



EUROPEAN COMMISSION  
HEALTH AND CONSUMERS DIRECTORATE-GENERAL  
Directorate F - Food and Veterinary Office

DG(SANCO) 2012-6390 - MR FINAL

FINAL REPORT OF AN AUDIT  
CARRIED OUT IN  
BULGARIA  
FROM 11 TO 15 JUNE 2012  
IN ORDER TO EVALUATE THE ANIMAL HEALTH CONTROLS ON FOOT AND MOUTH  
DISEASE

## ***Executive Summary***

*This report describes the outcome of a Food and Veterinary Office (FVO) audit in Bulgaria, carried out 11 to 15 June 2012.*

*The objective of the audit was to evaluate the implementation of Directive 2003/85/EC and in particular the measures contained in the Bulgarian plan for the eradication of foot-and-mouth disease (FMD) in wild animals approved by Commission Implementing Decision 2011/493/EU. Attention was also paid to the actions taken by the competent authorities in response to certain recommendations in FVO report DG(SANCO)2009-8210.*

*In Bulgaria there is an overall well functioning system in place for implementation of contingency and control measures against FMD and for the implementation of disease surveillance in domestic and wild animals. The implementation of the contingency plan for FMD was generally effective, however certain deficiencies were noted with regard to the instructions for sampling and for disinfection and cleansing of animal transport vehicles.*

*Adequate measures were taken before the lifting of restrictions linked to the 2011 FMD outbreak. The implementation of the Eradication Plan for FMD in wild animals was in accordance with the plan, which had been approved under Commission Implementing Decision 2011/493/EU. Even after the conclusion of the Eradication Plan in April 2012 movement controls and certain surveillance measures in the areas closest to the border with Turkey are still in place under national legislation.*

*Intensive monitoring of domestic animals during 14 months after the last outbreak has shown that the stamping out of the 2011 outbreaks was successful. The results from wild animals sampled until January 2012 indicate that the spread of FMD virus serotype O, which caused the 2011 outbreak, to wild animals had taken place only in the vicinity of the outbreaks in domestic animals and that the spread of the virus to juvenile wild boar (born in 2011) had been very limited.*

*The main deficiencies in this system are seen in the national reference laboratory, which is responsible for all testing for FMD. A chronic lack of sufficient supplies of adequate consumables has resulted in the use of sub-optimal test methods which, although sufficient to determine the spread of foot-and-mouth virus linked to the 2011 outbreaks, are not suitable for serological surveillance in wildlife and domestic animals intended to detect future possible introductions of other serotypes of FMD virus into Bulgaria. In addition, the two methods commonly used for the Eradication Programme for FMD in wildlife are not included in the scope of accreditation, as required under EU legislation.*

*The report makes a number of recommendations to the Bulgarian competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.*

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#### ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

<b>Abbreviation</b>	<b>Explanation</b>
BFSA	Bulgarian Food Safety Authority
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
EU-RL	European Union reference Laboratory ( <i>here: for foot-and-mouth disease</i> )
FMD	Foot-and-Mouth Disease
ISO	International organisation for Standardisation
LBPE	Liquid-phase blocking ELISA (for detection of antibodies to structural proteins of FMD virus)
NDRVI	National Diagnostic and Research Veterinary Institute
NRL	National Reference Laboratory
NSP-ELISA	ELISA for detection of antibodies to non-structural proteins (of FMD virus)
OIE	World Organisation for Animal Health
Real time RT-PCR	Real time reverse-transcription polymerase-chain reaction method
RFSD	Regional Food Safety Directorate
SCFCAH	Standing Committee on the Food Chain and Animal Health
Type O ELISA	ELISA for detection of antibodies to FMD virus serotype O

## 1 INTRODUCTION

This audit took place in Bulgaria from 11 to 15 June 2012. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. The audit was undertaken as part of the FVO's planned audit programme.

An opening meeting was held on 11 June 2012 with the central competent authority, the Bulgarian Food Safety Authority (BFSA). At this meeting, the objectives of, and itinerary for, the audit were confirmed by the audit team and the control systems were described by the authorities. Representatives from the BFSA accompanied the audit team during the whole audit.

## 2 OBJECTIVES

The objective of the audit was to evaluate the implementation of Directive 2003/85/EC and in particular the measures contained in the Bulgarian plan for the eradication of foot-and-mouth disease (FMD) in wild animals approved by Commission Implementing Decision 2011/493/EU. Attention was also paid to the actions taken by the competent authorities in response to recommendations two and three in FVO report DG(SANCO)2009-8210.

As regards Regulation (EC) No 882/2004, special attention was paid to staff training and equipment, laboratory capability, verification of effectiveness of official controls and enforcement measures.

The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		n	Comments
Competent Authorities	Central	2	Opening and closing meetings with the Bulgarian Food Safety Authority
	Regional	2	Regional Food Safety Directorate in Burgas; Regional Police Force in Burgas
	Local	1	Local (municipal) veterinary office in Sredets municipality
Laboratory		1	The National Reference Laboratory for FMD: Testing Laboratory for Exotic and Extremely Dangerous Infections in the National Diagnostic and Research Veterinary Institute
Holdings		2	One village with an East Balkan pig herd; one village with common grazing grounds for large and small ruminants
Establishment		1	One slaughterhouse slaughtering animals from the "Cordon Sanitaire"
Other		1	One meeting with representatives of hunting organisations involved in FMD sampling of wild animals

### **3 LEGAL BASIS**

The audit was carried out under the general provisions of EU legislation, and in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and
- Article 27(9) of Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field.

A full list of the legal instruments referred to in this audit report is provided in the Annex and refers, where applicable, to the last amended version.

In addition to the standards established by the relevant EU legislation, account was taken of other international standards, in particular the standards, guidelines and recommendations developed by the World Organisation for Animal Health (OIE).

### **4 BACKGROUND**

#### **4.1 SUMMARY OF PREVIOUS FVO AUDIT RESULTS**

The two most recent FVO audits with relevance for the current audit were carried out from 6 to 16 September 2009 on contingency plans (DG (SANCO)2009-8210, hereafter referred to as the 2009 FVO report) and from 27 to 28 May 2010 on the security systems applied in national laboratories handling live FMD virus (DG (SANCO) 2010-8412, hereafter referred to as the 2010 FVO report). The reports of both audits have been published on the website of the Directorate-General for Health and Consumers ( [http://ec.europa.eu/food/fvo/ir\\_search\\_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm) ).

With relevance for FMD controls, the 2009 FVO report concluded that although a contingency plan for FMD was in place, all requirements in Council Directive 2003/85/EC had not been met: the FMD-specific operational manual did not contain all required provisions and no real-time alert exercises had been organised for FMD. In addition, there was a potential conflict of interest with regard to the involvement of private veterinary practitioners contracted part-time by the competent authority for carrying out official tasks while being employed or paid for clinical services by owners/keepers of farm animals. The corresponding recommendations (two and three) in the 2009 FVO report have been addressed in an updated action plan which has been provided to the FVO by the competent authorities.

The 2010 FVO report concluded that in several critical areas the national reference laboratory did not meet the requirements in EU legislation for handling of live FMD virus. The Bulgarian national reference laboratory is no longer included on the list of laboratories authorised to handle live FMD virus in Part A of Annex XI to Council Directive 2003/85/EC. The actions taken by the competent authority in response to the recommendations in the 2010 FVO report will not be followed up in this report.

## 4.2 FMD SITUATION IN BULGARIA

In brief: On 5 January 2011 the Bulgarian competent authorities reported a confirmed case of FMD in a wild boar (with lesions indicative of FMD) which had been shot in the Burgas region about two kilometres north of the Turkish border on 30 December 2011. Isolation and typing of the virus were made by the EU Reference Laboratory (EU-RL).

Measures in accordance with Council Directive 2003/85/EC were implemented from 5 January 2011. Clinical and serological surveillance was initiated and 11 outbreaks in domestic animals were detected in south-east Bulgaria between 9 January and 7 April. These were the first outbreaks of FMD in Bulgaria since 1996.

Certain protection measures against FMD in Bulgaria were introduced 6 January 2011 through Commission Decision 2011/8/EU, which was repealed by Commission Decision 2011/44/EU of 19 January 2011. Protection measures applied until 30 September 2011.

Surveillance in susceptible wildlife, particularly wild boar was initiated in January 2011. A plan for the eradication of FMD in wild animals (hereafter referred to as the Eradication Plan), taking into account Part B of Annex XVIII of Council Directive 2003/85/EC, was submitted to the Commission on 4 April 2011 and approved by Commission Implementing Decision 2011/493/EU of 5 August 2011.

Bulgaria is not currently included among those countries with officially recognised FMD-free status according to OIE Resolution No 14 (adopted during the 80th General Session of the OIE International Committee, May 2012), which has been published on the OIE website:

<http://www.oie.int/en/animal-health-in-the-world/official-disease-status/fmd/list-of-fmd-free-members/>

The Commission and the EU Member States have been kept informed of the FMD situation in Bulgaria *inter alia* through several presentations made to the Standing Committee on the Food Chain and Animal Health (SCFCAH) Section Animal Health & Animal Welfare. These presentations have been made available on the internet: [http://ec.europa.eu/food/committees/regulatory/scfcah/animal\\_health/index\\_en.htm](http://ec.europa.eu/food/committees/regulatory/scfcah/animal_health/index_en.htm).

Virus strains from the index case in wild boar and from outbreaks 1, 2, 5 and 6 have been genotyped and the results have been published on the website of the World FMD Reference Laboratory ([http://www.wrlfmd.org/fmd\\_genotyping/2011.htm](http://www.wrlfmd.org/fmd_genotyping/2011.htm)). The genotyped strains from the outbreaks in domestic animals (cattle) were all of FMD serotype O, topotype ME-SA and strain PanAsia-2 ANT-10.

A Scientific Opinion by the European Food Safety Authority (EFSA) on foot-and-mouth disease in this geographical region (Thrace) was published on the EFSA website on 4 April 2012 together with an External Scientific Report on the epidemiology of FMD virus in wildlife in Thrace (<http://www.efsa.europa.eu/en/publications/efsajournal.htm>).

The Bulgarian competent authorities and EFSA have concluded that the introduction of FMD virus into Bulgaria most likely took place in December 2010 and that the FMD virus strains isolated in Bulgaria appear to share a single recent ancestor most closely related to strains circulating in Anatolian Turkey. Spread of FMD within Bulgaria is believed to have taken place both through the

wildlife population and through human intervention procedures.

## **5 FINDINGS AND CONCLUSIONS**

### **5.1 LEGISLATION**

#### **Legal requirements**

Article 4 of Regulation 882/2004 requires the CA to have the legal powers to carry out official controls.

#### **Findings**

The legal basis for eradication of emergency diseases is described under point 1 of Part 1: Strategy and Resource Plan, Contingency Plan for Emergency Diseases in Bulgaria. Legislation related to disease in bovine, ovine and caprine animals (point 1.4) and swine (point 1.3) includes Ordinance No 17 dated 3 February 2006 transposing Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease. In addition, an overview of the relevant legislation pertaining to registration of holdings and animals is included in the Operation Manual for Foot-and-Mouth Disease and the legal requirements for humane killing of animals are included in the Instruction on Humane Killing of Animals Annex II. A list of legal requirements, linked to the measures under the Eradication Plan, with legal references and examples of violations, administrative and punitive actions is included in the approved Eradication Plan. The FVO team noted that:

- Ministerial Orders and instruction letters were issued promptly whenever needed during the eradication of the 2011 FMD outbreaks and for the implementation of the Eradication Plan;
- no evidence was seen that measures had been delayed or otherwise hampered by a lack of legal powers.

#### **Conclusion**

The competent authority has the legal powers to carry out official controls and additional legal documents can be issued rapidly when needed.

### **5.2 COMPETENT AUTHORITIES AND HORIZONTAL ISSUES**

#### **Legal requirements**

Regulation (EC) No 882/2004 lays down general rules for the performance of official controls to verify compliance with rules aimed at preventing, eliminating or reducing to acceptable levels, risks to humans and animals. In particular, this includes Article 3 in respect of the general obligations with regard to the organisation of official controls, Article 4 in respect of designation of competent authorities, operational criteria and audits, Article 6 in respect of staff performing official controls, Article 8 in respect of control and verification procedures, Article 9 in respect of reports, Article 54 in respect of action in case of non-compliance and Article 55 in respect of sanctions.

Article 72 of Council Directive 2003/85/EC requires the CA to ensure coordination with neighbouring EU Member States and encourage cooperation with neighbouring third countries for

the rapid and efficient eradication of an outbreak of FMD.

Section I of Annex I to Regulation (EC) No 854/2004 requires that, in slaughterhouses, inspection tasks have to be carried out by official veterinarians (Chapter II) and health marking has to be supervised by official veterinarians (Chapter III).

## Findings

The central competent authority for animal health is the BFSA under the Ministry of Agriculture and Food. The Animal Health and Welfare Directorate of the BFSA is responsible for harmonisation and drafting legal documents relevant to its competencies. It also arranges for veterinary preventive measures against infectious and parasitic diseases including zoonoses and prepares the annual prophylactic, monitoring and eradication programmes. This Directorate is responsible for the preparation of contingency plans and for drafting guidelines and instructions for the 28 Regional Food Safety Directorates (RFSD) on the implementation of animal health measures.

The Training and Qualification Directorate of the BSFA maintains a database for qualification of BSFA staff at central and regional levels and it plans, coordinates and organises staff training.

The Internal Audit Directorate in the BFSA is responsible for carrying out audits on the official controls implemented by the RFSD, by the official veterinarians in the municipalities and by the authorised (private) veterinarians. Between January 2011 and April 2012 audits in the field of animal health had been carried out in nine regions, none of which was visited by this FVO team.

Each RFSD is responsible for planning, coordination, supervision and verification of the effectiveness of official controls in the region. In the regions there are official veterinarians in each of the 275 municipalities, who are responsible for the implementation of official controls in their municipality. In addition, the RFSDs sign annual contracts with private veterinarians (organised in *circa* 1000 districts) for tasks related to *inter alia* government vaccination programmes, identity controls on animals and surveillance (tuberculosis, Newcastle disease etc). These contracts are based on a standard contract agreed annually between the BFSA and the Bulgarian Veterinary Association, where fees for each activity are specified. An individual plan for each contracted veterinarian is drawn up based on the national BFSA annual programme.

The effectiveness of official controls in municipalities is checked by RFSD using standardised check lists. The RFSDs of Burgas, Yambol and Haskovo had each carried out checks on the effectiveness of such official controls in two municipalities during 2011, comprising verification of tasks carried out by the official veterinarians as well as those carried out by contracted private veterinarians.

The National Diagnostic and Research Veterinary Institute (NDRVI) which includes the national reference laboratory (NRL) for FMD, operates under the Laboratory Activities Directorate of the BFSA.

The Executive Forest Agency, which is the central competent authority for hunting of wild game, belongs to the same ministry as the BFSA. The Regional Directorates of Forestry are involved in the monitoring of FMD in wild game with the help of members of the National Union of Hunters and Anglers. The national police and the border police of the Ministry of Interior are involved *inter alia* in checks on movement restrictions in the restricted zones. The FVO team noted that:

- during the course of the 2011 FMD outbreak the former National Veterinary Service was reorganised into the BFSA. There were no major changes to the Directorates most involved (Animal Health and Food Control) and there was no evidence that this reorganisation had been disruptive to the eradication of FMD;
- on 6 January, the day after FMD was diagnosed in a wild boar in Burgas region, the first Order was issued which re-allocated official veterinarians and veterinary inspectors (official staff) from other regions to RFSD Burgas, where the control measures were implemented;
- detailed written instructions (issued 5 January) were provided to the teams of official staff sent out to assist the official veterinarians in the municipalities in checking susceptible animals for signs of FMD and collecting blood samples;
- the members of staff re-allocated from other regions were briefed on arrival by representatives from BFSA and daily briefings for staff involved in the 2011 FMD outbreaks were held in the regional crisis centre;
- members of the regional police and the Regional Forestry Directorate were part of the regional crisis centre from the very beginning of the outbreaks;
- Burgas RFSD stated that no contracted private veterinarians had been involved in the official controls relating to the FMD outbreaks. All FMD-related documents seen in the regional and local offices were signed by official veterinarians. Consequently, no specific follow-up of recommendation 2 in the 2009 FVO report was possible during this audit;
- an Official Letter (No 3563, 4.8.2011) ordered the three regions concerned to arrange training regarding the implementation of the Eradication Plan for all official veterinarians from the nine municipalities in the geographical area covered by this plan. This training had been organised 10.8.2011 and course documentation and a participation list were available;
- official staff, police and hunters interviewed by the FVO team had generally received adequate briefings, instructions, training and equipment for their tasks, with the exception of staff in the NRL (see point 5.3) and certain aspects of the tasks delegated to hunters (see point 5.6);
- in the slaughterhouse visited an official veterinarian was present and supervised the activities when slaughter took place;
- the verification visits in the slaughterhouse visited by the FVO team had comprised annual inspections of the establishment by staff of the Food Control department of the RFSD. The compliance of the establishment was used as a measurement of the effectiveness of the official controls conducted by the official veterinarian on site. These verification visits were well documented and the reports were compiled at RFSD level;
- a list of enforcement measures during 2011 and the first quarter of 2012, relevant within the framework of the FMD eradication was provided by the BFSA. This list showed that in total 675 non-compliances had been identified in 18 regions. In total 262 warning letters ("prescriptions") and 410 penalties had been issued. Penalties (within the limits laid down in national legislation) were adjusted according to the level of income of the persons or legal bodies subject to penalties in order to be effective, proportional and dissuasive.

## Conclusion

The division of responsibilities between competent authorities at all levels are well defined. There was good cooperation and coordination between and within the authorities involved in the 2011 FMD outbreaks. Staff involved in the 2011 FMD outbreaks had the necessary training, instructions and equipment to carry out their tasks effectively. There is a system in place for verification of effectiveness of official controls and the way verifications are carried out at regional level should be sufficient to form a basis for an overall assessment by the central competent authority.

### 5.3 LABORATORY

#### Legal Requirements

Requirements for designation of official laboratories are laid down in Article 12 of Regulation (EC) No 882/2004. Article 4(2)(c) of Regulation (EC) No 882/2004 requires the competent authorities to ensure that they have access to an adequate laboratory capacity for testing.

Article 33 of Regulation (EC) No 882/2004 requires each Member State to designate a national reference laboratory (NRL) for each EU reference laboratory and defines the tasks of an NRL.

The diagnostic tests and standards for FMD and for the differential diagnosis of other vesicular virus diseases are laid down in Annex XIII of Council Directive 2003/85/EC. Point 8 of Annex XVII to Council Directive 2003/85/EC requires that provisions are made in the contingency plan for adequate resources including personnel, equipment and laboratory capacity.

#### Findings

The NDRVI is designated as the NRL for *inter alia* FMD and swine vesicular disease by Ministerial Order No RD 09-773 of 15.09.2011. As required under Article 33(4) of Regulation (EC) No 882/2004 this information has been made publicly available on the website of the Commission.

The FVO team visited the Testing Laboratory for Exotic and Extremely Dangerous Infections, within the NDRVI, which is responsible for the FMD NRL tasks as well as for all routine testing for FMD. This laboratory is located in the suburbs of Sofia and not on the same premises as the main NDRVI laboratory. The NDRVI is accredited to the standards of International Organisation for Standardisation (ISO) 17025:2005 by the Bulgarian Accreditation Service. The separate location of the FMD NRL is specified in the current accreditation certificate, which is valid until 30 June 2013.

The NRL informed the FVO team that actions had been taken to upgrade the items listed under "machinery" in Annex 6 to the Eradication Plan. These actions relate to the recommendations in the 2010 FVO report on handling of live FMD virus which will be followed up separately by the Commission. The FVO team noted that:

- as required in Part I of the general contingency plan the NRL had a laboratory contingency plan for FMD comprising *inter alia* those methods which would be available for detection of FMD antibodies or antigen. However, although the FMD NRL is not authorised to handle live FMD virus the current laboratory contingency plan, which had been updated in 2012, still included certain methods requiring the handling of live virus. In addition, the laboratory contingency plan did not provide sufficient information on how to handle incoming samples with regard to the sequence of analyses to use;

- staff responsible for FMD testing was well trained for the range of methods applicable and was well aware of the advantages and limitations of each method;
- samples were under official control while transported to the laboratory;
- maximum sample turnaround times have not been defined but turnaround times had been satisfactorily short (1-3 days) also during the peak of the 2011 outbreaks;
- three enzyme-linked immuno-sorbent assays (ELISA) listed in the laboratory contingency plan for detection of antibodies against non-structural proteins of FMD virus (NSP-ELISA), antibodies against structural proteins of FMD virus by liquid-phase blocking ELISA (LPBE) and antigen of FMD virus and swine vesicular disease virus (indirect sandwich ELISA) were included in the scope of accreditation;
- although routinely used for analyses of FMD samples from domestic and wild animals, neither the ELISA for antibodies to FMD virus serotype O (type O ELISA) nor the real-time reverse-transcription polymerase-chain reaction method (real time RT-PCR) used for FMD virus genome detection were included in the scope of accreditation;
- there were no procedures in place in the NRL describing the sequence in which the available analytical methods should be applied on incoming samples. Nor has this been agreed between the BFSa and the NRL. According to NRL staff the methods used and the sequence of testing were decided day by day based among other things on the availability of kits and reagents;
- whilst in the beginning of the 2011 FMD outbreaks serological samples were analysed using NSP-ELISA and LPBE (albeit using only reagents for serotype O), towards the end of the outbreaks and for the subsequent serological surveys under the Eradication Plan the vast majority of serum samples were screened only with the type O ELISA. Screening positive samples were re-tested with the same method or occasionally tested with NSP-ELISA;
- the laboratory had participated in the annual proficiency tests for FMD organised by the EU-RL, mostly with successful results. No results had been received from the EU-RL for the 2011 proficiency test which was carried out in June 2011;
- immediately after receipt (in August 2011) of the results of the 2010 proficiency tests an action plan to increase the sensitivity of the type O ELISA had been drawn up by the NRL in line with recommendations from the EU-RL. However, the actions taken had not been documented. Nor had they been verified by the quality manager of the laboratory or by the accreditation body during the subsequent audit in February 2012;
- due to a lack of storage facilities the NRL does not retain samples which have been analysed so there is no possibility to re-test samples with other methods at a later stage;
- most of the planned actions to upgrade the NRL, which were outlined in Annex 6 to the Eradication Plan, had not been taken. These actions included purchase of i) equipment for storage and testing ii) sufficient quantities of consumables for serology iii) sufficient quantities of consumables for antigen detection. The competent authorities stated that the reason for this lack of action was unsuccessful tendering.

## Conclusion

Whilst the NRL, which is accredited to EN ISO/IEC 17025:2005, has the competence and capability to provide rapid and reliable test results, and did so during the 2011 FMD outbreak, the documenting routines in the laboratory are inadequate. A number of the analytical methods routinely used for official FMD samples are not included in the scope of accreditation which does not meet the requirements of Article 12 point (2) of Regulation (EC) NO 882/2004. The main weakness in the FMD surveillance system is a chronic lack of sufficient supplies of adequate consumables. This has resulted in the use of sub-optimal test methods which, although sufficient to determine the spread of foot-and-mouth virus linked to the 2011 outbreaks, are not suitable for serological surveillance in wildlife and domestic animals intended to detect future possible introductions of other serotypes of FMD virus into Bulgaria.

### 5.4 LIFTING OF RESTRICTIONS IN THE PROTECTION AND SURVEILLANCE ZONES

#### Legal requirements

Article 3 of Council Directive 2003/85/EC requires Member States to notify the Commission when an outbreak of foot-and-mouth disease or a primary case of foot-and-mouth disease in wild animals is confirmed and to provide information and written reports to the Commission and the other Member States in accordance with Annex II of the Directive.

Measures to be taken if an outbreak of FMD is suspected are laid down in Articles 4-9 of Council Directive 2003/85/EC. Measures to be taken in case of confirmation of FMD are laid down in Articles 10-14 of this Directive. Protection and surveillance zones shall be established in accordance with Article 21 Council Directive 2003/85/EC and measures to be applied in those zones are laid down in Articles 22-35 (protection zone) and Articles 37-43 (surveillance zone). Articles 36 (protection zone) and 44 (surveillance zone) specify the requirements which have to be met before the restrictions can be lifted.

Certain interim protection measures against foot-and-mouth disease in Bulgaria were laid down in Commission Decision 2011/8/EU of 6 January 2011<sup>1</sup>. This Decision was repealed on 19 January by Commission Decision 2011/44/EU. Annexes I and II to these Decisions defined those areas in Bulgaria which were subject to specific measures regarding animals and animal products. The boundaries of the areas in Annexes I and II were amended on 19 January and 1 July 2011. These measures applied until 30 September 2011.

#### Findings

When the first case of FMD was diagnosed on 5 January 2011 in a wild boar which had been shot on 30 December 2010 notification was immediately provided to the other Member States and to the Commission and measures in line with the requirements of Council Directive 2003/83/EC were applied. Eleven outbreaks of FMD in two series (outbreaks 1-3 and outbreaks 4-11) were detected in domestic animals between 9 January and 7 April 2011.

The Bulgarian competent authorities provided the Commission and other Member States with regular updates of the FMD situation in Bulgaria *inter alia* through presentation to the Section: Animal Health & Animal Welfare of the Standing Committee on the Food Chain and Animal Health

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<sup>1</sup> Commission Decision 2011/8/EU of 6 January 2011 concerning certain interim protection measures against foot-and-mouth disease in Bulgaria. OJ L 6, 11.1.2011, pp 15-29.

(SCFCAH). The last Bulgarian presentation about the 2011 outbreak, made in July 2011, has been published on the SCFCAH website:

[http://ec.europa.eu/food/committees/regulatory/scfcah/animal\\_health/presentations/0506072011\\_fm d\\_Bulgaria\\_en.pdf](http://ec.europa.eu/food/committees/regulatory/scfcah/animal_health/presentations/0506072011_fm d_Bulgaria_en.pdf)

The FVO team noted that:

- the measures laid down in Commission Decision 2011/8/EU and Commission Decision 2011/44/EU had been implemented without delay;
- protection zones and surveillance zones in line with EU legislation had been implemented around each of the 11 FMD outbreaks. The protection and surveillance zones around the second wave of outbreaks (outbreaks 4-11) detected 19 March – 7 April 2011 were merged forming a common inner protection zone and outer surveillance zone until all measures in each zone were finalised for all eight outbreaks;
- in accordance with official Orders, on 18-19 April 2011 clinical examinations were carried out and samples were collected from susceptible animal species in the 17 villages inside the protection or surveillance zones where there were still animals. Sample numbers for each village were in excess of the minimum numbers calculated for a 5% detection rate with 95% confidence;
- sampling and clinical examination were carried out in 16 villages on 28-29 April and on 18-19 May 2011. All samples were negative for antibodies to FMD serotype O. One of the 17 villages, which was located near the outer edge of the 10 km zone for outbreak VII (24.3.2011), had been omitted from these two Orders and although sampled once, more than 21 days after outbreak VII, no sampling took place in this village in April or May 2011. However, this village was one of the 106 villages subject to regular clinical checks and sampling under the Eradication Plan from August 2011;
- on 18-19 April and on 18-19 May 2011 clinical examination and sampling were carried out in randomly selected villages (40 and 14, respectively) around the surveillance zone, i.e. more than 10 km from an FMD outbreak. Sample numbers for each village were in excess of the minimum numbers calculated for a 5% detection rate with 95% confidence. All samples were negative for antibodies to FMD serotype O;
- between February and April 2011, 19 wild boar and six roe deer were sampled and in June 2011 a further 52 wild boar, 17 roe deer and 2 red deer were sampled for detection of FMD antigen and antibodies. Two adult wild boar and three adult roe deer sampled in June had antibodies to FMD serotype O. No FMD antigen was detected in any of the samples;
- detailed minutes from a meeting in the National Crisis Centre on 30 June 2011 show that a thorough review was made on all measures taken to that date (more than 70 days after the last culling of an infected herd, sampling and clinical examinations in line with EU legislation, final disinfection carried out by 10 June). The amendments to Annexes I and II to Commission Implementing Decision 2011/388/EU were also discussed;
- on 4 July Order 11-713 lifted the protection and surveillance zones around outbreaks 4-11, implemented the amended restricted zones in Annexes I and II to Commission Implementing

Decision 2011/388/EU (valid until 30 September 2011), and reiterated the applicable restrictions.

## **Conclusion**

The measures taken before the protection and surveillance zones were lifted were in line with EU legislation and can be considered sufficient to establish that the FMD virus causing the 2011 outbreak was no longer circulating. The testing for antibodies only to FMD serotype O was sufficient for this purpose. In reality, the lifting of the protection and surveillance zones made little difference on the surveillance for FMD because regular clinical examinations and serosurveillance of domestic animals continued for another year under the Eradication Plan for FMD in wild animals and movement restrictions still remained in place in June 2012. In addition, these measures had been extended under the Eradication Plan to cover a larger area than that covered by last amended version of Commission Decision 2011/44/EU.

### **5.5 IMPLEMENTATION OF THE ERADICATION PLAN FOR FMD IN WILD ANIMALS**

#### **Legal requirements**

Measures to be taken if FMD is suspected in wild animals are laid down in Article 85.3 of Council Directive 2003/85/EC.

Article 3 of Council Directive 2003/85/EC requires Member States to notify the Commission when an outbreak of foot-and-mouth disease or a primary case of foot-and-mouth disease in wild animals is confirmed and to provide information and written reports to the Commission and the other Member States in accordance with Annex II of the Directive.

In accordance with Article 85.4, Part A of Annex XVIII of Council Directive 2003/85/EC specifies the measures to be applied immediately when FMD has been confirmed in wild animals. These measures include the drawing up of an Eradication Plan, meeting the requirements in Part B of the Annex, and the submission of the Eradication Plan to the Commission for approval.

Commission Implementing Decision 2011/493/EU approved the Bulgarian plan for eradication of FMD in wild animals and Commission Implementing Decision 2011/855/EU laid down the terms for a financial contribution from the Union for its implementation.

#### **Findings**

On 4 April 2011 the Bulgarian competent authorities submitted to the Commission a plan for eradication of FMD in wild animals. This Eradication Plan was approved by Commission Implementing Decision 2011/493/EU, which defines in its Annex the areas where the Eradication Plan was to be implemented, i.e. the Cordon Sanitaire. Commission Implementing Decision 2011/855/EU provided the legal basis for a financial contribution from the Union for certain costs incurred in implementing the Eradication Plan between 4 April 2011 and 3 April 2012. The main components of the Eradication Plan in the Cordon Sanitaire were:

- movement restrictions on animals and products;
- active surveillance (shooting/trapping, sampling and laboratory analysis) of susceptible wild animals;

- passive surveillance (sampling and laboratory analysis) of dead wild animals of susceptible species;
- documented clinical examination of domestic animal herds in all 106 villages in the Cordon Sanitaire at least every 21 days;
- at least every 90 days, blood sampling from susceptible animals for serological examination, aimed at detecting a 5% sero-prevalence with 95% confidence in each epidemiological unit (=village).

A report on the implementation of the Eradication Plan during the period from February 2011 to January 2012 and an intermediate technical and financial report for the period 4/4/2011 – 31/12/2012 were submitted to the Commission by the competent authority on 23 and 24 March 2012, respectively. The FVO team noted that:

- based on the EU approval of the Eradication Plan on 5 August 2011 an Order by the Minister of Agriculture and Food issued on 19 September approved the Eradication Plan at national level;
- once the restrictions imposed under Commission Decision 2011/44/EU had expired on 30 September 2011, BSFA Order 11-1234 of 12 October imposed the movement restrictions defined in the Eradication Plan. However, in the areas formerly covered by restrictions under Commission Decision 2011/44/EU all restrictions remained enforced by the competent authorities during the intervening 12 days;
- separate Orders had been issued by the BFSA for each round of sampling of domestic animals. The first sampling and clinical checks in the 106 villages in the Cordon Sanitaire established by the Eradication Plan were carried out 16-25 August 2011, i.e. before the formal approval of the Eradication Plan under national legislation;
- although the Eradication Plan ended 3 April 2012 all restrictions in the Cordon Sanitaire imposed by Order 11-1234 of 12 October 2011 were still in force at the time of this FVO audit (June 2012);
- when the measures under the Eradication Plan ended, the BFSA implemented a national surveillance programme (4 April to 31 December 2012) for FMD in domestic livestock in 37 villages in a 10 km zone along the Turkish border. Under this national programme the BFSA plans to continue the clinical and serological surveillance as under the Eradication Plan and to sample 100 wild boar in the area near the Turkish border during the 2012-13 hunting season.

#### ***5.5.1 Epidemiological surveillance in domestic animals***

##### **Findings**

Under the Eradication Plan sampling of domestic animals in 106 villages in the Cordon Sanitaire was carried out for serological investigation on 16-25 August 2011 (5203 samples), 21-25 November 2011 (5295 samples) and 20-25 February 2012 (5334 samples). In addition, serum samples from semi-domestic East-Balkan pigs were collected between February 2011 and May 2012 in the regions of Burgas (553 samples), Shumen (558 samples) and Varna (80 samples). All

samples were negative for antibodies to FMD virus serotype O. The FVO team noted that:

- after sampling in April and May 2011 in 16 villages within 10 km of the second cluster of outbreaks and in a number of randomly selected villages outside this zone, clinical checks and sampling of domestic animals in all 106 villages in the Cordon Sanitaire started in August 2011. Since then the sampling had been carried out at three-monthly intervals in accordance with the Eradication Plan;
- documents checked in the local office visited showed that clinical inspections, using a standardised protocol, had been carried out by the official veterinarian at three-weekly intervals in accordance with Eradication Plan;
- when determining the sample numbers needed to detect a 5% prevalence with 95% confidence each village had been considered as one epidemiological unit, also when certain groups of animals were kept some distance away with very limited or no contact with the other livestock in the village;
- the vast majority of samples taken for serosurveillance under the Eradication Plan and the national plan were tested only for antibodies to FMD virus serotype O;
- after the Eradication Plan ended 3 April 2012, surveillance had continued in 37 of the 106 villages under a national surveillance plan. Sampling had been carried out in these 37 villages 28-31 May 2012. All these samples had been negative for antibodies to FMD serotype O;
- the BFSA has submitted a 2013 surveillance plan to the Commission for approval.

### ***5.5.2 Epidemiological surveillance in wildlife***

#### **Findings**

During the thirteen months between January 2011 and January 2012, samples for FMD testing were collected from 812 wild boar (*Sus scrofa*), 68 roe deer (*Capreolus capreolus*), seven red deer (*Cervus elaphus*) and two moufflon (*Ovis orientalis musimon*). None of the sampled wild animals were positive for FMD virus.

However, 6.9% of the wild boar samples and 4.4% of the roe deer samples were seropositive for antibodies to FMD serotype O. The seropositive wild animals were all found in the vicinity of the FMD outbreaks in domestic animals. No seropositive red deer or moufflon were detected in the limited number of samples from these species.

Before each hunting day the hunting team must obtain a hunting licence from the Forest Service of the Municipality. A prerequisite is that at least one member of the team must have participated in a training regarding FMD provided by the regional or local staff of the BFSA. Each municipal office holds a list of approved freezers for storage of sampled carcasses pending laboratory results with a named keeper for each freezer. Practical instructions for hunters have been provided in the form of a leaflet describing the symptoms of FMD in wild animals, how to carry out sampling and how to package and store the carcass and all offal pending the analytical results. Sampling equipment is

collected from the official veterinarian in the municipality and samples are brought back after the hunt when the report of the outcome of the hunt, including a list of all participating hunters, is filed with the official veterinarian. For each sampled carcass, the official veterinarian issues an official document prohibiting further use of the carcass. Once sample results are available the official veterinarian either releases the carcass to the hunters or orders supervised rendering of the carcass and its offal. The FVO team noted that:

- in the municipality visited all sampling had been carried out by hunters. Records showed that at least one hunter in each hunting team had received training on how to carry out sampling of blood and tissue from wildlife and how to package and store the carcass and offal;
- a list of approved freezers, their locations and the names of the responsible keepers was available in the municipality visited;
- although comprehensive measures were in place to prevent a potential spread of FMD directly from the sampled wild animals pending the laboratory results there are no instructions about personal hygiene (hand wash, cleaning of clothes) or restricted contacts with domestic animals on return from the hunt to prevent indirect transfer of virus. No protective clothing (e.g. gloves and aprons) was provided with the sampling equipment to the hunters taking the samples;
- under the Eradication Plan "emergency hunting" and trapping was carried out during April, June, August and September 2011 (before the hunting season) resulting in sampling of 72 wild boar and 35 deer. Two adult wild boar and two adult roe deer were seropositive for FMD virus serotype O in June;
- during the 2011-2012 hunting season all killed wild boar were sampled, resulting in 723 samples between October 2011 and January 2012, of which 54 were seropositive to FMD virus serotype O. Of these, all four seropositive juvenile wild boar were killed in October (2) and November (2) when no remaining maternal antibodies were expected to be present;
- calculated on the 793 samples taken from wild boar between June 2011 and January 2012, the seroprevalence in juvenile wild boar (born in 2011) was 1.6% (four out of 254) which is significantly lower ( $p < 0.0001$ ) than the 9.6% seroprevalence in older wild boar (52 out of 539);
- no samples had been analysed from wild animals of susceptible species found dead (passive surveillance). The local authorities and hunters interviewed stated that finding such animals before they are eaten by scavengers or decomposed would be extremely difficult in the border area;
- on 23 March 2012 the BSFA issued an Order to all RFSDs that tests for FMD should be requested on the laboratory submission form for all samples taken from wild boar for analysis for classical swine fever anywhere in the territory of Bulgaria;
- fourteen wild boar had been sampled in areas to the north of the Cordon Sanitaire during March – May 2012. No antibodies to FMD serotype O had been detected in these animals;
- no further sampling of wild boar for FMD or classical swine fever is planned before the next

hunting season starts in October 2012.

### **5.5.3 Controls on movement of FMD-susceptible animals and animal products from the “Cordon Sanitaire”**

#### **Findings**

The road blocks and fixed check points, which had been in place during the 2011 outbreak, were removed when the restrictions linked to the outbreak were lifted. Controls on movement restrictions under the Eradication Plan and the subsequent national surveillance plan were carried out by mobile units. The FVO team noted that:

- checks on the restrictions on movement of animals and products under the Eradication Plan were carried out in cooperation between the road police, the border police and the regional and local staff of the BFS. Whenever a police unit detected potential non-compliances official veterinarians were called in to further investigate the transport;
- in the slaughterhouse and cutting plant visited the official veterinarians ensured that no products were sold to clients outside the region, in accordance with the restrictions under the Eradication Plan. These restrictions were still in place at the time of this audit (June 2012);
- a list of non-compliances detected within the framework of the FMD eradication since January 2011 showed that in excess of 200 non-compliances relating to movement of animals or animal products had been identified in the seven regions covered by the restrictions under Commission Decision 2011/44/EU. During the same period 37 non-compliances relating to movement and identification of animals had been reported in the other regions. In most cases penalties had been issued and in some cases animals had been euthanized and disposed of.

#### **Conclusions on the implementation of the Eradication Plan for FMD in wild animals**

The intensive controls on movements of animals and products, which were implemented during 2011, were facilitated by a well functioning cooperation between the competent authorities involved. Sampling and clinical checks on domestic animals and wildlife were mostly carried out in accordance with the EU-approved Eradication Plan. Regular clinical checks by official veterinarians in the 106 villages in the Cordon Sanitaire during the year following the last FMD outbreak in April 2011, and analyses of representative numbers of samples provided the competent authorities with reliable data showing that the "stamping out" of the 2011 outbreaks had been successful. Although the passive surveillance of wild animals found dead was never implemented, the results from analyses carried out on samples from wild animals (mostly wild boar) shot or trapped in the Cordon Sanitaire indicate that there was no circulation of FMD virus outside the vicinity of the 2011 outbreaks and very limited spread of the infection to juvenile wild boar, which would have been born during the end of the outbreak.

## **5.6 FMD CONTINGENCY PLAN**

### **Legal Requirements**

Article 72 of Council Directive 2003/85/EC requires that a contingency plan be drawn up specifying the national measures required to maintain a high level of FMD awareness and preparedness, and environmental protection and to be implemented in the event of an outbreak of FMD. Criteria and requirements for contingency plans are laid down in Annex XVII to the Directive.

## Findings

As described in the 2009 FVO report the Bulgarian contingency plan is divided into three parts, where part I is a strategy and resource plan, which needs to be adapted to local conditions by each Regional Food Safety Authority. Part II comprises the disease-specific Operational Manuals and Part III comprises Annexes with detailed instructions for specific practical aspects of the contingency. In addition part I requires the NRL to have a contingency plan (see section 5.3). The FVO team noted that:

- there is a joint Ordinance between the Minister of Interior and the Minister of Agriculture and Food in which cooperation/coordination between the police forces and the BFSA is regulated. In addition, Article 11 of the Law on Veterinary Activities obliges all other authorities to assist official veterinarians when necessary;
- during the outbreak key members of the national crisis centre spent most of their time between the briefing meetings at central level in the regional crisis centre in Burgas in order to supervise and assist the regional crisis centre and staff involved in measures to control the outbreaks and eradicate FMD;
- the cooperation between the RFSD, the regional police and the regional Forestry Department was well established before the outbreak and the regional police was represented in the regional epizootics board;
- during the outbreaks regular meetings were held at all relevant levels and detailed minutes were available at central level and in the office visited. Meeting minutes from the national crisis centre outlined the rationale for major decisions taken during the eradication and for the lifting of restrictions;
- numerous awareness campaigns were carried out using a range of media. Private veterinarians were specifically briefed but were not involved in the official control measures. During the initial visits to holdings in 2011 each owner/keeper was obliged to receive and sign for information about FMD and how to proceed if signs of the disease were observed in the herd;
- in response to recommendation 3 of the 2009 FVO report the Operational Manual for FMD was updated in 2010 and now comprises a section about "worst case scenario" which makes reference to Annex X of Directive 2003/85/EC, discusses the decision process regarding the use of vaccination and identifies the national integrated information System (VetIS) as the tool to determine which regions contain densely populated livestock areas;
- following the 2011 FMD outbreak Part III, Annex II: "Killing of animals" was amended and a new system was introduced for colour markings, using one colour to mark an anesthetized animal and adding a second colour mark once the animal had been given the preparation for euthanasia;

- in the Contingency Plan information on disinfectants and disinfection are included in the Strategy and Resource Plan (part I, general) , in the Operational Manual for FMD (part II, disinfection of infected holdings) and in the practical instruction on "disinfection, disinsectisation and deratisation" (part III, general information). Whilst in Part II information is provided that disinfectants should be applied only to cleaned surfaces, Parts I and III do not provide information on these or other limitations of certain products;
- Order 11-11 from January 2011 comprised *inter alia* requirements for cleaning of animal transport vehicles to prevent spread of FMD and made reference to Part III of the Contingency Plan. These instructions had been adhered to in the slaughterhouse visited and the procedure for cleaning and disinfection of vehicles had been approved by the official veterinarian on site. However, the disinfectant was applied twice, once on the manure before its removal and once on the dirty surfaces afterwards, before the final mechanical cleaning took place. In addition, the product chosen for disinfection of manure and dirty surfaces in transport vehicles was one which rapidly loses its effect in contact with organic material and consequently would have been unlikely to inactivate FMD virus had it been present;
- there are no general or disease specific instructions regarding precautions which should be taken when sampling for an epizootic disease in order to prevent indirect spread of the virus via samplers or equipment in the General Contingency Plan (Part I), the Operation manual for FMD (Part II) or in the instructions under Part III.

### **Conclusions on the FMD contingency plan**

Recommendation 3 of the 2009 FVO report has been satisfactorily addressed. In general, the implementation of the contingency plan during the FMD outbreak was effective, all actions were well documented and when deficiencies in the contingency plan were identified the necessary amendments of the contingency plan were made. However, the lack of instructions in the contingency plan regarding biosafety measures during sampling increases the risk of indirect spread of highly infectious agents, e.g. FMD virus. In addition, the BSFA Order on *inter alia* the use of disinfectants on animal transport vehicles for animals from restricted zones made reference to a part of the contingency plan where instructions were not sufficiently detailed to ensure that infectious agents (e.g. FMD virus) were inactivated under field conditions. These two deficiencies could potentially have led to inadvertent spread of the infection during the 2011 FMD outbreaks.

## **6 OVERALL CONCLUSIONS**

In Bulgaria, there is an overall well functioning system in place for implementation of contingency and control measures against FMD and for the implementation of disease surveillance in domestic and wild animals. The implementation of the contingency plan for FMD was generally effective, however certain deficiencies were noted with regard to the instructions for sampling and for disinfection and cleansing of animal transport vehicles.

Adequate measures were taken before the lifting of restrictions linked to the 2011 FMD outbreak. The implementation of the Eradication Plan for FMD in wild animals was in accordance with the plan, which had been approved under Commission Implementing Decision 2011/493/EU. Even after the conclusion of the Eradication Plan in April 2012 movement controls and certain surveillance measures in the areas closest to the border with Turkey are still in place under national

legislation.

Intensive monitoring of domestic animals during 14 months after the last outbreak has shown that the stamping out of the 2011 outbreaks was successful. The results from wild animals sampled until January 2012 indicate that the spread of FMD virus serotype O, which caused the 2011 outbreak, to wild animals had taken place only in the vicinity of the outbreaks in domestic animals and that the spread of the virus to juvenile wild boar (born in 2011) had been very limited.

The main deficiencies in this system are seen in the national reference laboratory, which is responsible for all testing for FMD. A chronic lack of sufficient supplies of adequate consumables has resulted in the use of sub-optimal test methods which, although sufficient to determine the spread of foot-and-mouth virus linked to the 2011 outbreaks, are not suitable for serological surveillance in wildlife and domestic animals intended to detect future possible introductions of other serotypes of FMD virus into Bulgaria. In addition, the two methods commonly used for the Eradication Programme for FMD in wildlife are not included in the scope of accreditation, as required under EU legislation.

## 7 CLOSING MEETING

A closing meeting was held on 15 June 2012 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take what ever actions were necessary in order to rectify the identified deficiencies.

## 8 RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this audit report.

N°.	Recommendation
1.	Ensure that the laboratory has adequate resources for reliable testing of official samples for FMD virus and antigen in order to meet the requirements of Article 4(2)(c) of Regulation (EC) No 882/2004 as well as of Annex XIII and Annex XVII Point 8 of Council Directive 2003/85/EC.
2.	Ensure that all analytical methods used for official samples are included in the scope of accreditation in order to meet the requirements of Article 12(2) of Regulation (EC) No 882/2004.
3.	Ensure that the contingency plan is amended with regard to sampling procedures to make sure that FMD virus is not transferred by persons involved in the sampling of animals and the handling of sampled carcasses to meet the requirements of point 9 of

N°.	Recommendation
	Annex XVII to Council Directive 2003/85/EC and that sampling instructions and sampling equipment are amended accordingly.
4.	Ensure that the instructions for disinfection provided under the contingency plan for foot-and-mouth disease are clear and sufficiently detailed to make sure that the recommended disinfection methods inactivate the virus under field conditions in order to meet the requirements of points 1.2, 1.4, 1.6.2 and 1.6.3 of Annex IV to Council Directive 2003/85/EC.

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

[http://ec.europa.eu/food/fvo/rep\\_details\\_en.cfm?rep\\_inspection\\_ref=2012-6390](http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6390)

## ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
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
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
Dir. 2003/85/EC	OJ L 306, 22.11.2003, p. 1-87	Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC
Dec. 2011/44/EU	OJ L 19, 22.1.2011, p. 20-33	2011/44/EU: Commission Decision of 19 January 2011 concerning certain protection measures against foot-and-mouth disease in Bulgaria
Dec. 2011/493/EU	OJ L 203, 6.8.2011, p. 32-35	2011/493/EU: Commission Implementing Decision of 5 August 2011 approving the plan for the eradication of foot-and-mouth disease in wild animals in Bulgaria
Dec. 2011/855/EU	OJ L 336, 20.12.2011, p. 75-80	2011/855/EU: Commission Implementing Decision of 15 December 2011 on a financial contribution from the Union towards certain measures to eradicate foot-and-mouth disease in wild animals in the south-east of Bulgaria in 2011-2012