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COUNTRY PROFILE OF BULGARIA

ON FOOD AND FEED SAFETY, ANIMAL HEALTH, ANIMAL WELFARE AND
PLANT HEALTH



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EXECUTIVE SUMMARY

Overview

The Ministry of Agriculture and Food (MAF) and the Ministry of Health (MH) have overall responsibility for food safety (including animal health, animal welfare and plant health) in Bulgaria.

The National Council for Food Safety (NCFS) was established within the Council of Ministers in 2005. Its main task is to co-ordinate policy on food safety. Its members are the Deputy Ministers of the Ministry of Agriculture and Food, Health, and Economy and Energy, the head of the Bulgarian association of the food processing and beverage industry and a representative of consumer protection associations.

Bulgaria is divided into 28 regions. The regions are administrative units executing the policy of central government bodies at regional and local level. The regional governors are appointed by the Council of Ministers. Local government in Bulgaria is organised through 264 municipalities.

The responsible bodies within the Ministry of Agriculture and Food are:

- *Food Safety and Quality Directorate* with the role of coordination of the control authorities within the ministry and the audit function.
- *National Veterinary Service* responsible for official controls in the areas of animal health, veterinary public health, animal welfare and feedingstuffs.
- *National Service for Plant Protection* responsible for official controls in the areas of plant health (harmful organisms), authorisation of pesticides and controls on their marketing and use and monitoring pesticide residues in products and raw materials prior to their placing on the market.
- *National Grain and Feed Service* responsible for the official controls of animal feedingstuffs in relation to quality issues, feed hygiene and control of undesirable substances in feedingstuffs and feedingstuffs intended for particular nutritional purposes.

The responsible bodies within the Ministry of Health are:

- *Public Health Directorate* with the role of coordination and supervision of official controls on food of plant origin in production, processing and distribution establishments including retail and catering, and also the import controls of food of plant origin. Regional Inspectorates for Protection and Control of Public Health are responsible for implementation of official controls throughout the country.

Multi-annual Control Plan (MANCP)

The MANCP has been developed for the period of 2008 – 2010. The plan was approved by the National Council for Co-ordination of Controls in October 2008 and sent to the FVO. The plan is structured vertically according to the competent authorities involved in official controls and was prepared in accordance with the Commission Decision 2007/363/EC. The implementation of the plan is carried out through well established, documented procedures. In some sectors, a detailed methodology for prioritization of official controls based on risk categorisation is established and applied.

Audit systems

An internal audit function to verify the implementation of official controls has been established within each of the competent authorities. The audits carried out are based on the principles set out in the Commission Guidelines 2006/677/EC. The summary of reports from such audits is in the case of the National Grain and Feed Service and the Public Health Directorate of Ministry of Health made available to public through their websites. The issue of co-ordination between the audit bodies to produce a seamless audit process has not yet been addressed.

Staff resources

Overall number of full-time equivalent (FTE) staff involved in food safety, animal and plant health, and animal welfare controls in Bulgaria is 3262 staff of which about 3100 work at the regional or local level implementing the controls.

Inspections in Bulgaria by the Food and Veterinary Office (FVO)

Since 2003, the FVO has carried out 47 inspections and 3 general review missions in Bulgaria. The following table gives an overview of the main sectors that have been covered by these inspections:

SECTOR	2003	2004	2005	2006	2007	2008	2009	Total per sector
1. Animal Health		1	1	1	3	1		7
2. Food of Animal Origin	2	1	1	1	4	2		11
3. Imports of animals and food of animal origin		1		2	1	1		5
4. Feedingstuffs and animal nutrition			1	1	1			3
5. TSEs/ABP	1		1	2		3	1	8
6. Veterinary medicines and residues			1	1				2
7. Foodstuffs and food hygiene		1	1	1	1			4
8. Imports of food of plant origin		1	1	1		1		4
9. Plant Protection Products		1	1	1		1		4
10. Animal Welfare			1	1		2		4
11. Plant Health		2	2	1				5
General Review				1	1	1		3
Total no. inspections	3	5	7	13	9	12		50

Progress on FVO recommendations

For 39 of the 47 completed inspections in Bulgaria since 2003, final reports have been issued and action plans received from the Bulgarian authorities setting out how they have responded or intend to respond to the reports' recommendations. These action plans have been assessed by the FVO to determine whether sufficient progress is being made by the Bulgarian authorities to deal with the weaknesses in control systems identified in the inspections. Progress on these recommendations was reviewed during the general review mission in November 2008. The table below summarises the overall situation after the mission.

	Pre-General review mission 2008	Post-General review mission 2008
Action taken / No longer relevant	287	316
For verification / In progress	51	20
Outstanding / Action still required	4	6
Total number of recommendations	342	342

Of the 342 recommendations made in 39 finalised reports, 316 have been closed. Of the remainder, in 6 cases action is still required by the competent authorities and in 20 cases action is in progress.

The main issues that still require to be addressed by the authorities include:

Horizontal issues

Laboratories

The analytical capability of laboratories for analysis of residues of veterinary medicinal products in live animals and in food of animal origin and pesticides in food of plant origin is insufficient. There is need for an increase in the range of analytes covered by the analytical methods for pesticide residues in food of plant origin. Some laboratories designated for official food and feed controls are not accredited yet.

Sector specific Issues

ABP

A proper system for collection of ABP and for official controls needs to be established in particular for: fallen stock, SRM produced during home slaughter of cattle and small ruminants, and rejected foodstuffs in the retail sector

Animal welfare

The system of rearing laying hens in un-enriched cages is not compliant with requirements of EU legislation. The measures taken by the competent authorities need to be reinforced.

Residues of VMP

There is need to cover all mandatory substance groups within the national residue control plan and to have laboratories able to analyse samples including the development and implementation of appropriate analytical methods for all mandatory substance groups (both method development and validation).

Pesticides

A strategy for disposal of obsolete pesticides stored over recent years in the country (13,500 tonnes) needs to be developed and urgent action taken.

Upgrading of establishments

Out of the 585 meat and milk processing establishments on the list of Commission Decision 2007/716/EC - those requiring transitional arrangements to comply with structural requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 - there are currently 425 establishments that still need to comply with such EU requirements. In terms of official controls, these 425 establishments are treated as high risk category establishments. The final assessment of all these establishments needs to be carried out and report prepared by the end of 2009. The FVO inspection planned for October 2009 will assess the progress made.

Recent FVO inspections

For 8 of the 47 FVO inspections in Bulgaria, the process has not yet reached final assessment stage. The following table shows the stage reached for each of these inspections.

2008 Inspections

Ref No.	Mission Date	Sector	Subject of Inspection	Current Status	Issue Date
2008-7687	15/01/2008	Animal welfare	Animal welfare of laying hens and animal welfare during long distance transport	Final Report Action Plan	07/05/2008 (EN) 29/05/2008 (BG) 08/04/2008 (EN)
2008-7950	28/01/2008	Food of animal origin and animal welfare	Food of animal origin and animal welfare at the time of slaughter	Final Report Action Plan	07/07/2008 (EN) 01/09/2008 (BG) 16/06/2008 (EN)
2008-7747	04/02/2008	Imports of animals and food of animal origin	Import/transit controls and border inspection posts (BIPs)	Final Report Action Plan	09/07/2008 (EN) 12/08/2008 (BG) 20/10/2008
2008-7847	26/05/2008	Imports of food of plant origin	Import controls on food and feed of non-animal origin	Final Report	10/10/2008 (EN)
2008-7800	17/06/2008	Animal health	Surveillance, control and eradication of Classical Swine Fever in domestic and feral pigs	Action plan Final Report	4/11/2008 21/11/2008
8013/2008	24/11/2008	Residues	Residues	Final Report	23/02/2008
2008-8023	17/11/2008	Animal health and food of animal origin	Salmonella risk in the table egg sector	Draft Report	18/12/2008
2009-8110	16/02/2009	BSE	Bovine Spongiform Encephalopathy (BSE)	Draft report in reparation	

The main elements identified in these more recent inspections, and not already mentioned above, include:

- Shortcomings in supervision of the BIPs, identification of consignments and implementation of transit requirements
- Implementation of animal welfare checks during transport
- Salmonella National Control Programmes are not yet implemented in line with EC requirements (organisation of programmes, compliance of sampling protocols, review and evaluation of implementation, accreditation of laboratories and their participation in ring tests)
- 2007 and 2008 residues control plans have not been implemented in line with EC requirements. There are no provisions in place to outsource NRCP samples that cannot be analysed in the national laboratory due to lack of analytical capability
- Deficiencies in BSE monitoring (discrepancies in figures concerning sampled and tested animals at central and local levels; no notification of clinical suspects; samples of fallen animals remains very low)

Future FVO inspections

The following inspections are planned in Bulgaria for 2009:

Ref No.	Mission Date	Sector	Subject of Inspection	Current Status
2009-8263	15/06/2009	Animal Welfare	welfare of laying hens and the protection of animals at the time of slaughter or killing	In preparation
2009-8210	06/09/2009	Animal Health	To evaluate the disease contingency plans for epizootic diseases	In preparation
2009-8100	28/09/2009	All	General Review mission	In preparation
2009-8235	19/10/2009	Public Health	safety of food of animal origin, in particular meat, milk and their products	In preparation

INTRODUCTION

This country profile has been drawn up by the Food and Veterinary Office (FVO), a directorate of the Directorate General for Health and Consumers of the European Commission.

The aim is to present in summary form the latest information available to the FVO on how control systems for food safety, animal health, animal welfare and plant health are organised in Bulgaria.

The information in the country profile has been compiled from:

- written submissions and background documentation from the Bulgarian authorities to the Commission detailing how control systems are organised;
- the results of missions to Bulgaria carried out in recent years by teams from the FVO and, in particular, a general review mission in Bulgaria in November 2008 to analyse the full range of control systems for food safety, animal health, animal welfare and plant health.

The country profile is presented in three parts:

- Part 1 describes the overall organisation of the Bulgarian authorities and the respective responsibilities of Ministries and government agencies in relation to the different components of the control system. A chart is used to help the reader better understand the inter-relationships between the responsibilities of the different bodies.
- Part 2 gives a more detailed description of the main responsibilities for each of the eleven separate systems that form the complete range of controls system in Bulgaria covering the whole chain of plant, animal and food production. As in Part 1, organisation charts are used to help the reader.
- Part 3 contains an overview of the missions carried out by the FVO to Bulgaria since 1999 and, for each control system gives an assessment of progress on specific recommendations reviewed in the general review mission of November 2008.

The country profile will be updated at regular intervals based on the results of future FVO missions and other relevant information received by the Commission from the Bulgarian competent authorities.

Acronyms are used extensively throughout the country profile for the sake of brevity. A list of acronyms, abbreviations, special terms and websites is given in an Annex I to the report as a guide for the reader.

1. COMPETENT AUTHORITIES AND OVERALL DISTRIBUTION OF RESPONSIBILITIES

The Ministry of Agriculture and Food (MAF) and the Ministry of Health (MH) have overall responsibility for food safety (including animal health, animal welfare and plant health) in Bulgaria. The Ministry of Health is responsible for control of foodstuffs of non-animal origin and the Ministry of Agriculture and Food for control of foodstuffs of animal origin.

As provided by the Food Law, a National Council for Food Safety (NCFS) was established within the Council of Ministers. Its main task is to co-ordinate state policy on food safety. Its members are representatives of the Ministry of Agriculture and Food, the Ministry of Health, the Ministry of Economy and Energy, the Bulgarian Association of the Food Processing and Beverage Industry and a representative of consumer protection associations.

The principle framework legislation is the Food Law (SG No. 102/2003, last amend. No 36/2008), Veterinary Activity Law (SG No. 87/2005, last amend. No 51/2007), Feed Law (SG No. 55/2006) and the Plant Protection Law (SG No. 91/1997, last amended SG No13/2008). These are the main empowering laws in Bulgaria and create the legal framework for food safety controls. Detailed requirements are set out in specific Ordinances relating to specific areas.

The administration in the food safety sector is organised in line with the territorial division of the country. The territory of the Republic of Bulgaria is divided into 28 regions. The regions are administrative units executing the regional policy of central government bodies. The regional governor is appointed by the Council of Ministers. Local government in Bulgaria is organised through 264 municipalities.

Ministry of Agriculture and Food

Food Safety and Quality Directorate

The Food Safety and Quality Directorate (FSQD) has been established as a new directorate of the Ministry of Agriculture and Food and started operating in 2005. The role of the directorate is to implement the food safety policy within the Ministry. The Directorate is responsible for defining the food safety strategy, harmonisation of legislation and co-ordination of the control authorities within the Ministry. The Directorate also performs audits within the meaning of Regulation (EC) No. 882/2004. The Directorate represents the Ministry at the international forums such as WHO, FAO or Codex Alimentarius.

The main task of the Food Safety and Quality Directorate are:

- To develop the Ministry's strategy in the field of food and feed safety
- To develop the principles for coordinating the implementation of the food and feed safety and prepare the proposals for discussing an the National Council on Food Safety
- To coordinate the activities of the official control bodies within the Ministry and to verify the their performance
- To draft legislative acts and amendments of the current legislation in the field of food and feed safety
- To coordinate the work of the Ministry of Agriculture and Food with the Ministry of Health and other national bodies involved in food and feed safety including the food industry associations

- To collect and analyse the information on the implementation of the commitments to the international organizations in the field food safety
- To coordinate and manage the control bodies within the Ministry during the preparation of multi-annual national control plan and the contingency plans
- To coordinate the trainings of the control bodies within the Ministry
- To accept the applications for placing on the market of genetically modified organisms and participate in the Commission for of genetically modified organisms (GMOs) as well as maintain the register of the authorised GMOs
- To function as the national contact point for RASFF in Bulgaria
- To participate in the joint activities of the EFSA, WHO , FAO, Codex Alimentarius and other international organizations in the field of food and feed safety
- To participate in the working groups of the Council of the EU and the meetings of the Standing Committee on Food Chain and Animal Health
- To manage and coordinate the control of conformity to the marketing standards applicable to fresh fruit and vegetables

National Veterinary Service

The National Veterinary Service (NVS) is a specialised body of the Ministry. It is responsible for official controls in the area of animal health, animal welfare and border control of feedingstuffs. It is also responsible for official control over establishments producing and handling food of animal origin. This control extends to supervision of retail establishments trading solely animal origin products.

It has its central headquarters in Sofia and an operational structure in 28 regions of the country. Each region has a Regional Veterinary Service (RVS). Each is responsible for a number of municipalities.

The National Service for Plant Protection

The National Service for Plant Protection (NSPP) is responsible for official controls in the areas of plant health (harmful organisms) and for biological testing and authorisation of plant protection products and controls on their marketing and use. It also has responsibilities in relation to monitoring pesticide residues in products and raw materials prior to their placing on the market. The National Plant Protection Service executes official control also on primary agricultural production of plant origin intended for feed.

It has its central office in Sofia and 14 regional services for Plant Protection (RSPP) distributed across the country. Each is responsible for 1-3 regions according to the area.

National Grain and Feed Service

The National Grain and Feed Service is responsible for the official control of feedingstuffs, for the implementation of the requirements for registration and approval of feed sector operators, feed hygiene requirements, feed traceability, compliance with the requirements for release on the market, the use and labeling of feed additives, feed raw materials, and compound feedingstuffs, the presence of undesirable substances and products in the feedingstuffs in all

stages of production, processing, storage, transportation, distribution, including use of feedingstuffs.

The service has headquarters in Sofia and 15 Territorial Units (TU) in the country. Each unit is responsible for 1-3 areas, depending in the region.

Ministry of Health

Public Health Directorate

The Public Health Directorate (PHD) is the body responsible for official controls on food of plant origin in production, processing and distribution establishments including retail and catering. The Directorate is also responsible for import controls of food of plant origin.

It co-ordinates and supervises the control activities of the 28 Regional Inspectorates for Public Health Protection and Control (RIPHPC) which are responsible for implementation of official controls on food safety throughout the country.

Expert Council

Expert Council as a risk assessment body has been created by Order No. RD 09-75 /13.02.2008 within the Ministry of Health. The members of the Council are representatives of all scientific organisations in the field of food safety. The chairman of the Council is the Deputy Minister of Health. The Deputy Chairs are two associated professors - from the National Centre of Public Health Protection and the National Diagnostic and Research Veterinary Institute. The main function of the Council is to provide independent scientific advice on matters related to food safety. Within the Council, expert committees and working groups corresponding to those of the European Food Safety Authority are created.

National Council for Food Safety

The National Council for Food Safety (NCFS) is a policy-making body that has been established under the Food Law to co-ordinate state policy on food safety at Government level. The Council proposes structural and administrative changes in the control system, assigns and co-ordinates the drafting of legal texts. The Council establishes committees and working groups to study and work out proposals for specific issues.

The Chairmen of the NCFS are the Deputy-Minister of Health and the Deputy-Minister of Agriculture and Food on rotation each for six months. The other members are the Deputy-Minister of Economy and Energy, the head of the Bulgarian Association of Food Processing and Beverage Industry and one representative of the Association for Consumer Protection. The Council meets at least once every two months.

Within the framework of the NCFS, the National Council for Co-ordination of Controls (NCCC) has been established. Its Members are the Chief State Health Inspector, the Chief Veterinary Officer, the Director of the General Directorate for Control of Veterinary Activities within the NVS, the Director General of the National Plant Protection Service, the Director General of the National Grain and Feed Service, the Director of the Customs Authority and the Director of Police. The chairman is the same as that of NCFS. The main function is the co-

ordination and planning of control activities at all stages of the food chain and the exchange of information between the different bodies of all competent authorities involved. It is responsible for approval of the integrated multi-annual national control plan required by Regulation (EC) 882/2004. The rules of operation of the National Council for Coordination of Control has been published in July 2008 (SG № 63/15.07.2008). Regular meetings are envisaged on a monthly basis. The first meeting was held in October 2008.

Institutes, Laboratories and other bodies

The National Diagnostic and Research Veterinary Institute (NDRVI) in Sofia provides laboratory support to the National Veterinary Service. It acts as the National Reference Laboratory for a number of animal diseases. The Institute has two subordinate branches in Veliko Tarnovo and Stara Zagora. It provides methodological guidance to other laboratories involved in official controls in the veterinary area.

The Central Laboratory for Veterinary Control and Ecology (CLVCE) is the National Reference Laboratory for control on residues of veterinary medicines and environmental pollutants. This laboratory, together with the Directorate for Research, Laboratory Control and Training of the National Veterinary Service, is responsible for drawing up the National Residue Control Plan. The CLVCE is accredited to EN ISO 17025.

There are 15 regional veterinary laboratories carrying out veterinary analysis of samples taken during official controls. These laboratories are adjacent to 15 Regional Veterinary Services. Some of these laboratories provide services to two or more regions. They receive methodological guidance from the CLVCE and the NDRVI. Eight regional laboratories are accredited according to EN ISO 17025.

The National Centre of Public Health Protection (NCPHP) is a research institute in the field of public health and food safety subordinated to the Ministry of Health. It also assists other governmental bodies, municipal authorities and non-governmental organisations. It carries out applied research activities and works on capacity-building in the area of health care. The Department “Food and Nutrition” at the NCPHP has tasks in the field of risk assessment of food additives, food contact materials, pesticide residues, contaminants – mycotoxins, nitrates, microbiological contaminants, GMO and nutrients. The Department also develops and implements the methods of food analysis and organizes training of laboratory staff from the Regional Inspectorates of Protection and Control of Public Health. Laboratories at this Department are accredited according to BDS EN ISO/EC 17025 by National Accreditation Board since 2003. Two of the laboratories of the Centre have been determined as National Reference Laboratories in the field of GM foods and pesticide residues in cereals.

On 30 of January 2008 the Chief State Health Inspector has endorsed the National Program for the development of the laboratory network under the Ministry of Health. According to the Program the laboratory analyses of food of plant origin for the purposes of the official controls are carried out by 6 of the 28 laboratories of the Regional Inspectorates of Public Health Protection and Control (RIPHPC). With Order No RD 09-155 / 04.04.2008 the Minister of Health has designated these 6 laboratories for official controls analyses. They are RIPHPC laboratories in Sofia, Plovdiv, Pleven, Varna, Burgas and Veliko Tarnovo. Laboratories coordinate their day-to-day activities based on sampling plans developed at national level in the MoH. The NCPHP is responsible for methodological guidance to the RIPCPH laboratories.

The Central Laboratory for Plant Quarantine (CLPQ) is the official reference laboratory as regards plants, plant products and harmful organisms. It carries out phytosanitary laboratory analyses, final diagnostics and identification of harmful organisms; investigates, tests and introduces new methods of analysis and ways to control the quarantine of pests; prepares information materials on quarantine pests; carries out training of specialists in the field of phytosanitary control. It is located in Sofia and has a branch in Samokov. It supervises the activity of regional and BIP laboratories, validates the positive and doubtful results and issues the methodology for analyses. It is also involved in co-ordinating regional activities, issuing methodological guidelines for inspection and drafting monitoring programmes.

The Central Laboratory for Chemical Testing and Control (CLCTC) carries out controls on plant raw materials and plant products, soils, soil ameliorants and irrigating waters for chemical and biological contamination; monitoring of plant raw materials for pesticide residues; control for correspondence of pesticides, fertilizers, soil ameliorants, biologically active substances and feeding substrates; agrochemical analyses of soils, substrates, sediments, plants and irrigating waters. It is accredited under EN ISO 17025 for all its activities and is the National Reference Laboratory in the field of pesticide residues in fruits and vegetables. As part of the NSPP the laboratory of toxicology at the *Plant Protection Institute (PPI)* also carries out controls on plant raw materials and products of plant origin for pesticide residues.

The Central Laboratory for Qualification of Grain, Grain Products and Feedingstuffs (CLQGGPF) in Sofia is a specialised administrative structure within the National Grain and Feed Service and performs quality analyses of grains and feedingstuffs. It co-ordinates the activities of the six regional laboratories and gives methodical guidance. The laboratory is accredited under EN ISO 17025 for all its activities. By Order of the Minister of Agriculture and Food No. RD 09/181/10.04.2008 CLQGGPF has been determined as a National Reference Laboratory for some feed additives.

Implementation of Regulation (EC) No. 882/2004

Organisation and implementation of official controls

The organisation of control system for food and feed safety, animal health, animal welfare and plant health in Bulgaria is well structured with clear responsibilities and control functions allocated to respective competent authorities. Overall coordination is ensured via the National Council on Food Safety which brings together all competent authorities. Coordination and cooperation between competent authorities at the operational levels is ensured via various agreements between the competent authorities and joint control programmes. In general, the competent authorities carry out official controls in accordance with well structured documented procedures containing information and instructions for staff performing official controls.

The administration in the food safety sector is organised in line with the territorial division of the country. The territory of Bulgaria is divided into 28 regions and 264 municipalities. The regions are administrative units executing the policy of central government bodies at the regional and local level.

Overall organisation and implementation of official controls in Bulgaria is reflected in the flowchart on page 12 of the country profile. The organisation and implementation of controls within individual sectors is described in Part 2 of the country profile.

Resources for performance of controls

In total, 3262 staff are involved in controls on food and feed safety, animal health and animal welfare, including 1704 in National Veterinary Service, 349 in National Service for Plant Protection, 76 in National Grain and Feed Service and 1133 within the structures of Ministry of Health. About 3000 staff work at the regional or local level and actually implements the controls. Details of staff resources for all services are provided in Annex III of the country profile.

Multi-annual national control plan (MANCP)

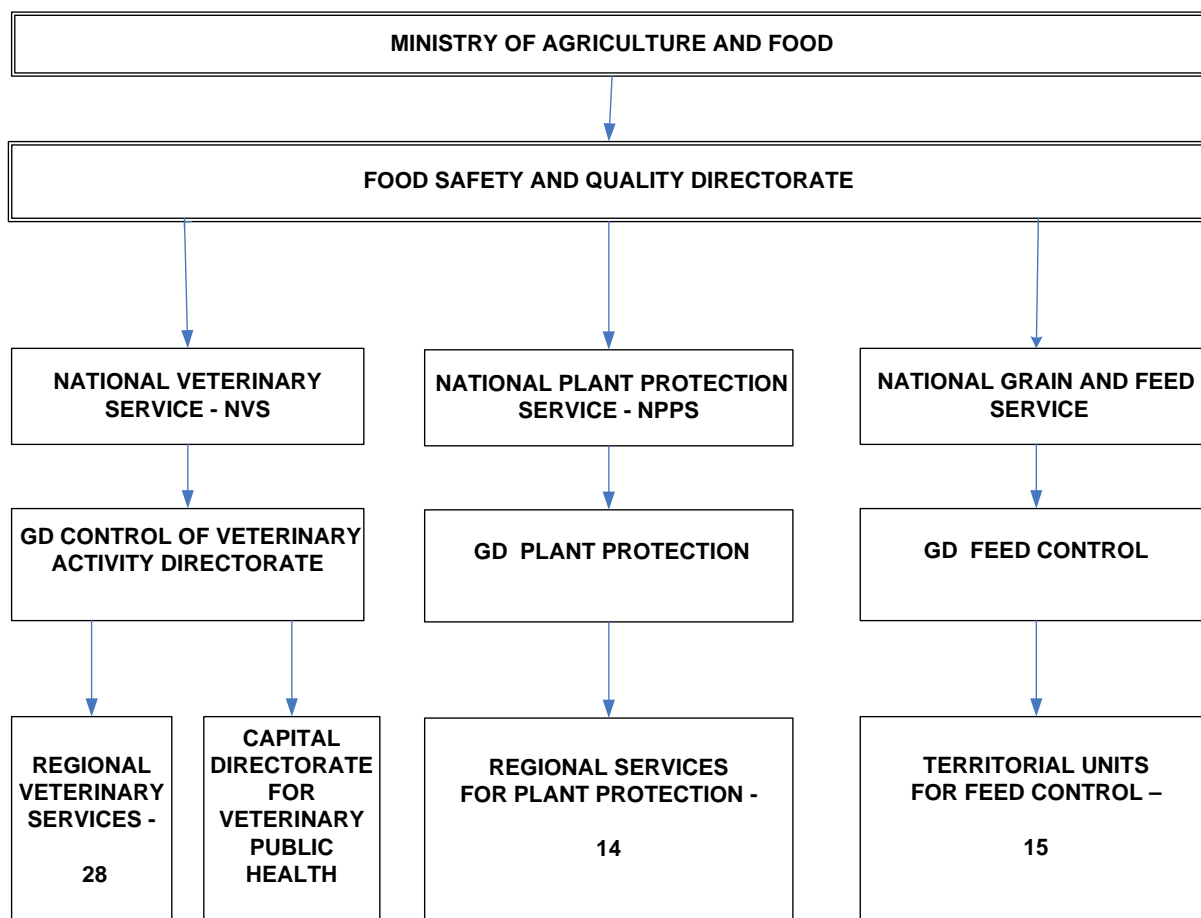
The MANCP has been developed for the period of 2008 – 2010. A working group to prepare and oversee the implementation of the plan has been established and consists of representatives of all competent authorities in Bulgaria chaired by the representative of the Food Safety and Quality Directorate within the MAF. The plan was approved by the National Council for Co-ordination of Controls in October 2008. The plan is structured vertically according to the competent authorities involved in official controls and was prepared in accordance with the Commission Decision 2007/363/EC. The implementation of the plan is carried out through well established, documented procedures. In some sectors, a detailed methodology for prioritization of official controls based on risk categorisation is established and applied.

Verification and review of official controls and procedures

Several types of audit arrangements planned to meet the requirements of Regulation (EC) No. 882/2004 are carried out in Bulgaria. They are both internal and external audits and their scope and extent vary between different competent authorities. The audits carried out are based on the principles set out in the Commission Guidelines 2006/677/EC. The summary of reports from such audits is in the case of the National Grain and Feed Service and the Public Health Directorate of Ministry of Health made available to public through their websites. The details of such audits are described under specific control systems in Chapter 2. The issue of co-ordination between the audit bodies to produce a seamless audit process has not yet been addressed.

The Food Safety and Quality Directorate (FSQD) perform verification of the official control activities in the area of food and feed safety, animal health and welfare and plant health carried out by the NVS, NSPP and NGFS within the MAF (see chart below). The Department has established the audit programme according to which three audits have been performed on the NVS, NGFS and NSPP at central level in 2008. Further audits are planned for 2009 including the regional and local level audits of the services within the MAF. The team 14 of auditors has been trained on ISO19011:2000 standard.

**AUDIT ON THE ACTIVITIES OF BODIES'S PERFORMING OFFICIAL CONTROL
WITHIN THE MINISTRY OF AGRICULTURE AND FOOD**



The team of three experts within the general administration department of the NGFS carries out internal audits according to the audit program for 2008-2010. In 2008, the audits of the central office of the Chief Directorate for Feed Control and 5 territorial units of the Directorate were carried out. The remaining territorial units of the NGFS will be audited in 2009 and 2010. Summary of the audit findings are published on the NGFS website.

Within the PHD, the program and the procedures for the internal audits of the RIPHPC is endorsed by the Chief State Health Inspector. Three specialized audits of import controls, pesticide residue controls and RASFF procedures were carried out on RIPHPC in 2008. Further audits are planned for 2009 in six of the RIPHPC. Audits are carried out by expert from the PHD and a regional expert from region different than that which is audited.

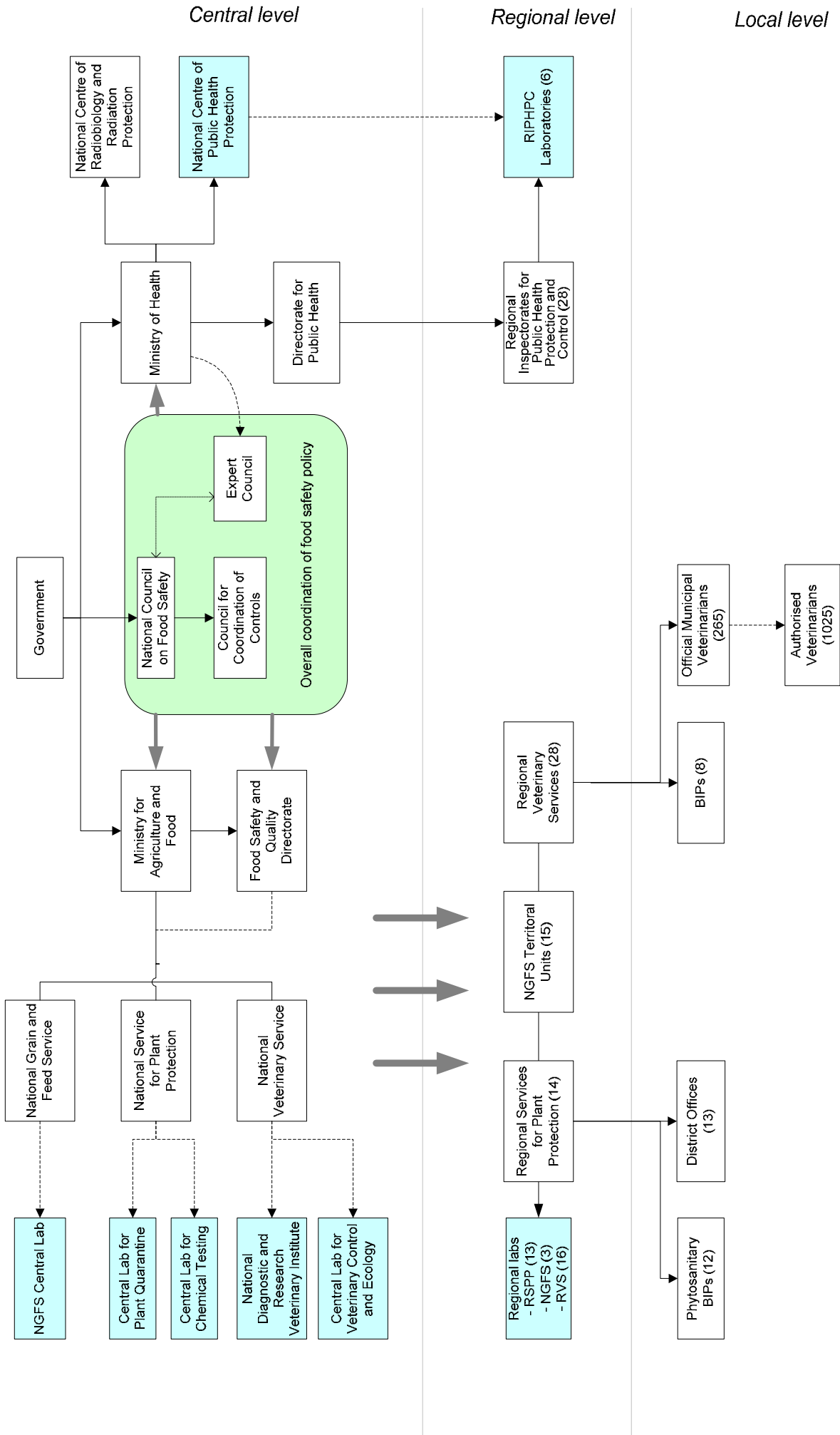
The General Directorate for Control of Veterinary Activities (GDCVA) perform audits within the whole structure of the NVS covering the activities of all administrative levels (central, regional, local and authorised veterinarians). Audit programme is approved by the CVO. The audits are carried out by a committee usually consisted of representative of the GDVCA and other six experts based on the scope of audit and territory covered. There were 12 audits performed in 2008 and further 12 are planned for 2009.

Within the NSPP the audits / supervision is performed by the heads of unit on 27 regional units. The plan is to carry out the audit once in two year for each regional unit. Independent review / scrutiny of a part of the audit process within the NSPP has been done by the competent authority of other EU Member State (France) in the framework of a bilateral cooperation with “DGAL” for 2008.

The following charts give an overview of the responsibilities of different competent authorities in relation to control systems and operational levels. More detailed descriptions of responsibilities for each control system are given in the Part 2.

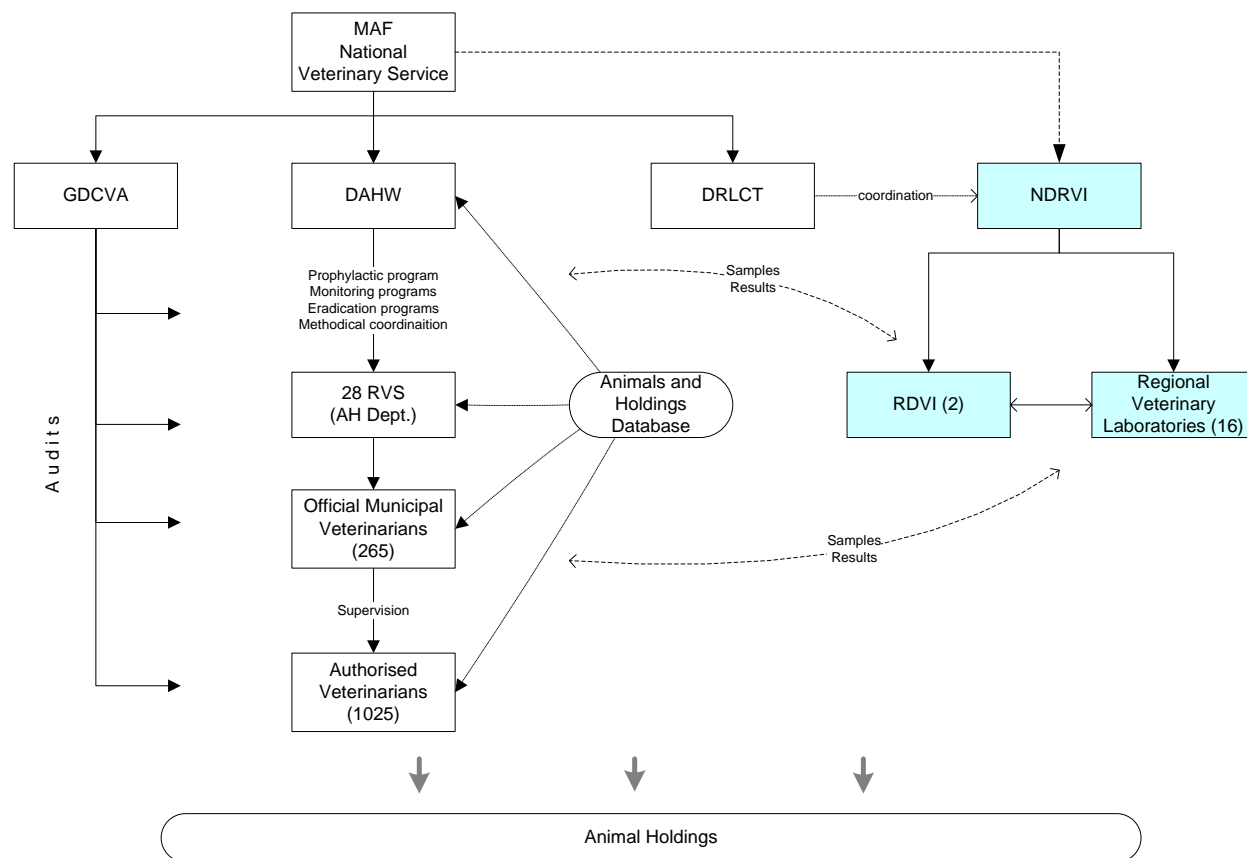
Sector	Policy co-ordination	Co-ordination of controls	Implementations of controls	Laboratories	Risk assessment, scientific advice
1. Animal Health	NVS (DAHW)		RVS AV	NDRVI, RVS	NCFS
2. Food of Animal Origin	MAF (FSQD) NVS (DVPH)		RVS RIPHPC	NDRVI, CLVCE, RVS	NCFS
Food post primary/retail	MH, (PH)D MAF (FSQD) NVS (DVPH)			RIPHPC	NCPHP
3. Imports of animal and food of animal origin	NVS (DBVC)		BIPs Customs	RVS	
4. Feedingstuff - quality and safety aspects	MAF (FSQD) NGFS (CDFC)		TU	DCLQGGPF NDRVI CLVCE	NDRVI
Import of feedingstuffs	NVS (DBVC)		BIPs Customs	NDRVI CLVCE	
Feedingstuffs - primary agricultural production of plant origin, intended for feed.	NSPP (PPD)		RSPP	CLCTC PPI	
Primary producers mixing feedingstuffs for their own needs without using additives and premixtures	NGFS (CDFC)		TU	DCLQGGPF NDRVI CLVCE	
5. TSEs/ABP	NVS (DAHW)		RVS AV	NDRVI	
6. Veterinary medicines and residues	NVS (DCLCT)		ICVMP RVS BIPs	CLVCE	
7. Foodstuffs and Food hygiene	MH (DPH) MAF (FSQD)	NVS	RIPHPC RVS	NCPHP RIPHPC	NCPHP
8. Imports of food of plant origin	MH (DPH)		RIPHPC Customs	RIPHPC	NCPHP
9. Plant protection products and residues	NSPP (CLCTC)	MH (DPH)	RSPP RIPHPC	PPI CLCTC RIPHPC	
10. Animal Welfare	NVS (DAHW)		RVS, BIPs, AV		
11. Plant Health	MAF (FSQD) NSPP	PPD	RSPP	CLPQ	Consulting Council

Food and Feed Safety Control System in Bulgaria



2. INDIVIDUAL CONTROL SYSTEMS

2.1 Control system for animal health



MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
DAHW	Directorate for Animal Health and Welfare
GDCVA	General Directorate for Control of Veterinary Activities
DRLCT	Directorate for Research, Laboratory Control and Training
RVS	Regional Veterinary Service
NDRVI	National Diagnostic and Research Veterinary Institute
RDVI	Regional Diagnostic Veterinary Institute
RVL	Regional Veterinary Laboratories

Competent authorities

The CCA for animal health is the NVS.

The Directorate for Animal Health and Welfare (DAHW) is responsible for harmonisation and drafting the legal documents in the area of animal health. The directorate arranges for veterinary preventive measures against infectious and parasitic diseases. It prepares the annual prophylactic, monitoring and eradication programmes and is responsible for the elaboration of contingency plans. The Directorate prepares guidelines and instructions for the Regional Veterinary Services (RVS) in order to implement the animal health measures.

The total number of staff involved in the animal health sector in the official services in Bulgaria is 643 officials (20 NVS, 28 RVS + 160 veterinary auxiliaries, 265 OMV, 80 NDRVI, 50 RDVI, and 40 RVL). Furthermore, 1025 authorised veterinarians perform official tasks assigned to them in the framework of the animal health programmes. Overall there are approximately 950 full time equivalent staff involved in official animal health controls in Bulgaria.

Holding registration, animal identification and movement controls

Animal holdings keeping cattle, pigs, sheep and goats are registered on the central database (CDB) and a unique holding number is allocated to each holding. The CDB (World Vet system) is an internet based system designed for multi-species functionality. The DAHW is responsible for overall management and an external administrator was contracted to operate the CDB. There are around 400 users of the CDB including all RVSs, OMVs and some commercial farms and slaughterhouses.

The national system of identification and registration of animals requires identification of all species by an individual number. The authorised veterinarians are responsible for tagging and registration of animals. The authorised veterinarians then provide the data monthly to the OMVs who are responsible for entering them into the CDB.

The system for animal movement control is based on animal health movement certificates issued by the authorised veterinarian responsible for the farm. Passports are issued for large ruminants. All holdings are required to keep holding registers and each change to the herd is entered in such a record books. Reporting to the CDB is carried out by the OMVs.

The effectiveness of the CDB in the country is questionable due to frequent technical problems with software and slow internet connections in some areas of the country. A new module of the CDB is currently being developed to control the movement of animals.

There is no system for registration of livestock vehicles and hauliers.

Animal health controls

Control measures prepared by the DAHW and approved by the Ministry of Agriculture and Food (MAF), are implemented (sampling, testing, and vaccinating) by the RVS, official municipal veterinarians and authorised private veterinarians. At regional level, there is one animal health department in each of the 28 RVS. At local/district level, there are 265 municipalities each supported by an official municipal veterinarian who supervises the performance of the authorised veterinarians within the territory of municipality. There are 1,025 authorised private veterinarians appointed for the official tasks – prophylactic and monitoring animal health programmes. The authorised veterinarians are under contract to the RVS. The authorised private veterinarians dedicate 30% of their working time to official tasks.

The authorised veterinarians (AV) report the results of their work on a monthly basis to the official municipal veterinarian (OMV) who summarises the input from all AV and report further to the RVS. The RVS reports to the DAHW on the implementation of animal health programmes on the territory of their region also on a monthly basis.

Specific eradication and monitoring programmes are approved for Bluetongue, CSF in East Balkan pigs, CSF in relation to vaccination (serological testing), CSF in wild boars, FMD (at the border with Turkey), equine viral arthritis, horse influenza and African Horse Fever (AHF), TSE and some fish diseases.

The General Directorate for Control of Veterinary Activities (GDCVA) perform audits within the whole structure of veterinary services covering the activities of all administrative levels (DAH, RVS, OMV and authorised veterinarians). These also include the audits of activities in animal health area.

Animal health status

The table below gives a basic overview of outbreaks of animal disease in Bulgaria. More detailed information about the diseases notified by Bulgaria can be accessed on www.oie.int.

Disease	Outbreaks of the disease
FMD	1996
CSF	2000 - 1 outbreak 2001 – 1 outbreak 2002 – 32 outbreaks 2003 – 11 outbreaks 2004 – 4 outbreaks 2005 – 5 outbreaks in wild 2006 – 1 outbreak
Blue-tongue	First outbreak 1999 2001 – 1 outbreak
Rabies	1977 first reported cases in foxes 2001 – 61 outbreaks in wild 2002 – 15 outbreaks in wild 2003 – 17 outbreaks in wild 2004 – 10 outbreaks in wild 2005 – 10 outbreaks in wild 2006 – 1 outbreak in wild

Source: MAF and OIE

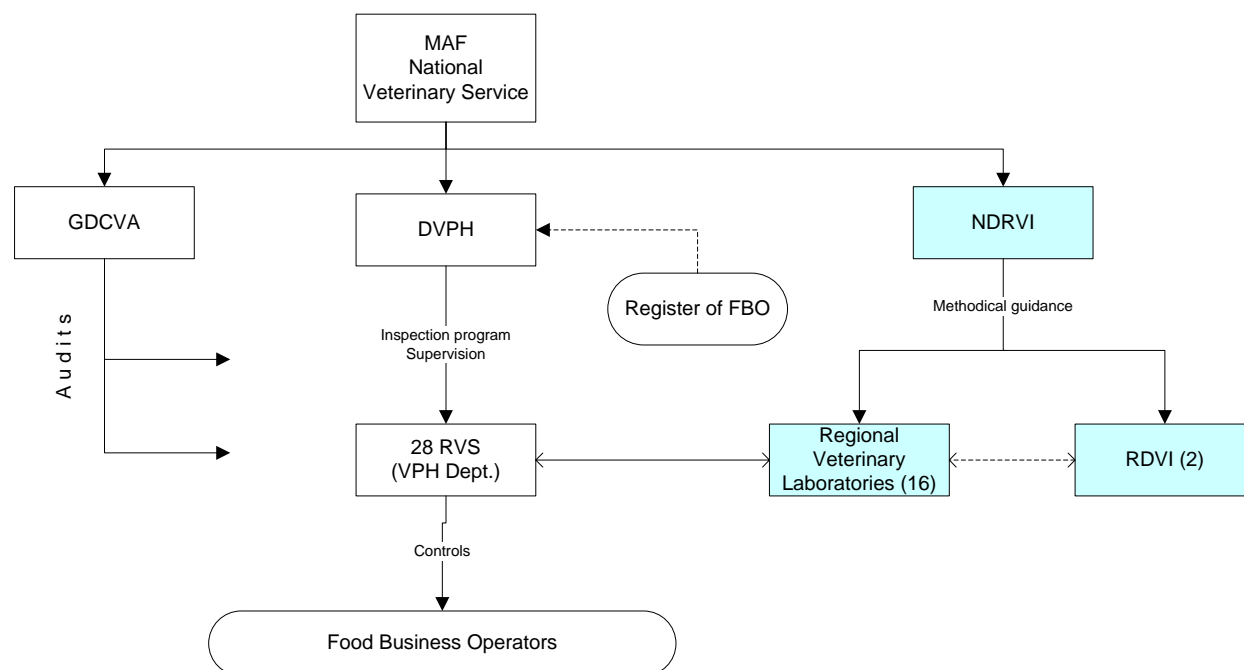
Contingency plans

Contingency plans are drawn up for most OIE list A diseases (FMD, Sheep and Goat Pox, CSF, BT, ND and AI). The plans follow EU guidelines and are updated to meet new EU requirements or changes in the epizootic situation.

Laboratories

The National Diagnostic and Research Veterinary Institute (NDRVI) in Sofia is a specialised body of the NVS on diagnostics and research activities in the field of animal health. There are also two RDVI in Veliko Tarnovo and Stara Zagora and another 12 regional veterinary laboratories which are involved in diagnostics of animal health.

2.2 Control system for food of animal origin



MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
DVPH	Directorate for Veterinary Public Health
GDCVA	General Directorate for Control of Veterinary Activities
RVS	Regional Veterinary Service
NDRVI	National Diagnostic and Research Veterinary Institute
CLVCE	Central Laboratory for Veterinary Control and Ecology

Competent authorities

The CCA for controls of food of animal origin is the NVS. The Directorate for Veterinary Public Health (DVPH) has 13 staff and is responsible for legislation and policy making in the area of veterinary public health control. It manages, organises and co-ordinates the activities of the RVS which covers preventive, regular and permanent veterinary inspections on animals, raw materials and products of animal origin in the establishments producing or processing food of animal origin. This control extends to supervision of retail establishments trading solely with products of animal origin.

Approval and register of establishments

A procedure for approval and registration of food business operators has been established. The commission responsible for approval and registration consists of representatives of the RVS. The RVS register the establishments for production, processing, storing and packing of raw materials and foodstuffs of animal origin, as well as the establishments of wholesale trade in foodstuffs of animal origin. The RVS also registers retail outlets selling solely food of animal origin.

A special procedure for approval of establishments for EU intra-community trade has been established and applied from January 2007. The establishments are evaluated in a four-step

evaluation procedure. (1) The first step is a food business operator self assessment. (2) Then the official veterinarian responsible for establishment carries out checks to verify the compliance with EU requirements and drafts a protocol. If the establishment meets all the necessary criteria the official veterinarian gives guarantees in the conclusions of the protocol and makes a proposal the establishment to be inspected by a regional commission. (3) The regional commission carries out an audit/inspection in the establishment for compliance with EU requirements and drafts a protocol. If the establishment has met all the criteria the regional commission grants guarantees in the conclusions of the protocol and makes a proposal that the establishment is audited by a national evaluation team. (4) The national audit team carries out a visit in the establishment to check for compliance with EU requirements and drafts the final protocol with the final conclusions. The national audit team consists of three officials from different regions of the country and its members are nominated by the General Director of the Veterinary Service. The pool of officials which can be used for national audits consists of 49 veterinarians. The national auditors have a common working procedure and check lists reflecting the relevant Community legislation.

The register of all food business operators is kept centrally at the NVS. Software for the national register of establishments is under development. The lists of approved establishments for both intra-community trade and national market only are published on www.nvms.government.bg/content.php?cntid=42

The register of food business operators trading composite food (catering, retail outlets, supermarkets, etc.) is kept at the Ministry of Health - the Public Health Directorate and available on www.nvms.government.bg/content.php?cntid=42

Official controls and inspection at establishments

The DVPH issues a yearly inspection programme and supervises the performance of the RVS in implementing this programme. It also issues manuals, instructions and checklists concerning inspections and audits in the establishments. Each RVS develops detailed annual programme for official controls in each food business operator in the region. The frequency of visits is determined by the capacity of establishment and the results of previous inspections and audits. The RVS reports the results of the controls to the NVS on a monthly basis and in some cases on a weekly basis (i.e. HACCP audits).

In December 2007 the DVPH developed instructions on the implementation of a multi-annual national control plan. Based on the instructions and the criteria for risk assessment each RVS draw up a plan of official controls (inspections and audits) over each establishment on its territory. The plan includes the frequency of control exercised by the official veterinarians, heads of sectors and heads of departments of the DVPH.

The controls of food of animal origin are performed by veterinary inspectors at the RVS. The inspectors at the RVS are organised within the veterinary public health departments. The departments are further divided into sections. The total number of inspectors involved in carrying out the veterinary public health controls is 597 (out of which 565 are official veterinarians).

The General Directorate for Control of Veterinary Activities (GDCVA) perform audits within the whole structure of veterinary services covering the activities of all administrative levels (DVPH, RVS). These also include the audits of activities in the area of veterinary public health control.

Establishments in transition

The upgrading process of establishments producing and processing food of animal origin started in 2003. Taking into account the situation in Bulgaria before accession, it was appropriate to provide for transitional measures as regards the dispatch of certain products of the meat and milk sector to other EU Member States.

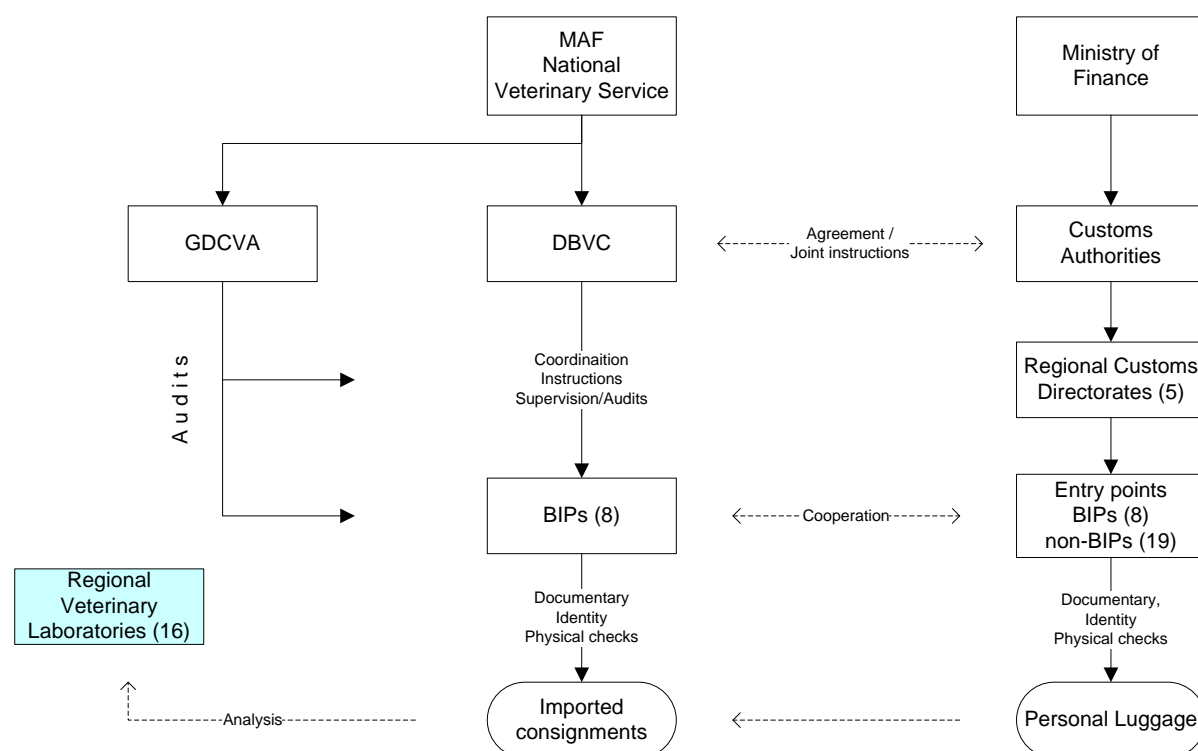
After the publication of Commission Decision 2007/716/EC laying down transitional period until 31.12.2009 for the establishments which had not complied with the structural requirements of Regulation (EC) 852/2004 and 853/2004 the owners of affected establishments have drawn up plans for their compliance with the requirements. The plans include specific deadlines by when the full compliance will be achieved. The plans have been submitted to the official veterinarians responsible for the establishment. The RVS then carries out the check of the establishment for compliance with the requirements of the EU legislation. If the establishment meets the criteria a proposal is made to delist the establishment from the negative list of the Decision 2007/716/EC. If the establishment does not meet the criteria a proposal to terminate its activity is made. Based on these proposals, a central committee consisted of three members carries out further check for compliance with the EU legislation. The proposals for delisting of establishments from the positive list are sent every two months for a vote by SCFCAH.

Laboratories

Routine laboratory testing of products of animal origin are performed in NDVRI, two RDVI and 16 laboratories of the RVS. The results are sent to the RVS and in the case of serious findings also communicated to central authorities. All laboratories receive methodological guidance from the NDVRI.

Laboratory analyses for residues, pollutants and contaminants are carried out in CLVCE.

2.3 Control system for imports of food of animal origin



MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
DBVC	Directorate for Border Veterinary Control
GDCVA	General Directorate for Control of Veterinary Activities
BIP	Border Inspection Post
MF	Ministry of Finance
CA	Customs Authorities

Competent authorities

The CCA for import controls of products of animal origin and live animals is the NVS. The Directorate for Border Veterinary Control (DBVC) is responsible for policy making and coordination of controls. The directorate drafts legislation, issues instructions and monitors the activities of the BIPs. Twenty three border posts (8 BIPs and 15 non-BIP entry points) have been designated in Bulgaria.

The Customs Authorities within the Ministry of Finance are organised into five Regional Customs Directorates and 17 local Customs Houses with 82 customs offices and border points.

Import controls

The monitoring programmes, instructions and checklists concerning the implementation of import controls developed by DBVC are disseminated and available in all BIPs. The BIPs submit monthly reports to DBVC containing information on controls carried out. Since accession, TRACES is used as the registration system to record data on consignments.

Audits of the operation of BIPs are at the early stage of implementation and are intended to be carried out at two levels. Regular audits by the DBVC and audits performed by the GDCVA twice a year.

The Customs Authorities identify and select incoming consignments for veterinary checks. The CA together with the NVS also executes import controls for personal luggage at eight BIP and 15 non-BIP entry points.

After accession, all necessary checks (documentary, identity and physical) are carried out at 8 BIPs listed in the table below. The individual BIPs are under direct authority of the DBVC. There is 78 staff employed at these BIPs. Apart from import controls on live animals and animal products, BIPs staff are involved in checks on imports of animal feedingstuffs and veterinary medicinal products. They also check exported consignments.

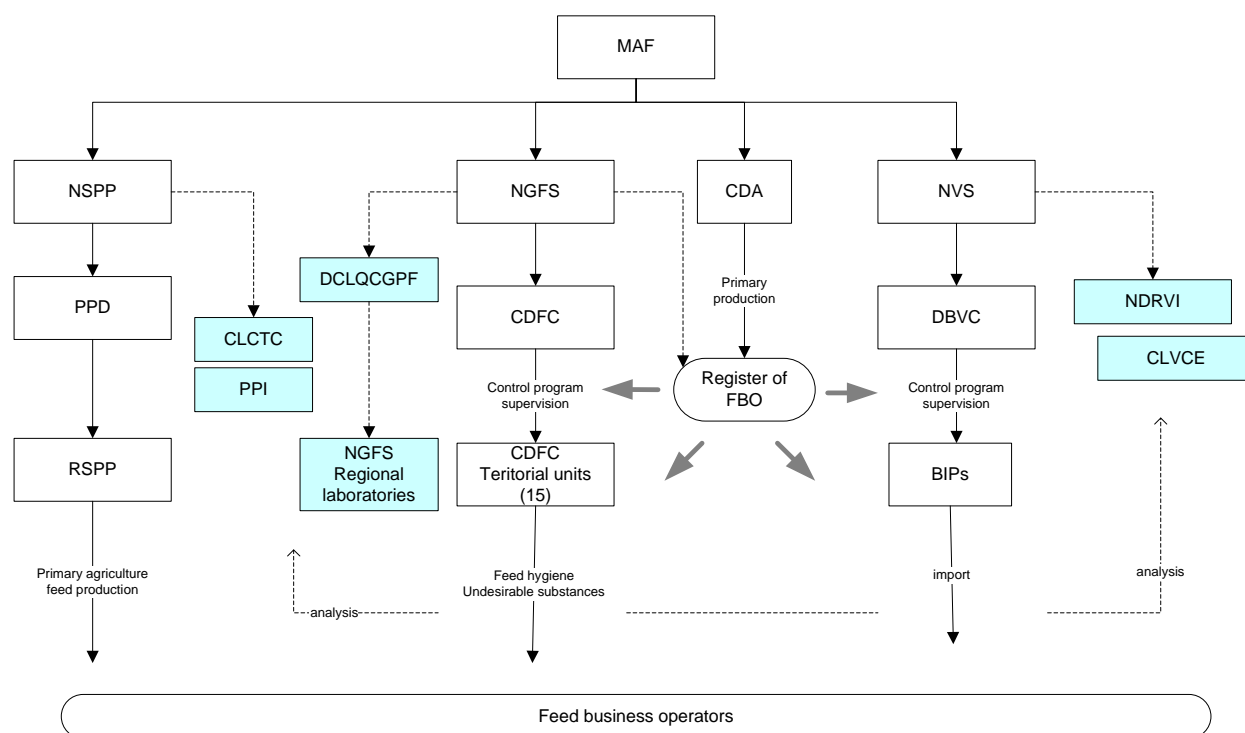
BIP	Border	Type	Approval
Bregovo	Serbia	Road	HC, NHC
Burgas	Black Sea	Port	HC, NHC
Gueshevo	FYROM	Road	HC, NHC
Kalotina	Serbia	Road	HC, NHC, U, E, O
Kapitan Andreevo	Turkey	Road	HC, NHC, U, E, O
Sofia	n.a.	Airport	HC, NHC, E, O
Varna	Black Sea	Port	HC, NHC
Zlatarevo	FYROM	Road	HC, NHC

Co-operation between the Customs Authorities and the NVS takes place within the framework of a high level agreement which foresees regular contact meetings between the services. Implementation is via a joint instruction of Customs and NVS. At local level there is working co-operation by exchange of information in relation to the positive list and regular meetings at the entry points between BIP veterinarians and Customs officials.

Laboratories

Laboratory tests of imported products of animal origin are performed in the laboratories of the RVS.

2.4 Control system for feedingstuff and animal nutrition



MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
DBVC	Directorate “Border Veterinary Control”
BIP	Border Inspection Post
NDRVI	National Diagnostic and Research Veterinary Institute
CLVCE	Central Laboratory for Veterinary Control and Ecology
NGFS	National Grain and Feed Service
CDFC	Chief Directorate for Feed Control
CDA	Chief Directorate for Agriculture
DCLQCGPF	Directorate “Central Laboratory for Qualification Grain Grain Products and Feedingstuffs”
NSPP	National Service for Plant Protection
PPD	Plant Protection Directorate
RSPP	Regional Service for Plant Protection
CLCTC	Central Laboratory for Chemical Testing and Control
PPI	Plant Protection Institute

Competent authorities

The CCA in the area of feedingstuffs and animal nutrition is the Ministry of Agriculture and Food (MAF). Three authorities belonging to MAF share responsibility for the official controls on animal nutrition – the National Veterinary Service (NVS), the National Grain and Feed Service (NGFS) and the National Service for Plant Protection (NSPP).

Pursuant to Article 4 of Regulation (EC) 882/2004 agreements for cooperation and information exchange have been concluded between the NGFS and the NVS, and between the NGFS and the NSPP.

An agreement between the NGFS and Public Health Directorate at the Ministry of Health is being prepared with the objective to improve the cooperation in situations when feedingstuffs might enter the food chain as foodstuffs and vice versa.

Approval and register of establishments

The National Grain and Feed Service, through the Chief Directorate for Feed Control (CDFC) is responsible for the approval and registration of feed business operators. This is done on the basis of Regulation (EC) 183/2005 and the Feed Law (SG No55/2006, amended SG 54/2008).

Establishments which apply for approval submit an application form to the competent authority which subsequently makes on the spot visit to check whether the applicable requirements have been met. After each visit, a report is issued describing the findings and recommendations. Within six months, the establishments have to comply with the relevant requirements and it is followed by either approval or refusal.

In compliance with Article 18, para 4 of Regulation (EC) 183/2005, primary producers of feedingstuffs are registered in 28 District Agriculture Directorates at the Chief Directorate Agriculture (CDA). The CDA keeps a register of all kind of primary agricultural producers and provides information from its register to NGFS which keeps the list of primary producers of feed public.

In compliance with Article 19 of Regulation 183/2005 the NGFS maintains public register of approved establishments and lists of registered establishments on its website: <http://www.nszf.bg> and the website of the MAF: <http://www.mzh.government.bg>.

Directive 98/68/EC and Directive 98/51/EC have been transposed in the national legislation in Ordinance No. 109 on the official control of feedingstuffs (SG, issue 84/2006, amended and supplemented in SG, issue 64/2008, amended in SG. issue 82/2008). The NGFS keeps Register of Approved and a List of Registered Representatives of Enterprises for feed import from third countries - <http://www.nszf.bg>.

Official controls

The NGFS exercise the control on feedingstuffs in all stages of production, processing, storage, transport, distribution and use. The NGFS carries out controls through the CDFC, which has 15 territorial units (TU) in the country. The total number of employees of the CDFC is 22, including 16 employees in the territorial units. The Directorate is also responsible for keeping registers and lists of feed business operators.

The NVS through the Directorate for Border Veterinary Control is responsible for the border control of feedingstuffs. The import control is carried out at 8 BIPs.

The NSPP is responsible for the control of primary production of agricultural crops for feed in accordance with the Law on Feed (last amended by SG 54/2008). The Operative Plant Protection Department coordinates the activity, while the RSPP carries out control. The NGFS presents to the NSPP a list of the registered primary agricultural feed producers for the purposes of control.

The official control of feedingstuffs is carried out based on multi-annual control plan (MANCP) for 2008-2010. Based on the MANCP, a framework control plan is drawn up every year. The

official control covers the control of processes (check of the establishment and document inspections) as well as product control (taking samples for analysis on feed content, prohibited or undesirable feed additives, undesirable substances, prohibited substances, microbiological contamination and compliance with the feed ban). The control also covers the checks for compliance with the indicators declared by the producer to secure fair practices in feed trade and protection from misapprehension and deceit. The framework feed control plan for 2008 includes the control activities of the NGFS and NVS. The plan for 2009 covers the control activities of the NSPP as well.

The control plans are drawn up jointly by the services in compliance with their competence and based on the risk assessment. Every service develops its own operational instructions and control checklists. The NSPP carries out its own control programme for 2008.

The Agreements between the NGFS and the NVS, and the NGFS and the NSPP stipulate the procedures for information exchange aiming to provide constant information on the control activities of the services in order to raise the effectiveness in planning and conduct of feed control.

Controls on imports

The competent authority for the border control is NVS. The controls are performed at the BIPs. The framework control plan includes also import control. Importers are obliged to notify the NVS on the place and time of import of every batch of feed 24 hours in advance. The inspectors from the DBVC check whether the business establishment is on the list of the registered or approved representatives as required by Regulation EC 183/2005. Prior to the release on the market of the imported products, the inspectors carry out physical checks under the operational instructions and issue the standard document under Directive 98/68/EC. After the consignment is released for free circulation, feedingstuffs are controlled by the NGFS.

Laboratories

Analyses of the samples taken by inspectors of the CDFC are analysed in laboratories of NGFS, NVS, other accredited laboratories in Bulgaria and, in some cases, also in laboratories in other Member States.

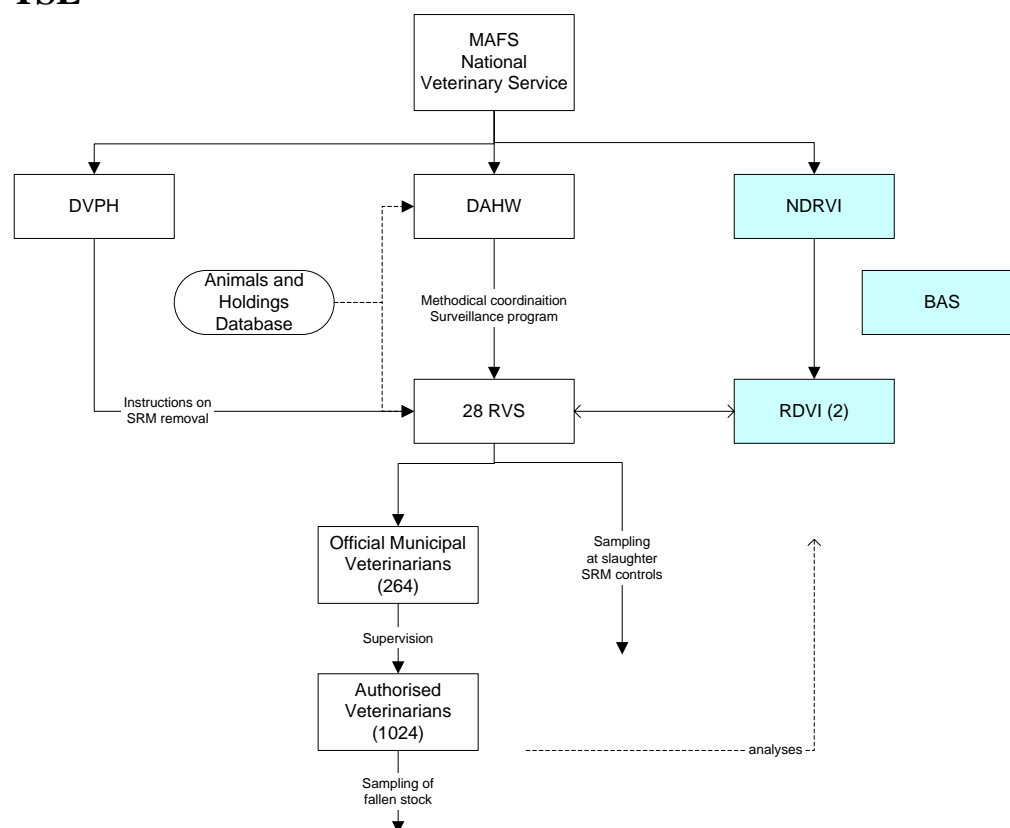
Analyses of the samples taken by inspectors of the RVS are analysed in the NDRVI in Sofia, two RDVI, the CLVCE and laboratories of some of the RVS.

Laboratories in Sofia and Dobrich (within the NGFS) are accredited according to ISO 17025.

Analyses of the samples taken by inspectors of the NSPP are analysed at the Central Laboratory for Chemical Testing and Control (CLCTC) and the Plant Protection Institute (PPI).

2.5 Control system for TSE and Animal-By-Products (ABP)

TSE



MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
DVPH	Directorate for Veterinary Public Health
DAHW	Directorate for Animal Health and Welfare
DBVC	Directorate for Border Veterinary Control
RVS	Regional Veterinary Service
NDRVI	National Diagnostic and Research Veterinary Institute
BAS	Bulgarian Academy of Science

Competent authorities

The CCA for Transmissible Spongiform Encephalopathies (TSEs) controls is the NVS.

The DAHW is responsible for policy and transposition of legislation on TSEs. The directorate develops the epidemio-surveillance monitoring programme and instructions as regards the removal and control of Specified Risk Material (SRM). The directorate also issues general instructions and operational procedures regarding BSE clinical suspects. The directorate is also responsible for the development of contingency plans.

Monitoring and surveillance of TSE

Samples for TSEs testing are taken by official veterinarians at slaughterhouses or by authorised veterinarians on farms in the case of fallen stock or emergency slaughter.

Within the active surveillance programme, the following bovines are tested: all over 24 month animals that died in farms or during transport, all emergency slaughtered animals over 24 month, all over 30 month animals intended for human consumption and all over 24 months animals found sick at ante mortem inspection. Within the passive surveillance programme, all bovine animals showing clinical signs similar to those of TSE irrespective of their age are tested by pathohistology, immunohistochemistry or immunoblotting.

Within the TSE surveillance programme for small ruminants, random samples of sheep and goats over 18 months intended for regular slaughter and human consumption are tested. Samples of all dead sheep and goats over 18 months are also tested as well as all sheep and goats that have shown clinical signs characteristic to TSE irrespective of their age.

Specified Risk Material

Measures to control SRM have been introduced by the DVPH. Official veterinarians responsible for the official controls of removal and staining of SRM in slaughterhouses and cutting plants are also responsible for guaranteeing their proper disposal. In addition, the RVS carry out regular supervisory inspections in some establishments. Supervision of the RVS by DVPH over the implementation of SRM measures is not carried out.

Total Feed Ban

The total feed ban entered into force in January 2006. There is an annual inspection plan to take samples to monitor the implementation of the ban. Guidelines on the requirements for the numbers of samples to be taken are disseminated to the RVS. Each RVS then drafts a local sampling plan which is sent back to the NVS at central level for approval. There have been no cases of positive results in the samples taken so far. The costs of the laboratory tests for the presence of Meat and Bone Meal (MBM) in animal feedingstuffs are covered by the State.

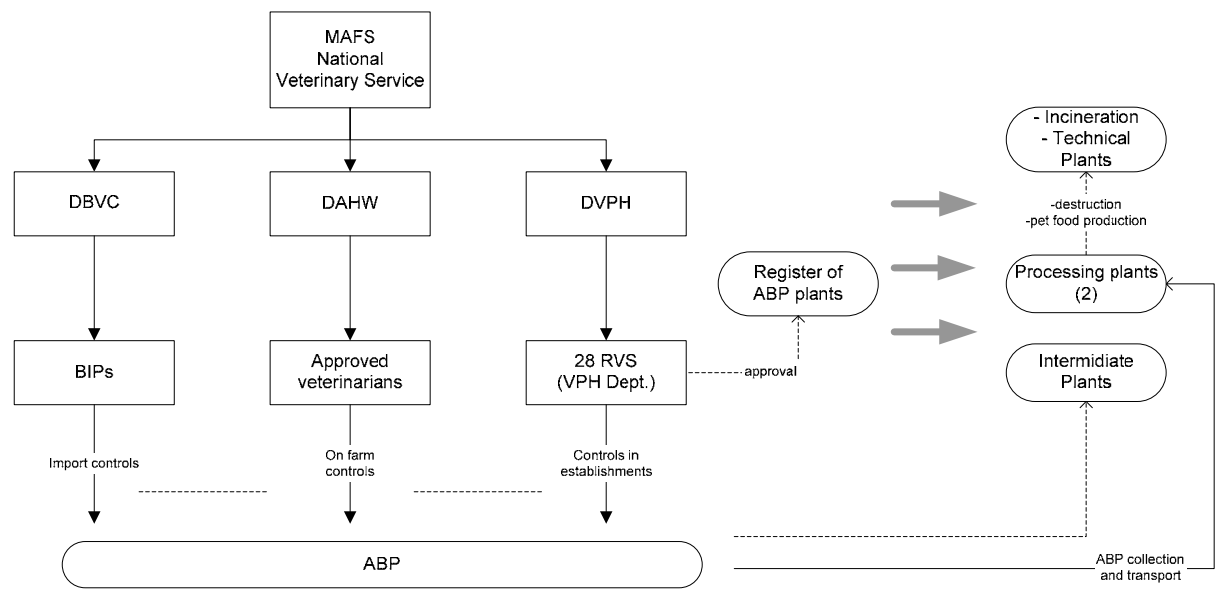
All feed establishments producing feed using derogated PAO are approved by the NVS in line with the requirements of Annex IV to Regulation (EC) No. 999/2001.

Laboratory services

The diagnostic testing on TSE is carried out by approved rapid tests at the national reference laboratory at the NDRVI in Sofia and the RDVI in the cities of Veliko Tarnovo and Stara Zagora. The confirmation tests are carried out in NDRVI by pathohistology and immunoblotting. Pathohistology is also carried out in the laboratory at the Institute of experimental immunology and pathology at the Bulgarian academy of science in Sofia.

The rapid tests used are Platelia “Biorad” tests based on the sandwich ELISA principle with use of monoclonal antibodies for detection of abnormal prion proteins and Ceditest based on the chemiluminescent ELISA method. Confirmatory analyses are tested pathohistologically or by another confirmatory method – immunohistochemistry or immunoblotting.

ABP



MAF	Ministry of Agriculture and Food
DVPH	Directorate for Veterinary Public Health
DAHW	Directorate for Animal Health and Welfare
DBVC	Directorate for Border Veterinary Control
RVS	Regional Veterinary Service

Competent authorities

The NVS is the CCA responsible for supervision and controls throughout the ABP chain. The Directorates involved are the DVPH for public health issues in meat establishments, the DAHW for fallen stock and collection, transport and processing, and the DBVC for imports, exports and transit. One official is appointed as a co-ordinator for ABP at central level.

The Ministry of Environment is responsible for the approval of landfill sites (the total number of landfill sites in Bulgaria are 52, there is at least one in each RVS) and incineration plants. The Ministry of Health is in principle responsible for official controls at retail level, however all retailers dealing with animal products and producing ABP are also under official control by the RVS.

Official controls

The controls on ABP in slaughterhouses are based on the permanent presence of an official veterinarian. On-farm slaughtering is carried out without the involvement of a veterinarian and the channelling of ABP is thus not fully known. Authorised veterinarians performing some official tasks at farm level notify the RVS about irregularities in the collection of fallen stock and illegal burial of animals.

Processing plants are regularly supervised by the RVS and the DVPH. Two permanent staff of the RVS are responsible for controls. Once a month, the processing plant sends detailed data on their activities to the RVS, which forwards this information to the DAHW. The data include the amount of material collected in each individual establishment or farm, amounts of MBM and rendered fats produced thereof and amounts dispatched and used as fuel.

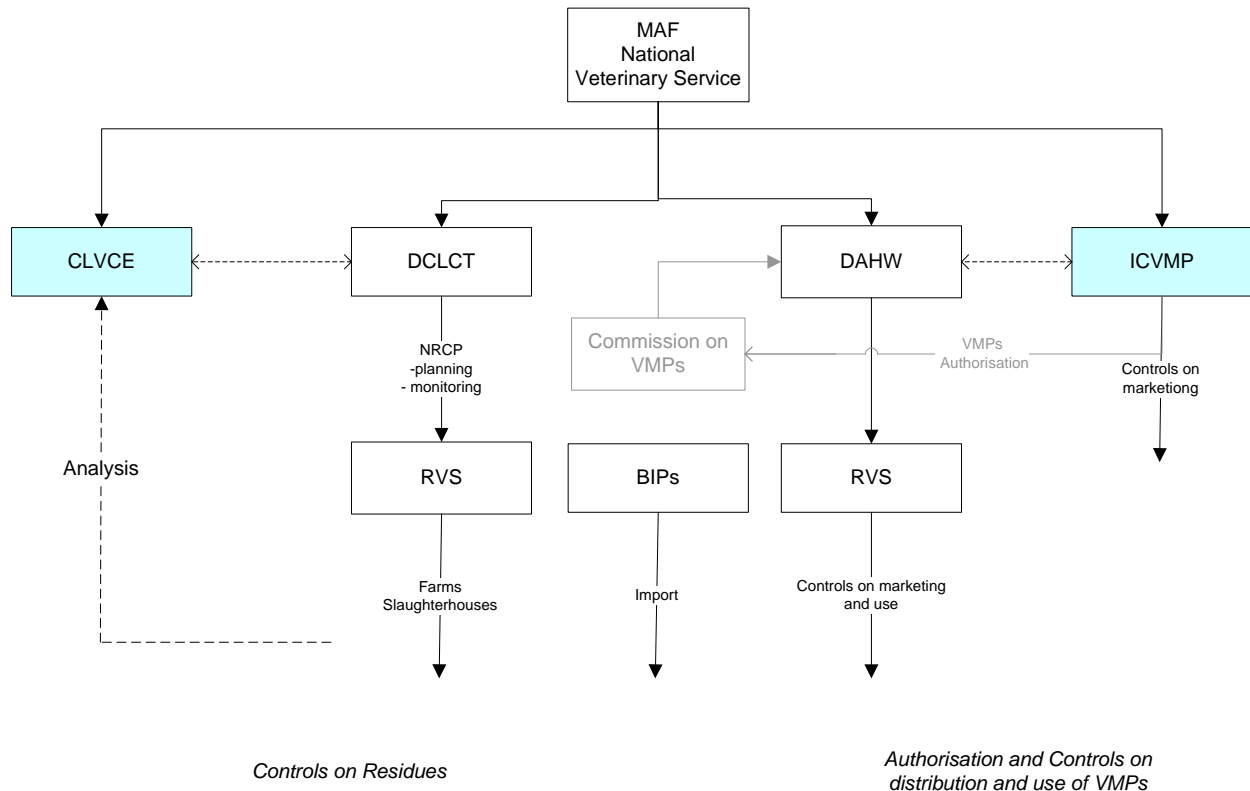
Collection, processing and disposal of ABP

From February 2006, the burial of SRM and fallen stock is banned in the whole country.

Two rendering plants in towns of Shumen and Varna are approved for processing ABP in Bulgaria. They have a capacity to process all ABP produced in Bulgaria including fallen stock and cadavers of small ruminants. The rendering plant in Shumen has two lines (one intended for processing materials of Category 1 and 2 – 40 tons / day and another line intended for processing materials of Category 3 - 100 tons / day). The rendering plant in Varna has one line intended for processing materials of Categories 1, 2 and 3 - 40 tons / day. The processing of ABP in the rendering plants is carried out under method 1 of the Regulation (EC) No. 1774/2002. After the process in the rendering plants the meat and bone meal is sent for burning to the cement plant in the village of Beli Izvor, administrative district of Vratsa. The only use of rendered products derived from ABP is pet food.

The NVS signed contracts with both rendering plants which are obliged to collect SRM from the whole Bulgaria. For the collection of the dead animals and SRM from the territories of all 28 administrative regions of the country, the rendering plants have developed and submitted to NVS a scheme of a transport system, specifying a route map showing the district covered by the respective transport route, list of the sites, which are to be offered services (farms, meat production and meat processing facilities), the days of the week when collection takes place, the names of the drivers, their mobiles and the registration numbers of the vehicles. The collection of the ABP together with their processing is fully financed by the state budget.

2.6 Control system for veterinary medicinal products (VMP) and residues



MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
DAHW	Directorate for Animal Health and Welfare
DCLCT	Directorate for Science, Laboratory Control and Training
RVS	Regional Veterinary Service
ICVMP	Institute for control on VMPs
CLVCE	Central Laboratory for Veterinary Control and Ecology

Competent authorities

The CCA in the area of veterinary medicinal products (VMPs) and their residues in live animals and animal products is the NVS. The ICVMP and the CLVCE are part of the structure of the NVS. The implementation of controls is assigned to official veterinary inspectors at the RVS. There is 1 official veterinarian responsible for VMPs and their residues in each RVS.

VMP

Authorisation of the VMPs

The NVS is responsible for the authorisation of VMPs. The ICVMP carries out assessments of the dossiers and analyses and reports to a commission on approval of VMPs which is an advisory body of the NVS. The final authorisation of VMPs is issued by the NVS on the basis of the

commission's proposal. The authorisation has five years validity from the date of issue. The dossiers for the marketing authorisations are kept in the ICVMP. Currently, there is about 1140 VMPs authorised in the country and the full list is published on the internet website of the NVS.

Official controls on marketing and use of VMPs

The DAHW and the ICVMP are responsible for the control of distribution of VMPs. The inspectors of the RVS and the ICVMP carry out the checks. There is one official veterinarian responsible for control of VMPs at each RVS. An annual inspection plan is devised at central level. Minimal inspection frequencies for wholesale, retail (pharmacies) and private practitioners is at least twice per year. Checklists are prepared by DAHW and disseminated to all RVS. The analyses of the samples are carried out in the ICVMP.

The DAHW is responsible also for the control of use of the VMPs. It elaborates the annual control plan specifying the frequency of controls. Big farms are checked at least twice per year. Actual checks are carried out by official veterinarians at the RVS. The criteria checked are VMPs approvals, proper application and compliance with withdrawal periods. Checklists for control of use of VMPs are not elaborated.

Residues

Official controls on residues

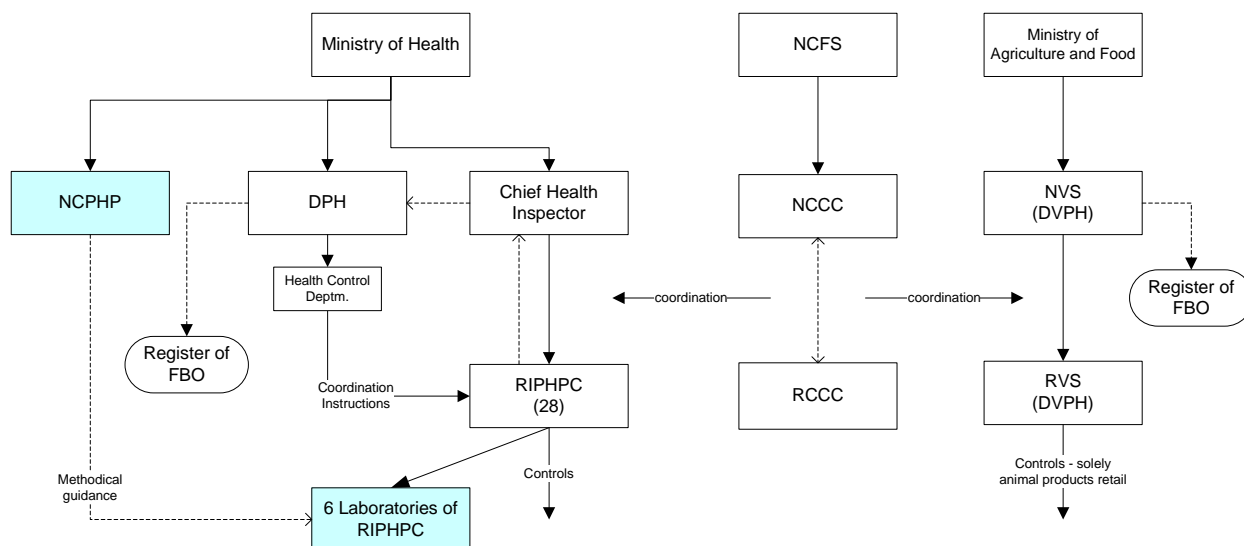
The DCLCT together with the CLVCE prepares and monitors the implementation of the National Residues Control Plan (NRCP). The implementation of the NRCP within the country is carried out by the RVS. The RVS develop regional residue control plans (approved by DCLCT) and report its results back to the DCLCT. At each RVS there is one official veterinarian responsible for co-ordination of sampling. Samples are taken by official veterinary inspectors at the RVS. The results of analyses are sent to official veterinarians with copy to DCLCT in case of a positive result.

Sampling of imported products is part of the NRCP. Residue controls on import are part of the border control activities at BIPs.

Laboratories

The CLVCE in Sofia is the only residue control laboratory involved in testing for the NRCP. The CLVCE is accredited according to ISO 17025 by the Bulgarian Accreditation Service.

2.7 Control system for foodstuffs and food hygiene



MH	Ministry of Health
CSHI	Chief State Health Inspector
DPH	Directorate for Public Health
RIPHPC	Regional Inspectorate for Public Health Protection and Control
NCPHP	National Centre of Public Health Protection
MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
NCFS	National Council for Food Safety
NCCC	National Co-ordination Council for Control

Competent authorities

The CCA for general food hygiene controls is the Directorate for Public Health (DPH) under the Ministry of Health. The NVS is competent authority for retail control in premises trading solely animal origin products.

The DPH is the policy making body that manages and co-ordinates the official control activities of 28 Regional Inspectorates for Public Health Protection and Control (RIPHPC). The Department for State Health Control within the DPH prepares an annual control programme. The programme is risk based taking into account the nature of FBO, past records and frequency requirements. The Department also prepares ad hoc thematic control programmes. It also prepares and issues guidelines and instructions for the implementation of control. The Department plans, organises and controls the monitoring of contaminants and pesticide residues in food. The Department also issues health certificates for foods of non animal origin intended for export. In its work, the Directorate is assisted by the NCPHP, a research institute in the field of food safety.

The newly established National Co-ordination Council for Control (NCCC) within the structures of NCFS is responsible for vertical and horizontal co-ordination between the different services

involved in official control of foodstuffs. The chairmanship alternates in 6 six month periods between the Deputy-Minister of Health and the Deputy-Minister of Agriculture and Food.

Licensing and registration of food premises

The registration of food business operators (FBO) takes place at regional level. A commission of representatives of both competent authorities – RIPHPC and RVS - is responsible for the registration of those FBO where food of animal and plant origin is sold (e.g. supermarkets, catering). The register of food business operators under the control of MH (FBO processing non-animal origin products, catering, retail outlets, supermarkets, premises selling composite food) is kept centrally at DPH and accessible via the internet webpage of the MH http://www.mh.government.bg/registers_licences.php. The register of retail outlets selling solely animal origin food is kept at NVS.

Official controls of food premises

The RIPHPC is responsible for the implementation of official control in food premises including taking samples. In order to implement the requirements of art. 8 of Regulation (EC) No 882/2004, the MH has developed the Standard Operating Procedures for inspection of food establishment, for audit of food establishment and for sampling. Check list for control of production establishments, retail sector, wholesalers, and restaurants has also been developed.

The reporting on the activities of RIPHPC is to the DPH through the Chief State Health Inspector (CHI) on a quarterly basis.

Joint inspections are carried out by inspectors of the RIPHPC and the RVS according to a protocol agreed between the MH and MAF in premises where both animal and plant origin food are sold (e.g. supermarkets).

Inspectors of RVS carry out controls in premises trading solely animal origin products (butchers, fish outlets, etc).

HACCP and Good Hygiene Practice Guides

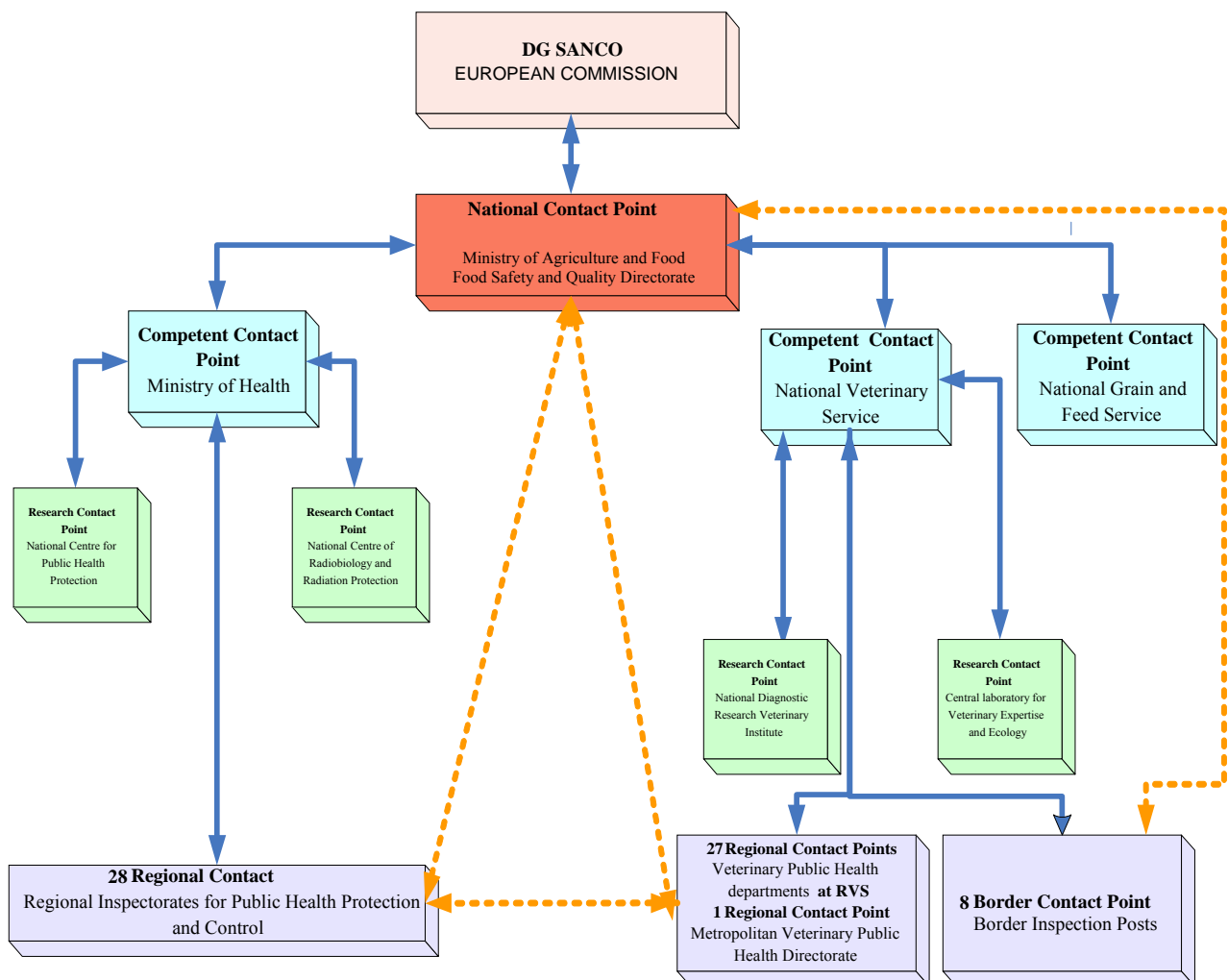
As stipulated by the Food Law, all food business operators have to implement and maintain procedures based on HACCP principles from 1 January 2007. The implementation of HACCP system in all FBO is currently checked by the RIPHPC and/or RVS and should be concluded by mid 2007. Detailed instructions on controls of HACCP requirements were developed by DPH and disseminated to all RIPHPC. Training for inspectors of RIPHPC and RVS in auditing HACCP based systems is being provided.

Guides to Good Hygiene Practice are developed by branch organisations of the food industry in consultation with other interested parties such as consumer associations and competent authorities. All guides are approved by NCFS.

RASFF

Bulgaria became a full member of the Rapid Alert System for Food and Feed (RASFF) network on 1 January 2007. Food Safety and Quality Directorate within the MAF is a National Contact Point (NCP) of the RASFF and communicate with the European Commission. NCP coordinate the activities of the contact points within the MAF and the Ministry of Health (MoH) who perform official controls of food and feed. The structure, functions and activities of the contact points of the RASFF in Bulgaria are described in the RASFF manual of procedures issued in 2006.

The structure of the RASFF includes National Veterinary Service, 27 RVS, 8 Border Inspection Posts, National Diagnostic and Research Veterinary Institute, Central Laboratory for Veterinary Control and Ecology, National Grain and Feed Service, Public Health Control Directorate of the MoH, 28 RIPHPC, National Centre of Radiology and Radiation and National Centre of Public Health Protection.



Laboratories

Laboratory analyses are carried out by 6 laboratories of RIPHPC designated for official control of food. They are performing all the chemical, toxicological and microbiological analyses. One of those laboratories has capacity to perform analysis for GM foods. The laboratory of Sofia RIPHPC is the National Reference Laboratory for analyses of mycotoxins. The laboratories of Pleven RIPHPC and the NCPHP are designated as National Reference Laboratories for pesticide residues in fruits and vegetables and cereals. The GM Food Laboratory of the NCPHP is designated as National Reference Laboratory for GM Foods.

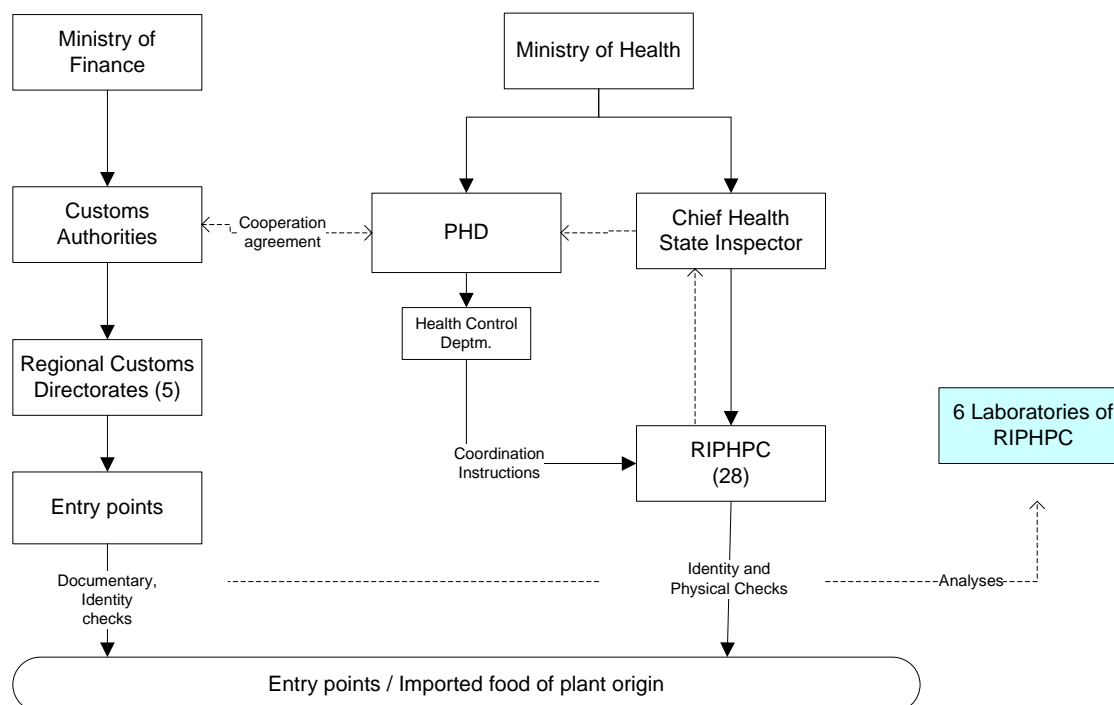
The NCPHP, a research institute under the Ministry of Health, provides methodological guidance to the RIPHPC laboratories.

All laboratories are accredited to BDS EN 45001. The six laboratories are in the process of accreditation to EN ISO/IEC 17025 standard. The accreditation will be performed by the Bulgarian Agency for Accreditation.

Food borne illness

Among food-borne diseases, salmonella is the main cause of intoxications followed by staphylococcus aureus and shigella. Meat and meat products, eggs and confectionary are the most common products causing the illness.

2.8 Control system for imports of food of plant origin



MH	Ministry of Health
CSHI	Chief State Health Inspector
PHD	Public Health Directorate
RIPHPC	Regional Inspectorate for Public Health Protection and Control
NCPHP	National Centre of Public Health Protection
MF	Ministry of Finance
CA	Customs Authorities

Competent authorities

The CCA for import of food of plant origin is the Ministry of Health.

The PHD has overall responsibility for controls on imports of foodstuffs of plant origin. The PDH co-ordinates the activities of RIPHPC in the areas of import control. It prepares and issues guidelines and instructions for the implementation of controls.

The import controls on food of plant origin are implemented by the Customs Authorities at the points of entry and by the RIPHPC at the points of import or destination prior to the release of goods for free circulation.

The Customs Authorities within the Ministry of Finance are organised into five Regional Customs Directorates and 17 local Customs Houses with 82 customs offices and border points.

Import controls

The customs authorities carry out documentary checks of imported foodstuffs at the points of entry of goods into the territory of Bulgaria and release consignments into free circulation.

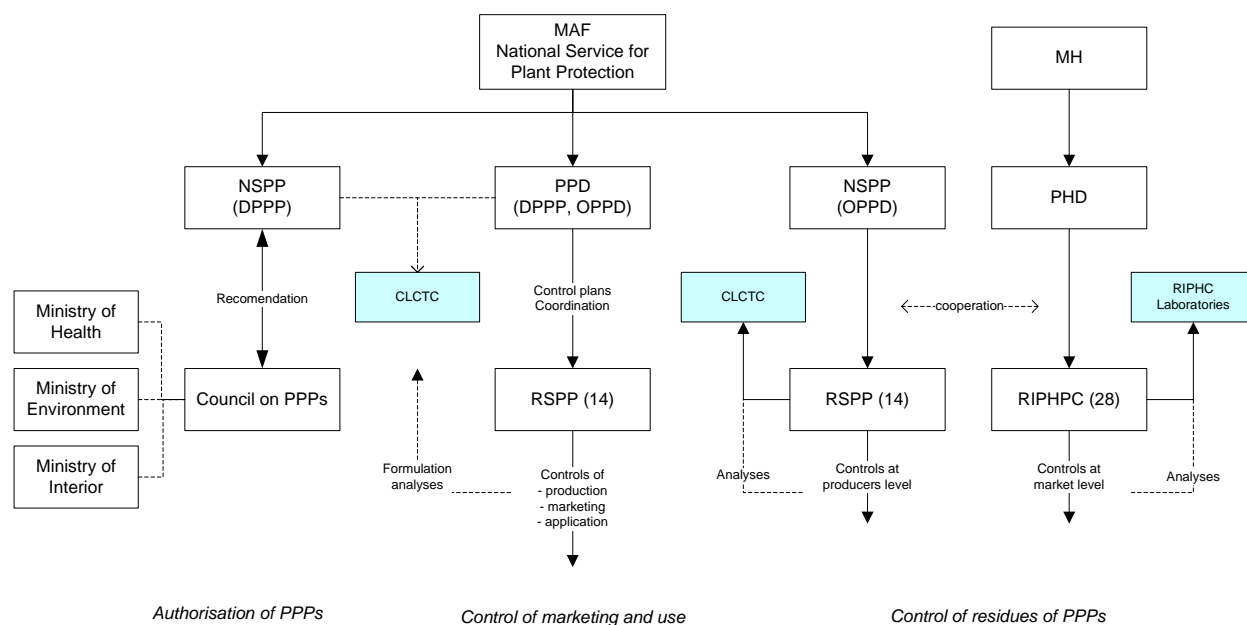
In case of suspicion, the relevant inland customs authority is notified and addresses the foodstuff consignments to the regional RIPHPC for carrying out documentary, identity and/or physical checks and sampling if needed. Alternatively, the customs authority can notify the RIPHPC, which may decide to take samples at the point of entry. The import documents along with the internal control documents (company registration and health certificate from the country of origin) are assessed and, if necessary, an inspector is sent to the declared premises to take samples. The consignments can be cleared by the customs authority only after the examination of the RIPHPC.

There is a co-operation agreement between the customs authorities and the Ministry of Health concerning the control on import of food of non-animal origin. Provisions of Article 5 relate to import of certain foodstuffs that are subject to an increased level of official controls and to which specific Commission Decisions apply. These products can enter into Bulgaria only via 12 designated points of entry. Laboratory analyses are required for these foodstuffs and they are released only after negative analyses are received.

Laboratories

The six laboratories of RIPHPC are used for analyses of the imported foodstuffs of plant origin.

2.9 Control system for plant protection products (PPP) and residues



MAF	Ministry of Agriculture and Food
NSPP	National Service for Plant Protection
PPD	Plant Protection Directorate
DPPP	Department for PPP
OPPD	Operative Plant Protection Department
RSPP	Regional Service for Plant Protection
CLCTC	Central Laboratory for Chemical Testing and Control
MH	Ministry of Health
PHD	Directorate for Public Health
RIPHPC	Regional Inspectorate for Public Health Protection and Control

Control of marketing and use

Competent authorities

MAF is the competent authority for the authorisation of PPPs. A National Council on PPPs has been established by an order of the Minister as a consultative body on PPPs. Its members are representatives of MAF, MH, Ministry of Environment and Water (MEW), Bulgarian Academy of Science (BAS) and Research Institutes.

Authorisation and registration of PPP

The dossier for authorisation of PPP is presented to the National Service for Plant Protection (NSPP) and subsequently reviewed by all involved ministries (MH, MOW). Final authorisation of PPP is issued by the MAF on the basis of the Council's proposal. The NSPP keeps the

documentation and register of authorised PPPs. Currently, there are 689 PPPs authorised for marketing in Bulgaria and 232 active substances.

Official controls on marketing and use of PPP

The NSPP is the competent authority for controls on import, marketing and application of the PPP including labelling checks and checks for correspondence of the PPP with the indicators approved by the authorisation. Within the NSPP, the Operative Plant Protection Department (OPPD) prepares the national annual plans for control of marketing of PPPs and their use at farm level. The Department co-ordinates and manages the control activities of RSPP. It issues checklists for inspections and instructions for taking samples.

Control is carried out by inspectors of the RSPP at production, import, packaging, storage, transport and at farm level. Each RSPP has one official responsible for PPP control (planning and reporting), but in practice 86 regional inspectors are dealing with control of PPP on the territory of the country. Two checks are carried out annually for all PPP producers as well as for repackaging companies. Control covers 100% of the wholesale traders and 80 - 100% of the retailers (agricultural pharmacies). NSPP annually controls 1% of the registered farmers for the PPP usage. In case of suspicion, random control is carried out.

Formulation analyses of samples taken are performed by the Central Laboratory for Chemical Testing and Control (CLCTC) which is the part of the NSPP and is accredited according ISO 17025 standard. Registers of PPP producers, traders and users are kept at both central and regional level.

Audits of activities of RSPP are carried out by the experts from the OPPD, within the NSPP. NSPP is under the process of preparation for accreditation to ISO 17020 in three "pilot regions". Fourteen Regional Quality Managers have been designated and are already trained under standards ISO 17020 and ISO 19011.

A strategy for dealing with obsolete pesticides has been developed by the Ministry of Environment and Waters. The implementation of the strategy is partly the responsibility of the NSPP, particularly as regards control of obsolete pesticides and monitoring places for storage of these products. The destruction of obsolete pesticides has not started yet.

Residues

Competent Authorities

The NSPP is the competent authority for control and monitoring of pesticide residues in fresh, frozen, dried and processed fruit and vegetables at producers level (before the goods are placed on the market). The MH is competent authority for monitoring pesticides residues in domestic and imported foodstuffs at market level.

Official controls on residues

The annual control and monitoring programme of NSPP is endorsed by the Director general of NSPP and it is implemented by the inspectors of RSPP and CLCTC.

The monitoring programme of the MH is drawn up centrally by PHD on the basis of the results of the NSPP monitoring programme and own monitoring programme. It is part of an annual official control plan developed by the PHD. Sampling is carried out by RIPHPC and samples are analysed in their laboratories.

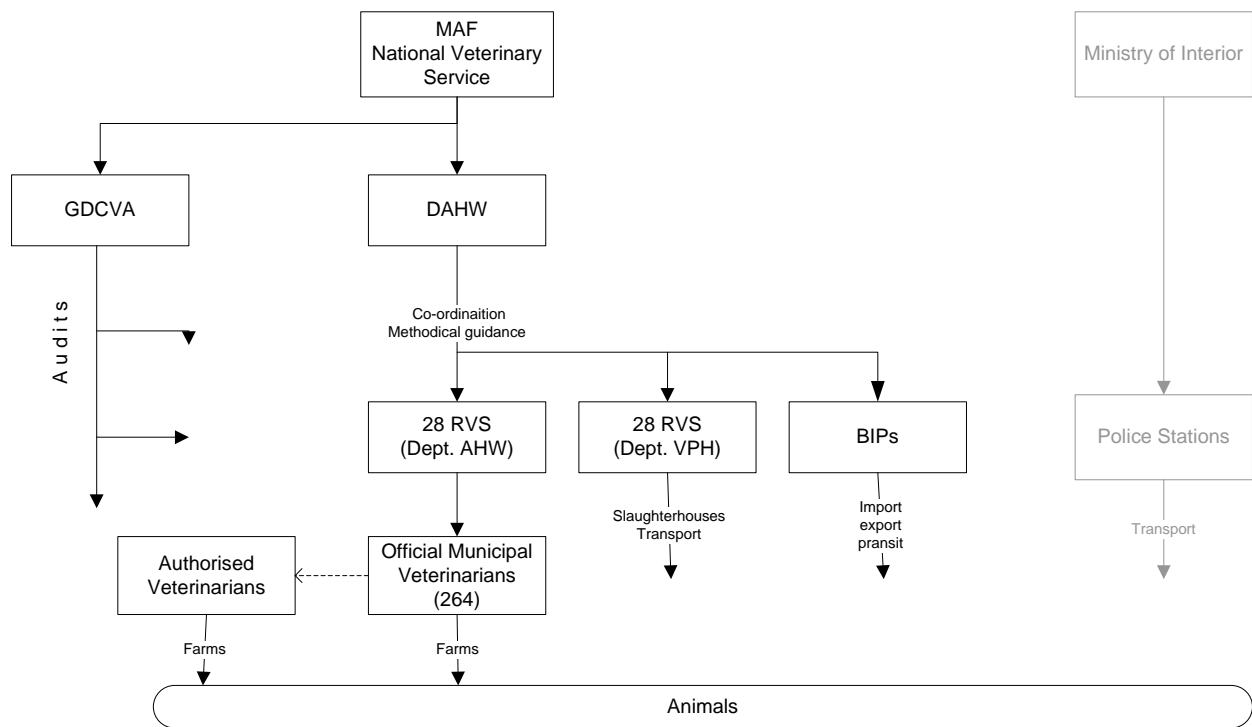
Maximum Residue Limits (MRLs) are stipulated in the Ordinance of the MH. The Ordinance is drafted by a working group comprised of participants from both ministries - MH and MAF.

Laboratories

The six laboratories of RIPHPC and the CLCTC laboratory are used for analyses of the pesticides residues in food of plant origin.

Co-operation between the MH and the NSPP has been initiated and a common monitoring programme for pesticide residues for 2009, based on the common EU pesticide residues programme, has been elaborated.

2.10 Control system for animal welfare



MAF	Ministry of Agriculture and Food
NVS	National Veterinary Service
DAHW	Directorate for Animal Health and Welfare
GDCVA	General Directorate for Control of Veterinary Activities
RVS	Regional Veterinary Service
MI	Ministry of Interior (Police)

Competent authorities

The CCA for animal welfare is NVS. The DAHW is responsible for policy making and legislation in the sector. Two staff from the DAHW (*organised within the Animal Welfare Department since July 2007*) with a help of another two from the Directorate for European Integration work on animal welfare issues at central level. The DAHW organises, co-ordinates and manages the activities of the RVS in the animal welfare area. It issues instructions concerning inspection programmes, guidelines, protocols and forms for the inspections and manuals for farmers. The Directorate also organises training for all inspectors involved in welfare checks.

The General Directorate for Control of Veterinary Activities (GDCVA) perform audits within the whole structure of veterinary services covering the activities of all administrative levels (DAHW, RVS, OMV and authorised veterinarians). These also include audits of activities in animal welfare area.

Official controls on farm and at slaughter

Animal welfare control plans are developed at regional level and submitted to the DAHW for approval. With the adoption of new Animal Welfare Law, the control plans will be prepared centrally.

Checks on animal welfare are carried out by inspectors of the RVS and official veterinarians at BIPs. In each of the 28 RVS there is one official veterinarian responsible for animal welfare issues. Official municipal veterinarians and authorised veterinarians carry out checks on animal welfare requirements at farms. The inspectors of the public health department at the RVS are responsible for animal welfare checks at slaughterhouses.

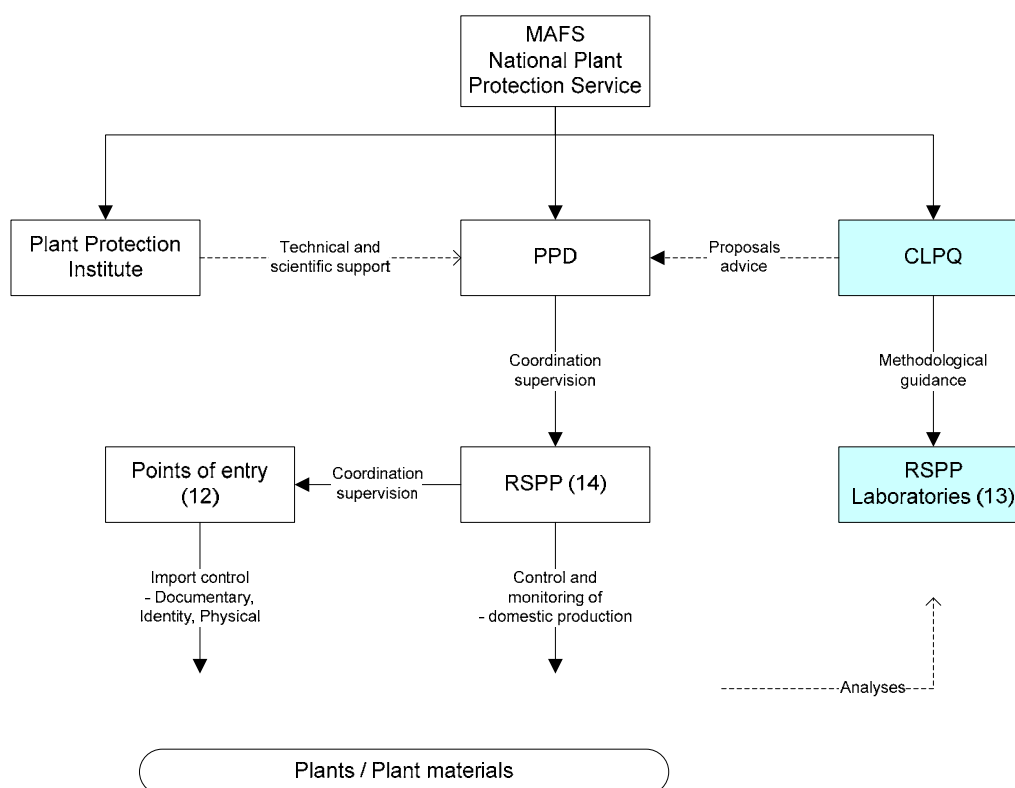
A summary report on animal welfare inspections performed in each region is submitted by the RVS to the DAHW twice a year.

Official controls during transport

The Law on animal welfare gives a legal basis for the police to perform animal welfare controls at transport. An Ordinance for co-operation and joint actions with police on transport checks has been prepared, but is not implemented yet. No systematic animal welfare checks during transport are carried out. The police may undertake random checks. However, no reporting to the NVS is done.

Veterinarians at BIPs check the animal welfare transport requirements at import, export and transit of the animals.

2.11 Control system for plant health



MAF	Ministry of Agriculture and Food
NSPP	National Service for Plant Protection
PPD	Plant Protection Directorate
PPI	Plant protection Institute
RSPP	Regional Service for Plant Protection
CLPQ	Central Laboratory for Plant Quarantine

Competent authorities

The CCA for plant health issues is the National Service for Plant Protection (NSPP) within the Ministry of Agriculture and Food.

The Phytosanitary Control Department (PCD) within the Plant Protection Directorate (PPD) operates in the field of harmful organism controls and is responsible for legislation drafting, planning and co-ordinating inspections at places of production, import, export and transit, and also for surveys and training of the personnel. The Department employs five staff. It co-ordinates and supervises the activities of Regional Services for Plant Protection (RSPP) on plant quarantine issues. It issues orders and guidelines for the regional inspectors. The co-ordination of laboratory activities (sampling and analyses) is mainly delegated to the CLPQ.

The Plant Protection Institute, as part of the NSPP, provides technical and scientific support to all departments within the Plant Protection Directorate.

The NSPP has 14 regional services (RSPP) throughout Bulgaria of which some are divided into district units. The RSPP are responsible for enforcement of legislation in regions. They carry out inspections at the place of production, surveys, import and export certification and run the alert system for producers regarding identification of pests and application of plant protection products. Fourteen RSPP plus 13 district units are directly subordinated to NSPP.

A Consulting Council provides technical expertise and scientific advice on all phytosanitary matters and on specific issues at the request of the NSPP. The Council includes representatives from universities, plant protection associations and other experts.

Internal market controls

Monitoring programmes are prepared by PCD and CLPQ every year. There are nine regional-based rapporteurs for each of the nine monitoring programmes (potatoes, fruit trees, vine planting material, greenhouse plants, strawberries, forest species, *Diabrotica virgifera virgifera*, potato cyst nematode, wood packaging materials). Reports of the activities carried out by RSPP are sent monthly and half-yearly to PCD. This information is compiled in an annual report which is subsequently used to establish the monitoring programmes for following years.

Import controls

There are 12 points of entry for goods subject to phytosanitary controls as follows.

BIP		Border
Kapitan Andreevo	Road	Turkey
Svilengrad	Railway	Turkey
Zlatarevo	Road	Macedonia
Gueshevo	Road	Macedonia
Kalotina/ Dimitrovgrad	Road/ Railway	Serbia
Vrushka chuka	Road	Serbia
Bregovo	Road	Serbia
Burgas	Port	n.a.
Varna	Port	n.a.
Vidin	Port	n.a.
Ruse	Port	n.a.
Sofia	Airport	n.a.

At points of entry, plant health inspectors carry out documentary, identity and physical checks. There are 73 inspectors employed at the phytosanitary BIPs. Samples for analysis are taken in cases where presence of harmful organisms is suspected, or if the article is included in a special list (seeds and planting material). Once the consignment has been checked and is in compliance with the phytosanitary provisions, it can be cleared by the customs authorities and released for free circulation.

Laboratories

The Central Laboratory for Plant Quarantine (CLPQ) carries out phytosanitary tests of imported and domestic plants, plant products, soil and other materials and validates the positive and doubtful results of the analyses made at RSPP laboratories. CLPQ is involved also in coordinating the activities of RSPP, issuing methodological guidelines for inspection and drafting monitoring programmes. CLPQ also provides training and instructions to staff on diagnostics and identification of pests.

CLPQ is located in Sofia and has a branch specialised in potato analyses in Samokov.

There are laboratories attached to each RSPP (except Sofia RSPP), where tests are carried out.

Plant diseases

The tables below give the overview of outbreaks of quarantine pests on domestic materials in the period of 2002-2007.

Year	Pest	Crop	Place of outbreak / area	Measures taken
2002	<i>Bemisia tabaci</i>	Christmas star	“Iris”, “L2 Company” Glasshouse - Sofia,	The infection destroyed
	<i>Colletotrichum acutatum</i>	Strawberries for fruits	Kovachevo village, Pazardjic district	The infection destroyed
2004	<i>Synchytrium endobioticum</i>	Plant & soil samples	In private yards – Rainovo village, Sofia district	The outbreak limited
	<i>Pepino mosaic virus (PepMV)</i>	Tomatoes	Glasshouse – Marten village, Russe district	The infection destroyed
	<i>Xanthomonas fragariae</i>	Strawberries	Lozen village, Pazardjic district	The infection destroyed

Year	Pest	Crop	Place of outbreak / area	Measures taken
2005	<i>Synchytrium endobioticum</i>		24,7 ha	35670 kg of infested potatoes are destroyed disinfected 1,55 ha
	<i>Erwinia amylovora</i>		38, 82 ha Mother trees Separate trees	Destroyed Trees in 4,9 ha orchard Mother trees - 8 pcs. Saplings - 24 pcs. Separate trees- 41 pcs.
	<i>Diabrotica virgifera</i>		404ha –high infestation 19 513 ha -low infestation	Keep an appropriate crop rotation within the larger part of the region.

	<i>Globodera rostochiensis</i>		93,84 ha	Registered plots and prescribed measures
	<i>Colletotrichum acutatum</i>		16.4 ha	Chemical treatment, burning
	<i>Xanthomonas fragariae</i>		6.6 ha	Destroying
	<i>Bemisia tabaci</i>		1,35 ha	prescriptions for chemical treatment and destroying.
	<i>Liriomyza huidobrensis</i>		19,74 ha	prescriptions for chemical treatment
	<i>Franklinella occidentalis</i>		21,3 ha	prescriptions for chemical treatment
	<i>Plum pox potyvirus</i> (PPV)		9 ha-plums 20 pcs. mother trees – apricot trees	Infested plants in the orchard are destroyed, 2,765 pcs. saplings, 20 pcs. mother trees
	<i>Strawberry latent ringspot virus (SLRV)</i>	Strawberry	0,5 ha	Destroyed
	<i>Raspberry ringspot virus</i>	Raspberry	1,25 ha	Destroyed
	<i>Clavibacter michiganensis ssp. michiganensis</i>		0,3 ha	Solarization of the greenhouse, crop change
	<i>Strawberry mild yellow edge virus</i>	Separate strawberry plants		Eradication of infested plants No new symptoms
	<i>Puccinia horiana</i>		0,2 ha greenhouse	eradication and destruction

Year	Pest	Crop	Area of outbreak	Measures taken
2006	<i>Erwinia amylovora</i>	2 pcs mother trees 202 saplings	23, 82 ha	Destroyed mother trees - 2 pcs. 202 saplings
	<i>Diabrotica virgifera virgifera</i>		594 ha	Keep an appropriate crop rotation within the larger part of the region.
	<i>Globodera rostochiensis</i>		810,5 ha	Registered plots and prescribed measures
	<i>Colletotrichum acutatum</i>		29,9 ha	Chemical treatment, burning
	<i>Xanthomonas fragariae</i>		5 ha	Destroying
	<i>Bemisia tabaci</i>		15,5 ha	chemical treatment and destroying of infested plants.
	<i>Liriomyza huidobrensis</i>		4,084 ha	prescriptions for chemical treatment
	<i>Franklinella occidentalis</i>		190,9 ha	prescriptions for chemical treatment
	<i>Plum pox potyvirus (PPV)</i>	7231 pc. saplings, 77 pc. mother trees	1,54 ha	Infested plants in the orchard are destroyed, 7231 pcs. saplings, 77 pcs. mother trees

Year	Pest	Crop	Area of outbreak	Measures taken
2007	<i>Colletotrichum acutatum</i> Simmod	Strawberry	12,6 ha	Treatment
	<i>Xanthomonas arboricola</i> <i>pv. pruni</i>	Sour cherry	5 ha	destroyed 50 fruit trees
	<i>Clavibacter michiganensis</i> subsp. <i>sepedonicus</i>	Potato	60,35 ha	19579 kg of infected potatoes are destroyed and change crop
	<i>Clavibacter michiganensis</i> subsp. <i>michiganensis</i>	Tomato	7,7 ha	Prescriptions to destroyed contamination plants, to chemical treatment, disinfection and crop change.
	<i>Erwinia amylovora</i>	Fruit trees	1,8 ha	Destroyed: 1,3 ha mother garden, Mother trees – 32 pcs. Trees in 0,43 ha garden, Saplings – 1252 pcs.
	Pear decline Phytoplasma	Pear	0,4 ha	Destroyed 11 mother trees
	Apple Proliferation Phytoplasma	Apple	0,5 ha	Destroyed 2 mother trees
	Strawberry latent ringspot virus (SLRSV)	Strawberry	11,7 ha	Scheduling of strawberry plots for future observation and destroyed all plants around infected
	Strawberry mild yellow edge virus (SMYeV)	Strawberry	10,6 ha	Scheduling of strawberry plots for future observation and destroyed all plants around infected
	Potato Stolbur Phytoplasma	Potato	6 ha	destroyed all potato production
	Plum pox virus (PPV)	Fruit stone trees	Mother trees – 70 Saplings – 11150 pcs	Infected plants in the orchards and saplings are destroyed
	<i>G. rostochiensis</i> <i>G.pallida</i>	Potato	106,8 ha	Registered plots and prescribed measures
	<i>Liriomyza huidobrensis</i>	Tomato and cucumbers	17,25 ha	Prescriptions for chemical treatment
	<i>Bemisia tabaci</i>	Pot flower	2,8 ha	Prescriptions for chemical treatment and infection destroying
	<i>Diabrotica virgifera</i> <i>virgifera</i>	Zea	1175 ha	Confirmation for infection in a 8 new area in country
<i>Opogona sacchari</i>	Pot flowers	0,05 ha	Destroyed infected 3 plants	

Source : MAF

3. FOLLOW-UP OF FVO MISSIONS

This part of the country profile gives an overview of the action taken on the recommendations made by the FVO to the Bulgarian authorities in its inspection¹ reports.

As part of the accession preparations the FVO carried out 28 pre-accession missions in Bulgaria in the period of 2003 to 2006 to assist and monitor progress on the adoption of the relevant EU requirements. As Bulgaria was not a Member State at the time, the reports of these missions were not published. In the tables on follow up below, these are flagged as “pre-accession missions”. The FVO has carried out a further 21 inspection missions to Bulgaria since accession.

At the time of the general review mission to Bulgaria in November 2008, a total of 342 recommendations had been made in the 41 finalised inspection reports for Bulgaria in the period since 2003.

Prior to the 2008 general review mission, the Commission had closed 287 recommendations either on the basis of action taken² by the Competent Authority or because they were no longer relevant. The remaining 55 recommendations will be followed up during the general review mission in November 2008³. These consisted of four recommendations classified as "outstanding / action still required" and 51 recommendations classified as "in progress / for verification). The overall position before and after the general review mission in November 2008 is summarised in the following table:

	Pre-General Review mission 2008	Post - General Review 2008
Action taken/ No longer relevant	287	316
Outstanding/ Action still required	4	6
For verification/ In progress	51	20
Total number of recommendations	342	342

¹ Those in respect of which the technical assessment by the FVO had been finalised at the time of the general review.

² For the purpose of the Country Profile the terms: "Action taken," "In Progress", “No longer relevant” and "Action still required" are defined as follows:

"Action taken": Appropriate measures to address the recommendation have been implemented by the Competent Authority. The recommendation is therefore closed.

"No longer relevant": For administrative, technical or legal reasons follow up of the recommendation is no longer appropriate. The recommendation is therefore closed.

"In Progress": Appropriate measures to address the recommendation have been initiated by the Competent Authority but not all of the measures have been implemented. The recommendation therefore remains open.

"Action still required": Appropriate measures to address the recommendation have not been initiated by the Competent Authorities. The recommendation therefore remains open.

³ It should be noted that the number of recommendations in this overview does not represent, of itself, a measure of the degree of responsiveness by the Competent Authorities or of the seriousness of problems. Some recommendations may be related to minor technical aspects while others may refer to more problematic, systemic, issues.

The final assessment is based on information and documentation received and reviewed during meetings with the Competent Authorities in the course of the general review mission. Given the nature and scope of the general review mission, no verification through inspection on the spot will be carried out. The assessment undertaken through the general review mission is considered complementary to other follow up actions and verifications that may be necessary and carried out as part of future sectoral inspections by the FVO. In this regard, unless otherwise indicated, recommendations classified as “in progress ”or“ action still required ”are not considered to require any immediate specific legal or administrative action on the part of the Commission. These recommendations will remain the subject of monitoring by the Commission to assess progress. If, as a result of this monitoring, the Commission considers the situation in regard to any of these recommendations warrants additional action on its part, it will take the appropriate measures.

The following table gives an overview of FVO inspections to Bulgaria since 2003 and the assessment in relation to the 55 recommendations identified for further follow up in the general review mission of 2008. The findings in relation to individual recommendations are presented in a separate chapter for each control system.

Summary of follow-up status

X: no recommendation identified for follow-up during the FVO general review mission of April 2007

O recommendations outstanding

V recommendations for verification

A: recommendations on which action has been taken

P: recommendations on which action is still in progress

R: recommendations on which action is still required

() recent inspections for which responses from the CCAs awaited or are being assessed by the FVO*

S: Scheduled FVO mission

Inspection reference number and objectives of the inspection		Animal health	Food of animal origin	Imports of animals and food of animal origin	Feedings and animal nutrition	TSEs\ABP	Veterinary medicines and residues	Foodstuffs and food hygiene	Imports of food of plant origin	Pesticides	Animal welfare	Plant health
2003	Pre-accession	Enlargement – TSEs				X						
	Pre-accession		X									
	Pre-accession		X									
2004	Pre-accession	Enlargement – Plant Health										X
	Pre-accession	Evaluation of CA in TC – Potatoes										X
	Pre-accession	X	X									
	Pre-accession			X								
	Pre-accession							X	X	X		
2005	Pre-accession	Enlargement – Plant Health										X
	Pre-accession	Plant Health - Evaluation of CA in TC - Potatoes										X
	Pre-accession				X	X						
	Pre-accession	X	X									
	Pre-accession							X	X	X		
	Pre-accession										X	
	Pre-accession	Enlargement – Residues					X					

Inspection reference number and objectives of the inspection		Animal health	Food of animal origin	Imports of animals and food of animal origin	Feedingstuffs and animal nutrition	TSEs\ABP	Veterinary medicines and residues	Foodstuffs and food hygiene	Imports of food of plant origin	Pesticides	Animal welfare	Plant health	
2006	Pre-accession	Poultry – CP Avian Influenza	X										
	Pre-accession	Plant Health Controls										X	
	Pre-accession	BSE					X						
	Pre-accession	Feed Controls				X							
	Pre-accession	Animal by-products					X						
	Pre-accession	General Review Mission	X	X	X	X	X	X	X	X	X	X	X
	Pre-accession	Import Controls			X								
	Pre-accession	Import Controls			X								
	Pre-accession	General Food Hygiene Controls							1P				
	Pre-accession	Pesticides, marketing and uses								1R			
	Pre-accession	Residues						1P 1R					
	Pre-accession	Animal Welfare									3A 1P 1R		
	Pre-accession	Animal Health/ Veterinary public health		X									
	2007	7571/2007	Import controls, BIPs			X							
7527/2007		Avian Influenza, Newcastle Disease	4A 1P										
7574/2007		Veterinary public health / Establishments		X									
7584/2007		Veterinary public health / Establishments		X									
7590/2007		Veterinary public health / Establishments		X									
7465/2007		General Review	X	X	X	X	X	X	X	X	X	X	
7483/2007		Classical Swine Fever	X										
7197/2007		General Food Hygiene/ Bottled water							4A 1P				
7272/2007		Feed Hygiene				8A 1P							

Inspection reference number and objectives of the inspection		Animal health	Food of animal origin	Imports of animals and food of animal origin	Feedingstuffs and animal nutrition	TSEs\ABP	Veterinary medicines and residues	Foodstuffs and food hygiene	Imports of food of plant origin	Pesticides	Animal welfare	Plant health
2008	7687/2008	Animal Welfare									*	
	7950/2008	Veterinary public health / Establishments	*									
	7747/2008	Import controls, BIPs		*								
	7837/2008	Pesticides								3A 4P		
	7728/2008	BSE					1A 3P 1R					
	7732/2008	TSE					3A 4P 1R					
	7847/2008	Import controls on food and feed on non-animal origin							*			
	7800/2008	Classical swine fever	*									
	7736/2008	Animal by-products						3A 3P 1R				
	8023/2008	Salmonella		*								
	8013/2008	Residues						*				
		7710/2008	General Review	X	X	X	X	X	X	X	X	X
2009	8110/2009	BSE					*					

3.1 Control system for animal health

Since 2003 the FVO has carried out six inspections in Bulgaria in relation to animal health. Of 49 recommendations contained in the reports of these inspections, five were identified for follow-up during the 2008 general review mission all of which were contained in reports that had reached closeout stage since the 2007 general review mission.

As shown in the following tables, 4 recommendations have been classified as "action taken" and for 1 recommendation action is in progress.

Recommendations carried over from the country profile of 2007

Inspection 7527/2007 of 5 March 2007 on Avian Influenza and Newcastle Disease		
Reference No. and recommendation	Findings	Assessment
2007-7527-1 As already recommended in the 2006 FVO report, the CA should endeavour to complete the installation of the NDCC and LDCCs (Council Directives 92/40/EEC Annex VI and 92/66/EEC Annex VII).	A National crisis centre was set up at the central level of the NVS and supplied with the necessary equipment (maps, telephone, fax, internet connection and e-mail) Regional crisis centres are also set up and furnished with the necessary equipment and maps in all RVS. Maps of the districts and municipalities with the appropriate scale recommended by the FVO mission have been supplied.	Action taken
2007-7527-2 The CA should satisfy itself that the NRL review the diagnostic protocols to guarantee the use of appropriate, internationally recognised and valid AI testing methods following the requirements in Council Directive 92/40/EEC Annex III and of the Diagnostic Manual in Commission Decision 2006/437/EC.	The NRL issued new protocols for the diagnosis of AI (No 204, 03/10/2008) and ND (No 277 20/10/2008) which are in compliance with the Community requirements.	Action taken
2007-7527-3 The CA should require that the NRL finalises the accreditation procedure as required in Article 12 of Regulation (EC) No 882/2004 (Taking into consideration the provisions of Article 18 of Decision 2007/6/05/EC).	The accreditation procedure has already been completed, but the NRL has not yet been issued the official certification from the Bulgarian Accreditation Service.	In progress
2007-7527-4 The CA should complete the CPs for ND and AI, following the requirements of Annex VI to Council Directive 92/40/EEC	The Contingency plans for ND and AI have been corrected and amended, following the FVO mission recommendations and EU requirements. There was an AI simulation exercise in April 2008. The CCA and the regional CAs tested the CP and	Action taken

Inspection 7527/2007 of 5 March 2007 on Avian Influenza and Newcastle Disease		
Reference No. and recommendation	Findings	Assessment
and Annex VII to Council Directive 92/66/EEC.	agreed that the plan is useful and usable on the field.	
2007-7527-6 The CA should ensure that the epizootiological inquiries are carried out in accordance with Article 7 of Council Directive 92/40/EEC and Article 7 of Council Directive 92/66/EEC.	The plans for the epizootiological investigation of ND and AI were elaborated and attached to the contingency plans. See findings in rec. 2007-7527-4 above.	Action taken

3.2 Control system for food of animal origin

Since 2003 the FVO has carried out eight inspections in Bulgaria in relation to food of animal origin. The recommendations related to food of animal origin have been either closed because the action was taken by competent authorities or have been followed-up in a recent inspection and are dealt with in chapter 3.12.

3.3 Control system for imports of food of animal origin

Since 2003 the FVO has carried out four inspections in Bulgaria in relation to import controls. The recommendations related to import of food of animal origin have been either closed because the action was taken by competent authorities or have been followed-up in a recent inspection and are dealt with in chapter 3.12.

3.4 Control system for feedingstuff and animal nutrition

Since 2003 the FVO has carried out three inspections in Bulgaria in relation to feedingstuff and animal nutrition. Of 34 recommendations contained in the reports of these inspections, nine were identified for follow-up during the 2008 general review mission all of which were contained in reports that had reached closeout stage since the 2007 general review mission.

As shown in the following tables, 8 recommendations have been classified as "action taken" and for 1 recommendation action is in progress.

Recommendations reaching closeout note stage since the 2007 general review mission.

Inspection 7272/2007 of 2 October 2007 on Feed Hygiene controls		
Reference No. and recommendation	Findings	Assessment
2007-7272-1 To ensure that feed inspectors are responsible for verification of the implementation of requirements on HACCP	Project 2007/019-303.03.02 „Strengthening of the official control of feedingstuffs in Bulgaria” foresees several trainings of NGFS feed inspectors including HACCP and auditing. The project was sent to Commission for approval in October 2008, will commence at the beginning of 2009 and will last one	Action taken

Inspection 7272/2007 of 2 October 2007 on Feed Hygiene controls		
Reference No. and recommendation	Findings	Assessment
procedures and quality control, as laid down in Art. 6 of Regulation 183/2005 and its Annex II respectively, are trained to undertake their duties competently, as required by Art. 6 of Regulation (EC) No 882/2004.	year. 10 inspectors of NGFS completed a training course at the Centre for Raising Qualifications at the University for Food Technologies, Plovdiv on Food Safety Control and Management System (HACCP system).	
2007-7272-2 To ensure that the annual control plan for inspections of FBOs and sampling of feed takes into account the reliability of FBO own checks as required by Art. 3.1 (c) of Regulation (EC) No 882/2004.	The control plan for 2008 includes frequency criteria and the guidelines and checklists for HACCP. The plan is effective from 1.1.2008. Work continues on compilation of the control database. Details of follow up actions in cases of detected non-compliances were provided by CA.	Action taken
2007-7272-3 To designate laboratories able to carry out the analyses of all samples taken during official controls on feed, as required by Art. 12 of Regulation (EC) no 882/2004.	Relations have been established with a number of laboratories from other MS (Czech Republic, Germany, Belgium) where the analysis for official control purposes are carried out. Samples are analyzed there on coccidiostats, antibiotics and other feed additives with fixed maximum content as well as dioxins. Number of samples analysed for coccidiostats increased from 26 to 33 (2007 to 2008), prohibited substances (Germany) from 457 to 780 and dioxins (Belgium) from 6 to 18.	Action taken
2007-7272-4 To designate a NRL for feed additives as required by Art. 33 of Regulation (EC) No 882/2004.	The Central Laboratory for Qualification of Grain Products and Feedingstuffs has been designated by order of the MAF 09/181/10.04.2008 as the NRL for feed additives. The NRL undertakes analysis of feed additives for micro-elements (about 2% of samples) and the bulk of samples (98%) are analysed by UKZUZ in Czech Republic.	Action taken
2007-7272-6 To take steps to ensure that the HACCP procedures laid down by Art. 6 of Regulation (EC) No 183/2005 are implemented.	Project 2007/019-303.03.02 „Strengthening of the official control of feedingstuffs in Bulgaria” foresees several trainings of NGFS feed inspectors including HACCP and auditing. The project will commence at the beginning of 2009 and will last one year. 2008 control plan includes checks of the procedures based on HACCP principles. Details of follow up actions in cases of detected non-compliances were provided by CA. The results from the inspections will be summarized in IT database that will be developed as part of the above project.	In progress

Inspection 7272/2007 of 2 October 2007 on Feed Hygiene controls		
Reference No. and recommendation	Findings	Assessment
2007-7272-7 To authorise imports only under the conditions laid down in Art. 6 of Directive 98/51/EC, establishing a list of representatives in the EU of establishments located in third countries and requiring a declaration of compliance with EU requirements for feed hygiene. <i>(ref. now Regulation EC 183/2005)</i>	Directive 98/51/EC has been transposed in the national legislation in Ordinance No. 109 on the official control of feedingstuffs (SG, issue 84/2006, amended and supplemented in SG, issue 64/2008, amended in SG, issue 82/2008). The NGFS keeps register of approved and a list of registered representatives of enterprises for feed import from third countries on the its websites http://www.nszf.bg .	Action taken
2007-7272-8 To transpose Directive 98/68/EC. <i>(ref. now Regulation EC 183/2005)</i>	Directive 98/68/EC has been transposed in the national legislation in Ordinance No. 109, Article 22, Annex III. BIPs send the document electronically to central CA.	Action taken
2007-7272-9 To reinforce the sampling programme aimed at ensuring compliance with the phasing out of antibiotics as feed additives laid down by Art. 11 of Regulation (EC) No 1831/2004.	In the feed control plan for 2008 the sampling on antibiotics not authorized as feed additives is envisaged. As of end September 2008, 32 samples were taken for screening for antibiotics and 480 analyses were conducted. <i>(see also findings for recommendation 2007-7272-3 above)</i>	Action taken
2007-7272-11 To reinforce compliance with the rules on dioxins laid down by Directive 2002/32/EC on undesirable substances in order to ensure that the maximum levels set out in Annex II are not exceeded.	Number of samples analysed for dioxins (in Belgium) increased between 2007 and 2008 from 6 to 18.	Action taken

3.5 Control system for TSE and Animal-By-Products (ABP)

Since 2003 the FVO has carried out six inspections in Bulgaria in relation to TSEs and ABP. Out of a total of 54 recommendations contained in the reports of this mission, 20 were identified for follow-up during the 2008 general review mission all of which were contained in reports that had reached closeout stage since the 2007 general review mission.

As shown in the following tables, 7 recommendations have been classified as "action taken", 10 have been classified as "in progress" and for 3 recommendation action is still required.

MR 7728/2008 of 18 February 2008 on BSE controls		
Reference No. and recommendation	Findings	Assessment
2008-7728-1 To develop the CDB so that it can become a useful tool for monitoring the implementation of epidemio-surveillance for BSE in accordance with the requirements of Annex III to Regulation (EC) No 999/2001.	<p>The number of the authorized persons with access to enter data in to the system increased (265+56 official vet, all SH, 2 rendering plant, 100 big farmers).</p> <p>Despite the development of various additional modules within the CDB (module for automatic determination of the age of animals, module for automatic traceability of suspected or positive animals) is in progress, there is not currently a system which could be a useful tool to help the monitoring of the BSE epidemio-surveillance.</p>	In progress
7728-2008-2 To ensure that all categories of bovines (including those animals over 24 months old found to be sick at ante-mortem examination) are sampled for BSE in accordance with the requirements of Annex III to Regulation (EC) No 999/2001.	<p>The order PĎ 11-751/ 29.09.2008 specifies the compulsory sampling for BSE of all bovines over 24 months old found to be sick at ante mortem examination.</p> <p>The CA has changed the reporting format of the BSE from the regions to the central in March 2008. The new format contains the number of the bovines over 24 months old found to be sick at ante mortem examination. There has not been any bovine reported in this category yet.</p>	In progress
7728-2008-3 To continue implementing education and training programmes to encourage the reporting of clinical BSE suspects as required by Art. 10 of Regulation (EC) No 999/2001.	<p>Trainings on BSE clinical signs and reporting of clinical BSE suspects as required by Art. 10 of Regulation (EC) No 999/2001 have been carried at the RVSs for official and private veterinarians.</p> <p>In 2008, 113 veterinarians were trained (out of 294 official veterinarians and 630 private veterinarians). No BSE suspects have been reported during 2008.</p> <p>The NVS will continue implementing education and training programmes to encourage the reporting of clinical BSE suspects as required by Art. 10 of Regulation (EC) No 999/2001. Trainings are envisaged for all private veterinarians in relation to the clinical signs of BSE in order to ensure that all clinical BSE suspects will be reported and tested.</p>	In progress

MR 7728/2008 of 18 February 2008 on BSE controls		
Reference No. and recommendation	Findings	Assessment
7728-2008-5 To ensure that SRM produced during home slaughtering of cattle is controlled and disposed of in accordance with the requirements of Annex V to Regulation (EC) No 999/2001.	The leaflets on the requirements of Regulation (EC) No 999/2001 have been distributed to farmers containing useful information for handling with SRMs. However, the collection of the fallen stocks and the SRM of the home slaughtered animals is unsolved and there is no plan to deal with the problem. There is a legal requirement that every district (1-3 villages) has to ensure a collection ground for the fallen stocks but only very few districts implement this rule. The collection of the SRM of home slaughtered animals is not implemented at all.	Action still required
7728-2008-6 To ensure that all Category 1 MBM is kept under official control and disposed of in accordance with the requirements of Article 4 of Regulation (EC) No 1774/2002.	The all amount of Category I MBM from previous stock has already been disposed of. However, the co incineration has been stopped now for at least three month, because the industries are undergoing the reconstruction to increase their capacities. In the meantime they are collecting and storing the MBM on a separated, secured area and the stock will be incinerated when the operation of the plant starts again.	Action taken

MR 7732/2008 of 25 February 2008 on controls of TSE in sheep and goats		
Reference No. and recommendation	Findings	Assessment
2008-7732-1 To keep on developing the capabilities of the identification and registration system for small ruminants so that it can become fully operational and reliable as a useful tool for: a) planning, implementation and verification of epidemio-surveillance for TSEs in accordance with the requirements of Annex III to Regulation (EC) No. 999/2001, and b) application of eradication measures in the event of a confirmed TSEs case in accordance with requirements of Annex VII to the say regulation. <i>Recommendation similar to 2008-7728-1 above.</i>	The number of the authorized persons with access to enter data in to the system increased (265+56 official vet, all SH, 2 rendering plant, 100 big farmers). Despite the development of various additional modules within the CDB (module for automatic determination of the age of animals, module for automatic traceability of suspected or positive animals) is in progress, there is not currently a system which could be a useful tool to help the monitoring of the BSE epidemio-surveillance.	In progress

MR 7732/2008 of 25 February 2008 on controls of TSE in sheep and goats		
Reference No. and recommendation	Findings	Assessment
2008-7732-2 To reinforce implementation of education and training programmes as required by Art. 10 of Regulation (EC) No 999/2001 in order to: a) raise awareness of the clinical signs and epidemiology of TSEs amongst all parties concerned with their epidemio-surveillance, and b) ensure that all animals suspected of being infected by a TSE are notified in accordance with Art.11 of the say regulation. <i>Recommendation similar to 2008-7728-2 above.</i>	Trainings on TSE clinical signs and reporting of clinical TSE suspects as required by Art. 10 of Regulation (EC) No 999/2001 have been carried at the RVSs for official and private veterinarians. In 2008, 113 veterinarians were trained (out of 294 official veterinarians and 630 private veterinarians). No TSE suspects have been reported during 2008. The NVS will continue implementing education and training programmes to encourage the reporting of clinical TSE suspects as required by Art. 10 of Regulation (EC) No 999/2001. Trainings are envisaged for all private veterinarians in relation to the clinical signs of TSE in order to ensure that all clinical TSE suspects will be reported and tested.	In progress
2008-7732-3 To ensure that the monitoring targets set out in Chapter A, II (2a and 3) of Annex III to Regulation (EC) No 999/2001 are complied with.	The order PĎ 11-751/ 29.09.2008 specifies compulsory sampling for scrapie of all healthy slaughtered sheep and goats for human consumption over 18 months, emergency slaughtered sheep and goats over 18 months and fallen sheep and goats over 18 months. The CCA provided a table that contains the number of the sampled animals in the above mentioned categories since 2002 divided by regions.	Action taken
2008-7732-4 To ensure that the sampling carried out for TSEs epidemio-surveillance complies with requirements on representativity laid down in Chapter A, II (4) of Annex III to Regulation (EC) No 999/2001.	The CCA provided a table which shows the number of the sampled animals in the relevant different categories since 2002 divided by regions. The CCA promised to send another table which shows the percentage of the small ruminant farms sampled in three different regions in 2008.	In progress
2008-7732-5 To ensure that a representative sample of the ovine population consisting at least of 600 animals is selected for genotyping as required by Chapter A, II (8.2) of Annex III to Regulation (EC) No 999/2001.	As of October 2008, a total of 591 samples fit for analysis from 25 different sheep breeds were submitted to NRL on TSE and genotyping of sheep. DNA genotype models are obtained from 427 samples. The samples are being processed and the genotype is interpreted. Two specialists at the genotyping laboratory underwent training in England – VLA – Waybridge in order to increase their competence in the application of the genotyping methods. A tender for the purchase of genotyping reagents was carried out in order to ensure the continuation of the research.	Action taken

MR 7732/2008 of 25 February 2008 on controls of TSE in sheep and goats		
Reference No. and recommendation	Findings	Assessment
2008-7732-6 To reinforce the co-ordinating and monitoring role of the NRL on the two other laboratories of the network so as to: a) further train and update all relevant parties on TSEs diagnosis in the case of small ruminants according to the available scientific advice and the guidelines of the Community Reference Laboratory, and b) further verify the reliability of the diagnostic methods carried out therein; in order to ensure that the diagnostic system is sensitive enough to always detect a TSE when present and bring it totally in line with requirements of Annex X (Chapters A and C) to Regulation (EC) No 999/2001.	<p>Training of one expert from the Regional Laboratory for TSE diagnostics at the RDVI in Stara Zagora took place in November 2008 in England – VLA – Waybridge in order to raise the competence in TSE diagnostics through quick Elisa tests.</p> <p>In relation to the verification of the reliability of the quick Elisa method used in the regional diagnostic laboratories, NRL at the NDRVI in Sofia City carried out ring-testing of two regional laboratories (in Stara Zagora and Veliko Turnovo) in March 2008. Both laboratories read successfully (correctly) the samples. The companies maintaining the equipment carry out regular tests of the equipment.</p> <p>The NRL plans to organise similar ring tests to the regional laboratories at least once per year in the future.</p>	Action taken
2008-7732-7 To ensure that in the event that a TSE case is confirmed in small ruminants, all parties concerned are sufficiently prepared to handle it, in particular with respect to carrying out proper epidemiological inquiries and to applying eradication measures in compliance with Annex VII to Regulation (EC) No 999/2001.	<p>There were four scrapie cases discovered in Bulgaria in 2008 - 2 confirmed (one was a classical and one an atypical case), 1 is inconclusive and 1 is under examination. There is no special check list or working instruction which helps the veterinarians in the field in diagnosis of scrapie.</p> <p>The CA is planning a simulation exercise on scrapie in the second half of 2009.</p>	In progress
2008-7732-8 To ensure that dead animals and, in the case of on-farm slaughter of small ruminants, SRM are removed and disposed of in accordance with the requirements of Annex V to Regulation (EC) No 999/2001 and Art. 4 of Regulation 1774/2002. <i>Similar to recommendation 7728-2008-5 above.</i>	<p>The leaflets on the requirements of Regulation (EC) No 999/2001 have been distributed to farmers containing useful information for handling with SRMs.</p> <p>However, the collection of the fallen stocks and the SRM of the home slaughtered animals is unsolved and there is no plan to deal with the problem.</p> <p>There is a legal requirement that every district (1-3 villages) has to ensure a collection ground for the fallen stocks but only very few districts implement this rule.</p> <p>The collection of the SRM of home slaughtered animals is not implemented at all.</p>	Action still required

Inspection 7736/2008 of 23 June 2008 on ABP		
Reference No. and recommendation	Findings	Assessment
2008-7736-1 To ensure efficient and effective coordination between the competent authorities involved in official controls on ABP as required by Art. 4.3 of Regulation (EC) No 882/2004.	By a letter of the NVS 191/07.07.2008, instructions have been given to the Regional Veterinary Services to organize meetings with representatives of the Regional Inspectorates for Environmental Protection and Water and the Regional Inspectorates for Protection and Control of Public Health for the discussion of issues related to possible ways of destruction of animal by-products as required by the legislation for environmental protection, Regulation (EC) 1774/2002, and Regulation (EC) 197/2006. Meetings in all Regional Veterinary Services were held as scheduled by 18.07.2008. Agreements for future cooperation were approved at these meetings.	Action taken
2008-7736-2 To ensure that adequate arrangements and infrastructures for collection and transport of ABP exist as required by Art. 3.3 of Regulation (EC) No 1774/2002, in particular for fallen stock, former foodstuffs and whey from dairy plants.	Adequate infrastructure for collection of fallen stock will not be set up before 2010 when the new rendering plant should be built. In the meantime the CA stated that the allocation of additional budget funds to increase the frequency of transportation to the two rendering plants will be secured. By the letter of the NVS 191/07.07.2008, instructions have been given to the Regional Veterinary Services to organize meetings with representatives of processing plants, storage warehouses, hypermarkets, etc., for discussing the urgent need for construction of intermediate plants ensuring the collection of ABP from retail trading sites located on the territory of the particular region. Those meetings were held in all RVS as scheduled by 18.07.2008.	In progress
2008-7736-3 To ensure that ABP collected and transported are accompanied by commercial documents as required by Art. 7 of Regulation (EC) No 1774/2002 and that such documents contain all the information required by Annex II to the said Regulation.	By a letter 191/07.07.2008, instructions have been given to all official veterinarians to undertake measures ensuring that all plants producing and trading in foodstuffs of animal origin should use only a form of commercial document as required by Regulation (EC) 1774/2002 for the delivery to a rendering plant or for transportation to another approved location. The CA carry out regular checks on the accompanying documentation of the transported ABP. All transporters use the officially approved document.	Action taken
2008-7736-4 To assess the efficacy of the own-checks made by the ABP plants as required by Annex V (Chapter IV) to Regulation (EC) No 1774/2002.	HACCP has been recently introduced in the two rendering plants and the performance of audits by the respective RVS has been planned by end of 2008. After the audits in the two rendering plants by the RVS, a check will be conducted by the Central Office (Headquarters) of the NVS - Animal Health Directorate on the results of the audits.	In progress
2008-7736-5 To ensure that all Category 1 MBM is kept under appropriate official control and is disposed of in accordance with the requirements of Art. 4 of	The all amount of Category I MBM from previous stock has already been disposed of. However, the co incineration has been stopped now for at least three month, because the industries are undergoing the reconstruction to increase their capacities. In the meantime they are collecting and storing the MBM on a separated, secured area and the	Action taken

Inspection 7736/2008 of 23 June 2008 on ABP		
Reference No. and recommendation	Findings	Assessment
Regulation (EC) No 1774/2002. <i>Similar to recommendation 2008- 7728-6 above.</i>	stock will be incinerated when the operation of the plant starts again.	
2008-7736-6 To comply with the requirements of Regulation (EC) No 79/2005 as regards the use of milk and milk products, notably as regards performing risk assessments prior to the dispatch of these products to animal holdings.	A letter 153/29.05.08 has been sent to the RVS containing further explanations of the requirements for the implementation of Regulation (EC) 1774/2002 and Regulation (EC) 79/2005 regarding ABP category 3 in a dairy plant. With a letter 191/07.07.2008 additional instructions have been given that on concluding a contract between a dairy plant and a given farm about using whey as feed (ABP 3), it is compulsory that a risk assessment analysis of the farm should be performed as required by instructions of the Animal Health Directorate of the NVS. If a risk analysis has not been carried out the RVS cannot allow the use of whey for feeding to animals. The RVS are doing the risk based assessment of the farms to allow the use of whey for feeding to animals. The assessments should be finished by end 2008. The list of the approved farms will be available at the central level and published on internet.	In progress
2008-7736-6 To put in place arrangements and infrastructures in the retail sector, as required by Art. 3 of Regulation (EC) No 1774/2002, in order to enforce provisions set out in Regulation (EC) No 197/2006 on former foodstuffs, in particular by ensuring that the derogation therein does not apply to raw material of animal origin.	With a letter 191/07.07.2008 the instructions have been given to the Regional Veterinary Services to organize meetings with representatives of processing plants, storage warehouses, supermarkets, etc., for discussing the urgent need for construction of intermediate plants ensuring the collection of ABP from retail trading sites located on the territory of the particular region. Those meetings were held in all RVS as scheduled by 18.07.2008. The expertise of the VPH Directorate in Sofia, on whose territory the only approved intermediate plant in Bulgaria is located, was shared at the meetings. The representatives have manifested their great interest to find the solution to the collection and storage of ABPs from the retailer sector, but no any further action has been promised. The CA has not decided a clear deadline for the solution of this problem.	Action still required

3.6 Control system for veterinary medicinal products (VMP) and residues

Since 2003 the FVO has carried out two inspections in Bulgaria in relation to veterinary medicines and residues. Out of a total of 19 recommendations contained in the reports of these inspections, two were identified for follow-up during the 2008 general review mission. Both recommendations were carried over from the country profile of 2007.

As shown in the following table 1 recommendation has been classified as "in progress", and for 1 recommendation action is still required.

Recommendations carried over from the country profile of April 2007.

Inspection 8017/2006 of 16 October 2006 on Residues		
Reference No. and recommendation	Findings	Assessment
26631 Ensure that the NRCP covers all mandatory substance groups listed in Annex I to Council Directive 96/23/EC. If the national laboratory can not meet Community requirements in the short term, ensure that samples can be analysed elsewhere to fulfil the obligations of the NRCP regarding the provision of appropriate analytical methods for all of the mandatory substance groups. <i>Similar recommendation issued also in MR 8013/2008</i>	Outsourcing of analyses of samples that was foreseen in foreign laboratories has not taken place because the funding has not been granted to the laboratory from the CCA. Samples for a number of the missing substance groups had been collected during 2007 and 2008 and stored in the laboratory (CLVCE) pending their possible analysis in foreign laboratory. CLVCE continue the development and validation of the methods for these groups.	Action still required
26633 Develop and implement appropriate analytical methods for all mandatory substance groups and provide an indicative timetable for both method development and validation with appropriate deadlines.	Progress has been made in method development and validation. A time schedule was provided. For some substance groups the methods will not be available until later in 2009.	In progress

3.7 Control system for foodstuffs and food hygiene

Since 2003 the FVO has carried out four inspections in Bulgaria in relation to foodstuffs and general food hygiene. Out of a total of 34 recommendations contained in the reports of these inspections, six were identified for follow-up during the 2008 general review mission. One recommendation was carried over from the country profile of 2007 and five recommendations were contained in reports that had reached closeout stage since the 2007 general review mission.

As shown in the following tables, 4 recommendations have been classified as "action taken" and for 2 recommendation action is in progress.

Recommendations carried over from the country profile of April 2007.

Inspection 8129/2006 of 9 October 2006 on General Food Hygiene / Food of plant origin		
Reference No. and recommendation	Findings	Assessment
26992 For the enforcement of EC legal limits for contaminants and additives, in accordance with Article 17.2 of Regulation (EC) No. 178/2002, the competent authorities must address the continued lack of appropriate equipment in official control laboratories. They are invited to establish a plan for the development of the laboratories designated for analyses of contaminants and additives, specifying the substances to be sought by each designated laboratory, the equipment to be provided, the analytical training to be provided, and deadlines by which the above will be achieved.	The National program for the development of the laboratory network under the Ministry of Health has been approved in January 2008 by the Chief State Health Inspector. The plan specifies the laboratories designated for analyses of contaminants and additives, the substances to be sought by each designated laboratory, the equipment to be provided and the deadlines by which the above will be achieved. Not all the equipment envisaged under the plan has been delivered to laboratories.	In progress

Recommendations that had reached closeout stage since the 2007 general review mission.

Inspection 7197/2007 of 25 June 2007 on General Food Hygiene		
Reference No. and recommendation	Findings	Assessment
2007-7197-1 Ensure that inspectors with responsibility for carrying out food hygiene inspections receive adequate training as required by Article 6 of Regulation (EC) No 882/2004. This is particularly important with reference to the assessment of HACCP principles (Article 5 of Regulation (EC) No 852/2004) and of general food hygiene requirements (Annex II of Regulation (EC) No 852/2004) as required by Article 10(2) of Regulation (EC) No	Trainings of the inspectors in the Sofia and Pleven Inspectorates in several areas of activity has been provided as a follow-up to the FVO mission. In addition, the Food Safety Training Co-ordination and Supporting Centre (www.foodsafety.bg) under the NCPHP has conducted 12 trainings on "Development, implementation, verification and control of HACCP System". The participants in the training were health food control inspectors from the RIPHPC. Further trainings included topics such as "Sampling for testing pesticides and mycotoxins in foods"	Action taken

Inspection 7197/2007 of 25 June 2007 on General Food Hygiene		
Reference No. and recommendation	Findings	Assessment
882/2004.	and “Official food control, Audit and inspection”. The annual plans and the training program for 2008 was presented to the mission team.	
2007-7197-2 Finalise measures for national contingency plan as required by Article 13 of Regulation (EC) No 882/2004.	The contingency plan was approved in March 2008 by the Chief State Health Inspector.	Action taken
2007-7197-4 Ensure that official control samples are taken in accordance with Article 11 of Regulation (EC) No 882/2004.	The Ministry of Health has examined the SOPs for sampling and made sure that they reflect the requirements of the Article 11 of Regulation (EC) No 882/2004. The sampling was a subject of trainings organised by the Food Safety Training Co-ordination and Supporting Centre in 2007 and 2008. Trainings on sampling procedures were also provided within the MATRA project by Dutch competent authorities. Internal audit plan includes also the audit of sampling procedures.	Action taken
2007-7197-5 Ensure that the requirements for food allergen labelling (Article 6 of Directive 2000/13/EC) are enforced in accordance with Article 10 of Regulation (EC) No 882/2004.	In 2008, two thematic inspections have been carried out by all RIPHPC on labelling of foodstuffs, including implementation of the requirements for food allergen labelling (one inspection on fruit drinks, candies and sweets and another on bread and bread products). 2134 establishments have been checked, 32 recommendations issued, 20 penalties imposed and 2 establishments had to close down. Furthermore, the representatives of all RIPHPC have attended the trainings where the inspection of food labelling (including labelling for food allergens) was part of the lectured topics.	Action taken
2007-7197-6 Ensure that only laboratories which comply with Article 12 of Regulation (EC) No 882/2004, or at least with the derogation under Article 18 of Regulation (EC) No 2076/2005, are designated to carry out analysis of samples taken during official control.	The National program for the development of the laboratory network under the Ministry of Health has been approved in January 2008 by the Chief State Health Inspector. 6 laboratories have been designated for official control purposes. There has been some slippage in accreditation process. 4 laboratories has been already assessed by BAS (national accreditation service), but the final accreditation has not been awarded yet. Other 2 laboratories still remain to be assessed by BAS.	In progress

3.8 Control system for imports of food of plant origin

Since 2003 the FVO has carried out two inspections in Bulgaria in relation to imports of food of plant origin. The recommendations related to imports of food of plant origin have been either closed because the action was taken by competent authorities or have been followed-up in a recent inspection and are dealt with in chapter 3.12.

3.9 Control system for plant protection products (PPP) and residues

Since 2003 the FVO has carried out four inspections in Bulgaria in relation to plant protection products. Out of a total of 39 recommendations contained in the reports of these inspections, eight were identified for follow-up during 2008 general review mission. One recommendation was carried over from the country profile of 2007 and seven recommendations were contained in reports that had reached closeout stage since the 2007 general review mission.

As shown in the following tables, 3 recommendations have been classified as "action taken", 4 have been classified as "in progress" and for 1 recommendation action is still required.

Recommendations carried over from the country profile of April 2007.

Inspection 8123/2006 of 9 October 2006 on controls on pesticides in food of plant origin		
Reference No. and recommendation	Findings	Assessment
27553 Ensure that all stocks of obsolete pesticides are identified at both distribution and use levels.	Stocks amounted to 14,111 tonnes in 2006 and 13,655 tonnes in 2007. Storage and disposal is the responsibility of the municipal authorities and 50% co-financing is available from the State. 13 tonnes were disposed of by one such authority. The cost of storage since 1998 amounts to €5.5 million. There is no national strategy to dispose safely of the stocks.	Action still required

Recommendations that had reached closeout stage since the 2007 general review mission.

Inspection 7837/2008 of 7 April 2008 on controls on pesticides in food of plant origin		
Reference No. and recommendation	Findings	Assessment
2008-7837-1 The CAs should continue implementing audit systems, as required by Article 4(6) of Regulation (EC) No 882/2004.	<p>The NSPP carries out internal audits of RSPP in accordance with Art.4(6) of Regulation 882/2004 since 2006. The audit is carried out according to the plan endorsed by the NSPP's Director General. In case of non compliance the corrective measures are stipulated in a special check-list form. There is the exact time limit specified for eliminating non-compliance and a person responsible for this. The results of follow-up audit or a report prepared by the responsible person is used as evidence of corrective measures taken. In 2007, 15 internal audits were implemented. In 2008 (January to October), 7 audits and 1 follow-up audit (due to non-conformities found) were implemented.</p> <p>The 2008 programme for the audits of the Regional Inspectorates for Public Health Protection and Control (RIPHPCs) carried out by the Ministry of Health (MoH) included the audit to evaluate controls of pesticide residues in food of plant origin.</p>	Action taken
2008-7837-2 The CA should ensure that that the written procedures for the operation of the RASFF system include a reference to the Draft guidance document SANCO/3346/2001 (version: rev. 7).	<p>The update of the RASFF procedures endorsed by the Chief State Health Inspector was distributed to the RIPHPC during one of the national meetings of the directors of the RIPHPC in 2008.</p>	Action taken
2008-7837-3 The CAs should ensure that the NRLs work closely together to ensure efficient co-ordination between them, with other national laboratories and with the CRLs, in accordance with Article 33(5) of Regulation (EC) No 882/2004.	<p>Regular meetings between the two NRLs for pesticide residues in Fruits and vegetables (CLCTC and RIPHPC – Pleven) were held in 2008. The National Monitoring Program for 2009 was jointly prepared.</p> <p>CLCTC annually participates in EU proficiency testing for pesticide residues in fruits and vegetables organized by CRL.</p>	In progress
2008-7837-5 The CAs should consider providing the necessary resources, especially for equipment and training, to all laboratories responsible for pesticide residue analysis in food of plant origin.	<p>CLCTC laboratory was equipped with new analytical instruments (HPLC/UV system, Centrifuge, System for high purity water for HPLC end AAS). New LC/MS/MS was also envisaged to be received in the RIPHPC - Pleven laboratory by end of 2008.</p> <p>Within the MATRA project between Bulgaria and Netherlands “National programme for monitoring of pesticide residues and mycotoxin contamination of food, products and raw materials of plant origin” a training for the laboratory staff of the NRLs was carried out. The training of one expert from CLCTC on LC/MS in France and in BG on site has also been carried out.</p>	In progress

Inspection 7837/2008 of 7 April 2008 on controls on pesticides in food of plant origin		
Reference No. and recommendation	Findings	Assessment
2008-7837-6 The CAs should ensure that (i) all laboratories involved in the official control of pesticide residues are designated in accordance with Article 12 of Regulation (EC) No 882/2004, and (ii) all designated laboratories comply with Article 12 of Regulation (EC) No 882/2004, or are availing of the derogation foreseen in Article 18 of Commission Regulation (EC) No 2076/2005. The quality control system in the laboratories availing of Article 18 should be based on the Method validation and quality control procedures for pesticide residue analysis in food and feed Document No SANCO 2007/3131.	4 of the 6 laboratories for the official control analyses within the PHD had been assessed by the National accreditation body was foreseen to receive their accreditation certificates by end of 2008. The remaining 2 RIPHPC laboratories are still waiting for the assessment. Audit was expected by end of 2008. NCPHP /CCFAD (NRL for cereals) has applied for re-accreditation as it now occupies two sites. CLCTC is one of the two NRLs for fruits and vegetables and NRL for single residue methods. It is accredited according to EN ISO 17025: 2005 and all procedures related to pesticide residues analysis are based on the principles of SANCO Document No 2007/3131. As regard the laboratory of Plant Protection Institute, Department on Toxicology, which is one of the two NRL's for cereals and feeding stuff, it is under preparation for accreditation and due to long procedures of Bulgarian Service for Accreditation, the accreditation is envisaged by end of 2009.	In progress
2008-7837-7 The CAs should consider substantially increasing the range of analytes covered by their analytical methods for pesticide residues in food of plant origin, in order better to reflect the substances marketed and used and to ensure effective implementation of Article 7 of Directive 86/362/EEC, Article 4 of Directive 90/642/EEC, Article 7 of Directive 2006/125/EC and Article 10 of Directive 2006/141/EC. They should ensure that the analytical methods used comply with Article 11 and Annex III of Regulation (EC) No 882/2004 and, for analysis of baby food with Article 7.2 of Directive 2006/125/EC and Article 10 of Directive 2006/141/EC.	The joint monitoring programme for 2009 covers 84 analytes and includes a total of 845 samples, including 30 samples of baby food (the same level as in 2008). The PHD laboratories will increase the capacity from 14 to 44 analytes. There were no plans to further increase the range of analytes covered. In the beginning of 2009 one of the laboratories of MoH was provided with LC/MS/MS and by the second half of the year the range of analytes covered by the analytical methods for pesticide residues in food of plant origin will increase in more than 80.	In progress
2008-7837-8 The CAs should ensure that sample preparation for pesticide residue analysis is carried out in accordance with Annex I of Commission Regulation (EC) No 178/2006.	The SOP has been changed in order to include the sample preparation in accordance with requirements of Annex I of Regulation (EC) No 178/2006.	Action taken

3.10 Control system for animal welfare

Since 2003 the FVO has carried out two inspections in Bulgaria in relation to animal welfare. Out of 22 recommendations contained in the reports of these inspections, five were identified for follow-up during the 2008 general review mission, all of which were carried over from the country profile of 2007.

As shown in the following tables, 3 recommendations have been classified as "action taken", 1 has been classified as "in progress" and for 1 recommendation action is still required.

Recommendations carried over from the country profile of April 2007

Inspection 8054/2006 of 6 November 2006 on Animal welfare		
Reference No. and recommendation	Findings	Assessment
27253 Inspections are carried out on a statistically representative sample of the different rearing systems used, as required by Article 7 of Directive 91/630/EC.	A control check list was developed for animal welfare control of the animals kept in backyard holdings, including pigs. The check-list was approved by NVS Order № 1026 of 27.11.2007. In 2007 the official veterinarians and the responsible persons for animal welfare from the RVS carried out 2110 checks on small holdings.	Action taken
27257 Supervision of the different levels of the CA takes place in relation to animal welfare checks to ensure the effectiveness, quality and consistency of official controls at all levels (Articles 4.2(a) and 4.4 of Regulation (EC) 882/2004) and verification of the effectiveness of inspections and any corrective actions taken (Article 8.3 of Regulation (EC) 882/2004). <i>Similar recommendation issued also in MR 7687/2008</i>	In the monthly report (form 12 БД) there is a column introduced for reporting the animal welfare checks conducted. 28 RVS submit the report on a monthly basis which is assessed in the animal Health Directorate at the central level of NVS. In 2007 according to the reports presented 13 185 animal welfare checks were carried out.	In progress
27258 Take action so that only compliant cage systems are in use after Accession as required by Article 5.1. of Directive 99/74/EC <i>Similar recommendation issued also in MR 7687/2008</i>	The RVS carried out checks for the dimensions of all the cages for laying hens and ordered the owners of non-compliant establishments to change the cages with bigger ones or to transfer to alternative systems. 70% of all holdings using unenriched cages were found non-compliant (art.5.1). No follow-up to the findings were done by the NVS. No deadlines were provided by when the system for rearing laying hens will be compliant with EU requirements.	Action still required
27262 Investigate the transport of injured animals to slaughterhouses, which is	By letter of the NVS No. 1 / 04.01.2007 it has been arranged that the persons in charge of animal welfare will carry out checks for transport of injured animals to slaughterhouses. The annual programmes of RVS for official	Action taken

Inspection 8054/2006 of 6 November 2006 on Animal welfare		
Reference No. and recommendation	Findings	Assessment
prohibited by 3.1(b) of the Directive 91/628/EEC and that they are treated in slaughterhouses is in accordance with the provisions of Annex A.I.6 of the Directive 93/119/EC.	control provide for thematic animal welfare checks by Heads of sectors and Heads of Departments of the VPH. The official veterinarians controlling the slaughterhouses in all regions underwent training on animal welfare. No cases of the transport of injured animals were identified by the competent authorities.	
27264 Take measures so that animals killed for personal consumption to be stunned before slaughtered as required by Article 9 of the Directive 93/119/EC.	A leaflet/brochure on animal welfare during slaughtering was developed for the backyard animal owners. It is envisaged that in 2009 all private veterinarians will buy a captive bolt pistol for stunning in the premises where animals are slaughtered for personal consumption. These will be paid for by the owners.	Action taken

3.11 Control system for plant health

Since 2003 the FVO has carried out five inspections in Bulgaria in relation to plant health. None of a total of 40 recommendations contained in the reports of these inspections were identified for follow-up during 2008 general review mission. All recommendations were satisfactorily dealt with.

3.12 Overview of more recent inspections

In addition to the finalised inspection reports and recommendations arising thereof dealt with in chapters 3.1 - 3.11 above, reports of a further eight inspections had not reached the closeout stage at the time of the general review mission in November 2008. The following tables give a brief summary of the position on these inspections as of March 2009.

MR 7687/2008 of 15 January 2008 on Animal welfare (laying hens, transport)

The competent authorities has provided an action plan upon reception of the final report in which it has addressed five out of ten recommendations in a constructive and acceptable manner. The competent authorities has provided an update on 18.11.2008 which provided additional information on actions planned to be taken to address certain recommendations. Three recommendations did not receive a satisfactory response. The main outstanding issues relate to:

- verification of the effectiveness of official controls of animal welfare on laying hen farms and of the transport
- production systems for laying hens and its non compliance with the requirements of Directive 1999/74/EC
- effective, proportionate and dissuasive actions when the deficiencies are detected

A further FVO mission on animal welfare in Bulgaria is planned in June 2009.

MR 7950/2008 of 28 January 2008 on Safety of food of animal origin

The final report was sent to the Bulgarian competent authorities on 10 July 2008. In general, the competent authorities satisfactorily responded the reports' recommendations. The main outstanding issues relate to the official controls over the food business operators own check programs and the accreditation of three laboratories used for official control purposes.

MR 7747/2008 of 4 February 2008 on Import controls

In response to final mission report, the Competent Authorities submitted an action plan on 20 October 2008. The CA has responded to all recommendations. However, no reply was received to a clarification letter sent on 30.10.2008 and a number of subsequent reminders. The main outstanding issues relate to:

- instructions and manuals in order to facilitate and ensure correct implementation of veterinary checks on import
- the proper application of personal baggage checks and non-commercial pets in all points of entry
- the system of supervision for transit consignments
- the collection, transport and records for destruction of kitchen waste from international means of transport
- shortcomings for facilities, equipment and hygiene for the BIPs Sofia and Kapitan Andreevo
- operation of the TRACES system and the issuing of duplicate CVEDs
- exchange of information and access to databases between the veterinary services and

customs

- penalties and liabilities for the cost of destruction of illegal imports
- system of BIPs supervision / audit

MR 7848/2008 of 26 May 2008 on Import controls of food of plant origin

The final report was sent to the Bulgarian competent authorities on 10 October 2008. Some minor problems were identified as regards laboratories (accreditation process at a very early stage and lack of participation in collaborative or proficiency tests), audits and RASFF notifications. The competent authorities satisfactorily responded the all reports' recommendations.

MR 7800/2008 of 17 June 2008 on Classical swine fever

The final report was sent to the Bulgarian competent authorities on 21 November 2008. The competent authorities responded the all reports' recommendations on 18 December 2008. The main outstanding issues relate to:

- the use of reporting tools for verification of effectiveness of the CSF control activities
- operation of the central database and its effective use in the control of CSF

MR 8023/2008 of 17 November 2008 on salmonella risk in table eggs

The final report was sent to the Bulgarian competent authorities on 12 February 2009. The action plan provided by the competent authorities is currently being assessed. The main outstanding issues relate to:

- monitoring and sampling programme applied in breeding flocks
- laboratories involved in the monitoring programme and their regular participation in collaborative testing
- biosecurity standards in laying hen farms
- eggs labelling and marking

MR 8013/2008 of 24 November 2008 on residues of VMPs

The final report was sent to the Bulgarian competent authorities on 23 February 2009. The action plan provided by the competent authorities is currently being assessed. The main outstanding issues relate to:

- validation of the methods for analysis in the national laboratory
- availability of instructions for on-farm investigations
- controls on veterinary medicinal products, including those on farms for food producing animals and in feed mills producing medicated feedingstuffs

MR 8110/2008 of 16 February 2009 on BSE

The draft report from this mission is currently being prepared.

ANNEX I – ACRONYMS, ABBREVIATIONS, SPECIAL TERMS AND WEBSITES

ACRONYM	DESCRIPTION	WEBSITE
ABP	Animal by-products	
BIP	Border Inspection Post	
BSE	Bovine Spongiform Encephalopathy	
CA	Customs Authority	
CCA	Central Competent Authority	
CCCA	Council for Co-ordination of Control Activities	
CDFC	Chief Directorate for Feed Control	
CLCTC	Central Laboratory for Chemical Testing and Control	
CLPQ	Central Laboratory for Plant Quarantine	
CLVCE	Central Laboratory for Veterinary Control and Ecology	
CSF	Classical Swine Fever	
CSHI	Chief State Health Inspector	
DAHW	Directorate for Animal Health and Welfare	
DBVC	Directorate for Border Veterinary Control	
DCLCT	Directorate for Science, Laboratory Control and Training	
DG SANCO	Directorate General for Health and Consumer Protection	
DPH	Directorate for Public Health	
DPPP	Department for Plant Protection Products	
DVPH	Directorate for Veterinary Public Health	
EC	European Commission	
FFSCD	Food and Feed Safety Control Directorate	
FVO	Food and Veterinary Office	
GBR	Geographical BSE Rating	
GDCVA	General Directorate for Control of Veterinary Activities	
GMO	Genetically Modified Organism	
HACCP	Hazard Analysis Critical Control Point	
I&R	Identification and Registration	
ICVMP	Institute for Control on VMPs	
MAF	Ministry of Agriculture and Food	www.mzh.government.bg
MH	Ministry of Health	www.mh.government.bg
MI	Ministry of the Interior (Police)	
MRL	Maximum Residue Limit	
Mt	Metric tonne	
NCCC	National Co-ordination Council for Controls	
NCFS	National Council for Food Safety	
NCPHP	National Centre of Public Health Protection	www.ncphp.government.bg
NDRVI	National Diagnostic and Research Veterinary	

	Institute	
NGFS	National Grain and Feed Service	www.nszf.bg
NRCP	National Residues Control Plan	
NSPP	National Service for Plant Protection	www.nsrz.government.bg
NVS	National Veterinary Service	www.nvms.government.bg
PHARE	Pre-accession financial instrument	
PHD	Public Health Directorate (MH)	
PPD	Plant Protection Directorate	
PPI	Plant Protection Institute	
PPP	Plant Protection Product	
RASFF	Rapid Alert System for Feed and Food	
RCCCA	Regional Co-ordination Council for Control Activities	
RDVI	Regional Diagnostic Veterinary Institute	
RIPHPC	Regional Inspectorate for Public Health Protection and Control	
RSPP	Regional Service for Plant Protection	
RVL	Regional Veterinary Laboratories	
RVS	Regional Veterinary Service	
SRM	Specific risk material	
TOC	Tables of correspondence	
TSE	Transmissible Spongiform Encephalopathy	
VMP	Veterinary Medicinal Product	

ANNEX II – AGRICULTURAL PRODUCTION AND TRADE

Annex II gives a summary overview of the structure and scale of agricultural and food production in Bulgaria, and of the major components of trade in food, animals and plants between Bulgaria, the EU and other important trading partners.

Production

Bulgaria has a total of 5.7 million ha of agriculture land constituting 52.1% of the national territory (11 mil. ha). About 3.2 million ha of agricultural land are cultivated. There are 680.000 agricultural holdings operating in Bulgaria. The average size per farm is 4.4 ha. There are, however, large deviations in the size of farm (80% of holdings are small farms up to 1 ha that cultivate less than 10% of agricultural land). 99% of all holdings belong to individuals and the output goes to subsistence whereas legal entities produce for the market (only 1% of agriculture farms).

The share of the agricultural sector has retained its downward trend and accounts for 11% of total GDP. The share of the agricultural in GDP employment is 6 %.

Plant production

More than 75% of cultivated land is occupied by cereals and oil crops, 7% by meadows and fodder crops and 3.5% by fallow land (farmland laid to rest during the economic year in question). The most wide spread crops, in most cases on very small areas, are maize (in 41% of farms), potatoes (31%), wine-growing vineyards (31%), and natural and artificial grassland. A breakdown of crop production in 2005 is given in the table below.

	Harvesting area (Ha)	Production (T)
Cereals, Total	1,644,600	5,750,000
- Wheat	930,000	3,500,000
- Barley	274,000	650,000
- Maize	375,000	1,600,000
Potatoes	52,000	420,000
Sunflower Seed	540,000	950,000
Fruit, Total	172,300	550,000
- Grapes	110,000	380,000
Vegetables, Total	142,500	1,300,000
- Watermelons	30,000	210,000
Maize for Forage +Silage	40,000	750,000
Grasses nes, Forage +Silage	60,000	300,000
Alfalfa for Forage +Silage	85,000	1,800,000

Source: FAOSTAT

Animal production

Pig breeding accounts for more than half of the total national meat output. There are 650 large livestock farms with more than 100 pigs in each operating entirely commercially and breeding 45% of the overall number of pigs in the country. Other pigs are bred in households and small farms intended mostly for their own consumption.

The average number of cattle per farm is three animals (two for milk cows). The number of large scale cattle breeders is relatively small, with most of the animals (60%) being kept in rather small holdings of less than 10 animals. 90% of cattle are bred in farms belonging to physical entities. The most widely spread bovine breed is Friesland Holstein, which is the choice of more than 50% in the cow holdings and constitutes 58% of the cows nationwide. 15% of the cows are of the Rhodope and 12% of the Brown breed.

The average number of sheep per farm is also very small: 57% of sheep are bred in farms that keep less than 10 animals and only 17% belong to holdings having more than 50 animals. Most of the ewes are either used for milk alone (36%), or for a combination for milk and meat (62%), with a mere 2% being bred for meat alone. Bulgarian farms seem to prefer goats to sheep. 40 % of holdings keep one goat at least. 99% of goat-herding farms belong to physical entities.

Livestock production accounts for 38% of the total value of agricultural production with the significant pigs and poultry dominating. The breakdown of animal origin production in 2005 is given below.

	Live animals	Slaughtered animals	Meat production (tonnes)	Milk and eggs (tonnes)
Pigs	931,402	-	74,532	-
Poultry	17,159,000	9,966,000	79,508	97,546
Cattle	671,579	368,719	29,783	1,286,909
Sheep	1,692,507	1,351,212	17,729	105,057
Goats	718,117	578,501	6,699	109,114

Source: FAOSTAT

Fish production

Fisheries production in Bulgaria comes mainly from two sources: freshwater (the inland basins and the Danube River) and marine catches from the Black Sea.

The bulk of fish production is from the Black Sea. The dominant species caught is European sprat (*Sprattus sprattus*) which accounts for over 90% of Black sea fish catches. Another major object of commercial fishing is the anchovy. About 90% of the total mollusc catches is sea snail (*Rapana* spp.). Other fish species that were taken in smaller quantities included Mediterranean horse mackerel (*Trachurus mediterraneus ponticus*), garfish (*Belone belone*) and Atlantic bonito (*Sarda sarda*).

The breakdown of catches (in tonnes) by type of fish and aquaculture is given below.

	2002	2003	2004
Sea fish species	12,680	9,813	3,272
Rapana, mussels and shrimps	754	340	2,462
Migratory (sturgeon)	24	16	18
Migratory (Danube herring)	141	67	100
Danube fresh water fish	364	464	368
Internal water fish	1,457	1,795	2,026
Total fish catches	15,420	12,495	8,246

Source: Executive agency for fishery and aquaculture (EAFA), [MAF Annual Report 2005](#)

Trade

The trade balance surplus in agricultural commodities in Bulgaria accounted for 185,171,000 USD in 2003. The relative share of agricultural exports in the total exports represented 10.5% whereas the agriculture imports accounted to 5.6% of the total imports into Bulgaria.

Foreign trade with agriculture commodities ('000 USD)

	Export	Share in total exports	Import	Share in total imports	Balance
2002	716,001	12.6 %	476,009	6 %	239,992
2003	783,193	10.5 %	598,022	5.6 %	185,171

Source: [MAF Annual Report 2005](#)

Trade by agricultural products

Leading agriculture commodities in Bulgarian export and import are given in the tables below. [Click here](#) to find more detailed information.

Export in 2004

	Commodity	Quantity (Mt)	Value (000 US\$)	Unit value (US\$)
1	Tobacco Leaves	42231	114615	2714
2	Sunflower Seed	291765	84854	291
3	Wine	92342	80189	868
4	Wheat	667036	79997	120
5	Fruit Prepared nes	34809	46550	1337
6	Cheese (Whole Cow Milk)	14811	43087	2909
7	Barley	338197	37031	109
8	Mutton and Lamb	7047	34752	4931
9	Chicken Meat	5684	33945	5972
10	Cigarettes	4283	28275	6602
11	Pastry	13578	27943	2058
12	Maize	251747	27115	108
13	Oil of Sunflower Seed	40311	23649	587
14	Food Wastes	7449	19350	2598
15	Wafers	8352	18821	2253

Source: [FAOSTAT](#)

Imports in 2004

	Commodity	Quantity (Mt)	Value (000 US\$)	Unit value (US\$)
1	Food Prepared nes	27678	51694	1868
2	Sugar (Centrifugal, Raw)	279742	51640	185
3	Tobacco Leaves	13950	38748	2778
4	Maize	165522	34615	209
5	Cotton Lint	20126	31224	1551

	Commodity	Quantity (Mt)	Value (000 US\$)	Unit value (US\$)
6	Wool Tops	3436	29525	8593
7	Wheat	134472	28607	213
8	Beef and Veal	33214	27530	829
9	Cake of Soya Beans	86279	25762	299
10	Wool, Greasy	7947	21373	2689
11	Pork	14230	19701	1384
12	Beverages Dist Alcoholic	4580	18163	3966
13	Oils Hydrogenated	19502	17938	920
14	Flour of Wheat	56081	14830	264
15	Pastry	9928	14059	1416

Source: [FAOSTAT](#)

Trade in fish and fish products

90% of import of fish and fish products to Bulgaria is frozen fish (species that cannot be bred in Bulgaria – salmon, herring, sardine, dogfish, hake, etc.). The majority of fish imports were of mackerel. The major trading partners from which Bulgaria imports fish include the USA (35% of the total imports), Canada (20%), Ireland (15.7%), UK (5.8%), and Norway (4.5%). The imports of fresh or chilled fish come mainly from Turkey and Greece.

Fish and fish products (frozen, dried, smoked, salted fish) exports are primarily to central and eastern Europe markets (the Former Yugoslav Republic of Macedonia, Romania and Serbia). France, Japan and Turkey are preferred markets for shellfish exports.

Breakdown of trade with fish and fish products in Bulgaria

	2001	2002	2003	2004	2005
Import (tonnes)	18,306	17,659	23,185	23,562	24,000
Export (tonnes)	4,155	5,108	5,807	5,630	5,800

Source: [MAF Annual Report 2005](#)

Trade by countries

The EU is the main Bulgarian partner in the trade of agricultural commodities, accounting for more than 50% of the total trade. Given their geographic proximity and production specialisation, the Balkan and TACIS countries are also significant trade partners of Bulgaria. The following table gives an indication of exports to and imports from its main trading partners in 2004.

	Export (%)	Import (%)
EU 25	45.9	51.4
Balkan countries	7.5	1.4
TACIS countries	6.6	4.2
USA	6.8	2.5
Russia	3.9	0.5

Source: [MAF Annual Report 2005](#)

ANNEX III – STAFF RESOURCES AND RELATED CONTROLS

Annex III of the country profile gives summary data on the staff employed by public authorities on food safety, animal health, animal welfare and plant health and the nature and scale of food and feed businesses subject to official controls.

The following table gives a summary of the data on staff resources by authority. The information has been updated by the competent authorities during the FVO general review mission of November 2008. Overall number of full-time equivalent (FTE) staff involved in food safety, animal and plant health, and animal welfare controls in Bulgaria is **3, 262 staff**.

Staff (full time equivalent) employed in the food and feed control systems

Competent authority	Staff
Ministry of Agriculture and Food	17
- Food Safety and Quality Directorate	17
National Veterinary Service	1,704
- Veterinary Public Health	711
- Animal Health	643
- Authorised Veterinarians	350
Ministry of Health	1,133
Directorate for Public Health	5
Regional Inspectorates	1,128
National Grain and Feed Service	76
- Chief Directorate “Feed Control” (territorial units)	22
- Laboratory Directorate	15
- NGFS other directorates (territorial units)	39
National Service for Plant Protection	349
- Plant Health (including border controls)	225
- Pesticides (authorisation and control of marketing and use of PPP)	124
TOTAL	3262

Source: Bulgarian Competent Authorities

Food and feed business operators subject to controls by public authorities

Competent Authority	Number of businesses
Directorate for Public Health (MH)	
- Food businesses for production of food of non-animal origin (excluding retail)	7,536
National Veterinary Service (MAF)	
- Food business operators	848
- Rendering plants	2
National Grain and Feed Service	
Feed primary producing businesses	6888
Registered feed businesses	1808
Approved feed businesses	150
TOTAL	17,232

Source: Bulgarian Competent Authorities