENERAL

Unit G5 - Veterinary Programmes

SANCO/10831/2012

Programmes for the eradication, control and monitoring of certain animal diseases and zoonoses

Survey programme for Bluetongue

Approved* for 2012 by Commission Decision 2011/807/EU



^{*} in accordance with Council Decision 2009/470/EC

version: 2.1

1. Identification of the programme

Member state :	SVERIGE
Disease	Bluetongue in endemic or high risk areas
Species :	Bovines and sheep and goats
This program is multi annual	:no
Request of Community co-financing from	
Request of Community co-financing from beginning of:	2012

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1.1 Contact

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2. Historical data on the epidemiological evolution of the disease

A concise description is given with data on the target population (species, number of herds and animals present and under the programme), the main measures (testing, testing and slaughter, testing and killing, qualification of herds and animals). The information is given for distinct periods if the measures were substantially modified. The information is documented by relevant summary epidemiological tables, graphs or maps.

(max. 32000 chars) :

An analysis of the outbreak in 2008 and the surveillance and vaccination until 2009 was submitted with the program for 2011. In short: monthly surveillance with bulk milk ELISA on bovines was ongoing when the first case was found on the 6th of September 2008. The surveillance was concentrated to the area of most risk ie the southern parts. 70 bovines and sheep were detected positive in 30 herds either for presence of virus or antibodies during 2008 and early 2009. All animals were infected in 2008. The final restriction area from February 2009 contained 14 000 bovine herds with 950 000 animals and 8000 sheep herds with 200 000 animals. The vaccination area contained 700 000 bovines and 150 000 sheep. Testing in 2009 showed no signs of viral circulation. In 2008, 20 000 bulk milk ELISA were done and 10 000 animals were tested individually. In 2009, 10 000 Bulk milk ELISA were done and 2900 animals were tested individually. In 2010, 2800 bulk milk ELISA were done and 2700 PCR tests were done on bovines and sheep in the vaccination area in order to declare freedom from bluetongue serotype-8. The surveillance had to be adapted each year mainly due to the vaccination campaign. In 2008, 30 animals were culled initially before the area of viral spread was defined as too large to manage by culling. for more information and maps on animals and testing see annex 1.

A vaccination plan was submitted in January 2008 and was executed immediately after the first case was found. The vaccination program ran two whole seasons starting in fall 2008. In 2008, 430 000 bovines and 71 000 sheep were vaccinated, in 2009, 500 000 bovines and 210 000 sheep were vaccinated and in 2010, 233 000 bovines and 193 000 sheep were vaccinated. Sweden was declared free from bluetongue serotype-8 on December 3rd 2010. Vaccination was also discontinued after successful eradication. in 2011 surveillance continues with testing of 300 bovines in 150 herds which will detect a prevalence of approximately 2% on herd level. Vector monitoring was ongoing monthly during summer 2007, 2008

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and 2009. in 2010 only the periods for beginning and ending of the vector period were monitored. Sweden applied vector free period from November until March-April.

3. Description of the submitted programme

A concise description of the programme is given with the main objective(s) (monitoring, control, eradication, qualification of herds and/or regions, reducing prevalence and incidence), the main measures (testing, testing and slaughter, testing and killing, qualification of herds and animals, vaccination), the target animal population and the area(s) of implementation and the definition of a positive case.

(max. 32000 chars):

For 2012 the main objective is surveillance since restriction zones for BTV-8 and 1 are present in Europe. The herds that will be tested may be concentrated in the areas of most risk, southern areas. Random testing in import animals is also part of the surveillance of risk animals/herds. Virological testing with BTV pan-PCR will be done on animals that have spent the summer outside, preferently animals that has not been vaccinated previously, although the guarantee period of the vaccine will have expired for all animals. The period of testing will be in November 2012 just after the period of most likely highest viral circulation or viral transmission. If viral circulation is detected in nearby member states the testing could be modified to achieve best possible coverage. Depending on the outcome of the amendment regarding vaccination in the bluetongue directive which is not finalized when submitting this form, the Swedish Board of agriculture may decide to allow preventive vaccination in free areas as a result of a risk analysis. Awareness campaigns and clinical surveillance will be ongoing.

An animal will be considered positive based on the criterias in the bluetongue legislation. Viral circulation in Sweden will lead to restriction areas according to the bluetongue directive.

4. Measures of the submitted programme

4.1 Summary of measures under the programme

Duration of the programme: 2012
First year:
Control
Slaughter and animals tested positive
☐ Killing of animals tested positive
Vaccination
Treatment
Disposal of products
Eradication, control or monitoring

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4.2 Organisation, supervision and role of all stakeholders involved in the programme

Describe the authorities in charge of supervising and coordinating the departments responsible for implementing the programme and the different operators involved. Descrive the responsabilities of all involved.

(max. 32000 chars):

The Swedish Board of Agriculture (SBA) has, according to the Swedish regulation on epizootic diseases (1999:65 2§), the responsibility for preventive measures and for combating all diseases listed in the Swedish epizootic legislation which includes bluetongue.

The National Veterinary Institute (SVA) is designated according to the governmental ordinance on instructions for the SVA (1999:341 §3) to execute diagnostic investigations and other tasks ordered by the SBA, such as epidemiological investigations.

The County Administrative Board (CAB) is the authority responsible for control of compliance with some restrictive measures.

4.3 Description and demarcation of the geographical and administrative areas in which the programme is to be implemented

Describe the name and denomination, the administrative boundaries, and the surface of the administrative and geographical areas in which the programme is to be applied. Illustrate with maps.

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(max. 32000 chars):

The smallest possible administrative areas are the counties. County administration is responsible for control functions, such as control of movements of live animals and animals for slaughter. However, administration and control of the legislation, surveillance and testing of animals or vaccination is managed centrally at the SBA for the entire country. The National Veterinary Institute (SVA) is responsible of designing the surveillance program for the whole country. The programme may become risk based and is also based on the density of bovines (few herds and lower risk in the north). There will only be one administrative area.

4.4 Description of the measures of the programme

A comprehensive description needs to be provided of all measures unless reference can be made to community legislation. The national legislation in which the measures are laid down is mentioned.

4.4.1 Notification of the disease

(max. 32000 chars):

According to Commission regulation 1266/2007 and Council Directive 2000/75 According to the Swedish law on epizootic diseases suspected or confirmed cases of bluetongue are immediately notifiable to the SBA.

4.4.2 Target animals and animal population

(max. 32000 chars):

Targets for surveillance are bovine herds. There are approximately 23 000 herds in Sweden and 14 000 herds in the former restriction area (approximately one fourth of the area of Sweden) animal density maps are available in annex 1

4.4.3 Identification of animals and registration of holdings

(max. 32000 chars):

All holdings are registered at SBA. The CDB (bovine data base) has information and localization of every bovine in Sweden. CDB is also used to register bovines that have been vaccinated for bluetongue.

4.4.4 Qualifications of animals and herds

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(max. 32000 chars):
N/A
4.4.5 Rules of the movement of animals
(max. 32000 chars) :
N/A
4.4.6 Tests used and sampling schemes
(max. 32000 chars) :
The number of animals tested will be based on the prevalence of the 2008 outbreak. Pan-PCR tests on 300 animals in 150 herds (2 in each herd) will show freedom at a prevalence of 2% on herd level. The animals will be tested in November, just after the end of the vector season.
4.4.7 Vaccines used and vaccination schemes
(max. 32000 chars):
no vaccines used
4.4.8 Information and assessment on bio-security measures management and infrastructure in place in the holdings involved.
(max. 32000 chars):
N/A
4.4.9 Measures in case of a positive result

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A short description is provided of the measures as regards positive animals (slaughter, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, the therapeutic or preventive treatment chosen, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter and the creation of a surveillance zone around infected holding)

(max. 32000 chars):

Restriction zones and movement restrictions according to the bluetongue directive 2000/75/EC and the bluetongue regulation 1266/2007/EC will be applied. No culling. Increased monitoring, vaccination on an volontary level.

4.4.10 Compensation scheme for owners of slaughtered and killed anima	เไร
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(max. 32000 chars):	
N/A	
4.4.11 Control on the implementation of the programme and reporting	
(max. 32000 chars) :	

5. Benefits of the programme

A description is provided of the benefits for farmers and society in general

SBA is responsible for implementing and reporting all measures.

(max. 32000 chars):

It is still uncertain how or if bluetongue would affect the ruminant population on a clinical level. Economical consequenses would likely be largest in dairy herds. A comprehensive cost benefit analysis was made for future bluetongue outbreaks and it was concluded that detection and eradication would be more economical in certain models. Early detection also facilitates possible eradication and lifting of restrictive measures which are costly for stakeholders.

The surveillance programme is also mandatory according to the bluetongue regulation 1266/2007/EC

Data on the epidemiological evolution during the last five years

6

Data already submitted via the online system for the years 2006 - 2009 :

yes

6.1 Evolution of the disease

Evolution of the disease:

○ Not applicable ○ Applicable...

6.1.1 Data on herds for year:

2010

			;		:	:		:		Indicators	:	
l otal I lotal number of Number of Number of Number of Number of Number of herds number of herds number of herds herds herds herds herds depopulated	lotal lotal number of Number of Number of number of herds under the herds positive new positive herds herds herds herds	lotal number of	Number of Number of Number of herds positive new positive checked herds herds	Number of Number o positive new positiv herds herds	Number o new positiv herds	- e -	Number of herds depopulated	% positive herds depopulated	% herds coverage	% positive herds Period herd prevalence	% positive herds % new positive Period herd herds prevalence Herd incidence	
Restriction zone outside vaccinated Bovines 3 367 3 996 1 771 0	966		1 771 0	0		0	0		118,771			×
Bovines 10 732 296 308 0	296		308	0		0	0		104,054			×

free area	Bovines	8 875	1 134	1 052	0	0	0	92,769		×
Restriction zone outside vaccinated	Sheep	2 226	0	0	0	0	0			×
vaccinated area	Sheep	6 145	300	266	0	0	0	88,667		×
free area	Sheep	7 477	0	0	0	0	0			×
Total		38 822	2 726	3 397	0	0	0	124,615		
								Adda	Add a new row	

6.1.2 Data on animals for year:

2 010

							Slaughtering	əring	Indicators	ators	
Region	Animal species	Total number of animals	Number of Total animals to be number of tested under the animals programme	Number of animal tested	Number of animals tested individually	Number of positives animals	Number of animals with positive result slaughtered or culled	Total number % coverage of animal at animal level	% coverage at animal level	% positive animals Animal prevalence	
Restriction zone outside vaccinated area	Bovines	257 868	1 992	1 771	0	0	0	0	88,906	0	×
vaccinated area	Bovines	703 053	1 500	1 527	1 527	0	0	0	101,8	0	×
	Bovines	534 669	1 134	1 052	0	0	0	0	92,769	0	×
Restriction zone outside vaccinated area	Sheep	54 768	0	0	0	0	0	0		0	×

		٠	•	•			•		
vaccinated area	Sheep	145 134	1 500	1 606	1 606	0	0	0 107,067	0
free area	Sheep	194 390	0	0	0	0	0	0	0
Total		1 889 882	6 126	5 956	3 133	0	0	0 97,22	0
								ADD A NEW ROW	Mo

6.2 Stratified data on surveillance and laboratory tests

Stratified data on surveillance and laboratory tests for year: 6.2.1

2010

	×	×	×	×
Number of positive samples	0	0	0	0
Number of samples tested	1 794	125	1 158	1 052
Test Description	bulk milk ELISA	individual milk ELISA	rt-PCR	bulk milk ELISA
Test Type	serological test	serological test	microbiological or virological tee	serological test
Animal Species	Bovine	Bovine	Bovine	Bovine
Region	Restriction zone outside vace Bovine	vaccinated area Bovine	vaccinated area Bovine	free area Bovine

whole country Bovine	Bovine	serological test	serumELISA	326	0	×
whole country Bovine	Bovine	microbiological or virological tea	rt-PCR	43	0	×
vaccinated area Sheep	Sheep	microbiological or virological te: rt-PCR	rt-PCR	1 606	0	×
Total				6 104		
				ADD A NEW ROW	ROW	

6.3 Data on infection

○ Applicable... ○Not applicable Data on infection

6.4 Data on the status of herds

○ Applicable... ○ Not applicable Data on the status of herds:

Data on vaccination or treatment programmes

6.5

○ Applicable... ○ Not applicable Data on vaccination or treatment programmes is

Data on vaccination or treatment programmes for year:

6.5

					Inform	ation on vaccination	Information on vaccination or treatment programme	mme		
Region	Animal Species	Total number of Total number of herds animals	Total number of animals	Number of herds in vaccination or treatment programme	Number of herds vaccinated or treated	Number of herds Number of animals vaccinated or treated treated	Number of doses of vaccine or treatment administered	Number of adults vaccinated	Number Number of young animals vaccinated	
vaccination area	Bovines	10 732	703 053	8 052	5 750	233 518	497 978	0	0	×
vaccination area	Sheep	6 145	145 134	2 748	2 469	192 936	192 936	0	0	×
Total		16 877	848 187	10 800	8 219	426 454	690 914	0	0	
								Add a new row	ew row	

6.6 Data on wildlife

Data on Wildlife is:

Not applicable

Applicable...

7. Targets

The blocks 7.1.1, 7.1.2.1, 7.1.2.2, 7.2, 7.3.1 and 7.3.2 are repeated multiple times in case of first year submission of multiple program.

Targets related to testing (one table for each year of implementation)

7.1.1 Targets on diagnostic tests for year: 2

2012

	×		
Number of planned tests	300	300	·ow
Objective	surveillance	Total	Add a new row
Type of sample	serum		
Target population	Bovines		
Type of the test	п-PCR		
Region	whole country		

7.1.2 Targets on testing herds and animals

7.1.2.1 Targets on testing herds

○ Not applicable

○ Applicable...

7.1.2.1 Targets on the testing of herds for year:

2012

	% positive herds % new positive Expected herds period herd Expected herd prevalence incidence	X	0	row
Target indicators	% positive herds Expected period herd prevalence			Add a new row
	Expected % herd coverage	100	100	Ad
	% positive herds expected to be Expected % depopulated herd coverage	0	0	
	Number of herds expected new expected to be positive herds	0	0	
	Number of expected new positive herds	0	0	
	Number of Number of herds expected expected rositive herds positive herds depopulated	0	0	
	Number of herds expected to be checked	150	150	
	Number of Total number herds Total number of herds under expected to be of herds the programme checked	150	150	
	Total number of herds	22 947	22 947	
	Animal species	Bovines		
	Region	whole country	Total	

7.1.2.2 Targets on testing animals

○ Not applicable ○ Applicable...

7.1.2.2 Targets on the testing of animals for year:

2012

		×		
Target indicators	% positive animals (Expected animal prevalence)	0	0	WC
Target ir	Expected % coverage at animal level	2	9	Add a new row
tering	Number of animals with positive result expected to be slaughtered or culled to be slaughtered	0	0	Ad
Slaughtering	Number of animals with positive result expected to be slaughtered or culled	0	0	
	Number of expected positive animals	0	0	
	Number of animals to be tested individually	0	0	
	Number of animals expected to be tested	300	300	
	Number of Number of Total number animals under animals expected of animals the programme to be tested	000 9	000 9	
	Total number of animals	1 495 590	1 495 590	
	Species	Bovine		
	Region		Total	
		sweden		

Targets on qualification of herds and animals

Targets on qualification of herds and animals Not applicable

○ Applicable...

7.3 Targets on vaccination or treatment

7.3.1 Targets on vaccination or treatment is

○ Applicable...

○ Applicable...

○ Not applicable

7.3.2 Targets on vaccination or treatment of wildlife is

Detailed analysis of the cost of the programme for year: 2012

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The blocks are repeated multiple times in case of first year submission of multiple program.

1. Testing							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested	
Cost of analysis	PCR (animal samples)	Individual animal sample/test	008	31	9300 yes	yes	×
Cost of sampling	PCR (animal samples)	Individual animal sample/test	300	55	16500 no	no	×
					Add a new row	row .	
2. Vaccination or treatment							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested	
					Add a new row	row	
3. Slaughter and destruction							
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested	
					Add a new row	row	
4. Cleaning and disinfection							

Standard requirement for the submission of programme for eradication, control and monitoring

Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested
					Add a new row	row
5. Salaries (staff contracted for the programme only)	or the programme only)					
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested
					Add a new row	row
6. Consumables and specific equipment	equipment					
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested
					Add a new row	row
7.Other costs						
Cost related to	Specification	Unit	Number of units	Unitary cost in EUR	Total amount in EUR	Community funding requested
					Add a new row	row
	Total				25 800,00 €	

Attachments

IMPORTANT:

- 1) The more files you attach, the longer it takes to upload them .
- 2) This attachment files should have one of the format listed here: zip, jpg, jpeg, tiff, tif, xls, doc, bmp, pna.
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Bluetongue serotype 8 outbreak in Sweden

Surveillance of animals and vectors

Swedish Board of Agriculture National Veterinary Institute November 2010

Summary: Surveillance and monitoring due to findings of BTV-8 PCR positive ruminants in Sweden in autumn 2008 has been aimed at firstly, to define the geographical area of the incursion and secondly, to detect virus circulation during the following seasons. The testing and the two full years of vaccination in the infected area was designed to eradicate BTV-8. Due to the low prevalence the testing had to be carefully structured in order to detect any virus circulation. The monitoring and surveillance fullfills the criteria layed down in Regulation 1266/2007/EC. No viral circulation was detected during and after the vector seasons of 2009 and 2010 and the conclusion is that Sweden can be considered free from bluetonge from 1 of November 2010.





Animal monitoring and surveillance, setup general aspects

According to Art. 4 and Annex I. 2.1 and 2.2 in Regulation 1266/2007, the surveillance setup each year was designed to detect a prevalence of at least 0,5 % with 95 % confidence on a national level (herd level). Targeted risk based testing (monitoring) according to Annex I 1.1.1 and 1.1.2. was performed in high-risk restricted areas and on a monthly basis during the high-risk season with the aim of detecting viral activity and spread of the virus from the infected area. Surveillance in free areas and monitoring in restricted areas were separate investigations. However, in the maps provided in this document both monitoring and surveillance may be displayed in the same map to provide a comprehensive view of the testing. Criterias have also been met for testing to demonstrate the absence of virus circulation during 2 years according to Annex I 1.3. Vector surveillance was setup according to Annex I.1.2 in the regulation, and the criterias for seasonal vector free periods were set according to Annex V in the Regulation.

The animal population. Bovines were primarily used for monitoring and surveillance in accordance with Regulation 1266/2007. Sheep herds were only tested in the final surveillance in 2010 in order to exclude viral spread in that population. The total number of bovines in the vaccination area is over 700 000, and the number of adult sheep is about 150 000. In the restriction zone outside the vaccination area there are 260 000 bovines and in the free area there is a total of 550 000 bovine animals. Density maps show the distribution of herds of cattle and sheep in 2008 (figure 1). In northern areas the density of herds is very low compared to the density in the south. In all dairy herds and the majority of beef herds, with the possible exception of a few fattening establishments, animals are outdoor during the vector active period. Bulk milk surveillance was chosen because of the even distribution of dairy farms and the possibility to test 50 animals/herd in one test. The target groups for testing were re-evaluated each year due to changing conditions i.e. the risk of outbreaks and also due to the ongoing vaccination campaign.

Surveillance was initially to a high degree targeted to populations in a geographical location susceptible to vectors from overseas. The closest outbreaks have been in Denmark and Germany. Sweden has a low degree of transports of animals from other Member States but all such animals were also included in the national risk based surveillance.

Risk of virus circulation was also assessed based on the distribution of cattle and sheep in Sweden. The population of wild ruminants was assessed and also tested in 2008 (785 serology and PCR tests). It is not known to which degree the wildlife population contribute to the spreading of bluetongue. This population cannot be controlled or vaccinated. However, the hunting season peaks in fall and the game is always inspected for clinical disease. Table 1 shows test summary tables of 2009 and 2010.

<u>Follow up of positive bulk milk tests</u>: a positive or grey zone result from a bulk milk sample was followed by serological testing of all the cows contributing to the milk. If an animal was found positive by serology, the whole herd was tested with both serology and PCR.

Laboratory testing

A real time PCR system specific for BTV-8 ("the Hoffman rRT-PCR") is used for the detection of viral RNA in whole blood or internal organs. Commercial ELISA tests from ID-VET are used for the detection of antibodies in milk and serum (ID Screen® Blue Tongue Competition and ID Screen® Blue Tongue Milk, respectively). In 2010, a PANBTV PCR

(Touissant and others 2007) was introduced as a primary test, so as to cover all serotypes of BTV.

Surveillance in 2007

Surveillance was done by bulk milk sampling only. The first bulk milk sampling was performed after the first BT outbreak in Denmark in October 2007. All 662 dairy farms in Skåne County were tested in November and all were seronegative. The surveillance zone from the Danish case only included the southwest part of Skåne, so the testing covered twice the area of that zone. Sweden was able to remove the small surveillance area in Skåne in spring 2008.

Surveillance in 2008 before the first case

National surveillance in whole of Sweden included: 428 randomly selected beef herds (648 serum samples) and 580 dairy herds (617 bulk milk samples). Samples were collected from May 1 until November 30th 2008.

In the geographical area of highest risk monthly bulk milk testing for BTV-8 was performed in the counties of Skåne, Halland and Blekinge from the beginning of the vector active period. All dairy farms were included in this surveillance. The extent of the monthly bulk milk testing is shown in figure 2. The total number of dairy herds in the southern risk area was 1048.

Monitoring in 2008 after the first case

The first case was detected initially in the monthly bulk milk testing and confirmed on the 6th of September. The positive case is seen in fig 2 as a red dot. Initially extensive testing was done in the 20 km area around the first case. In total 30 PCR positive animals were culled before the area of positive cases was enlarged to include Skåne County about three weeks after the first case. After that only vaccination and movement restrictions were applied. In figure 3 all the bulk milk testing that was done after the first case, until December 31, 2008 is shown. Approximately a third of the positive cases were detected by bulk milk tests, the other cases were found in the extensive testing done during the early investigations and during the early vaccination where every 50th animal was sampled. The estimated individual prevalence at this time was 0,1 %. This figure is based on testing of every 50th animal tested during the vaccination in 2008. 6 PCR positive animals were found in 5782 animals tested.

All positive cases found during September and October were PCR positive with a high CT (cycle threshold) value, i.e. low levels of virus.

After the 30th of September, no PCR animals were seronegative (i.e. all PCR positive animals that were detected had already seroconverted after this date).

In figure 4 the restriction area by the end of 2008 is seen. All positive cases are shown except for the two that were detected in February 2009 (but infected in summer/autumn 2008), which changed the restriction zone one final time.

<u>Vaccination</u> begun on the 8th of September 2008 and was performed according to the national contingency plan. This was around the time of the breaking point after which immediate vaccination was not necessary to stop virus circulation due to the absence of vectors.

However, due to the large undertaking such a mass vaccination would be, it was decided to start vaccination anyway in order to have 80% of the population vaccinated until the beginning of the next vector period. Herds with 10 animals (cattle/sheep) or less were not mandatory vaccinated and later used for monitoring in 2010. The target of 80% was achieved.

A detailed account of the 2008 BTV-8 incursion in Sweden is available in: Infection with bluetongue virus serotype 8 in Sweden in 2008. S. Sternberg Lewerin et al. 2010 Vet Rec 167:165-170

NB! Statements in this paper about "infection occurring" refer to the general definition of infected herds as herds that were **infected** mainly during July-August-September 2008 and **detected** by PCR and/or serology in September-October. That is, the term "infection occurred" was used for both recent infections and earlier infections and the time points given are the time points of **detection**. This is also valid for all data reported to BTnet, where detection date has been given as the "date of infection".

Surveillance and monitoring in 2009

<u>Vaccination.</u> The vaccination was done in order to eradicate the disease in case the virus somehow was able to survive the 6 months of winter. During spring, summer and fall additional vaccinations of animals born during the year were done in order to maintain 80 % coverage throughout the season.

Risk based monitoring in the restriction area

The main aim of the monitoring in 2009 was to search for previously (in 2008) infected but undetected herds outside the vaccination area. The figures (5 and 6) show maps with bulk milk testing, number of tested animals and number of positive samples excluding those that were due to testing of vaccinated animals. All tested herds have not been placed on the maps in the figures so information on the number of tested herds/animals and how many of them are marked on the map has been added in the figure. Moreover, the geographical distribution of the actual tests is seen including negative and positive tests. In 2009 the first testing in the vector free season is seen in 2 different maps. The first map in Figure 5 shows the screening of the area just outside the restriction area, as it was in January 2009. In January-February 2009 the bulk milk testing was performed in the restriction zone outside the vaccinated area. Moreover, an area close to the Norwegian border was screened in this period due to the Norwegian findings of BTV-8 positive animals at this time. The testing in January-February was targeted at pregnant heifers that had been out on pasture during summer and autumn 2008 and thus only contributed to the bulk milk late in the vector free period, after calving. In this testing two herds that had been infected in 2008 were detected and the restriction area was amended accordingly. The logic behind this was that the vaccination campaign should be extended to include all areas where infection had occurred in 2008. The vaccination area was immediately enlarged to include the new area and the aim was to have the area vaccinated before the start of the vector period. The new positive herds are seen as red dots in the map (figure 5). 83 positive bulk milk samples in total were found. The majority of them were positive because of vaccinated animals. In the others testing on the farm ruled out the presence of infection. The map in figure 6 shows all the 7 positive bulk milk samples that were not attributed to vaccinated animals. Five of them were concluded to be "false positive" tests based on negative results from individual testing (serology and PCR) of all animals that had contributed to the bulk milk and a negative follow-up bulk milk sample). Some of the

targeted testing was done in areas overlapping the bulk milk sampling area. A "clean" map of all positive cases is provided in the last figure 13. The localization of the new positive tests consisted with the area where the other positive herds were found and with this testing it was reasonable to assume that the area where the infection had occurred in 2008 was well defined and that the vaccination area covered at least this area.

National monthly surveillance in May-November outside the risk area consisted of bulk milk tests from 400 farms from a selection of 2600 dairy farms and serology tests from 800 farms from a selection of 7100 beef herds were planned. During July-November monthly risk based tank milk screening was performed in the area just outside the vaccination zone in the same 900-1000 dairy farms in the area each month. The number and distribution of samples for both the national and the risk based bulk milk testing is seen in figure 7. The number and distribution of the tests on beef herds is seen in figure 8.

Transplacentally infected calves

In the February screening testing of calves born after the beginning of the vector free period on the bulk milk positive holdings was also done. One such calf (from a heifer infected in 2008) was born in December 2008 and was found PCR positive. Two more calves were found in an independent (not statistically valid) testing on farms infected in 2008 (2 out of 215 calves tested PCR positive.) These findings suggested that more such calves could be present in the area. The calves were PCR negative in a second testing after some time.

Testing of beef calves in the vaccination zone.

Approximately 600 beef calves at least 4-6 months of age were serologically tested in November and December 2009 before they were vaccinated (Figure 8). The calves were out on pasture all summer. Some of them may have had vaccinated mothers, however the maternal immunity would have waned during the summer. The seropositive calves marked in figure 8 were either shown to be vaccinated or, in one case, a very young calf with maternal antibodies. The dam of this calf had been vaccinated. Thus, none of the beef calves tested in the vaccination zone was shown to be infected. Based on this, the conclusion was that with 95% confidence any level of remaining infection would be below 1% on herd level and 0.5% on animal level.

Areas of testing: Skåne: 326 tests

Blekinge: 234 test Halland: 6 tests Jönköping: 12 tests Kalmar: 13 tests

Follow up of seroconversion of vaccinated animals.

In order to determine that the goal of vaccine protection of 80% of the animal population, a study was conducted in 2009, before the peak of the vector season. A random sample of all vaccinated cattle and sheep was selected, designed so as to detect a seroprevalence of 80% in the total population in the restriction zone with 95% confidence. The samples were taken as serum samples from sheep, serum or individual milk samples from cattle. Analysis of the results demonstrated that the goal of 80% seroprevalence in the vaccinated population had been met in spring 2009. (Hultén and co-workers, submitted manuscript)

Surveillance and monitoring in 2010

The national surveillance for 2010 was done by tank milk testing only, once a month in June-November. To detect a herd level seroconversion of 0,5 % a sample of 162 herds were tested every month of vector activity, actual testing in shown in figure 9 and the monthly figures are seen below the next heading. In this area there are a total of 2600 dairy farms and 7100 beef herds.

The target risk based monitoring was also done by tank milk tests in the area just outside the vaccination area once in February and once in September. There are approximately 1000 dairy farms in the restriction area outside the vaccination zone. The total bulk milk testing in Sweden is visualized in figure 10. The bulk milk surveillance in the vector free period was similar to the one in 2009, in order to find heifers that had been out on pasture during 2009 and that started contributing to the bulk milk in the vector free period. These heifers typically graze on the most distant fields until they approach calving. No infected herds were found. Additional data are given below and in figure 10.

Monthly total bulk milk tests including national surveillance and targeted risk based monitoring as follows: February = 367, March = 397, April = 134, which means a total of 898 tests in the vector free period. In June samples were taken 176, in July 187 samples, in August 101 samples, in September 1008 samples, in October 193 samples, and in November 189 ordered but not all analysed yet.

4 positive bulk milk tests were investigated, none of them were concluded to be true positive.

2010 intensive targeted risk based monitoring:

This testing addressed the area in which two full years of vaccination was done. Small herds where no vaccination was done in 2008-2010 were chosen for PCR testing in order to detect any virus circulation. As these herds were never vaccinated they may have been exposed to virus during the peak of prevalence in 2008, and thus some animals could have seroconverted during that period. Thus, it was decided to use PCR as the method of detection and test all animals during the period when it was most likely that they would be PCR positive, i.e. just after the peak of vector activity. This way, the likelihood of detection was maximized and the sensitivity of the survey would be maximized as well. The total number of animals in all the tested herds was not known in advance. Thus, the sampling was performed as a two-stage stratified sampling based on the assumption that the infection would cluster on herd level (a likely assumption based on the Swedish experience as well as internationally published data). All animals in each herd were sampled, as the herds were comparatively small and to compensate for any naturally seroconverted (and thereby protected) animals. Figure 11 shows the distribution of the tested herds in the vaccination area.

Total number of tests (sheep and bovine): 2764 Total number of tested herds (sheep and bovine): 574

Number of tested bovine herds: 308 Total number of tested bovines: 1158

Number of tested sheep farms: 266 Total number of tested sheep: 1606 About 50% of the samples were taken in October (when vector activity had ceased in all but one site), with about 25% of the herds and animals included in the survey sampled after the 9th of October, when vectors were last collected from the last active site (see tables 1 and 2 in Annex 1) until October 29.

No positive samples were found. In all, the survey confirmed with 95% confidence that virus was absent below 1% on herd level in the vaccinated area. For the time period after the last collection of vectors on the last active site, the sample size was sufficient to ascertain a <1.1% herd prevalence with 90% confidence.

All 147 sampled herds in the time period between 9th of October and 23rd of November are shown in the map in Figure 12.

Serum samples from all tested animals were collected but not tested.

Clinical surveillance

All clinically suspect cases were tested during 2008-2010. In 2008 before the first case 28 animals, both cattle and sheep, were investigated. In 2008 after the first case 137 animals were investigated due to clinical signs. Only one bull, which was tested by the vaccination team and was positive with PCR had mild symptoms of lacrimation and crusts around the nostrils. None of the other cases were PCR positive for bluetongue. In 2009, 34 cases with clinical symptoms were tested and in 2010, 12 cases were tested. Some of the cases had classical clinical signs of the disease but tested negative for bluetongue.

Vector surveillance

Surveillance of vectors from selected geographical locations has been performed since 2007 Annex I shows a summary of vector period beginnings and end since 2007. In general only a few of the traps show any significant vector activity in September and October. A table on relevant vector data is submitted in Annex I, table 1 and 2.

A summary of key points of the surveillance

- All testing in the restriction and non-restriction areas was done at least in conformity with the minimum required testing in the regulation 1266/2007 also taking into consideration the low prevalence situation.
- All tested animals were non-vaccinated and at pasture during summer.
- Testing in the different zones was either randomly within that area or as the case with the risk based bulk milk, all the dairy farms in the zone of choice were selected.
- The density of animals and herds is very different in the northern and southern parts of the country, which was also taken into consideration for the surveillance. The summer is progressively shorter the further north in Sweden and thus the possibility of virus circulation is less likely when all known facts of the virus and the vectors are considered.
- Based on the known facts of virus survival during the vector free period, the only way the virus would survive a 6-month long vector free period is through placental

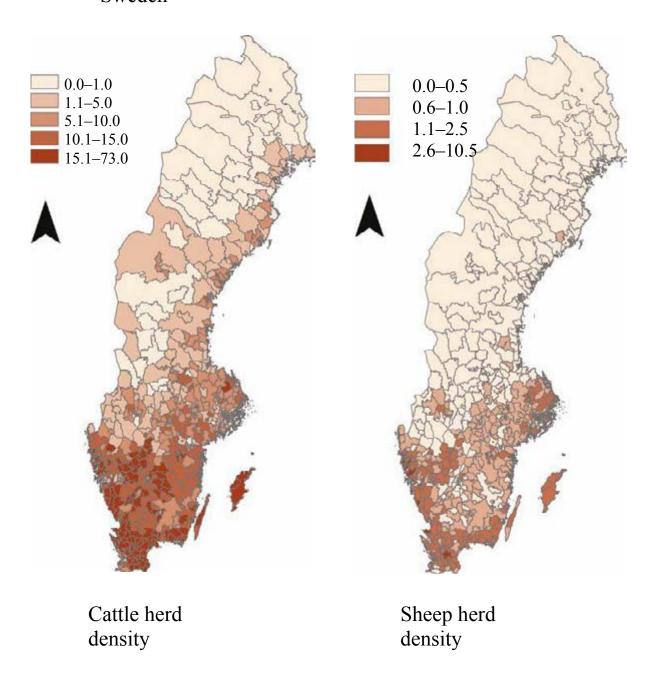
transmission in bovines. Based on current knowledge, as well as findings in a few transplacentally infected calves detected in Sweden, these calves lose their PCR reactivity within a few months. Because of the vaccination with 80 % coverage in the beginning of the vector period it would be epidemiologically difficult for the virus to even begin circulating.

- The PCR tests in 2008 had high CT values, which suggests that the infection dose was very low. Possibly low enough not to cause clinical disease and thereby not high enough to cause significant viral replication in the animal. Subsequently it may disappear faster from the blood than if there is clinical disease. Waiting to test until well into the vector free period would therefore lower the sensitivity of the survey.
- The last testing was done in order to prove eradication at least to the prevalence level seen in 2008. It is highly unlikely that a vector transmitted disease such as bluetongue with such a low level of infection to begin with is able to maintain even the same level of infection during 2 years of a continuous vaccination program.
- If no PCR positive animals are found in September October, the last few remaining vectors in October would have no viraemic animals to feed on.

• Aim of the surveillance

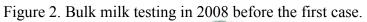
The two years of surveillance were designed to find signs of virus spreading into the non-vaccinated area and also to find proof of virus circulation at the time when it would be most likely be found i.e. just after most likely time of seasonal peak viral transmission. The low prevalence situation and specific epidemiological conditions of animals and vectors in the Nordic countries is not addressed in the Regulation. Considering the known behavior of the Swedish vector population as well as the low prevalence in 2008, if there was any kind of viral circulation maintained through spring and summer this would be most noticeable in September –October when the critical PCR testing was done. The fact that there was no detection of spread to herds where no animals were vaccinated, together with the fact that there was a total absence of positive animals during both whole vector periods of 2009 and 2010 shows that bluetongue serotype 8 is eradicated from the Swedish restriction area.

Fig 1. Density of cattle and sheep herds in Sweden



Data from Infection with bluetongue virus serotype 8 in Sweden in 2008. S. Sternberg Lewerin

et al. 2010 Vet Rec 167:165-170.



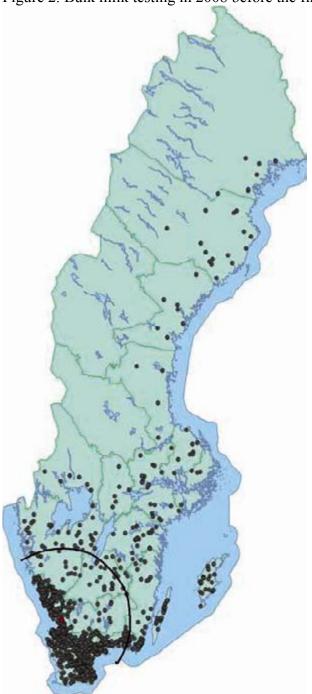
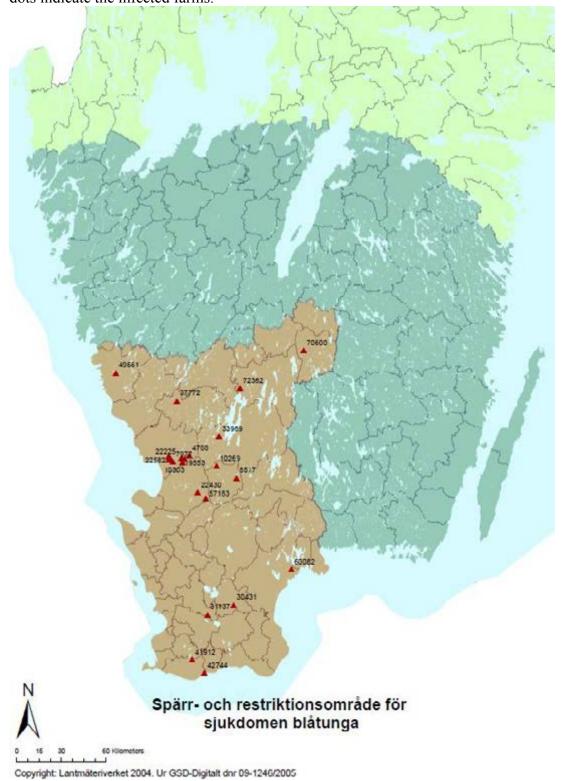
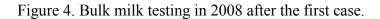


FIG 2: Herds included in the bulk milk screening fromJuly 2008 until the detection of the first case of bluetongue (red). The area of the restriction zone as of September 9, 2008, is demarcated by the black line. © Lantmäteriverket

Figure 3. The restriction area in December 2008 before the addition of the last cases. The red dots indicate the infected farms.





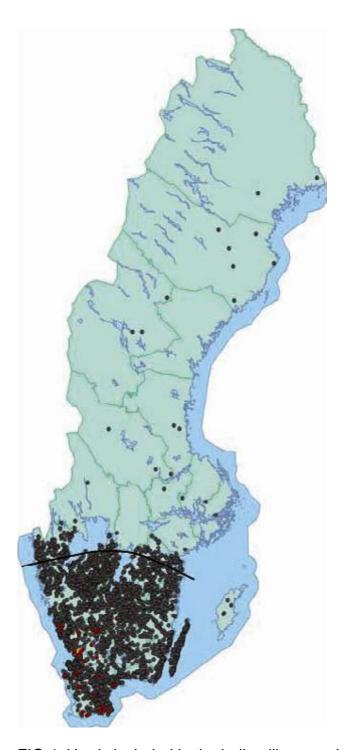
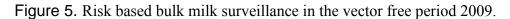


FIG 4: Herds included in the bulk milk screening from the detection of the first case of bluetongue until December 2008. Herds with positive reactions (by serology or PCR, or both) are indicated in red; the index case is in yellow. The northern boundary of the restriction zone as of December 31, 2008, is demarcated by the black line. © Lantmäteriverket



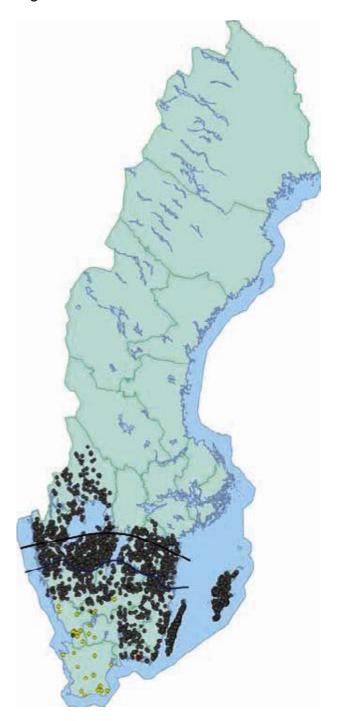
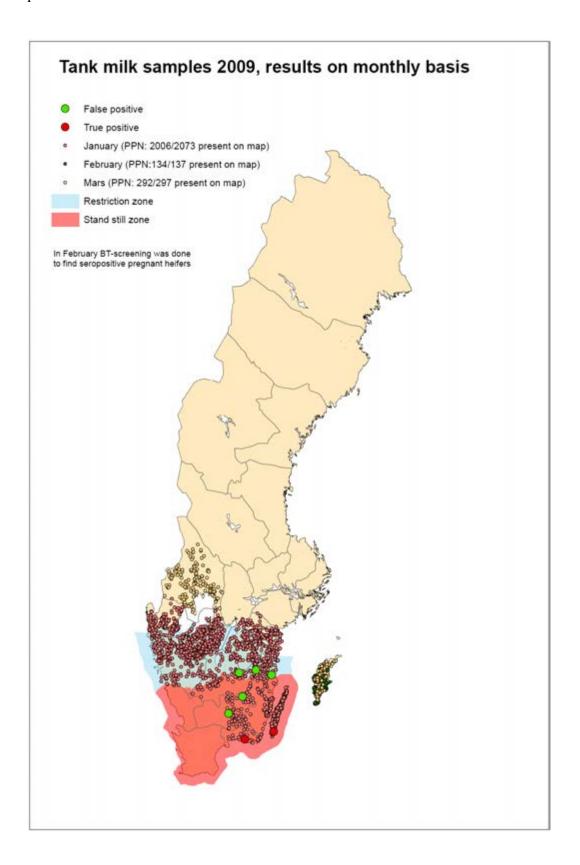
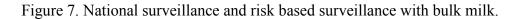
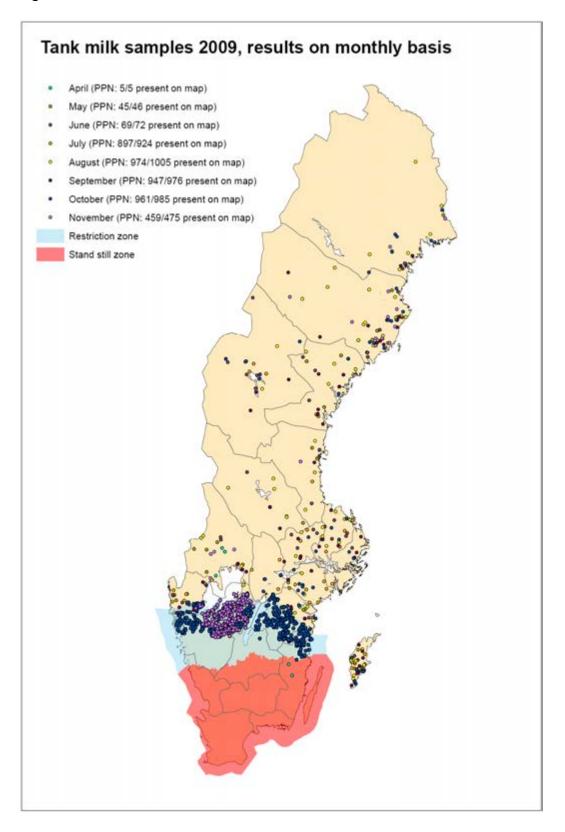


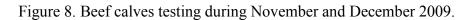
FIG 5: Herds included in bulk milk screening for bluetongue during the vector-free season in early 2009. Positive herd identified in 2009 is shown in red, and herds identified previously in yellow. The northern boundary of the restriction zone and the vaccination area as of February 2009 are demarcated by the black line and the blue line, respectively. © Lantmäteriverket

Figure 6. Risk based bulk milk surveillance in the vector free period 2009 including all positive bulk milk cases.









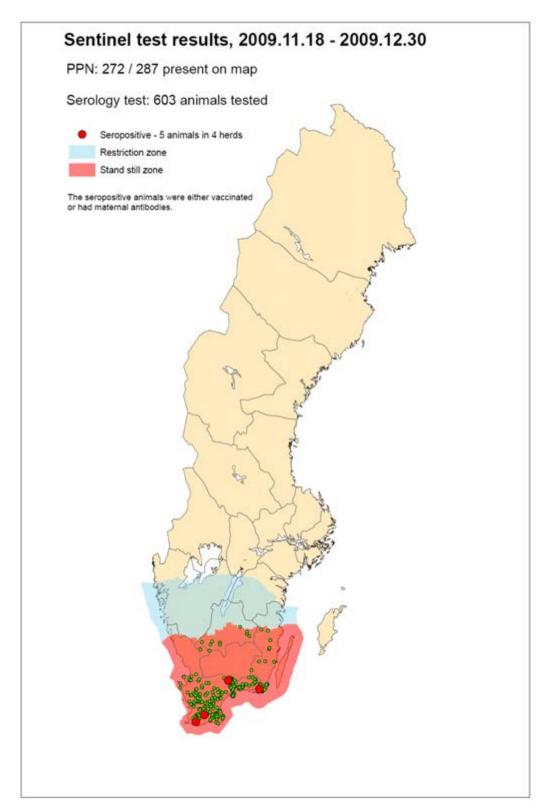


Figure 9. National surveillance testing at abattoir 2009.

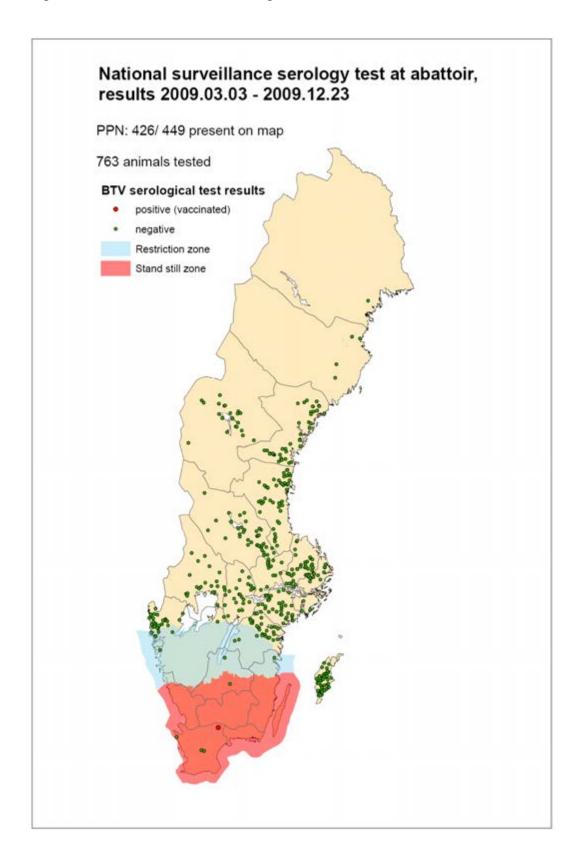


Figure 10. Bulk milk sampling in 2010.

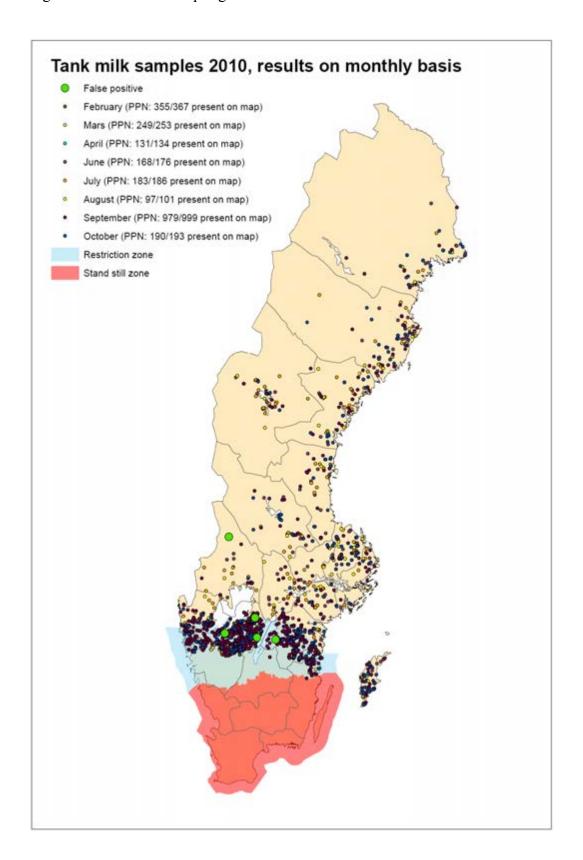


Figure 11. Geographical distribution of the bovine and sheep herds tested in September and October 2010.

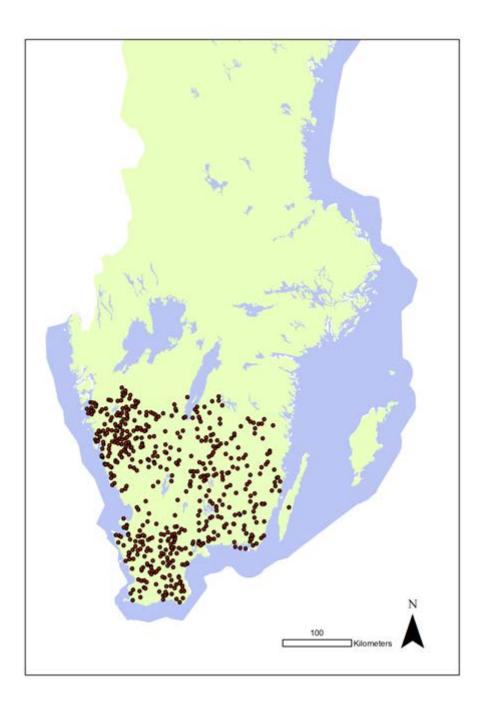
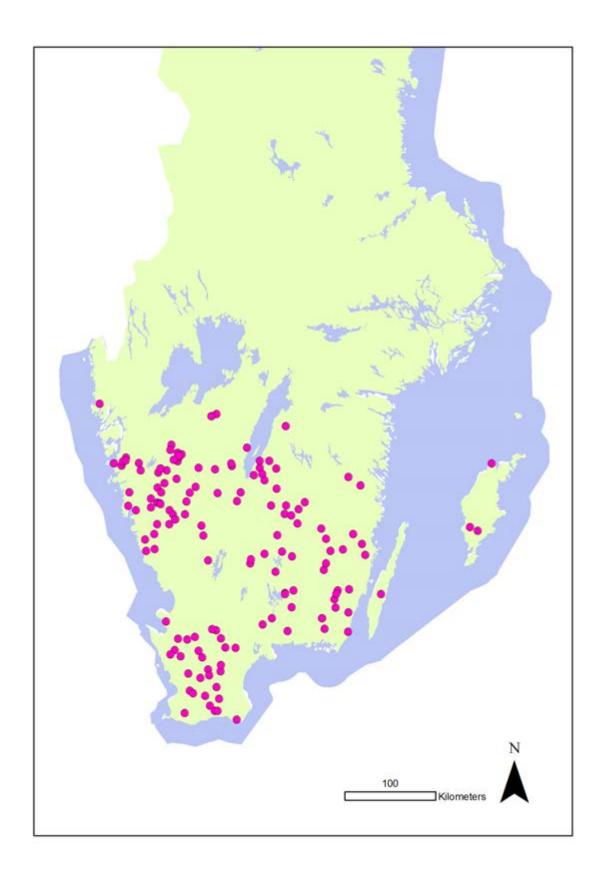
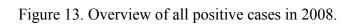


Figure 12. Geographical distribution of herds sampled after 9th of October 2010.





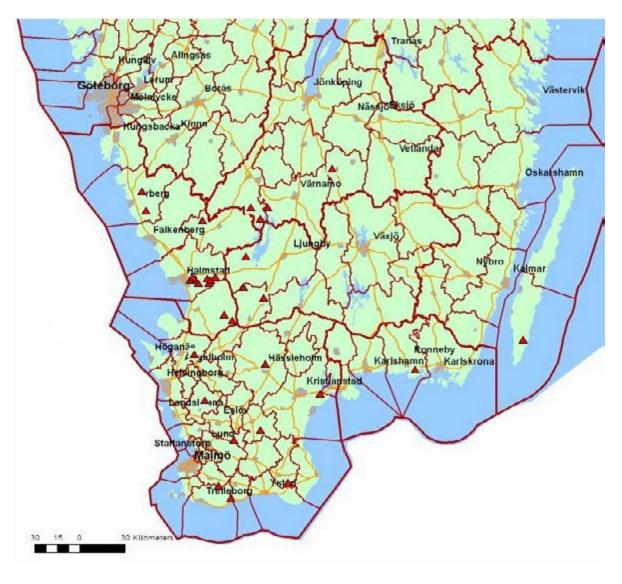


Table 1. Summary of tests for 2009 and 2010, the majority of the tests are visualized in the maps.

2009	PCR	ELISA serum	ELISA milk	Time of tests	Geographic localization	comment
game		7		January	Restriction area	From 2008
other	256	1020	229	whole year	Whole country	investigations positive bulkmilk and other (illegal movements)
calves in vaccination zone	3	603		November 2009	Vaccination area	
clinical suspicions	35	34		Whole 2009	Whole country	
national screening + risk based screening in restriction zone			7689	Monthly july- october (approx 600 herds/month) Once in February	Restriction zone- non vaccinated	
national screening beef cattle at abbatoir		763		vector season	Outside restriction zone	
transplacentally infected calves	215	2		spring	Vaccinated zone	

2010	PCR	ELISA serum	ELISA milk	Time of tests	Geographic localization	comment
other	29	150	5	whole year	Whole country	Investigations positive bulkmilk Illegal movements
testing in vaccination zone		121			Vaccination area	
clinical suspicions	12			whole year	Whole country	
risk based surveillance			764	Febr-march	Restriction zone- non vaccinated	
national monthly surveillance			1677	June-Nov	Free area including restriction area outside vaccination zone	
Intence target risk based screening	2764			September – end of October	Vaccination area see map for distribution	

Annex I. SWEDISH SURVEY OF BLUETONGUE VECTORS 2007-2010

The Swedish survey of Bluetongue-vectors was implemented on the 22^{nd} of July 2007. Thus, only the end of collection of ≥ 5 parous *Culicoides*/trap/night could be established for that year. However, data from 2008, 2009 and 2010 in Table 2 display the first and the last collection of ≥ 5 parous *Culicoides*/trap/night. The collection sites are shown in table 1 and the results in table 2.

Table 1 Sampling sites of *Culicoides* 2007-2010

~ ~ ~ ~ ~	pring sites or cuit.	2010.00 2007 2010			
No.	Site	County	Coordinates	S EU-BTNET [x, y]	
1	Bara	Skåne	13,209502	55,590624	
2	Löberöd	Skåne	13,542875	55,755854	
3	Svalöv	Skåne	13,091801	55,915806	
4	Svängsta	Blekinge	14,715195	56,301630	
5	Vittsjö	Skåne	13,701596	56,334670	
6	Torsås	Småland	15,825888	56,354064	
7	Ljungbyholm	Småland	16,213806	56,529475	
8	Hemse	Gotland	18,360799	57,210810	
9	Romakloster	Gotland	18,494280	57,377366	
10	Torestorp	Västergötland	12,658971	57,404260	
11	Axvalla	Västergötland	13,718974	58,456779	
12	Dingle	Bohuslän	11,583443	58,581520	
13	Uppsala LH	Uppland	17,750151	59,812581	
14	Uppsala BO	Uppland	17,750151	59,812581	
15	Orsa	Dalarna	14,631517	61,147317	
16	Oviken	Jämtland	14,470597	63,079	
17	Kalix	Norrbotten	23,605450	65,745869	
18	Abisko	Lappland	18,748908	68,349000	

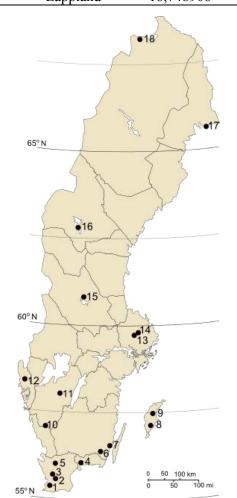


Table 2 First and last detection of ≥ 5 parous *Culicoides* in traps in Sweden during 2007-2010

	2007 (DD- MM)	2008 (D	D-MM)	2009 (DD-MM)		2010 (DD-MM)		
Trap ID	Last detection of ≥5 par.	First detection of ≥5 par.	Last detection of ≥5 par.	First detection of ≥5 par.	Last detection of ≥5 par.	First detection of ≥5 par.	Last detection of ≥5 par.	
	25 par . C/t/n*	23 par . C/t/n	23 par . C/t/n	23 par . C/t/n	23 par . C/t/n	23 par . C/t/n	C/t/n	
1	NA	30/5	1/8	NA	NA	NA	NA	
2	16/10	10/6	28/8	NC	NC	NC	NC	
3	NA	14/5	$1/8^{1}$	NA	NA	NA	NA	
4	10/10	4/6	2/10	5/5	10/8	NA	NA	
5	15/10	6/6	28/9	17/5	31/8	15/6	3/9	
6	27/10	17/5 [†]	15/10	20/5	20/9	3/6	9/10	
7	17/9	NA	NA	NA	$4/10^{\dagger}$	7/6	NA	
8	23/8	26/6	8/9	26/8	26/8	NA	NA	
9	26/9	5/6	7/9	NC	NC	NC	NC	
10	3/11	13/6	20/8	1/5 [†]	25/9	2/6	25/9	
11	23/8	1/6	29/8	30/6	6/8	30/6	8/9	
12	1/10	NA	NA	NA	NA	NA	NA	
13	9/10	NA	25/9	9/7	21/9	29/6	6/9	
14	NA	NA	NA	5/8	23/9	NA	NA	
15	NA	NA	28/9	4/8	4/8	30/7	26/8	
16	NA	NA	27/9	30/5	26/9	17/6	5/9	
17	NA	NA	23/8	7/8	7/8	22/8	22/8	
18	NA	NA	NV	NV	NV	NV	NV	

^{*}C/t/n = Culicoides/trap/night
† First/last collection made inside stable

NA = Trap not operated

NC = No collections of ≥ 5 parous female C/t/n that year. NV = No vector species

¹Trap removed