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INTRODUCTION

This overview has been drawn up by the Food and Veterinary Office (FVO), a Directorate of the Directorate-General for Health and Food Safety of the European Commission based on information supplied by Romania.

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 Romania.

Chapter 1 describes the overall organisation of the Romanian 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 Romania, covering the whole chain of plant, animal and food production. As in Chapter 1, organisation charts are used to help the reader.

Annex I provides details on the number of control staff in Romania. The statistics on staff resources have been provided by the Member States on a non-standardised basis.

The overview was updated following the most recent general follow-up audit in November 2014 and will be updated at regular intervals based on relevant information received by the Commission from the Romanian 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 II as a guide for the reader.
SUMMARY

In Romania, five competent authorities have responsibilities for control systems for food safety, animal health, animal welfare and plant health: the National Sanitary Veterinary and Food Safety Authority (NSVFSA), the Ministry of Health (MH), the National Authority for Consumer Protection (NACP), the Ministry of Agriculture and Rural Development (MARD), the Ministry of Environment and Climate Change (MECC) has responsibilities regarding genetically modified organisms.

Most of the competencies for food safety, animal health and welfare are assigned to the National Sanitary Veterinary and Food Safety Authority (NSVFSA), and to a lesser extent, the Ministry of Health. The National Phytosanitary Agency (NPA) within MARD co-ordinates monitoring programmes for pesticides residues in food of plant origin and is also the single central competent authority for plant health.

The NVFSA is responsible for the State Veterinary Network, which is organised at central, county and local level.

At national level and subordinated to NSVFSA are organised three Central Veterinary Institutes, respectively: Institute for Diagnosis and Animal Health (IDAH), Institute for Hygiene and Veterinary Public Health (IHVPH) and Institute for Control of Veterinary Biological Products and Medicines (ICVBPM).

At county level, the CSVFSD mirrors the structure of the central authority. Each of the 42 CSVFSD (including Bucharest SVFSD) is managed by an Executive Director and a Deputy Director. The Deputy Director organizes co-ordinates and controls the following offices activity: Official Control on Animal Health Office, Official Control on Food Safety Office and Electronic Monitoring and Administrative Control Office.

At local level, within the structure of CSVFSD, operates the Zonal Sanitary Veterinary Circumscriptions (ZSVCs) and the Sanitary Veterinary and Food Safety Circumscriptions (SVFSCs). The veterinarians from ZSVC’s have the following responsibilities:

- evaluation of the establishments and premises under sanitary veterinary and food safety controls in order to be authorized/registered;
- report to the management of SVFSD deficiencies found in the field, regarding the failure of the Annual National Strategic Programme;
- can receive other responsibilities, specific for SVFSCs, if the territory does not have such a circumscription;

In September 2014 the organisational charts of NSVFSA and subordinated structures were changed.

Overall, there are approximately 7301 staff employed in the control systems for feed and food safety, animal health, animal welfare and plant health (information is not yet available as "full time equivalent").

The most recent annual report on the implementation of the MANCP for 2013 was provided to the European Commission in September 2014.

The MANCP and annual report are available for members of the Consulting Committee of the NSVFSA, which includes public institutions and stakeholders' representatives. They are not available on the internet but on the intranet page of NSVFSA.
1. Arrangements for the implementation of certain requirements of Regulation (EC) No 882/2004

Designation of competent authorities

National Sanitary Veterinary and Food Safety Authority

The NSVFSA was established in 2004 by Government Ordinance No. 42/2004. Since December 2012 by Government Emergency Ordinance no. 96/2012 NSVFSA is subordinated to the Government and under the co-ordination of the Minister of Agriculture and Rural Development. It is managed by a president, with the rank of Secretary of State, and two vice-presidents, each with the rank of Undersecretary of State. The Government Decision no. 1415/18.12.2009 established the organisation and operation of NSVFSA and its subordinated units. The Government Decision no. 701/2014 modified Government Decision no. 1415/2009 and amended the organisation and operation of NSVFSA and CSVFSD. The NSVFSA is now organised in 13 Directorates - three of these are General Directorates:

1) The General Sanitary Veterinary and Food Safety Directorate (GSVFSD) is composed of:
   - Animal Health Directorate (AHD);
   - Veterinary Medicinal Products and Animal Nutrition Directorate (VMPAND);
   - Food Safety of Animal Origin Directorate (FSAOD);
   - Food Safety of Non-Animal Origin Directorate (FSNAOD);
   - Laboratory Compartment (LC)

2) General Directorate for Official Control (GDOC) is composed of:
   - Inspection and Official Control Directorate (IOCD) that consist of:
     - Animal Health Control Service (AHCS);
     - Food Safety Control Service (FSCS);
     - Medicinal Products, Nutrition and Laboratories Control Service (MPNLCS)

     - Directorate of Electronic Monitoring, Identification and Registration of Animals (DEMIRA);
     - Import, Export, Trade and BIPs Directorate (IETBIPsD);
     - Anti-Fraud Service (AFS);
     - Animal Sanitary Veterinary Police Service (ASVPS)

3) General Directorate for Internal Affairs and Administration (GDIAA) is composed of:
   - Economic Directorate (EC);
   - Juridical and Human Resources Directorate (JHRD)
   - Archive Compartment (AC)

4) Audit Directorate (AD) is composed of:
   - Technical Audit Office (TAO);
   - Risk Assessment Compartment (RAC)
Within the Authority, two consultative bodies (the Scientific Council and the Consultative Council) have been operational since the end of 2005.

At county level, the CSVFSD mirrors the structure of the central authority. Each of the 42 CSVFSD (including Bucharest SVFSD) is managed by an Executive Director and a Deputy Director. The Deputy Director organizes, co-ordinates and controls the following offices activity: Official Control on Animal Health Office (OCAHO), Official Control on Food Safety Office (OCFSO) and Electronic Monitoring and Administrative Control Office.

At local level, within the structure of CSVFSD, operates the Zonal Sanitary Veterinary Circumscriptions (ZSVCs) and the Sanitary Veterinary and Food Safety Circumscriptions (SVFSCs). In the ZSVCs, private veterinarians are approved to carry out public veterinary activities, whereas, in the Official Control on Food Safety Office, there are official veterinarians working in establishments that process food of animal origin.

The Ministry of Health (MH)

The Government Decision no.144/2010 regarding the organising and functioning of the Ministry of Health was modified and completed by the Government Decision no. 993 of 11th of December 2013. The GD 993/2013 modifies the flow chart of the Ministry of Health.

GD 301/2014 amended and completed GD no. 144/2010 on the organization and functioning of Ministry of Health, as amended and completed.

Reorganization of the Ministry of Health has been completed, so that at their level there are two structures in the field food:

1. HEALTHCARE AND PUBLIC HEALTH GENERAL DIRECTORATE (HPHGD)
2. STATE SANITARY INSPECTION (SSI)

The main responsibilities in the field of food safety are:

- developing of legal acts; epidemiological surveys communication with the public on food related risks and measures to avoid food-borne disease (HPHGD).

- carrying out monitoring and control of food safety in accordance with national public health programs of the Ministry of Health (HPHGD);

- carrying out official food control according to the annual plans of CPHD as well as control thematic actions initiated at the central level, (SSI– MH) and in case of complaints from the population;

- co-ordinating the activity of inspectors from the County Public Health Control Departments (SSI). Sanitary inspectors from CPHDs checks the compliance of food products and food contact materials, the health status of the employees in food establishments and carries out official controls to ensure compliance with public health rules at all stages of production, processing, distribution and food supply to the final consumer of the food products for which the MH is competent authority:

- food additives, flavouring and enzymes;
- natural mineral waters, bottled waters;
- foodstuffs with ionising radiation treatment;
- food supplements;
- foodstuffs with special nutritional destination;
- evaluation of iodine level from iodate salt for the human consumption;
- novel food.
Other responsibilities according to the national legislation:
- health and nutritional claims;
- food products with addition of vitamins and minerals and of certain other substances;
- control of compliance with the rules of food preparation, according to nutritional regulations in hospitals, school premises (including after school), social assistance, school camps and premises which organize activities similar those of school camps;
- control of compliance with the rules regarding the distribution in schools and kindergartens of dairy and bakery products and fruits (school fruits programme).

- RASFF notification (Rapid Alert System for Food and Feed) and taking the necessary measures for food categories in the fields of competence;

According to the Governmental Decision no. 1414/2009 regarding the establishing, organising and functioning of the National Institute of Public Health at regional level a National Public Health Institute with 6 regional public health centres in Bucharest, Iasi, Cluj-Napoca, Timisoara, Targu-Mures and Sibiu was set up.

The responsibilities of the County Public Health Directorates are established by the Ministerial Order no. 1078/ 2010 for organising and functioning of the CPHDs and the Ministerial Order no 824/2006 regarding the Norms for functioning and organizing of the sanitary state inspection.

National Authority for Consumer Protection

The National Authority for Consumers Protection (NACP) is the public authority responsible for checking the conformity of foodstuffs labelling, the conformity of the products with the declarations, advertising, price indication. NACP is also responsible for solving individual consumer complaints. In this regard, the Department for Control and Market Surveillance co-ordinates market surveillance activity and co-operates with other public authorities that have competences regarding food safety. The NACP has 8 regional commissary offices that include 41 territorial commissary offices, plus the commissary office for Consumers’ Protection in Bucharest. The NACP also has an internal audit department.

Ministry of Agriculture and Rural Development

Within the Ministry of Agriculture and Rural Development (MARD), there are two departments which have responsibilities in relation to food safety, the National Phytosanitary Agency (NPA), the State Inspections Directorate (SID) which includes the National Inspection for Quality of Seeds (NIQS). Two central staff co-ordinate the work of the 47 inspectors based in the territorial offices (counties directorates for agriculture) - CDA) and the office in Bucharest.

The NPA co-ordinates monitoring programmes for pesticides residues in food of plant origin and is also the single central competent authority for co-ordination related to plant health.

The TDIVS deals with manufactured food products and also compliance with legislation on GMOs (including traceability within growers). Although primarily dealing with quality issues (ensuring that products meet their technical specification), they ensure that the conditions of production are satisfactory before granting manufacturing licences. The Unit has 1 co-ordinating inspector at central level and 91 inspectors at county level which carry out the local control.

The NIQS co-ordinates the analysis of seeds for the adventitious presence of GMO’s.
Competencies of the Ministry of Environment and Climate Change (MECC) and of its subordinated units

Regarding Pesticides

Having in view the requirements of the management of pesticides, the Ministry of Environment and Climate Change (MECC) and its subordinated units are responsible for the environmental risk assessment of pesticides at the national level.

The National Environmental Protection Agency (NEPA) is responsible for the assessment of studies on the effect of pesticides on the environment (in accordance with the Council Directive 91/414/EEC and Regulation 1107/2009) and preparing the assessment reports. If products perform in a satisfactory way, the NEPA issues the “Environmental Agreement” and submits it to MARD. The final authorisation of pesticides requires the approval of MECC - National Committee for Plant protection Products Authorisation (NCPPPA)

NEPA is also involved in the assessment of dossiers for pesticides that are undergoing the centralised (community) approval procedure.

MECC is also responsible for the management of obsolete pesticides.

Regarding Genetically Modified Organisms (GMOs)

NEPA, acting under MECC, is the competent authority for issuing authorisations and the import permits according to the Emergency Governmental Ordinance No 43/2007 on the deliberate release of GMOs into the environment approved by the Law No 247/2009, which transposes Directive 2001/18/EC

Also, NEPA is the competent authority according to the Emergency Governmental Ordinance No 44/2007 on the contained use of genetically modified microorganisms, approved by the Law No 3/2008, which transposes Directive 2009/41/EC.

NEPA is the competent authority for exports of GMOs, according to Governmental Decision on the establishment of measures to implement the Regulation (EC) No 1946/2003 on the transboundary movements of GMOs

The National Environmental Guard (NEG) working under the Ministry of Environment and Climate Change (MECC) has control responsibilities for pesticides and GMOs (Genetically Modified Higher Plants and Genetically Modified Micro-organisms).

For accomplishing its duties, NEG co-operates with the inspectors of the other authorities: MARD, NSVFSA, MH and National Custom Authority (NCA)

National accreditation body

RENAR is the National Accreditation Body in Romania and a member of EA - European Co-operation for Accreditation, ILAC - International Laboratory Accreditation Co-operation and IAF - International Accreditation Forum.

SRAC (Romanian Society for Quality Assurance) is a national body accredited by RENAR (Romania), RVA (Holland), ESYD (Greece) and OLAS (Luxembourg). It is also a member of IQNet (the International Certification Network, which is the international association of organisations performing management system assessment and certification.)
Co-ordination between Competent Authorities

In 2005 a specific protocol between NSVFSA, NACP, MH and MARD was issued for delineation of responsibilities in official control. On 24th of April 2012 an updated version of the specific protocol between NSVFSA and MH was signed by the two CAs.

Governmental Decision no. 194/2006 also established an Inter-ministerial Committee to analyse control and surveillance programmes and propose measures for control system improvements. The Secretariat is provided by NSVFSA. MARD has three representatives on the committee and also participates in the preparation of the MANCP. Although the Ministry of Transport (MT) does not have members on the committee, one MT representative has been invited to each meeting, thus allowing MT-PHA activities to be taken into account. The Ministry of Health has 3 representatives in the Inter-ministerial Committee for supervising and official control of food and feed. This committee has worked to improve co-ordination between CAs and facilitate the preparation and co-ordination of the MANCP. In addition, common working groups on various issues related to legislation were created with participation of relevant CAs and other stakeholders.

In preparation for updated versions of the MANCP, working groups met to define more clearly the duties and areas of competence for all authorities involved in official controls of foodstuffs. In particular consideration was given to avoiding overlaps (e.g. co-ordinate surveillance programmes and inspection in establishments). The updated MANCP provides details of specific areas of co-operation for plant health, animal health, animal welfare, animal nutrition, foodstuffs, veterinary medicinal products and organic farming in chapter 4.

A forum is established and periodic meetings held for all CAs involved in food control at the county level, to discuss co-ordination.

Co-operation within Competent Authorities

On a day to day basis co-operation within the NSVFSA is ensured through a daily briefing for all key management staff (i.e. the president, vice-president, general directors and directors).

By Government Decision no 625/21.08.2013 reorganisation of the NSVFSA was carried out and the following three General Directorates: General Sanitary Veterinary and Food Safety Directorate (GSVFSD), General Directorate for Official Control (GDOC) and General Directorate for Internal Affairs and Administration (GDIAA) were established.

GDOC regulates, organizes, co-ordinates, monitors and controls the official control activity carried out by food safety official control offices within the county and Bucharest SVFSDs and verifies the official control activities performed by the structures at local level in food establishments which are veterinary authorised or registered.

Vertical communication within the NSVFSA is established mainly through “Service Notes” sent from the central authority to the local level. They are accessible from the intranet system, which is available to all CSVFSDs. Communication is also conducted by phone, e-mail, the RASFF system and in training courses.

Delegation of specific tasks related to official controls

There is no delegation of specific tasks other than the submission of samples for analysis when this cannot be performed by a suitable laboratory in Romania (e.g. for certain GMO analyses).
Contingency planning

There is a national committee for emergency situations, overseen by the Prime Minister and coordinated by the Ministry of the Interior. Where an animal health issue is involved, a "national centre for combating animal disease" is established. The Minister of the Interior is the president of the centre, and the president of the NSVFSA is the vice-president. National legislation which establishes the responsibilities of the National Disease Control Centre was published. (Government Decision No. 1189/2009. For further information on specific animal/plant health contingency plans see chapters 2.1 and 2.11 respectively.

Also, a Contingency Plan on Food Safety Crisis Management was issued by NSVFSA and approved by the Inter-ministerial Committee in its meeting held on July 21st, 2011.

Resources for performance of controls

Legal powers for controls

The NSVFSA, NACP, MH and MARD (for plant health issues) have broad legal powers to carry out official controls. Official measures and sanctions on infringements are provided in specific national legislation which includes:

- Government Ordinance No. 2 of 2001, (sanctions at national level – all sectors);
- Government Ordinance No. 42/2004 (basis for official controls carried out by NSVFSA);
- Government Decision No. 984 of 2005 (infringements on food law);
- Government Decision No. 173 of 2006 (includes sanctions related to traceability and labelling of GMOs);
- NSVFSA Presidential Order No. 111 of 2008 (procedure for registering establishments);
- Government Emergency Ordinance No. 27 of /2009 (amending Government Ordinance 42/2004);
- Government Ordinance No. 136/2000 with all amendments (sanctions for plant health);
- Government Decision No. 1197/2002 for approval of Norms regarding the food contact materials, amended and supplemented;
- Government Decision No. 144/2010 amended and supplemented (basis for official controls carried out by the Ministry of Health);
- Government Decision No. 857/2011 (regarding the sanctions imposed by the Ministry of Health);
- Ministerial Order No. 1078/2010 for organising and functioning of the CPHDs;
- Ministerial Order No. 824/2006 regarding the Norms for functioning and organizing of the sanitary state inspection.

Government Ordinance 984 of 2005 which provides the legal base for sanctions imposed by the NSVFSA has been amended 4 times in the last 2 years.

Government Ordinance No. 21 of 1992 on consumer protection gives the NACP legal powers to undertake measures where there have been infringements of labelling requirements (including product shelf-life). See also section 4.1.
Staffing provision and facilities

Overall, there are 7301 staff employed in the control systems for feed and food safety, animal health, animal welfare and plant health (this information is not yet available as "full time equivalent" staff), see Annex I. In 2010 and 2011, due to budgetary constraints, many of the previous vacancies were removed from the organisational chart. This has resulted in staff being re-allocated to permanently take over the functions represented by vacant posts.

The CA is seeking to make the best use of the staff resources available by redistributing work and ensuring that through the national training programme, they have the relevant competencies.

Staff qualifications and training

At recruitment, staff qualifications must meet the minimum requirements of the job description in accordance with rules on appointing civil servants. Thereafter, it is mandatory for staff to participate in a national training programme. Each staff member has their own training file and an assessment is made each year to identify training requirements for the following year. This file describes the training performed, the results obtained and action taken if unsatisfactory results are obtained (e.g. additional courses attended).

Organisation and implementation of official controls

Registration / approval of food business establishments

See under chapter 2.2 and 2.7 of the country profile.

Prioritisation of official controls

The organisation of official controls for food of animal origin is established under the National Surveillance and Monitoring Plan (NSMP), drawn up by the Food Safety of Animal Origin Directorate (FSAOD) (see chapter 2.2). Similarly, the controls for non-animal origin products are made in the Food Safety Surveillance Programme, drawn up the FSD (see chapter 2.7) using published guidelines. The territorial services within the CSVFSD, implement these plans taking into account local circumstances.

Inspection and Official Control Directorate (IOCD) sets up yearly the national official control program in the food safety field, based on:

- risk category of food establishments;
- assessment results of official control activity performed by the CSVFSD.

The MANCP provides details of control activity priorities for plant health, animal health, animal welfare, animal nutrition, foodstuffs, veterinary medicinal products and organic farming. However, the risk assessment process is not always described or is described in very general terms (e.g. the assessment is to take account of previous controls/evaluations made by the territorial services).

Risk Assessment Compartment (RAC)

The primary objectives of RAC are:

- establishes and updates continuously a database of scientific experts specialized in the sanitary veterinary and food safety field working in research institutes, education and other academic environments, in order to constitute a network of specialists who work outside the Authority. They will be co-opted and will cooperate for the risk assessments in specific fields concerned by the NSVFSA;
- draws up reports/studies on specific risk assessments in various sanitary veterinary and food safety fields and issues recommendations/proposals/opinions on the measures to be taken, and subsequently submit them to the interested structures within NSVFSA;
- participate to the development of operational concepts and procedures for the risk assessment of certain substances / residues and the epidemiological crisis situations, in order to determine their impact on the consumer health or, where appropriate, animal health.

**Control activities, methods and techniques**

Each year, the relevant directorates within the NSVFSA draw up an annual strategic programme, which constitutes the legal framework for the inspection/control activities undertaken by official staff throughout the entire territory of Romania. These activities (inspection, verification, monitoring/surveillance and analysis) are carried out following written procedures prepared at central level, using standard evaluation and inspection forms.

The updated MANCP provides details of control methods and techniques used under the relevant sector in chapter 4. Specifically in the plant health sector, the NPA within the MARD distributed general procedures to be followed by the County Phytosanitary units and Border Inspection Posts (BIPs) (see chapter 4.1.2).

**Sampling and Laboratory analysis**

Sampling and analysis in the sectors of interest is primarily performed by the laboratory networks belonging to the three main CAs (NSVFSA, MH and MARD). Each of these CAs has its own annual national laboratory strategy, although an overarching strategy was to be discussed within the inter-ministerial committee when reviewing the MANCP. The process of laboratory accreditation is on-going, through the national accreditation body RENAR.

During 2012, NSVFSA has carried out the assignment of CSVFSDs to CSVFSLs which have methods accredited by sending four service notes.

MH sent in 2012 an official paper no 30989/19.06.2012 to all the CPHDs regarding the procedures which must be used in the official control of food products. These procedures foresee that all food products must be analysed by accredited laboratories.

**NSVFSA Laboratory co-ordination**

Starting October 2014 the Laboratory Compartment was formed in the framework of The General Sanitary Veterinary and Food Safety Directorate and its main responsibilities are:

- carries out, national wide, the assessment activities in view of sanitary veterinary authorization of the national veterinary institutes and of the sanitary veterinary and food safety laboratories;
- draws up and updates the list of authorized sanitary veterinary and food safety laboratories and publishes the information on the NSVFSA site
- elaborates the establishment documentation and proposes the composition of the analysis commissions regarding the designation and monitoring of veterinary reference laboratories and/or national reference laboratories, sanitary veterinary and food safety laboratories which can carry out the analysis of the samples collected during the official control in the field of feed and food products, animal health and welfare;
- analyses and proposes for authorization to the technical directorates the proposals on the assignment of the sanitary veterinary and food safety laboratories which can carry out the analysis of samples collected during the official control, analysis drawn up by the national veterinary reference institutes;
- monitors and centralizes the provision of laboratory equipment of the national veterinary reference institutes and of the sanitary veterinary and food safety laboratories from the SVFSD.

The Institute for Diagnosis and Animal Health (IDAH), the Institute for Hygiene and Veterinary Public Health (IHVPH) and the Institute for Control of Veterinary Biological Products and Medicines (ICVBPM) are co-ordinated by the NSVFSA President and from the technical point of view is directly related with relevant Sanitary Veterinary and Food Safety General Directorates.

NSVFSA

The IDAH (through its National Reference Laboratories for animal health and welfare) co-ordinates the diagnostic and surveillance work on animal health of the 40 County Sanitary Veterinary and Food Safety Laboratories (CSVFSLs). It is also the National Reference Laboratory for GMO in Food and Feed. The specialists from IDAH participate, through an ad-hoc technical commission, organized by NSVFSA, to check the compliance with the terms of the CSVFSLs authorisations. The IDAH provides, in certain circumstances, technical guidance for CSVFSLs and has the responsibility of performing confirmatory tests. The IDAH has also the responsibility to organize the annual inter-laboratory comparative tests for checking the diagnostic capability of CSVFSLs, training and continuous training activities, in order to teach the specialists working in the CSVFSLs. The IDAH also received an attestation from the National Authority for Scientific Research, to initiate/participate/conduct research programs in areas falling within their competence. IDAH is accredited to ISO 17025 since 2003, by RENAR.

IDAH has renewed its accreditation in 2014 and the new Certificate no. LI 222 / 10.31.2014 contains 250 methods in the field of animal health, welfare and GMOs.

Also, in the period 2012-2014, IDAH designed and implemented a quality management system for accreditation as proficiency testing provider according to requirements of ISO 17043. There was completed and submitted the necessary documentation to RENAR in December 2014 and in the course of 2015, IDAH will be assessed by the national accreditation body.

According to the NSVSA Order no. 81/2008, IDAH performs specific activities to verify the diagnosis value of reagents, kits or diagnosis sets, used for surveillance and diagnosis laboratory activities, as well as for laboratory expertise, related to animal health.

The IHVPH co-ordinates the National Reference Laboratories for products of animal origin, for animal feed and on all substance groups listed in Annex I to Council Directive 96/23/EC. The Institute is accredited to ISO 17025. It co-ordinates the activities of the CSVFSLs in the field of hygiene and food safety for products of animal origin. As at March 2013, there are 38 laboratories in the field of food safety for products of animal origin and 34 laboratories in the field of feedingstuffs which were accredited to ISO 17025 by RENAR.

The IHVPH and eight zonal laboratories are responsible for analysing samples within the National Residues Control Plan.

There are 5 routine (zonal) laboratories and 4 (including IHVPH) National Reference Laboratories (Commission implementing Decision 2011/717/EU).

The Sanitary Veterinary and Food Safety Laboratory Bucharest co-ordinates the activities of the CSVFSLs in the field of food safety for products of non-animal origin. The Laboratory is National Reference Laboratory, and it is accredited to ISO/CEI 17025:2005. At present there are 41 laboratories in the field of food safety for products of non-animal origin which are accredited to ISO/CEI 17025 by RENAR. (41 labs for microbiological, 15 labs accredited for mycotoxins and 14 labs accredited for heavy metal).

The Institute for Control of Veterinary Biological Products and Medicines (ICVBPM) is the national authority responsible for the assessment, authorisation and testing of veterinary medicinal products and other products for veterinary use. The Institute is certified to ISO 9001 by SRAC
(Romanian Society for Quality) from 2007. The Institute has accredited 4 laboratories (2 of them in February 2011 and 2 of them in March 2012), by RENAR – national accreditation body, according to requirements ISO/CEI 17025. The Laboratories from ICVBPM are integrated in the European network of Official Medicines Control Laboratories (Official Medicines Control Laboratories - OMCL), coordinating by the European Directorate for the Control of Medicines (EDQM) and participate in their specific activities (PTS, Collaborative studies, meetings, Sampling Programme, Testing Programme, etc).

**MH**

Within the network of laboratories belonging to the Ministry of Health there are 25 laboratories with ISO 17025 accredited by RENAR (23 labs belong to the CPHDs and 2 labs belongs to the National Public Health Institute).

**MARD**

The Central Phytosanitary Laboratory (CPL) was created in 2010, by merging the Central Laboratory for Phytosanitary Quarantine and Central Laboratory for Pesticide Residues Control in Plants and Plant Products. According to Article 5 of Government Decision no.753/2010 the Central Phytosanitary Laboratory (CPL) has two subunits in its structure, without legal powers, namely:

- Phytosanitary Quarantine Laboratory (PQL);
- Laboratory for Pesticides Residues Control in Plants and Plant Products (LPRCPPP).

The Central Phytosanitary Laboratory (CPL) is national reference laboratory through which National Phytosanitary Agency solves the problems on phytosanitary quarantine, quality control of pesticides and control of pesticide residues in plants and plant products. The work of the Central Phytosanitary Laboratory is co-ordinated by National Phytosanitary Agency (NPA) within MARD

**Phytosanitary Quarantine Laboratory (PQL)** has the following compartments in its structure:

- phytopathology laboratory;
- entomology laboratory;
- laboratory for quality control of pesticides (LQCP) and
- 9 border inspection posts (BIPs).

The Phytosanitary Quarantine Laboratory (phytopathology and entomology laboratories) carries out analyses of plants and plant products samples taken by phytosanitary inspectors in order to detect and identify harmful organisms. There are also four regional laboratories of which three are specialised in nematology (within county phytosanitary units Brasov, Bucuresti and Suceava) and one in bacteriology (within county phytosanitary units Bacau).

The Laboratory for the Quality Control of Pesticides (LQCP) and four regional laboratories, which are within the County Phytosanitary Units of Arad, Bacau, Mures and Olt, carry out analyses for official controls on marketing of pesticides. They also perform analyses for the National Monitoring Programme for Quality of pesticides.

**Laboratory for Pesticides Residues Control in Plants and Plant Products (LPRCPPP)** and two regional laboratories (Mures and Dolj) are responsible for the analysis of pesticide residues in fruit, vegetables and cereals through the National Monitoring Programmes for Pesticides Residues in Plants and Plant Products.
The Romanian National Centre for Product Testing and Appraisal (LAREX) and its county branches, and the Laboratory for Wines and Spirits, perform analyses for the National Authority for Consumer Protection.

National Reference Laboratories (NRLs)

Since 2007, in Romania there are recognized 56 National Reference Laboratories for feed, food and health animal, as provided by NSVFSA President's Order no. 205/2007. The Order matches each NRL to the relevant EU-RL. In certain cases a NRL has been appointed for single residue methods, Dioxins and PCBs (NRL for single residue methods – Amitraz (IHVPH), NRL for dioxins – SVFSL Bucharest).

In November 2011, the Environment and Food Chemistry Laboratory within the National Institute of Public Health was designated as National Reference Laboratory in the field of materials and objects that come in contact with food (Ministerial Order no 1554/2011).

Procedures for performance and reporting of control activities

The reports on the results of routine control activities carried out under the annual strategic programmes are communicated on standard forms to the central level (typically each month for the CAs – NSVFSA, MH and MARD). More detailed descriptions are contained within chapter 4 of the MANCP.

MH carries out control activities according to the National Annual Control Plan and Annual Control Plan of CPHDs. The results of these activities are reported to the MH on a monthly and quarterly basis, according to standard reporting models.

MH organises thematic actions annually in the competent fields. For each thematic action MH sends to the CPHDs an official paper with instructions for realising the official control. Each report from the CPHDs is analysed by the PHCPHD. The results of thematic actions are centralising and reported to the Minister of Health.

Transparency and confidentiality

The inspection procedures are available on the website www.ansvsa.ro. The NSVFSA publish reports on this website containing the results of official controls. Periodically, press communications are made regarding the controls carried out, deficiencies found out and measures taken by the CA.

To ensure confidentiality, personal data, establishment names and commercially sensitive information are not published. However, if the health/safety of the public is endangered, data on the products, producers or retail outlets are made public.

The MANCP and annual report are available for members of Consulting Committee of the NSVFSA, which includes public institutions and stakeholders' representatives. They are not available on the internet, but on the intranet page on NSVFSA.

Enforcement measures

Measures in the case of non-compliance

For FBOs, the CAs can apply measures taking into account the nature and gravity of the non-compliances and past performance. The measures broadly include: fines, detention of food/ingredients, and suspension of activity (ordinance of suspension can be issued once case reviewed by manager at county level), prohibition of activity and withdrawal and/or destruction of
the food products. Where activities are prohibited, the "Financial Guard" and other authorities are notified to avoid on-going (illegal) production/activity.

The NSVFSA maintains a central table for the 42 counties identifying the non-compliances recorded and the measures taken. At present there are no central statistics on follow-up (i.e. to see if remedial action has been taken within the deadline); this information is available at county level.

The Ministry of Health co-ordinates the activity of taking measures and centralises data with the non-compliances recorded and the measures taken by the 42 CPHDs, on a quarterly basis.

Sanctions

National legislation provides sanctions for any breaches of relevant legislation. Applying sanctions and measures where an operator does not correct deficiencies found during official controls, is done on the basis of Government Decision no. 984/2005. During 2012 a draft amendment to Government Decision no. 984/2005 was drawn up and by March 2013 it remained in the internal approval process.

The Ministry of Health applies legal measures in conformity with its competences. The MH imposes sanctions according to Governmental Decision no 857/2011.

Verification and review of official controls and procedures

Verification procedures

NSVFSA

Instructions on how to perform the inspections activities in the sanitary veterinary and food safety field, in order to verify the implementation and compliance with legal provisions by feed and food business operators, are described in Presidential Order 58 of 2008.

According to the new tasks established by NSVFSA and CSVFSD Organisation and Functioning Regulation, approved in November 2013, the official controls in the establishments subject to sanitary veterinary and food safety checks are carried out by the staff of official control on food safety offices in CSVFSD and by the personnel under its subordination, the control frequency is established according to the National Control Programme.

IOCD regulate, organize, co-ordinate, monitor and control the official control activity carried out by the official control on food safety offices within the CSVFSD and verify the structures at local level in the sanitary veterinary and food safety field.

Since November 2013, the Official Control on Food Safety Office (OCFSO) is responsible for performing the official controls and inspection to verify the activity of those staff carrying out official controls in food establishments.

MH

The State Sanitary Inspection of the Ministry of Health (SSI) co-ordinates the control activity of CPHDs and the central staff performs controls at county level in special situations (with impact on public health).
According to MARD, due to a lack of staff at central level, there has been no direct supervision of the phytosanitary inspectors in the field, contact being maintained through the issue of documented procedures. Each procedure has an annex as to how results are to be reported to the central level. The CA has appointed national reporters to monitor the activities of the phytosanitary units and liaise with central staff.

Audit

Internal audit in sanitary veterinary and food safety fields, to check the effectiveness of the official control systems, according with art.4 (6) of Regulation 882/2004 was started in NSVFSA in 2010. With the re-organisation of NSVFSA in 2013, internal audits are carry out by the Audit Directorate (AD) through Technical Audit Service (9 people) subordinated directly to the NSVFSA President and separated from any structure involved in official control, taking into account the guidelines set out in Commission Decision 2006/677/EC.

According to the current organizational chart, SVFSDs do not include Technical Audit Compartments any more.

For a systematic approach, the Audit Directorate developed an audit procedure that was revised in September 2012 and audit sheets specific to each audited control system. The plan for carrying out each audit mission includes assessment of the central, regional and local structures that have responsibility for the official controls in the audited field, and premises where on-site checks will be performed. After each audit mission, a draft audit report containing findings of the audit team and specific recommendations related to the non-conformities found shall be drawn up and submitted to the audited structures within the NSVFSA for the development of the Action plan. The final audit report shall be submitted to the President of the NSVFSA and audited structures within the NSVFSA.

A Multiannual audit programme approved by the President of NSVFSA and, covering all areas for which the NSVFSA has competencies, has been developed for the period 2014 - 2017.

For the MH, - the Ministerial Order no. 17/10.01.2012 establishes the organising of internal audit in the field of food safety. A National Plan regarding internal audit for 2013 has been drawn up and approved.

Impartiality, consistency and quality of official controls

NSVFSA staff carrying out official controls are civil servants who must work in conformity with the basic principles laid down in Law No. 188 of 1999. They must not engage in any activities that result in a conflict of interest, to ensure their impartiality when carrying out official controls.

MH inspectors are civil servants and they work in conformity with the basic principles laid down in Law No. 188 of 1999 and Ministerial Order no 824/2006 regarding the Norms for functioning and organizing of the sanitary state inspection. They must not engage in any activities that result in a conflict of interest, to ensure their impartiality when carrying out official controls.

Multi-annual national control plan (MANCP) and annual reports

The current Multi-annual National Control Plan is valid from 2014 – 2016. An inter-ministerial working group met on a regular basis to prepare an updated MANCP which was submitted to the Commission in March 2013. Annual reports on the MANCP are submitted to the Commission services each year – the most recent for 2013, submitted in September 2014.
### Overview

The following chart gives an overview of the distribution of responsibilities in relation to control systems and operational levels. More detailed descriptions of the allocation of responsibilities between authorities in relation to each control system are given in chapter 2.

<table>
<thead>
<tr>
<th>Sector</th>
<th>Policy co-ordination</th>
<th>Co-ordination of controls</th>
<th>Implementation of controls</th>
<th>Laboratories</th>
<th>Risk assessment, scientific advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Animal Health</td>
<td>NSVFSA</td>
<td>NSVFSA</td>
<td>CVFSD</td>
<td>IDAH and CSVFSLs</td>
<td>NSVFSA IDAH on: identification, characterization, hierarchization, evaluation and assessment of risk factors</td>
</tr>
<tr>
<td>3. Imports of animals and food of animal origin</td>
<td>NSVFSA</td>
<td>NSVFSA</td>
<td>CVFSD</td>
<td>IDAH – animals and GMO in Food and Feed IHVPH - food of animal origin and CSVFSLs</td>
<td>IDAH on: identification, characterization, hierarchization, evaluation and assessment of risk factors</td>
</tr>
<tr>
<td>4. Feedingstuffs and animal nutrition</td>
<td>NSVFSA</td>
<td>NSVFSA</td>
<td>CVFSD</td>
<td>ICVBPM - additives (animal nutrition) IHVPH - animal proteins (feedingstuffs) IDAH – GMO in Food and Feed and CSVFSLs</td>
<td>IHVPH* IDAH on: identification, characterization, hierarchization, evaluation and assessment of risk factors</td>
</tr>
<tr>
<td>5. TSEs/ABP</td>
<td>NSVFSA MARD</td>
<td>NSVFSA</td>
<td>CVFSD</td>
<td>IDAH and CSVFSLs</td>
<td>IDAH on: identification, characterization, hierarchization, evaluation and assessment of risk factors</td>
</tr>
<tr>
<td>6. Veterinary medicines - authorisation, marketing &amp; distribution</td>
<td>NSVFSA</td>
<td>NSVFSA</td>
<td>NSVFSA ICVBPM CVFSD</td>
<td>ICVBPM</td>
<td>ICVBPM</td>
</tr>
<tr>
<td>7. Foodstuffs and Food hygiene</td>
<td>NSVFSA MH</td>
<td>NSVFSA MH</td>
<td>CVFSD</td>
<td>LAREX; CSVFSLs and MH Labs</td>
<td>Scientific Council</td>
</tr>
<tr>
<td>8. Imports of food of non-animal origin</td>
<td>NSVFSA</td>
<td>NSVFSA</td>
<td>NSVFSA CSVFSLs</td>
<td>NSVFSA</td>
<td></td>
</tr>
<tr>
<td>Import of food contact materials</td>
<td>MH</td>
<td>MH</td>
<td>MH/ CPHD</td>
<td>MH Lab</td>
<td>MH</td>
</tr>
<tr>
<td>9. Plant protection products - authorisation, marketing and use</td>
<td>MARD - NPA</td>
<td>MARD - NPA</td>
<td>CPU</td>
<td>CPL and four regional laboratories</td>
<td></td>
</tr>
<tr>
<td>Plant protection products - residues</td>
<td>MARD - NPA, NSVFSA</td>
<td>MARD - NPA, NSVFSA</td>
<td>CVFSD, CPU</td>
<td>LPRCPPPP</td>
<td></td>
</tr>
<tr>
<td>Sector</td>
<td>Policy co-ordination</td>
<td>Co-ordination of controls</td>
<td>Implementation of controls</td>
<td>Laboratories</td>
<td>Risk assessment, scientific advice</td>
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<tr>
<td>10. Animal Welfare</td>
<td>NSVFSA</td>
<td>NSVFSA</td>
<td>CVFSD</td>
<td>IDAH and CSVFSLs</td>
<td>NSVFSA IDAH on: identification, characterization, hierarchization, evaluation and assessment of risk factors</td>
</tr>
<tr>
<td>11. Plant Health</td>
<td>MARD - NPA</td>
<td>MARD - NPA</td>
<td>CPU, BIP</td>
<td>CPL and four regional laboratories</td>
<td></td>
</tr>
<tr>
<td>Plant Health (Seeds)</td>
<td>MARD</td>
<td>NIQS</td>
<td>Territorial Inspectorate for Seeds and Propagating Material Quality - TISPMQ and CLSPMQ</td>
<td>Institute for Food Bio-resources - IBA</td>
<td></td>
</tr>
<tr>
<td>12. Quality labelling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Organic production</td>
<td>MARD</td>
<td>MARD</td>
<td>MARD, DSI, CBs</td>
<td>All laboratory used by CBs, accredited SR EN ISO/CEI 17025</td>
<td>MARD DSI on: identification, characterization, hierarchization, evaluation and assessment of risk factors</td>
</tr>
<tr>
<td>- PDO/PGI/TSG</td>
<td></td>
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</tbody>
</table>

* Provides only scientific advice – undertook 2 steps of the risk assessment: hazard identification and hazard characterization.
2. INDIVIDUAL CONTROL SYSTEMS

2.1 Control system for animal health
NSVSFA National Sanitary Veterinary and Food Safety Authority
GDOC General Directorate for Official Control
IOCD Inspection and Official Control Directorate
AHD Animal Health Directorate
AHCSS Animal Health Control Service
GSVFSD General Sanitary Veterinary and Food Safety Directorate
VMPAND Veterinary Medicinal Products and Animal Nutrition Directorate
OCASO Official Control on Animal Health Office
CSVFSD County Sanitary Veterinary and Food Safety Directorates
CSVFLSL County Sanitary Veterinary and Food Safety Laboratory
EV Empowered veterinarian (contractual veterinarian authorized for certain official activities)
IDAH Institute for Diagnosis and Animal Health
AD Audit Directorate
ZSVCs Zonal Sanitary Veterinary Circumscriptions

Competent authorities

NSVSFA, through the Animal Health Directorate (AHD) within General Sanitary Veterinary and Food Safety Directorate (GSVFSD), is responsible for animal health.

In accordance with article 51 of Government Ordinance no. 42/2004 regarding the organization of the veterinary and food safety activity, approved with amendments by Law no. 215/2004, with further amendments, AHD draws up rules for the implementation of the Programme of supervision, prevention, control and eradication of animal diseases, those transmitted from animals to humans, animal welfare and environmental protection, identification and registration of cattle, pigs, sheep and goats.

AHCS has the following responsibilities:

- organises, coordinates, monitors and controls the activity of official control in animal health field, performed by CSVFSD in all authorised/registered establishments subjected to sanitary veterinary controls:

- performs inspections/official controls regarding the compliance with the programs and policies applied by CSVFSD in animal health field:

- carries out inspections/official controls in all establishments in animal health field on national territory, subjected to sanitary veterinary control and orders legal measures when non-compliances are found:

- verifies, whenever necessary, the activity of staff from CSVFSD who ensures the enforcement of animal health legislation and orders legal measures when non-compliances are found:

- all the results of controls performed are submitted to the management of NSVSFA:

- monitors monthly data submitted by CSVFSD according to official control program in the animal health field, and the identified non compliances are submitted to the management of NSVSFA and the technical directorates.

- monitors the correct implementation of the measures ordered during inspection/official controls.

Forty-two County Sanitary Veterinary and Food Safety Directorates (CSVFSD) including local Zonal Veterinary and Food Safety Circumscriptions (ZSVCs) are territorial (county) sanitary veterinary and food safety authorities, subordinated to the NSVSFA. The CSVFLSLs, within the structure of CSVFSD, are technically co-ordinated by NSVSFA. At county level, competencies
are split between the Official Control on Animal Health Office (OCAHO) and the Official Control on Food Safety Office (OCFSO), accountable to the Sanitary Veterinary Deputy Director.

The OCAHO are primarily responsible for animal health issues (e.g. monitoring programmes), including the official control. The CA acknowledged that there had been poor cooperation/communication between the central and local levels, in the past, in particular in relation to the action needed to deal with significant animal health problems (e.g. BT, CSF and rabies). Law no. 1/2008 has been adopted and as a consequence, place the NSVFSA and the Ministry of Administration and Internal Affairs under the direct co-ordination of the Prime Minister. This approach facilitates improved co-operation between CA and CCA with County prefects; new structures for disease outbreak controls; and implementation of control measures.

**Holding registration, animal identification and movement controls**

*Cattle and small ruminants*

According to the CCA, commercial cattle, small ruminant and pig holdings are registered and most are recorded on the National Animal Identification and Registration System (NAIRS). However, discrepancies have been noted between census and database figures. Dam information for bovine animals is included in NAIRS since January 2007.

Since the publication of the Emergency Ordinance no. 23/2010, the animals’ identification and registration in the commercial farms has been under the farm owner's responsibility. The Emergency Ordinance no. 23/2010 also provides the possibility for the owners of non-commercial holdings to choose that the animals’ identification and registration to be carried out through the Professional Associations of Animals Breeders.

On January 1, 2014 in the national database were recorded:

<table>
<thead>
<tr>
<th>Animal</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle</td>
<td>2,391,794</td>
</tr>
<tr>
<td>Swine</td>
<td>2,322,659</td>
</tr>
<tr>
<td>Sheep</td>
<td>12,448,068</td>
</tr>
<tr>
<td>Goats</td>
<td>1,821,612</td>
</tr>
</tbody>
</table>

Most of the animals are farmed in non-commercial holdings.

The Romanian authorities have stated that animal movements take place in compliance with NSVFSA President Order no. 40/2010 (with subsequent amendments) on the identification and registration of animals. For each animal leaving a holding, the authorised veterinarian fills in a movement form on the request of the animal holder, and registers the movement in NAIRS the same day. The movement form remains valid for 72 hours until animals arrive at their destination, except for animals in transhumance movements. For animals arriving on a holding, the owner of the holding notifies the authorised veterinarian, and gives him a copy of the movement form or introduces and/or confirms data in the NAIRS. The Veterinarian introduces and/or confirms data in the NAIRS on the same day. In addition, for bovines, he adds data on the movement to the bovine passport.

Information on movement restrictions must be communicated by the Executive Director of the CSVFSD to local authorities.
**Pigs**

As part of the national CSF strategic programme a new system for the registration of pig holdings (professional holdings, commercial "microfarms" and subsistence farms) was introduced in 2006 and restrictions placed on the sale/movement of live pigs and their products from subsistence farms (from the end of December 2006). From 1 July 2007, keepers of commercial "microfarms" must comply with more stringent bio-security requirements and maintain a holding register which is checked during vaccination campaigns.

In 2012 Order no. 46/2012 of NSVFSA President was published, amending and supplementing Order no. 85/2012 of NSVFSA President which established the rule that the owners of such farms have to register in the NDB the movements and slaughter of pigs from their holdings, within three days of the event. Also, this order repealed the obligation to send copies of Movement Forms to the CSVFSD.

**Equines**

According to the Law no. 191/2012 for approval of the Emergency Government Ordinance no. 23/2010 concerning the identification and the registration of swine, sheep and goats and for amending and completing of some regulations, the identification activity is performed by the official empowered veterinarians and the registration of the data and management of the equine database is performed by NAIRZ.

**Animal health controls**

**Poultry**

In Romania there are: 206 holdings of laying hens, 45 holdings of chicken breeders, 268 holdings of broilers, 1 holding of ratites, 7 holdings of pheasants, 11 holdings of quails, 9 holdings of turkeys and 2 holdings of palmipedes.

In relation with the general animal health situation, a national surveillance, prevention and eradication programme is annually applied for diseases, covering a large number of listed diseases. The programme is annually approved by the NSVFSA and the strategy for sampling is prepared at county level. Each authorised veterinarian receives the schedule for his locality. Penalties may be applied by the OV if non-compliances to complete the programme in time are identified.

Where non-compliances in the activity of the staff from the county animal health and welfare disease monitoring offices and those under their subordination are found, the personnel of inspection offices notifies the non-compliances to the executive director and proposes adequate measures to remedy the non-compliances.

**Equine infectious anaemia (EIA)**

The surveillance is performed in accordance with the Strategic Program, approved by Government Decision and by NSVFSA President Order. The serological surveillance is performed on all equidae older than 6 months of age.

The Eradication Program for EIA restarted in April 2010 and remains in progress. The objectives of the program are: the testing of all eligible equidae from the entire national territory, the removal by culling or killing of all equidae with positive results in the confirmation tests, the compensation of the owners and the removal of outbreaks. To achieve these objectives, NSVFSA elaborated national legislation provisions which set the movement conditions of equidae on the territory of Romania, for the surveillance, control and eradication of EIA.
Since March 24, 2009, the payment of compensation for the owners is made from funds provided in the budget of the National Sanitary Veterinary and Food Safety Authority, in conformity with the Government Decision no. 1214/2009 provisions, the financial effort being substantial. The compensations are granted on the basis of the evaluations made by a Committee designated by Order of the Prefect in each county.

The final objectives of the eradication program are the eradication of EIA and lifting of the restrictions imposed by the Commission Decision No. 2010/346/EU on protective measures with regard to equine infectious anaemia in Romania.

**Classical Swine Fever (CSF)**

Following the outbreaks of CSF in pig holdings in 2006 the trade of live pigs, porcine semen and embryos, and fresh pig meat from Romania to other Member States was prohibited by Commission Decision 2006/779/EC (and subsequently by Commission Decision 2008/855/EC). A series of FVO audits on CSF between 2007 and 2010 found continuing shortcomings in implementing the control and monitoring programme, in particular in relation to sampling levels of wild boar population and pigs in backyard farms. No cases of classical swine fever have been detected since November 2007.

The FVO carried out a further audit in Romania in July 2011 in relation to the then proposed channelling system for pork which concluded that the implementation of such a system had the potential to function effectively, following correction of some deficiencies. The programme for the control and monitoring of classical swine fever submitted by Romania for the period from 1 January 2012 to 31 December 2012 was approved by Commission Implementing Decision 2011/807/EU of 30 November 2011. Under that programme, Romania implemented additional surveillance measures with regard to classical swine fever.

Commission Decision 2013/764/EU (repealing Decision 2008/855/EC) allows, under the conditions laid down in Decision 2013/764/EU the dispatch to other Member States of fresh pigmeat and meat preparations and meat products consisting of or containing such meat from the areas listed in the Annex to Decision 2013/764/EU.

**Avian influenza (A.I.)**

Since 2007 Romania develops annual A.I. surveillance programs co-financed by the EC. These programs apply to poultry in commercial farms, backyards and wild birds.

While the developed programs ensure a high protection level, there are a number of particular risk factors:

- the territory of Romania is crossed by three main migration corridors of wild birds;
- the existence of more than 7 million backyards;
- the existence of The Danube Delta;
- location on the Eastern border of the EU, bordering with third countries;

In Romania there are: 206 commercial farms of laying hens, 45 commercial farms of chicken breeder, 268 commercial farms of broiler, 1 commercial farms of ratites, 7 commercial farms of pheasant, 11 commercial farms of quail, 9 commercial farms of turkey, 2 commercial farms of palmiped. Also, based on risk analysis 729 "target” localities have been identified in which there are poultry in backyards and which are subject to surveillance.

The main objective of the surveillance program in wild birds is the timely detection of HPAI of the virus subtype H5N1, in order to protect poultry and safeguard veterinary public health.
Sampling procedures from poultry and wild birds and their testing is carried out in accordance with the Diagnostic Manual for Avian Influenza.

In accordance with The Final Technical and Financial Report for the 2014 AI program developed, Romania have performed:

- wild birds 96 IH tests H5/H7, 340 RT-PCR tests and 24 tests for the virus isolation on embryonated eggs SPF. The results of the tests have been negative.

- poultry 22073 IH tests H5/H7, 1024 RT-PCR tests and 316 tests for the virus isolation on embryonated eggs SPF.

From all IH tests H5, only 12 results of IH tests H5 have been positive. All the results of IH tests H7 have been negative. The results of the RT-PCR tests and for the virus isolation on embryonated eggs SPF tests have been negative.

The National Reference Laboratory specialists participate annually in the training organized by the Community Reference Laboratory for AI and Newcastle Disease and in the inter-laboratory tests, where they obtained good results. The NSVFSA’s representative responsible with the management of the AI surveillance programs has participated in the working group organized by the EC for the completion of the animal health law.

**Rabies**

Since 2007, Romania has drawn up a Strategic Plan for the Oral Vaccination of Foxes, in compliance with SCOFCAH report adopted on 23 October 2002, with the aim of eliminating rabies within 10 years. This plan also establishes the annual compulsory vaccination of dogs and cats. When positive cases of rabies appear in domestic or wild animals in the areas known to be of high risk, there is an option to vaccinate domestic animals.

An FVO audit in May 2012 concluded that a satisfactory start had been made in respect of the implementation of the first aerial fox vaccination campaigns in 2011 and deficiencies identified were of a nature that can be addressed in future campaigns, with minor alterations to procedures. At the time of the audit, it was of major concern that fox vaccination campaigns had not yet been resumed for the 2012 eradication programme due to legal and administrative difficulties. The Romanian authorities had subsequently provided a satisfactory action plan addressing the recommendations of the report.

In 2013, Romania implemented oral antirabies vaccination of foxes, by manual and air distribution of vaccine baits in two campaigns.

In 2014 Romania implemented oral antirabies vaccination of foxes, by manual and air distribution of vaccine baits in one autumn campaign.

**Contingency plans**

Contingency plans drawn up by NSVFSA and approved by the European Commission are in place for Foot and Mouth Disease (Commission Decision No 2007/18/EC), Newcastle Disease (Commission Decision No 2007/24/EC), Classical Swine Fever (Commission Decision No 2007/19/CE) and Avian Influenza (Commission Decision no 2007/24/EC). The contingency plan for Bluetongue has been drawn up and submitted to the European Commission for evaluation.

In the autumn of 2009, a contingency plan for African Swine Fever was drafted, finalized in 2010 and posted on ANSVSA website. It was issued in accordance with the article no. 21 of the Council Directive 2002/60/EC, which provides the requirement of each Member State to issue an
intervention plan, in which to specify the national measures for applying in case of appearance of an African Swine fever outbreak. The Plan was issued in accordance with the criteria and requests provided in the Annex VI of the aforementioned Directive.

The Contingency Plan for African Swine Fever was revised and sent to DG SANCO in October 2012, and may be found posted at the web address: http://www.ansvsa.ro/?pag=831. An operational manual for ASF was issued in 2013 and posted on the NSVFSA website at the address http://www.ansvsa.ro/?pag=843


The other existing contingency plans and operational manuals were updated during 2011-2014 and may be found at the web address: http://www.ansvsa.ro/?pag=831.

Simulation exercises were organized in 2011-2014 to verify the efficacy of the Romanian contingency plans.

In 2013 two national simulation exercises were organized: in May, in Constanta County, for Foot and Mouth disease, and in October, in Bistrita Nasaud, for African Swine Fever, the last one with international participation.

In 2014, a national simulation exercise for African Swine Fever and African Swine Fever in wildlife was organized, in September 2014, in Iasi County, in order to test the functionality of the operational manual afore mentioned. At this exercise were also invited to attend representatives of the veterinary authority of Republic of Moldova. The Agenda, scenario, report and some photos are available at the web address http://www.ansvsa.ro/?pag=904.

A general contingency plan was drafted for all major diseases of animals, but has not entered into force so far.

Laboratory services

The Institute for Diagnosis and Animal Health (IDAH) is the NRL for animal health and welfare (accredited by RENAR) and is co-ordinated by NSVFSA President and from technical point of view is directly related with the Sanitary Veterinary and Food Safety General Directorates and CSVFS laboratories. A special liaison is to be created with animal owners, farmers, animal rearing associations and patronates.

40 county veterinary state laboratories perform analyses in the field of animal health and welfare. Under the Law no. 151/1998, regionalization has been applied and 8 regions were established with 16 laboratories renewed using Commission financing through SAPARD.
2.2 Control system for food of animal origin

NSVFSA (President)

NSVFSA (Vice President)

GDOC (IOCD)

GSVFSD (FSAOD)

FSCS

42 CSVFSDs Deputy Executive Director

CSVFSLs 41

CRETO Catagraphy, Registration, Evaluation, TRACES Office

OCFSO

SVFSC

Establishments

NSVSFA National Sanitary Veterinary and Food Safety Authority
GDOC General Directorate for Official Control
IOCD Inspection and Official Control Directorate
FSCS Food Safety Control Service
OCFSO Official Control on Food Safety Office
CRETO Catagraphy, Registration, Evaluation, TRACES Office
FSAOD Food Safety of Animal Origin Directorate
CSVFSD County Sanitary Veterinary and Food Safety Directorates
CSVFSL County Sanitary Veterinary and Food Safety Laboratory
IHVPH Institute for Hygiene and Veterinary Public Health
SVFSC Sanitary Veterinary and Food Safety Circumscriptions
AD Audit Directorate
ZSVCs Zonal Sanitary Veterinary Circumscriptions
Competent authorities

According to the provisions of the NSVFSA President Order no. 57/2010, the County Animal Origin Food Safety Offices (CAOFSEO) are responsible for evaluation and audit of food industry establishments requesting veterinary approval for intra-Community trade.

The Food Safety of Animal Origin Directorate (FSAOD) within NSVFSA is responsible for granting and communicating the approval number of food industry establishments requesting veterinary approval for intra-community trade which were audited, with favourable results, by the County Animal Origin Food Safety Offices.

The FSAOD sent Service Note 8486/04.12.2009 concerning the procedure to be implemented by the OV acting in the field of food hygiene in order to carry out the official control in establishments producing, processing and storing foods of animal origin, and to classify the establishments into risk groups.

According the new tasks set up by the NSVFSA President Order no. 751/26.09.2014 the Inspections and Official Control Directorate (IOCD) is responsible for audit of food industry establishments approved for intra-Community trade and for export to third countries, taking into account the classification of establishments into risk groups.

The FSAOD is also responsible for contaminants in food of animal origin.

Inspections and Official Control Directorate (IOCD), via the Official Control Food Safety Office (OCFSO), is responsible for the activity check of the staff within the food establishments and those of their subordination, according to the provisions drawn up in article 3 (1) and article 4 (2) letter a) of Regulation (EC) no. 882/2004.

According to the criteria of food safety, drawn up by the NSVFSA Service Note no. 25475/19.02.2014, forty-two County Sanitary Veterinary and Food Safety Directorates (CSVFSDs) have been classified into 3 categories of risk, as follows:

- Category I (high risk) = 28 CSVFSDs
- Category II (medium risk) = 12 CSVFSDs
- Category III (low risk) = 2 CSVFSDs

The NSVFSA Service Note no. 25475/19.02.2014 establishes the frequency of official controls performed by the IOCD in order to check the activity of the CSVFSDs staff responsible for official controls of food, as well as the program for audit the food industry establishments approved for intra-Community trade, according to the NSVFSA President Order no. 57/2010.

General Directorate for Official Control (GDOC) – IOCD (Inspections and Official Control Directorate) draws up the yearly National Official Control Programme, based on:

- risk category of food establishments;
- assessment results of official control activity performed by the CSVFSD.

Forty-two County Sanitary Veterinary and Food Safety Directorates (CSVFSDs) form the intermediate level between the NSVFSA and the local, zonal level.

The Official Control Food Safety Office (OCFSO), accountable to the IOCD has competences for performing official controls of the operators. OCFSO is responsible for the activity check of the staff within the food establishments and those of their subordination, including inspections carried out directly in establishments, when it is the case.

At county level, the Catagraphy, Registration, Evaluation, TRACES Offices (CRETO) are primarily responsible for establishment approvals. A number of FVO audits had identified an
overlap in the controls on food businesses – one element of the May 2011 re-organisation of tasks was to eliminate such overlapping.

The overall organisation of the competent authorities has been changed significantly at central level. On 22 December 2012 by Government Emergency Ordinance no. 96/2012 NSVFSA is subordinated to the Government and under the co-ordination of the Minister of Agriculture and Rural Development. Government Decision no. 1415/18.12.2009 established organisation and operation of NSVFSA and subordinated units. The Government Decision no. 625/2013 for modification of the Government Decision no. 1415/2009 established new organisation and operation of NSVFSA and CSVFSD as well as new attributions, responsibilities and competences for all directorates within NSVFSA.

The National Surveillance and Monitoring Plan (NSMP)

The NSMP, drawn up by the FSAOD, represents the legal framework (established by the NSVFSA through Order no 64/2007 (as amended), for actions to be taken by OVs in Romania for: contaminants in food of animal origin monitoring; veterinary surveillance in slaughterhouses and food processing establishments; laboratory tests for animal origin foods; and controls on the efficiency of sanitation procedures. The CAOFSO are to implement this plan taking into account local circumstances. This plan is based on risk assessment and describes the number of inspections and controls to be carried out by the OV at each establishment, and samples to be taken.

Since 2010, the NSMP comprises a checklist concerning the criteria for evaluation and classification into risk groups of establishments producing, processing and storing products of animal origin, issued by TAOFSD; this checklist shall be filled twice/year by the OV within CAOFSO at each establishment.

Registration and approval of establishments

The NSVFSA Order no. 57/24.06.2010 set up the procedure for the veterinary approval of establishments producing, processing, storing, transporting and/or delivering food of animal origin.

The FSAOD has drawn up a national procedure for the veterinary approval of establishments producing food of animal origin.

To be approved for intra-community trade the following conditions apply:

- The establishment has to make an application to CSVFSD citing the activities proposed;
- The application has to be accompanied by a file comprising: a blueprint of the establishment showing the flow of materials/product; a map of the surrounding area; a copy of the registration certificate; and other documents issued by the Registering Office of Commerce;
- An audit on the spot is carried out by a team comprising an OV from CAOFSO and local levels to verify compliance with Community requirements and a report is issued with/without proposal for authorisation;
- In the case of a satisfactory report, a letter is sent to the FSAOD, with a request for an approval number granted by central level;
- The CAOFSO issue, a specific approval (i.e. detailing activities, capacity, and approval number, granted by the FSAOD, etc.) for each establishment;
- Conditional approval may be issued for a period of 3 months and be extended to 6 months if a HACCP programme is being implemented;
- The NSVFSA Order no. 35/10.08.2011 set up the minimal conditions for operating of low capacity slaughterhouses in Romania, according to the provisions drawn up in article 10(4), letter b) of Regulation (EC) no. 853/2004.
The food industry establishments’ situation in 2014 shows as follows:

<table>
<thead>
<tr>
<th>SECTOR</th>
<th>ESTABLISHMENTS APPROVED FOR INTRA-COMMUNITY TRADE</th>
</tr>
</thead>
<tbody>
<tr>
<td>RED MEAT</td>
<td>394</td>
</tr>
<tr>
<td>MILK</td>
<td>183</td>
</tr>
<tr>
<td>POULTRY MEAT</td>
<td>93</td>
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<tr>
<td>FISH</td>
<td>105</td>
</tr>
<tr>
<td>EGGS</td>
<td>113</td>
</tr>
<tr>
<td>INDEPENDENT STOREHOUSES</td>
<td>176</td>
</tr>
</tbody>
</table>

Registration of direct and retail sale activities

The FSAOD has drawn up national legislation to create the legal framework for direct sale and retail sale through NSVFSA Order No. 301/2006 (in accordance with Art. 3 of Regulation (EC) No 853/2004), repealed by NSVFSA Order No. 111/2008 as last amended.

For registered for direct/retail sales, the following conditions apply:

- The FBO must apply to CSVFSD, providing data on location, activities, place of marketing of the products, capacity, number of personnel, etc.
- The County Animal Origin Food Safety Offices (CAOFSO) perform an on-site visit to verify that the requirements of Regulation (EC) No. 852/2004 are met;
- If the finding of the site visit is satisfactory, CSVFSD issue the registration document which enables the FBO to carry out direct sale and retail sale activities.

In accordance with Art 7 of Regulation (EC) No 2074/2005, the FSAOD has issued Order 34/2008 which lists certain exemptions from the provisions of Regulation (EC) No. 852/2004 for establishments producing food using traditional methods.

Official controls regarding health/identification marks and traceability

To address deficiencies noted by in the FVO mission of March 2007 concerning application of health/identification mark and traceability control in food industry, the FSAOD issued NSVSA Order No. 10/2008 establishing procedures for marking meat and products of animal origin and revised certification procedures for fresh meat. The Order contains details of the identification marks for use by the Romanian food industry and model health certificates for fresh meat obtained from slaughterhouses. Service note (No. 7125/2009) was issued by the FSAOD on implementation of the provisions of NSVSA Order No. 10/2008. Additional Service notes No. 65162/2007 and No. 68130/2007 give further guidance on: veterinary certification; official controls on products of animal origin for intra Community trade and import from third countries.
2.3 Control system for imports of food of animal origin

NSVSFA National Sanitary Veterinary and Food Safety Authority
GDOC General Directorate for Official Control
TIEBIPsD Trade, Import, Export and BIPs Directorate
IOCD Inspection and Control Official Directorate
IECBIPsC Import – Export Compartment and BIPs Control
BIPs Service Border Inspection Posts Service
BIPs Border Inspection Posts
FSAOD Food Safety of Animal Origin Directorate
CSVFSDs County Sanitary Veterinary and Food Safety Directorates
AD Audit Directorate
NCA National Customs Authority

AD Reporting NSVFSA (President)
NSVFSA (President) Reporting NSVFSA VicePresident
NSVFSA VicePresident Reporting GDOC (General Director)
GDOC (General Director) Reporting IOCD (Director)
IOCD (Director) Reporting TIEBIPsD (Director)
TIEBIPsD (Director) Reporting IECBIPsC
IECBIPsC Reporting BIPs Service
BIPs Service Reporting BIPs
BIPs Reporting BIPs Audit
BIPs Audit Reporting AD
AD Reporting CSVFSD’s
CSVFSD’s Control of kitchen waste

Ports Airports without a BIP

FSAOD (Director) Approval

Customs warehouse
Ship suppliers
Warehouses
Competent authorities

The General Directorate for Official Control is responsible for supervising BIPs and for the employment and supervision of BIP staff. There is a centralised management structure with a chain of command from the CCA to those carrying out import controls. The procedures manual for border veterinary controls has been updated in 2011 and has been posted on the NSVFSA website and is available to both BIP staff and importers.

BIPs staff is responsible for checks on accompanied non-commercial pets under Regulation (EC) No. 596/2013. Customs are responsible for checks on passenger luggage under Regulation 206/2009 and for checks on CITES live animals and CITES products. BIP staffs are responsible for seizure and disposal of POAO from personal luggage at BIP entry points. For non-BIP entry points, this task is to be allocated to the OVs of the relevant CSVFSDs (this remains in legislative process).

The airport and port BIPs are responsible for checks on kitchen waste disposal from international transport. For airports without a BIP, the OVs of the relevant CSVFSD are responsible. Veterinary staff from Ministry of Transport and Infrastructure was integrated into the structure of NSVFSA according to Government Decision no. 1399/2009.

Approval of customs’ warehouses from the free zones and of ships suppliers’ warehouses is given by Trade, Import, Export and BIPs Directorate (TIEBIPsD). Supervision of non-compliant animal products in customs warehouses in the Constanta BIP areas is carried out by OVs in the relevant BIPs.

A protocol of co-operation was signed on October 2008 between the NSVFSA and the National Customs Authority (NCA). A working group at central level has been established to further develop co-operation and co-ordination.

Import Controls

A system for auditing BIPs is in place. The customs authorities have a system to identify and select consignments which require veterinary controls. When identified, the veterinary authorities are notified so that they can arrange the necessary checks.

In December 2011 the additional act of the Protocol of Co-operation between NSVFSA and National Customs Authority (NCA) was signed. The main provision of this act relates to mutual access of both institutions, NSVFSA and NCA, to their databases. Official veterinarians from the BIPs have access to the customs databases and the customs staff has access to Traces system.

A system is in place to follow up transit or transhipped consignments. For consignments crossing the EU territory (along the Danube river), checks are made at the North and South Constanta BIP. In order to meet the transit procedure in accordance with art. 11 of Council Directive 97/78, at the exit of the EU territory towards Serbia of animal origin products checked at BIP Constanta South and BIP Constanta North, it was designated the exit point Drobeta Turnu Severin according to provisions of Common Order no. 10/2011. Exit control is performed on request of BIP Constanta South and BIP Constanta North by the staff of BIP Moravita.

The competent authorities with powers in control of travellers luggage and post parcels are provided in the draft of Government Decision in order to approve the Procedure of destruction of animal origin products seized from travellers' luggage and post parcels coming from third countries. On 24.02.2015 was reconvened the working group of institutions involved in promoting of this government decision.
It is estimated that by the end of 2015 National Sanitary Veterinary and Food Safety Authority to publish the government decision in Official Gazette.

**Listed BIPs**

Details of BIPs are provided in Commission Decision 2009/821/EC of 28 September 2009 (OJ L296 of 12.11.2009), which can be found at:

http://ec.europa.eu/food/animal/bips/approved_bips_en.htm
2.4 Control system for feedingstuff and animal nutrition
Competent authorities

NSVFSA is responsible for official controls on feedingstuffs and for feed hygiene, through its Animal Nutrition Service from Veterinary Medicinal Products and Animal Nutrition Directorate within General Sanitary Veterinary and Food Safety Directorate (GSVFSD) and Veterinary Medicinal Products, Animal Nutrition and Laboratory Control Service within General Directorate for Official Control (GDOC).

Registration and approval of establishments and intermediaries

The procedure for approval and registration is in line with Regulation (EC) No. 183/2005.

Following the entry into force of the NSVFSA President Order no. 109/2010 for the approval of the sanitary-veterinary norm for the procedure of approval/registration of establishments in the field of farm animal nutrition and means of transport for animal feed, the CSVFSDs began the process of authorization/re-authorization and registration/re-registration of the operators from the field of animal nutrition. At the end of 2010, the CSVFSD sent the list of authorized/registered operators to the National Sanitary Veterinary and Food Safety Authority (NSVFSA) and subsequently, if it was necessary, they also sent all the modifications of this list. The centralized list of the authorized/registered establishments was published on the NSVFSA website in February 2011 and its latest update was in August 2013.

A good practice guide has been published and training on the evaluation of HACCP in feed units is on-going.

Official controls

IHVPH, which is the NRL, develops the control programme for feed safety, using information such as: reported non-compliances; rapid alert system information; and laboratory results. The control programme is largely in accordance with the requirements of Article 3 of Regulation (EC) No. 882/04. The control programme for 2008 was drawn up based on Service Note No. 67026/10.01.2008 and takes account of a preliminary risk assessment. Modifications have been made to this programme to include tests on an increased number of antibiotic substances in compound feed. It also covers imported feedstuffs, and the frequency of checks is to be revised once a specific risk analysis is complete.

GDOC is responsible for developing the official control policy and the instructions, drawing up the National Framework Inspection Programme, inspection procedures, and checklists and also for...
monitoring the inspections performed, achieving of the Feed Control Program and nonconformities identified in the feed sector operators.

Each CSVFSD draws up its own inspection and sampling plan according to the criteria.

At county level – OCAHO is responsible for performing inspection in the feed sector, based on the FNIP (National Framework Inspection Programme) and for implementation of Feed Control Programme, including sampling of feed and for sending the samples to the County Sanitary Veterinary and Food Safety Laboratory.

The counties activity reports are sent quarterly to NSVSFA - General Directorate for Official Control.

Laboratories

The laboratory network for feed safety consists of one NRL (IHVPH) and the 41 County Sanitary Veterinary and Food Safety Laboratories (CSVFSLs). Now 8 of all 41 laboratories are specialised on residues control and the range of tests has been extended as well. For feed analysis are specialised 11 laboratories for animal protein (PAP), 3 laboratories for pesticides, 10 laboratories for mycotoxins, 6 laboratory for heavy metals and 6 laboratories for antibiotic substances and coccidiostats in feeds.
2.5 Control system for TSE and Animal-By-Products (ABP)

TSE

Red – Official control (sampling & inspections)
Blue – Reporting of data concerning results of official control and results of TSE tests.
Black – Command chain and flow of information (instructions, trainings)
The NSVFSA is the CCA for TSE including BSE issues. Within the NSVFSA, the Animal Health Directorate (AHD) of the GSVFSD, is responsible for epidemiological surveillance and BSE/TSE monitoring while the Food Safety of Animal Directorate (FSAOD), performs controls on SRM in slaughterhouses and cutting plants. The AHD has experts responsible for TSEs, ABP and aspects of animal nutrition related to the feed ban. The County Sanitary Veterinary and Food Safety Directorates (CSVFSD) are the CAs at county level. There are also officials responsible for TSE, ABP, and animal nutrition in all 42 CSVFSDs. Each county is divided into Zonal Sanitary Veterinary Circumscriptions (ZSVCs). Officials at ZSVCs carry out some routine controls in the area of TSE (sampling of fallen stock on farm).

**TSE situation**

The TSE surveillance programme has not shown any positive case of BSE in Romania, however, there is some incidence of scrapie and four flocks were found TSE – positive in 2007. The results of the Romanian TSE/BSE testing programme can be found at: [http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_annual_reports_en.htm](http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_annual_reports_en.htm)

Among the conclusions of the most recent FVO audit on BSE (2011-8950, February 2011) are the following:

A system for identification and registration of bovine animals is in place as required by Regulation (EC) No 1760/2000. However, existing limitation in extraction of up-to-date data concerning bovines’ movement combined with frequent difficulties in obtaining whole set of documents concerning animals movement at backyard farm (where a significant proportion of bovine animals is kept) could affect the BSE control measures concerning monitoring and eradication, as laid down in Annex III and VII to Regulation (EC) No 999/2001.

The requirements concerning training and for the notification of BSE suspect cases laid down by Article 10 and Article 11 of Regulation (EC) No 999/2001 are largely complied with, but there is still reluctance to notify animals that could be considered as BSE suspects. Although there are procedures concerning BSE suspects and the measures to be taken following suspicion of BSE, which in principle, are in line with the requirements of 12 and 13 of Regulation (EC) No 999/2001, these are not always properly implemented.

The requirements concerning BSE monitoring laid down by Points I.2, I.3 and I.6 of Chapter A of Annex III Regulation (EC) No 999/2001 are largely complied at slaughterhouses and commercial farms. However, these requirements are not followed in backyard farms, where the vast majority of bovine animals are kept.
The requirements concerning SRM laid down by Article 8 and Annex V to Regulation (EC) No 999/2001 are satisfactorily complied with at meat establishments. However, these requirements are not followed at backyard farms, where the vast majority of bovine animals are kept and slaughtering takes place on a significant scale. The requirements concerning official controls on SRM set out by Article 8 and Annex V to Regulation (EC) No 999/2001 are satisfactorily complied with at meat establishments. However, these requirements are not followed at backyard farms.

The report concludes that BSE active epidemi-surveillance and compliance with SRM rules are significantly affected by the lack of arrangements for the collection of brain samples and SRM at backyard farms, where the majority of the bovine population is kept. There are also weaknesses concerning feed-ban controls.
Ministries involved

MARD  Ministry of Agriculture and Rural Development
MECC  Ministry of Environment and Climate Change
MIA  Ministry of Internal Affairs
MRDPA  Ministry of Regional Development and Public Administration

Central level

NSVSFA  National Sanitary Veterinary and Food Safety Authority
GSVFSD  General Sanitary Veterinary and Food Safety Directorate (farm sector & food sector & ABP plants – two people responsible for ABP within Animal Welfare Service).
GDOC  General Directorate for Official Control
AD  Audit Directorate
IHVPH  Institute for Hygiene and Veterinary Public Health

County level

CSVFSDs  County Sanitary Veterinary and Food Safety Directorates
OCAHO  Official Control on Animal Health Office
OCFSO  Official Control on Food Safety Office
Red – Official control (inspections)
Blue – Reporting of data concerning results of official control, flow of ABP and derived products, quantities of
ABP/derived products, updating of lists of ABP plants, etc.
Black – Command chain and flow of information (instructions, trainings)

Competent Authorities

NSVFSA is the main body with responsibilities in the ABP sector. However, some responsibilities
lie with the Ministry of Agriculture and Rural Development (MARD), the Ministry of Internal
Affairs (MIA), the Ministry of Regional Development and Public Administration (MRDPA) and
Ministry of Environment and Climatic Change (MECC).

Approval of ABP plants and other premises

The procedure for approval of ABP plants is implemented under NSVFSA President Order (No
16/2010), and the CA at county level are responsible for granting approvals at ABP plants. All
approved ABP plants are mentioned in the list of ABP plants which is regularly updated and
placed on the NSVFSA website.

ABP situation

Among the conclusions of the most recent FVO audit on ABP (2011-8941, February 2011) are
that there still are major deficiencies in compliance with the requirements of Regulation (EC) No
1774/2002 (subsequently replaced by Regulation (EC) No 1069/2009). This concerns notably the
burial or landfilling of unprocessed ABP originating at backyard farms, which represent a
significant part of the farming system, but also the poor hygiene conditions in some ABP plants
and weaknesses in official controls at such plants. Although there are some deficiencies in hygiene
requirements, the requirements for the approval of ABP plants are largely complied with. The
November 2012 GFA found no progress in relation to the collection and disposal of ABP from
backyard farms. This issue is now been pursued in the context of an EU Pilot.

Within the context of EU Pilot No. 4210/12/SANCO, European Commission has requested
additional information from Romanian authorities in July 2013 and Romanian authorities have
provided these data in October 2013.

The data provided by Romanian authorities were assessed by Commission services and the
measures proposed by Romanian authorities were accepted by Commission on January 2014.

NSVFSA contacted the European Commission at the end of 2014 and the first quarter of 2015
with a view to obtaining assistance. In order to improve its action plan, NSVFSA asked all
Member States, in January 2015, through its permanent representation to the EC, to describe the
organisation of their systems of collection, transport and disposal of ABP, authorities involved and
their responsibilities, financial mechanisms and state aids.
2.6 Control system for veterinary medicinal products (VMP) and residues

All confirmatory methods for Group A and B are developed and validated in the Romanian laboratory network with exception of dapsone and some antibiotics (macrolide). Exceptions are the confirmatory methods for group B1 and dapsone.

NSVSFA National Sanitary Veterinary and Food Safety Authority
CSVFSD County Sanitary Veterinary and Food Safety Directorates
CSVFSL County Sanitary Veterinary and Food Safety Laboratory
VMPAND Veterinary Medicinal Products and Animal Nutrition Directorate
SVMP Service for Veterinary Medicinal Products
GDOC General Directorate for Official Control
ICVBPM  Institute for Control of Veterinary Biological Products and Medicines  
IHVPH  Institute for Hygiene and Veterinary Public Health  
NRCP  National Residue Control Plan  
IOCD  Inspection and Official Control Directorate  
AD  Audit Directorate  
VMP  Veterinary Medicinal Products  
ZSVC  Zonal Veterinary and Food Safety Circumscriptions  
OCAHO  Official Control on Animal Health Office

Competent Authorities

In October 2013, following the publication of GD No. 625/2013 amending Government Decision no. 1.415/2009 regarding the organization and operation of the National Sanitary Veterinary and Food Safety Authority and its subordinate units, the NSVFSA was reorganized and Service of Medicinal Products Control, Nutrition and Laboratories was established, with responsibilities of control in the field of veterinary medicinal products according to Order no. 823 of 23.09.2013 approving the detailed organizational structure and the Rules of organization and operation of the National Sanitary Veterinary and Food Safety Authority.

VMPAND-SVMP draws up and updates or proposes amendments/completions to the legislative framework for veterinary pharmaceutical domain. VMPAND-SVMP draws up, updates specific technical /operational documentations and sends them to the CSVFSDs, ICVBPM, IHVPH to ensure a coherent and uniform activity throughout the country, in the domain of veterinary pharmaceutical and VMPs residues.

The Institute for Control of Veterinary Biological Products and Medicines (ICVBPM) is responsible for assessment, marketing authorisation and laboratory testing of Veterinary Medicinal Products (VMP) and other products for veterinary use. The marketing authorizations issued by ICVBPM are valid for five years. After renewed, the marketing authorisations are valid for an unlimited period, unless that ICVBPM decides, on justified grounds relating to the risk-benefit balance, to proceed with one additional five year renewal. A list of authorised veterinary medicinal products (including the information on veterinary medicinal products) is available on the ICVBPM website.

CSVFSD is responsible for official controls on distribution of veterinary medicinal products including medicated feedingstuffs through Official Control Animal Health Office.

Official controls on distribution/use of VMPs

Wholesale distribution of VMP and operation of pharmacies are regulated by NSVFSA president Order no. 83/2014 approving the sanitary veterinary conditions concerning the organization and functioning of the pharmaceutical veterinary establishments and the veterinary procedure for registration/authorisation of the establishments and the activities in veterinary pharmaceutical field. Wholesalers distribute VMP to pharmacies, veterinarians and farms where a private veterinary practitioner is present. In Romania, VMPs may not be traded without a marketing authorization, and may not be used without a medical prescription in accordance with Order No 64/2012 (approving the sanitary veterinary norm regarding prescription forms with special regime and the methodological norms for their use) and Order No 187/2007 approving the Sanitary veterinary norm on the Code relating to veterinary medicinal products, with subsequent modifications and completions.

Animal holders must keep a record of VMP use, including withdrawal time. Although VMPs may be purchased by farmers, they must be administered by a veterinarian. For backyard farms, private veterinary practitioners treating animals are obliged to keep records, and are subject to CSVFSD controls.
The NSVFSA and CSVFSDs perform inspections and controls to check compliance with withdrawal periods in farms (controls are typically targeted on large farms) and clinics to ensure compliance with the prohibition of use of certain substances. In each of the 42 CSVFSD, there is one person responsible for pharmacovigilance. Controls are carried out by the CSVFSDs at all levels in the distribution chain of VMP. The checks are done regularly on an unannounced basis.

**Residues**

**Official controls on residues**

VMPAND-SVMP (Technical directorate) in collaboration with IHVPH participates in the preparation and planning of the NRCP. NRCP development is based on data provided by CSVFSD and IHVPH concerning: livestock and animal origin products, the non-compliance identified in previous year, the non-compliance of the rapid alert system and self-controls. The NRCP is prepared in accordance with President NSVFSA Order no.95/2007 transposing Directive Council 96/23/EC. Zonal and NRL laboratories analyse samples from CSVFSD as per the plan.

VMPAND of NSVFSA is responsible for co-ordination of controls by the 42 CSVFSDs. The NRCP is approved by VMPAND-SVMP (Technical directorate) of NSVFSA and submitted to the Commission.

Each CSVFSD assigns the number of samples to be taken on a quarterly basis in certain farms and establishments.

CSVFSDs produce quarterly NRCP progress reports, which are checked at the IHVPH. A summary report is communicated to the VMPAND of NSVFSA.

**Laboratory services**

The laboratory network is co-ordinated by the IHVPH in Bucharest (the NRL) and analyses a significant proportion of the total NRCP samples. There are 10 designated laboratories for testing of residues - 6 routine (zonal) laboratories and 4 national Reference Laboratories including IHVPH (Commission implementing Decision 2014/745/EU).

All confirmatory methods for Group A and B are developed and validated in the Romanian laboratory network with exception of dapsone and some antibiotics (macrolide). The previous agreements with laboratories in Netherlands, Finland and Germany are no longer in place (there are only one agreement with laboratory LAVES from Germany and one with EURL Fougeres).
2.7 Control system for foodstuffs and food hygiene and GMOs

NSVSFA  National Sanitary Veterinary and Food Safety Authority
GDOC  General Directorate for Official Control
IOCD  Inspection and Official Control Directorate
FSNAOD  Food Safety of Non-animal Origin Directorate
OFCFO  Official Control Food Safety Office
CRETO  Catagraphy, Registration, Evaluation, TRACES Office
CDAs  County Directorates for Agriculture
C.I.T.C.R.P.P.I.A.  Technical Inspections and Control in Manufacturing and Promoting Food Industry Products
CPHD  County Public Health Directorates
CSVFSD  County Sanitary Veterinary and Food Safety Directorates
Competent Authorities

The competent authorities for foodstuffs and food hygiene are NSVFSA, the Ministry of Health (MH), the National Authority for Consumer Protection (NACP) and the Ministry of Agriculture and Rural Development (MARD). The Ministries of Internal Affairs and Administrative Reform, Justice and Defence and the National Agency for Mineral Resources also play a limited role.

NSVFSA, through its General Sanitary Veterinary and Food Safety Directorate (GSVFSD), is the principal body responsible for food hygiene. Within the GSVFSD there are two directorates: Food Safety of Animal Origin Directorate (FSAOD) and Food Safety of Non-Animal Origin Directorate (FSNAOD). FSNAOD implements food hygiene legislation and performs risk assessment. 10 persons work on food hygiene.

General Directorate for Official Control (GDOC) – IOCD (Inspection and Official Control Directorate) draws up the yearly National Control Programme for verification of official control activities performed by the CSVFSD.

The Ministry of Health (MH) was reorganised in 2010. Its responsibilities include controls of food additives/flavourings/enzymes, natural mineral waters, novel foods, food contact materials, food supplements, foodstuffs with ionising radiation treatment, foodstuffs with specific nutritional requirements bottled drinking water, foods with addition of vitamins and minerals and of certain other substances, health and nutrition claims associated with foodstuffs, iodised salt.

Other responsibilities according to the national legislation:
- control of compliance with the rules of food preparation, according to nutritional regulations in hospitals, school premises (including after-school), social assistance, school camps and premises which organize activities similar to those of school camps;
- control of compliance with the rules regarding the distribution in schools and kindergartens of dairy and bakery products and fruits (school fruits scheme program).

In 2010, the Government Decision No. 144 regarding the organization and functioning of the MH came into force. There are two structures within the MH with responsibilities in the field of food safety: HPHGD and SSI. This directorate have responsibilities in the field of nutrition and food safety.

The HCPHD issues legal acts in the field of food safety, nutrition and communicates to the public the food related risks and measures to avoid food-borne disease and co-ordinates the activity of the County Public Health Directorates. The inspectors from the CPHDs check the compliance of food products and food contact materials, the health status of the employees in food establishments, and carries out official controls to ensure compliance with public health rules at all stages of production, processing, distribution and food supply to the final consumer, according to their legal responsibilities.
While the NSVFSA and MH co-operated in the case of rapid alerts, they did not exchange their food hygiene control plans and there is the possibility that their activities could overlap or inspections could take place at the same time in a food premises. (See below in relation the April 2012 Protocol between NSVFSA and MH)

The National Authority for Consumer Protection (NACP) is responsible for labelling of foodstuffs, the conformity of food with legal requirements, for solving consumer complaints and for advertising.

MARD through the State Inspections Directorate works to ensure that food processors use recognised/suitable technologies and that the final product complies with the characteristics laid down in their product specification. This unit has two co-ordinating inspectors at the central level and 84 inspectors at the County Directorates for Agriculture (CDA) which carries out local control and authorizations. The MARD and its local units are also responsible for supervision of establishments dealing with food supplements which consist of other substances than mineral sand vitamins (such as herbs, oils and specific concentrates).

The National Agency for Mineral Resources (NAMR) is the CA with regard to the recognition of NMW sources in Romania as well as NMW imported from Third Countries (TC).

A protocol was signed by the NSVFSA, the MPH, the MARD and the NACP in July 2005, which outlines the control activities for each competent authority and designates the NSVFSA as the co-ordinating body for food safety. The purpose of the protocol is to ensure the efficient operation of the official control system and adequate co-ordination of activities between the competent authorities with responsibility for food safety. On 24th of April 2012 an updated version of the Protocol was signed by NSVFSA and MH. In addition, common working groups have been set up to deal with a number of legislative issues, with the participation of relevant CAs and other stakeholders.

The updated Protocol between NSVFSA and MH signed in April 2012 sets out the division of responsibilities for policy and for controls. NSVFSA is responsible for food hygiene controls in all establishments, except for catering in hospitals and educational institutions.

NSVFSA started the procedure to update the Protocol further, by including NACP, in the first semester of 2014.

The responsibilities of the MH included into the protocol signed in 2012 are according to the legislation on food safety.

These responsibilities are in the field of:
- food additives/flavourings/enzymes,
- natural mineral waters,
- novel foods,
- food contact materials,
- food supplements,
- foodstuffs with ionising radiation treatment,
- foodstuffs with specific nutritional requirements,
- bottled drinking water,
- foods with addition of vitamins and minerals and of certain other substances,
- health and nutrition claims associated with foodstuffs,
- iodised salt
- drinking water
- control of food preparation, according to nutritional regulations in hospitals, school premises (including after-school), social assistance, school camps and premises which organize activities similar those of school camps;
- control of hygiene and nutrition rules regarding the distribution in schools and kindergartens of dairy and bakery products and fruits (school fruits scheme program);
- control of canteens in hospitals and educational institutions, school camps, catering for school, hospitals, school camps;
- control of health status of the employees in all food establishments.

**Inter-ministerial committee**

An Inter-ministerial Committee was set up by Governmental Decision no. 194/2006. The aim of the committee is to analyse control and surveillance programmes and propose measures for control system improvements. The Secretariat is provided by NSVFSA. MARD has three representatives on the committee and also participates in the preparation of the MANCP. The Ministry of Health has 3 representatives in the Inter-ministerial Committee for supervising and official control of food and feed.

**Licensing and Registration of food premises**

Registration for direct sale of primary products, and manufacturing and retail of foodstuffs (except food sold by canteens in hospitals and educational establishments) is covered by Order no. 111/2008. Registration takes place at the CSVFSD level. At county level, the Catagraphy, Registration, Evaluation, TRACES Offices (CRETO) are primarily responsible for establishment approvals.

Producers of primary products must apply to the CSVFSDs for registration. The application is registered, and compliance with hygiene conditions is verified by an official inspector. The inspector then gives a registration number to the producer and issues a registration document.

In addition to registration (described above) food retailers must also have a certificate issued by the National Trade Registry Office (NTRO) which specifies the nature of the activity.

All food establishments, including natural mineral water sources, are subject to the control of the CPHD. The NTRO communicates an updated list of registered establishments to the unit responsible for authorisations within the CPHDs on a weekly basis. The representatives of the unit for public health control undertake on-site visits in these establishments in order to verify compliance with legal requirements. However, FBOs can start operating before the final approval is granted.

In addition to the system described above, a foodstuffs manufacturing licence is required from CDAs for food premises dealing with: milk products; meat/processed meat; fish processing and preserving and fish products; bread and bakery products; fruits and vegetable processing and preserving; oils and food vegetable fats; sugar and sugar product; beverages; starch; glucose and yeast; other food products; and packing and/or bottling food products. CDAs also issue certificates for the manufacture of traditional products, and authorisations for warehouses storing cereals that are marketed and used as raw material in foodstuffs. The manufacturing licence is issued on condition that food business operator operate in accordance with specific manufacturing and testing criteria. This license is not applicable for premises selling directly to the public. This licensing requirement does not refer to Regulation (EC) No 882/2004 and is an additional system of ensuring compliance with quality parameters in the above mentioned food establishments.
Recognition of Natural Mineral Water Sources

Requests for recognition of NMW sources must be submitted by the operator to the National Agency for Mineral Resources (NAMR). The contract between the NAMR and the operator requires that the source be monitored over 2 years at a specified frequency. All surveys required in Annex I of Directive 80/777/EC have to be conducted by companies approved by NAMR. After 2 years, the documentation is submitted to the NAMR, and assessed for granting of recognition. This procedure does not include any official sampling. However, samples taken for monitoring purposes must be performed in accredited laboratories. The National Health Programme of the MH includes NMW monitoring activities annually.

Official controls of food premises

NSVFSA

NSVFSA is the main body responsible for ensuring that HACCP and basic hygiene requirements are implemented by food establishments. The frequency of sampling and inspection is required to be risk based and in line with the National Surveillance and Control Programme for Food Safety (NSCPFS).

The Official Control on Food Safety Offices (OCFSO) are primarily responsible for performing official controls of the operators. They also have competences in controlling the activities performed by the contractual staff.

Food of non-animal origin

Since 2008 a specific risk categorisation system has been implemented within the NSVFSA using the “Guidelines regarding the assessment and classification of food establishments for which is applicable the EC Regulation 852/2004, according to risk”. Three FBO categories and inspection frequencies were established in 2008 and updated in 2013:

• Low risk – inspection every 12 months
• Medium risk – inspection every 4 months
• High risk – inspection every 2 months

Since 2008, the inspection procedures have been posted on the official web-site of NSVFSA. The inspection procedures approved by NSVFSA President Order no. 58/2008 can be used both by the representatives of CSVFSD who performs official controls.

"Mixed” establishments

For each “mixed” establishment an assessment is performed by a joint team from Catagraphy, Registration, Evaluation, TRACES Office (CRETO) in order to classify the units in “low, medium or high risk”. Otherwise official controls are organised by the OCFSO on the basis of the two approaches described above (for food of animal and non-animal origin), with co-operation between personnel from county food safety and sanitary veterinary hygiene sections.

MH - CPHDs

Starting with 2011, the MH has a biannual Public Health Programme, in order to protect human health and prevent diseases related to food risk factors. For this programme, the budget is approved annually.

The frequency of official controls for each FBO is decided at the county level of the SSI on the basis of risk assessment and according to the annual control plan.
The inspection programme is implemented according to the CPHDs control plans. The programme includes thematic actions.

Specialists from the County Public Health Control Departments carry out inspections on food hygiene, according to procedures and using standard questionnaires during an inspection visit. In cases of non-compliance they can impose fines, temporary suspension of activity, withdraw non-compliant products from the market, impose corrective measures and perform rechecks. In some cases they inform other competent authorities such as the Financial Guard.

The protocol has not changed the responsibilities of the MH, which are according to the legislation. The protocol was concluded in order to exclude the overlaps between authorities.

**MARD**

MARD issues certificates for traditional products and authorisations for cereals storage.

**Co-ordination of controls**

Each competent authority has its own control programme, issued on an annual and three monthly basis, integrated into MANCP and approved by Interministerial Committee. As a consequence of the parallel control systems, an establishment could be visited a number of times each year by one or more control bodies (i.e. from the NSVFSA, DCPH or NACP) but the scope of the official control depends on their range of activities. In some cases joint activities are planned at CA and Government level. Control activity results are discussed and analysed in the inter-ministerial committee.

**HACCP**

An FSNAOD survey in 2013 of establishments for food of non-animal origin showed that 27% have fully implemented a system (some certified), 24% are in the process of implementation and 49% have a prerequisite programme.

**Good Hygiene Practice Guides**

Seventeen guides to Good Hygiene Practice (GHP) have been developed by industry and approved by the NSVFSA for: the bakery industry; the pastry and confectionery industry; the vegetable and fruit canning industry; the milling industry (both wheat and maize); storing seeds for consumption; the meat industry; the malt and beer industry; the sugar industry; public food services; and for redraw/recall of foodstuffs as follows:

1. Guide on Good Hygiene and Manufacturing Practices in milk and dairy products industry;
2. Guide on Good Hygiene Practices for red meat and meat products establishments;
3. Guide for handling of wild game at primary production level;
5. Guide of Good hygiene practices in bakery (ROMPAN);
6. Guide of Good practice for food safety – food safety management – Bakery industry (ANAMOB);
10. Guide of Good practices for food safety - HACCP - Food safety system for pastry and confectionary products (ROMPAN);
11. Guide of Good practices for food safety - HACCP - Food safety system for pastry and confectionary products (ANAMOB);
13. Guide of Good practice in Malt and Beer Industry;
14. Guide of Good hygiene practices in sugar industry;
15. Guide of Good hygiene practices in the Industry of canned fruit and vegetables;

Rapid Alert System for Food and Feed

National Sanitary Veterinary and Food Safety Authority (NSVFSA) is the national co-ordinator and contact point for the European Commission for the Rapid Alert System for Food and Feed. The current legal basis for the system is represented by European legislation: Regulation (EC) 178/2002 and Regulation (EC) 16/2011 and also by national legislation: Law no. 150/2004 regarding Food and Feed Safety, representing the transposition of the Regulation no. 178/2002 and Common Order No. 772/68/859/442/2005 of the minister of Agriculture, Forests and Rural Development, of the president of the National Sanitary Veterinary and Food Safety Authority, of the minister of Health and of the president of the National Authority of Consumers’ Protection for approving the norm for the rapid alert system for food and feed. In this Governmental Order the institutions involved in food and feed safety (National Sanitary Veterinary and Food Safety Authority, Ministry of Agriculture and Rural Development, Ministry of Health and National Authority of Consumers’ Protection), at central and local level, are organised as a network, in the coordination of the NSVFSA. All authorities involved in safety of food and feed have contact points at central and local level and also there are contact points for RASFF in Border Inspection Post (BIP) within NSVFSA.

Laboratory services

Now, 40 county veterinary state laboratories and the Bucharest municipality laboratory (within the NSVFSA) perform analyses in the field of public health (5 are not accredited). Under Law 151/1998 rationalisation took place and 8 regions were established and 16 laboratories identified for external financing through SAPARD. Both the NSVFSA and MH state that those laboratories which will not have been accredited by 2010, cannot perform analyses for official control. At this time there are 1208 accredited methods in the food safety domain in the county veterinary state laboratories and 107 accredited methods for IHVPH.

Bucharest Laboratory was accredited first, in April 2007. Surveillance and extension audit (extension for pesticides, mycotoxins, food additives, contaminants, nitrates and illegal dyes). There are 41 laboratories in the field of food safety for products of non-animal origin, accredited ISO CEI 17025. Irradiated food is analysed only at the Institute for Hygiene and Veterinary Public Health.

For radioactivity control of foods there are 15 laboratories.

Control laboratories and accredited methods

Within the network of laboratories belonging to the Ministry of Health there are 25 laboratories with ISO 17025 accredited by RENAR (23 labs belong to the CPHD and 2 labs belongs to the National Public Health Institute).

The Laboratory of Environmental Chemistry and Microbiology and Food of the Public Health Bucharest Regional Center - National Institute of Public Health - was designated in 2011 as the National Reference Laboratory for food contact materials.
None of the laboratories of MARD or NACP perform laboratory tests for official controls in relation to food hygiene.

**GMOs**

**Competent Authorities**

NSVFSA is the CA for GMO controls regarding food and feed including import controls, being responsible for the official controls of traceability and the labelling of GM food (excluding the retail level) and feed. NACP (National Authority for Consumer Protection) is responsible for official control on GM food labelling at retail level.

MARD is responsible for GMO controls of seed, GM maize MON810 cultivation, GMO controls in soybean cultivation and GMO trials and for the maintenance of official registration of transgenic varieties. Order 61/2012 of MARD regulates the cultivation of GM crops; GM maize MON810 is cultivated.

NEPA (The National Environment Protection Agency) acting under the MECC (Ministry of Environment and Climate Change) is the CA for the deliberate release of GMOs into the environment.

NEPA is the Competent Authority under EU Directive 2001/18/EC. In the decision-making process, NEPA consults the Biosafety Commission, takes into consideration the Risk Assessment and the emergency plans, submitted by the notifiers, co-operates with the Ministry of Agriculture and Rural Development (MARD), and ensures public information and participation.

NEG (National Environment Guard), also under MECC, is responsible for controls of GMO trials and GMO cultivation together with MARD.

NEPA manages a register, accessible to the public via the internet, of the notifications received and rejected by them and the authorisations issued for GMO trials.

NEPA keeps and ensures the functioning of the National Register on locations of the release of genetically modified organisms, according to the Ministerial Order 1205/2009 on the functioning of the National Register regarding the locations of the release into environment of genetically modified organisms. The Register is a database providing annual records on the locations of the release into the environment of genetically modified organisms and contains two sections:

Section 1: data on the locations for the deliberate release into the environment, for testing genetically modified organisms (Field trials - Part B of the Directive 2001/18/EC)

Section 2: data on the locations for deliberate release into the environment, for commercial cultivation of the genetically modified higher plants (Part C of the Directive 2001/18/EC).

A Protocol of Cooperation (Nr 3090/12.07.2006) exists between NSVFSA, the National Authority for Consumers Protection (NACP), MARD and NEG regarding collaboration in the field of official control for GM food, feed and seeds, which includes the division of responsibilities in the entire GM food, feed and seed chain.

**Laboratories**

The Molecular Biology Laboratory of IDAH is designated by NSVFSA as the NRL for GM food and feed. It is accredited by RENAR in accordance with ISO 17025 and the scope of the accreditation covers GMO analysis. The laboratory carries out analysis of official and private samples. Official controls of GM food and feed are performed by IDAH (NRL) and 7 county laboratories (Calarasi, Constanta, Iasi, Satu-Mare, Salaj, Suceava, Tulcea).
MARD took the decision to develop and accredit by RENAR the lab for GMO’s testing of the Central Laboratory for the Quality of Seeds and Propagating Material (which is an ISTA accredited laboratory for seeds testing) and during the process of accreditation the lab will accomplish all the recommendations made by the FVO. This laboratory has, in 2013, acquired all the necessary equipment for PCR techniques. In the present the Lab is fully functional. This summer took place the entire process of national accreditation of two methods of GM maize and soybean detection included in Compendium of EUR-L-GMFF.
2.8 Control system for imports of food of plant origin

NSVSFA – National Sanitary Veterinary and Food Safety Authority
GDOC – General Directorate for Official Control
IETBIPsD – Import, Export, Trade and BIPs Directorate
IOCD – Inspection and Control Official Directorate
IECBIPsC – Import-Export Compartment and BIPs Control
BIPs Service – Border Inspection Post Service
BIPs – Border Inspection Posts
FSAOD – Food Safety of Animal Origin Directorate
CSVFSDs – County Sanitary Veterinary and Food Safety Directorates
AD – Audit Directorate
NCA – National Customs Authority
Competent authorities

Within NSVFSA, the General Directorate for Official Control (GDOC) is responsible for import controls of foodstuffs of plant origin. The Import, Export, Compartment BIPs (IECBIPs) draws up specific guidelines and legislation regarding import controls, collects results of the official controls from Entry Points, Designated Import Points and Designated Point of Entry and organises training.

NSVFSA Order No. 145/2007, as amended, establishes national procedures on import, export and transit for monitoring and surveillance of foodstuffs of non-animal from third country origin. This order covers all food of non-animal origin using the TARIC codes.

The GDOC is responsible for the co-ordination of Entry Points, Designated Import Points and Designated Point of Entry staff and includes inspectors carrying out official control of foodstuffs of non-animal origin. One or two inspectors deal with import controls on foodstuff of plant origin at each Entry Points, Designated Import Points and Designated Point of Entry.

There are 8 Designated Point of Entry (DPE) responsible to check imports of food of non-animal origin under Regulation 669/2009 and certain foods of non-animal origin under special conditions for import according with EU legislation. In accordance with Regulation no. 1152/2009 are designated 9 DIP (designated import points), including DIP Giurgiu.

Governmental Decision no 144/2010 designates the MH as national competent authority for FCM including at the border crossing points. The MH/ Order no 1224/2011 establishes the measures for implementing Regulation 284/2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People’s Republic of China and Hong Kong Special Administrative Region, China.

Import Controls procedures

Importers of foodstuffs of non-animal origin from third countries have to complete part A of the "Entry Document for Foodstuff of Non-animal Origin" for each consignment according to NSVFSA President Order no. 145/2007. The information provided has to include: the name of the imported product; the country origin; the customs tariff code; the warehouse of destination; and a declaration on GMO presence.

The NSVFSA inspectors from Entry Points perform documentary, identity, physical control checks and sampling and complete part B of the Entry Document for Foodstuff of Non-animal origin. This document is forwarded to Food Safety Departments within the County Sanitary Veterinary and Food Safety Directorates at the warehouse of destination.

The inspectors from County Sanitary Veterinary and Food Safety Directorates carry out controls at import only if the consignments of foodstuff of non-animal origin from third countries, with Romania destination enter on EU territory through another MS point of entry.

Co-operation with the customs authority

A protocol has been signed between the NSVFSA and the Customs National Border Agency (NBA) at central level. It makes reference to co-operation between NSVFSA inspectors and Custom officials operating at points of import. Foodstuffs of non-animal origin are also included in the “tariff list” used by the Customs.

A periodical Working Group takes place between NSVFSA and Customs' National Border Agency to update import measures in the TARIC-RO database, according with new EU legislation.
It was prepared a draft Common Order of NSVFSA and National Custom Authority for establishing conditions on Import, Export, Transit and Intra-Community Trade of food of non-animal origin. For preparing of this draft order its have been taken into account by the procedures on Import, Export and Intra-Community trade provided by the NSVFSA Order no.145/2007. The draft Common Order includes the new provisions on re-import and small quantities of food of non-animal origin imported.

The draft Common Order has not been approved yet

**Laboratories**

The Sanitary Veterinary and Food Safety Laboratory Bucharest co-ordinates the activities of the CSVFSLs in the field of food safety for products of non-animal origin. The Laboratory is National Reference Laboratories, in four fields (mycotoxins, heavy metals, pesticides, dioxins) accredited to ISO/CEI 17025:2005. Bucharest SVFSL is the only laboratory which analyses pesticides samples of non-animal origin from imports. During 2014 - 2015 Bucharest SVFSL intends to accredit dioxins method for meat and vegetable oil.

The Sanitary Veterinary and Food Safety Laboratory Bucharest is nominated NRL by NSVFSA Order No. 205/2007 for mycotoxins, heavy metal, pesticides in nonanimal products and dioxins.

SVFSL-NRL Mycotoxins-Bucharest meets the requirements according to article 33 of Regulation (EC) No 882/2004.

For official control in nonanimal products for mycotoxins 15 laboratories are involved, all labs are accredited ISO/CEI 17025:2005 by National Accreditation Body –RENAR.

All mycotoxins in nonanimal products provided in Commission Regulation (EC) No 1881/2006 are analysed.

SVFSL Bucharest developed a multitoxins method for deoxynavalenol, zearalenone, T2 toxin and HT2 Toxin using LC-MS/MS technique.
2.9 Control system for plant protection products (PPP) and residues

Authorization of PPPs

CPL

Regional Labs

MECC

Obsolete pesticide controls

CPL

Residues Reporting

Regional Labs (2)

Residues control

CPL

Residues control

National pesticide residues control programme

CPL

Reporting Analyses of PPPs Co-ordination

Reporting

Prepare

42 CPUs

- Marketing & use controls
- Sanctions
- Fines
- Information to distributors & farmer

- Residues control (plants plant products)

CSVFSLs

Imported plant products

MECC

PPPs Quality programme

Prepare

MECC county level units

CPL (LQCP)

CPL (LPRCPPP)

MARD

NPA

NSVFSA FSNAOD

MH

General Directorate of Public Health, Medical Assistance and Programs

Ministry of Agriculture and Rural Development

Ministry of Environment and Climate Change

Ministry of Health

National Environmental Guard

National Phytosanitary Agency

National Sanitary Veterinary and Food Safety Authority

Plant Protection Products Registration

Food Safety of Non-animal Origin Directorate

Central Phytosanitary Laboratory

Laboratory for Pesticides Residues Control in Plants and Plant Products

Laboratory for Quality Control of Pesticides

County Phytosanitary Unit

County Sanitary Veterinary and Food Safety Laboratory

General Directorate of Public Health, Medical Assistance and Programs

Ministry of Agriculture and Rural Development

Ministry of Environment and Climate Change

Ministry of Health

National Environmental Guard

National Phytosanitary Agency

National Sanitary Veterinary and Food Safety Authority

Plant Protection Products Registration

Food Safety of Non-animal Origin Directorate
Plant Protection Products

Authorisation and registration of PPPs

The competent authorities involved in the authorisation procedure for PPPs are MARD, MH and the Ministry of Environment and Climate Change (MECC) through NEPA.

The National Commission for Registration of Plant Protection Products is responsible for the authorisation of PPPs. The Commission is chaired by MARD and includes representatives from the competent authorities involved in PPP issues as well as representatives from the Academy of Agriculture and Forestry Science and the Central Phytosanitary Laboratory (CPL).

Government Decision 1559/2004 provides provisions for the registration of PPPs including packaging and labelling. Under Law no. 37/2006, the NPA is responsible for plant protection and quarantine, and for registration of PPPs.

Official controls on marketing/use

The National Phytosanitary Agency (NPA) within MARD controls the marketing and use of PPPs through the 42 County Phytosanitary Units and has direct authority over the Central Phytosanitary Laboratory (CPL).

There is an annual control plan in place to ensure the correct use of authorised PPPs. Procedures drawn up by the NPA are used for carrying out inspections throughout the distribution chain and at farm level. The procedures describe how inspections should be performed (documentary checks, authorisation for marketing and use, presence of unauthorised substances, labelling and packaging, storage, and sampling), the method of reporting and application of sanctions (e.g. seizure of products, administrative measures and fines).

The number of inspections to be carried out monthly is established at County Phytosanitary Unit (CPU) level, based on the number of operators authorised for marketing and/or use of PPPs, the users and the results of inspections performed in previous years. Each county sends the annual plan to the NPA for information and provides monthly activity reports to the central authorities where it is checked to ensure that controls are carried out in accordance with the plans. The CPUs are also in charge of keeping a register for users authorised to apply toxic (T) and high toxic (T+) PPPs. CPL reports the results of analyses quarterly and annually to the NPA.

Specific national provisions on the marketing and use of PPPs, including sanctions in case of non-compliance are laid down in Government Ordinance no. 41/2007 and Government Ordinance no.4/1995 and Government Decision No. 1230/2012.

Residues

The NPA and the NSVFSA are joint competent authorities for the control of pesticide residues in food of non-animal origin.

NSVFSA coordinates the preparation of the national pesticide residues control programme for food of plant and animal origin and baby food.

NSVFSA is responsible for the controls on pesticide residues in and on food of plant origin originating from other Member States (MS) and third countries (TCs).

NPA is responsible for the control of pesticide residues in and on domestically produced food of plant origin. The controls are carried out by the County Phytosanitary Units (CPUs) within the Counties Directorates for Agriculture (CDA)
MH is the competent authority for the monitoring and control of pesticide residues in foods produced for specific nutritional purposes (e.g. baby food).


Official controls on residues

An annual national control programme for pesticide residues is in place. NSVFSA compiles the individual control programmes into a national multi-annual control programme for pesticide residues (MANCP-PR) which is discussed and approved by the interministerial working group (IMWG). In September 2011, the first MANCP-PR was established and submitted to EFSA and covers the period 2012-2014. It is made up of the individual programmes of the CAs involved in the sampling of foodstuffs of plant origin for pesticide residues.

The programme contains information on the responsibilities of the CAs and laboratories involved in the official controls for pesticide residues, the analytical scope of accredited methods, criteria for the selection of consignments, the products to be sampled and the planned number of samples.

Each CA applies the criteria referred to in the MANCP-PR relevant to its area of responsibility. The NSVFSA takes trade data into account as well as information on non-compliances and consignments with a higher risk of containing pesticide residues. The draft control programme of MARD is prepared by the CPL and takes into account, in particular, data on agricultural production, past history of FBOs, requirements of the EU coordinated multi-annual control programme as well as the number of inhabitants in the counties. CPL also prepares individual control plans for each county taking information from local inspectors into account (e.g. changes in the production).

Samples to be taken for the EU coordinated multi-annual control programme are an integrated part of the national programme. Both NSVFSA and MARD each take at least the minimum number of samples as required in Annex II of Commission Regulation (EU) No 915/2010.

Overlaps between the CAs with regards to the establishments where samples are taken have been reduced, as the CPUs focus on warehouses of producers and the CSVFSD inspectors on warehouses of traders (for produce originating from other MSs or TCs).

The Ministry of Health organises controls of pesticide residues in food products for specific nutritional purposes, including baby food. Two Regional Centres for Public Health (RCPH) carry out laboratory analysis of the respective food samples taken by the County Public Health Departments (CPHD).

Obsolete pesticides

Controls on obsolete pesticides are coordinated by the Ministry of Environment and Climate Change (MECC) and carried out jointly by commissioners of NEG at county level together with representatives of CPU inspectors and the police units.

Prior to accession, 2516 tons of obsolete pesticides stored in 218 sites in Romania were collected and repackaged during two phases of the Phare project “Collection, repackaging, transporting and destruction of pesticide residues from the territory of Romania” managed by the NPA during the periods December 2004 – November 2005, and March 2006 – November 2006. The entire quantity was transported to and destroyed in an incinerating facility for hazardous waste in Germany.
Laboratories

PPPs:

The national monitoring program for the quality of PPPs is elaborated by CPL, in co-operation with MARD, and approved by MARD.

The Laboratory for Quality Control of Pesticides – Central Phytosanitary Laboratory (LQCP-CPL) together with four laboratories within the County Phytosanitary Units (Arad, Olt, Bacau and Mures) participate in this program and submit reports on a quarterly and annually basis to MARD. CPL co-ordinates from technical point of view the monitoring activity of these laboratories for quality control of PPPs. LQCP is accredited to EN/ISO/17025 since 2008, reaccredited in 2013.

Residues:

Romania has two designated NRLs for analysis of pesticide residues in and on food of plant origin - the CLPRCPPP (co-ordinated by the NPA) and the Bucharest SVFSL within NSVFSA. Both are accredited to EN/ISO 17025.

An NSVFSA service note of May 2011 reduced the number of NSVFSA laboratories for official pesticide residue analysis to two: the Sanitary Veterinary and Food Safety Laboratories (SVFSL) Bucharest, which is one of the two national reference laboratories (NRL) for fruits and vegetables, and the CSVFSL of Iasi. Three CSVFSDs send their fruit and vegetable samples to the CSVFSL Iasi and the remainder to the Bucharest SVFSL.

Starting 2014, only Bucharest laboratory is accredited according with ISO 17025 for analysis of pesticide residues, laboratory from Iasi will be reaccredited according with ISO 17025, in the first trimester of next year. All samples of non animal origin are analyzed in Bucharest SVFSL.

Within MARD-NPA, the LPRCPPP in Bucharest together with the two regional laboratories in Târgu Mureș and Dolj is responsible for the analysis of pesticide residues in fruit, vegetables and cereals samples taken by CPU inspectors.

Within the MH network there is one laboratory which performs analysis of pesticide residues in baby food (Cluj Napoca). This laboratory is accredited.
2.10 Control system for animal welfare

NSVSFA    National Sanitary Veterinary and Food Safety Authority
GSVFSD    General Sanitary Veterinary and Food Safety Directorate
GDOC      General Directorate for Official Control
AWS       Animal Welfare Service
APS       Animal Police Service
APC       Animal Police Compartment
CRETO     Catagraphy, Registration, Evaluation, TRACES Office
CSVFSD    County Sanitary Veterinary and Food Safety Directorates
BIPs Service Border Inspection Posts Service
AD        Audit Directorate
EC        European Commission
MIA       Ministry of Internal Affairs
SIRTC     State Inspectorate for Road Transport Control
Competent authorities

The Animal Welfare Service (AWS) within the General Sanitary Veterinary and Food Safety Directorate (GSVFSD) of NSVFSA is responsible for animal welfare.

The animal welfare service was established by the Governmental Decision no. 701/2014 for modification and completion of the Governmental Decision no. 1415/2009 on the organization and functioning of NSVFSA and the units under its subordination.

The Animal welfare service has a Head of office.

The Animal Welfare Service is responsible for regulation, training programs, developing inspection sheets and guides.

Starting with 2014, the official control of animal welfare is the responsibility of the General Directorate for Official Control (GDOC) – Animal Police Service. At local level, official controls on animal welfare are carried out by the Animal Police Compartment. Within the Animal Police Compartment, there is at least one official veterinarian with control responsibilities for animal welfare. The National Inspection Programme for 2015 was drawn up and sent to the CSVFSD through Service Note 5677/26.02.2015.

At local level, the competent department for evaluation and authorization of establishments, transporters and means of transport is the Catagraphy, Registration, Evaluation, TRACES Service.

One training in animal welfare field took place in 2014 and two training sessions are planned for 2015, according to the Annual Training Programme.

Official controls on farm

Inspections take place on the basis of a National Inspection Programme prepared by GSVFSD.

NSVFSA has drawn up check lists for farm animals, laying hens, broilers, calves, pigs (one for commercial holding, one for backyards). All these checklists are available on NSVFSA website at: http://www.ansvsa.ro/?pag=792.

Those checklists were sent through service note no. 4449/30.12.2011, and they started to be used in inspections beginning with 2012. The checklists for protection of animals during slaughtering/killing were updated in 2014.

We mention that the NSVFSA communicates annually to the European Commission the controls performed in the field of protection of farmed animals and protection of animals during transport.
2.11 Control system for plant health

- Managing and issuing plant passports for propagating material which is certificated

- Plant health controls
- Survey
- Certification

Warning systems
- Registration of producers
- Preparing and issuing plant passports

Co-ordination

42 CPUs

NIQS

NPA (PPPQS)

Training Procedures
Plant health
Co-ordination Guidance
Training

Co-ordination

Regional labs (4)

CPL

Co-ordination

BIPs (9)

Competent authorities

The CA is the National Phytosanitary Agency (NPA) within MARD (according to Article 1(4) of Council Directive 2000/29/EC). The NPA, with the County Phytosanitary Units (CPUs), laboratories and Border Inspection Posts (BIPs), is also the official body responsible for implementing national plant health legislation, as provided for in Article 2(g) of Directive 2000/29/EC.

According to Law no. 37/2006, the National Phytosanitary Agency (NPA) has tasks in plant protection and phytosanitary quarantine, registration and controls the marketing and use of PPPs through the 42 County Phytosanitary Units:

CPL Central Phytosanitary Laboratory
CPU County Phytosanitary Unit
MARD Ministry of Agriculture and Rural Development
NIQS National Inspection for Quality of Seeds
NPA National Phytosanitary Agency
PPPQS Plant Protection and Phytosanitary Quarantine Service
BIPs Border Inspection Posts
The NPA’s main tasks and responsibilities for harmful organisms (HOs) include:

- legislation, organisation and co-ordination guidance of CPU’s and staff training;
- promotion and co-ordination of a plant health quality system;
- co-ordination of the plant passport system and internal market checks;
- providing databases and statistics for their main activities: monitoring the import, export and transit of plants and plant products, monitoring pests as part of territorial surveillance;
- maintaining and updating the "Fitoexpert" database;
- EU and international relation providing technical notifications to the Commission and the other Member States (Europhyt database);
- participation in meetings of the Standing Committee on Plant Health.

The CPUs are located in the main towns of each of the 42 counties with responsibilities for:

- implementation of national legislation including, registration of procedures; the issuing plant passports; export certifications; and managing the warning system in Plant protection;
- implementation of the quality assurance system;
- planning and conducting inspections at places of production, and national surveys and sampling plants and plant products according to the monitoring programmes;
- organise training (practical and theoretical) for agricultural producers, on plant protection and phytosanitary quarantine activities and the update of the "Fitoexpert" database system, which is managing import, export activities and registration of producers, issue of plant passports.

The plant passport system is implemented by NPA through the CPUs, BIPs and by the National Inspection for Quality of Seeds (NIQS). Plant passports are issued only by these three bodies. NIQS is also responsible for managing and issuing official labels with mention plant passports for certified seed and propagating material through the Territorial Inspectorates for Quality Seed and Propagating Material.

The inspection procedures developed by the NPA and implemented by CPUs and BIPs are available on the website www.madr.ro, at phytosanitary section.

Import controls
The 9 BIPs responsible for checks on imported commodities are administratively attached to the Phytosanitary Quarantine Laboratory within Central Phytosanitary Laboratory (CPL) but their work is co-ordinated by the National Phytosanitary Agency.

Laboratory services
The Central Phytosanitary Laboratory (CPL) performs diagnoses for harmful organisms and supervises the county plant quarantine laboratories. It also co-ordinates the administrative activities of the 9 BIPs and provides training to improve analyses from the regional laboratories. The CPL is the National Reference Laboratory for detection and diagnosis of harmful organisms, accredited by RENAR to SR EN ISO/CEI 17025/2005 for the following methods:

- detection of quarantine bacteria Ralstonia solanacearum and/or Clavibacter michiganensis ssp. sepedonicus on potato tubers by immunofluorescence;
- Plum pox virus;
- detection and morphological identification of Globodera pallida and Globodera rostochiensis.
- serological tests by Elisa for Pepino mosaic virus;
- detection of quarantine bacteria Xanthomonas campestris pv. vesicatoria and/or Clavibacter michiganensis ssp.michiganensis by immunofluorescence;
- detection of Momilinia fructicola by isolation on culture media;
- detection of Clavibacter michiganensis ssp. sepedonicus by PCR multiplex.
2.12 Control system for quality labelling

Organic production

Competent authorities

MARD is the Central Competent Authority in the field of organic farming, according to Emergency Ordinance No 34 of 17 April 2000.

Within the MARD, the General Directorate for Agricultural Policies and Strategies (DGPAS) - Department for Organic Farming and Processed Products - is responsible for:

- Approval of Control Bodies (CB);
- On-site audits of approved CBs;
- Managing the seed database.

The responsibility for allowing the use of seeds and vegetative propagating materials not obtained by organic production methods according to Article 45 of Regulation (EC) No 889/2008 has been delegated to the CBs.

Within MARD, the Directorate for State Inspections (Directia Inspectii de Stat – DSI) - Department of Technical Inspections in Organic Farming – is responsible for the control and supervision of CBs, on the basis of an annual control programme approved by the Minister. This Department along with the DGPAS monitors and centralises the statistical data reported by the CBs.

Both the DGPAS and the DSI are represented in the County Directorates for Agriculture (County Directorates for Agriculture - DAJ) in the 41 County Offices and the Municipality of Bucharest. The DAJs are in charge of annual registration of organic operators, of verifying the performance of the CBs by inspecting a random sample of operators (monthly activity reports are sent to MARD) and for the control on the full chain in organic farming, including market controls at retail level.

RENAR is responsible for accreditation of CBs according to ISO/EN 45011.

Accreditation is granted by RENAR for six specific classes of activities:

1. plant and products derived thereof;
2. seaweed and products derived thereof,
3. animals and products derived thereof,
4. aquaculture animals and products derived thereof,
5. processed foodstuffs; and
6. feedstuffs.

During annual audits, which are included in the four year accreditation cycle, RENAR may exclude some activities from the scope of accreditation if the conditions are no longer complied with.
In order to allow newly established CBs to be approved by the CCA, RENAR has established a specific procedure for granting a “conditional accreditation” valid for two years; this “conditional accreditation” allows RENAR to evaluate, with a witness assessment, the competency of the CB when starting its activity in the absence of clients. If within two years the CB has no organic operators under contract or if the witness assessment has had negative results, the “conditional accreditation” is withdrawn.

Other CAs with limited control responsibilities in the organic farming sector are:

- **NSVFSA** – is responsible for the controls on imported organic products introduced into national territory through the designated BIPs;

- **NACP** – which controls compliance of products with legal provisions by conducting market controls and by sanctioning offences; it also collects samples of foodstuffs for analyses and the verification of labelling requirements. In accordance with the collaboration protocol no. 4511/8793/1851/407/2005 signed with the MARD, the Ministry of Health and NSVFSA, the NACP carries out market controls under the MANCP. When Governmental Decision No 131/2013 will enter into force, however, the NACP will no longer carry out specific controls on organic products, but will continue to perform routine controls at retail level, except the control of the fraudulent use of terms “organic”, “ecologic” and “biologic”.

According to the Governmental Decision No 131/2013, MADR performing controls and applying penalties to the operators from the organic farming system.

Also, since the entering into force of the Ordinance No. 29/2014 which amending the art. 6 alin. (2) of the Government Emergency Ordinance no. 34/2000 regarding the organic food, MADR performing controls and applying financial penalties to the operators from the organic farming system.

- **APIA** (Agency for Payments and Intervention in Agriculture) – which is entitled to carry out checks on-the-spot on at least 5% of farmers who have applied for direct support schemes and who are registered as organic producers.

**Control Bodies (CB)**

The inspection and certification activities in the organic farming sector are carried out by CBs, approved annually by the MARD.

The procedure for approval, supervision and withdrawal of approval of CBs is provided by the MARD Order No 181/2012.

One of the CB approval prerequisites is accreditation according to ISO/EN 45011 granted by RENAR or another equivalent Accreditation Body established within the EU.

In August 2014, 13 CBs had been approved by MARD. The list of approved CBs is published annually on the MARD web-site, at [http://www.madr.ro/ro/agricultura-ecologica/organisme-de-inspectie-si-certificare.html](http://www.madr.ro/ro/agricultura-ecologica/organisme-de-inspectie-si-certificare.html)
ANNEX I – STAFF RESOURCES

Number of Control Staff in Romania

Summary Table

<table>
<thead>
<tr>
<th>Competent Authority</th>
<th>Staff</th>
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<td>County Sanitary Veterinary and Food Safety Directorates</td>
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<tr>
<td>Institute for Control of Veterinary Biological Products and Medicines</td>
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<td>Institute for Diagnosis and Animal Health</td>
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<tr>
<td>Institute for Hygiene and Veterinary Public Health</td>
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</tr>
<tr>
<td>Empowered veterinarian (contractual veterinarian authorized for certain official activities)</td>
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<p>| <strong>Ministry of Agriculture and Rural Development</strong> | |
| Central level: | |
| - National Phytosanitary Agency (NPA) – plant health | 4 |
| - Central Phytosanitary Laboratory (CPL) | |
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<td>Multi-Residue Method</td>
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<td>RAC</td>
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<td>RASFF</td>
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<td>TSG</td>
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<td>TSE</td>
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