EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/ 2008-8310 - MR - FINAL

FINAL REPORT OF A MISSION
CARRIED OUT IN
GERMANY
FROM 24 NOVEMBER TO 28 NOVEMBER 2008
IN ORDER TO
EVALUATE THE EMERGENCY VACCINATION AGAINST BLUETONGUE

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected;any clarification appears in the form of an endnote.

Executive Summary

The mission to Germany was carried out from 24 to 28 November 2008 in order to evaluate the emergency vaccination against bluetongue. The mission was added to the mission programme on request of DG SANCO D as part of a series of missions to certain Member States, which requested co-finance for the implementation of the approved vaccination plan.The German emergency vaccination plan against BT virus serotype 8 (BTV-8) for 2008 has been approved by means of Commission Decision 2008/655/EC.

The German authorities have been implementing the approved vaccination plan against BTV-8, which is still ongoing. The number of outbreaks of BT-8 between August 2008 and November 2008 decreased significantly in all but one Land compared with the number of outbreaks during the same period in 2007.

Differences in the implementation of the plan have been identified between and within the Länder. Control procedures are established only to a limited extent, in particular to verify the accuracy of the number of vaccines used and the number of animals vaccinated.

Although the approved vaccination plan 2008 requires, in principle, the mandatory vaccination of all cattle, sheep and goats in Germany, a wide range of exemptions from vaccination were granted by federal, regional and local legislation. At present less than 60% of the eligible cattle population is under vaccination protection and it is doubtful that the target of 80% sero-conversion of the targeted population will be achieved for the 2008 BT vaccination campaign.

The CAs did not submit the information about the BT monitoring and surveillance programmes and vaccination data to the BT-Net system. The monitoring and surveillance system in place against BTV-8 and BTV-6 is not fully in compliance with the requirements of Regulation (EC) No 1266/2007.

TABLE OF CONTENTS

ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
ADNS	Animal Health Notification System
BB	Brandenburg
BE	Berlin
BT	Bluetongue
BTV-6	Bluetongue Virus Serotype 6
BTV-8	Bluetongue Virus Serotype 8
BW	Baden-Württemberg
BY	Bayern
CA	Competent Authoritie(CAs)
CCA	Central Competent Authority
ELISA	Enzyme Linked Immunosorbent Assay
EMEA	European Medicines Agency
EU	European Union
FVO	Food and Veterinary Office
HB	Bremen
HE	Hessen
HH	Hamburg
Land / Länder	Region (s)
Landkreis(e)	Local Administrative Unit(s)
MV	Mecklenburg-Vorpommern
NI	Niedersachsen
NW	Nordrhein-Westfalen
OIE	World Animal Health Organisation
PAN-PCR	Particel-Associated Nucleic Acid PCR
PCR	Polymerase Chain Reaction
RP	Rheinland-Pfalz

Abbreviation	Explanation
SH	Schleswig-Holstein
SL	Saarland
SN	Sachsen
SNT	Serum Neutralisation Test
ST	Sachsen-Anhalt
TH	Thüringen
TSN	*Tierseuchennachrichten-System* (German animal disease notification system)

1 INTRODUCTION

The mission took place from 24 to 28 November 2008. This mission did not form part of the Food and Veterinary Office's (FVO) planned mission programme. The mission was added to the FVO mission programme on request of DG (SANCO)/D as part of a series of missions to certain Member States which requested co-finance for vaccination against bluetongue (BT).

The mission team comprised two inspectors from the FVO and was accompanied during the whole mission by a representative of the "*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*" and representatives of the regional competent authority (CA), the "*Nordrhein-Westfälisches Landesamt für Natur, Umwelt und Verbraucherschutz* " - (LANUV).

The mission itinerary in pursuit of the mission's objectives included the following:

visits			**Comments**
Competent authorities	Central	√	Opening and closing meeting
	Regional	√	*Land* Nordrhein-Westfalen (NW)
	Local	√	3 veterinary local offices in NW
Animal holdings		3	2 dairy holdings and 1 sheep holding
Veterinary practitioners		3	Located in 3 different *Landkreise*
Vaccine storage		4	1 storage in a regional laboratory; 3 storage facilities at local veterinary offices

At the opening meeting which took place with representatives of the central competent authority (CCA), the "*Ministerium für Ernährung, Landwirtschaft und Verbraucherschutz*" the objectives, itinerary, and reporting procedures were confirmed, and information complementary to that received in the course of the preparation of the mission was requested by the mission team. During the mission the team received from all 16 regions (*Länder*) the required documentation.

The mission team visited only one region (*Land)* (Nordrhein-Westfalen, NW) and although requested before and during the mission, the CCA could not organise at short

notice a visit to another *Land*.

2 OBJECTIVES OF THE MISSION

The objectives of the mission were to evaluate the implementation of the emergency vaccination plan against BT and to examine, from a veterinary point of view in accordance with Article 9 (1) of Council Decision 90/424/EEC, the arrangements that Germany has put in place to control BT using emergency vaccination.

3 LEGAL BASIS FOR THE MISSION

The mission was carried out under the general provisions of Community legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

References to Community legislation relevant to this mission are set out in Annex I to this report.

4 BACKGROUND

Since 2000, outbreaks of BT have occurred in southern Europe and, since 2006, in central and northern Europe.

The emergence of this disease represents a serious risk to the Community's livestock population. BT is a vector-borne disease, which cannot be eradicated by culling affected animals. Mass emergency vaccination campaigns are considered the best means to reduce clinical disease and losses.

Council Directive 2000/75/EC has provided the possibility for Member States to use vaccination as a measure to control the disease. Certain Member States which vaccinate against BT have presented their plans for emergency vaccination for 2007 and 2008 to the Commission services. The emergency vaccination plans against BT for certain MS, including Germany, have been approved by Commission Decision 2008/655/EC.

Following the first outbreak of BT serotype 8 (BT-8) in August 2006, the disease spread over the entire territory of Germany within one year. Entomological investigations commencing in April 2007 have shown that the vectors of *Culicoides*, in particular *C. obsoletus* and *C. pulicaris* are the main vectors for the spread of the disease. On 12 January 2008, Germany declared the entire territory as a BT restricted zone (BT-8) in line with Article 6 of Commission Regulation (EC) No 1266/2007. The dramatic economic losses in the cattle and sheep population, the widespread presence of the vector and continuous new outbreaks were reasons for establishing the vaccination plan.

The number of BT outbreaks in the period from August to November 2008 decreased significantly compared with the same period in 2007. However, the number of outbreaks

in one *Land* (NI) is significantly higher in August and September 2008.

On 3 November 2008, after the detection of BT serotype 6 (BT-6) circulation in Niedersachsen (NI) the German CCA has declared an area of a radius of 150 km around the outbreaks as a restricted zone for BTV-6.

5 MAIN FINDINGS

5.1 COMPETENT AUTHORITY PERFORMANCE

5.1.1 Designation of competent authorities, co-ordination and operational criteria

At federal level, the "*Ministerium fur Ernährung, Landwirtschaft und Verbraucherschutz*" is responsible for the establishment of the emergency vaccination plan. At regional level, the competent authorities of the *Länder* are responsible for the organisation, implementation and control of the vaccination plan, in line with paragraph 2 of the "*Tierseuchengesetz*" of 22 June 2004.

Federal, regional and local (*Landkreis* or *kreisfreie Stadt*) legislation has been established. The mst relevant federal legislation regarding vaccination against BT is:

– "*Verordnung zum Schutz gegen die Blauzungenkrankheit*" of 22 March 2002;

– "*EG Blauzungenbekämpfung-Durchführungsverordnung*" of 31 August 2006;

– "*Verordnung über bestimmte Impfstoffe zum Schutz vor der Blauzungenkrankheit und zur Änderung der EG-Blauzungenbekämpfung-Durchführungsverordnung*" of 2 May 2008; and

– "*Verordnung zum Schutz vor der Verschleppung der Blauzungenkrankheit des Serotype 6*" of 6 November 2008.

The CCA sent the vaccination plan to the Commission services on 15 February 2008, as an amendment to the plan of 19 December 2007. The amended vaccination plan was approved by means of Commission Decision 2008/655/EC (hereafter referred to as the approved vaccination plan 2008). No further amendments have since been made. The CCA sent the interim report on the progress of vaccination against BT to the Commission services on 28 October 2008. The CCA informed the mission team that it intends to continue vaccination against BT in 2009. The BT vaccination plan for 2009 was submitted to the Commission service for assessment and was approved on 28 November 2008 by means of Commission Decision 2008/897/EC.

Observations

- On the basis of documents received from the 16 *Länder*, the mission team identified differences between the *Länder* in the implementation of the approved vaccination plan 2008 in the following areas (for details see Annex to report: overview of the implementation of the vaccination plans of the 16 *Länder* of Germany in respect of certain criteria):

- the legal basis for the obligation to vaccinate animals;
- the appointment of the veterinary practitioner vaccinating the animals;
- exceptions for vaccination of cattle sub-populations and sheep and goats sub-populations and farmed game;
- the use of vaccine for cattle, sheep and goats;
- the registration of vaccinated animals/herds in the central database.

- Differences in the implementation of the approved vaccination plan 2008 at the veterinary offices in the *Länder* visited are reported in chapter 5.2.

5.1.2 Legal powers/enforcement

Observations

- No shortcomings were identified in relation to the legal powers to control and to take measures.
- At local veterinary offices in the *Land* visited, the CA stated that some animal keepers refused to participate in the vaccination campaign. The cases were forwarded to the regional CA, but final decisions had not yet been taken.
- The mission team was given evidence of enforcement measures taken in some other *Länder* against animal keepers who refused to participate in the vaccination campaign.

5.1.3 Staff resources

Observations

- Within the scope of this mission no additional resources were recruited at federal level or at regional and local level in the *Land* visited.
- The BT vaccination is performed by veterinary practitioners, who are either nominated by the animal keeper or designated by the local veterinary offices for an area.
- In this respect the CA informed the mission team that the local veterinary offices had not reported any lack of staff, as needs had been covered by staff reorganisation in the local veterinary office.

5.1.4 Procedures on tasks, responsibilities and duties of staff

Observations

- Federal legislation has been established for the implementation of the approved vaccination plan 2008. The mission team did not have evidence of further

instructions issued at federal level.

- The regional CAs, responsible for the implementation and control of the vaccination, have transposed the approved vaccination plan 2008 in regional legislation (*Allgemeinverfügung*) or instructions.
- In the *Land* visited, the CA has sent their regional vaccination plan dated April 2008 of the local veterinary offices and relevant stakeholders and the vaccination plan was also published on their website. The plan includes mandatory notification of side-effects after application of the nationally approved vaccines. Some financial losses are eligible for re-imbursement.
- The three local veterinary offices visited had established local legislation (*Allgemeinverfügung)*, based on the information received from the regional CA.
- The mission team received evidence of training to the veterinary practitioners in particular regarding the implementation of the vaccination campaign, and registration of vaccinated herds or animals in the central database.
- Instructions were issued from regional to local level and from local level to the veterinary practitioners. However the mission team noted that:
    - at regional and local level no instructions were issued for the veterinary practitioners on how to register the entry and use of vaccines delivered;
    - no instructions were issued on the cross-check of vaccinated animals and the number and type of vaccines delivered, or on the number of vaccinated animals against the vaccine used.

5.1.5 Audits of competent authorities

Observations

- Internal or external audits of the activities of the CA within the scope of this mission did not take place in the *Land* visited.
- Furthermore, the mission team did not have evidence of audits regarding BT vaccination in the other *Länder*.

5.2 IMPLEMENTATION OF THE APPROVED VACCINATION PLAN 2008

5.2.1 Duration of the programme and calendar of application

In accordance with the approved vaccination plan 2008, vaccination against BT started in May 2008 from the time that inactivated vaccine against BTV-8 became available and will last until 31 December 2008.

5.2.2 Geographical delimitation

Vaccination is being carried out in all 16 *Länder*.

5.2.3 Authorisation, distribution and storage of vaccines

5.2.3.1 Authorisation of vaccines

At present, there is no vaccine against BTV-8 authorised by the European Medicines Agency (EMEA).

The federal legislation "*Verordnung über bestimmte Impfstoffe zum Schutz vor der Blauzungenkrankheit und zur Anderung der EG-Blauzungenbekämpfung-Durchführungsverordnung*" of 2 May 2008 allows the possibility to use three non-authorised inactivated BTV-8 vaccines from three different manufacturers in BT susceptible animals.

Two of the vaccines used have been recommended for sheep and for cattle. Whilst sheep need to be vaccinated once, cattle need two initial vaccinations, repeated thereafter at a yearly interval. The third vaccine has been developed for cattle only and needs initially two and thereafter bi-annual vaccination.

Observations

- The two vaccines which are recommended for sheep and cattle are also used in goats.
- All three inactivated vaccines could be used in farmed game.
- The CA of the *Land* Mecklenburg-Vorpommern (MV) had carried out an efficacy test for the three inactivated vaccines in cattle and sheep populations in co-operation with the national reference laboratory for BT. Results showed that 95-100% of cattle were sero-positive following the two initial vaccinations and that 71-98% sheep sero-converted after one vaccination.
- In one *Landkreis* visited, a field study on the efficacy of the vaccines used showed that the vaccines tested caused sero-conversion in 93% of the tested cattle. However the percentage of tested sheep showing sero-conversion was lower than in the results in MV, even following a booster vaccination.

5.2.3.2 Storage of vaccines

Observations

- The storage facilities for the vaccines were well maintained.
- The BT vaccines were stored with the required temperature at all sites visited. However, no records of temperature controls during vaccine storage were kept.
- At the accredited laboratory visited, a dedicated room for the storage of vaccines did not match with the number recorded for the automatic temperature registration.

5.2.3.3 Distribution of vaccines

Following the launch of a tender for BT vaccines, the *Länder* have ordered vaccines from

the vaccine manufacturers. Vaccines have been in general directly delivered from the manufacturer to the local veterinary offices and from there delivered to the veterinary practitioners.

Observations

- Since the start of the vaccination campaign in May 2008 no major delays in the delivery of vaccines have occurred.
- Records of receipt, storage and delivery or use of the vaccines were kept at the places visited. The mission team however identified a number of inaccuracies which are described below.
    - regarding the entry registers. For example, in one case the laboratory received the accompanying document for the vaccines 8 days after delivery. In another case the date of the accompanying delivery document did not match with the date mentioned on the transport temperature record.
    - regarding the storage. Discrepancies were identified between the number and batches of vaccines in stock and the records at the laboratory, at one local veterinary office and at one veterinary practice.
    - regarding the exit registers. For example deliveries to intermediate storages were not recorded at the laboratory and at one local veterinary office. The laboratory did not specify accurately the amount of vaccines delivered for each batch
- Records kept at the veterinary practices visits varied. In one veterinary practice visited, records were well kept, contained detailed information on use and matched with the vaccine stock.

5.2.4 Selection of holdings and animals to be vaccinated, movement controls

5.2.4.1 Targeted animal population

According to the approved vaccination plan 2008, vaccination against BT is mandatory for sheep and goats and in principle for all cattle. The approach for wild game is risk based. Exceptions for vaccination are possible for single animals, group of animals or per area as laid down by federal legislation, the "*EG Blauzungenbekämpfung-Durchführungsverordnung*" of 31 August 2006. The target is to obtain a BTV-8 sero-conversion of 80 % of the cattle, sheep and goat population.

Observations

- At federal level, no overview was available on the number of animals per sub-population which were exempted from vaccination.
- The reasons for exemptions from vaccination are not indicated in the approved vaccination plan 2008, e.g. the exemption to exclude fattening animals kept inside. These animals have the same exposure to BT as dairy cattle.
- Criteria for risk based vaccination of wild game are not established at federal level.

- The approved vaccination plan 2008 gives priority of vaccination for cows and young animals (*Prioritär sollen Kühe sowie Jungtiere geimpft werden*). Following the vaccination, the mission team was informed in the *Land* visited that no plans were established to vaccinate the offspring of the vaccinated cows and young animals. In addition, based on the documentation received, 2 *Länder* allow an exemption for suckling cattle herds.
- The approved vaccination plan 2008 states that fattening cattle kept inside (*in Stall gehaltene Mastrinder sollen nicht geimpft werden*) may be exempted from vaccination. However, 5 out 15 *Länder* exempt fattening cattle from vaccination without restriction on housing. In addition, in 9 *Länder*, exemption from vaccination of fattening cattle starts for young animals (older than 3 months). The number of fattening cattle eligible for exemption in Bavaria (BY) might be 0.5 million, based on information received in the documentation.
- At regional level, in the *Land* visited, differences in the implementation of the vaccination plan at local veterinary offices were identified by the mission team regarding:
    - exemption of vaccination of cattle, sheep and goat sub-populations and farmed game, e.g. in one *Landkreis* fattening cattle kept inside were exempted, in another *Landkreis* all fattening cattle were exempted;
    - keepers of animals have the right to decide to make use of the exemptions for vaccination or not. Their requests are validated by the local veterinary officers.
    - registration of vaccinated animals in the central database (see for details chapter 5.2.5).
- Differences in the implementation of the vaccination plan at local veterinary offices were also identified by the mission team in the documentation received from the 16 *Lander*. In NW, in one *Landkreis* all fattening cattle might be exempted, in another only fattening cattle which are kept inside. In BY in one *Landkreis* cattle, sheep and goats, intended to be slaughtered within the next four weeks following vaccination, might be exempted from vaccination.
- Following the data provided by the CAs in November 2008 more than 15.2 million doses of vaccines were used in up to 7.6 million cattle (79.7% of the targeted cattle population of 9.5 million animals). At the time of the mission, according to available information, the vaccination coverage of the entire national cattle population of 12.9 million animals (source internet publication on cattle population in Germany on 25 July 2008 of the *Statistisches Bundesamt*) is 58.9%.

5.2.4.2 Selection of holdings and animals

In the *Land* visited, the planning of the vaccination in three local veterinary offices was organised uniformly. Animal keepers received a request to submit information to the local veterinary office on the species and number of animals eligible for vaccination, to designate the veterinary practitioner as well as to provide the designated veterinary

practitioner with the mandate to have access to the central database regarding their herd(s). The names and addresses of the animal keepers were extracted from the central database.

Observations

- In the three local veterinary offices visited, planning of the number of animals to be vaccinated was based on the completed applications by the animal keepers. Those keepers who did not send the required information were reminded.
- Registered animal keepers who reported not keeping animals are not systematically checked either by the local veterinary officers or, on their request, by the veterinary practitioner.

5.2.4.3 Movement controls

The approved vaccination plan 2008 does not lay down movement restrictions within Germany for vaccinated animals or for animals which are not or incompletely vaccinated.

Animals intended for intra-Community trade must fulfil the requirements laid down in point A.5 of Annex III to Commission Regulation (EC) No 1266/2007.

Observations

- The mission team was informed by the CA in the *Land* visited that movement of animals which were not, or incompletely vaccinated is allowed within Germany, but that the vaccination must be initiated or completed at the next destination, unless the keeper of the animals can provide evidence of vaccination by the first keeper. However, this has not been established in federal or regional legislation.
- In addition, one veterinary practitioner visited claimed not to have vaccinated any cattle which moved to a holding without completion of vaccination.
- Examples were seen of incomplete and non-vaccinated cattle which were moved within Germany without evidence of vaccination.
- At one holding visited, injured or diseased sheep were moved to another holding in order to be killed. These animals were moved without a completed movement document or without authorisation from the competent authority to transport injured or diseased animals for the purpose of slaughter or killing provided that such transport does not entail further suffering for the animals.
- At the same holding, healthy sheep were moved to another holding without completed movement documents, in particular regarding transport.

5.2.5 Reporting procedures on vaccination

The approved vaccination plan 2008 states that the vaccination status of the holdings must be entered in the central database. Animals are not individually identified as being vaccinated, but the holdings will be flagged in the central database as being vaccinated. However, the CA also has the option to record the vaccination of individual animals.

Amongst other information, the following information is entered following vaccination of animals by the veterinary practitioner responsible for vaccination or by the local veterinary office:

- type of vaccine used
- batch-number of vaccine used
- number of animals vaccinated.

Observations

- The registration of vaccination in the central database differs between the *Länder*. In the *Land* (NW) visited, individual cattle are registered as vaccinated, whilst in a neighbouring *Land* (HE) only cattle herds were registered following vaccination (for details see Annex to report: overview of the implementation of the vaccination plans of the 16 *Länder* of Germany in respect of certain criteria).
- At local level, the mission team identified differences in authorisation for registration of vaccination in the central database, e.g. in one *Landkreis* visited the veterinary practitioners located in another *Land*, but vaccinating animals in this *Landkreis* were not authorised to enter the vaccination details in the central database. The veterinary practitioners located in and vaccinating animals in this *Landkreis* however, were authorised to enter the vaccination details in the central database.

5.2.6 Supervision of the vaccination programme

Observations

- No verification procedures of the implementation of the vaccination programme has been organised at regional level in the *Land* visited.
- Supervision of the vaccination at local level is limited and is mainly based on cross-checks for financial reasons (the declaration of vaccination by the veterinary practitioners against the number of vaccinated animals registered in the central database).No evidence was given from on-the-spot checks or cross-check of all available data e.g. of the number of delivered vaccines against the number of animals vaccinated was not cross-checked.
- In addition, no evidence of procedures was given at local or regional level for cross-check vaccination data, including vaccine deliveries of vaccines to veterinary practices located in neighbouring *Kreise* or *Länder,* in particular to verify the accuracy of the amounts declared. In two cases, the number of animals declared being vaccinated by the veterinary practice did not match with the number of vaccines delivered at local level. Acceptance criteria for loss during vaccination were not defined at any level.
- Concerning the use of vaccine, the mission team identified that in some cases the amount of vaccine used was higher than the registered number of vaccinated animals.

- In a few cases less vaccine was used or distributed than needed for the number of registered vaccinated animals.

5.2.7 Controls of immunisation

The CCA informed the mission team that no strategy has been yet established for monitoring the immunisation following the vaccination campaign in 2008.

5.3 BT NOTIFICATION AND MONITORING AND SURVEILLANCE PROGRAMMES

5.3.1 BT notification

BT is a mandatory notifiable disease and a legal obligation to notify each suspicion of a mandatory notifiable infection disease to the CA is laid down by Article 9 of the "*Tierseuchengesetz"*. Confirmed BT outbreaks are forwarded by the CA to the German animal disease notification system (*Tierseuchennachrichten-System* - TSN) and to the European Animal Disease Notification System (ADNS).

Observations

- Awareness of BT and potential economical losses has been made widely available by various means of communication (meetings, notes, media, electronic systems etc).
- The animal keepers met during the mission were aware of their obligation to notify any BT suspicion to the local veterinary office.
- Until August 2007, following the notification of a BT suspicion the local veterinary office notified TSN of each positive test result, even in animals belonging to a herd where virus circulation was earlier confirmed.
- Since September 2007, the notification to TSN changed and local veterinary offices have to notify only new BT outbreaks of herds, i.e. once BT positive test results are received from the laboratory for animals belonging to a herd where virus circulation was not earlier confirmed. The mission team did not receive documented evidence of this new procedure.
- Following the epidemic of thousands of BT outbreaks in 2007, the CCA decided, in order to facilitate the notification procedure to ADNS, to submit the relevant information of the BT outbreaks in electronic form to the Commission services. However, due to technical problems these data could not be entered into the ADNS and the ADNS web-site shows at present only one BT outbreak in Germany in 2008.

5.3.2 Monitoring and surveillance programmes - BTV-8

In February 2007, a monitoring and surveillance programme for BTV-8 was put in place. The CCA stated that 353 sentinel animals were tested in geographical units defined by a grid of approximately 2000 square km.

Observations

- In September 2007 the CCA decided to cease the BT monitoring and surveillance programme which was based on serological testing (enzyme linked immuno-sorbend assay - ELISA) of sentinel animals. Serological testing (ELISA) of animals suspected from BT and pre-movement test continued. In 2007, in 11 *Länder* from which data were available a total of 82.373 cattle and 590 sheep and goats were serologically (ELISA) tested
- In 2007, wild game were randomly serologically tested (ELISA) for BT. In the *Land* visited, 18 out of 824 tested animals, mainly roe, red deer and moufflons were BT positive. Since 2006 109 farmed game holdings were BT-8 affected.
- Since the start of the BTV-8 vaccination, animals suspected of BT and pre-movement tests have been polymerase chain reaction (PCR) tested. In the *Land* visited, data were available on particle-associated nucleic acid PAN-PCR tests. One laboratory had carried out 15.087 PAN-PCR tests from June to November 2008.
- The CAs stated that the testing of animals suspected of BT and pre-movement test are considered to be the BT monitoring system in the restricted zone.
- The CA collected entomological data from the BT monitoring programme until May 2008. After this period no entomological investigations were carried out.

5.3.3 Monitoring and surveillance programmes - BTV-6

On 3 November 2008 a new serotype of BT, serotype 6, occurred in four clinically healthy cattle which were tested during the pre-movement tests in three holdings in NI close to the Dutch border.

The CAs have taken the following measures:

- Movement restrictions for susceptible animals are established in a 20 km, 50 km and 150 km radius zone by federal legislation ("*Verordnung zum Schutz vor der Verschleppung der Blauzungenkrankheit des Serotype 6*" of 6 November 2008).
- BTV-6 monitoring was carried out from 10 to 14 November 2008 in a 1000m radius zone round the three outbreaks randomly.
- All ruminants originating from the Netherlands must be tested for BTV-6.
- Random monitoring in a 50 km corridor along the Dutch border is being carried out.

The CA informed the mission team that so far 1.346 animals had been PAN-PCR tested, of which six were positive to BTV-8. These positive samples were sent to the German national reference laboratory (NRL) for further investigation on contemporaneous infection with other BTV and for genetic identification of the BTV strain.

Observations

- A serum neutralisation test (SNT) for the diagnosis of BTV-6 has not been developed in Germany (see Endnote). Therefore serum samples are sent to the Community reference laboratory in UK and the OIE reference laboratory in Italy in so far as sufficient diagnostic capacities are available there.
- The monitoring and surveillance programmes established respectively in- and

outside the BTV-6 restricted zone are not fully in compliance with the requirements laid down in Annex I to Regulation (EC) No 1266/2007.

5.3.4 Notification to the BT-Net system

In order to ensure an integrated approach at Community level and to be able to analyse the epidemiological information about the BT monitoring and surveillance programmes and vaccination data, the Member States are obliged to submit their data to the European BT-Net system as set out in Article 5 of Regulation (EC) No 1266/2007.

Observations

- The CCA has not yet submitted the requested information to the BT-Net system. The CCS explained that legal aspects regarding personal data protection are not clarified.In order to avoid having to enter data again, interfaces should be created between the local and central (HIT) databases, but this too has yet to be clarified.

6 CONCLUSIONS

6.1 COMPETENT AUTHORITIES PERFORMANCE

Federal, regional and local legislation are in place to ensure proper implementation of the approved vaccination plan 2008.

The regional CAs are designated for the implementation of the approved vaccination plan 2008. Sufficient staff resources, including veterinary practitioners carrying out the vaccination are available and training regarding the vaccination campaign was sufficiently provided.

Whilst adequate instructions on the vaccination were provided to animal keepers and veterinary practitioners, instructions were limited in respect of verification procedures.

The CAs are implementing the approved vaccination plan 2008 against BTV-8, which is still ongoing. The implementation of the vaccination plan differs between the *Lander* and even at local level, in particular regarding the exemptions of sub-populations for vaccinations, the vaccines used and the registration of the vaccinated animals/herds in the central database.

No justification for animal sub-population to be excepted from vaccination was given.

Internal or external audits on the implementation of the approved vaccination plan 2008 were not established.

6.2 IMPLEMENTATION OF THE APPROVED VACCINATION PLAN 2008

In order to launch the vaccination campaign against BT-8, the CCA approved three inactivated BT-8 vaccines, which are not approved by EMEA. Although the

manufacturers recommend using the three vaccines in cattle and sheep population only, federal legislation authorises the use of inactivated vaccines in all BT susceptible animals.

The efficacy studies of the used vaccines showed satisfactory sero-conversion in cattle. The results concerning the vaccination of sheep were ambiguous and an assessment of the vaccination of goats was not carried out.

The vaccinated animals or herds are correctly registered in the central database in accordance with the approved vaccination plan 2008. However, no movement restrictions are in place for animals which are not or insufficiently vaccinated. No legal obligations are established to forward the information on insufficiently vaccinated animals to the next animal keeper.

Supervision and verification procedures regarding the implementation of the approved vaccination plan 2008 are established to a limited extent by the *Länder* and the local veterinary offices. Control procedures, in particular in co-operation between local veterinary offices and between *Länder* were not established. Deficiencies were, however, identified by the mission team regarding the vaccine storage, distribution and record keeping at the sites visited, including one accredited laboratory which were not identified by the CA. The control procedures applied do not ensure , in particular the verification of the accuracy of the amounts declared, which is not in compliance with the Annex to Commission Decision 2008/655/EC.

Although the approved vaccination plan 2008 requires, in principle, the mandatory vaccination of all cattle, sheep and goats in Germany, a wide range of exemptions from vaccination were granted by federal, regional and even by local legislation. At present less than 60% of the eligible cattle population is under vaccination protection and concerns were raised that the target of 80 % sero-conversion of the targeted population will not be achieved for the 2008 BT vaccination campaign.

In some *Länder* the BT immune status of the susceptible cattle population raises concerns as there are, in particular, a large number of fattening cattle exempted from vaccination and a low sero-conversion rate of these exempted animals cannot be excluded.

At one holding visited, transport of injured or diseased sheep or goats for the purpose of slaughter or killing were not authorised by the competent authorities, which is not in compliance with Art. 12 of Council Directive 92/119/EC and movement of sheep and goats from this holding were not accompanied with completed movement documents, which is not in compliance with Article 6(1) of Regulation (EC) 21/2004.

6.3 BT NOTIFICATION, MONITORING AND SURVEILLANCE PROGRAMMES

Notification to the CA if circulation of BT virus is suspected or confirmed is in compliance with Article 3 of Council Directive 2000/75/EC.

Germany did not implement a BTV-8 monitoring programme in accordance with Article 4 of Regulation (EC) No 1266/2007. Pre-movement testing does not justify geographical unit of references as mentioned in Point I of Annex I of this Regulation.

The CCA failed to transmit the required information gathered in the course of the implementation of BT monitoring and surveillance programmes and vaccination data to

the BT-Net system, which is not in compliance with Article 5 of Commission Regulation (EC) No 1266/2007.

As a routine SNT for the diagnosis of BTV-6 is not yet available, samples have to be analysed externally.

7 CLOSING MEETING

A closing meeting was held on 28 November 2008 with the representatives of the CCA, during which the mission team presented its initial findings.

The CCA took note of these findings and provided the mission team with some additional information.

8 RECOMMENDATIONS

An action plan describing the action taken or planned in response to the recommendations of this report and setting out a time table, and a description of the actions taken to correct the deficiencies found should be presented to the Commission within 25 working days of receipt of the report.

No.	Recommendation
1	To establish at federal level precise and justifiable criteria for exceptions of sub-populations from BT vaccination in order to ensure the targeted BT-8 vaccination coverage of the national cattle, sheep and goat population as set out in the approved vaccination plan 2008.
2	To ensure that control procedures are established, in particular to verify the accuracy of the number of vaccines used and the number of animals vaccinated to be declared as required in Annex to Commission Decision 2008/655/EC.
3	To conduct BT monitoring and surveillance programmes as required in Point 1 of Annex I to Regulation (EC) No 1266/2007.
4	To submit the information about the BT monitoring and surveillance programmes and vaccination data to the BT-Net system as required by Article 5 of Regulation (EC) No 1266/2007.
5	To ensure that movement of sheep and goats are accompanied with completed documents as required by Article 6(1) of Regulation (EC) No 21/2004 and movement of injured or diseased animals for the purpose of slaughter or killing are authorised by the competent authorities as required by Art. 12 of Council Directive 92/119/EC.
6	To consider to establish the laboratory test method SNT for the detection of BTV-6.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_germany_8310_2008.pdf

9 ENDNOTES

Concerning	Detail
Section 5.3.3	In their response to the draft report the German Authorities stated that the national reference laboratory for BT is currently developing a serum neutralisation test for the diagnosis of BTV-6, but this has not yet been cleared for routine diagnosis.

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Legislation relating to Animal Health		
Directive 64/432/EEC	OJ 121, 29.7.1964, p. 1977–2012	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine
Directive 82/894/EEC	OJ L 378, 31.12.1982, p. 58–62	Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community
Directive 91/68/EEC	OJ L 46, 19.2.1991, p. 19–36	Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals
Directive 2000/75/EC	OJ L 327, 22.12.2000, p. 74–83	Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue
Regulation (EC) No 1266/2007	OJ L 283, 27.10.2007, p. 37–52	Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue
Decision 90/424/EEC	OJ L 224, 18.8.1990, p. 19–28	90/424/EEC: Council Decision of 26 June 1990 on expenditure in the veterinary field
Decision 2008/655/EC	OJ L 214, 9.8.2008, p. 66–69	2008/655/EC: Commission Decision of 24 July 2008 approving the emergency vaccination plans against bluetongue of certain Member States and fixing the level of the Community's financial contribution for 2007 and 2008
Regulation (EC) No 494/98	OJ L 60, 28.2.1998, p. 78–79	Commission Regulation (EC) No 494/98 of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97 as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals
Decision 93/444/EC	OJ L 208, 19.8.1993, p. 34–35	93/444/EEC: Commission Decision of 2 July 1993 on detailed rules governing intra-Community trade in certain live animals and products intended for exportation to third countries
Decision	OJ L 322,	2008/897/EC: Commission Decision of 28

Reference	OJ Ref.	Detail
2008/897/EC	2.12.2008, p. 39–49	November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and following years
Legislation on the identification of animals and the control of animal movements		
Regulation (EC) No 1760/2000	OJ L 204, 11.8.2000, p. 1–10	Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
Regulation (EC) No 21/2004	OJ L 5, 9.1.2004, p. 8–17	Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC
Regulation (EC) No 1082/2003	OJ L 156, 25.6.2003, p. 9–12	Commission Regulation (EC) No 1082/2003 of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals
Regulation (EC) No 911/2004	OJ L 163, 30.4.2004, p. 65–70	Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers
Regulation (EC) No 1505/2006	OJ L 280, 12.10.2006, p. 3–6	Commission Regulation (EC) No 1505/2006 of 11 October 2006 implementing Council Regulation (EC) No 21/2004 as regards the minimum level of checks to be carried out in relation to the identification and registration of ovine and caprine animals
Legislation relating to official controls		
Regulation (EC) No 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal

Reference	OJ Ref.	Detail
	re-published in OJ L 191, 28.5.2004, p. 1	health and animal welfare rules
Directive 90/425/EEC	OJ L 224, 18.8.1990, p. 29–41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market
Legislation relating to animal welfare		
Directive 92/119/EEC	OJ L 62, 15.3.1993, p. 69–85	Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease