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FINAL REPORT OF A MISSION
CARRIED OUT IN
BULGARIA
FROM 06 TO 11 SEPTEMBER 2009
IN ORDER TO EVALUATE THE DISEASE CONTINGENCY PLANS FOR EPIZOOTIC
DISEASES

Executive Summary

Sporadic outbreaks of classical swine fever (CSF), Newcastle disease (ND) and avian influenza (AI) have been reported in Bulgaria in recent years.

The present report concerns the outcome of a mission which the Food and Veterinary Office carried out in Bulgaria from 7 to 11 September 2009 in order to investigate the current state of preparedness of the competent authorities to cope with outbreaks of epizootic animal diseases.

The mission team concluded that the situation in Bulgaria has improved compared to previous missions and in general the competent authorities are well prepared to cope with animal disease outbreaks.

Nevertheless, certain issues can further be improved, in particular some aspects of the state of preparedness of the relevant National Reference Laboratory for outbreaks of African swine fever, a disease currently occurring in some countries on the East Coast of the Black Sea

The report includes recommendations to the CAs addressing areas in which further improvements are required.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AHS	African Horse Sickness
AI	Avian Influenza
ASF	African Swine Fever
BT	Bluetongue
CA(s)	Competent Authority (ies)
CCA	Central Competent Authority
CP	Contingency Plan
CRL	Community Reference Laboratory
CSF	Classical Swine Fever
EC	European Commission
EU	European Union
FBO(s)	Food Business Operator(s)
FMD	Foot-and-Mouth Disease
FVO	Food and Veterinary Office
LDCC	Local Disease Control Centre
MAF	Ministry of Agriculture and Food
NCC	National Crisis Centre
NDCC	National Disease Control Centre
NDRVI	National Diagnostic and Research Veterinary Institute

NRL	National Reference Laboratory
NVS	National Veterinary Service
OIE	Office International des Epizooties (International Animal Health Bureau)
OM	Operational Manual
OV(s)	Official Veterinarian(s)
RCC	Regional Crisis Centre
RVS	Regional Veterinary Service
SVD	Swine Vesicular Disease
TAIEX	Technical Assistance Information Exchange Unit

1 INTRODUCTION

The mission took place in Bulgaria from 7 to 11 September 2009. The mission team comprised two inspectors from the Food and Veterinary Office (FVO).

The mission was undertaken as part of the FVO's planned mission programme.

The mission team was accompanied throughout the mission by a representative of the Central Competent Authority (CCA).

2 OBJECTIVES OF THE MISSION

The objective was to evaluate the resources and arrangements put in place to implement the European Community requirements for contingency plans in the event of one or more outbreaks of epizootic diseases, with special regard to foot-and-mouth disease (FMD), classical swine fever (CSF), avian influenza (AI), bluetongue (BT), African horse sickness (AHS), African swine fever (ASF), Newcastle disease (ND), and swine vesicular disease (SVD). This evaluation included a follow-up of the actions taken by the competent authorities (CAs) following the recommendations of certain previous missions as far as contingency plan issues are concerned (missions DG(SANCO)/8306/2006, DG(SANCO)/2007 – 7527, DG (SANCO)/2007 – 7483 and, in particular, DG(SANCO)/2008 – 7800).

See http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1576
http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1769
http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=1914
http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_id=2057

In pursuit of these objectives, the following sites were visited:

Site	No	Remarks
CA at central level	2	Initial and final meetings
CA at regional level	3	
CA at local level	3	met during site visits
Disease Control Centres (DCC)	3	National DCC and 2 LDCC
Laboratories	1	Meeting at the Laboratory for Exotic Diseases of the National Diagnostic and Veterinary Institute
Livestock Holdings	2	One large scale pig farm and one assembly centre
Food establishments	1	Combined slaughterhouse, cutting plant and meat processing plant
Other	1	Rendering plant

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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.

Community legislation of relevance for the mission is listed in the Annex to this report. References to legal acts refer to the latest amended version unless otherwise specified.

4 BACKGROUND

In the last few years, missions covering contingency plans for epizootic diseases were carried out by the FVO in all Member States. Whilst it was found that Member States were aware of the threats posed by such diseases to the health status of their national livestock populations, and that all had contingency plans in place, deficiencies were detected and there was considerable variation in the level of preparedness in the various Member States.

Recent outbreaks of epizootic diseases in previously disease free territories within the European Union (EU) (AI, FMD, BT) demonstrated the threat posed by the sudden spread of former exotic diseases, and further highlighted the need for well developed and resourced contingency plans in order to be prepared to implement immediate emergency measures.

5 FINDINGS AND CONCLUSIONS

5.1 COMPETENT AUTHORITIES AND OFFICIAL CONTROLS

5.1.1 Competent Authorities

Information on the structures of the Bulgarian CA can be found in the country profile (see http://ec.europa.eu/food/fvo/country_profiles/CP_bulgaria.pdf).

5.1.1.1 Designation of Competent Authorities

Legal Basis

Article 4.1 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for official controls.

Findings

Article 3 of the Law of Veterinary Activity (*Prom. SG. 87/1 Nov 2005, amend. SG. 30/11 Apr 2006, amend. SG. 31/14 Apr 2006, amend. SG. 55/7 Jul 2006, amend. SG. 88/31 Oct 2006, amend. SG.*

51/26 Jun 2007) designates the National Veterinary Service (NVS) of the Ministry of Agriculture and Food* (MAF) as the CA for the national animal health policy implementation. In the same law its 28 regional branches, the Regional Veterinary Services (RVS), are charged with the implementation on the ground.

As far as contingency planning is concerned, Article 48 charges the NVS with drawing up a CP to be applied in the event of a suspicion of particularly dangerous animal diseases as designated by the Minister (of MAF).

* In the text of the Law "Ministry of Agriculture and Forests"

Conclusions

The situation found is in compliance with the requirements of Article 4.1 of Regulation (EC) No 882/2004.

5.1.1.2 Co-operation between Competent Authorities

Legal Basis

Article 4.3 of Regulation (EC) No 882/2004 provides for efficient and effective co-ordination and co-operation between competent authorities.

Findings

Specific co-operation in the field of animal health between the CA and different authorities and organisations is organised through the so-called Epizootic Commissions, established at regional (*Oblast*) and local (municipal) level in accordance with Article 128 of the Law of Veterinary Activities. These commissions are official bodies whose members are nominated by Order of the relevant authority (governor or mayor). In general, representatives from the RVS or its district bodies, public enforcement authorities such as the police, forestry and environmental authorities, farmers and hunters organisations are members of these commissions, but the composition of represented authorities and organisations can vary slightly according to the region or municipality.

In addition, from a meeting with a police officer in one region, it was clear that there is a good working collaboration between the RVS and the regional police.

In one region visited, the composition of these commissions had not been updated formally following certain changes in available persons. However, the relevant RVS took corrective action within 24 hours of the team's visit to have a new order signed by the governor and evidence thereof was provided to the team before the final meeting.

Conclusions

Provisions are in place to ensure adequate co-operation between relevant authorities.

5.1.1.3 Co-operation within Competent Authorities

Legal Basis

Article 4.5 requires that, when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

In the slaughterhouse visited, there was a clear demonstration of the collaboration by the Public Health Department of the RVS with its animal health counterpart. The public health official veterinarian (OV) had prepared the *ad hoc* CP for this plant in collaboration with the plant's manager and private veterinarian.

Conclusions

It can be concluded that in the case seen there was adequate co-operation within different departments of the RVS, thus maximising the use of resources.

5.1.1.4 Contingency planning

Legal Basis

Article 4 of Regulation (EC) No 882/2004 also requires that competent authorities have contingency plans in place, and are prepared to operate such plans in the event of an emergency. Article 13 requires Member States to draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to present a serious risk.

Findings

Contingency plans have been prepared for suspicions and outbreaks of the relevant diseases as explained in detail in section 5.5 . Therefore, this aspect of Regulation (EC) No 882/2004 is not treated specifically in the present section.

Conclusions

Conclusions on the issue of contingency planning can be found in section 5.5.

5.1.2 Resources for performance of controls

5.1.2.1 Legal basis for controls

Legal Basis

Article 4 of Regulation (EC) No 882/2004 requires that the necessary legal powers to carry out controls are in place and that there is an obligation on food business operators to undergo inspection by the CAs. Article 8 requires that competent authority have the necessary powers of access to food business premises and documentation.

Findings

Article 132 of the Law of Veterinary Activities obliges the owners of animals to provide access to veterinarians.

There is no indication that OV's would have a lack of legal power to carry out their activities. They carry service cards which allows them to enter farms and premises without the permission of the owners or keepers.

Conclusions

No problems were found with regard to legal powers and therefore, it is concluded that the relevant provisions of Article 4 and 8 of Regulation (EC) No 882/2004 are complied with.

5.1.2.2 Staffing provision and facilities

Legal Basis

Article 4 of Regulation (EC) No 882/2004 requires the competent authority to ensure that they have access to a sufficient number of suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Findings

Sufficient staff numbers appear to be available at different levels. Apart from the officials at the NVS and its 28 RVSs, 264 municipal OV's and OV's in plants, including rendering plants, 1025 private practitioners have a contract with the CA to carry out certain tasks in the field of animal health surveillance and eradication programmes. These contracts ensure territorial coverage in the whole country. As these practitioners are paid by the owners or keepers of the animals for the non-official work, some of them even being employed full-time, as was the case in the farm visited, a potential conflict of interest arises. The contract with the CA foresees a clause to terminate it in case of irregularities in the official duties, which is considered by the CA as sufficient to prevent conflict of interest.

Official staff, in accordance with the Civil Servant Act, are obliged to make an annual statement that they do not have any conflict of interest and do not own businesses. In addition, Article 8 (2) of the Law of Veterinary Activities excludes them from having an interest in activities which are under the control of the NVS.

As far as equipment is concerned, through a programme funded by a foreign government, all OV's and contracted veterinarians have been provided with a laptop and portable printer as well as a Geographical Positioning System device (GPS). The laptops have a wireless internet connection which allows them to access the NVS and MAF databases during their on-the-spot visits, while the GPS allows them to determine the exact location of any holding visited.

In general, OV's have an official car for their visits. In the audit carried out by the relevant service, the General Directorate for Control of Veterinary Activities (from the CCA) in one of the RVS visited by the team, one of the deficiencies noted was the lack of such a car for two OV's. This problem was not yet solved at the time of the FVO mission.

Conclusions

In general, sufficient staff and equipment are available, including modern communication tools. However, not all necessary vehicles are available.

5.1.3 Organisation and implementation of official controls

5.1.3.1 Sampling and Laboratory analysis

Legal Basis

Article 4 of Regulation (EC) No 882/2004 requires competent authorities to have, or to have access to, adequate laboratory capacity. Article 11 establishes requirements for sampling and analysis. Article 12 requires the competent authority to designate laboratories that may carry out analysis of samples taken during official controls and lay down accreditation criteria for laboratories so designated.

Findings

The Laboratory for Exotic Animal Diseases, a branch of the National Diagnostic and Research Veterinary Institute (NDRVI), comprising the National Reference Laboratories (NRLs) for epizootic diseases, has been accredited by the Bulgarian Accreditation Body on 18.06.2009 against EN ISO/IEC 17025:2006 standards. The accreditation lists a number of validated tests, but not for all diseases within the scope of this mission. In particular, tests for ASF have not yet been validated.

This laboratory carries out the diagnostic tests for all diseases covered by this mission. In addition, surveillance tests for AI are carried out in its branch in Varna and surveillance tests for CSF are carried out in two RVS laboratories. These laboratories were not visited during the mission as surveillance was not within its scope.

Further aspects of testing and contingency planning in this laboratory can be found in section 5.5.6.

Conclusions

As far as accreditation of the relevant laboratory is concerned, the requirements of Article 12 can be considered to be complied with although diagnosis of a disease is not an official control. Nevertheless, the fact that testing methods for certain diseases are not included in the scope of the accreditation is considered a non compliance with Article 11 of Regulation (EC) No 882/2004.

5.1.3.2 Transparency and confidentiality

Legal Basis

Article 7 of Regulation (EC) No 882/2004 requires that competent authorities carry out their activities with a high degree of transparency, in particular by giving relevant information to the public as soon as possible. However, information covered by professional secrecy and personal data protection is not to be disclosed.

Findings

Although contingency planning is not an official control, it can be mentioned that all main documents prepared in this context by the NVS, namely the strategic plan, the operational manuals (OMs) and the instructions are available on the NVS website.

There were no findings in relation to confidentiality issues.

Conclusions

In the field of contingency plans, the Bulgarian authorities have complied with the obligations for

transparency of Article 7 of the Regulation.

5.1.4 Audit

Legal Basis

Under Article 4 of Regulation (EC) No 882/2004 competent authorities are required to carry out internal audits, or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Findings

In two of the three regions visited, a recent audit by the competent NVS Directorate had taken place and a detailed audit report containing some recommendations was available. The team saw also evidence of corrective action taken, although at least one recommendation, namely to provide official cars to the OV's who were lacking one, could not be solved and this for budgetary reasons. In the other RVS audited, one of the recommendations was to keep documents updated but the mission team saw a document on the composition of an Epizootic Commission which was no longer up to date. This oversight was corrected however before the end of the mission (see also section 5.1.1.2).

Conclusions

Although not all aspects of audits were checked, it can be concluded that the elements investigated show that the principles of Article 4 regarding audits are complied with.

5.2 LEGISLATION

Legal basis

A specific article in each of the relevant control directives for epizootic diseases (as listed in the Annex to this report) obliges the Member States to have a contingency plan in place and to submit it to the European Commission (EC) for approval.

Findings

The Law of Veterinary Activities provides for the legal framework while the different directives have been transposed into national Bulgarian law by a series of ordinances. The same Law, in its Article 48 charges the NVS with drawing up a CP to be applied in the event of a suspicion of particularly dangerous animal diseases as designated by the Minister (of MAF)

Conclusions

No problem was found regarding the legislation aspects in relation to the main objective of the mission.

5.3 EPIDEMIOLOGICAL SITUATION, DISEASE SURVEILLANCE AND OUTBREAKS

Legal basis

In accordance with Council Directive 82/894/EEC, MS must notify, to the EC and to the other MS,

primary and secondary outbreaks of certain diseases listed in the Annex. Similar provisions exist in the different disease control directives.

Findings

The Bulgarian authorities report regularly, through the Animal Disease Notification System (ADNS) as well as in the framework of meetings of the Standing Committee for the Food Chain and Animal Health on their situation regarding epizootic diseases. In addition, the mission team received before the mission, an overview of the situation in recent years.

In the last three and a half years, some outbreaks of CSF and ND were reported in various regions of Bulgaria. These concerned mainly small farms and, for poultry, back-yard flocks. In addition, four cases of AI were reported in wild birds in 2006. Also in 2006, 13 outbreaks of BT were reported, all of them in the region of Burgas.

Table: overview of outbreaks/cases of epizootic diseases 2006-2009

Disease >>	CSF outbreaks in domestic pigs	ND outbreaks	HPAI in wild birds (cases)	LPAI in wild birds (cases)	BT
Year					
2006	7	5	4	-	13
2007	3	13	-	-	-
2008	1	3	-	1	-
2009*	-	6	-	-	-

* = situation up to 30.06.09

During the mission, the team was informed about a case of CSF in a wild boar being discovered in the North of the country.

Vaccination in wild boars against CSF takes place in a zone following the Northern and Western borders, while special surveillance measures for BT are in place along Southeastern borders.

The team learnt in Varna RVS that certain additional surveillance measures were in place for AI and for ASF, in view of a possible incursion of those diseases in the coastal areas of the Black Sea.

Conclusions

The Bulgarian CA have respected their notification and information obligation in accordance with the relevant Community legislation. From the information provided, it appears that the current situation regarding epizootic diseases is rather satisfactory and measures are in place regarding surveillance for some of these diseases as required by the Community legislation.

5.4 CONTINGENCY PLANS

5.4.1 Documentation, coverage and distribution of the contingency plans and operational manuals, and procedures for review and updating

Legal basis

Article 72 of Directive 2003/85/EC obliges the Member States (MS) to draw up a contingency plan (CP) specifying the national measures required to maintain a high level of FMD awareness and preparedness, which should be implemented in the event of an outbreak of that disease. It provides for the CP to be sent to the EC for approval (Article 92), while Article 72, 8 requires the MS to notify the EC of significant modifications in view of a possible approval of the amended plan.

Annex XVII, Point 9 obliges the MS to have an operational manual available prescribing the details and practicalities of the procedures, instructions and measures to be employed in the handling of an FMD outbreak. Article 72, 3 requires the CP to provide for measures in a worst case scenario as described in Point 12 of Annex XVII.

Similar provisions, except for those concerning the worst case scenario exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others). A list of disease control directives is available in the annex to this report.

Findings

Before its Accession to the EU, Bulgaria had prepared CPs for AI, ND, CSF, FMD and BT and sent them to the EC. They have been approved by Commission Decisions 2007/18/EC (CP for FMD), 2007/19/EC (CP for CSF) and 2007/24/EC (CPs for AI and ND).

In view of some weaknesses in some of the plans and in view of harmonising the approach, as noticed in particular in a previous FVO mission (SANCO/2007-7527), the NVS has prepared in 2009, with the assistance of an expert from another MS and of TAIEX (Technical Assistance Information Exchange Unit) a new common CP for all diseases. The mission team received before the mission the text of Part I of the CP, being the strategy and resource plan. During the mission, the team was informed about the other parts and about the way to accede them on the NVS website. (<http://www.nvms.government.bg/>)

The structure in this new approach is as follows:

- Part I: Strategy and Resource Plan. This document provides all the basic elements, such as legal references, financial provisions, chain of command, set up of national and regional crises centres (NCC and RCCs, being the equivalent of the respective disease control centres - NDCC and RDCCs), expert groups, staff, equipment, diagnostic laboratories, etc.
- Part II: the Operational Manuals (OMs): providing detailed technical information for each disease concerned, such as regarding nature of the disease, susceptible species, symptoms, diagnosis, including differential diagnosis, historical information, actions to take etc. They contain also a detailed form for epidemiological inquiries.
- Part III: the Annexes to the CP, providing detailed instructions on different practical aspects:
 - Annex I: Personal Safety and Protective Equipment during Outbreak Management,
 - Annex II: Humane Killing of Animals for Disease Control Purposes,
 - Annex III: Carcass Management and Manure Disposal.
 - Annex IV: Disinfection, Disinsectisation, Deratisation

While parts II and III are to be used in the whole country in a horizontal way, each RVS had to prepare its own Part I as financial resources, staff and equipment, chain of command etc. differ from region to region;

The NVS informed the relevant EC service in DG SANCO of the updating of the CPs by letter of 3 September 2009.

The team made the following findings:

- The documents available on the website provide a global approach to the issue of contingencies. They are very detailed and well structured and appear to cover the different aspects required by the relevant Community legislation in an adequate way.
- As recommended in mission report SANCO/2008-7800, the documents were either available in the sites visited in a hard copy or the OVs and contracted veterinarians knew how to access them.
- Hard copies of the documents did not always carry a date, nor did they indicate their version other than on the front page.
- No worst case scenario is included in the FMD OM, nor in any of the instructions. However, Part I of the CP contains a section on handling large numbers of outbreaks or outbreaks over a long period of time. This section does not contain all the provisions of the relevant paragraph in Directive 2003/85/EC. In particular, it does not provide indication of the vaccine requirements, nor does it indicate how the expert group will avail of meteorological advice.
- In the regions where RVS offices were visited, the team checked the regional strategy and resource plans, which contained the necessary information adapted to the local situation (e.g. by mentioning the available staff and equipment, composition of the epizootic committees for all the municipalities in the *oblast* and the composition of the regional expert group, the persons and organisations to contact etc.
- The RVS in the region where this point was checked had taken contact with the regional meteorological service to ensure access to their information system in case of need and evidence of that contact was available.
- In the slaughterhouse visited, tailor-made documents were available. The plan provided details on the measures to be taken in the event of an outbreak on the premises, but not regarding actions which could be necessary if the establishment were cut off from its supply of live animals because of an outbreak in the surroundings. The OMs for the diseases relevant to the business were also available. The management of the plant had been involved in the preparation and had received a copy of the documents. Some training had been organised on the issue by the OV from the Food Safety Department of the RVS who had also prepared the documents in close collaboration with his animal health counterparts.
- In the rendering plant visited, tailor-made documents were available with the emphasis on destruction of carcasses and the organisation of the collection of material resulting from stamping-out activities.
- In the farm visited, no tailor-made documents were available but the contracted veterinarian was able to consult the documents from the NVS and RVS. Together with the farm manager, he had reflected on certain aspects with regard to contingencies.
- In the assembly centre, no real reflections had yet taken place on the issue. As in the other sites visited, the responsible OV had the relevant OMs available (in particular AHS, BT and FMD, but also VS, Rift Valley fever, lumpy skin disease and rinderpest) as he had downloaded them from the NVS website. The OV was not well aware of the background of the changed approach for the CP.

Conclusions

While in the past only some of the CPs had been prepared and forwarded to the EC, the Bulgarian CA has now a comprehensive system in place regarding contingency planning. It has, therefore, complied with the relevant obligations of the various control Directives. In addition, the structure of the plan through its different parts provide a rather comprehensive coverage, thus largely complying with the obligations in the matter. However, a few shortcomings exist where the CP does not comply completely with all the requirements, in particular regarding the OM for FMD.

5.4.2 *Organisation, chain of command and resources*

Legal basis

Annex XVII, Points 2 and 3 to Directive 2003/85/EC require the CP to contain provisions regarding resources and to establish a chain of command respectively.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

The organisation of the CA and chain of command are clearly described, both in the national strategy plan and in their regional counterparts. All strategy plans contain the necessary detail on available staff and equipment. In particular, these plans contain indication of the members of the relevant expert groups and epizootic commissions, which are responsible for preparing orders in the event of need for additional measures.

As far as financial resources are concerned, there is currently no emergency budget available in Bulgaria. However, section VII (Funding of activities for covering epizootic risks) of the Law on Veterinary Activities foresees in its Article 111 that the Council of Ministers shall adopt an ordinance on the order under which is the fund to be established, managed, executed and reported. From discussions with CCA representatives, the team understood that the establishment of this fund is being considered but not yet implemented. Pending its creation, the necessary funds would be made available, when necessary, from the General State Emergency Fund.

Conclusions

The relevant provisions of the different Community directives regarding organisation, chain of command and resources are complied with, although a further development on funding is still being considered.

5.4.3 *Communication*

Legal basis

Article 74, 3, h), of Directive 2003/85/EC foresees the NDCC to be responsible for liaising with the media, while Article 76, 2 requires the CP to foresee that the LDCCs be equipped with communication lines and information channels.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

In part I of the CP, the composition of the NDCC foresees that there is a press liaison officer, and one for each LDCC.

In addition, the fact that all OV's have been equipped with laptops equipped with wireless access to the internet and, hence, to email, provides for the necessary communication tools.

Conclusions

The requirements regarding communication in the event of disease outbreaks have been catered for in a comprehensive way.

5.4.4 Legal powers in "peace time" and in emergencies

Legal basis

Point 4 of Annex XVII to Directive 2003/85/EC foresees that the MS must ensure the legal powers of the implementation of the CP and allow for a rapid and successful eradication campaign.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

While the Law of Veterinary Activities provides the NVS and its regional services, the RVS, with the necessary legal powers regarding animal health issues in peace time, Article 47 of this Law specifies its powers in the event of emergencies. The General Director of the NVS can, in such cases, adopt Orders for additional measures which have to be published in the State Gazette and cannot be appealed .

The team did not see any indication that there would be a lack of legal powers as these are granted to the OVAs by the Law of Veterinary Activities as explained in section 5.1.2.1. In addition, as mentioned in section 5.1.1.2, there is a good collaboration with the police authorities which can be called upon if any problem were to arise.

Conclusions

The requirements regarding legal powers in "peace time" and in emergencies have been adequately addressed.

5.4.5 Financial provisions - eradication, compensation

Legal basis

Point 2 of Annex XVII to Directive 2003/85/EC foresees that the CP must make provisions for ensuring access to emergency funds, budgetary means and financial resources to cover all aspects of the control and eradication of the epizootic.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

The Law of Veterinary Activities provides the legal obligations as far as compensation of owners is concerned. As mentioned in Section 5.5.2, no emergency fund as such is available. This is mentioned explicitly in Part I of the CP, under financial provisions.

There were no indications that this has led to any delays in paying compensation in past disease outbreaks.

Conclusions

Although the lack of an emergency fund could be seen as a non-compliance with the relevant legal obligations, procedures in place to seek the necessary funding in the event of a disease outbreak appeared to have worked adequately in the past.

5.4.6 *Epidemiological capacity, laboratories*

Legal basis

Point 8 of Annex XVII to Directive 2003/85/EC foresees that the CP must make provisions for having laboratory capacity.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

Part I of the CP gives an overview of the diagnostic capacities for the different diseases covered by this mission. In addition, the operational manuals for the different diseases contain detailed information on diagnosis as well as an epizootiological inquiry form, which should provide the necessary information to do such an inquiry if it is completed adequately and consistently in outbreaks and contact herds. The development and use of this form was a recommendation of a previous FVO mission (SANCO/2007-7527)

The diagnosis and confirmation of the animal diseases covered by the present mission is done exclusively in the Laboratory for Exotic Animal Diseases of the NDRVI, located in a suburb of Sofia. Surveillance testing by serology for AI is also done in a recently created branch of the Laboratory located in Varna, while two RVS laboratories (Veliko Tarnovo and Stara Zagora) have been equipped for CSF serology.

The Laboratory of Exotic Animal Diseases has prepared its own CPs for FMD, CSF, BT, AHS, AI and ND, but not yet for some other diseases like ASF. The CPs are mainly a document regarding capacity calculation for the different tests used in "peace time". The head of the laboratory estimated the maximum capacity in emergency situation at the double of the indicated figures as capacity would be restricted by space and increasing the numbers could only be achieved by increasing the number of working shifts. Personnel were trained for diagnostics for more than one disease and evidence of this was available: this allows swapping of people from one unit to another one. There is no contract with suppliers of test kits etc. as purchases up to a certain number of tests would not create a problem and the number of holdings in Bulgaria is relatively low.

No contract or agreement with foreign laboratories exists for mutual assistance in the event of an outbreak and the Head of the Laboratory admitted that this could be useful and would consider it. However, intense contacts exist with similar laboratories in neighbouring countries while the Laboratory participates in annual meetings organised by the Community Reference Laboratories (CRLs) for the different diseases.

For ASF diagnosis, the Bulgarian NRL had not yet participated in ring-tests organised by the CRL, mainly because they had not yet validated their methods. The responsible staff had not yet been trained specifically for diagnosis of this disease, but had participated in annual meetings at the relevant CRL.

Conclusions

Although in general the laboratory responsible for diagnosing the relevant diseases is relatively well prepared, the absence of a CP for certain diseases combined with a lack of validated methods and sufficient training could create a problem in the event of an outbreak. This is particularly the case for ASF, which occurs on the Eastern shores of the Black Sea.

5.4.7 *Killing of animals in disease outbreaks*

Legal basis

Point 9 of Annex XVII to Directive 2003/85/EC foresees that an OM should be available describing all actions and procedures needed to deal with an outbreak.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Council Directive 93/119/EC describes the requirements for protection of animal welfare at slaughter and killing. It includes provisions for the killing in the framework of disease control measures.

Findings

The instruction on killing animals in the context of disease contingencies contains a detailed description of animal welfare considerations as well as procedures to be respected during the killing.

One of the methods chosen to kill pigs in outbreaks or for sampling is a lethal injection of a substance which paralyzes respiratory muscles while leaving the animal fully conscious. The text in this respect is somewhat ambiguous but from clarifications received from the CA it appears that this injection would only take place after an earlier injection with an hypnotic or anaesthetic substance. In addition, Article 181 of the Law of Veterinary Activities explicitly bans the use of a substance which paralyzes respiratory muscles while leaving the animal fully conscious for killing animals. As such, its use would therefore not go against the EFSA [1] opinion of 2004 recommending not to use this product for killing conscious animals [2].

[1] EFSA = European Food Safety Authority

[2] Opinion of the Scientific Panel on Animal Health and Welfare on a request from the Commission related to welfare aspects of the main systems of stunning and killing the main commercial species of animals (Question N° EFSA-Q-2003-093) - Adopted on the 15th of June 2004

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775454.htm

Another killing method elaborated in detail was one elaborated together with the US Department of Agriculture for the killing of poultry, using dry ice. This method appears to give good results for killing poultry humanely as all precautions are taken to have sufficiently high concentration of CO₂ before placing the poultry in the disposable container.

Conclusions

The necessary precautions have been taken to comply with the relevant requirements of Directive 93/119/EC for killing animals in a humane way in disease emergency situations. However, the text of the instruction regarding the use of lethal injection is not completely clear.

5.4.8 *Cleaning and disinfection, disposal*

Legal basis

Point 9 of Annex XVII to Directive 2003/85/EC foresees that an OM should be available describing

all actions and procedures needed to deal with an outbreak. In addition, Points 13 and 14 of that Annex require the CPs to include the necessary arrangement for disposal of the carcasses and animal waste resulting from the stamping out operations.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

Part I of the CP describes the material needed for cleaning and disinfection briefly as well as the territorial competence of the two rendering plants, which is annually agreed upon through a tender and a service contract.

As explained in section 5.5.1 of this report, *ad hoc* detailed instructions exist for disinfection and other sanitation operations, and for disposal of carcasses and waste material.

Conclusions

The relevant requirements of the different control Directives are complied with in a horizontal way.

5.4.9 Training and real-time alert exercises

Legal basis

Article 73 of Directive 2003/85/EC and Point 11 of Annex XVII to that Directive foresee the CP to contain provisions and arrangements for regular training of staff involved in contingency operations. This includes the organisation of real-time exercises.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

The team received a list of training sessions organised in relation to the subject before the mission, while further explanations were provided at the opening meeting. Staff from the CCA participated in training in Denmark.

Evidence was available at different levels of training organised repeatedly in relation to different aspects of disease control. This included a real time exercise for AI organised in Dobrich in April 2008. Practical training sessions were also organised to make staff familiar with the dry ice method for killing poultry (see Section 5.5.7). No other real-time exercises are currently planned but a new training series following the adoption of the new approach is being considered.

There was no recent real-time exercise for FMD.

Conclusions

Although no specific training has been provided yet following the change in approach for contingency planning, the organisation of previous training sessions including a real-time exercise for AI is largely in compliance with the relevant provisions of the Community legislation. However, more specifically for FMD the situation is not in compliance with the requirements of Article 73 of Directive 2003/85/EC.

5.5 DISEASE CONTROL CENTRES AND EXPERT GROUPS

Legal basis

Point 4 of Annex XVII to Directive 2003/85/EC foresees that the MS must be prepared to establish a functional NDCC immediately, while point 5 of that Annex requires the MS to have detailed plans for the establishment of LDCCs. Articles 74 to 77 define the functions and technical criteria for these centres.

Article 78 of the same Directive requires the MS to create a permanently operational expert group.

Similar provisions exist for the other diseases falling within the scope of this mission (AI, ND, CSF, ASF, AHS, SVD, BT and others).

Findings

In previous FVO missions, some issues were raised about the establishment and equipment of disease control centres.

The strategy and resource plans now describe the functioning and establishment of the diseases control centres at different levels. In the documents, they are referred to as National Crisis Centre and Regional Crisis Centres (NCC and RCCs respectively).

The opening and final meetings took place in a meeting room which the CCA indicated as being the location for the NCC in the event of an outbreak. The room offers space for at least twenty persons who could use their laptop as wireless connection to the internet is available, as well as a fax machine and phones. Only one large map of Bulgaria (scale 1/200 000) was available and the mission team was informed that plans existed to acquire a computer based mapping system.

For the establishment of RCCs, the RVSs both regions where offices were visited have considered the use of a larger office in their currently used building for a minor LDCC, while they would move to larger premises which they have available and were partly unused. However, no written plan to prepare for this was available and in one region, some preparatory work for such a move would be needed.

In the larger office, a number of maps were available, one of them at a scale of 1/50 000 covering the whole *oblast*. This was action taken in response to a recommendation in mission report SANCO/2008/7800.

In Part I of the CPs seen at national and regional level, detailed information on the creation of Expert Groups is included. In the OM for FMD, there is however no provision for obtaining meteorological information as required by Article 78, 3, e) of Directive 2003/85/EC. Nevertheless, in one of the regions visited, where the team verified this issue, a letter was available from the regional meteorological service undertaking to provide immediate assistance when requested by the RVS.

Conclusions

In general, the conditions for establishing NDCC and LDCCs are complied with, but a lack of a detailed plan to explain the procedures in place for moving the LDCC to another location could delay temporarily the operations in large scale outbreaks.

5.6 OTHER ISSUES

Legal basis

Chapter I of Annex V of Regulation (EC) No 1774/2002 provides for the hygiene and approval requirements of processing plants for animal by-products; These provisions contain requirements regarding cleaning and disinfection and separation between clean and unclean areas.

Findings

In the rendering plant visited, parts of external walls, roads and equipment were in a bad state of repair and showed cracks and holes. As a result, cleaning and disinfection would be difficult. Parts of the roads were not surfaced at all.

According to information received, this plant produces only material for later incineration.

Conclusion

Although this was not explicitly within the scope of the mission, the state of the premises could present a risk of contamination of the environment and of cross-contamination of disinfected vehicles before they leave the plant. However, as the plant does not produce animal by-products for further use, the final products leaving the plant do not present a risk.

6 OVERALL CONCLUSIONS

A number of actions undertaken by the Bulgarian CA should enable them to intervene rapidly in the case of most epizootics. Some of these actions addressed recommendations from previous missions. However, some problems remain to be solved such as the state of preparedness of the National Reference Laboratory in the event of outbreaks of ASF and some shortcomings in the FMD operational manual.

7 CLOSING MEETING

The FVO team held a closing meeting with the CCA on 11 September 2009, at which the main observations and preliminary conclusion of the mission were presented. The CCA provided clarification on a number of observations, which are reflected in the report where relevant.

8 RECOMMENDATIONS

The Competent Authorities of Bulgaria are invited to present 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 identified, within 25 working days of receipt of the report.

N°.	Recommendation
1.	To provide officials with the necessary equipment, in particular means of transport enabling them to visit any relevant sites without undue delay, in accordance with Article 4, 2, d, of Regulation (EC) No 882/2004.
2.	To take further action to reduce the risk for conflict of interest for veterinarians carrying out official control tasks in accordance with Article 14, 3, B, (ii) Directive 64/432/EEC.
3.	To ensure that the necessary amendment to the contingency plan in relation to FMD is made in order for it to comply fully with the relevant provisions of Article 72,

N°.	Recommendation
	Paragraph 3 of Directive 2003/85/EC as far as the worst case scenario is concerned.
4.	To ensure that the necessary action is taken in relation to the expert groups for FMD in order for them to have access to the necessary meteorological data without delay, in accordance with the provisions of Article 78, Paragraph 3, e) of Directive 2003/85/EC.
5.	To take the necessary action to improve the situation for ASF diagnosis in the Laboratory for Exotic Diseases, in particular by having the relevant staff fully trained, by having the testing methods validated against EN:ISO 17025, by participating in inter-laboratory proficiency testing and by drafting a contingency plan for the use of the Laboratory for this disease, in accordance with Article 18 of Directive 2002/60/EC.
6.	To establish access to an emergency funding system for disease outbreaks, in accordance with the relevant provisions of the different disease control directives, in particular Point 2 of Annex XVII to Directive 2003/85/EC
7.	To maintain efforts for organising training of official staff, in particular by organising the required real-time exercises, in accordance with the requirements of Article 73 of Directive 2003/85/EC.
8.	To consider drafting the instructions regarding the use of lethal injections in a way that they cannot be interpreted as being contrary to the obligations of article 3 of Directive 93/119/EC.
9.	To take urgent remedial action to ensure that rendering plants can be easily cleaned and disinfected in accordance with Chapter I of Annex V of Regulation (EC) No 1774/2002.

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

http://ec.europa.eu/food/fvo/ap/ap_bg_2009-8210.pdf

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 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
Dir. 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
Dir. 92/35/EEC	OJ L 157, 10.6.1992, p. 19;27	Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness
Dir. 92/66/EEC	OJ L 260, 5.9.1992, p. 1-20	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease
Dir. 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
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Dir. 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
Dir. 2001/89/EC	OJ L 316, 1.12.2001, p. 5-35	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever
Dir. 2002/60/EC	OJ L 192, 20.7.2002, p. 27-46	Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever
Dir. 2003/85/EC	OJ L 306, 22.11.2003,	Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of

Legal Reference	Official Journal	Title
	p. 1-87	foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC
Dir. 2005/94/EC	OJ L 10, 14.1.2006, p. 16-65	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC
Dir. 2008/71/EC	OJ L 213, 8.8.2008, p. 31-36	Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs (Codified version)
Reg. 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
Reg. 1774/2002	OJ L 273, 10.10.2002, p. 1-95	Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption
Reg. 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
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	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 health and animal welfare rules

Legal Reference	Official Journal	Title
Dec. 2007/18/EC	OJ L 7, 12.1.2007, p. 36;37	2007/18/EC: Commission Decision of 22 December 2006 approving contingency plans for the control of foot-and-mouth disease pursuant to Council Directive 2003/85/EC
Dec. 2007/19/EC	OJ L 7, 12.1.2007, p. 38-40	2007/19/EC: Commission Decision of 22 December 2006 approving contingency plans for the control of classical swine fever pursuant to Council Directive 2001/89/EC
Dec. 2007/24/EC	OJ L 8, 13.1.2007, p. 26;28	2007/24/EC: Commission Decision of 22 December 2006 approving contingency plans for the control of avian influenza and Newcastle disease