



DG Health  
and Food Safety

# COUNTRY PROFILE **Organisation of Official Controls**

*Health and  
Food Safety*

## TABLE OF CONTENTS

INTRODUCTION .....	3
SUMMARY .....	4
1 ARRANGEMENTS FOR THE IMPLEMENTATION OF CERTAIN REQUIREMENTS OF REGULATION (EC) N° 882/2004 .....	5
Designation of competent authorities .....	5
Resources for performance of controls .....	13
Organisation and implementation of official controls .....	16
Enforcement measures .....	17
Verification and review of official controls and procedures .....	20
Multi-annual National Control Plan (MANCP).....	22
2. COMPETENT AUTHORITIES AND DISTRIBUTION OF RESPONSIBILITIES IN RELATION TO INDIVIDUAL CONTROL SYSTEM.....	24
2.1 Control system for animal health.....	24
2.2 Control system for food of animal origin .....	27
2.3 Control system for imports of food of animal origin.....	31
2.4 Control system for feedingstuff and animal nutrition.....	33
2.5 Control system for TSE and Animal By-Products (ABP) .....	37
2.6 Control system for veterinary medicinal products (VMP) and residues.....	43
2.7 Control system for foodstuffs (food of non-animal origin) and food hygiene and GMOs .....	47
2.8 Control system for imports of food of plant origin.....	51
2.9 Control system for plant protection products (PPP) and residues .....	53
2.10 Control system for animal welfare.....	55
2.11 Control system for plant health.....	57
2.12 Control system for quality labelling .....	60
ANNEX I – ACRONYMS, ABBREVIATIONS AND SPECIAL TERM .....	64

## **INTRODUCTION**

This overview has been drawn up by the Health and food audits and analysis (HFAA), a Directorate of the Directorate-General for Health and Food Safety of the European Commission based on information supplied by Bulgaria.

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

Chapter 1 describes the overall organisation of the Bulgarian authorities and the respective responsibilities of the 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.

Chapter 2 gives a more detailed description of the main responsibilities for each of the eleven separate systems that form the complete range of control systems in Bulgaria, covering the whole chain of plant, animal and food production. As in Chapter 1, organisation charts are used to help the reader.

The overview was updated following the most recent general follow-up audit in March 2016 and will be updated at regular intervals based on relevant information received by the Commission from the Bulgarian authorities.

Acronyms are used extensively throughout this overview for the sake of brevity. A list of acronyms, abbreviations and special terms is given in Annex I as a guide for the reader.

## SUMMARY

The Minister of Agriculture and Food and the Minister of Health perform state policy in the field of food safety. Within the Ministry of Agriculture and Food (MAF), the Policies on Agri-food Chain Directorate (PAFCD) is responsible for the development and co-ordination of the implementation of MAF policy in the field of food safety and quality, feed safety, animal health and welfare and plant health. The Bulgarian Food Safety Agency (BFSA) under the Ministry of Agriculture and Food is the competent authority performing official control of food safety and food quality, feed, plant protection products and fertilizers, animal by-products, animal health and welfare, and plant health.

The Ministry of Health (MH) is also responsible in developing food safety policy in the field of food of non-animal origin. State Health Control Directorate (SHCD) has as well the role of co-ordination and supervision of official controls on bottled natural mineral, spring and table waters, performed by the 28 Regional Health Inspectorates (RHI).

Bulgaria is divided into 28 regions. The regions are administrative units executing the regional policy of central government bodies. The regional governors are appointed by the Council of Ministers. Local government is organised through 264 municipalities. At regional level BFSA has 28 Regional Food Safety Directorates (RFSD) responsible for the implementation of the official controls.

The new MANCP covering period 2015-2017 is published on the website of the Ministry of agriculture and food:

[http://www.mzh.government.bg/MZH/Libraries/%d0%97%d0%96%d0%91%d0%a5-%d0%bd%d0%b0%d1%86\\_%d0%b7%d0%b0%d0%ba%d0%be%d0%bd%d0%be%d0%b4%d0%b0%d1%82%d0%b5%d0%bb%d1%81%d1%82%d0%b2%d0%be/SMANCP\\_2015-2017\\_final.sflb.ashx](http://www.mzh.government.bg/MZH/Libraries/%d0%97%d0%96%d0%91%d0%a5-%d0%bd%d0%b0%d1%86_%d0%b7%d0%b0%d0%ba%d0%be%d0%bd%d0%be%d0%b4%d0%b0%d1%82%d0%b5%d0%bb%d1%81%d1%82%d0%b2%d0%be/SMANCP_2015-2017_final.sflb.ashx)

The 2014 annual report on the implementation of the MANCP was provided to the Commission in October 2015.

# **1 ARRANGEMENTS FOR THE IMPLEMENTATION OF CERTAIN REQUIREMENTS OF REGULATION (EC) N° 882/2004**

## **Designation of competent authorities**

The Minister of Agriculture and Food and the Minister of Health perform state policy in the field of food safety.

The BFSA under the MAF is the competent authority performing official control of food safety and food quality, feed, food contact materials, plant protection products and fertilizers, animal by-products, animal health and welfare, and plant health. The MH is responsible for the controls on bottled natural mineral, spring and table waters carried out by the RHIs.

### Ministry of Agriculture and Food

The framework legislation for food and feed safety controls comprises: Law on BFSA (SG 8/2011, last amended SG No 61/2014); Food Law (SG No 102/2003, last amended SG No 8/2011, last amended SG 14/2015); Veterinary Activity Law (SG No 87/2005, last amended SG No 14/2015); Feed Law (SG No 55/2006, last amended SG No 12/2015) and the Plant Protection Law (SG No 61/2014, last amended SG No 12/2015). Detailed requirements are set out in specific Ordinances.

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 which execute 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.

### Policies on Agri-food Chain Directorate (PAFCD)

The Directorate is responsible for development and co-ordination of the implementation of MAF policy in the field of food safety and quality, feed safety, animal health. The Directorate is responsible for harmonisation of legislation and co-ordination of the control authorities within the Ministry. The Directorate performs audit of the official control carried out by the Bulgarian Food Safety Agency in accordance with art. 4 (6) of Regulation (EC) № 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The Directorate represents the Ministry at international forums including WHO, FAO and Codex Alimentarius.

The main tasks of the PAFCD are to:

- Develop and co-ordinate the implementation of MAF policy in the field of food safety and quality, feed safety, animal health and welfare and plant health;
- Draft legislative acts and amendments of the current legislation in the field of food and feed safety, animal health and welfare and plant health;
- Prepare the MANCP in accordance with Regulation (EC) № 882/2004 and the annual report on its implementation;
- Co-ordinate the work of the control bodies, laboratories and other national bodies within MAF performing official feed and food control;
- Performs audits of official control carried out by the Bulgarian Food Safety Agency in accordance with art. 4 (6) of Regulation (EC) № 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the

verification of compliance with feed and food law, animal health and animal welfare rules;

- Co-ordinate and manage the control bodies within the MAF during the preparation of contingency plans for food and feed;
- Receive applications for the placing on the market of Genetically Modified Organisms (GMOs) according to Directive 2001/18/EC, and participate in the Consultative Commission on GMOs, as well as, maintaining the register of authorised GMOs;
- Receive applications for the initial placing on the market of Genetically Modified Feeds;
- Function as the national contact point for the Rapid Alert System for Food and Feed (RASFF);
- Function as a National Contact Point for Codex Alimentarius;
- Participate in joint activities of EFSA, WHO, FAO, Codex Alimentarius and other international organisations in the field of food and feed safety, animal health and plant health;
- Prepare Bulgaria's position for participation in Council meetings, working groups and meetings of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) in the field of food and feed safety, animal health and plant health;
- Participate in EU working groups and meetings of PAFF Committee in the field of food and feed safety, animal health and plant health.

#### *Bulgarian Food Safety Agency (BFSA)*

The BFSA is a specialised body of the MAF. It was created with the adoption of the Law on the BFSA in January 2011 (*SG 8/2011*). The BFSA is in operation since mid-February 2011 when its Code of Organisation was published in the State Gazette (*SG 15/2011, last amended SG 91/2013*). The BFSA incorporates the former National Veterinary Service (NVS), the former National Plant Protection Service (NPPS) and the former National Grain and Feed Service (NGFS), as well as the regional food health inspectors, who were responsible for the control of food of non-animal origin in the Regional Health Inspections (former Regional Inspections for Public Health Protection and Control) under the MH and the quality compliance of fresh fruits and vegetables (under MAF) with the European Commission (EC) standards for placing on the market.

The BFSA is the competent governmental authority for carrying out official controls in Bulgaria in terms of phytosanitary issues; plant protection products and fertilizers; veterinary activities; animal health and welfare; animal by-products not intended for human consumption; feedingstuffs; raw materials and foodstuffs with the exception of bottled natural mineral, spring and table water; materials and articles intended for contact with food; and the quality compliance of fresh fruits and vegetables with the European Commission (EC) standards for placing on the market.

The agency has its central office in Sofia. It has also 28 Regional food safety directorates (RFSD) distributed across the country.

## *Risk Assessment Centre*

With the adoption of the Law on BFSA and its Code of Organisation, a Risk Assessment Centre (RAC) was created, managed by a Management Board and assisted by an Advisory Board. The RAC provides independent scientific assessment of risks related to food safety, animal health and welfare, food and feed additives, GMOs, dietetic products, nutrition and allergens, materials and articles intended for contact with food, enzymes, flavourings and supporting substances, biological hazards, contaminants, plant health and plant protection.

RAC informs the public and stakeholders about problems connected to food and feed safety, animal and plant health.

According to the Law on the BFSA, all functions of the National Council for Food Safety, Expert Council and National Council for Co-ordination of Controls are implemented by the BFSA and respectively the RAC. The management bodies of the Risk Assessment Centre are Director and Management Board.

Under the authority of the Director are two directorates: "Financial management" and "Risk assessment". The "Risk assessment" directorate is composed of two sections: "Risk assessment" and "Focal point".

## Ministry of Health

### ***State Health Control Directorate (SHCD)***

The SHCD develops the food safety policy including the official controls on bottled natural mineral, spring and table waters and the nutrition of the different population groups.

The main tasks of SHCD are to:

- Develop and co-ordinate the implementation of MH policy in the field of food of non-animal origin, bottled natural mineral, spring and table waters and the nutrition of the population as a whole;
- Prepare legislative acts and amendments of the current legislation in the field of horizontal legislation and food of non-animal origin with the MAF;
- Participate in the preparation of the MANCP in accordance with Regulation (EC) 882/2004 and the annual report on its implementation;
- Co-ordinate the official control of the regional bodies on bottled natural mineral, spring and table waters and the nutrition of the population and execute the procedures for the recognition of the natural mineral waters;
- Co-ordinate the work of the laboratories within MH performing official food analyses;
- Develop instructions, guidelines, opinions and plans of action for the implementation of the legislation in the field of bottled natural mineral, spring and table waters and the nutrition of the population;
- Prepare and co-ordinate training activities of the regional control bodies within the MH;
- Receive applications for the placing on the market of Genetically Modified Foods, (GMFs) and Novel Foods, registration of food irradiation facilities and registration of its activities;
- Function as a competent contact point for the RASFF;
- Participate in joint activities of EFSA, WHO, FAO, Codex Alimentarius and other international organisations in the field of food safety and nutrition, natural mineral waters;

- Prepare Bulgaria's position for participation in Council meetings, working groups and Standing Committee on Plants, Animals, Food and Feed (SCPAFF) meetings for which it is designated by an order of the Minister of Health;
- Participate in EU working groups and meetings of SCPAFF in the field of food safety.

### Institutes, Laboratories and other bodies

#### *Laboratory network between the BFSA*

There is a special Council of Ministers' Decree of ref. No 59 of 23 March 2016 to enter into effect certain amendments and riders of the BFSA Organisation Rules adopted latest by CoMs' Decree No 35 of 2011). Based on his new version of BFSA Organisation Rules the activities previously delegated to "Laboratory activities and standards" Directorate have been allocated to few other BFSA Central Office directorates of its so called, specialized administration'.

As for "Food Controls" Directorate, these new obligations include:

1. Participate in the development and to monitor the implementation and reporting of control programs related to food safety;
2. Coordinate laboratory diagnostic tests, analyses and expertise related to raw materials, food, food-contact materials and articles, GMOs and products containing, consisting of or produced of GMOs;
3. Develop criteria and develop procedure for determining the laboratories, which will carry out research for the purposes of official controls and in accordance with the EU law;
4. Develop, jointly with the directorates of BFSA specialized administration and BFSA specialized structural units, the National Programme for Control of pesticide residues in and on food of plant and animal origin, and to its implementation.

The Food Control Directorate (FCD), CVMP Directorate, AHWFcC Directorate, PPC Directorate and the specialised structures CLVCE and CLCTC, prepare annually monitoring programs:

1. National monitoring program for control of residues of veterinary medical products and contaminants from the environment in live animals and products of animal origin (NMPCR) in accordance with Directive 96/23/EC;

The NMPCR is approved by the Minister of agriculture and food and by 30 March each year is sent for approval also to the European Commission;

2. National control programme for pesticide residues in food of plant and animal origin, in accordance with Regulation (EC) № 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides.

The testing of samples for NMPPR is carried out in CLVCE and in CLCTC. When non-compliances are found, a letter with the results from the analyses is sent to the Executive Director of the BFSA and to the director of the relevant RFSD, where the sample was taken. For every case of non-compliance an investigation is initialised by the director of the RFSD for the purpose to clarify the reasons for the presence of residues in animals and products and contamination of the environment. After the detection of the source for contamination, relevant measures are taken to avoid future non compliances in accordance with national and EU legislation.

The sampling for NMPCR and NMPPR is performed by the inspectors within the RFSD throughout the country. Enforcing art.33 of Regulation (EO) № 882/2004, NRLs within the BFSa structure are defined and they are in connection with the EU-RL, listed in Annex VII (amended with Regulation (EC) № 208/2011). The NRLs in the animal health and food areas implement their functions, including the participation in ring tests (organised by the EU-RL), co-ordination of the official laboratory activities, performance of analysis of the samples in accordance with art. 11 of Regulation (EO) № 882/2004, organisation of proficiency tests with the official laboratories and ensurance of the adequate following measures afterwards etc.

NRLs within the BFSa according to Order RD 09-315/107.05.2015 from MAF:

- 1 National Diagnostic and Research Veterinary (Medical) Institute (NDRVI) – National Centre on Food Safety: within this laboratory the following NRLs are defined:
  - NRL Salmonella, campylobacter, staphylococcus and antimicrobial resistance (AMR)
  - NRL Listeria and Escherichia coli and contaminants of live bivalve molluscs
  - NRL Marine biotoxins
  - NRL Water content in poultry meat

NDRVI – National Centre on Animal Health (NCAH): within this laboratory the following NRLs are defined:

- NRL Rabies and monitoring the effectiveness of rabies vaccination
- NRL Brucellosis
- NRL Transmissible spongiform encephalopathies (TSE)
- NRL Parasites (in particular Trichinella, Echinococcus and Anisakis)
- NRL Leptospirosis
- NRL Tuberculosis and Anthrax
- NRL Enzootic bovine leucosis
- NRL Animal proteins in feedingstuffs
- NRL Honeybee health

NDRVI - Testing Laboratory for exotic and extremely dangerous infections. Within this laboratory the following NRLs are defined:

- NRL Classical Swine Fever (CSF) and African swine fever and Sheep and goats Pox
- NRL Foot-and-mouth disease and swine vesicular disease
- NRL African horse sickness
- NRL Avian influenza and Newcastle disease
- NRL Bluetongue

NDRVI has also its two country units located in the towns of Veliko Tarnovo and Stara Zagora, where serological diagnostics of CSF is performed.

NDRVI - Testing Laboratory for fish diseases and mollusc diseases. Within this laboratory the following NRLs are defined:

- NRL Fish diseases, mollusc diseases and crustacean diseases.

The Central Laboratory for Veterinary Control and Ecology (CLVCE). Within this laboratory the following NRLs are defined:

- NRL for residues of anabolic medicines and unauthorised substances in biological fluids, raw materials and food of animal origin (Group A (1), (2), (3), (4), (5) and (6) to Directive 96/23/EU);
- NRL for residues of veterinary medicines in biological fluids, raw materials and food of animal origin (Group B (1), (2)(a), (b), (d), (e) and B (3)(e) to Directive 96/23/EU);
- NRL for residues of environmental contaminants in raw materials and food of animal origin (B (2)(c), (3)(a), (3)(b), (3)(c) and (3)(d) to Directive 96/23/EU);
- NRL for residues of gamma-emitting radionuclides in water, beverages, feed, raw materials and food (B (3)(f) to Directive 96/23/EU);
- NRL for safety and quality of honey and bee products.

The CLVCE is accredited to EN ISO/IEC 17025 for all its activities.

Central Laboratory for Chemical Testing and Control (CLCTC). Within this laboratory the following NRLs are defined:

- NRL for single pesticide residue methods
- NRL for pesticide residues in fruits and vegetables including commodities with high water and high acid content
- NRL for mycotoxins in foods of plant origin
- NRL for heavy metals in foods of plant origin

This laboratory is responsible for drafting and implementation of the National Monitoring Programme for Pesticide Residues in food of plant origin. It is also responsible for official control of plant protection products and fertilizers. CLCTC is accredited to EN ISO/IEC 17025 for all its activities and is the NRL for both pesticide residues in fruits and vegetables and single pesticide residues methods, as well as mycotoxins analysis and heavy metals of plant products.

Food Safety and Quality Laboratory in the RFSD- Sofia city. Within this laboratory the following NRL is defined:

- NRL Milk and milk products

BFSA has contracted the Austrian agency for health and food safety to fulfill the requirements of art. 33 (1) of Regulation 882/2004 as a NRL for PAH in food and feed products in Bulgaria.

Within BFSA there are nine Regional Testing laboratories (RTL) located in the following RFSD – RFSD Sofia city, RFSD Blagoevgrad, RFSD Vratsa, RFSD Gabrovo, RFSD Plovdiv, RFSD Sliven, RFSD Haskovo, RFSD Shumen and RFSD Varna. The laboratories are accredited according to the requirements of EN ISO/IEC 17025 and carry out tests in the area of food and feed safety and animal health. The RTL carry out tests of samples taken from more than one region in the country according to a distribution schedule. Their work is methodologically co-ordinated by the NRLs.

Central Laboratory for Plant Quarantine (CLPQ):

This 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 and carries out training of phytosanitary specialists. It is located in Sofia and has a branch in Samokov. The CLPQ supervises the activity of six Regional and Border Inspection Posts' (BIP) laboratories, validates positive and suspect 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 National Centre of Public Health and Analyses (NCPHA) is a research institute in the field of public health and food safety, under the MH. 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. Experts of the NCPHA participate in the risk assessment of food additives, food contact materials, pesticide residues, contaminants - mycotoxins, nitrates, microbiological contaminants, GMO and nutrients, carried out by the RAC within the BFSa. Its laboratories are accredited since 2003 according to EN ISO/IEC 17025 by the National Accreditation Board. Two of the laboratories are the NRL for GM foods and food contact materials. The NCPHA develops and implements methods of analysis and organises training of laboratory staff from the RHI.

#### Central Laboratory for Qualification of Grain and Feed (CLQGF)

Due to organization changes within structural units with the Ministry of Agriculture and Food, and pursuant to amendments in BFSa Organizational Rules (adopted by Council of Ministers' Decree No 236 of 31.08.2015 promulgated in State Gazette, issue No 68 of 04.09.2015) since September 2015 there is a new structural unit within BFSa (Central Laboratory for Qualification of Grain and Feed in Sofia).

It is accredited by "Bulgarian Accreditation Service" Executive Service in accordance with the standard titled BDS EN ISO/IEC 17025:2006 to perform analyses of cereals, bean crops, oilseeds and products derived from their processing, premixes, feed, raw materials and additives thereto, including foodstuffs for any home-pet species.

The laboratory performs testing of samples taken from feed-stuffs, premixes, raw materials and additives there, where these have been taken for the purposes of official controls by testing for the following indicators: humidity/dry substance, raw protein, raw fibers, raw fats, raw ashes, chlorides, ashes insoluble in hydrochloric acid, calcium, phosphorous, natrium, potassium, urease activity, magnesium, cuprum, zinc, ferum and manganum.

Pursuant to Ordinance No 23 of 29.15.2015 of the Ministry of Agriculture and Food, this laboratory is the one to annually impose performance of laboratory analyses of the indicators relevant to quality of the produced crops of wheat, maize, barley, sunflower and rice paddy.

#### *National laboratory network under the Ministry of Health*

Laboratory analyses of food of non-animal origin, including mineral waters, for the purposes of the official controls. These are the laboratories in Sofia, Plovdiv, Pleven, Varna, Burgas and Veliko Tarnovo. The laboratories co-ordinate their day-to-day activities based on sampling plans developed at national level in the MH. The NCPHA is responsible for methodological guidance of the RHI laboratories. All six laboratories are accredited to EN ISO/IEC 17025. In the NCPHA there are two NRL – NRL for GMO foods and NRL for food contact materials.

## National Accreditation Body

The Executive Agency ‘Bulgarian Accreditation Service’ (BAS) under the Ministry of Economy is the National accreditation body for testing and calibration of laboratories, product certification bodies, management systems certification bodies, personnel certification bodies and inspection bodies. It also performs inspection and certification of compliance of laboratories with Good Laboratory Practice EA "BAS" is a signatory to the Multilateral Agreement for mutual recognition of the accreditation schemes for the following fields: Calibration laboratories; Testing laboratories; Inspection bodies; Products certification bodies; Persons certification bodies; Management systems certification bodies; Environmental management systems certification bodies.

BAS has been accepted as a full member of the European Co-operation for Accreditation-EA.

Executive Agency "BAS" operates on the basis of the, EN ISO/IEC 17000 series of standards and the EA and ISO/IEC guidance documents. Executive Agency "BAS" has developed and adopted for implementation a variety of regulations, norms, procedures, documents and organizational practices.

The Law of National Accreditation of Conformity Assessment Bodies (SG 100/2005, last amended SG 14 /2015r) lays down the structure and activities of BAS, as well as, the conditions on accreditation of the bodies performing testing, calibration, certification of products, certification of management systems, certification of personnel and inspection and environment inspection bodies. The process of accreditation follows the conditions and procedure set down in the Law and in the BAS procedures and rules of accreditation. The procedures and rules of accreditation are published in the Bulgarian State Gazette and on the Internet.

### Co-ordination between Competent Authorities

BFSA is the CA carrying out official control on food throughout the country, with the exception of bottled natural mineral, spring and table waters.

Co-ordination and co-operation between competent authorities at the operational levels takes place via various agreements between the competent authorities and joint control programmes (e.g. BFSA and Customs; MAF and MH for monitoring programmes). The RAC plays an important role in the co-ordination and co-operation between CAs.

### Co-operation within Competent Authorities

The PAFCD is responsible for developing and co-ordination of the implementation of MAF policy in the field of food safety and quality, feed safety, animal health and plant health,, harmonisation of legislation and co-ordination of the control authorities within the MAF and with other ministries and institutions.

### Delegation of specific tasks related to official controls

There are no delegated control bodies.

### Contingency planning

Contingency plans are drawn up for most OIE listed diseases.

Apart from a number of contingency plans drafted by the BFSA for animal health emergency situations, the following general emergency plans have been established:

- Operation action plan in emergency situations (BFSA)
- Action Plan for Emergency Situations related to Feed (BFSA)
- Plant protection contingency plans (BFSA)
- Contingency plan for food emergencies (MH, BFSA)

A detailed description of the individual plans is provided in the MANCP.

See also section 2.1. for more information.

### **Resources for performance of controls**

#### Legal powers for controls

The framework legislation provides the CAs with the necessary legal powers to carry out controls, including the powers of access to food business premises and documentation. There is an obligation on food/feed business operators to undergo inspection by the competent authorities. The framework legislation for food and feed safety controls comprises: Law on BFSA (SG 8/2011, last amended SG No 61/2014); Food Law (SG No 102/2003, last amended SG No 8/2011, last amended SG 14/2015); Veterinary Activity Law (SG No 87/2005, last amended SG No 14/2015); Feed Law (SG No 55/2006, last amended SG No 12/2015), Plant Protection Law (SG No 61/2014, last amended SG No 12/2015) and the Law of Health (SG No 70/2004, last amended SG No 9/2015). Detailed requirements are set out in specific Ordinances.

See also measures in case of non-compliance below.

#### Staffing provision and facilities

In total, 2,296 staff are involved in controls on food and feed safety, animal health and animal welfare, and plant health within the BFSA. Under the MH, 43 staff are involved in the control of bottled natural mineral, spring and table waters.

### BFSA

All inspectors from the PHD within the RFSD who are authorised to perform control activities are provided with the following materials, instruments and equipment:

1. Inspection documentation – forms and reports filled in quadruplicate during the inspection; one copy is submitted to the representative of the site visited.
2. Sampling for analyses – labels, stick-on band with BFSA's logo, polyethylene bags, drills and other materials.
3. Self-protection devices – protection clothes, latex gloves, face-guards.
4. All BIPs are fully equipped according to the requirements set out in Annex 6 of Council Directive 2000/29/EC and Annex 6 of Ordinance No. 1 on phytosanitary control: office equipment, inspection tables for carrying out checks, binoculars, microscopes, sieves, magnifying glasses, glass-ware, etc. There are also equipped

loading platforms for load handling operations and warehouse premises for storage of consignments under quarantine.

5. As regards the phytosanitary control on production, each phytosanitary department is provided with suitable motor vehicles to reach every investigated area, regardless of terrain. Each vehicle is fully equipped with all the necessary devices for sampling, packing, sealing, disinfectants, etc.

Each Food Control Department (FC Department) within the RFSD has calibrated thermometers and equipment for proper transportation of samples of food.

### Conflict of interest

The Law on Conflict of Interest and the Law on the Civil Service prescribes the obligation of public officials as regards independence and involvement in other activities. Each public official has to sign annually a declaration that he/she has no conflict of interest and a declaration on the property owned (civil service law). There is also the code of ethics developed by the MAF.

There is a system of signals of possible conflict of interest developed at the level of each competent authority. These signals can be lodged by individual citizens, civil servants, colleagues etc. Competent authority has developed the procedures/internal rules on dealing with signals on conflict of interest. Rotation of inspectors is also used with the same aim.

### Staff qualifications and training

Policies on Agri-food Chain Directorate

The training needs of experts from the PAFCD are defined by:

- New legislation;
- Annual attestations of experts carried out by the Director of the PAFCD according to the Ordinance on Conditions and the Order on Attestations of officials in State administration. The attestation contains training on the basis of the working plan for the next year of the expert and on the basis of his/her professional experience.

Individual training plans are available for all staff, which includes induction training, training relevant to the job and also some general training such as languages. These plans are approved by the Director to ensure that they match the job description and the training needs identified. A training procedure for experts of PAFCD has been developed and approved. The procedure is published on the webpage of MAF. Training records are kept for all experts of the directorate (record of participation on training courses and qualification of experts).

Pursuant to Article 6 of Regulation (EC) № 882/2004, experts of the PAFCD participate in training to achieve a uniform approach and harmonised procedures for implementing the requirements of European legislation. Experts are trained in the regulations of the hygiene package, food and feed, animal health and plant health.

Information on training on various topics is available on the website of the MAF (<http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/Obuchenia/MaterialiObuchenia.aspx>).

Recording and archiving of all training participation documents is done by an expert in the Directorate, who has been assigned

responsibilities for the training of competent authorities.

With the creation of the BFSA, a new contact point within BFSA was nominated to co-ordinate the activities under the BTSF programme. In 2015 a second contact point to co-ordinate the activities under the BTSF programme has been nominated within Ministry of Agriculture and Food.

### Bulgarian Food Safety Agency

Training and Qualification Department (TQD) within Human Resources, Training and Qualification Directorate is responsible for co-ordinating the training and the qualifications of the employees of BFSA, including training by the European Commission, international organisations and third parties. Since July 2011 the National Contact point for BTSF programme is within the TQD of BFSA.

After completion of BTSF training, each expert drafts a report and provides it together with a copy of the certificate to the Training and Qualification Department (TQD) and also reported for the conducted cascade training. All presentations and the information received during the training are available to the all experts from the certain directorates, colleagues and other stakeholders. After passing a training under BTSF, the experts are obliged to conduct a cascade training on the topic within 30 days.

According to the Statutes of the BFSA, the tasks of the TQD are as follows:

1. To take part in the development of programs for initial training of new employees of the agency.
2. To co-ordinate training of the agency staff, organised by the European Commission, international organisations and third countries.
3. To co-ordinate reporting of training, the Directorate has created training registers which contain details on the training carried out, topics covered, trainers and trainees and session dates, etc.
4. To prepare programs, organise and co-ordinate training courses for the qualification of BFSA staff.
5. To maintain a database for: Qualification of BFSA staff at regional and national level; Universities and Institutes eligible to train employees of the agency; Professors and associate professors, lecturers, experts and specialists with appropriate qualifications to conduct training. Appropriate steps have been taken in order to achieve the licensing of a Professional Training Centre of the BFSA.
6. To plan in co-operation with the heads of all BFSA Directorates, precise criteria for the development of training programmes as well as criteria for analysing and reporting results. The criteria for identification of training needs will be defined on the same basis.

TQD summarises Annual plan for the training of officials from BFSA on animal health, food and feed safety, import controls and plant health with input from the regions. The plan is approved by the Executive Director of BFSA.

All officials involved in food safety control are civil servants and licensed veterinarians. The official veterinarians performing food safety control according to Art. 9.1 and 2 of the Law on Veterinary Activities must also have three years of service in the field of food safety control and have been trained in food safety issues.

Officials responsible for the organisation and inspection of plant health controls must have agricultural university degrees, with specialisation in the field of plant protection.

With the creation of the BFSA, training assessment started but it is planned to formalise it further in a near future.

As regards effectiveness of training, the CA indicated that at the end of each training course official veterinarians were obliged to pass an exam. Currently, the new Training Department is assessing new options to improve the system. Evidences of training needs being formally assessed could not be found. A database was being created containing information on skills/qualifications of staff, training institutes and qualified trainers. In addition, separate database of all trainings conducted at national level and under the BTSF program is created.

The Internal Regulations of organisation, co-ordination, analyses and evaluation of trainings of the employees in BFSA are established by Order RD 11-1355/ 28.10.2011 of the BFSA Executive Director and published on the BFSA's web site:

The New terms and procedure for conducting the training of employees in BFSA and reporting of results are established by Order № RD 11 – 31/ 15.01.2015 on the approval of Standard Operating Procedures (SOPs) of the BFSA Executive Director and published on the BFSA's web site:

<http://babh.government.bg/bg/Page/proc-OK/index/procOK/%D0%9F%D1%80%D0%BE%D1%86%D0%B5%D0%B4%D1%83%D1%80%D0%B8%20%D0%9E%D0%B1%D1%83%D1%87%D0%B5%D0%BD%D0%B8%D0%B5%20%D0%B8%20%D0%BA%D0%B2%D0%B0%D0%BB%D0%B8%D1%84%D0%B8%D0%BA%D0%B0%D1%86%D0%B8%D1%8F>

### **Organisation and implementation of official controls**

There is a structure for the organisation of a control system for food and feed safety, animal health, animal welfare and plant health in Bulgaria. There are documented procedures containing information and instructions for staff performing official controls.

The organisation and implementation of official controls within individual sectors is described in Part 2 of the country profile.

#### *Registration / approval of food business establishments*

Detailed information on registration and approval of food/feed business operators is given under chapters 2.2, 2.4 and 2.7 of the country profile.

The RFSD register the establishments for production, processing, storing and packing of raw materials and foodstuffs of animal and non-animal origin, as well as establishments for the wholesale trade in foodstuffs of animal and non-animal origin. The RFSD also registers retail outlets selling solely food of animal origin and non-animal origin. See the following link: <http://www.babh.government.bg/en/registers.html>

#### *Prioritisation of official controls*

Detailed information on risk prioritisation is given under respective control systems in part 2 of the country profile and in the MANCP.

#### *Control activities, methods and techniques*

Detailed information on control activities, methods and techniques used by competent authorities is given under the respective control systems in part 2 of the country profile.

#### Sampling and Laboratory analysis

Laboratories used for official control purposes are designated by the CAs for the respective sectors. The laboratories used for official controls belong to BFSA or the MH.

Laboratory activities are described under designation of competent authorities (section I above).

The NRLs also perform analyses as routine laboratories in the area of their competences.

#### Procedures for performance and reporting of control activities

All procedures are available and accessible on the respective websites, electronically and in hard copy.

Detailed information on procedures for performance and reporting of control activities are given in the respective sectors in part 2 of the country profile.

#### Transparency and confidentiality

Information on control activities (including programmes and results) and the relevant legislation is published on the individual competent authorities' websites.

The MANCP, the annual report, audit information and RASFF information are published on the MAF website.

MANCP:

<http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/zakon.aspx>

Audits:

<http://www.mzh.government.bg/MZH/bg/ShortLinks/ZJBH/Oditi.aspx>

The BFSA has its own website where they publish the names of the establishments closed down, outbreaks, press releases, etc.

[www.babh.government.bg](http://www.babh.government.bg)

The MH publishes the results of controls on the regional websites.

### **Enforcement measures**

#### Measures in case of non-compliance

Measures taken in cases of non-compliance are described in the MANCP and also in the annual report under the relevant sectors of official controls.

According to the Bulgarian CAs, the official control on food is implemented by appropriate methods and techniques such as monitoring, surveillance, verification audit, inspection, sampling and analysis.

The Food Law establishes that official control of food is carried out under procedures in compliance with Regulation (EC) No 882/2004 and is implemented by appropriate methods and techniques. The Law describes the activities that constitute official controls.

In case of infringements for which prescriptions are already issued and fines and sanctions imposed, the producers and traders are obliged to pay a tax for the inspection and for controls on imported or exported food and food to be placed on the market.

In accordance with the Food law, in case of non-compliance the CAs have the right to:

1. Suspend the full or part operation of the food production and marketing establishment temporarily or permanently in case of infringements of the norms and requirements specified in legislation;
2. Carry out monitoring;
3. Stop the manufacturing of foodstuffs which directly or indirectly threaten the health of people and to order their return, withdrawal, destruction, reprocessing or use for other purposes;
4. Issue acts for established administrative infringements;
5. Restrict the access to the establishments under prohibition through certifying signs;
6. Restrict or prohibit placing on the market the foodstuffs;
7. Undertake the necessary actions ensuring the food safety and compliance with the normative requirements.

According to the Law on veterinary activities, on suspicion of deviation from the requirements of safety on raw materials and foods of animal origin or products, obtained from animal by-products (ABP), the official veterinarians:

1. Shall impose a written temporary ban and put under restriction the raw materials, foods of animal origin and their products, obtained from ABP, in a warehouse of the owner or their consignee;
2. Shall carry out inspections.

Depending on the type and extent of the breaches, indicated in the record or the report some of the following measures shall be taken:

1. Give binding instructions for removal of the breaches;
2. Ban of transportation, trade and placing on the market of raw materials and foods of animal origin and their products, obtained from ABP;
3. Instructions for processing or destruction of raw materials and foods of animal origin and products, obtained from ABP;
4. Ceasing of a part or the whole activity at the establishments.

Where the owner of the establishment had removed the breaches before the expiry of the prescribed period indicated in the prescription, he shall, in writing, inform the issuing veterinarian, and request him to carry out an inspection of the establishment.

Within 3 days of the expiry of the period for removal of the breaches, indicated in the prescription, the official veterinarian, who had issued it, shall carry out an inspection at the establishment and in cases where the breaches have been removed, shall reflect this in the prescription, by entering a date, signature and stamp.

Where the breaches have not been removed, after expiry of the indicated prescription period, the official veterinary shall within 3 days issue an order to stop that part or the whole activity at the establishment.

Measures shall be imposed independently or simultaneously by imposing an administrative penalty (Act for administrative infringement followed by punitive decree that is issued by the director of the RFSD).

The official veterinarians by imposing an order shall require the destruction of the raw materials, foods of animal origin, or ABP, obtained from them, where:

1. They find, that the materials or feed are unfit for consumption or dangerous to human and/or animal health;
2. They find, that the commodities are of unknown origin;
3. They find, that the commodities are imported in violation of requirements;
4. Official information is received indicating that these goods are dangerous to human and/or animal health;
5. They find that the commodities are produced in sites which have been stopped from operating according to the order of the Law on veterinary activities or of the Law for Foodstuffs or in sites not registered according to the order of the Law for Foodstuffs.

The official veterinary shall draw up a record, wherein shall be described the type, the quantity, the number and other characteristics of the establishments, subjected to a destruction order. The record is an integral part of the order.

The losses from the imposed ban following non-compliance with the veterinary medical requirements shall be charged to owners of the establishments, subject to control.

The Law on veterinary activities contains lists of establishments where controls on animal health shall be carried out including units for production, processing and storage of raw materials and foods of animal origin.

The control on animal health shall also be carried out on the activities of the veterinarians, who have been registered for execution of a veterinary medical practice.

The animal health control shall be carried out through veterinary medical checks of the establishments and of the documentation; Clinical examinations, killing and autopsy of animals with a diagnostic purpose. Testing and sending of samples for laboratory examinations; Issuing of veterinary medical documents; Imposing of measures of prophylactics, limitation and eradication of the animal diseases and notifying of the interested parties and juridical persons; Imposing of compulsory administrative measures; conducting of epizootic study for detection of the reasons for the occurrence of the disease.

When the CAs identify breaches, depending on their type and severity, they shall undertake one or several of the following measures: give binding prescriptions, wherein deadlines for the elimination of the breaches shall be fixed; impose bans; order an eradication or a redirection for a thermal or a chemical re-processing of raw materials and foods of animal origin, ABPs and products, derived therefore, feed materials, feed additives and complete feedingstuffs.

The measures in case of non-compliance in the feed sector are performed in accordance with the requirements of Article 54 and 55 of Regulation (EC) No 882/2004. The penalties and sanctions are laid down in the Chapter - Administrative penal provisions of the Feed law.

When carrying out official controls and non-compliances are detected, the protocol to be drawn up should contain the infringements that have been detected. Short but reasonable deadline should be prescribed in order to correct the deficiencies. Within the deadline, a second, non-planned inspection is carried out. In cases where the prescription is not fulfilled, an administrative act is issued. Fines and sanctions for legal entities are higher than those for individual persons. An increase in the amount of the fine or sanction is foreseen when the non-compliance is repeated.

According to the Law on veterinary activities and the secondary legislation, BFSA (Control of VMPs Directorate) carries out controls on all the activities with regard to manufacturing, storage, sale, use and residues of veterinary medicinal products.

According to Article 388, paragraph 1 of the Law on veterinary activities, the inspectors from the Control of VMPs directorate and the RFSDs shall check at any time the establishments for manufacturing, storage, sale and administration of veterinary medicinal products; shall demand and examine all documents, relevant to manufacturing and quality of veterinary medicinal products; shall issue prescriptions for the removal of detected breaches/inconsistencies; shall put a ban on veterinary medicinal products in the case of a suspicion of deviation in the quality indicators until the results of the laboratory tests have been received; and shall take samples.

According to Article 389, paragraph 1 of the Law on veterinary activities, when breaches are detected, inspectors from the BFSA shall issue instructions for their correction; stop temporarily the activity of part or the whole establishment, until the breaches have been corrected, confiscation and destroy of VMPs. According to Article 472 of the same Law, measures for violations found shall be imposed by acts, drawn up by veterinaries of the BFSA according to the requirements of the Law on the administrative infringements and punishments.

### Sanctions

The legal basis for imposition of administrative sanctions arises from the framework legislative acts. The framework legislation for food and feed safety controls comprises: Law on BFSA (SG 8/2011, last amended SG No 61/2014); Food Law (SG No 102/2003, last amended SG No 8/2011, last amended SG 14/2015); Veterinary Activity Law (SG No 87/2005, last amended SG No 14/2015); Feed Law (SG No 55/2006, last amended SG No 12/2015), Plant Protection Law (SG No 61/2014, last amended SG No 12/2015) and the Law of Health (SG No 70/2004, last amended SG No 9/2015) as mentioned above.

## **Verification and review of official controls and procedures**

### *Verification procedures*

The Directorates within BFSA have individual procedures to verify the effectiveness of official controls, which include supervision of staff performance. The verification process comprises an appropriately qualified and designated person supervising control staff documentation (plans, inspection reports, sampling forms, etc.) based on the checks on-the-spot. The main purpose of these checks is to assess skills and abilities of control staff to apply and use the methods and techniques of official controls, ability to identify non-compliances and take appropriate enforcement measures. According to the procedure, staff from Directorates at central level and each Head of Department/Head of sector/municipal official veterinarian within RFSDs should carry out supervision checks using developed check-lists in accordance with defined frequencies.

Since 2015, the eight BIPs in Bulgaria have formed part of the BFSA Border Control Directorate (BCD); the Organisation and Management of Border Control Department (OMBCD) of BCD is responsible for supervising the BIPs.

System for verification of effectiveness of official controls is being revised within BFSA (to be in place in the first half of 2016). New General Directorate "Verification of official controls" established with two Departments "Audit of official controls" and "Verification and administrative control activities of RFS" will lead future BFSA verification activities, with support from other Directorates.

By the newly adopted BFSA Organisation Rules, verification of official controls is to be performed experts staffed in the Chief Directorate for "Verification and Administrative Control of the Activities of the Regional Food Safety Directorates" that might be supported /case by case/ by experts from the BFSA specialized administration and specialized structures of BFSA. In order to ensure transparency and to unify the procedure for verification, there is a working group established on the basis of experts of directorates at central level, its main task being to develop and submit for approval new standard operational procedure for verification of official controls.

### Audit

Audits of official controls pursuant to Art. 4, point 6 of Regulation (EC) No 882/2004 are organized and performed by "Audit of Official Controls" Department. Since the very beginning of 2015 till 01.06.2015, this department was structurally placed within "Internal Audit" Directorate of BFSA Central Office. The latest amendments of the Organisational Rules of Bulgarian Food Safety Agency (publ. in the State Gazette /SG/, Issue No 29 of 21.04.2015), the obligations concerning the system of internal auditing within BFSA have been transferred to the "Verification of official controls" Chief Directorate with BFSA Central Office, this same department being already an integral part of the said Chief Directorate, which is subordinated directly to BFSA Executive Director.

"Audit of Official Controls" Department carries out planning, organization, implementation, documentation and follow-up activities related to the process of auditing official controls. There are completely developed and updated procedure regulating the rules and responsibilities of all the participants in the whole process of auditing official controls, an annual program (part of a five-year program for the internal audits in BFSA) and number of templates (model forms) of the documents related to the process of internal auditing in BFSA. All the new or updated documents related to the auditing process are publicized on the BFSA website and are publicly available free of charge.

The whole process of audit of official controls is complied with the rules laid down in Commission Decision 2006/677 of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules and in BS EN ISO 19011: 2004 "Guidelines for auditing systems for quality management and / or environment management systems", together with respective BFSA procedure on internal auditing. Members of the audit team shall be selected for each audit and approved under a special Order signed by BFSA Executive Director. Those shall be experts that are well qualified in their field, of modern training and certified in accordance with BS EN ISO 19011: 2004.

### *Policies of Agri-Food Chain Directorate (PAFCD)*

Policies of Agri-Food Chain Directorate (PAFCD) within MAF performs within MAF performs audit of the official control carried out by the Bulgarian Food Safety Agency according to art. 4 (6) of Regulation (EC) № 882/2004. A team auditors has been trained to IEC EN ISO19011:2004 and IEC EN ISO 9001:2008 standards. The audit team is multidisciplinary. Auditors participated in training courses organised by the European Commission's BTSF program.

The PAFCD is the National Contact Point (NCP) for the RASFF and also performs audit on the activities of the contact points within MAF.

### **Multi-annual National Control Plan (MANCP)**

A new MANCP for the period January 2015 – December 2017 is in place. The MANCP is published on the website of the Ministry of agriculture and food:

[http://www.mzh.government.bg/MZH/Libraries/%d0%97%d0%96%d0%91%d0%a5-%d0%bd%d0%b0%d1%86\\_%d0%b7%d0%b0%d0%ba%d0%be%d0%bd%d0%be%d0%b4%d0%b0%d1%82%d0%b5%d0%bb%d1%81%d1%82%d0%b2%d0%be/SMANCP\\_2015-2017\\_final.sflb.ashx](http://www.mzh.government.bg/MZH/Libraries/%d0%97%d0%96%d0%91%d0%a5-%d0%bd%d0%b0%d1%86_%d0%b7%d0%b0%d0%ba%d0%be%d0%bd%d0%be%d0%b4%d0%b0%d1%82%d0%b5%d0%bb%d1%81%d1%82%d0%b2%d0%be/SMANCP_2015-2017_final.sflb.ashx)

The 2014 annual report on the implementation of the MANCP was provided to the Commission in October 2015.

The following chart gives an overview of the distribution of responsibilities in relation to control systems and operational levels.

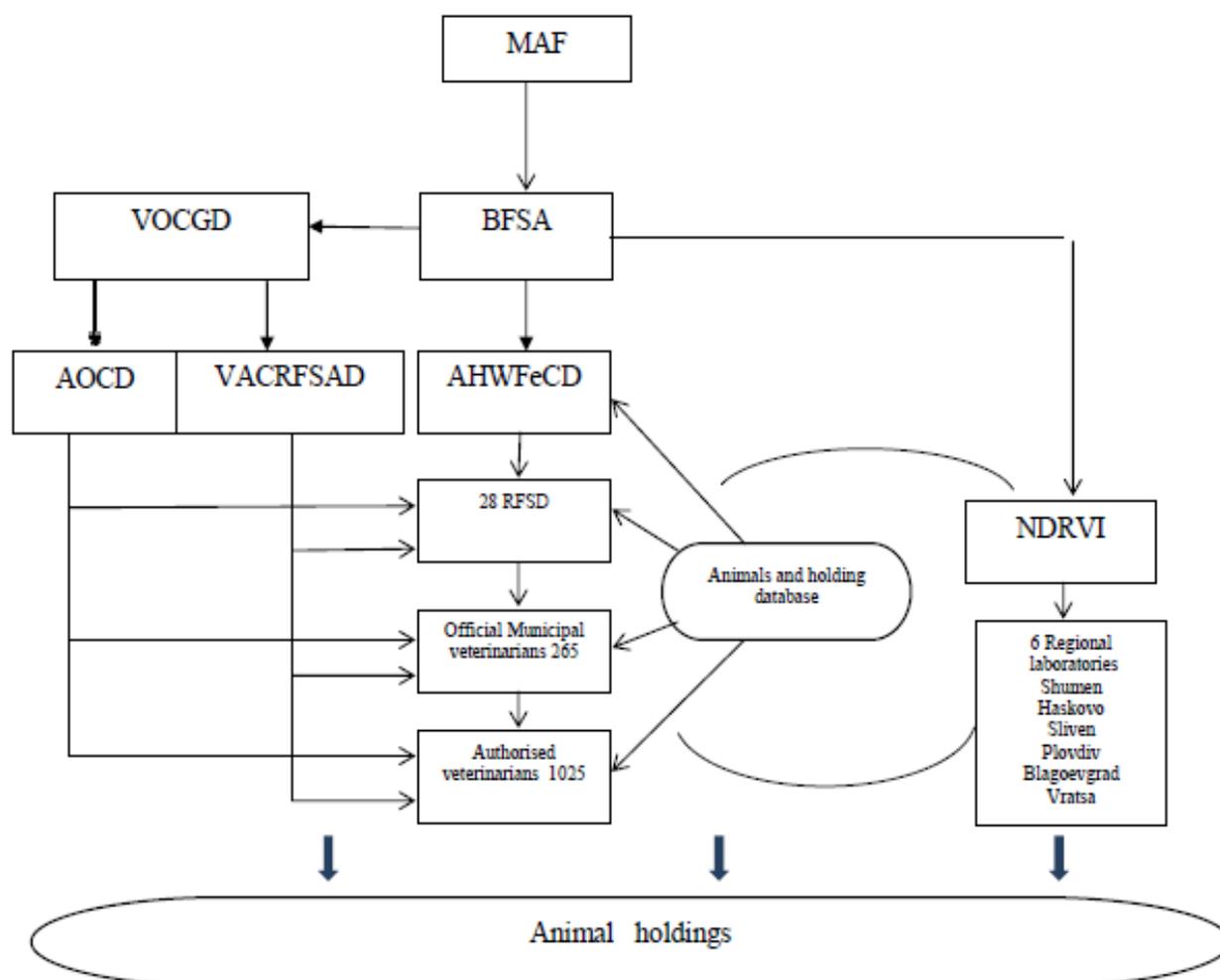
Sector	Policy co-ordination	Co-ordination of controls	Implementation of controls	Laboratories	Risk assessment/scientific advice
Animal Health	MAF (PAFCD)	BFSA (AHWFeCD, <sup>1</sup> )	RFSD	NDRVI (TL Stara Zagora and TL V Turnovo), RFSD - Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv, Biopharm-Sliven	RAC
Food of Animal Origin	MAF (PAFCD)	BFSA (FCD, )	RFSD	NDRVI, CLVCE, RFSD - Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv, Gabrovo, Sofia-town, SGS Bulgaria; RHI Kardjali	RFSD
Food post primary/retail	MAF (PAFCD)	BFSA (FCD, )	RFSD	NDRVI, CLVCE, RFSD - Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv, Gabrovo, Sofia-town	RAC
Imports of animal and food of animal origin	MAF (PAFCD)	BFSA (BCD, )	BIPs	NDRVI, CLVCE RFSD-Vratsa, Blagoevgrad, Shumen, Varna, Sliven, Haskovo, Plovdiv, Gabrovo, Sofia-town	RAC
Feedingstuff – quality and safety aspects	MAF (PAFCD)	BFSA (AHWFeCD, )	RFSD	NDRVI, CLVCE, CLQGF CLCTC, Shumen, Varna, Plovdiv, Haskovo, SGS-Bulgaria, External laboratory; CLPQ	NDRVI, RAC
Imports/exports and transit of any kinds of feed materials and feedingstuffs			BIPs	NDRVI Varna, Haskovo, CLVCE, CLCTC, SGS-Bulgaria, External laboratory; CLQGF	
Feedingstuffs: primary agricultural production of plant origin, intended for feed.	MAF (PAFCD)	BFSA (FCD, )	BIPs	CLCTC CLQGF	RAC
Primary producers mixing feedingstuffs for their own needs without using additives and premixtures	MAF (PAFCD)	BFSA (AHWFeCD)	RFSD	CLCTC, NDRVI CLQGF	RAC
TSEs/ABP	MAF (PAFCD)	BFSA (AHWFeCD, )	RFSD AV	NDRVI	RAC
Veterinary medicines and residues	MAF (PAFCD)	BFSA (CVMPD))	CVMPD RFSD BIPs	CLVCE	RAC
Foodstuffs and Food hygiene	MAF (PAFCD) MH (SHCD)	BFSA (FCD <sup>2</sup> , )	RFSD RHI	NDRVI, RHI CLCTC; RFSD Vratsa, Blagoevgrad, Shumen, Varna, Haskovo, Plovdiv, Gabrovo, Sofia-town	RFSD RAC
Imports of food of plant origin	MAF (PAFCD)	BFSA (BCD, )	DPEs/DPIs	CLCTC, RFSD Vratsa, Blagoevgrad, Shumen, Varna, Haskovo, Plovdiv, Gabrovo, Sofia-town Euro lab, also external laboratories	RAC
Plant protection products and residues	MAF (PAFCD)	BFSA (PPC, )	RFSD	CLCTC	RAC
Animal Welfare	MAF (PAFCD)	BFSA (AHWFeCD, )	RFSD, BIPs, AV	NDRVI	RAC
Plant Health	MAF (PAFCD)	BFSA (PPC)	RFSD	CLPQ	RAC

<sup>1</sup> As regards control of GMOs and laboratories.

<sup>2</sup> With the exception of the official controls on bottled natural mineral, spring and table waters.

## 2. COMPETENT AUTHORITIES AND DISTRIBUTION OF RESPONSIBILITIES IN RELATION TO INDIVIDUAL CONTROL SYSTEM

### 2.1 Control system for animal health



<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>RFSD</b>	Regional Food Safety Directorate
<b>AOCD</b>	Audit of Official Controls Department
<b>VACRFSAD</b>	Verification and Administrative Control of the activities of the Regional Food Safety Directorate Department
<b>AHWFeCD</b>	Animal Health, Welfare and Feed Control Directorate
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>NDRVI</b>	National Diagnostic and Research Veterinary Institute
<b>RL</b>	Regional Laboratories

#### Competent authorities

The central competent authority for animal health is the BFSA. The AHWFeCD of the BFSA is responsible for harmonisation and drafting legal documents relevant to its competencies. It also arranges for veterinary preventive measures against infectious and parasitic diseases including zoonoses and prepares the annual prophylactic, monitoring and eradication programmes. It is also responsible for the preparation of contingency plans, guidelines and instructions for the RFSD on implementing animal health measures.

## 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 AHWFeCD is responsible for overall management of the CDB. In the CDB data is entered by 1,400 users, including authorised private veterinarians (APV), veterinarians performing official controls on holdings, slaughterhouses, collection centres and others.

The national system of identification and registration of animals requires identification of all species by an individual number. The APV are responsible for tagging and registering the animals and providing monthly data to the OMVs who enter it into the CDB.

The system for animal movement control is based on animal health movement certificates issued by the APV responsible for the farm. Passports are issued for large ruminants and equines. All holdings are required to keep holding registers and each change to the herd is entered in a record book.

The system for registration of livestock vehicles and hauliers has been developed in accordance with the requirements of Council Regulation 1/2005/EC. The national registers of the approved vehicles for short and long journeys are published on the web site of the BFSA (<http://www.babh.government.bg/en/registers.html>).

## Animal health controls

Control measures (sampling, testing, and vaccination) prepared by the AHWFeCD and approved by the MAF, are implemented by the RFSD, OMV and APV. There is an animal health department in each of the 28 RFSD. At local/district level, there are 265 municipalities each supported by an OMV who supervises the performance of the AV. A total of 1,025 APV carry out prophylactic and monitoring of the animal health programmes (number of contracts signed could change from one year to another).

The APV report the results of their work on a monthly basis to the relevant OMV who summarises the input from all APVs and report to the RFSD. The RFSD reports to the AHWFeCD on the implementation of the animal health programmes in their region on a monthly basis.

Annually specific eradication and monitoring programmes are approved for Bluetongue, Classical CSF in East Balkan pigs, CSF in relation to vaccination (serological testing), CSF in wild boars, Foot and Mouth Disease (FMD) (at the border with Turkey), Equine Viral Arthritis (EVA), Horse Influenza and African Horse Fever, TSE and some fish diseases. The VOCDG performs internal controls at all administrative levels (AHWFeCD, RFSD, OMV and APV).

The following table gives an overview of the outbreaks of animal disease in Bulgaria. More detailed information about the diseases notified by Bulgaria can be accessed at [www.oie.int](http://www.oie.int).

## Contingency plans

For practical purposes the BFSA has based its overall contingency plan on three major types:

- A Strategy and Resource plan;
- Operational manuals;
- Instructions for practical matters during outbreak management.

The contingency plan for emergency diseases in Bulgaria (the strategy and resource plan, the operation manuals of the animal diseases and the practical instructions) is prepared in accordance with the requirements of national and European legislation, the OIE standards and characteristics of different diseases.

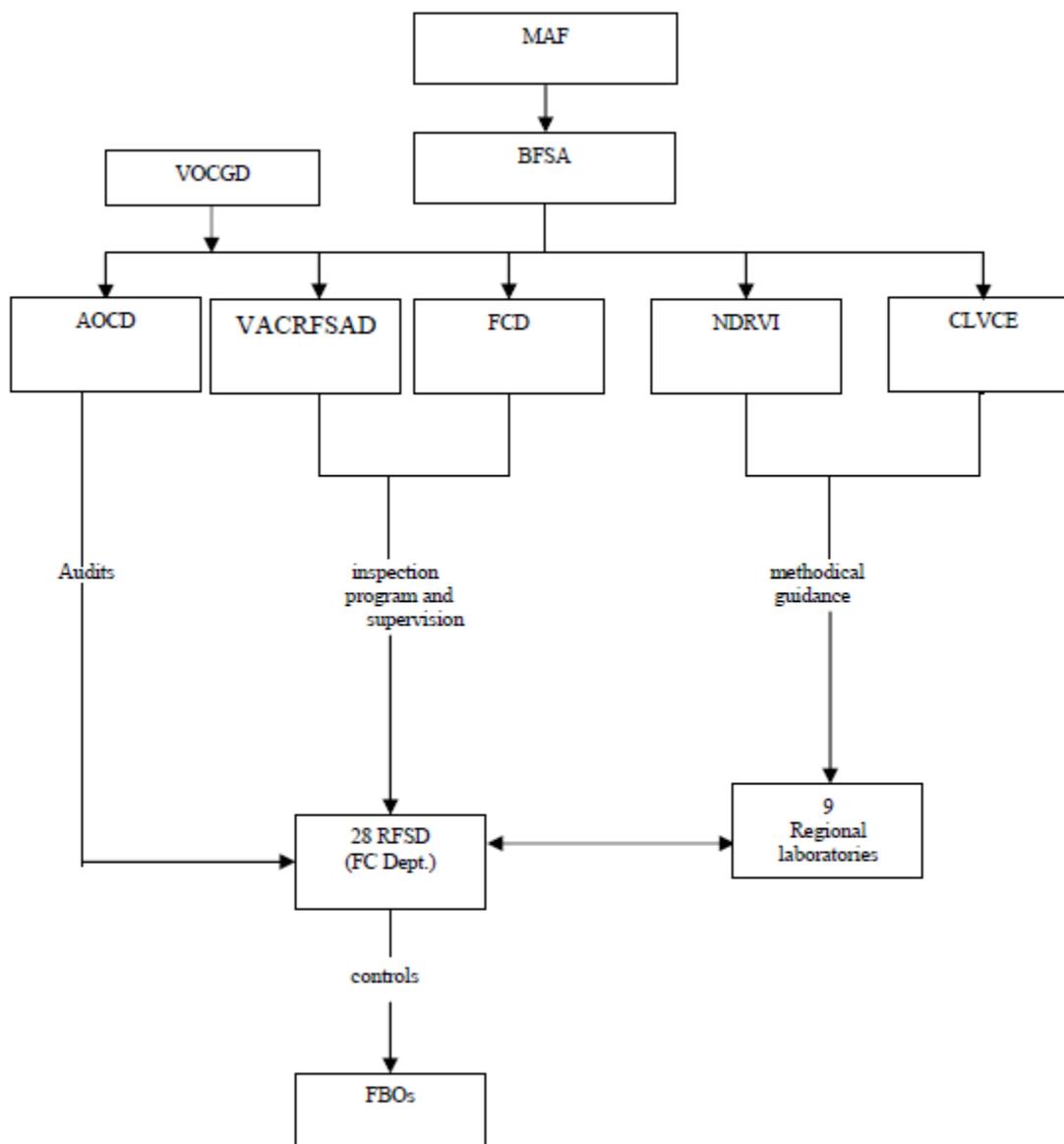
The documents are published and regularly updated on the web site of the BFSA: [http://babh.government.bg/bg/actualno-department-health&article\\_id=108.html](http://babh.government.bg/bg/actualno-department-health&article_id=108.html)

### Laboratories

The NDRVI in Sofia is a specialised body of the BFSA on diagnostics and research activities in the field of animal health. The NDRVI's reference activities are organised within 18 NRLs that have been designated the Minister of Agriculture and Food and structurally organised within two 'National Centres', which are the 'National Centre on Safety of Foodstuffs' and the 'National Centre on Animal Health' and another two 'Testing Laboratories'.

Within the Regional Food Safety Directorates in Shumen, Blagoevgrad, Vratsa, Sliven, Haskovo, Plovdiv there are laboratories, which perform diagnostic serological testing in the animal health area. The 7 regional testing laboratories within the RFSDs, are accredited according to IEC EN ISO 17025 and are methodologically guided by the relevant NRLs within the NDRVI.

## 2.2 Control system for food of animal origin



<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>FCD</b>	Food Control Directorate
<b>NDRVI</b>	National Diagnostic and Research Veterinary Institute
<b>VOCGD</b>	Verification of official controls General Directorate
<b>AOCD</b>	Audit of official controls department
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>CLVCE</b>	Central Laboratory for Veterinary Control and Ecology
<b>RFSD</b>	Regional Food Safety Directorate
<b>FC Dept.</b>	Food control Department
<b>FBO</b>	Food Business Operators

### Competent authorities

The Central Competent Authority for controls of food of animal and non-animal origin, food contact materials, food additives and food supplements is the BFSA. The Food Control Directorate (FCD) 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 RFSD in regard to preventive, regular and permanent veterinary inspections on animals in slaughterhouses, raw materials and products of animal origin in establishments producing or

processing food of animal origin. Official control includes supervision of general activity establishments and retail establishments trading solely in products of animal origin too.

"Food Controls" Directorate:

1. Participate in the development and to monitor the implementation and reporting of control programs related to food safety;
2. Coordinate laboratory diagnostic tests, analyses and expertise related to raw materials, food, food-contact materials and articles, GMOs and products containing, consisting of or produced of GMOs;
3. Develop criteria and develop procedure for determining the laboratories, which will carry out research for the purposes of official controls and in accordance with the EU law;
4. Develop, jointly with the directorates of BFSA specialized administration and BFSA specialized structural units, the National Programme for Control of pesticide residues in and on food of plant and animal origin, and to its implementation.

#### Approval and register of establishments

A procedure for approval and registration of Food Business Operators (FBO) has been established.

The establishments are evaluated by a two-step evaluation procedure. The first step is submission of an application form with self-assessment of the food business operator to the relevant RFSD. With an order issued by the Director of the relevant RFSD the commission is appointed, which, carries out an audit in the establishment for compliance with EU requirements and National legislation and draws the final conclusions. The president of the commission is designated by the Executive Director of the BFSA.

The register of all FBOs in Bulgaria is kept centrally by the BFSA. The Software for the national register of establishments is under development. The lists of approved establishments for both intra-EU trade and national market are published on:

<http://www.babh.government.bg/en/registers.html>

#### Official controls and inspection at establishments

The FCD prepares an annual inspection programme and supervises its implementation which is carried out by the RFSD. It also prepares manuals, instructions and checklists for the purpose of inspections and audits in the establishments. Each RFSD develops a detailed annual programme for official controls of each FBO in the region. The frequency of visits is determined by evaluation of risk assessment which is made in accordance with "Instructions on the Application of MANCP of Raw Materials, Foods, Food Ingredients, Food Additives and Materials in Contact with Food".

A Better efficiency of the system for official controls is provided through the above mentioned instruction, thereby ensuring safety in production, storage and supply of raw materials and foods, food additives and food contact materials. The directors of the RFSDs define teams of three inspectors who by visiting the establishments for production, processing, storage and wholesale of raw materials and food of animal origin, carry out risk assessment. Inspection teams must complete a form for risk assessment. The head of "Food

control" department upon checks on site, verify the categorisation of the establishments, made by the inspection team.

The assessment of the risk level is based on determining the impact of the 12 basic criteria directly affecting the probability of occurrence of the major hazards. These criteria are: buildings and technological equipment; capacity of the establishments; assortment technology (type of products); origin and quality of raw materials and foods; water sources; self-control systems; qualification and training of establishment's personnel; laboratory monitoring; management of the establishment; RASFF and records of the establishment (as regards results of inspections, checks and audits performed for the official control).

The criteria for risk assessment of FBOs dealing with storage and trade of foods are as follows: buildings and technological equipment; capacity of the establishments; assortment; origin and quality of raw materials and foods; water sources; self-control systems; qualification and training of establishment's personnel; RASFF and records of the establishment (as regards results of inspections, checks and audits performed for the official control).

To determine the frequency of the control in the establishments for production, trade with foods of non-animal origin and catering facilities the following criteria are used: compliance of buildings and equipment with the activity performed; establishments' capacity; the type (assortment) of the manufactured or offered foods, the effectiveness of the self-control system; location of the establishment (markets, public transport stops, crossings, etc.) and the number of clients (human flow).

The frequency of inspections of the sites for production, processing, storage and wholesale of raw materials and foods of animal origin, of the sites for production, processing, storage and wholesale of raw materials and food of non-animal origin, food contact materials, food additives food supplements, retail and catering must comply with the instructions.

The establishments producing, storing and marketing of foods are grouped in accordance with the sum of the points (based on risk assessment of possible risks) in one of the risk groups, depending on which is determined the frequency of official controls on site.

Committees appointed by an order of the Directors of the RFSD conduct evaluations of the HACCP system implemented in establishments on the territory of the relevant region. The frequency of these evaluations is at least once a year to establishments producing food of animal origin and once every two years to establishments producing food of non-animal origin. Officials with professional experience and who have completed training on HACCP are part of the teams. The inspector, which is responsible for the control on the establishment, is also present during the assessment, but he is not a member of the assessment committee.

The Directors of the RFSDs organise the performance of official control under the following principle: The official veterinarians who perform continuous monitoring of slaughterhouses, poultry slaughterhouse, wild game establishments and customs warehouses, are determined by an order. For the other establishments it is not necessary to determine the official by an order. Establishments, controlled indicators and inspectors who will carry out the checks, are determined if possible at least once every six months, according to the developed annual plan of inspections and audits, by the head of "Food control" Departments, agreed with the director of the relevant RFSD.

Upon order, issued by the Executive Director of the BFSA, other thematic checks are carried out as well, which are outside the scope of the Instruction.

In case of signals and complaints, submitted by consumers, immediate checks are carried out, in addition to those, foreseen in the Instruction.

The RFSD reports the results of the controls to the FCD on a monthly basis.

The FCD has developed instructions on the implementation of the MANCP when it is needed. Based on the instructions and the criteria for risk assessment, each RFSD draws up a plan for official controls for each establishment. The plan includes the frequency of control exercised by the official veterinarians and heads of FCD.

The FCD Directorate is responsible for the safety of the fresh fruit and vegetable in the market. The inspectors of RFSD carry out regular inspections in the market regarding the safety of the fresh fruit and vegetable. These inspections include a review of the documentation, physical inspection and an official sampling of testing for pesticides, heavy metals, nitrates.

The total number of RFSD inspectors carrying out the veterinary public health controls is 617, of whom 495 are official veterinarians.

#### Establishments in transition

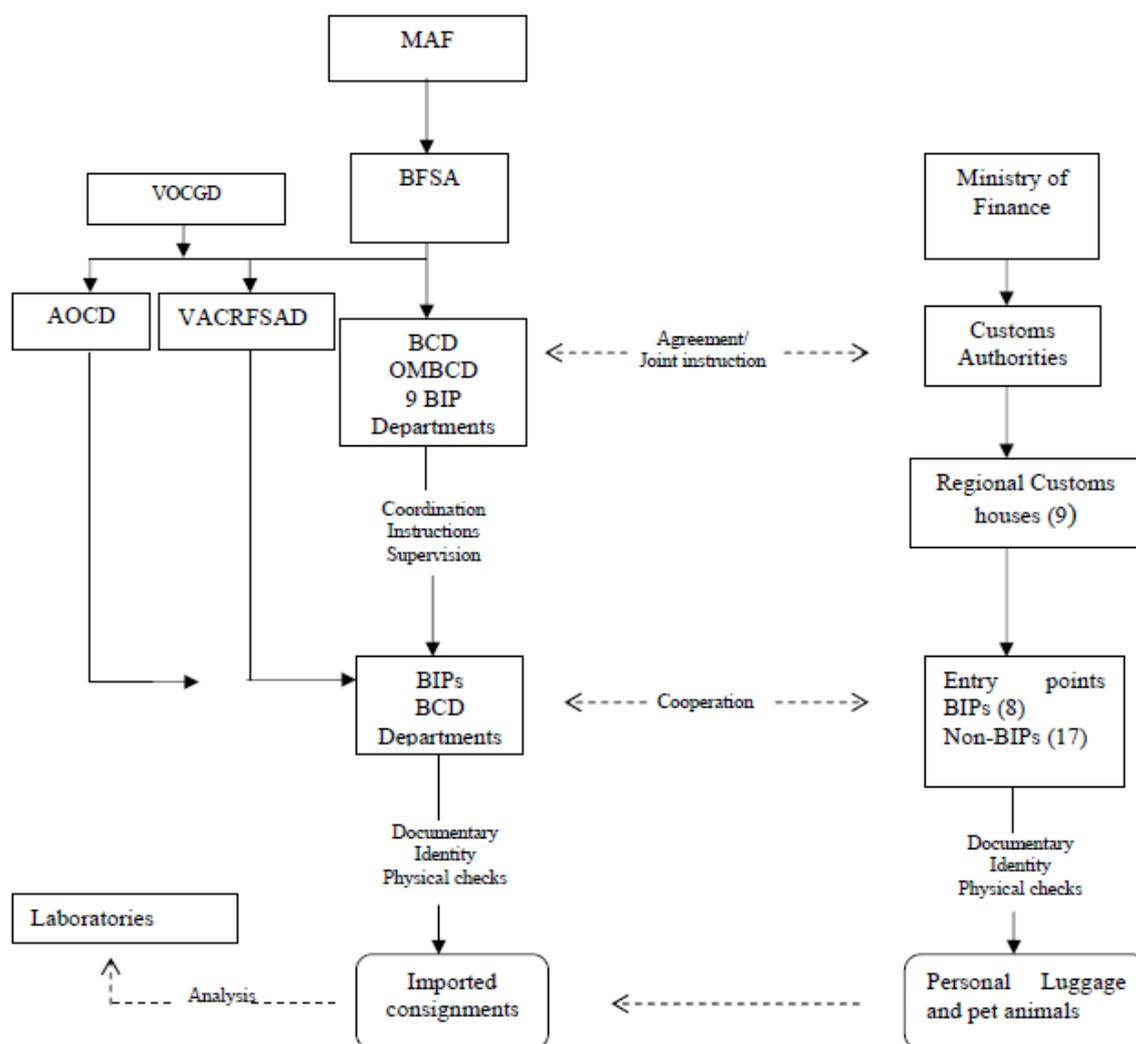
Commission Decision 2009/861/EC lays down a transitional period for milk processing establishments which process non-compliant raw milk.

#### Laboratories

Routine laboratory testing of products of animal origin are performed by 9 regional testing laboratories within the RFSDs, the confirmation of positive results is performed by the NDRVI. The 9 regional testing laboratories within the RFSDs, are accredited according to IEC EN ISO 17025. The results of analyses are sent to the RFSD and in the case of serious findings, are also communicated to the FCD.

Laboratory analyses for residues, pollutants and contaminants are carried out by the CLVCE. Within the scope of accreditation of the CLVCE raw materials and products of animal origin, biological fluids and honey are also included.

### 2.3 Control system for imports of food of animal origin



- MAF** Ministry of Agriculture and Food
- BIP** Border Inspection Post
- CA** Customs Authorities
- AOCD** Audit of official controls department
- OMBCD** Organization and Management of Border Control Department
- BCD** Border Control Department
- VACRFSAD** Verification and administrative control of the activities of the regional food safety directorate department
- VOCGD** Verification of the Official Control General Directorate
- MF** Ministry of Finance
- BFSA** Bulgarian Food Safety Agency

#### Competent authorities

Bulgarian Food Safety Agency (BFSA) is the CA (Central Competent Authority) for import controls of products of animal origin and live animals is the BFSA. The Border Control Directorate (BCD) is responsible for policy making and co-ordination of controls. The BCD drafts legislation, issues instructions and monitors the activities of the BIPs. Twenty five border posts (8 BIPs and 17 non-BIP entry points) have been designated in Bulgaria.

The National Customs Agency under the Ministry of Finance is organised in 9 Regional Customs Houses at territorial level and another 67 inland and border customs offices at local level.

## Import controls

The monitoring programmes, instructions and checklists for import controls developed by the OMBCD are disseminated and available in all BIPs. The BIPs submit monthly reports to the OMBCD on controls carried out. The TRACES registration system is used to record data on consignments. Planned supervisory checks on a verification of proper implementation of EU legislation by BIPs official veterinarians are carried out by OMBCD within BCD at central level for each BIP twice per year.

Audits of the operation of BIPs are foreseen to be performed. Customs Authorities support veterinary authorities for identification and selection of incoming consignments for veterinary checks. The CA together with the BFSa also carries out import controls on personal luggage.

All necessary checks (documentary, identity and physical) are carried out at 8 BIPs listed in the table below. Since 05.2015 the individual BIPs are the departments under the direct authority of the Border Control Directorate at central level. BIPs staff check import controls on live animals and animal products, imports of animal feedingstuffs and veterinary medicinal products.

<b>BIP</b>	<b>Border</b>	<b>Type</b>	<b>Approval</b>
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

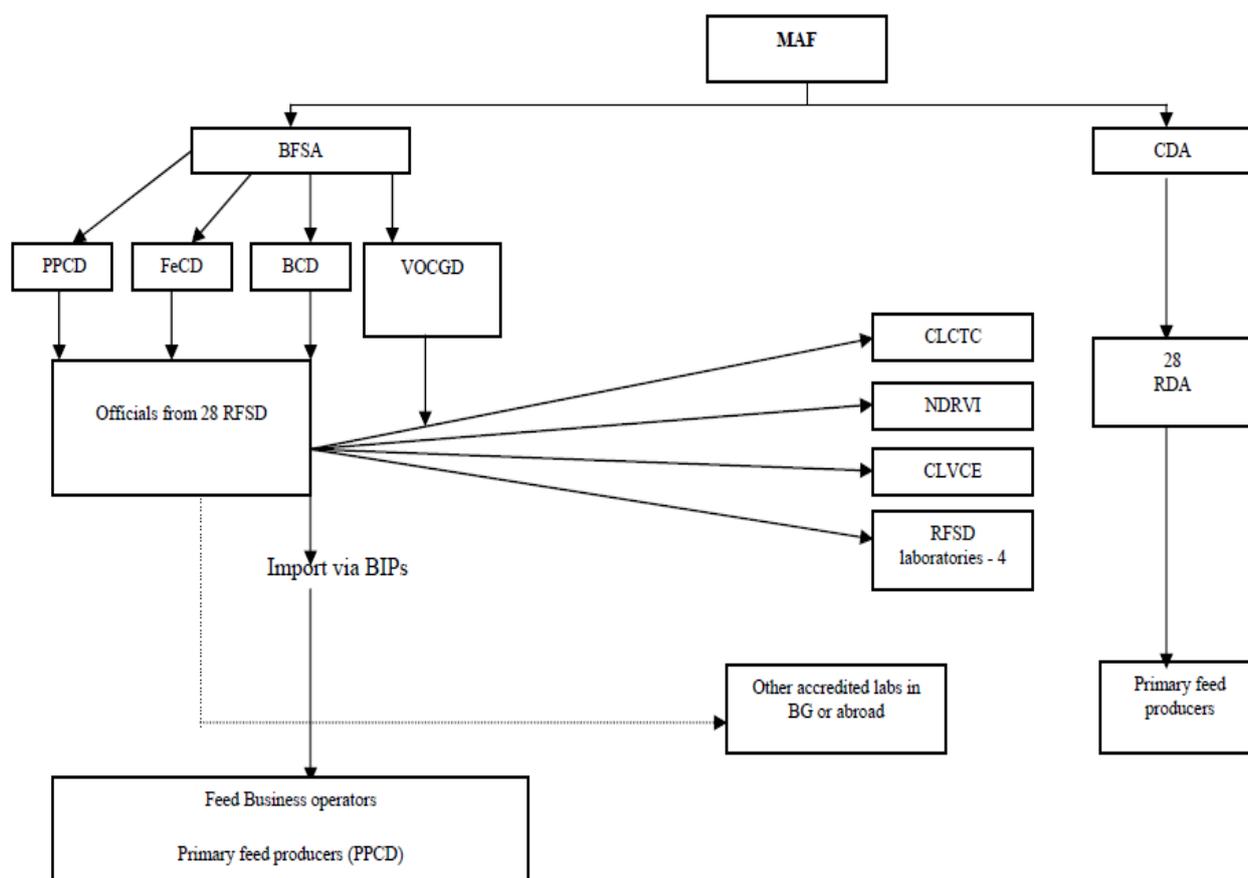
Co-operation between Customs and the BFSa takes place under a high level agreement. Implementation takes place through a joint instruction between Customs and BFSa. At local level, co-operation takes place through exchange of information in relation to the positive list and regular meetings at entry points between official veterinarians and Customs officials.

Customs Authorities support veterinary authorities for identification and selection of incoming consignments for veterinary checks. Customs officers together with the officials from BFSa also carry out import controls on personal luggage.

## Laboratories

Laboratory tests of imported products of animal origin are performed in the laboratories of the RFSD, CLVCE and NDRVI and external. All laboratories are accredited according to the requirements of EN ISO/IEC 17025.

## 2.4 Control system for feedingstuff and animal nutrition



<b>MAF</b>	Ministry of Agriculture and Food
<b>BIP</b>	Border Inspection Post
<b>CDA</b>	Chief Directorate for Agriculture
<b>RDA</b>	Regional Departments for Agriculture
<b>FeCD</b>	Feed Control Department
<b>PPCD</b>	Plant protection and Control Directorate
<b>CLQGF</b>	Central Laboratory for Qualification of Grain and Feed
<b>CLVCE</b>	Central Laboratory for Veterinary Control and Ecology
<b>BCD</b>	Border Control Directorate
<b>MAF</b>	Ministry of Agriculture and Food
<b>NDRVI</b>	National Diagnostic and Research Veterinary Institute
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>RFSD</b>	Regional Food Safety Directorate
<b>VOCGD</b>	Verification of the Official Control General Directorate

### Competent authorities

The CCA for feedingstuffs and animal nutrition is the BFSA. Within the structure of BSFA, within the headquarters, there is Feed control department within the Animal health and welfare, and Feed control directorate (AHWFeCD) which is responsible for official controls on animal nutrition, namely the AHWFeCD. The Feed control department organises execution of control activities under the Feed Law.

Taking into account that controls on feedingstuffs are associated with other control systems, appropriate links and procedures for interaction between directorates (VOCGD, PPC Directorate, Food Control Directorate) have been set up in order to provide co-ordination, exchange of information and proper interaction.

A Contingency plan, updated in accordance with the structure and activities of the BFSA, has also been worked out. It is published on the web-site of the agency.

### Approval and register of establishments

The BFSA is the CA responsible for the approval and registration of feed business operators. In the RFSD, 56 staff are in charge to approve and register feed business operators as well as to execute official control on feed sector on the whole.

Registration and approval of feed business operators is done on the basis of Regulation (EC) No 183/2005 and procedures to be performed are available in the Feed Law (SG No. 55/2006, last amended SG 12/2015).

Applications for approval are submitted to the director of the respective Regional Directorate where the manufacturing or trade site is situated. A subsequent check on the spot is carried out in order to find out whether the applicable requirements have been met. A report with findings and recommendations is made. Within six months, the establishment must comply with the relevant requirements in order to be approved.

Registration of operators is done by the same structural units following the respective procedures.

Primary producers of feedingstuffs are registered under Regulation (EC) No 183/2005 by the 28 District Agriculture Directorates of the Chief Directorate Agriculture (CDA), which is a unit within the structure of the MAF.

Following the requirements of Regulation (EC) No 183/2005, the AHWFCD maintains national public registers of approved establishments and of representatives of enterprises dealing with importation of feed from third countries. The national registers of registered and approved establishments are kept at central level. The national registers contain collected information, presented by the RFSD.

The said registers are available on website: [www.babh.government.bg](http://www.babh.government.bg)

### Official controls

Official control is carried out under the requirements of Regulation (EC) No 882/2004. It is carried out at all stages of production, processing, storage, transportation, distribution and use of feedingstuffs. Control activities start from the primary production of feeds and finishes with the use of feedingstuffs by animals.

Official control is based on risk assessment. The following data is considered: risk in relation to feed; activities connected with production taking account of: processing, storage, transportation, distribution and animal feeding; available data from official control; reliability of own-checks of feed business operators and recommendations from the Commission. For the categorisation of risk for performance of checks of feed establishments, the criteria for detection of probability and the severity of each event are used.

Samples are taken based on the risk and in cases of doubt and are analysed for compliance with the legal requirements and for observation of EU levels. Sampling is in accordance with Regulation (EC) No 152/2009. The sampling methods and analysis are in line with the requirements of Article 11 of Regulation (EC) No 882/2004.

When non-compliances are found, one or more of the following measures are taken: prohibition of marketing of feed and prescription; withdrawal the product from the market; use for other purposes or destruction. In case of system violations or non-application measures imposed by the CA, the registration of the operator is suspended and the operator is de-listed from the register.

The total number of staff, both at central and regional level, entrusted with the control of feedingstuffs is 62.

#### Organisation of the official control on feeds:

At regional level physical checks, inspections and audits of feed business operators are carried out throughout the country. Feed inspectors are appointed as inspectors and experts, and by one in each of the 28 regional directorates, located to the administrative division of the country and whose duties are entirely related to official controls of feed. In each RFSD there is also an official veterinarian, appointed for the replacement in case of absence of the abovementioned official, who also issues health certificates for export of feed to third countries. These official veterinarians combine other duties as well in the RFSD.

All inspectors, experts and official veterinarians performing the official control have undergone training on feed legislation and all 56 officials mentioned are appointed as a regional contact points for the RASFF with regard to feed.

The obligations of each expert or inspector, responsible for official control on feed are:

- to prepare an annual plan on the bases of risk assessment, to allocate it in monthly and weekly periods, in accordance with the guidance, provided at central level;
- to report weekly the official control performed by him, through sending copies of the documents, issued as a result of the official control;
- to comply with the provisions of the legislation and with the confidentiality of the information, when perform official control, and to work with the approved models of documents, check-lists and procedures;
- to participate in the trainings, organised at central level.

At central level there are 6 experts available of the foreseen to be appointed at central level, in accordance with the Statutes of the BFSA. The directorate is functioning as a competent contact point for the RASFF, with regard to feed. The following activities are responsibility of the FeC Department in accordance with the Law and Statutes of the BFSA:

1. Actively participate in the preparation of legislation, preparation of the template documents, drawing up check lists, operational procedures, procedures for co-operation and exchange of information between the RFSDs, between the RFSDs and the headquarters of the BFSA and between the directorates at central level and regional directorates;
2. Preparation of multi annual plan for control of feeds as an integral part of the multi annual plan of BFSA;
3. Annual submission for approval of a guidance for preparation and implementation of a framework plan for feed control, drawn up on risk assessment basis at regional level;
4. Annually draw up an annual framework plan for control of feed, which is the sum of the plans drawn up based on risk assessment at regional level; if necessary, based on new information related to risk assessment as well as on the results of control gathered at national level, corrections are made in connection with the obligation to manage risk;
5. Monthly preparation of a report to the Executive Director of the BFSA concerning the implementations of the plans at regional level;
6. Implementation of orders, issued by the Executive Director of the BFSA with regard to verification of the control, carried out at regional level;

## 7. Proposals of training of the officials of the directorate and of the RFSDs.

The Border Control Directorate within the BFSA is responsible for border control of feedingstuffs through its 8 approved BIPs.

The Directorate for Control of Plant Protection Products and Fertilisers – Plant Protection and Control Directorate is responsible for the implementation of the monitoring of mycotoxins and pesticides in the plant production, intended for feed, and produced as primary production of agricultural crops for feed in accordance with the Feed Act (last amended by SG 12/2015).

### Controls on imports

The competent authority for border control at BIPs is the BFSA. Importers are obliged to notify the BFSA of the place and time of import of each batch of feed 24 hours in advance. Inspectors of the BCD check whether the business establishment is on the list of the registered or approved representatives as required by Regulation (EC) No 183/2005. Prior to the release on the market of the imported products, inspectors carry out physical checks under the operational instructions and issue the standard document under Directive 98/68/EC. When the consignment is released for free circulation, feedingstuffs are controlled by the RFSDs.

### Laboratories

Analyses of the samples taken by inspectors for feed controls are analysed in: laboratories of BFSA and other accredited laboratories in Bulgaria; and in some cases, in laboratories in other Member States.

Contracts were signed (No 41 /27.09.2011 between BFSA and Fytolab Ltd., located in Plovdiv and No 42 /27.09.2011 between BFSA and “SGS Bulgaria” OOD) for analyses of feeds on certain indicators as well as for confirmatory tests, when there is lack of capacity within BFSA.

A working group has been appointed to contact accredited laboratories, situated in other Member States with the purpose to organise contracts for testing of certain indicators in feed. Contracts had been signed with two laboratories in Belgium and in Germany.

As from 2013, testing of feed samples taken within the country are performed in the following laboratories:

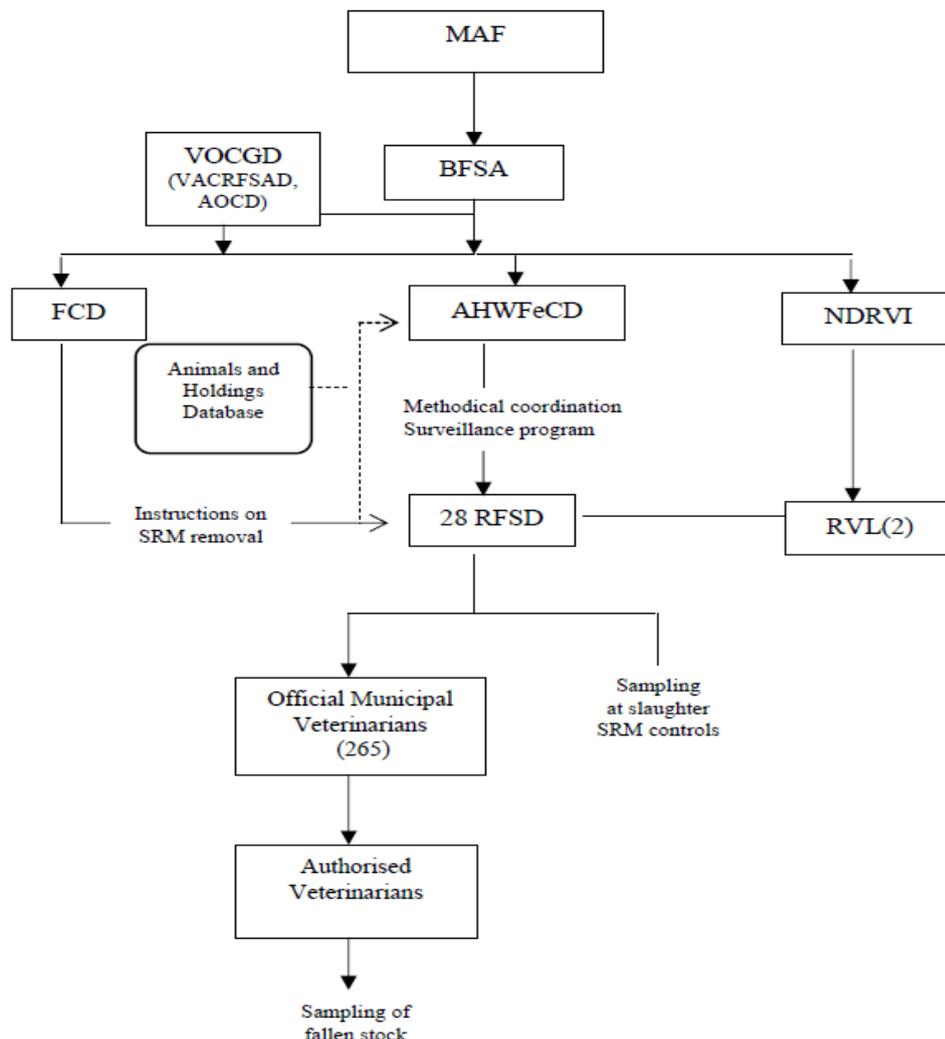
- Nutritional composition and micro and macro components – Central Laboratory for Qualification of Grain and Feed.
- Pesticide residues – Central Laboratory for Chemical Testing and Controls (CLCTC) performs analyses of feed samples taken all over the country, in cases these are positive, respective samples are then sent for confirmation to an external laboratory.
- Heavy metals - Central Laboratory for Veterinary Control and Ecology (CLVCE).
- Salmonella in feed – NDRVMI and in testing laboratories with the RFSD of Shumen, Varna, Plovdiv, Haskovo, and Blagoevgrad.

Testing of feed samples taken at BIPs is done, as follows:

- Pesticides in grain products as raw materials for production of animal feed are tested in CLCTC (with BFSA);
- Pesticides and mycotoxins in feed - External laboratory;
- Salmonella in feed is checked in NDRVMI or in testing laboratories with the RFSD of Varna and Haskovo and Blagoevgrad.

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

### TSE (Transmissible Spongiform Encephalopathy)



<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>RFSD</b>	Regional Food Safety Directorate
<b>AHWFeCD</b>	Animal Health and Welfare and Feed control Directorate
<b>FCD</b>	Food Control Directorate
<b>NDRVI</b>	National Diagnostic and Research Veterinary Institute
<b>RVL</b>	Regional Veterinary Laboratories
<b>AOCD</b>	Audit of official controls department
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>VACRFSD</b>	Verification and administrative control of the activities of the regional food safety directorate department

### Competent authorities

The central competent authority for TSEs controls is the BFSA.

The AHWFeD is responsible for policy and transposition of legislation on TSEs. It develops the epidemio-surveillance monitoring programme and instructions on the removal and control of SRM. It also issues general instructions and operational procedures regarding BSE clinical suspects and is also responsible for the development of contingency plans.

## Monitoring and surveillance of TSE

Samples for TSEs must be taken by official veterinarians at slaughterhouses or by APV on farms in the case of fallen stock or emergency slaughter.

Within the active surveillance programme, testing of bovines must cover: all animals over 24 months that died on farms or during transport; all emergency slaughtered animals over 24 months; all animals over 30 months intended for human consumption and all animals over 24 months found sick at ante-mortem inspection. Within the passive surveillance programme, all bovine animals showing clinical signs similar to those of TSEs, irrespective of their age, are tested by pathology, immunohisto-chemistry or immuno-blotting.

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

## Specified Risk Material (SRM)

Measures to control SRM have been introduced by the FCD. Official veterinarians responsible for official controls of removal and staining of SRM in slaughterhouses and cutting plants, are also responsible for guaranteeing their proper disposal. In addition, the RFSD carry out regular supervisory inspections in establishments.

The SRM and dead animals must be collected from the whole territory of the Republic of Bulgaria and rendered harmless in one of the two rendering plants – in Shumen and Varna. The territory of Bulgaria is separated into two regions in terms of collection of ABP, and the rendering plant which serves the relevant region is defined. The establishments and plants which generate SRM must have a contract with the relevant rendering plant. The mayors of the settlements and the official veterinarians are responsible to inform the rendering plants in case of dead animals in order to organise their collection. The rendering plants have schedule and routes for the collection of dead animals and other ABPs.

The SRM and dead animals must be collected from the whole territory of the Republic of Bulgaria and rendered harmless. For this activity the BFSA signed contracts with the two rendering plants.

## Total Feed Ban

At present control on the total feed ban is carried out by regional directorates, under supervision by the FeCD. Observance of the total feed ban by feed business operators is monitored through annual inspection plans, consistent with the multi annual control plan. Guidelines concerning elaboration and implementation of the annual control plan, risk assessment and risk analysis at national level, as well as risk management, are drawn up at central level then disseminated to the regional directorates. The said guidelines are based on risk assessment done on the ground of the results gained during the previous periods under review and current situation of the legislation and feed sector. The worked out draft plans at regional level are sent to the headquarters, reviewed if necessary, consolidated and approved by the Executive director of the BFSA and sent back to the regional services for implementation as it is required by the law.

Laboratory testing is carried out by the approved laboratory within the structure of NDVRI – Sofia. According to the Feed Law the costs of the laboratory tests for feed ban control are covered by the business operator.

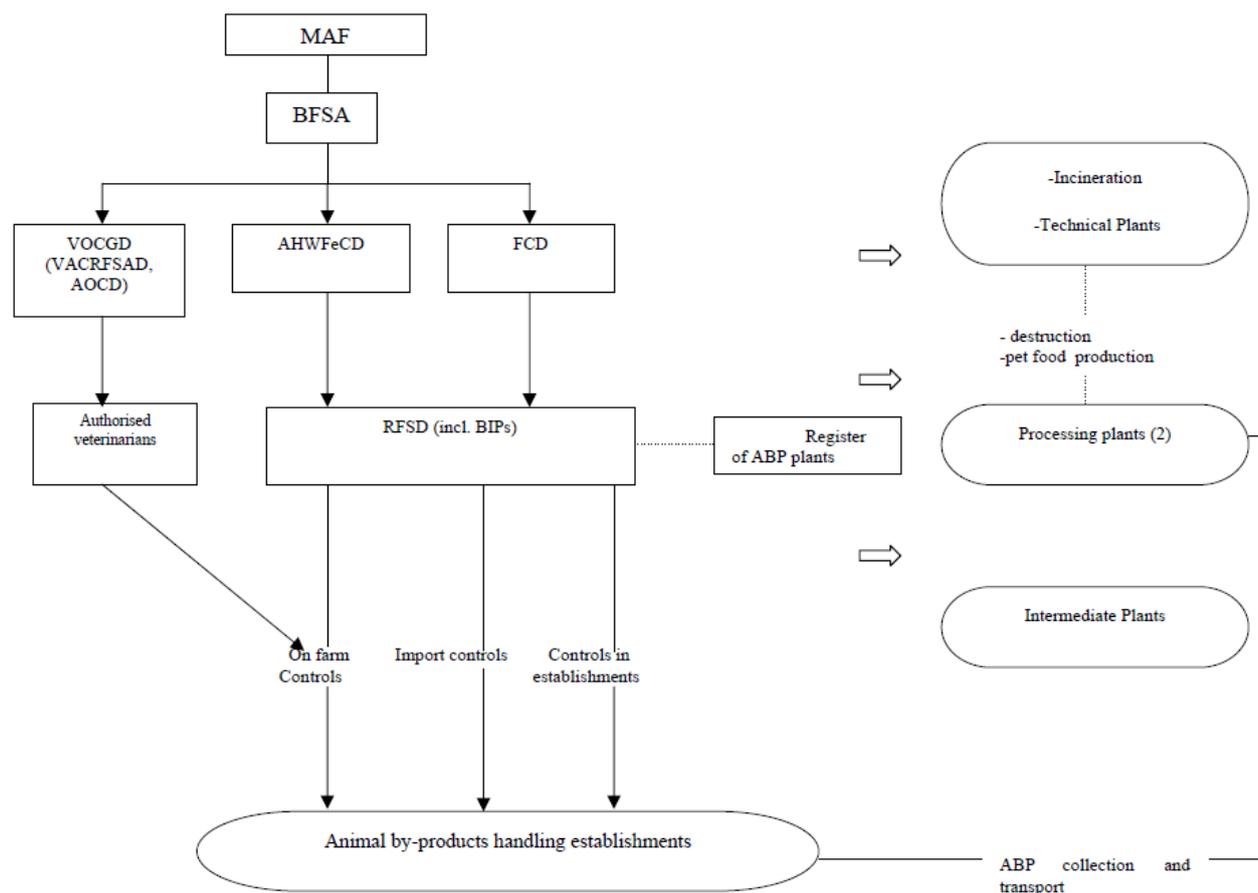
So far, due to the fact that there are no arrangements in the Veterinary Law for approving operators who use animal proteins in the production of feedingstuffs (under Annex IV to Regulation (EC) No 999/2001), such approval have not been applied. Such text is available in the amended and supplement of the Feed Law.

#### Laboratory services

The diagnostic testing on TSE is carried out by approved rapid tests in the NRL of the NDRVI in Sofia. Confirmation tests are carried out in the NDRVI by patho-histology and immuno-blotting.

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 patho-histologically or by immunohisto-chemistry or immuno-blotting.

## ABP (Animal By-Products)



<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>RFSD</b>	Regional Food Safety Directorate
<b>AOCD</b>	Audit of official controls department
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>AHWFeCD</b>	Animal Health and Welfare and Feed Control Directorate
<b>FCD</b>	Food Control Directorate
<b>BIPs</b>	Border Inspection Posts

### Competent authorities and official controls:

The BFSA is the central competent authority responsible for supervision and controls throughout the ABP chain. The FCD is dealing with public health issues in processing establishments for food of animal origin and official control at retail level, official control in case of export of ABP-products, official control of approved establishments for Intra Community trade with food products of animal origin, covered by Regulation (EC) No 1069/2009 (Intermediate plants, Storage plants, Processing plants, Oleo-chemical plants, Pet food plants, Technical plants, Incineration / Co-incineration plants).

The AHWFeCD within the BFSA is responsible for fallen stock and collection, transport and processing, and the BCD - for imports, exports and transit.

Organisation of veterinary sanitary controls at sites producing, processing and storing foods of animal origin. Furthermore at the respective approved plants performing activities subject to the rules laid down in Regulation (EC) 1069/2009 and respectively Regulation (EC) 1774/2002 before 4 March 2011.

On the basis of the Instruction for implementation of the MANCP for controls of ABP, there is an Annual Plan developed to ensure performance of following tasks or activities:

- Directly supervision of establishments/ plants subject to controls;
- Assessment of HACCP systems carried out by special commission of the relevant RFSD;
- Annual programme of internal audits by Food Control Department chiefs in the plants for production, processing and storage of food of animal origin. The frequency of inspections /checks/ and audits planned is determined on the basis of risk analysis in accordance with the criteria, formulations, digital values and forms for risk analysis, which are laid down in the Instruction.

Inspections and audits are documented in protocols and reports that include the subject of the inspection or audit and all non-compliances identified. Based on the deficiencies the official veterinarian issues prescriptions with a deadline for correction. Such document is been delivered to the business operator concerned, who is obliged to address those deficiencies within the deadline prescribed, as provided for in the Law on Veterinary Activity. If these Prescriptions are not fulfilled, and in case that the non-compliances are very serious and might result in potential risk for animal and/or public health, the official veterinarian might issue an Order for temporary suspension of a part or of the whole activity of the plant concerned or for withdrawal of its authorisation, as provided for in the Law on Veterinary Activity. Depending on the non-compliances detected, the aforementioned measures might be accompanied by imposition of the punitive sanctions laid down in the Law on Veterinary Activity.

Category 1 processing plants (the two rendering plants in Shumen and Varna) are controlled by official veterinarians, which are present daily and perform checks on the production process. The co-incineration of produced Meat and Bone Meals (MBMs) in the cement plant, village of Beli Izvor, Vratsa region, is also under the control of official veterinarian.

#### Collection, processing and disposal of ABP

Annually a contract is signed by and between BFSA and the rendering plant in the town of Shumen, under which this rendering plant undertakes the obligation to offer services to 18 administrative districts (out of 28 in all). From the territory of these districts the rendering plant collects and renders harmless materials of categories 1, 2 and 3, whereas the materials of categories 1 and 2 and the materials of category 3 are processed separately in two individual technological lines. The MBM from processing of materials of categories 1 and 2 is forwarded for final incineration in the cement plant in the village of Beli Izvor. The by-product fats are used after that as an alternative fuel in the rendering plant itself. The quantities of MBMs from the processing of materials of category 3 left unused (a small part is used to prepare foods for home pets) is also to be forwarded for further incineration to the cement plant and the by-product fats are to be used for technical purposes.

Annually a contract is signed by and between BFSA and the rendering plant in the town of Varna, under which this rendering plant undertakes the obligation to offer services to the remaining 10 administrative districts. From the territory of these districts the rendering plant collects and renders harmless materials categories 1, 2 and 3, whereas the materials of all the three categories are processed in one and the same technological line. For that reason the enterprise is ranked as

category 1 and is obliged therefore to deliver all the by-products (MBMs and fats) for destroying. The MBMs are to be forwarded for final incineration in the cement plant in the village of Beli Izvor.

The districts serviced by the rendering plants are specified not only in their respective contracts with the BFSA, but also in Order No. RD09-137 dated 28.02.2006 issued by the Minister of Agriculture and Forestry.

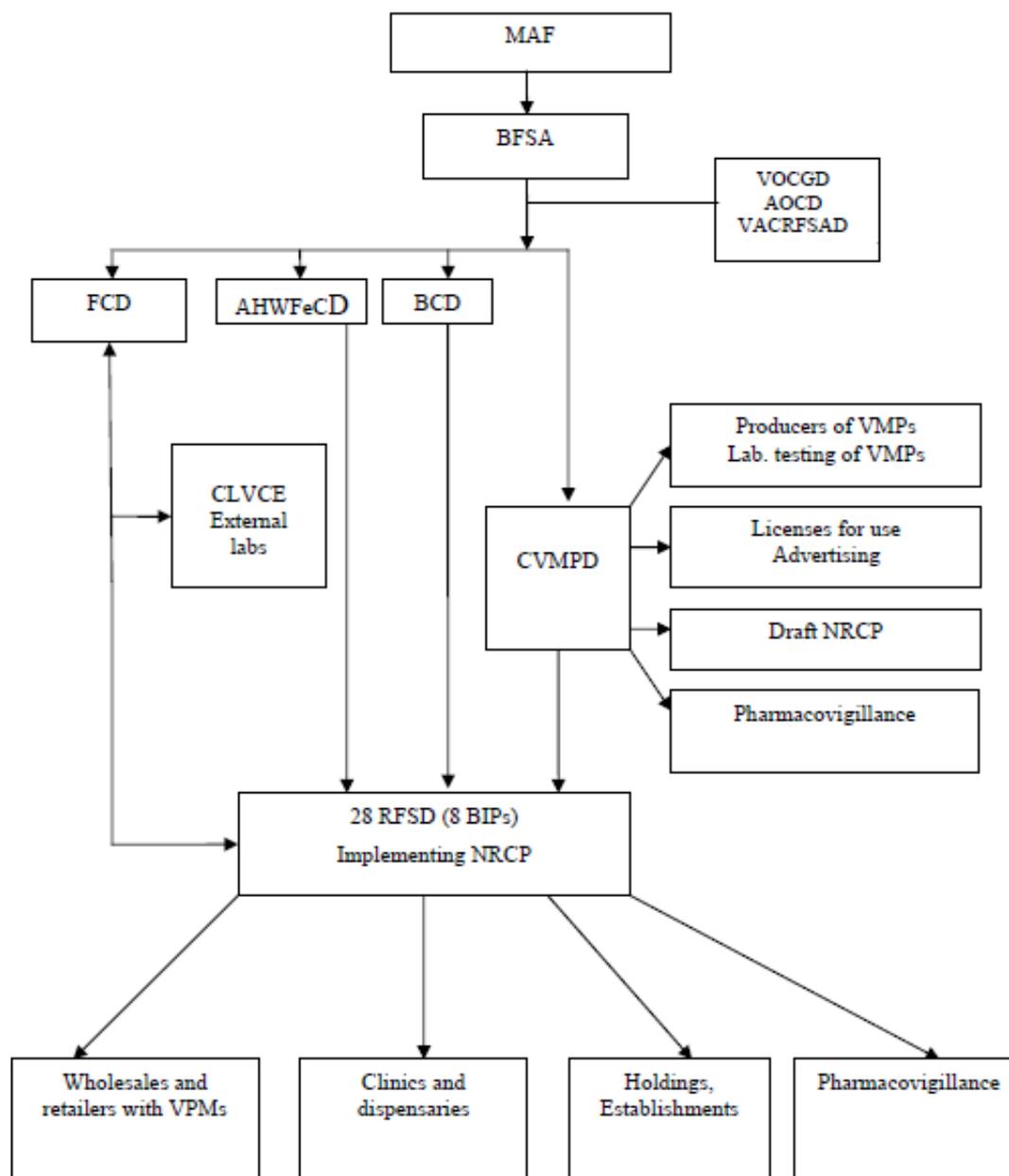
1. One plant is in charge for the collection of the dead animals from specific territories.
  - a) The rendering plant has prepared and submitted to BFSA a scheme of a transport system, which includes 8 transport routes, specifying:
    1. the places (towns and villages) each route passes through;
    2. a list of the sites, which are to be offered services (farms, meat production and meat processing facilities);
    3. the days of the week, on which the truck travel along these routes;
    4. the names of the drivers and the registration numbers of the trucks travelling along these routes, whereas two extra trucks are enlisted too;
    5. the mobile telephone numbers of the drivers;
    6. a route map showing the district covered by the respective transport route.
  - b) For the collection of SRMs, a scheme has been prepared and submitted to NVS describing the transport system, which includes 4 transport routes containing the same data as these specified in a).
2. The other plant offer services to services to 10 districts:
  - a) For the collection of the dead animals from these territories the rendering plant has prepared and submitted to BFSA a scheme of a transport system, which includes 8 transport routes containing the same data as these specified in the transport routes mentioned above.
  - b) For the collection of SRM, the same transport routes are used.

Financing from the state budget is provided, as follows:

1. 100% of the costs concerning the collection, transportation, processing and eradication of the dead animals;
2. Costs for the dead animals, ABP form slaughtered animals from holdings intended to own consumption,

The meat production and meat processing facilities and the commercial sites pay to the rendering plants for the transportation and the processing of the by-products of animal origin they supply to them.

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



<b>MAF</b>	Ministry of Agriculture and Food
<b>CVMPD</b>	Control on VMPs Directorate
<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>AOCD</b>	Audit of official controls department
<b>NRCP</b>	National Residue Control Plan
<b>RFSD</b>	Regional Food Safety Directorate
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department

### Competent authorities

The central competent authority for VMPs and their residues in live animals and animal products is the BFSA - Control on VMPs Directorate (CVMPD) and the CLVCE. The implementation of controls is assigned to official veterinary inspectors of the RFSD. One official veterinarian in each RFSD is responsible for VMPs and their residues.



## VMP

### Authorisation and control of the VMPs

The BFSA is responsible for the authorisation and control of VMPs. The CVMPD co-ordinates the implementation of wholesale, retail, storage, use and advertising of VMP by the RFSD.

Experts of CVMPD participate in the drafting of regulations, guidelines, procedures, instructions and samples of documents related to the official control of VMP, participate in working groups, standing committees and meetings at national and international institutions associated with its activities. They also evaluate dossiers and the quality of VMP, issue renewals and change of marketing authorisations on national procedures, mutual Recognition and Decentralised procedure and report the evaluation of the dossier and the quality of VMP:

- assess and give a statement on the evaluation report and documentation of the dossier country of reference procedures for Mutual Recognition and Decentralised procedures marketing authorisation of VMP;
- participate in the commissions according to art. 286;
- prepare public reports assessing the VMP and annual report on controlled VMP that are sent to the European Directorate for the Quality of Medicines and Health;
- assess periodic safety reports of VMP;
- prepare a statement to the Executive Director on the received reports of adverse reactions in marketing, other information obtained in system pharmacovigilance and variations in the quality of VMP;
- check the documentation relating to applications for approval of advertisement VMP and issue a statement to the Executive Director;
- examine the applications and attached documentation for the issuance or change of authorisations: a) Manufacturing of VMP; b) Wholesale of VMP;
- retail sale of a veterinary medicinal product;
- prepare authorisation for manufacturing, marketing, wholesale and retail VMP, Certificates of Good Manufacturing Practice and documents related to the control of the marketing; license for VMP containing narcotics substances;
- control for compliance with Good manufacturing practice for manufacturing of the VMP and APIs;
- keep registers with all issued authorisations for: a) Manufacturing of VMPs; b) Wholesale of VMPs; c) retail sale of VMPs; and d) marketing of VMPs;
- submit information in the database EudraGMP for issued Manufacturing authorisations of the VMP and Certificates of Good Manufacturing Practice and introduce and exchange information in a communication network and tracking procedures Mutual Recognition and Decentralised procedures;
- co-ordinate and control the information provided in the pharmacovigilance system vigilance and provide it with the competent authorities of Member States and the EMA information about suspected serious adverse reactions observed in territory;
- make proposals to the Executive Director to revoke the authorisation of manufacturing, wholesale, retail and marketing to ban use and marketing of a batch of VMP for blocking and withdrawal in cases provided for in Law on Veterinary Activities;

- prepare an annual inspection program for the official control of the VMPs and it submitted for approval by the Executive Director;
- involved in developing training programs for control of the marketing;
- perform laboratory analyses of qualitative and quantitative composition, physico-chemical properties, safety and efficacy of VMP;
- prepare with the directorates of specialized administration and specialized structures to BFSA The National Residue Control Plan (NRCP) and coordinate its implementation.

### Official controls on marketing and use of VMPs

The CVMPD is responsible for control of marketing authorisation, manufacture; distribution and advertisement of VMPs. Inspectors of the RFSD and the CVMPD carry out the inspections. One official veterinarian is responsible for control of VMPs at each RFSD. An annual inspection programme is devised at central level. The minimum inspection frequency for wholesale, retail (pharmacies) and private practitioners is at least once per year. Checklists are prepared by the CVMPD and disseminated to all RFSD. Analyses of the samples are carried out by the laboratories within the CVMPD.

Instructions had been provided for the inspection of on-farm establishments for the control of the use of VMP and medicated feedingstuffs.

Concerning the control on prescribing, production, labelling, transportation and use of medicated feedingstuffs, it is executed by FeCD through the regional directorates of the agency.

## **Residues**

### Official controls on residues

The National Residue Control Plan (NRCP) is drafted by CVMPs Directorate together with AHWFeC Directorate, Food Control Directorate, BCD and CLVCE. Then this draft is to be endorsed by BFSA head officers, which is prerequisite to be finally adopted and signed by the Minister of Agriculture and Food.

Within the process of this drafting, the experts of the aforementioned directorates are the ones to take into account all the relevant requirements of Directive 96/23 and the relevant application of secondary legislation for VMP usage and MRLs. They are responsible to identify and specify in the plan, the residues that are to be subject to monitoring, the matrixes that should be controlled and the number of samples for the next calendar year. These experts would decide for these NRCP elements after they have analysed all the data and relevant information gathered by and received from all the District Food Safety Directorates (the BFSA territorial units) that cover the following topics:

1. VMPs used in farmer practices;
2. numbers of farming animals countrywide broken by species, categories and age groups;
3. the manufactured amounts of raw materials and products of animal origin;
4. financial resources allocated to BFSA and testing capacities of CLVCE.

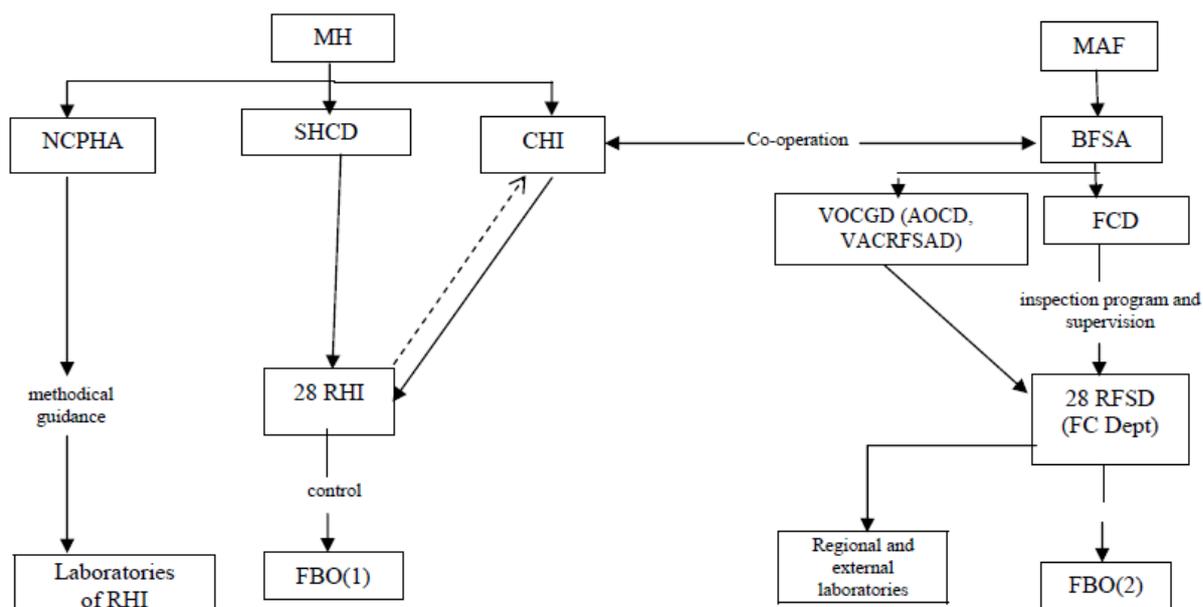
Any sampling provided for in and performed for the purposes of the NRCP is done by specifically designated OVs employed by RFSD. It is also at district level, where respective regional plans for monitoring control of residues are developed and forwarded into the CVMPs Directorate within BFSA. In each RFSD there is one OV designated for NRCP and responsible for its implementation.

All the samples taken under the NRCP are forwarded into the CLVCE. In case of non-compliances, the CLVCE must immediately inform directly the BFSA Executive Director and the CVMP Directorate and the relevant RFSD to decide the appropriate actions to identify the origin of contamination of animal(s) or product(s), of which respective sample(s) have been taken. The monitoring of products imported into EU from third countries is also part of the NRCP and it is one of the aspects of the border controls performed by border inspection posts (BIPs).

### Laboratories

The CLVCE is the only laboratory in the country for controls of residual amounts of substances subject to sampling and analysis provided for in the NRCP. It is accredited in accordance with the requirements of ISO 17025 by the national Bulgarian accreditation body.

## 2.7 Control system for foodstuffs (food of non-animal origin) and food hygiene and GMOs



<b>MH</b>	Ministry of Health
<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>FCD</b>	Food Control Directorate
<b>AOCD</b>	Audit of official controls department
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>RFSD</b>	Regional Food Safety Directorate
<b>CLCRCD</b>	Central Laboratory for Chemical Research and Control Directorate
<b>CHI</b>	Chief Health Inspector
<b>RHI</b>	Regional Health Inspector
<b>NCPHP</b>	National Centre of Public Health Protection
<b>SHCD</b>	State Health Control Directorate
<b>FBO(1)</b>	Food Business Operators–production of bottled natural mineral spring and table water
<b>FBO(2)</b>	Food Business Operators–establishments producing or processing food of non-animal origin, food additives, food ingredients and food contact materials, retail trading food of non-animal origin solely, retail both trading foods of non-animal origin and foods of animal origin

### Competent authorities

The central competent authority is BFSA, respectively FCD. FCD co-ordinates and monitors the activity of all 28 RFSD. Inspectors of Food Control Department in each RSFD have carried out official controls in establishments producing or processing food of non-animal origin, food additives, food ingredients, food contact materials. They have carried out official controls in general activity establishments for food of non-animal origin, retail establishments trading products of non-animal origin solely and retail establishments both trading products of non-animal origin and products of animal origin.

### Approval and registration of food premises

The establishments are evaluated by a two-step evaluation procedure. (1) The first step is the submission of an application form with self-assessment (please detail what you mean for self-assessment) of the food business operator to the relevant RFSD. With an order issued by the Director of the relevant RFSD the regional commission is appointed, which, carries out

an audit in the establishment to check compliance with EU requirements and National legislation.

Registration of FBOs retail trading takes place at regional level. A commission of inspectors of FC Department is responsible for the registration of FBOs where food of animal and non-animal origin is sold.

The register of all FBOs in Bulgaria is kept centrally by the BFSA. Software for the national register of establishments is under development. The list of approved establishments for intra-EU trade is published on the internet site of BFSA:

<http://www.babh.government.bg/bg/registers.html>.

The register of all FBOs retail trading (catering, retail outlets, supermarkets, etc.) is kept centrally by the BFSA and the software for this national register is under development. When finalised, it will be published on internet site of BFSA.

### Official controls of food premises

The FCD prepares an annual inspection programme and supervises its implementation. It also prepares manuals, instructions and checklists for the purpose of inspections and audits. Each RFSD develops a detailed annual programme for official controls of each FBO in the region. The frequency of visits is determined by evaluation of risk assessment which is made in accordance with “Instructions on the Application of Multi-annual National Control Plan of Raw Materials, Foods, Food ingredients, Food Additives in Food and Materials in Contact with Food”. The RFSD reports the results of the controls to the FBCD on a monthly basis about establishments and on a weekly basis about retail trading.

The FCD has developed instructions on the implementation of the MANCP when necessary. Based on these instructions and the criteria for risk assessment, each RFSD draws up a plan for official controls for each establishment and retail trading. The plan includes the frequency of control exercised by the inspectors and heads of the FCD.

### HACCP and Good Hygiene Practice Guides

Under the Food Law, all FBOs must implement and maintain procedures based on HACCP principles. The implementation of HACCP systems is checked by the RFSD. Training for inspectors of the RFSD in auditing HACCP based systems is 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.

### **RASFF**

The PAFCD of the MAF is the National Contact Point (NCP) on RASFF system of Bulgaria.

The NCP co-ordinates the activities of the contact points of the MAF, MH (RZI), Bulgarian Food Safety Agency (Headquarter and its 28 regional directorates, including 8 BIPs).

The structure, functions and activities of the contact points are described in Ordinance for the conditions and the establishment of the Rrapid Alert System for Food and Feed in the Republic of Bulgaria (Adopted by Decree № 17 of 02.02.2015).

According to the ordinance the NCP organises twice a year trainings of all contact points of the Bulgarian RASFF system, to acknowledge and inform them with the latest updates of iRASFF, RASFF Window and Traces systems.

The NCP is staffed with three experts and an expert reachable outside hours for emergency communications on a 24-hour/7-day-a-week basis.

NCP assess incoming notifications received by the European Commission and send them without undue delay to the competent contact points to take the necessary measures and actions.

The NCP receives, validates and sends notifications to the EC, which are prepared on the basis of the inspections carried out by the CA in Bulgaria.

The NCP performs audits of all contact points to control and verify their functionality in the RASFF system in Bulgaria.

### Laboratories

The laboratories performing official analysis have to demonstrate the compliance with requirements laid down in EN ISO 17025 and additional requirements according to Regulation (EO) № 882/2004 and the implementing Regulations for the methods, reporting, etc. for the laboratory control.

The CLCTC carries out testing of mycotoxins in food of plant origin. The CLCTC is accredited under EN ISO/IEC 17025 and nominated as NRL. The CLCTC carries out testing for pesticide residues, mycotoxins, heavy metals and nitrates content in food of plant origin. The CLCTC is nominated as NRL for pesticide residues in fruit and vegetable, for single pesticide residue methods as well as for mycotoxins and heavy metals in food of plant origin and accredited under EN ISO/IEC 17025.

In the CLVCE testing is performed of raw materials and products of plant origin for environmental contaminants - chemical elements and technogenic gamma-emitting radio nuclides.

### Food borne illness

Salmonella is the principal cause of food borne illness followed by *Staphylococcus Aureus* and *Shigella*. Meat and meat products, eggs and confectionary are the most common foodstuffs implicated. Ordinance № 9 of 17 November 2011 on the procedures for reporting, investigation and registration of food illness outbreak and procedures for sampling was adopted. The ordinance co-ordinates activities of the regional structures of MH and MAF to investigate the cases of food borne diseases-outbreaks.

## **GMO**

### Competent authorities and controls

The Competent authority for drafting the legislation and policy making body in the field of placing on the market and cultivation of GMO is PAFCD at the Ministry of Agriculture and Food.

The competencies for controls of GMO, GM food and GM feed are shared between the FCD and the FeC Department at AHWFeCD within BFSA.

FCD prepares a plan for control on GM food. The annual plan for GM food control is implemented by the Regional Directorates of the Agency. The control includes physical checks, sampling and analyses. The FCD supervise the implementation of the plan, summarise and analyse data from the results.

Under the requirements of the Feed Law, transposing the relevant European legislation, FeC Department at AHWFeCD is responsible for controlling the placing on the market and labelling of feedingstuffs, which contain or are consisted of GMO. The FeC Department has worked out a risk assessment and risk analysis concerning GM feed as well as a plan for control based on the multiannual plan. The plan is executed within the frame of the Annual plan for controlling feedingstuffs.

Physical control is executed through the Regional Directorates of the agency. Control is carried out within the country and includes sampling and checking for compliance with the requirements for labelling.

Control is focused on the implementation of the requirements of Regulation (EC) No. 1829/2003 and No. 1830/2003. Controls are carried out by checking the products, their labelling and the accompanied documentation. Regular sampling is applied to consignments imported from third countries or placed on the market and distributed from other MS.

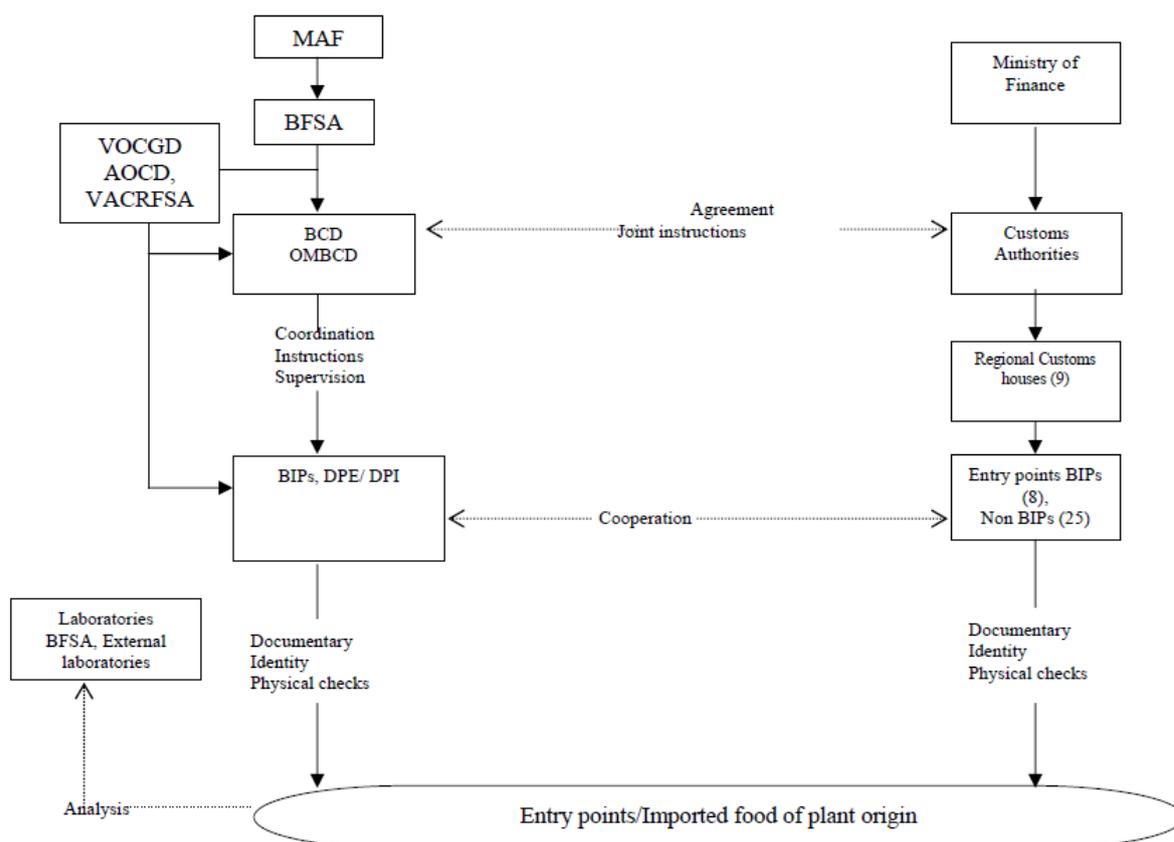
Within the MAF and according to the Law on GMO, the Food Law and Feed Law, the BFSA is responsible for control of raw material for feed and food use in processing establishments, placed on the market and import and export of food and feed. BFSA controls marketing, import and export of phytosanitary and veterinary medicinal products, containing, produced or including GMOs.

The Executive Agency for Plant Variety Testing (EAPVT) controls the presence of GMO during import, export and marketing of seed and planting material as well as variety testing field trials. The BFSA is responsible for the control of commercial cultivation of GM plants.

#### Laboratories

The National Reference Laboratory for GM food is in NCPHA under MH. The laboratory is accredited to ISO 17025 and performs analyses of GM food for the purposes of the official control. The laboratory that is used for the analysis of GMOs (including GM food) under the official control testing of BFSA is subject to tender procedures.

## 2.8 Control system for imports of food of plant origin



<b>DPE</b>	Designated points of entry
<b>DPI</b>	Designated points for import
<b>CA</b>	Customs Authorities
<b>OMBCD</b>	Organization and Management of Border Control Department
<b>BCD</b>	Border Control Directorate
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>AOCD</b>	Audit of official controls department
<b>VACRFSA</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>MAF</b>	Ministry of Agriculture and Food
<b>MF</b>	Ministry of Finance
<b>BFSA</b>	Bulgarian Food Safety Agency

### Competent authorities

The CA for import of Food of Non-Animal Origin (FNAO) is the BFSA. The BCD has overall responsibility for controls on imports of foodstuffs of plant origin. The unit OMBCD at the central level co-ordinates and supervises the activities of the Designated Points of Entry (DPEs), Designated Points for import (DPIs) and Control Points (CP) in the area of import controls. It prepares and issues guidelines and instructions for the implementation of controls.

### Import controls

All documentary checks of imported foodstuff of plant origin are carried out at the point of entry, identity and physical checks including sample are carried out at DPE, DPI and CP by officials in accordance with applicable legislation.

There is an updated endorsed Instruction for co-operation between Customs and the BFSA that covers also the mutual activities on the control of import of food of non-animal origin. Customs Authorities collaborate efficiently with official inspectors for identification and selection of incoming consignments. These products may enter into Bulgaria only via designated points of entry. Laboratory analyses have been performed according to a specific certainty and after satisfactory outcome of laboratory testing, consignments are being released.

DPE/DPI	Border	Type
Burgas	Black Sea	Port
Kapitan Andreevo	Turkey	Road
Sofia	n.a.	Airport
Varna	Black Sea	Port
Control Point/Designated point for import - Plovdiv		

### Laboratories

Official laboratories within the BFSA that are used for analyses of imported foodstuffs of plant origin are: CLCTC (mycotoxins, according to Regulation (EO) 669/2009 , Regulation (EO) 884/2014, 949/2015), RFSD Blagoevgrad, Varna, Vratsa, Gabrovo, Plovdiv, Sofia, Haskovo, Shumen within the BFSA (*Salmonella* according to Regulation (EC) No 669/2009); CLVCE of imported products of plant origin for technogenic gamma-emitting radionuclides according to Regulation (EC) No 2016/166 and Regulation (EC) No 1635/2006.

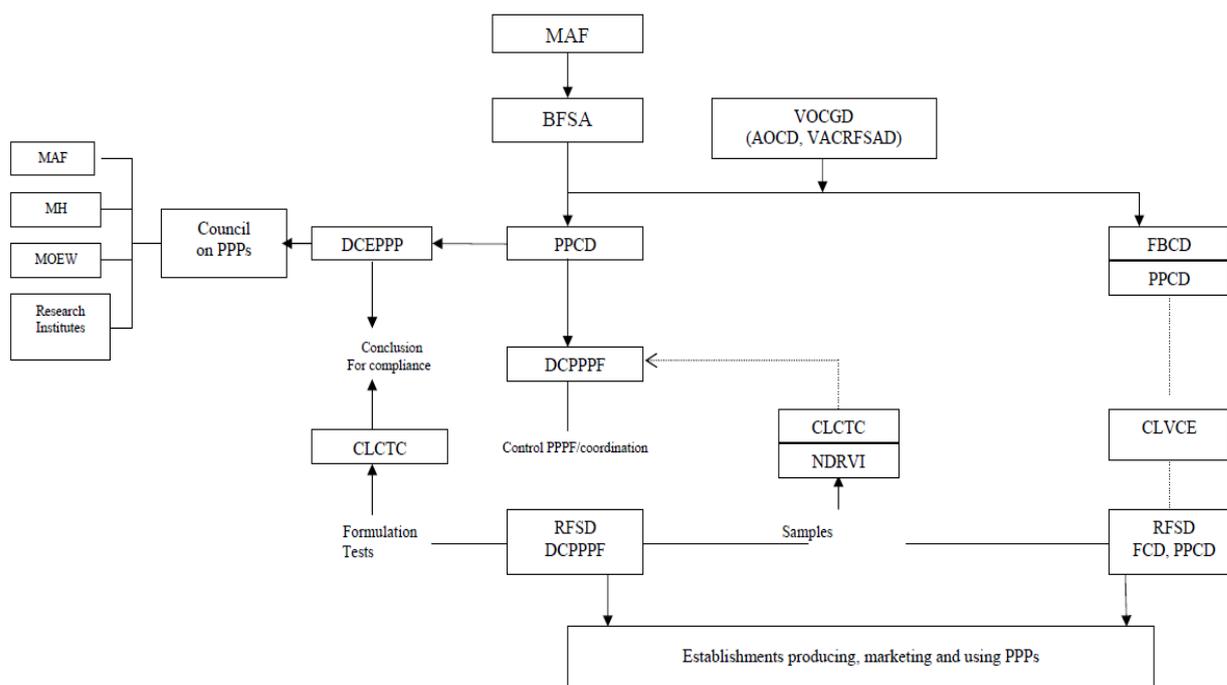
According to Regulation (EO) № 669/2009 and Regulation (EO) № 882/2004 in connection with the frequency of the official control on the import of feedstuffs and foodstuffs of non-animal origin and for the implementation of Decision 2006/504/EC the testing of fruits and vegetables for presence of pesticide residues is carried out in accredited laboratory defined in the order of the Minister of the agriculture and food NoPД 09-1432/21.12.2012:

- External laboratory – BIP "Kapitan Andreevo", Haskovo region;

Other external laboratories from other MS carry out laboratory analyses for: pesticides, sulphites, chloramphenicol, migration of PAHs and formaldehyde, Norovirus and Hepatitis A.

All laboratories are accredited according to the requirements of EN ISO/IEC 17025.

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



<b>CLCTC</b>	Central Laboratory for Chemical Testing and Control
<b>DCEPPPs</b>	Department for Control and Evaluation of Plant Protection Products
<b>MAF</b>	Ministry of Agriculture and Food
<b>MH</b>	Ministry of Health
<b>MOEW</b>	Ministry of Environment and Water
<b>PPCD</b>	Plant Protection and Control Directorate
<b>DCPPPF</b>	Department for Control of Plant Protection Products and Fertilizers
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>AOCD</b>	Audit of official controls department
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>RFS</b>	Regional Food Safety Directorate
<b>RIPHPC</b>	Regional Inspectorate for Public Health Protection and Control

### Control of marketing and use

#### Competent authorities

The BFSA is the CA for the authorisation of Plant Protection Products (PPP) through the Plant protection and control Directorate (PPCD). The PPCD methodologically co-ordinates activities of RFS in the area of plant protection regarding PPP and fertilizers. It also manages and co-ordinates the authorisation of PPP for their placing on the market and use. A National Council on PPP has been established by order of the Minister of agriculture and food to act as a consultative body on PPP. Its members are representatives of the MAF, the MH, the Ministry of Environment and Water (MEW), the BFSA and Research Institutes.

#### Authorisation and registration of PPP

The dossier for authorisation of PPP is presented to the BFSA and subsequently reviewed and assessed by the BFSA. Biological testing on new PPP for efficacy is performed in the 8 official bases of BFSA approved by order No RD 11-850/22.07.2011 of the executive director of BFSA (Plovdiv, Stara Zagora, Plevna, Russe, Vratsa, Bourgas, Veliko Tarnovo, Dobrich) and 4 more sub-divisions in Varna, Vidin, Haskovo and Blagoevgrad. Final authorisation of PPP is issued by the BFSA on the basis of the Council's proposal. The BFSA maintains the documentation and register of authorised PPP.

## Official controls on marketing and use of PPP

BFSA is the CA for controls on import, marketing and application of PPPs, including labelling checks and checks for correspondence of the PPP with the indicators approved by the authorisation. Within the BFSA, the Department for Control of Plant Protection Products and Fertilizers prepares the annual national plans for control of marketing of PPPs and their use at farm level. It also co-ordinates and manages the control activities of the RFSD and issues checklists for inspections and instructions for taking samples.

Control is carried out by inspectors of the RFSD at production, import, packaging, storage, transport and at farm level. Each RFSD has an official responsible for PPPs control (planning and reporting). Two checks are carried out annually on all PPPs producers as well as on repackaging companies. Control covers 100% of the wholesale trade and 80-100% of agricultural pharmacies. The RFSD annually controls 5-7% of the registered farmers for PPP usage. In case of suspicion, random control is carried out.

Formulation analyses of samples taken are performed by the CLCTC. Registers of PPP producers, traders and users are kept at both central and regional level.

A strategy for dealing with obsolete pesticides developed by the MEW is being implemented jointly with the municipalities.

## **Residues**

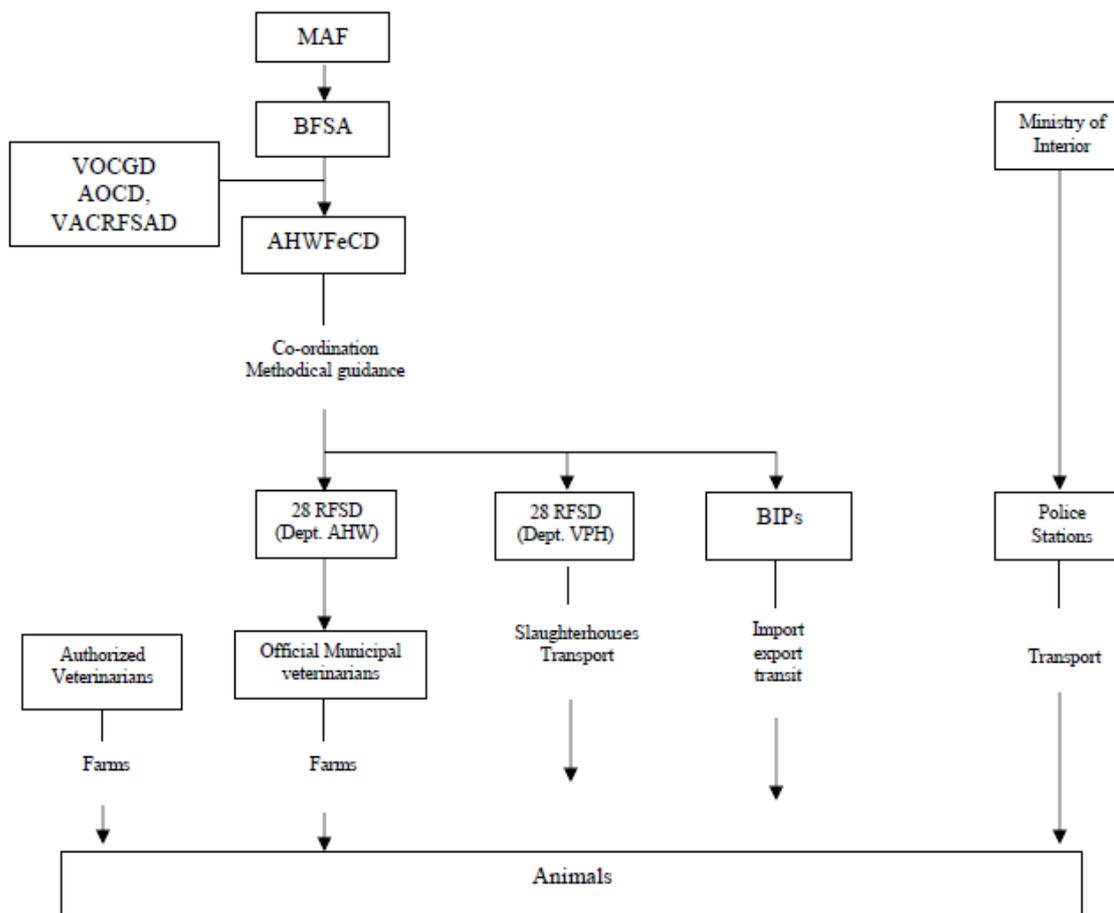
### Competent Authorities

The BFSA is the CA for control and monitoring of pesticide residues in fresh, frozen, dried and processed fruit and vegetables at producer level and for monitoring pesticides residues in domestic and imported foodstuffs at market level.

### Laboratories

Four accredited laboratories perform analyses of pesticides residues (CLCTC, CLVCE and 2 external laboratories).

## 2.10 Control system for animal welfare



<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>RFSD</b>	Regional Food Safety Directorate
<b>AHWFeCD</b>	Animal Health and Welfare and Feed Control Directorate
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>AOCD</b>	Audit of official controls department
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>BIP</b>	Border Inspection Post

### Competent authorities

The CA for animal welfare is the BFSA. The AHWFeCD is responsible for the control of animal health and welfare and its proper implementation, as well as preparation and active participation in the preparation of legislation in the respective area. The AHWFeCD organises, co-ordinates and manages the activities of the RFSD. It issues instructions on inspection programmes, guidelines, protocols and forms for inspections, and manuals for farmers and transporters. It also organises training for inspectors involved in welfare checks. The updated documents regarding animal welfare issues are published on the BFSA website: [http://babh.government.bg/bg/actualno-department-health&article\\_id=107.html](http://babh.government.bg/bg/actualno-department-health&article_id=107.html)

The VOCGD, “Audit of the official control” Department performs audits at all administrative levels (AHWFeCD, RFSD, OMV and APV). These include audits in the animal welfare area.

### Official controls on farm and at slaughter

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

Checks on animal welfare are carried out by inspectors of the RFSD and official veterinarians at BIPs. In each of the 28 RFSD, one official veterinarian is responsible for animal welfare issues. The OMV carry out checks on animal welfare requirements. The inspectors of the FCD of the RFSD are responsible for animal welfare checks in slaughterhouses.

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

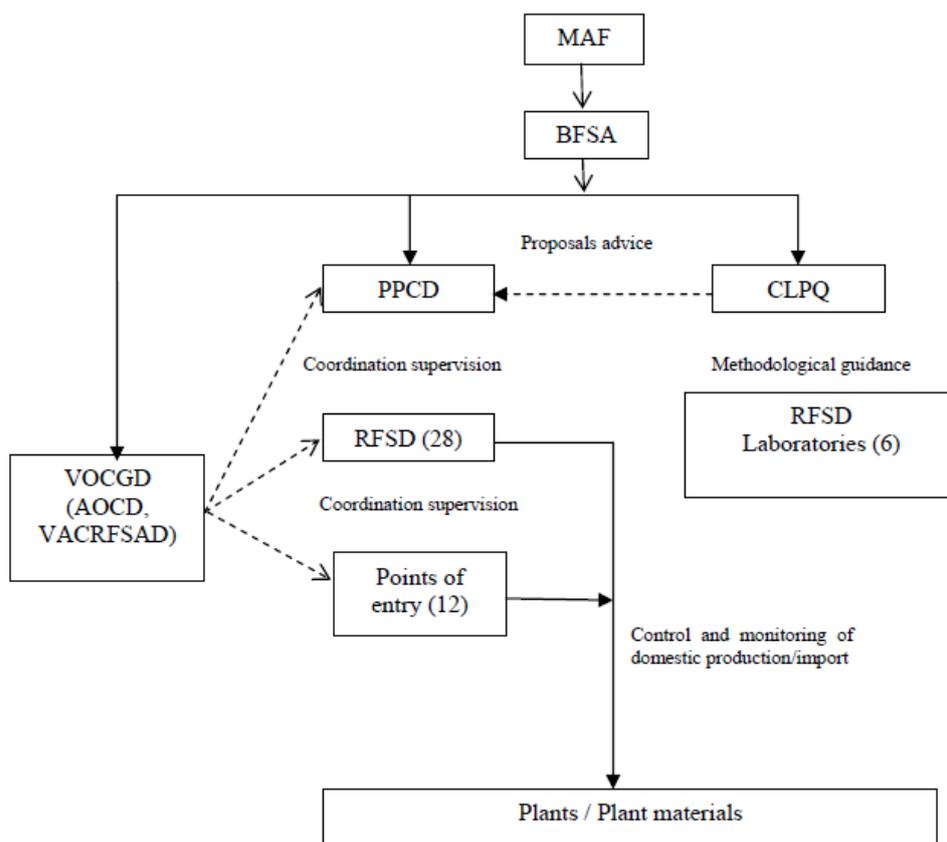
### Official controls during transport

The Animal Protection Law and the Law on veterinary activity provide the legal basis for the police to perform animal welfare controls on transport. An Ordinance on co-operation and joint actions by the veterinary services and police, on transport checks is in place since 2011.

According to the MANCP checks are carried out at place of loading, place of destination, at markets, at BIPs and on the road.

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

## 2.11 Control system for plant health



<b>CLPQ</b>	Central laboratory for Plant Quarantine
<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>AOCD</b>	Audit of official controls department
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>PPCD</b>	Plant Protection and Control Directorate
<b>RFSD</b>	Regional Food Safety Directorate

### Competent authorities

The CCA for Plant Health issues is the BFSA, Plant Protection and Control Directorate (PPCD).

The Plant Health & QCFFV Department (PH&QCFFV) within PPCD is responsible for the phytosanitary control of plants, plant products and other objects on the territory of the country; drafting the legislation; training the personnel.

Some of the main tasks of the PH&QCFFV Department are:

- To organize, coordinate and supervise: inspections of plants in cultivated areas, including fields, nurseries, gardens, greenhouses and laboratories and wild flora; inspections of storage and movement of plants, plant products and other objects; the occurrences and outbreaks of quarantine pests, the implementation of phytosanitary measures for their eradication and/or containment.
- To organize, coordinate and supervise the control activities related to international trade of regulated plants plant products and other objects, including export and where

appropriate, other non-regulated articles in order to prevent the introduction and/or spread of pests.

- To supervise the control of compliance of quality of fresh fruits and vegetables.

The Plant Health & QCFFV Department (PH&QCFFV) coordinate and supervise the activities of the RFSD on Plant Health issues.

The guidelines for the regional inspectors are drafted in collaboration with the experts of CLPQ. The coordination of laboratory activities is of the responsibility of the CLPQ.

The RFSD's are responsible for implementing of legislation on the regional level. They carry out inspections at the place of production; surveys; import and export certification. They also operate the alert system for producers as regards identification of pests and application of plant protection products.

#### Internal controls

Monitoring programmes are prepared annually by the PH&QCFFV Department and CLPQ. There are eleven regional-based reporters for each of the eleven monitoring programmes (quarantine pests of: potatoes, fruit trees, vineyards, vegetable crops grown in greenhouses and in the fields, strawberries and raspberries, forest species, ornamental plants, *Phytophthora ramorum*, *Xylella fastidiosa*, *Pseudomonas syringae* pv. *actinidiae*). Reports of the activities carried out by the RFSD are sent monthly and each semester to the PH&QCFFV within PPCD. This information is compiled in an annual report which is subsequently used to establish the monitoring programmes for the following years.

#### Import controls

There are 11 points of entry for goods subject to plant health controls:

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

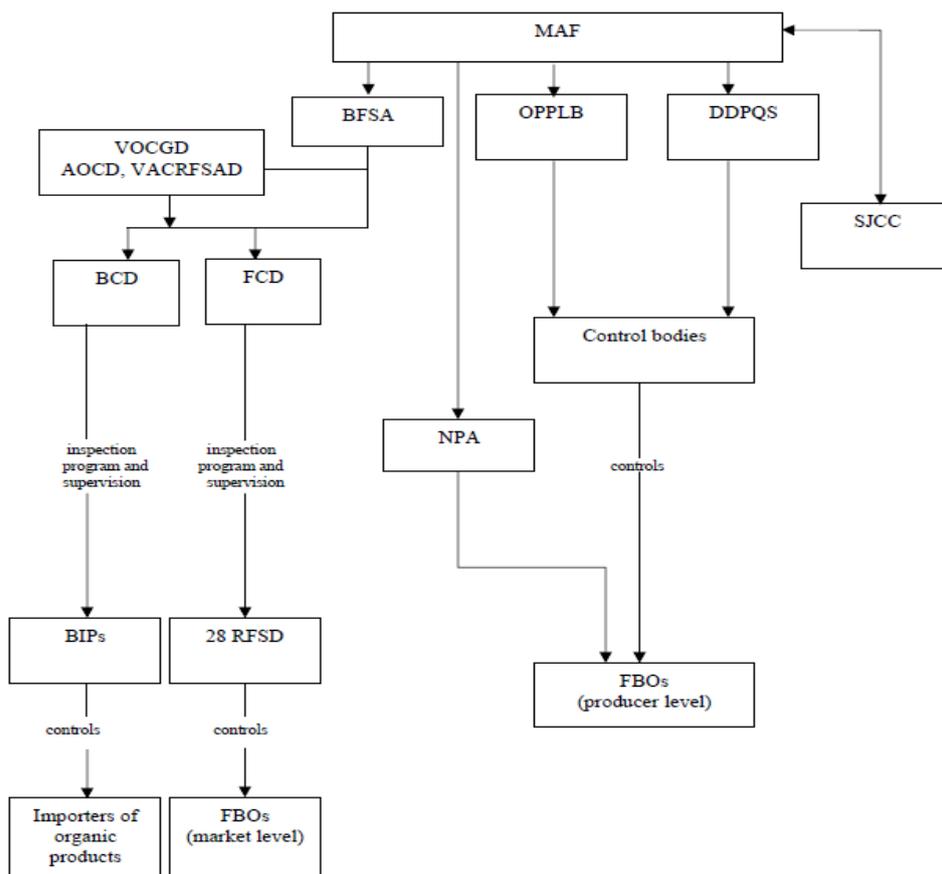
At the points of entry, plant health inspectors carry out documentary, identity and physical checks. Samples for analysis are taken in cases where presence of harmful organisms is suspected, or if the article is included in a special list (seeds and planting material). Once the consignment has been checked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

## Laboratories

The CLPQ is a NRL for plant health. It carries out plant health tests of imported and domestic plants, plant products, soil and other materials, conduct a final diagnosis and identification and validates the positive results of the analyses made by the 6 regional diagnostic laboratories on plant health. The CLPQ is also involved in the co-ordination of the activities of the RFSD, issuing methodological guidelines for inspection and drafting monitoring programmes and provides training and instructions to staff on diagnostics and identification of pests. The CLPQ is located in Sofia and has a branch which is specialised in potato analyses in Samokov.

Laboratories are attached to 6 RFSDs (Blagoevgrad, Burgas, Plovdiv, Ruse, Varna, Veliko Tarnovo), where some routine tests are carried out.

## 2.12 Control system for quality labelling



<b>MAF</b>	Ministry of Agriculture and Food
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>BIP</b>	Border Inspection Post
<b>BCD</b>	Border Control Department
<b>FCD</b>	Food Control Directorate
<b>VOCGD</b>	Verification of official controls General Directorate
<b>AOCD</b>	Audit of official controls department
<b>VACRFSAD</b>	Verification and administrative control of the activities of the regional food safety directorate department
<b>CLVCE</b>	Central Laboratory for Veterinary Control and Ecology
<b>RFSD</b>	Regional Food Safety Directorate
<b>FBO</b>	Food Business Operators
<b>SJCC</b>	Standing Joint Consultative Commission
<b>DDPQS</b>	Directorate Direct Payments and Quality Schemes
<b>OPPLB</b>	Organic Plant Production and Livestock Breeding
<b>NPA</b>	National Payment Agency

### Competent authorities for protected designations (PDO, PGI and TSG) and official controls

The Minister of Agriculture and Food carries out the quality policy in compliance with the requirements of Regulation (EU) 1151/2012 of the European Parliament and the Council on quality schemes for agricultural products and foodstuffs. Directorate “Direct Payments and Quality Schemes” (DPQS) at the Ministry of Agriculture and Food, by its unit “Quality schemes and promotions”, functions as the national competent authority pursuant to the EU legislation on agricultural products and foodstuffs with Geographical indications and Traditional specialities guaranteed.

The control on the compliance with the specifications of the registered products and foodstuffs with PGI, PDO and TSG is carried out by control bodies, accredited by an accreditation body for conformity with the requirements of Standard EN ISO 17065:2012 and which have a permission, issued by the Minister of Agriculture and Food, to exercise such control. They can be local or foreign persons – traders in the sense of the Trade Law or the legislation of an EU Member State or a country, which is part of the European Economic Area.

A procedure for issuing a permission to exercise this control activity is included in the national legislation, and for carrying out supervision over the control bodies activities. There is a Standing Joint Consultative Commission on Geographical indications and TSGs, which takes part in the examination of the applications for permission to exercise control and suggests to the Minister to grant permission for performing this control or to issue a motivated refusal. Until now, the Minister of Agriculture and Food has approved 2 control bodies, complying with the requirements to exercise control at the territory of the Republic of Bulgaria.

The control for compliance with the product specification of agricultural products and foodstuffs with PDO, PGI and TSGs is implemented through planned and additional on-the-spot checks by the control bodies to verify whether the requirements are observed – such as identification and traceability of the raw materials, of the product in storage, the processed product and, respectively, the final product. The labelling requirements to the final product are also checked. The control body sends to the competent authority / DPQS/ a filled-in check list after each inspection.

The supervision over the activity of the control bodies by the competent authority includes examination of the presented copies of check lists for each of the performed inspections and of the annual summary reports, as well as on-the-spot checks at producers' sites in case of more serious non-compliances, found by the control bodies. A protocol is drawn up as a result of the on-the-spot check and given to those under control. Directorate DPQS examines the check lists, sent by the control body, to monitor the measures and actions taken to correct the non-compliances.

The official control over the use at the marketplace of registered names is carried out by the Bulgarian Food Safety Agency (BFSA). The official control is performed at each stage of the production and marketing of the products; when exercising control, BFSA inspects the production units; the wholesale and retail stores; requires information and documents from those under control; checks the proper use of symbols, indications and names of agricultural products and foodstuffs with PGI, PDO and TSGs. The official inspections are planned, without prior warning and/or on a signal.

The official control inspections on agricultural products and foodstuffs with PGI, PDO and TSGs are scheduled in the Regional control plans of "Control of Foodstuffs" units at the Regional departments of BFSA and are carried out according to procedure approved by the Executive Director of BFSA. BFSA submits annually by the end of March to the Minister of Agriculture and Food a report on implemented checks, detected irregularities and measures taken in respect of official controls on the use of protected denominations.

Directorate DPQS at MAF, as a competent authority has established and maintains the following databases of:

1. Producers of agricultural products and foodstuffs with GIs;
2. Producers of agricultural products and foodstuffs with TSG;

3. Control bodies, responsible for verification of compliance of agricultural products and foodstuffs with GIs and TSG.

After each new entry into the European registers of Bulgarian agricultural product or foodstuff with GI or TSGs, Directorate DPSQ sends to BFSA the relevant database of producers to ensure the effective official controls on the market. The databases are simultaneously published on the website of MAF. A regular information exchange is performed between the DPQS and BFSA, also in case of a signal of misuse of Bulgarian or foreign denominations entered in the European registers.

#### Competent authorities and official controls on organic production

The Ministry of Agriculture and Food (MAF) is the Central Competent Authority (CCA) for draft legislation in the framework of organic production.

The department of Organic plant production and livestock breeding (OPPLB), under the umbrella of the MAF, is designated as the unit responsible for ensuring compliance with organic production legal requirements. Official controls to registered operators are delegated by the OPPLB to CBs fulfilling the basic conditions set out in the national legislation. The OPPLB is responsible for the approval, supervision and withdrawal of CBs. In addition, the OPPLB may also carry out direct inspections to operators, which may also be used in the framework of supervision to CBs. OPPLB is responsible for keeping the list of operators subject to the control system, which is publicly available since 2012. According to the national legislation, the OPPLB has the competence to grant derogations, except derogations on the use of conventional seeds and propagating material, which has been delegated to CBs. The OPPLB has adopted and notified to CBs a catalogue of enforcement measures to be applied in cases of non-compliances, in line with Article 92(d) of Regulation (EC) No 889/2008.

CBs carry out physical annual inspections to all operators. CBs have documented procedures to carry out controls. The main document used for the inspections is the report template, which also serves as a checklist for the inspectors. A copy of the report is given to operators, including the description of non-compliances and deadlines for the operators to apply corrective measures, which are followed-up by inspectors during the following inspection.

CBs carry out labelling and traceability checks during inspections at operators. Checklists used by CBs contain a specific aide-memoir for labelling and traceability checks to be performed at operators. CBs approved in advance the labels used by operators. CBs receive and assess the format of the labels, which can only be used after the CB notify the operators.

At the end of 2015 there were 12 CBs in Bulgaria approved for control and certification of organic products.

The OPPLB supervises the execution of delegated controls carried out by CBs. Supervision is carried out annually, covering all areas of the activity of the CBs. Office audits with a duration of two-three days are carried out at the headquarters of the CBs. Documented procedures are checked as well as at least 1% of operator's files. The OPPLB also checks the background, training of inspectors and their absence of conflict of interest. Also witness audits are carried out during two three days to observe the performance of inspectors. When non-compliances are found, they are reported to the CB as well as deadlines for the CBs to implement corrective action.

The Bulgarian Food and Safety Agency (BFSA) under the umbrella of MAF, is the CA designated for labelling and traceability controls at market level (retailers and wholesalers). BFSA is also the relevant CA for import controls, according to Article 13 of Regulation 1235/2008. The visits at market level are carried out in the framework of food safety controls and no specific risk-based planning is in place for organic products, although there is a specific procedure for these checks, approved by Order of the MAF. According to the procedure, labelling and documentary checks are carried out. In the case of major non-compliances found, a full traceability exercise is carried out to trace the product back to the operator responsible for placing it on the market. In this case the non-compliance is notified to MAF and to the relevant CB.

The Border Control Department under BFSA is responsible for policy making and co-ordination of controls. The department drafts legislation, issues instructions and monitors the activities of the Border Inspection Posts (BIPs). The monitoring programmes, instructions and checklists for import controls developed by the Border Control Department are disseminated and available in all BIPs. Release for free circulation of imported products is made only after the original certificate of inspection is endorsed in box 17 by BFSA after checking the certificates of import and commercial documents.

The Bulgarian Accreditation Service (BAS) under the Ministry of Economy is the sole National Accreditation Body of Republic of Bulgaria. BAS is responsible for the accreditation of CBs according to the International Organisation for standardization guide ISO/IEC 17065:2012/ БДС EN ISO/IEC 17065:2012.

The National Paying Agency (NPA) is the CA in charge of granting subsidies to farmers which are eligible based on their compliance with organic requirements. Payments are granted after receiving applications from farmers. The NPA may later apply total or partial deductions to payments if eligibility criteria are not complied with. The information on non-compliances is obtained by the NPA by carrying out direct inspections to 5% of operators and from the results of controls submitted by CBs. The information is uploaded directly by CBs onto the NPA information system.

ANNEX I – ACRONYMS, ABBREVIATIONS AND SPECIAL TERM

ACRONYM	DESCRIPTION
<b>ABP</b>	Animal by-products
<b>AMR</b>	Antimicrobial Resistance
<b>AHWFeCD</b>	Animal Health and Welfare, and Feed Control Directorate
<b>APV</b>	Authorised Private Veterinarians
<b>BAS</b>	Bulgarian Accreditation Service
<b>BCD</b>	Border Control Directorate
<b>BIP</b>	Border Inspection Post
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>BSE</b>	Bovine Spongiform Encephalopathy
<b>BTSF</b>	Better Training for Safer Food
<b>CA</b>	Competent Authority
<b>CB</b>	Control Body
<b>CCA</b>	Central Competent Authority
<b>CCP</b>	Competent Contact Points
<b>CDA</b>	Chief Directorate of Agriculture
<b>CDB</b>	Central Database
<b>CLCRCD</b>	Central Laboratory for Chemical Research and Control Directorate
<b>CLCTC</b>	Central Laboratory for Chemical Testing and Control
<b>CLPQ</b>	Central Laboratory for Plant Quarantine
<b>CLQGF</b>	Central Laboratory for Qualification of Grain and Feed
<b>CLVCE</b>	Central Laboratory for Veterinary Control and Ecology
<b>CSF</b>	Classical Swine Fever
<b>CSHI</b>	Chief State Health Inspector
<b>CVMPD</b>	Control of VMPs Directorate
<b>DCEPPPs</b>	Department for Control and Evaluation of PPPs
<b>DCPPPF</b>	Department for Control of PPP and Fertilizers
<b>DG SANTE</b>	Directorate General for Health and Food Safety
<b>DPE</b>	Designated Points of Entry
<b>EC</b>	European Commission
<b>EURL</b>	European Reference Laboratory
<b>EVA</b>	Equine Viral Disease
<b>FBO</b>	Food Business Operator
<b>EAPVT</b>	Executive Agency for Plant Variety Testing
<b>FCD</b>	Food Control Directorate
<b>FC Department</b>	Food Control Department
<b>FMD</b>	Foot and Mouth Disease
<b>FNAO</b>	Food of Non-Animal Origin
<b>FTE</b>	Full Time Equivalent
<b>GFA</b>	General Follow-up Audit
<b>GMF</b>	Genetically Modified Foods
<b>GMO</b>	Genetically Modified Organism
<b>HACCP</b>	Hazard Analysis Critical Control Point

<b>ACRONYM</b>	<b>DESCRIPTION</b>
<b>HFAA</b>	Health and food audits and analysis
<b>I&amp;R</b>	Identification and Registration
<b>MAF</b>	Ministry of Agriculture and Food
<b>MANCP</b>	Multi-Annual National Control Plan
<b>MBM</b>	Meat and Bone Meals
<b>MEW</b>	Ministry of Environment and Waters
<b>MH</b>	Ministry of Health
<b>MRL</b>	Maximum Residue Limit
<b>NCP</b>	National Contact Point
<b>NCPHA</b>	National Centre of Public Health and Analyses
<b>NCRRP</b>	National Centre of Radiology and radiation protection
<b>NDRVI</b>	National Diagnostic and Research Veterinary Institute
<b>NGFS</b>	National Grain and Feed Service
<b>NPA</b>	National Paying Agency
<b>NPPS</b>	National Plant Protection Service
<b>NCAH</b>	National Reference Centre on Animal Health
<b>NRCP</b>	National Residue Control Plan
<b>NVS</b>	National Veterinary Service
<b>NRL</b>	National Reference Laboratory
<b>OMV</b>	Official Municipal Veterinary
<b>PAFCD</b>	Policies on Agri-food Chain Directorate
<b>OPPLB</b>	Organic plant production and livestock breeding
<b>PCD</b>	Phytosanitary Control Department
<b>PHARE</b>	Pre-accession Financial Instrument
<b>PPP</b>	Plant Protection Product
<b>PPCD</b>	Plant Protection and Control Directorate
<b>IAD</b>	Internal Audit Directorate
<b>RAC</b>	Risk Assessment Centre
<b>RASFF</b>	Rapid Alert System for Feed and Food
<b>RFSD</b>	Regional Food Safety Directorates
<b>RHI</b>	Regional Health inspectorates
<b>RFSD</b>	Regional Food Safety Directorate
<b>RTL</b>	Regional Testing Laboratories
<b>SC on PAFF</b>	Standing Committee on Plants, Animals, Food and Feed
<b>SHCD</b>	State Health Control Directorate
<b>SRM</b>	Specific Risk Material
<b>TQD</b>	Training and Qualification Department
<b>TRACES</b>	Trade Control and Expert System
<b>TSE</b>	Transmissible Spongiform Encephalopathy
<b>VOCGD</b>	Verification of the Official Control General Directorate
<b>VACRFSAD</b>	Verification and Administrative Control of the activities of Regional Food Safety Directorate Department
<b>VMP</b>	Veterinary Medicinal Product