

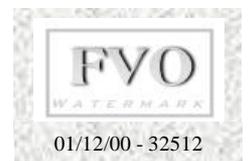


EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL  
Directorate F - Food and Veterinary Office

DG(SANCO)/1186/2000 – MR final

**FINAL REPORT OF A MISSION  
CARRIED OUT IN BULGARIA  
FROM 18<sup>TH</sup> TO 22<sup>ND</sup> SEPTEMBER 2000  
CONCERNING THE GENERAL ANIMAL HEALTH SITUATION  
AND IN PARTICULAR BLUETONGUE DISEASE**

*Comments from the Bulgarian authorities to the draft report relating to factual errors have been included in bold, italic print in the body of the report. Comments providing additional information or expressing their view on particular issues are included as footnotes (in bold, italic print).*



01/12/00 - 32512

## **TABLE OF CONTENTS**

1.	INTRODUCTION .....	4
2.	OBJECTIVES OF THE MISSION .....	4
3.	LEGAL BASIS FOR THE MISSION .....	5
4.	BACKGROUND.....	5
4.1.	SUMMARY OF PREVIOUS MISSION FINDINGS .....	5
4.2.	BACKGROUND TO PRESENT MISSION.....	5
5.	MAIN FINDINGS.....	6
5.1.	COMPETENT AUTHORITY.....	6
5.2.	ANIMAL HEALTH SITUATION.....	7
5.3.	FARM REGISTRATION .....	10
5.4.	ANIMAL IDENTIFICATION .....	11
5.5.	MOVEMENT CONTROLS .....	12
5.6.	CERTIFICATION .....	12
5.7.	INTERNATIONAL TRADE IN LIVE ANIMALS.....	12
5.8.	LABORATORY SERVICE (FOOT-AND-MOUTH DISEASE LABORATORY AT VRABNITSA, SOFIA) .....	13
6.	CONCLUSIONS.....	14
6.1.	COMPETENT AUTHORITY.....	14
6.2.	ANIMAL HEALTH SITUATION.....	15
6.3.	ANIMAL IDENTIFICATION, FARM REGISTRATION AND MOVEMENT CONTROL .....	15
6.4.	CERTIFICATION .....	15
6.5.	DISEASE OUTBREAKS .....	15
6.6.	IMPORTS OF LIVE ANIMALS .....	15
6.7.	LABORATORY SERVICE.....	15
7.	CLOSING MEETING .....	16
8.	RECOMMENDATIONS .....	16
8.1.	TO THE BULGARIAN AUTHORITIES.....	16
9.	ADDENDUM TO THE MISSION REPORT DG(SANCO) 1186/2000 .....	17

## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AGID	Agar Gel Immuno-Diffusion
BIP	Border Inspection Post
BT	Bluetongue disease
BTV	Bluetongue Virus
CA	Competent Authority
CSF	Classical Swine Fever
CVO	Chief Veterinary Officer.
CVRI	National FMD & exotic diseases laboratory (Sofia)
DCVO	Deputy Chief Veterinary Officer.
ELISA	Enzyme-Linked Immunosorbent Assay
FAO	Food and Agriculture Organisation of the United Nations
FAT	Fluorescent Antibody Test
FMD	Foot-and-mouth disease.
NVS	National Veterinary Service
MAFAR	<i>Ministry of Agriculture and Forests</i>
MS	Member States
OV	Official Veterinarian.
PCR	Polymerase Chain Reaction
RVS	Regional Veterinary Service
SOP	Standard Operating Procedure
SVC	Standing Veterinary Committee
TAIEX	Technical Assistance Information Exchange Office (web Site: <a href="http://cadmos.carlbro.be">http://cadmos.carlbro.be</a> )
VLP	Virus-Like Particles

## 1. INTRODUCTION

The mission took place in Bulgaria from 18 to 22 September 2000. The mission team consisted of two inspectors from the Food and Veterinary Office (FVO) and one Member State expert.

The mission was undertaken as part of a planned mission programme. The inspection team was accompanied during the whole mission by representatives from the central competent authority, the National Veterinary Service (NVS), *Ministry of Agriculture and Forests*.

An opening meeting was held on 18 September 2000 with the NVS. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team.

## 2. OBJECTIVES OF THE MISSION

The objective of the mission was to review the general animal health situation and in particular, assess the measures put in place to control and eradicate bluetongue and to prevent incursions of foot-and-mouth disease in the framework of:

- Commission Decision 99/542/EC<sup>1</sup> of 28 July 1999 concerning protective measures with regard to imports of certain animals from Bulgaria due to an outbreak of bluetongue.
- Commission Decision 99/606/EC<sup>2</sup> of 27 August 1999 concerning a special Community financial contribution towards the eradication of bluetongue in Bulgaria by means of vaccination in infected regions.

In pursuit of this objective, the following sites were visited:

<b>COMPETENT AUTHORITY VISITS</b>			
Competent authority	Central	1	Sofia city
	Regional	3	Yambol, Haskovo & Smolyan
	District	1	Elkovo
	Local	2	Slaveevo, Matochino
<b>LABORATORY VISITS</b>			
Central/reference		1	Vrabnitsa, Sofia
<b>LIVE ANIMAL CONTROL SITES</b>			
Farms		2	
Border Inspection Post		3	Nevo Selo, Kapitan Andreevo and the Railway <i>station</i> at Svilengrad.
Green border		2	Greek & Turkish border area located between fence and border line

---

<sup>1</sup> OJ No. L 207, 6/8/1999, p.33

<sup>2</sup> OJ No. L 237, 8/9/1999, p. 8

### **3. LEGAL BASIS FOR THE MISSION**

The mission was carried out under the general provisions of Community legislation and, in particular:

- Council Directive 72/462/EEC<sup>3</sup> of 12 December 1972 on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries.
- Commission Decision 98/140/EC<sup>4</sup> laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in the third countries.
- Council Decision 90/424/EEC<sup>5</sup> of 26 June 1990 on veterinary expenditure in the field.

### **4. BACKGROUND**

#### **4.1. Summary of previous mission findings**

The previous mission, reference number XXIV/1013/99 was undertaken from 8 to 12 February 1999, on account of the deficiencies previously identified in the veterinary controls along the south-eastern border of the country against incursion of OIE list A diseases, in particular FMD. The mission team concluded that the veterinary services understood their duties and that progress had been made on the identification and registration of bovines though small ruminants were found unidentified in the major part of the country except in the border corridor. Measures taken at the border to prevent incursions of important exotic diseases were deemed to be satisfactory. Furthermore, the mission team concluded that Bulgaria had adopted a stringent livestock import policy.

As a result, the mission team recommended to the Commission Services that the EU should lift the restrictions on the imports of bovine, ovine and caprine animals into the EU from certain banned regions in Bulgaria.

#### **4.2. Background to present mission**

The Commission followed the recommendations of the previous mission report by adopting Commission Decisions 1999/539/EC and 1999/541/EC on 26 July 1999 thereby permitting trade in bovines and small ruminants except for a 20 km wide border zone with Turkey.

In the interim, on 7 July 1999, Bulgaria reported to the OIE, FAO, neighbouring countries and the European Commission outbreaks of bluetongue in the province of Burgas along the Turkish border. Although the Regional Veterinary Services adopted a programme of

---

<sup>3</sup> OJ No. L 302, 12/12/1972, p.28

<sup>4</sup> OJ No. L 138, 12/02/1998, p.14

<sup>5</sup> OJ No. L 304, 01/11/1990, p 99

protective measures including a movement ban, the disease appeared in the three neighbouring regions along the Turkish border.

In response, protective measures were adopted under Commission Decision 1999/542/EC<sup>6</sup> on 28 July 1999, which effectively banned the importation of live bovine, ovine and caprine animals originating in Bulgaria.

On 27 August 1999, Commission Decision 99/606/EC provided a special Community financial contribution in support of Bulgaria's efforts to eradicate bluetongue in accordance with Article 8 of Commission Decision 90/424/EEC. Vaccination started in September 1999 and was completed in March 2000. Completion was notified to the OIE.

This is the first mission to Bulgaria since the reported elimination of bluetongue and the completion of the EU funded vaccination campaign.

## 5. MAIN FINDINGS

### 5.1. Competent authority

The National Veterinary Service is a specialised body for the organisation, co-ordination, management and control of veterinary activities and is part of the *Ministry of Agriculture and Forests*. The NVS has 10 departments, which work closely with the 28 regional<sup>7</sup> veterinary services and a number of other units. Eradication of animal diseases is the responsibility of two departments, the Departments of Contagious and Parasitic Diseases and the Veterinary Diagnostics Department. The Chief Veterinary Officer reports directly to the Minister. Both the CVO and the deputy CVO are appointed by the Minister. The structure of the service has been described in previous mission reports (see XXIV/1366/98) and a recent overview is available in TAIEX report ref.: AC/CVO/BP/(19) following a visit to Bulgaria from 30 August – 3 September 1999.

The most recent changes to the NVS include the integration of the National Service for Animal Breeding and due to progress with privatisation of 1134 veterinary stations/units, the Department for Privatisation of Veterinary Activity, has been given responsibility for the identification of animals/registration of holdings and informatics.

Bulgaria is a member of the WTO, Council of Europe, FAO and CITES and is an Associated Member of the EU. There are co-operation agreements between the NVS and Italy, France and Austria. A twinning project between the NVS and Italy is under way and has 13 subprojects.

#### 5.1.1. Relevant National Legislation

The basic law is the New Law on Veterinary Activities adopted by the Parliament on 22 June 1999 and published in State Gazette No 42/5 of May 1999/1. The law comprises a number of articles covering animal health/welfare, public health, statutory controls,

---

<sup>6</sup> OJ No. L207, 28/7/1999, p.33

<sup>7</sup> Each of the 28 regions is made up of a number of administrative areas (generally between 4 and 5) and there are 145 in total. For reporting purposes the "administrative areas" are referred to as districts.

finance of the NVS, diagnostic services and education. Much of the legislation covered by this mission has been implemented in ordinances of the MAFAR, though a number are at a draft stage. For example the NVS is in the process of preparing a draft ordinance (available for review) for the identification and registration of all small ruminants. It is not yet certain if the state will agree or be able to finance such measures in next year's budget.

## **5.2. Animal health situation**

Bulgaria is a founder member of the OIE. It sends in details of disease outbreaks ("Rapport D'Urgence") and provides routine updates on the animal health situation in the normal manner. The notification of occurrence and eradication of contagious disease of animals is laid down in Ordinance No. 1 of 7 January 1998.

The NVS has specific annual monitoring programmes for the main acute contagious and parasitic diseases. Farms are visited by private veterinarians who are required to report to the RVS. The border with Greece and Turkey is marked by a strip of ploughed earth and 2 km inside the border there is a barbed wire fence. Thus, the fencing does not prevent animals wandering onto Bulgarian territory. However, there are only 5 villages located in this zone which are monitored on a daily basis. All animals are ear-tagged in this zone, and since the BT outbreak in Bulgaria in July 1999 they have been denied access to the Bulgarian side of the fence. Likewise, villages with pastures in the 2 km buffer zone have been denied access. This is causing some hardship in the border areas, with farmers complaining that Greek/Turkish farmers are utilising these pastures while their animals go hungry. The situation has been compounded by the dry summer and poor grass growth.

### Foot-and-mouth disease and sheep and goat pox

At the time of the mission, Bulgaria was free from FMD and sheep and goat pox. Bulgaria declared itself free from FMD on 10 February 1997. The last sheep and goat pox outbreak was reported in September 1996. Bulgaria is currently on the list of OIE FMD free countries (see Resolution No. XII, August 2000), where vaccination is not practised, according to the provisions of Chapter 2.1.1 of the International Animal Health Code.

In 1999, according to revised figures presented on the last day of the mission, 8445 samples were taken from small and large ruminants originating in the 10 km border zone with Turkey and examined for FMD. For comparison, for the period 01.01.2000 – 19.09.2000, 4674 had been obtained. The CVRI had presented contradictory figures on the first day of the mission and had stated that the figures had been reduced to 1000 samples which was attributed to a shortage of funds as a result of other surveillance and eradication priorities, in particular the bluetongue campaign.

### Classical Swine Fever

According to the OIE disease information bulletin (7 April 2000, Vol. 13 – No. 13) the most recent report was on 3 April 2000 (1 outbreak in the North-Eastern part of the country). The affected population was non-vaccinated four-month-old pigs. Out of 104 susceptible animals, there were 15 deaths, 33 destroyed and 56 slaughtered. The diagnosis was made at the CRVI by immunofluorescence test. It was reported that non-vaccinated pigs of a local breed were fed with non sterilised slaughterhouse and kitchen waste. The pigs were treated with antibiotics one week before diagnosis. The control measures applied during the reporting period included quarantine and movement control inside the country, control of wildlife reservoirs and vaccination. It was stated that there is no CSF

in the wild pig population at present but there are regions with semi-wild pigs and they have CSF<sup>8</sup>. There is no routine sero-surveillance in wild pigs. There is a policy of compulsory vaccination in Bulgaria, however, the NVS acknowledged that control was difficult on small farms.

## Bluetongue

### 5.2.1. Outbreaks

On 7 July 1999, Bulgaria reported to the OIE, FAO, neighbouring countries and European Commission – outbreaks of bluetongue in the Burgas region in sheep reared on pastures close to the Turkish border. The infection was likely due to an influx of *culicoides* on the strong Southerly winds recorded in mid-June. Diagnosis was made at the CVRI using a competitive ELISA antibody test kit from the USA. The Bulgarian authorities immediately issued orders to the Burgas RVS to adopt a programme which included control of arthropods, wildlife reservoirs, quarantine and a ban on the movement and trade of animals. Immediate slaughter of all affected sheep was organised<sup>9</sup>. The mission team spoke with one of the farmers paid compensation as a result of compulsory slaughter and reviewed the documents detailing the payments which were found satisfactory. During the whole epizootic 669 animals were compensated and a total sum of €53.000 was paid in compensation.

Further outbreaks were reported in the region of Burgas and Yambol. In response, the EU adopted Commission Decision 1999/542/EC<sup>10</sup> on 28 July 1999 introducing measures which effectively banned the importation of live bovine, ovine and caprine animals originating in Bulgaria as well as their transit through the regions of Bourgas, Jambol, Sliven, Starazagora, Haskovo and Kardjali. On 27 August 1999, Commission Decision 99/606/EC was adopted to provide a special Community financial contribution in support of Bulgaria's efforts to eradicate bluetongue in accordance with Article 8 of Commission Decision 90/424/EEC.

A disease eradication programme was started in September 1999 and included insect control, establishing a line of sentinel animals and strict movement controls of susceptible animals in the affected regions. The Minister of Agriculture also approved a bluetongue control and eradication programme for the year 2000. The programme contains measures for a survey of bluetongue throughout the country, a survey on vector control (*culicoides*) and general and specific measures for the control and eradication of the disease in affected settlements. The programme also includes specific measures describing the treatment of susceptible animals against ectoparasites (both animal & environment), treatment of animal premises and vaccination.

---

<sup>8</sup> *In their comments the national authority stated that virus carriers have been detected in healthy pigs of the East Balkan semi-wild pig population, but no outbreaks were reported. The population is vaccinated against CSF every three months.*

<sup>9</sup> *In their comments the national authority added that destroying of sheep with clinical signs was carried out through killing and burying of the dead animals.*

<sup>10</sup> OJ No. L207, 28/7/1999, p.33

Also in September 1999<sup>11</sup>, a vaccination programme was initiated using live attenuated pentavalent vaccine from Onderstepoort, South Africa. This formula includes serotype 9, which is the only serotype found during the 1999 epizootic. As this vaccine cannot be administered in early pregnancy the campaign was repeated during the first two weeks in March 2000 in settlements situated within the 10 km border zone of the affected areas. As previously, the vaccinated animals were identified with individual ear tags and their movement restricted. Random blood samples were taken to check immunity levels.

During the course of the epizootic, outbreaks were reported in 85 villages in the regions of Burgas, Yambol, Haskovo and Kardjali.

#### 5.2.2. *Monitoring systems and sero-surveillance*

Diagnostic investigations into FMD, bluetongue and sheep and goat pox are undertaken along the border with Turkey, Greece and FYROM. Due to the low threat of Rinderpest and for financial reasons, the CVRI does not currently screen for this disease unless specifically directed. Due to the historic problems along the SE border, the RVS in Burgas, Yambol and Haskovo are supported by special inspectors of exotic diseases. Furthermore, the Regional Veterinary Services of Burgas, Yambol, Haskovo, Kardjali, Smoljan, Blagoevgrad and Kustendil are supported by sanitary technicians in charge of controlling exotic disease in the border zone.

For bluetongue, a system of sentinel herds were set up in 1999 at a distance of 40 km behind the infected zone, approximately 15 km apart in 19 settlements in the regions of Burgas, Yambol, Haskovo and Kardjali. The programme was drafted with the assistance of experts from the World Reference Laboratory in Pirbright. Each group of sentinel animals consisted of 10 cattle, 25 sheep and 25 goats giving a total population of 1140 animals all identified by ear tag. Blood samples were taken at 2 weekly intervals for testing at the CVRI, ending in November 1999 when *culicoides* activity ceased. The mission team was informed that in 1999 the CVRI tested 31,382 samples for bluetongue. As a continuation of the 1999 programme, in February 2000, blood samples were taken from 2000 cattle to assess their viral carrier status. The viral tests on blood samples from these serologically positive cattle in the affected settlements of Burgas and Yambol regions failed to detect bluetongue virus. The CA stated that up to 15 March 2000 no flights of *culicoides* were registered in settlements in Southern Bulgaria due to the persistence of low winter temperatures. The Bulgarian CA maintain therefore that cattle, which act as viral hosts for the longest periods, are already free of virus. Only 6 wild ruminants were blood sampled, one of which was positive.

Regular double blood samples were tested according to methods described in the OIE manual but with the limitations described in chapter 5.8. The RVS of Burgas, Yambol, Haskovo and Kardjali regions took blood samples from calves above 6 months old and kids above 4 months born in 2000 in settlements situated in the 10-km border zone. The RVS of the Smolyan and Blagoevgrad regions (on the Greek border) established 15 sentinel settlements in the 10km border zone and each 30 days took 10 double blood samples from large ruminants and goats identified with individual ear tags. The mission

---

<sup>11</sup> *In their comments the national authority added that during the first stage of the programme, which lasted from 1 till 15 September 1999, only lambs were vaccinated, not involved in the regular insemination campaign from August to November. These animals were revaccinated according to the vaccine producer instruction during the first two weeks in March 2000.*

team noted that at least one of these settlements was at a substantial altitude and thus unlikely to be frequented by *culicoides*.

In 2000, sentinel herds were again established 40 km behind the 1999 epizootic in the regions of Burgas, Yambol, Sliven, Stara Zagora, Haskovo and Kardjali. This year, however, only 10 large ruminants and 10 goats were used per sentinel herd and sampled only every 30 days instead of 15 days. Some of the sentinel herds used in 1999 were found to be sero-positive, particularly in low lying areas and new sentinels were selected. *Culicoides* were collected every 15 days using their own design of light trap located near animal holdings and water sources. A comparison was made with commercial designs and no difference was found.

The mission team observed that programmes for 2000 presented in the field were not always followed in practice with some sampling starting a number of months after the first risk period which is June/July though in time for the second possible peak in September/October. The NVS stated that this had occurred because meteorological conditions and their observations using light traps to count *culicoides* numbers indicated there was little risk of transmission. The mission team was informed that 6,496 blood samples had been taken for the period 1.1.2000 to 31.7.2000. This figure includes some 2,000 to 3,000 samples from sheep tested for BT, destined for export to Kosovo.

### Routine surveillance

The NVS in addition to the specific surveillance programmes (e.g. FMD & BT) monitors the animal health situation through a network of private veterinarians and licensed technicians. As well as participating during disease outbreaks they undertake routine tasks for the regional veterinary service on a contract basis. These include blood sampling, TB tests, vaccination against CSF and Newcastle Disease.

The mission team noted that one veterinarian in the field had submitted blood samples for Rinderpest examination unaware that the CVRI was not performing this test routinely. The veterinarian was, however, never informed that these tests were not undertaken on a routine basis.

In general, the mission team found that the regional and local veterinary services had difficulties in presenting laboratory test results in a systematic way. The difficulties were, however, due to the format in which the results had been communicated by the CVRI.

### **5.3. Farm registration**

The mission inspected the RVS copies of the bovine ID card (produced in quadruplicate) which provides general information, the code number of the animal holding and bears a declaration signed by the veterinarian *and the animal owner* at the time of tagging. This is a nation-wide scheme. Owners have been keen to tag animals, as the tags have been provided free of charge and without them they cannot obtain veterinary assistance or move/slaughter animals.

Sheep, goats and pigs have not been identified and the holding registered as for bovines, though the CA states that this is their intention. Details of animal owners and their stock are maintained in the municipality register as for cattle. The register, reflects, however, the fact that sheep are not kept on holdings in a strict sense. As stated above most people own

a few sheep which are grazed together on communal pastures. The register is therefore best described as a log of the owners and animals to be found within a particular village.

#### **5.4. Animal identification**

Animal identification for bovines is implemented by Ordinance No 4, SG 7/1998 and the NVS launched a nation-wide identification of large ruminants and registration of holdings in April 1998. Initially identification (small metal ear tags) and animal holding registration was performed in 17 regions, however, the mission team was informed that all 28 regions have now been completed. In the second tagging campaign started in 1999, yellow distance readable tags were applied. Those inspected by the mission team had the country and region identified (e.g. BG 26) followed by a six digit number. During the mission, cattle were seen to have either a metal tag or a single yellow tag in the left ear. Lost tags were replaced by a blank yellow tag on which the original number is to be written in indelible marker. The inspection team was shown examples of the cattle passport – a small green booklet in which it is stated that the owner must declare to the municipality details of the animal, any changes (eg bought/sold) within 3 working days or within 30 days of birth. A similar Ordinance is required for small ruminants and there is a draft version now under review.

The CA had planned to start a pilot project, whereby the information on the paper records would be transferred to a computerised animal identification and farm registration database (Eurovet) in a number of regions on the Turkish border. This did not take place, and the entire project has now been put out to tender.

#### Animal identification requirements of the Community funded vaccination programme

A financial contribution was made by the Community (see Commission Decision 99/606/EC) for the acquisition of 100,000 doses of bluetongue vaccine for an emergency vaccination campaign in the provinces of Burgas, Jambol, Haskovo and Kardjali. The Bulgarian authorities undertook to implement the following measures in the regions referred to above:

- Legal provisions making vaccination compulsory within the infected zone and surrounding areas. The extent of the vaccination zone shall be determined on the basis of geographic and environmental data,
- Registration of owners of herds or flocks of sensitive species (bovine, ovine and caprine animals),
- Marking of vaccinated ovine animals so as to allow easy identification subsequently,
- An information campaign aimed at stock keepers and veterinarians.

While sheep were identified in all the villages in the infected zone (10 km wide), this was not done with specific eartags. It is estimated that approximately 12% of sheep have been ear tagged in the affected regions and almost none in the remainder of the country<sup>12</sup>.

---

<sup>12</sup> *In their comments the national authority stated that vaccination against bluetongue only covered sheep. All vaccinated animals were identified by eartags. There is no approved Ordinance for the identification of small ruminants. Only vaccinated sheep have been identified. Apart from that all*

When ear-tags were read, the mission team could with difficulty trace them back to written entries in a register kept by the district veterinarian. Goats that were kept in the same flock were not identified. The RVS stated that with the assistance of the mass media and leaflets, the local population was informed about the clinical signs of the disease, the control measures and husbandry techniques to be applied and the vaccination campaign in sheep.

### **5.5. Movement controls**

Typically, the inhabitants of a village keep their animals in one herd/flock and graze them on communal pastures. For small numbers of animals, they may take it in turn to look after them or where more animals are involved they may pay for a shepherd to manage them on a permanent basis. The mission team was shown municipal registers which detailed the residents of a village and the animals owned by them. Each village would typically have its own watering area, close to the grazing land. Journey times between villages, which are often located in remote mountain regions, are large. The terrain is rugged in many places and in reality, due to the nature of subsistence farming very little movement of animals occurs beyond the village lands.

In addition to the compulsory measures described under the chapter on disease outbreak, the 2000 bluetongue eradication programme describes the daily examination in the settlements and the movement control of ruminants from the affected settlements. Livestock may only be slaughtered under the control of the regional veterinarian and only on the territory of the affected area in authorised slaughterhouses. The mission team observed that in general, there was one veterinarian for every 2-3 villages, and those spoken to were indeed inspecting flocks nearly every day. They also had to issue health certificates before any animals could be moved, which are in turn subject to scrutiny by the police.

### **5.6. Certification**

All certificates for export consignments have to be signed by a full time employee of the NVS. Private veterinarians, licensed to perform some regional duties, can sign health certificates and other documentation for internal movement. There has been no export certification for live animals in recent years due to the series of export bans imposed following incursions of list A diseases like FMD in 1991, 1993 and 1996, sheep and goat pox in 1995 and 1996 and bluetongue in 1999.

### **5.7. International trade in live animals**

Eurostat figures summarising EU trade with Bulgaria for the period 1999 show that the only substantial trade of animals to the EU is of young ducks and geese which are re-exported to Bulgaria for the production of “foie gras”. The register for 2000 kept at the NVS headquarters details two small consignments of young heifers imported from the Netherlands for breeding purposes. There have been almost no imports from other third countries in recent years, and import of live ruminants from Turkey has been banned since 1993. Import regulations, as described in report XXIV/1013/99 are stringent. In theory, subject to health certification and a valid import permit, animals can be imported from

---

*small ruminants are identified that are reared in the settlements situated in the 2-km zone, as well as those using the pasture in the 2-km border zone.*

suitable countries, principally the EU, to dedicated premises for a 30 day period of quarantine prior to reaching their destination.

A few consignments of sheep have transited the country from Romania to Greece, avoiding the prohibited regions. A small number of equidae have transited the country from Poland to Turkey.

The mission team visited 2 road BIPS: Novo Selo on the Greek and Kapitan Andreevo on the Turkish border, and a railway BIP at Svilengrad. It was confirmed that no livestock except competition horses had crossed these borders and that vehicles, irrespective of cargo, were sprayed with disinfectant. Although at Kapitan Andreevo a new site located beside the existing BIP had been agreed, the construction of the new BIP has not started<sup>13</sup>.

### **5.8. Laboratory service (Foot-and-Mouth Disease laboratory at Vrabnitsa, Sofia)**

The mission team visited the National Reference Laboratory for list A diseases. The laboratory is located within the Department of Virology of the Central Veterinary Research Institute of Bulgaria.

The facility is authorised to work with biosecurity group three agents. It was noted that the negative pressure system was in operation, HEPA filters for the inlet and outlet air circulation were in place and that there were adequate shower facilities at the entrance. It was also noted that the wastewater sterilisation system has not been checked for two years and that there was no incinerator on site.

The laboratory was last visited by a FVO mission team in February 2000, which reported on the equipment supplied and developments made during phase 1 of the PHARE programme.

#### BT & FMD tests

For BT the laboratory performs ELISA tests utilising commercial kits originating from USA. A filter was in use of a non standard wavelength, i.e. 405 nm rather than 620. The head of the laboratory stated that experience showed it gave satisfactory results, particularly for screening, however, it was accepted that the modified test method had not been fully validated<sup>14</sup>. Some data was inspected which showed apparent sero-conversion followed by a return to negativity. It was explained that in the absence of clinical symptoms in the animals involved, repeat tests were performed rather than proceeding with mouse inoculation. Pirbright test kits for competitive ELISA were also in use. In

---

<sup>13</sup> *In their comments the national authority stated that according to the PHARE project the construction of a new Border veterinary control post facility at the Border inspection post at Kapitan Andreevo is at the state of preparation of architectural and construction plans. There is no delay in the program, and the contract for the construction will be concluded after a tender.*

<sup>14</sup> *In their comments the national authority confirmed the use of a filter of 405 nm wavelength. Because of the lack of such a filter comparative validation tests have been carried out with the same samples by ELISA kit of the WRL in Pirbright, UK for bluetongue, which measures at 492 nm wavelength of the spectrometer, as well as the American kit VMRD measured at 405 nm. Result matching is +-0,86%.*

addition, locally produced antigens for AGID are in use, though it was acknowledged that the test was not very sensitive.

For bluetongue virus isolation, the technique of mouse intra-cerebral inoculation was in use. Five days after inoculation, infected mice develop clinical symptoms and in such cases, samples are sent to Pirbright for further isolation of the virus.

For FMD an ELISA test is in use which allows the identification of the serotypes present in Turkey. The reagents for this test are provided by Pirbright. Since last July the NSP ELISA is used. Staff have received training at IZS Brescia, the supplier of the test reagents.

For classical swine fever (CSF) a direct FAT is in use and for sheep and goat pox an AGID test is performed, using Russian reagents. The laboratory participates in annual ring tests organised by Pirbright with satisfactory results.

Personal operating notes are kept on file, however, no Standard Operating Procedures<sup>15</sup> are in place. Equipment and procedures were not under a quality control system in line with internationally recognised standards. The traceability of samples could not be guaranteed as identification of samples was not sufficient throughout the whole testing procedure. Initially the mission team was informed that 1000 samples had been tested for FMD in 2000, a figure which did not match that quoted in the field. For example, official veterinarians in the region of Haskovo stated that they alone had submitted 724 samples for testing.

The mission team inspected the results from the FMD and BT surveillance programmes. Non-standard laboratory reports were typed by hand, and letters often provided summary results for batches of samples taken at different times and places without making reference to individual sample numbers.

## **6. CONCLUSIONS**

### **6.1. Competent authority**

The National Veterinary Service mounted a rapid and effective response to the outbreak of bluetongue in July 1999 and there have been no further identified outbreaks since August 1999. Their vaccination campaign took into account the topography of the affected areas, e.g. rivers, lakes, valleys and mountain ranges, although due to the urgency of the situation, a commercially available pentavalent vaccine was used. They implemented the transit and export ban of live ruminants as adopted in Commission Decision 1999/542/EC. They have, in general, fulfilled the obligations of Commission Decision 99/606/EC which laid down the Community financial contribution in support of Bulgaria's efforts to eradicate bluetongue disease.

---

<sup>15</sup> *In their comments the national authority stated that the operating procedures entirely match the respective protocols for the operation of the various diagnostic kits. For example, the ELISA tests for FMD virus confirmation are carried out strictly according to the accompanying standard protocol of the producer IAH Pirbright.*

## **6.2. Animal health situation**

Bulgaria is currently on the list of OIE FMD free countries. Ongoing sero-surveillance indicates that there has been no recurrence of bluetongue in 2000. There has, however, been an outbreak of CSF on 28 March 2000 despite compulsory vaccination – attributable in part to limited control over small farms by the NVS. Due to the lack of sero-surveillance in wild and semi-wild pigs, there is no information on the epidemiological situation. In general, the national disease programmes for the control of BT and FMD have a sound scientific basis and are comprehensive. The programmes are ambitious, however, given the financial limitations constraining the NVS, and are difficult to evaluate due to the unnecessarily complex, fragmented and poorly presented data.

## **6.3. Animal identification, farm registration and movement control**

A manual system of identification and farm registration is in place for large ruminants and it is reported that all these animals have been ear tagged in all 28 regions of the country. Although all sheep were said to have been tagged in the 10km border zone where BT vaccination took place, goats have not been ear tagged<sup>16</sup> and nor have most of the small ruminants in the remainder of the country. Progress is likely to be slow, as funds for a national programme have not been confirmed. Furthermore, the plan to introduce an electronic data base (Eurovet) has been delayed. Despite incomplete tagging, movement control seemed reasonably effective.

## **6.4. Certification**

There has been no export certification for live animals in recent years, due to a series of export bans (see chapter 5.6).

## **6.5. Disease outbreaks**

Outbreaks of FMD, sheep and goat pox and bluetongue in recent years have been satisfactorily controlled.

## **6.6. Imports of live animals**

Very few live animals have been imported into the country, and only a few consignments have been issued transit permits. The Bulgarian CA has strict import and quarantine arrangements.

## **6.7. Laboratory service**

At the Central Reference laboratory in Sofia documentary records are not kept in a satisfactory way. Furthermore, there is no system of quality management including standard operating procedures, and the planned improvements are not yet completed, either in terms of structure and or in terms of equipment. The laboratory is, therefore, not yet prepared to seek accreditation to an international standard. The facility has up to now, however, been able to respond adequately during incursions of “list A” disease across its

---

<sup>16</sup> *The national authority stated that according to the program for the eradication of bluetongue, goats are not vaccinated throughout the country, and are therefore not identified. The only goats that are identified are those reared in the settlements within the 2-km border belt along the frontier with Greece and Turkey.*

borders (FMD, sheep and goat pox and bluetongue) and to outbreaks of endemic disease such as classical swine fever.

## **7. CLOSING MEETING**

The CA was in general agreement with the conclusions of the mission team. With regard to the CVRI, the CA stated that they had, following the visit given an instruction to improve the presentation and accuracy of summarised laboratory data. The mission team had been issued with summary tables at the closing meeting giving, according to the CA, an accurate account of the surveillance activities in 1999 and the year to date.

The major concern of the CA, however, was that after their experience with bluetongue and other List A diseases in the past – a regional centre for epizootic control should now be set up. The centre should be targeted to control exotic disease on the territory of the European part of Turkey, North-East Greece and South-East Bulgaria under the auspices of the European Union.

The NVS also informed the mission team that due to limited resources, they now have insufficient reserves of reagents to maintain adequate sero-surveillance for an incursion of FMD (serotype Asia 1) along both the Turkish (240 km) and Greek (494 km) borders. They alluded to the FMD vaccine programme currently being funded in Turkey and indicated that a small proportion of the cost of this project would have funded their programme.

## **8. RECOMMENDATIONS**

### **8.1. To the Bulgarian Authorities**

- 1) The bluetongue serological situation should continue to be monitored. Any further vaccination should contain only those serotypes which have been identified in Bulgaria and neighbouring countries.
- 2) The surveillance/control of CSF in wild and semi-wild pigs should be improved so that an eradication policy can be adopted, thus eliminating the need for compulsory vaccination. In the meantime, improved supervision is necessary over small pig holdings.
- 3) At the CVRI the accuracy, clarity and presentation of the laboratory management and recording systems should be improved as a matter of urgency. The administrative restructuring of the laboratory should take place as soon as possible with a view to seeking accreditation.
- 4) Record keeping at the regional and local level should be more transparent, recorded in a standard way and filed logically so information can be located quickly. A system should be introduced to allow the CA in Sofia to obtain an up-to-date overview of activities/results in all the regions.
- 5) Identification of small ruminants and registration of holdings should be put in place for the whole country as soon as possible and should include suitable ear-tags, registers and a central database.

A plan describing the actions to be taken and the deadlines by which they will be completed should be submitted to the Commission within two months of receipt of the final report.

## **9. ADDENDUM TO THE MISSION REPORT DG(SANCO) 1186/2000**

In their comments to the draft report the Bulgarian authority has responded to each of the recommendations at point 8.1. of the draft report indicating the action to be undertaken. Specific time frames and defined deadlines for the completion of some of these actions are given for recommendations 8.1.3, 8.1.4 and 8.1.5. With regards to recommendation 8.1.2 the CA states that the action has already been completed. In response to recommendation 8.1.1 the authority stated that no vaccination against bluetongue is likely to be carried out in 2001.