Government of Montenegro

Ministry of Agriculture, Forestry and Water Management

Questionnaire

Information requested by the European Commission to the Government of Montenegro for the preparation of the Opinion on the application of Montenegro for membership of the European Union

12 Food safety, veterinary and phytosanitary policy

Minister: Milutin Simovic

Podgorica, December 2009

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CHAPTERS OF THE ACQUIS – ABILITY TO ASSUME THE OBLIGATIONS OF MEMBERSHIP

Chapter 12: Food safety, veterinary and phytosanitary policy

I. GENERAL

Note: List of regulations from the field of food safety, veterinary and phytosanitary policy submitted to the European Commission for the Sub-Committee on Agriculture and Fisheries which was held in Podgorica on April 16, 2008 and for the Sub-Committee on Agriculture and Fisheries held on March 26, 2009 in Brussels.

Document sent **EC-MONTENEGRO SUB-COMMITTEE AND SECTORAL EPD MEETING** **ON AGRICULTURE AND FISHERIES** **Podgorica, April 16th, 2008**	**Document sent** **EC-MONTENEGRO SUB-COMMITTEE AND SECTORAL EPD MEETING** **ON AGRICULTURE AND FISHERIES** **Brussels, March 26th, 2009**
Animal Welfare Law	Law on Planting Material
Food safety law	Law on Plant Protection Products
	Law on the Agricultural Plant Seeds
	Amendments of Law on plant varieties protection
	Law on Plant Health Protection
	Law on Ratification of International Plant Protection Convection
	Veterinary Law
	Law for the Identification and Registration of Animals
	Table of Concordance for Law for the Identification and Registration of Animals
	Operational Program on Animal Health Protection for 2009

1. Please provide flowcharts/organigrammes outlining levels of competencies and showing management lines to describe the structure and organisation of the services in charge of food safety veterinary and phytosanitary policy. The division of competencies and the links between central, regional and local level should appear clearly (degree of decentralisation/devolution of competence should be defined).

Flow chart diagram - levels of competencies - management lines of services in charge of food safety, veterinary and phytosanitary policies

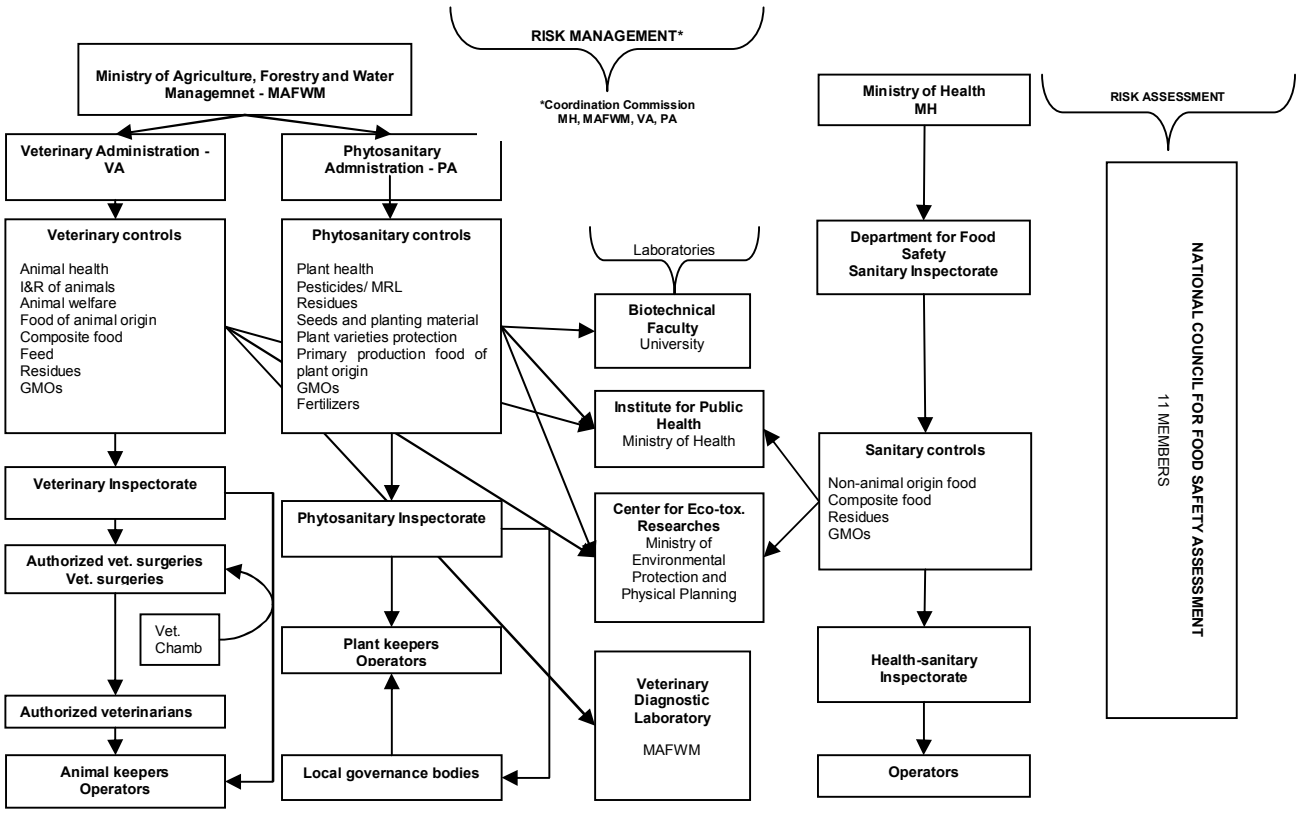

RISK MANAGEMENT*
*Coordination Commission MH, MAFWM, VA, PA
Ministry of Agriculture, Forestry and Water Managemnet - MAFWM
Veterinary Administration - VA
Phytosanitary Admnistration - PA
Veterinary controls
Animal health
I&R of animals
Animal welfare
Food of animal origin
Composite food
Feed
Residues
GMOs
Phytosanitary controls
Plant health
Pesticides/ MRL
Residues
Seeds and planting material
Plant varieties protection
Primary production food of plant origin
GMOs
Fertilizers
Laboratories
Biotechnical Faculty
University
Institute for Public Health
Ministry of Health
Center for Eco-tox. Researches
Ministry of Environmental Protection and Physical Planning
Veterinary Diagnostic Laboratory
MAFWM
Veterinary Inspectorate
Authorized vet. surgeries
Vet. surgeries
Vet. Chamb
Authorized veterinarians
Animal keepers
Operators
Phytosanitary Inspectorate
Plant keepers
Operators
Local governance bodies
Ministry of Health
MH
Department for Food Safety
Sanitary Inspectorate
Sanitary controls
Non-animal origin food
Composite food
Residues
GMOs
Health-sanitary Inspectorate
Operators
RISK ASSESSMENT
NATIONAL COUNCIL FOR FOOD SAFETY ASSESSMENT
11 MEMBERS

Chart flow diagram – levels of competencies - management lines of services in charge of veterinary policy

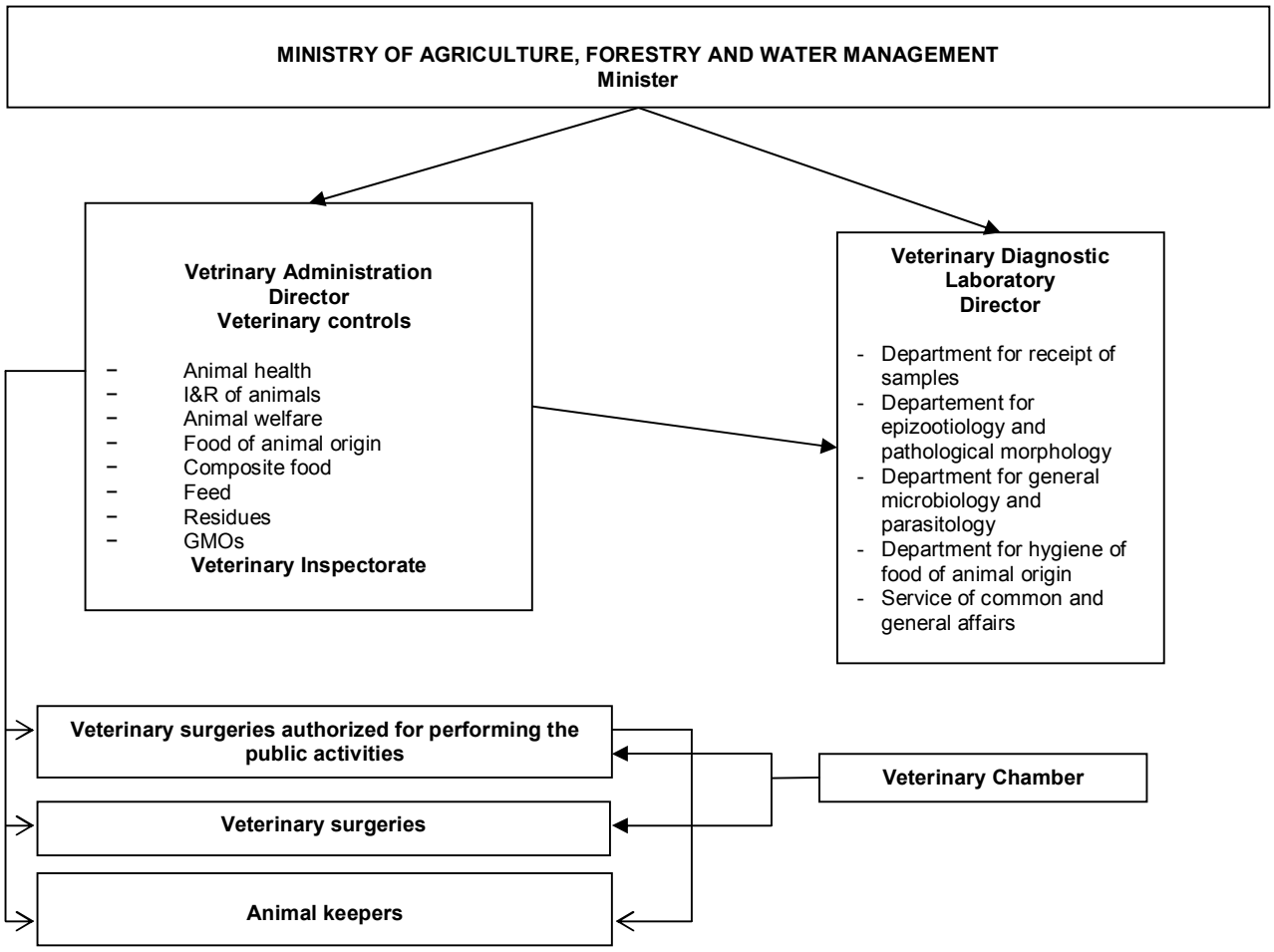
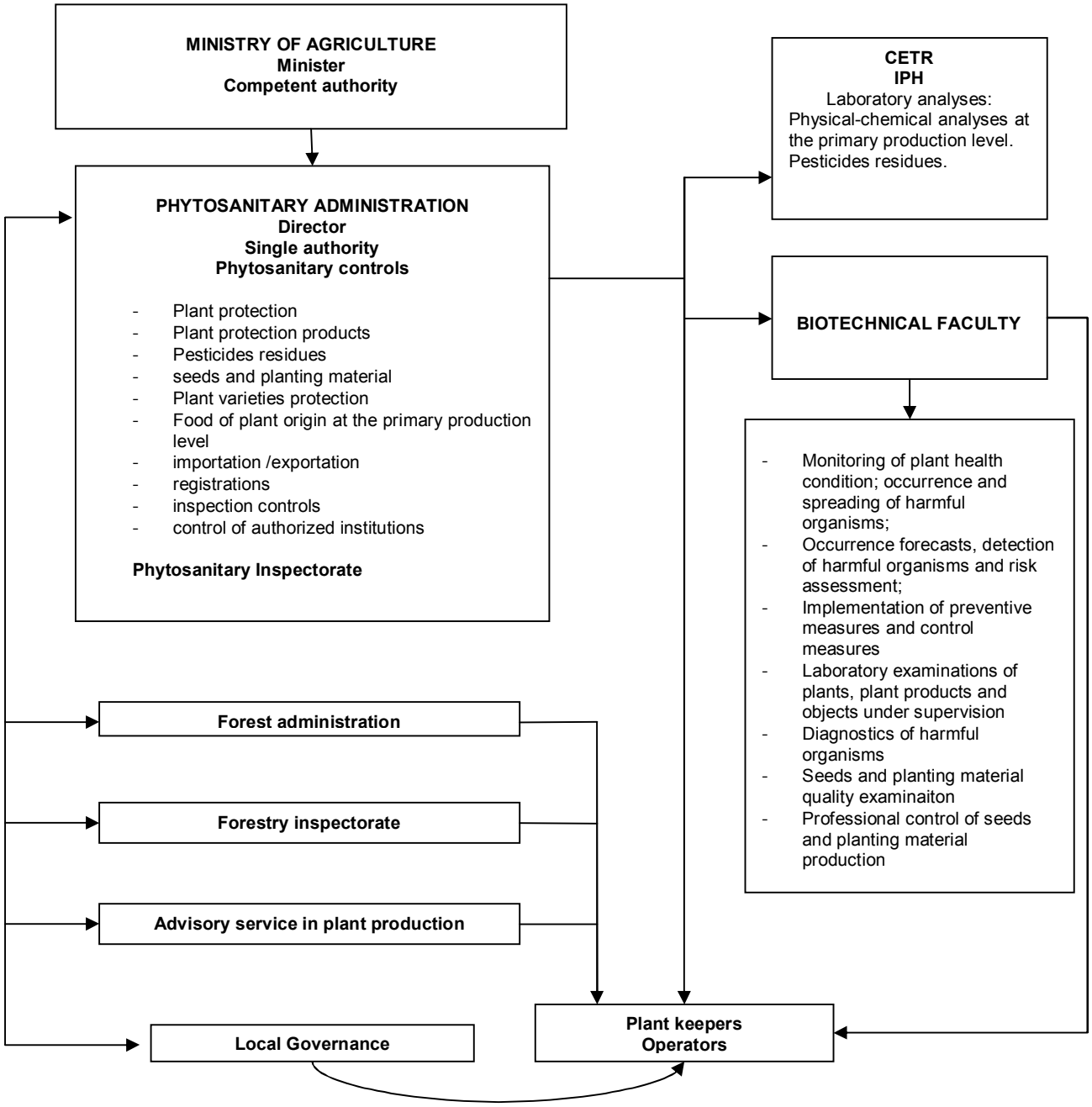


Chart flow diagram - levels of competencies - management lines of services in charge of phytosanitary policy*



*All institutions in charge of the phytosanitary field are at the central level, only the Register of Plant Producers who place their products on the market will be kept by the local governance bodies.

Description of the structure and organization of services in charge of food safety – current situation and envisaged development

Risk assessment

The National Council for Food Safety Assessment continually monitors and performs risk assessment concerning the food and feed safety aiming at promoting the life and health level of people and animals, makes proposals for deciding upon technical issues and provides scientific and professional assistance in decision-making and preparation of regulations from the field of food and feed safety.

The National Council for Food Safety Assessment was established in accordance with the Law on Food Safety, by the Government of Montenegro at the sitting on 3 September 2009, thereby institutionally rounding up the food safety field (risk assessment separated from risk management). The Council has the chairperson and 10 members. Members of the Council are competent experts

(prominent public, scientific and professional workers) from the fields related to food and feed safety. The National Council for Food Safety Assessment cooperates with all competent state bodies and other institutions in this field in performing its affairs.

Risk management

Bodies competent for risk management in the field of food and feed safety are:

Ministry of Health,

Ministry of Agriculture, Forestry and Water Management,

Veterinary Administration,

Phytosanitary Administration.

Ministry of Health is the competent public administration body in charge of the policy, adoption and implementation of regulations in the field of:

- Safety of food of plant origin following the primary production level,
- Composite food safety,
- Other food safety.

Department for Food Safety was formed within the Sector for Health Protection by job description act of the Ministry of Health which was adopted in July 2009. Department for Health-Sanitary inspections is also a part of this Sector.

Organigramme and description of the Ministry of Health is provided in detail in the answer to question 3 of this Chapter.

Ministry of Agriculture, Forestry and Water Management is the competent state body in charge of policy and adoption of regulations for implementation of laws in the food safety, veterinary and phytosanitary policy fields.

Organigramme and description of the Ministry of Agriculture, Forestry and Water Management is provided in detail in the answer to **question 1** in **Chapter 11.**

Veterinary Administration is the competent public administration body in charge of implementation of regulations from the food safety and veterinary fields:

- Food of animal origin ,
- Composite food,
- Feed,
- Animal health,
- Animal welfare,
- Animal identification and registration.

Veterinary Administration prepares technical basis for legislation and cooperates in policy-making in these fields.

Organigramme and description of the Veterinary Administration is provided in detail in the answer to question 3 of this Chapter

Phytosanitary Administration is the competent public administration body in charge of implementation of regulations in the field of:

- Plant health protection (single authority),
- Safety of food of plant origin at the primary production level,
- Plant protection products (pesticides),

- Pesticides residues in food of plant origin at the primary production level,
- Seeds material of agricultural plants,
- Planting material,
- Plant varieties protection,
- Plant nutrition products (fertilizers),
- Reproductive GMO of plants material or products containing, consisting of GMOs or obtained from GMOs intended for placement on the market.

Local government bodies are in charge of keeping the Register of producers of plants and plant products who place their products on the market,- (as regards control of pesticides use).

Phytosanitary Administration is in charge of preparation of legislation and cooperates in decision-making in these fields.

Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06), Law on Plant Protection Products (Official Gazette of Montenegro 51/08), Law on Agricultural Plants Seeds Material (Official Gazette of the Republic of Montenegro 28/06), Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) and the Law on Plant Varieties Protection (Official Gazette of the Republic of Montenegro 48/07 and 48/08) created the legal framework and the basis for adoption of regulations, in accordance with the NPI-defined dynamics.

Organigramme and description of the Phytosanitary Administration is provided in detail in the answer to question 3 of this Chapter

2. Resources and planned resources (human, material and financial) allocated to each sector must be indicated.

Ministry of Health – Human resources

Current situation

Human resources of the Ministry of Health are defined by the Rulebook on internal organization and job description of the Ministry of Health which was adopted in 2009. In accordance with this job description for the field of the food safety, the Department for food safety was formed with the 2 envisaged posts; one civil servant is currently employed. In the Department for health-sanitary inspection affairs, together with municipal offices, there are 42 envisaged posts – chief health-sanitary inspector, coordinator and 40 health-sanitary inspectors. Currently, the following are employed: the chief health-sanitary inspector, the coordinator and 35 inspectors.

Human resources of the Ministry of Health – current situation

MINISTRY OF HEALTH*	Number of professional staff	Education
Sector for Health Protection		
Department for Food Safety	1	1 graduate in law
Department for Health-Sanitary Inspection Affairs	37	6 doctors of medicine – specialists 4 doctors of dental medicine 1 doctor of veterinary medicine 15 graduate in technology 2 graduates in agronomy 6 graduates in biology 2 graduates in chemistry 1 graduate in environmental protection.
TOTAL	**38**	

*Presented structure of the Ministry of Health in human resources refers only to the food safety field
**Administrative and technical staff is within other organizational units of the Ministry of Health

In future

Fulfilment of six vacancies in envisaged in the following period in accordance with the adopted job description in the Ministry of Health, in the field of food safety.

Ministry of Health - material resources

Current situation

Material resources in the food safety field (Department for food safety, Department for the health-sanitary inspection affairs and Municipal units for health-sanitary inspectorate) do not fully satisfy the needs of staff: all employees have company cellular phones but the number of direct telephone and fax lines in insufficient, they do not have access to Internet (except for the chief health-sanitary inspector), office space and equipment do not satisfy the needs of staff and the number of company vehicles is insufficient (the existing vehicles are old) and some of the equipment necessary for performing inspection control is lacking.

In future

Setting-up of a single information system which would integrate all areas of sanitary inspection supervision is envisaged. Setting-up of the information system entails technical and logistical support (acquisition of the IT equipment, software development, staff education...) whereby, inter alia, electronic keeping of the Register of establishments approved for production and trade in food as well as implementation of the prescribed monitoring will be enabled.

Ministry of Health - financial resources

Salaries and other financial means related to carrying out of regular activities of the Ministry of Health are directed from the Budget of Montenegro. The financial means are envisaged through a multi-annual program budget, and annually in coordination with the Ministry of Finance.

Ministry of Agriculture, Forestry and Water Management

Human, material and financial resources of the Ministry of Agriculture, Forestry and Water Management are provided in detail in the answer to **question 1** in **Chapter 11. (*C11002)***

Veterinary Administration – human resources

Current situation

Human resources of the Veterinary Administration are defined by the Rulebook on internal organization and job description of the Veterinary Administration (adopted in 2008). In accordance with the job description, 50 civil servant and public employee posts are envisaged. All envisaged posts have not been filled; there are currently 42 civil servants and public employees in total.

Human resources of the Veterinary Administration – current situation

VETERINARY ADMINISTRATION	Number of staff	Education
Director Advisor to the Director	1 1	DVM Graduate in law
1. Veterinary Sector		
Department for Animal Health and Welfare Protection	6	4 DVM 2 HS
Department for Veterinary Public Health	3	2 DVM 1 HS
Department for Inspection Supervision	24	23 DVM 1 HS
2.Service for General Affairs	7	1 graduate in economics 1 graduate in law 5 HS
TOTAL	**42**	

*DVM – doctor of veterinary medicine
* HS – High school degree

Examination at the slaughter line (antemortem and postmortem) is carried out by authorized veterinarians (24 DVMs) who are employed in private veterinary surgeries, and who are granted authorizations by the Director of the Veterinary Administration.

In future

In the following period (2010-2012), Veterinary administration will fill the envisaged vacancies in accordance with the adopted job description. In order to fully respond to harmonization requirements in the veterinary policy harmonization, further strengthening of the Veterinary Administration capacities is envisaged by formation of the new organizational units (adoption of a new job description). In Montenegro, veterinary staff is highly deficient, therefore, difficulties in carrying out of the planned employment are expected.

Human resources of the Veterinary Administration – in future

VETERINARY ADMINISTRATION	Number of staff	Education
Director	1	DVM
Assistant Director	1	DVM
Advisor to the Director	1	Graduate in law
1. SECTOR FOR ANIMAL HEALTH AND WELFARE PROTECTION		
Department for Animal I&R	3	1 DVM 2 HS
Department for Animal Health	3	3 DVM
Department for Animal Welfare	1	1 DVM
2.SECTOR FOR VETERINARY PUBLIC HEALTH		
Department for Food Safety	3	2 DVM 1 HS
Department for Importation/Exportation Affairs	2	2 DVM
Department for Feed, TSE and By-products	2	2 DVM
3.SECTOR FOR INSPECTION SUPERVISION		
Department for Internal Veterinary Inspection	18	17 DVM 1 HS
Department for Border Veterinary Inspection	12	
4.SECTOR FOR EUROPEAN INTERATION AND INTERNATIONAL AFFAIRS	2	2 DVM
5.SERVICE FOR GENERAL AFFAIRS	7	1 graduate in economy 1 graduate in law 5 HS
IT Department	2	1 graduate degree 1 HS
TOTAL	**58**	

*DVM – doctor of veterinary medicine

* HS – high school degree

Veterinary Administration - material resources

Current condition

Veterinary Administration has material resources which satisfy needs of staff in the seat of the Veterinary Administration (Podgorica), as follows: it is equipped with the necessary IT equipment including a 24h internet connection; IT system for cattle identification and registration which is connected to the laboratory and border crossings with Serbia (importation of livestock), direct telephone and fax lines as well as company cellular phones, vehicles and the necessary office equipment. However, the current Veterinary Administration space capacities are limited, and it is, therefore, necessary to provide adequate space for the purpose of a more efficient Administration functioning.

Veterinary Inspectorate offices located outside the seat of the Veterinary Administration (in certain municipalities of Montenegro) are equipped with: direct telephone and fax lines and have continuous access to internet but the IT equipment is outdated, space capacities and office equipment do not satisfy the staff needs, a part of equipment for performance of inspection controls is lacking. All veterinary inspectors have company cellular phones and vehicles (a certain number of vehicles are old).

At border inspection posts, no prescribed infrastructural and other requirements for work of the veterinary inspectorate have been fulfilled. Existing offices are inappropriate in terms of space and equipment (except for the 3 newly constructed border crossings), there are no direct telephone or fax lines, and equipment for performance of inspection controls is partially lacking. All border inspectors have company cellular phones, internet, vehicles and a part of the sampling equipment necessary.

A part of the existing equipment (computers, vehicles and professional equipment for veterinary inspectors) has been acquired within the EU-supported projects and other donors during the last 10 years.

In future

Establishment of the veterinary information system is envisaged under the IPA 2007 - Development and Implementation of the Domestic Animals Identification and Registration/ Phase II/ I&R of small ruminants which commenced in August 2009. The Project envisages connection of the already established cattle I&R system with the sheep and goats I&R and movement control system, with the possibility of extension to other animal species, with animal disease monitoring (national epizootiological IT system), needs of the Veterinary Administration and the Veterinary Inspectorate (IT system for veterinary border inspection posts), as well as connection of operators and slaughterhouses.

Acquisition of the lacking equipment and enhancement of the existing border crossings are planned. Also, reconstruction of the existing or building of a new border inspection post Luka Bar (the Port of Bar) in accordance with the EU requirements is envisaged, under the MIDAS project (World Bank).

Veterinary Administration – financial resources

Salaries and other financial means related to carrying out of regular activities of the Veterinary Administration are established in the Budget of Montenegro and directed to the Veterinary Administration as a separate budgetary unit. Financial funds are envisaged through a multi-annual program budget, and at annual basis in coordination with the Ministry of Finance.

Phytosanitary Administration – human resources

Current situation

Human resources of the Phytosanitary Administration are defined by the Rulebook on internal organization and job description of the Phytosanitary Administration (adopted in February 2009). In accordance with the job description, the total number of 38 civil servant and public employee posts is envisaged. Currently, not all vacancies are filled; there are 27 civil servants and public employees employed in the Phytosanitary Administration.

Human resources of the Phytosanitary Administration – current situation

PHYTOSANITARY ADMINISTRATION	Number of staff	education
Director Assistant Director	1 1	Graduate in agriculture Graduate in agriculture
1. Sector for Phytosanitary Affairs		
Department for Plant Health Protection	3	2 graduates in agriculture 1 MA in bacteriology
Department for Seeds, Planting Material, Plant Varieties Protection and GMO	1	Graduate in agriculture
Department for Plant Protection Products, Plant Nutrition Products and Food Safety	2	Graduate in agriculture
Department for Inspection Supervision	16	Graduate in agriculture
2. Service for General Affairs	3	1 graduate in economics 1 graduate in law 1 HS
TOTAL	**27**	

*graduate in agriculture – graduate in agriculture, with respective specialization
* HS – High school degree

In future

In the following period, filling of the envisaged vacancies in the Phytosanitary Administration will be carried out in accordance with the adopted job description as well as division of inspectorate into

the internal and border inspectorates, in order to fully respond to harmonization requirements in the field of phytosanitary policy.

Human resources of the Phytosanitary Administration – in future

PHYTOSANITARY ADMINISTRATION	Number of staff	Education
Director Assistant Director	1 1	Graduate in Agriculture Graduate in Agriculture
1. Sector for phytosanitary affairs		
Department for Plant Health Protection	5	Graduate in Agriculture
Department for Seeds, Planting Material, Plant Varieties Protection and GMO	5	Graduate in Agriculture
Department for Plant Protection Products, Plant Nutrition Products and Food Safety	5	Graduate in Agriculture
2. Sector for Inspection supervision		
Department of Internal Phytosanitary Inspection	8	Graduate in Agriculture
Department of Border Phytosanitary Inspection	16	Graduate in Agriculture
3. Service for General Affairs	5	1 graduate in economics 1 graduate in law 3 HS
IT Department	1	IT graduate
TOTAL	**47**	

* graduate in agriculture – graduate in agriculture, with respective specialization
* HS – High school degree

Phytosanitary Administration – material resources

Current situation

Phytosanitary Administration, as a newly established body (commenced with work in 2009) has material resources which partially satisfy the staff needs in the seat of the Phytosanitary Administration (Podgorica), as follows: a 24h internet connection, direct telephone and fax lines as well as company cellular phones, it is partially equipped with the necessary IT equipment, vehicles and the office equipment necessary. However, the space where the Phytosanitary Administration is currently located is limited, therefore, it is necessary to provide adequate space for the purpose of a more efficient functioning of the service itself.

Phytosanitary inspectorate offices located outside the seat of the Phytosanitary Administration (in certain municipalities of Montenegro) are equipped with: direct telephone and fax lines and have continuous access to internet but the IT equipment is outdated; company cellular phones and vehicles, but they do not have a satisfactory space for work in part, a part of equipment for performance of inspection controls is lacking.

At border inspection posts, the prescribed infrastructure and other requirements for work of the border phytosanitary inspectorate have not been fulfilled. Existing offices are unsuitable in terms of space and office equipment (except for the 3 newly built border crossings), there are no direct telephone nor fax lines in some, and equipment for performance of inspection controls is partly lacking. All border inspectors have company cellular phones, vehicles and partly the necessary sampling equipment.

A part of the existing equipment (computers, vehicles and professional equipment for phytosanitary inspectors) has been acquired under the EU and other donators –supported projects.

In future

Establishment of the phytosanitary information system within the proposed IPA 2010- Strengthening of the Phytosanitary of Montenegro Project is envisaged. The Project envisages connection of the already existing registers in the phytosanitary field, connection of the Phytosanitary Administration, laboratories and phytosanitary inspectorate (IT system for border phytosanitary inspection posts).

Acquisition of the lacking equipment and enhancement of the existing border crossings is envisaged. Also, reconstruction of the existing or building of a new border inspection post Luka Bar

in accordance with the EU requirements is envisaged, within the MIDAS project (World Bank).

Phytosanitary Administration – financial resources

Salaries and other financial means concerning carrying out of regular activities of the Phytosanitary Administration are established in the Budget of Montenegro and directed to the Phytosanitary Administration as a separate budgetary unit. Financial funds are envisaged through a multi-annual program budget, and on annual basis in coordination with the Ministry of Finance.

3. Please provide a description of the current structure, as well as of the evolution foreseen. Two sets of organigrammes: one with the current structure and another one with the planned future structure (the dates foreseen for the establishment of new entities should be indicated).

Food Safety

Ministry of Health is in charge of:

policy, implementation of activities and controls in the field of safety of food of plant origin following the primary production, composite food and other food in production, international trade, wholesale, retail trade, as well as individually labeled packed food of animal origin and composite food in retail trade.

Internal organization units within which affairs from the field of food safety are performed are:

1. Department for food safety performs affairs referring to:
   - preparation of regulations from this area;
   - adoption of the annual plan of control, monitoring plan, crisis management plan in the field of safety of food of plant origin after primary production, composite food and other food;
   - cooperation with international organizations and competent bodies of other states;
   - approval of activities of operators with food of plant origin following the primary production, composite food and other food (establishing the compliance with the prescribed requirements);
   - keeping registers of establishments for production and trade in food and deletion of establishments from the register of approved establishments;
   - preparation of reports from the field of food safety;
   - other affairs under its competencies.
2. Department for affairs of health-sanitary inspection performs inspection supervision over:
   - prevention and control of food-borne infectious diseases;
   - drinking water, establishments and drinking water supply facilities;
   - establishments for production and trade in food of plant origin following the primary production, composite and other food; as well as food of animal origin which is individually labeled and packed;
   - food of plant origin following the primary production, composite and other food at all phases of production and trade, food of animal origin in retail trade, which is individually labeled and packed;
   - materials and wrappings coming in touch with food;
   - prepares information and reports and propose specific measures from the scope of its activities;

- performs administrative affairs concerning inspection supervision, undertake measure for initiation of procedures before the competent bodies against perpetrators of criminal offences, commercial offences and misdemeanors;
- and other affairs under its competencies.

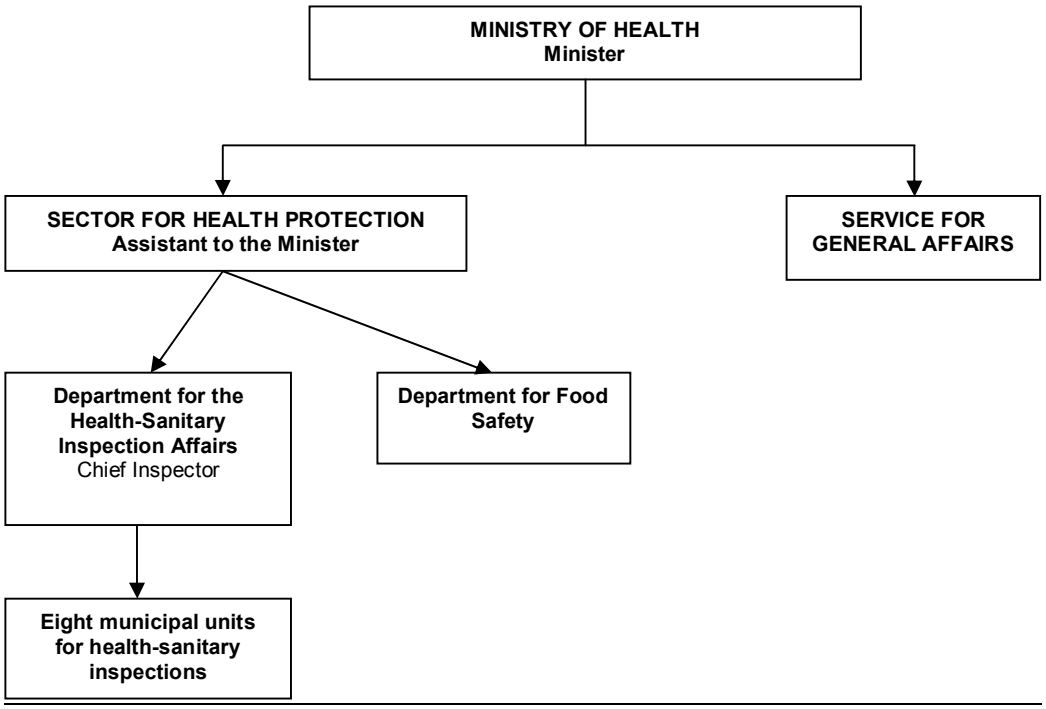
This department is managed by the chief health-sanitary inspector who coordinates the work of health-sanitary inspectors deployed by municipal units (with the seat in certain municipalities of Montenegro).

Municipal units of the Health-sanitary inspectorate:

- Municipal unit Podgorica (municipalities of Podgorica, Danilovgrad and Cetinje);
- Municipal unit Nikšić (municipalities of Nikšić, Šavnik and Plužine),
- Municipal unit Bijelo Polje (municipalities of Bijelo Polje, Mojkovac and Kolašin),
- Municipal unit Berane (municipalities of Berane, Plav, Rožaje and Andrijevica),
- Municipal unit Pljevlja (municipalities of Pljevlja and Žabljak),
- Municipal unit Bar (municipalities of Bar and Ulcinj),
- Municipal unit Herceg Novi (municipalities of Herceg Novi and Kotor),
- Municipal unit Budva (municipalities of Budva and Tivat).

Current situation:
Affairs defined by the rulebook are carried out in the Department for Food Safety by one person who is a law graduate in the capacity of senior advisor; further fulfillment of capacities of this department is envisaged with another advisor fulfilling the requirements (medical, dental medicine, mathematical-science, technological, chemistry or agriculture faculty).

Current structure of the Ministry of Health – part concerning food safety



Planned structure of the Ministry of Health – part concerning food safety

Founding of new organizational units in the Ministry of Health in the food safety field is not planned

in the following period; filling of the existing posts is envisaged in accordance with the adopted job description as well as a clearer division of responsibilities of the health-sanitary inspectors.

Ministry of Agriculture, Forestry and Water Management is in charge of:

veterinary, phytosanitary and policy of safety of food of animal origin, composite food, food of plant origin at the level of primary production and feed safety.

Ministry of Agriculture, Forestry and Water Management performs supervision over legality and appropriateness of work of the Veterinary and Phytosanitary Administrations.

Veterinary Administration is the competent body for safety of food of animal origin, composite food and feed in production, international trade, wholesale, retail trade in meat, fish and aquaculture.

Phytosanitary administration is the body competent for safety of food of plant origin at the primary production level.

Veterinary policy

Veterinary Administration is the body competent for administrative and related professional affairs and control affairs in the field of:

- animal health,
- identification, registration and control of animal movement;
- animal welfare;
- veterinary public health – production and internal and international trade in food of animal origin, feed and animal byproducts, monitoring of residues of pharmacologically active substances of veterinary medicinal products in raw materials of animal origin and feed, monitoring of food-borne zoonoses, monitoring of pesticide residues and the GMO);
- cooperation and coordination with the international veterinary organizations (OIE, FAO etc.), institutions, commercial entities and other institutions in the veterinary and food safety fields;
- other affairs delegated under its competence.

Veterinary Administration was founded in 2004 by the Decree on organization and Method of Work of Public Administration by which founding, manner of work and competencies of the Veterinary Administration have been determined.

Veterinary Administration is managed by the Director – doctor of veterinary medicine, who is accountable to the Minister of Agriculture and Government of Montenegro.

Internal organizational units within which the affairs under competencies of the Administration are performed are:

1. Veterinary sector

- Department for Animal Health and Welfare Protection
- Department for Veterinary Public Health
- Department for Inspection Supervision

2. Service for general affairs

Outside of organizational units, the post of Advisor to the Director is envisaged by the job description rulebook.

Veterinary sector – Rulebook on internal organization and job description of Veterinary Administration envisages the post of assistant director, who coordinates, manages and controls work of department within this sector, takes care of timely and lawful performance of affairs, cooperates with relevant bodies and directly participates in carrying out of the most complex affairs and tasks from the scope of activities of the Sector. Post of the Assistant is currently not filled, employment is planned during 2010.

Department for animal health and welfare protection performs affairs concerning:

- monitoring and prevention of outbreak, detection, control and eradication of certain infectious animal diseases;
- preparation and monitoring of implementation, efficiency and financing of individual programs of preventive measures for protection of animal health, crisis management plans;
- keeping records and reporting on movement of infectious animal diseases;
- animal welfare protection;
- issuing licenses for work and supervision over work of legal entities performing veterinary activities (veterinary surgeries, clinics, laboratories),
- registration of establishments for keeping, breeding, transportation and trade in animals;
- approval of establishments for production and trade in feed following the primary production,
- animal identification and registration;
- keeping single registers of establishments under its competencies;
- cooperation and coordination with international organizations, veterinary services of other countries, institutions, commercial entities, nongovernmental organizations;
- preparation of training programs in the field of animal health, welfare protection, animal registration and identification,
- monitoring of legislation and preparation of technical basis for drafting regulations under its competencies as well as other affairs under its competencies.

Department for veterinary public health performs professional affairs concerning:

- preparation and implementation of programs of monitoring of food-borne zoonoses , residues, safety of food of animal origin and feed following the primary production,
- preparation and implementation of plans for crisis management in the field of animal origin food safety and feed following the primary production;
- keeping records and preparation of a report on implementation of programs adopted;
- preparation and development of certificates and other prescribed veterinary documents for food of animal origin and feed following the primary production and harmonization of the importation and exportation requirements;
- registration and approval of establishments for performing of activities of production and trade in food of animal origin and establishments for byproducts;
- entering into registers and keeping registers of approved and registered establishments;
- categorization of establishments;
- cooperation and coordination with international organizations, veterinary services of other countries, commercial entities, nongovernmental organizations;
- preparation of the training program, manuals, guides and instructions from the field of hygiene of food of animal origin and feed;
- monitoring of legislation and preparation of technical basis for preparation of regulations under its competencies, as well as other affairs under its competencies.

Department for inspection supervision performs affairs concerning:

- carrying out of direct inspection supervision over implementation of the law and other regulations from the field of animal health, animal welfare, animal identification and

registration and safety of food of animal origin and feed following the primary production;

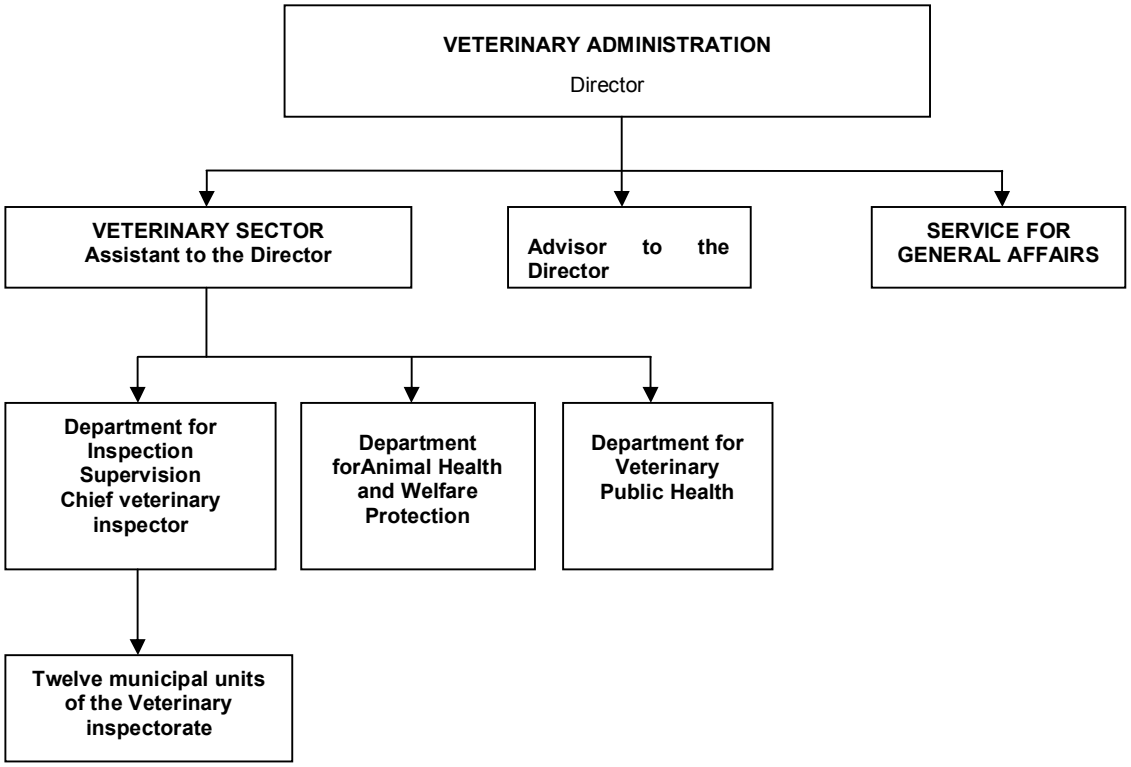
- initiation and conducting of the administrative procedure;
- initiation of a procedure before competent bodies against perpetrators of criminal offences, commercial offences and misdemeanors;
- proceeding and deciding upon applications and complaints;
- implementation of the prescribed plans of control and monitoring programs;
- preparation of technical and documentation basis and methodology for monitoring and implementation of the inspection supervision plan;
- preparation of the technical basis for the annual plan of controls, program of monitoring of the safety of food of animal origin and feed following the primary production;
- preparation of information and reports and propose specific measures from the scope of its activities;
- preparation of report on implementation of the plan of controls as well as other affairs under its competencies.

All veterinary inspectors are incorporated in the Department for inspection supervision, the department is headed by the chief veterinary inspector who coordinates work of veterinary inspectors deployed in municipal units (whose seat is in certain municipalities in Montenegro) and at border inspection posts:

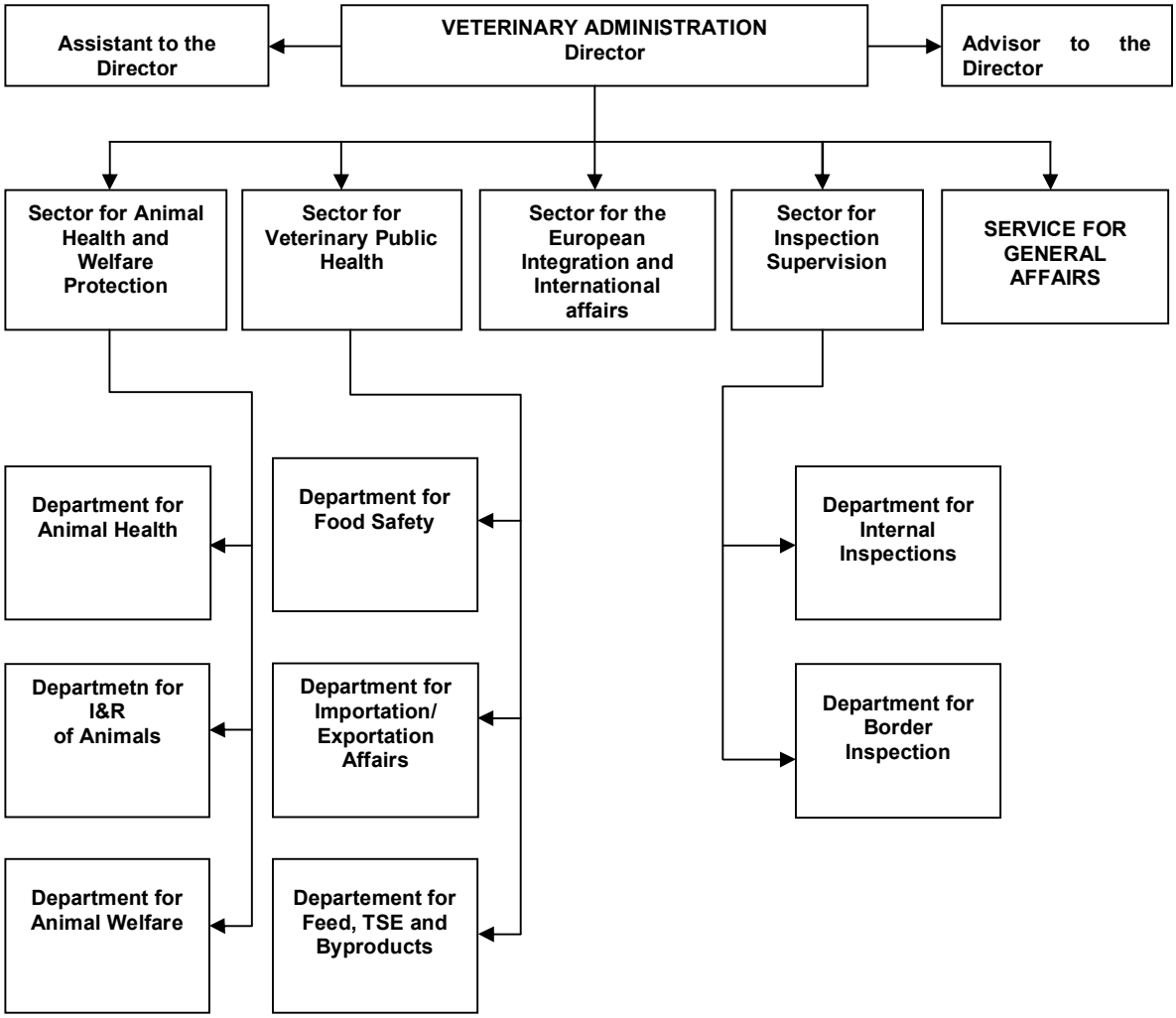
- seat in Podgorica (BIP Božaj, BIP Podgorica airport, municipalities: Podgorica, Kolašin and Danilovgrad);
- seat in Cetinje (municipality of Cetinje);
- seat in Nikšić (BIP Ilino Brdo, municipalities: Nikšić, Šavnik and Plužine);
- seat in Pljevlja (BIP Ranče, municipalities: Pljevlja and Žabljak);
- seat in Bijelo Polje (BIP Dobrakovo, municipalities: Bijelo Polje and Mojkovac);
- seat in Berane (municipalities: Berane, Andrijevica, Plav);
- seat in Rožaje (BIP Dračenovac, BIP Kula and municipality Rožaje);
- seat in Bar (BIP Luka Bar, municipality of Bar);
- seat in Ulcinj (municipality of Ulcinj);
- seat in Budva (municipality of Budva);
- seat in Tivat (municipalities of Tivat and Kotor);
- seat in Herceg Novi (BIP Debeli Brijeg and municipality of Herceg Novi).

Checks at the slaughter line (ante-mortem and postmortem) are carried out by authorized veterinarians, doctors of veterinary medicine, employed in private veterinary surgeries, who are granted the authorizations by the Director of the Veterinary Administration. Criteria for authorization comprise experience in performance of these tasks, as well as assessment of work from previous years. Veterinary Administration prepares and checks capabilities of authorized veterinarians for performance of these checks. Authorized veterinarians are not entitled to undertake administrative and penal measures; these measures are undertaken by veterinary inspectors.

Current structure of the Veterinary Administration



Planned structure of the Veterinary Administration



Phytosanitary policy

Phytosanitary Administration is the competent body which performs administrative and related professional affairs and control affairs in the field of:

- plant health protection (single authority),
- safety of food of plant origin at the primary production level,
- plant protection products (pesticides),
- pesticide residues in food of plant origin at the level of primary production,
- agricultural plants seeds material,
- planting material,
- plant varieties protection,
- plant nutrition products (fertilizers),
- reproductive GMO of plant material or products containing, consisting of GMO or GMO-generated, intended for placing on the market,
- cooperation and coordination with international organizations, institutions, commercial entities and other institutions in the phytosanitary and food safety fields;
- other affairs under its competencies.

- internal and border inspection controls.

Phytosanitary Administration is in charge of preparation of legislation and it cooperates in policy making in these areas.

Phytosanitary Administration was founded in 2008 by a Decree on Organization and Method of Work of Public Administration which determines establishment, method of work and competencies of the Phytosanitary Administration, and it commenced its work in 2009.

Rulebook on internal organization and job description of the Phytosanitary Administration was adopted at the sitting held on February 26, 2009 by the Government of Montenegro.

Phytosanitary Administration is governed by the Director who is accountable to the Minister of Agriculture and the Government of Montenegro.

Internal organizational units within which affairs under competencies of the Administration are performed are:

1. Sector for phytosanitary affairs

- Department for plant health protection
- Department for seeds and planting material, protection of plant varieties and GMO
- Department for plant protection products, plant nutrition products and food safety
- Department for inspection supervision

2. Service for general affairs

Sector for phytosanitary affairs – Rulebook on internal organization and job description of the Phytosanitary Administration provides for the post of Assistant Director who coordinates, manages and controls work of the department within this sector, takes care of timely and lawful performance of affairs, cooperates with the relevant bodies and directly participates in performance of the most complex affairs from the scope of activities of the Sector.

Department for plant health protection performs professional affairs concerning:

- affairs related to the plant health protection:
- measures for prevention of introduction and spreading of harmful organisms;
- measures for control of harmful organisms in plants, plant products and objects under supervision;
- organization and implementation of continuous supervision over harmful organisms;
- evaluation of the plant health condition for the purpose of detection of occurrence and spreading of harmful organisms;
- risk assessment in case of an outbreak and determination of new harmful organisms;
- ordering of technical instructions and measures;
- notification on plant consignments witheld due to noncompliance with the phytosanitary requirements;
- control and carrying out of restrictions or prohibitions of importation into Montenegro or transit of certain plant species through the territory of Montenegro;
- provision of technical basis for determination of limits of an area where extraordinary health supervision should be established;
- establishment and keeping of registers, records, preparation of programs of preventive measures undertaken for the purpose of prevention of introduction and spreading of harmful organisms and taking care of their implementation;
- propose implementation of measures for prevention, control and eradication of harmful

organisms and harmonization of their implementation;

- supervision over performance of affairs of authorized persons;
- informing the public on plant health protection;
- establishment and keeping of an information system in the field of plant health protection;
- preparation of technical basis for the plan of control, monitoring plan and crisis management;
- issuing of approvals, entering into registers, keeping registers and records;
- implementation of international conventions, treaties and exchange of information, participation in international bodies and organizations,
- establishment of the information system, collection, processing and storage of data;
- preparation of reports, analyses, information and other materials, in accordance with regulations and international treaties and agreements and other affairs under its competencies;
- monitor legislation and prepare technical basis for drafting of regulations under its competencies, as well as other affairs under its competencies;
- preparation and monitoring of implementation, efficiency and financing of individual phytosanitary measures programs for plant health protection, crisis management plans.

Department for plant protection products, plant nutrition products and food safety performs affairs concerning:

- registration and recognition of plant protection products and plant nutrition products;
- evaluation of active substances and plant protection products;
- post-registration control of plant protection products and plant nutrition products monitoring program;
- monitoring of trade in plant protection products and plant nutrition products;
- preparation, coordination and monitoring of prescribed programs in relation to safeguard measures and proper use of plant protection products and plant nutrition products as well as program implementation;
- introduction of the principles of good agricultural practice for plant protection products and plant nutrition products and integrated plant protection;
- preparation of technical basis, coordination and monitoring of the annual plan of control and plan of monitoring of plant protection products residues, monitoring plan in the field of food safety at the primary production level and crisis management plan;
- issuing of approvals, entering into registers, keeping registers and records;
- implementation of international conventions, treaties and exchange of information;
- participation in international bodies and organizations;
- establishment of the information system, collection, processing and storage of data;
- monitoring legislation and preparation of technical basis for drafting regulations in the field of plant protection products;
- preparation of reports, analyses, information and other materials, in accordance with regulations and international treaties and agreements and other affairs which fall under its competencies.

Department for seeds and seeds material, plant varieties protection and GMO performs affairs

concerning:

- determination of the extent of compliance with the requirements and method of production, processing, control, post-control, quality examination, trade in and importation of seeds material of agricultural plants ;
- approval of production for lower categories of seeds material,
- issuing certificates for seeds material,
- control and examination of seeds material;
- recognition of the DUS tests results;
- processing of results of variety examination on an experimental field;
- forming a professional commission, for the purpose of assessment of value for cultivation and use, as well as distinctness, uniformity and stability of the variety of a seeds material of agricultural plants;
- determination of the compliance and method of production, trade in and importation of planting material;
- authorized legal person for technical control of planting material production;
- issuing certificate on approval of production of planting material;
- control and examination of varieties of planting material;
- recognition of the DUS tests results, processing of results of a variety examination on an experimental field, forming of the professional commission for the purpose of assessment of value for cultivation and use, as well as distinctness, uniformity and stability of the variety of the planting material;
- establishing the compliance with the requirements and the procedure for plant varieties protection;
- control of the reproductive GMO of plant material or products containing, consisting of or obtained from GMOs, aimed at placing on the market;
- preparation of technical basis for the plan of control, monitoring plan;
- issuance of approvals, entering into registers, keeping registers and records,
- implementation of international conventions, treaties and exchange of information,
- participation in international bodies and organizations,
- establishment of the information system, collection, processing and storage of data;
- preparation of reports, analyses, information and other materials, in accordance with regulations and international treaties and agreements and other affairs under its competencies

Department for inspection supervision performs the affairs concerning:

- carrying out of immediate inspection supervision over implementation of laws and other regulations from the field of health protection of plants, seeds and seeds material, plant varieties protection, plant protection and plant nutrition products, GMOs and safety of food of plant origin at the level of primary production;
- initiation and conducting of the administrative procedure;
- initiates a procedure before the competent bodies against perpetrators of criminal offences, commercial offences and misdemeanors;
- proceeding and deciding upon applications and complaints;
- implementation of prescribed control plans and monitoring programs;

- preparation of professional and documented basis and methodologies for monitoring and implementation of the inspection supervision plan;
- preparation of technical basis for the annual plan of controls, monitoring program for safety of food of plant origin at the primary production level;
- preparation briefing notes and reports and propose specific measures from the scope of its activities;
- preparation of a report on implementation of the plan of controls as well as other affairs which fall under its competencies.

All phytosanitary inspectors are incorporated in the Department for inspection supervision, work of the phytosanitary inspectors is coordinated by the Assistant Director. Phytosanitary inspectors are deployed by municipal units (with seats in certain municipalities of Montenegro) and at border phytosanitary inspection posts:

- seat in Podgorica (BIP Božaj, BIP Podgorica airport, municipalities: Podgorica, Kolašin, Cetinje and Danilovgrad);
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- seat in Mojkovac (BIP Dobrakovo, municipalities: Bijelo Polje and Mojkovac);
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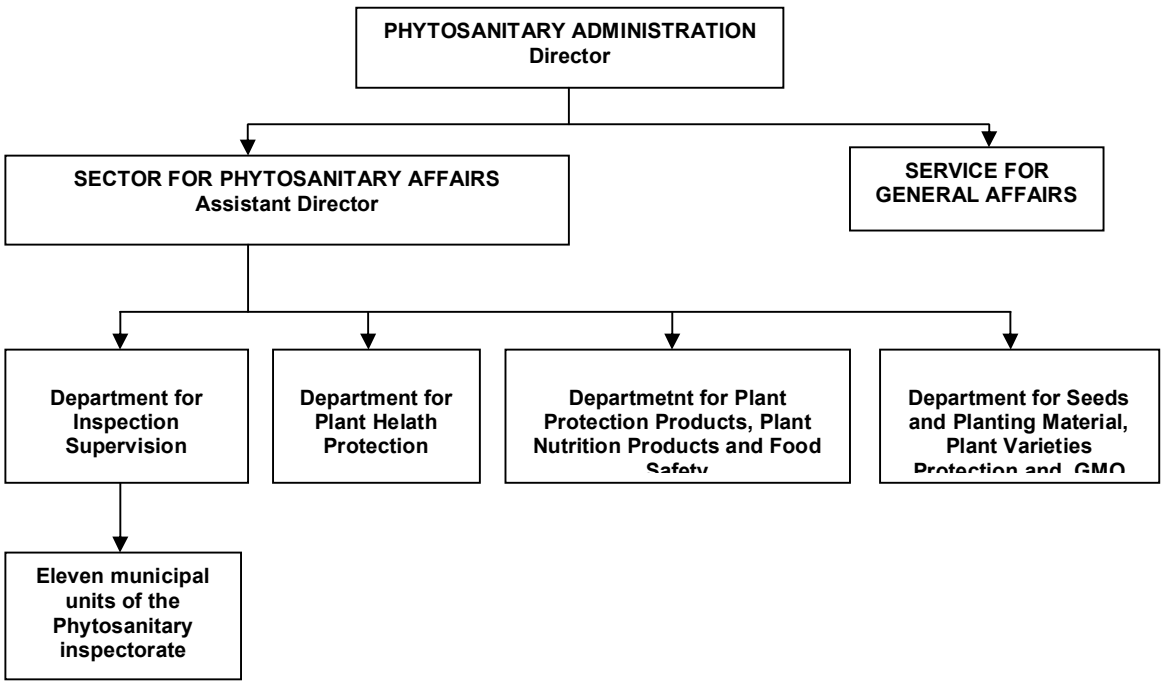
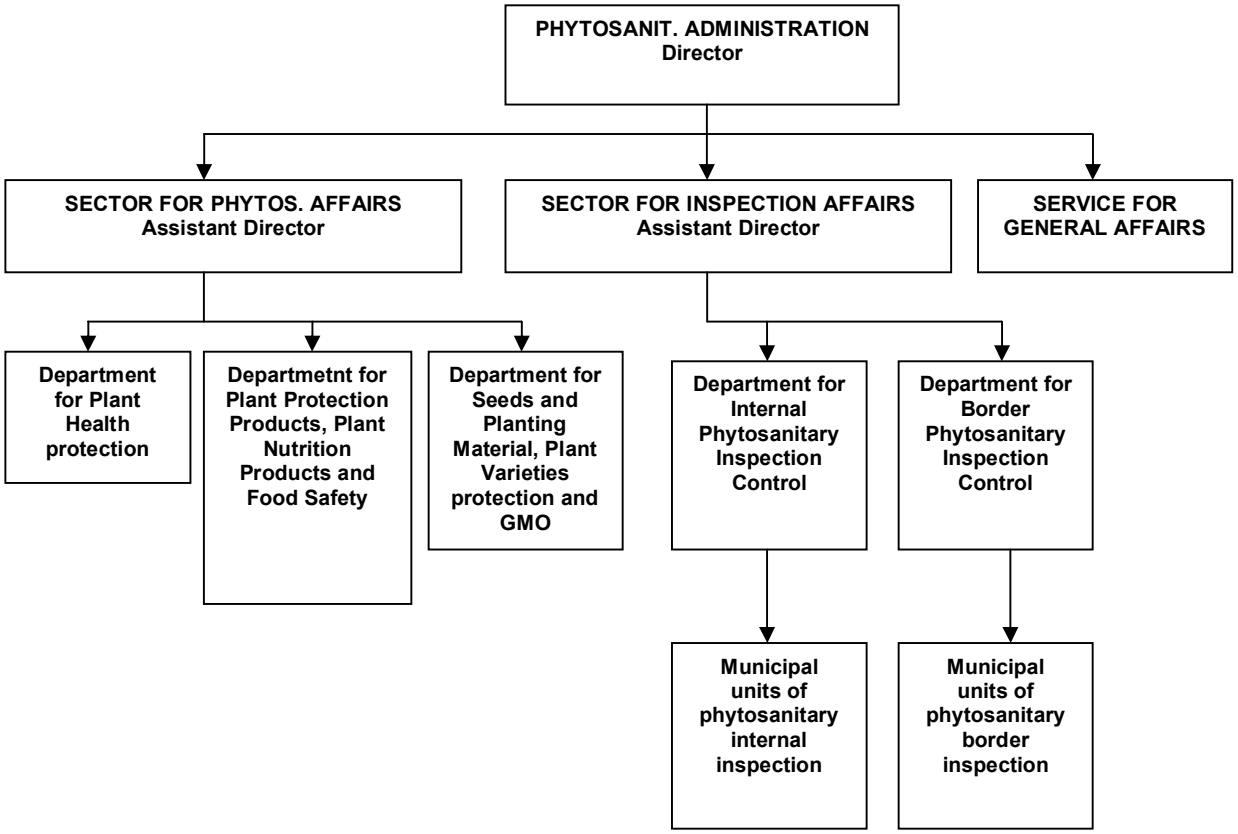
- seat in Rožaje (BIP Dračenovac, BIP Kula and municipality of Rožaje);
- seat in Bar (BIP Luka Bar, municipalities: Bar and Ulcinj);
- seat in Kotor (BIP Debeli Brijeg, municipalities: Budva, Kotor, Tivat);
- seat in Herceg Novi (BIP Debeli Brijeg, municipalities: Herceg Novi, Budva, Kotor, Tivat).

Current structure of the Phytosanitary Administration



Planned structure of the Phytosanitary Administration



4. Legislative powers in the fields of food safety, veterinary and phytosanitary legislation:

- specification of the competent authorities (for legislation) and how legislation will be passed (primarily through parliamentary procedure or ministerial orders or decrees);

Competent bodies for legislation in the field of:

- food safety are the Ministry of Agriculture, Forestry and Water Management and the Ministry of Health;
- veterinary policy is the Ministry of Agriculture, Forestry and Water Management;
- phytosanitary policy is the Ministry of Agriculture, Forestry and Water Management.

Dynamics of passing, i.e. adopting legislation under competencies of the Government are determined by the Annual Program of Work of the Government, in the field of legislation.

The Parliament of Montenegro passes laws upon a proposal of the Government of Montenegro.

Government adopts regulations, decisions etc. upon a proposal of the competent Ministry.

Ministries adopt rulebooks, orders and instructions for implementation of laws and other regulations.

Activities at drafting laws in the field of food safety, veterinary and phytosanitary policy

- Establishing of the Commission (working group) for preparation of laws, consisting of representatives of competent public administration bodies and experts in these fields outside public administration authorities: representatives of scientific institutions, laboratories, professional organizations, non-governmental sector etc. (formed by the

minister of the competent body);

- commission (working group) lays down text of a regulation in draft form which is submitted to competent authorities and interested parties for an opinion;
- following harmonization and receipt of a positive opinion, it is submitted to the Government for adoption;
- government lays down the Draft law upon the proposal of a competent authority;
- prepared Draft law is referred to a public debate;
- following the public debate and receipt of positive opinions from competent authorities, the Commission (working group) lays down the text of the Proposal of the law;
- Following deliberation, the Government lays down text of the proposal;
- Government submits Proposal of the law to the Parliament of Montenegro;
- Proposal of the law and possible amendments are deliberated by the competent committees in the Parliament along with representatives of the proposer (the Government);
- Parliament of Montenegro adopts the Law;
- President of Montenegro promulgates the law by a decree;
- Decree and the text of the Law are published in the "Official Gazette of Montenegro".

Activities at drafting of regulations under competencies of the Government of Montenegro

- Establishing of the Commission (working group) for preparation of regulations, decisions etc, consisting of representatives of competent public administration bodies and experts in these areas outside public administration bodies: representatives of scientific institutions, laboratories, professional organizations, non-governmental sector etc. (formed by the minister of the competent authority);
- commission (working group) lays down text of the regulation which will, following receipt of positive opinions from the competent authorities and stakeholders, be submitted to the Government;
- following deliberation, the Government adopts the regulation;
- Regulations and decisions are published in the "Official Gazette of Montenegro".

Activities for drafting of regulations under competencies of the ministry

- establishing of the Commission (working group) for drafting regulations under competencies of the ministry, consisting of competent public administration bodies and experts in these fields outside of public administration authorities: representatives of scientific institutions, laboratories, professional organizations, non-governmental sector etc. (formed by the minister of the competent authority);
- Commission (working group) lays down text of the legislation, which is submitted to the minister, following receipt of a positive opinion from competent bodies and stakeholders;
- minister submits the legislation to the Secretariat for Legislation, which is afterwards published in the "Official Gazette of Montenegro".

Regulations adopted by the Ministry – regulations for enforcement of relevant laws:

- rulebook elaborates certain provisions of laws and other regulations;
- order orders or prohibits acting in a specific situation (safeguard measures);
- instruction regulates the method of operation and performing of affairs of public administration bodies, local government body and other legal entities in performance of delegated i.e. entrusted affairs.

Director of the Administration adopts instructions for implementation of regulations under his/her competencies.

- explanation of how co-ordination is (or will be) ensured in terms of transposition, implementation, and policy-making to ensure that the food chain is fully covered.

The Regulation on Organization and Method of Work of Public Administration (Official Gazette of Montenegro 59/09) and Law on Food Safety (Official Gazette of Montenegro 14/07) establish competencies and coordination of competent public administration bodies concerning transposition and implementation of regulations and policy-making, which ensures complete comprising of food chain, including food safety, phytosanitary field and animal health and welfare.

National council for food safety assessment, in accordance with the Law on Food Safety, provides proposals for deciding upon technical issues, provides scientific and technical assistance in decision-making and preparation of regulations from the filed of food and feed safety.

The National Program for Integration of Montenegro into the EU (NPI) for period 2008 – 2012 lays down in detail the dynamics of transposition of the EU legislative in the area of food safety into national legislation.

In the following period (2010), appointment of a body as a central public administration body in charge of risk-management, coordination between competent authorities and organization of official controls in the field of food safety is envisaged and it will represent a contact point with the European Commission. This body will consist of relevant representatives of the competent state authorities.

Ministry of Agriculture, Forestry and Water Management is the competent public administration body for policy and adoption of regulations for enforcement of food safety, veterinary and phytosanitary policy laws.

Ministry of Health is the competent public administration body for policy, adoption and implementation of regulations for enforcement of laws in the area of: safety of food of plant origin following primary production, composite and other food.

Veterinary Administration is competent for direct enforcement of regulations and therewith connected technical affairs from the area of safety of food of animal origin, composite food and feed, animal health and welfare.

Veterinary administration is also responsible for preparation of legislation and it cooperates in policy-making in these areas.

Phytosanitary Administration is in charge of direct enforcement of regulations and administrative and therewith connected professional affairs from the field of plant health protection (single authority), safety of food of plant origin at the level of primary production, plant protection products and their residues (pesticides), seed and planting material of agricultural plants, protection of plant varieties and plant nutrition products (fertilizers).

Phytosanitary Administration is in charge of preparation of legislation and it cooperates in policy-making in these fields.

- legal possibility to adopt legislation which will be implemented progressively and which can incorporate EU notions.

There are certain legal limitations for efficient transposition of the EU legislation because the existing legislative procedure represents an obstacle in the sense of inability to incorporate the following into the national legislation: primarily, referral – referring to the EU regulation which is to be transposed, secondly, the possibility of using cross-references for referral to other EU

regulations and institutions and thirdly, possibility to define time of implementation by transitional provisions of the national legislation (e.g. by the day of accession to the European Union).

Since the EU veterinary, phytosanitary policy and food safety legislation is very comprehensive and technical, it is necessary to consider the possibility of the most efficient manner of transposition and adoption of the EU legislation into the national legislation from this area, by direct transposition of texts and their gradual implementation.

Food safety

Law on Food Safety (Official Gazette of Montenegro 14/07) creates a legal basis for adoption of regulations into which the EU notions can be incorporated, in accordance with the dynamics defined by the National Program for Integration of Montenegro into the EU (NPI) for the period 2008–2012. The NPI envisages, as a middle-term activity, an evaluation of efficiency of organization of the existing food safety system with the aim of establishing possible weaknesses of the system and proposal of measures for full harmonization of the Law on Food Safety – Amendments to the Law on Food Safety.

Also, the IPA 2008-Project Development of the food safety services in Montenegro contains a component for support of further harmonization of legislation and promotion of the existing food safety system, especially in the coordination between competent bodies.

Support of the TAIEX experts in preparation of the Law on Food Safety and secondary legislation from this field is also important.

Veterinary policy

Law on Animal Identification and Registration (Official Gazette of the Republic of Montenegro 48/07) and the Law on Animal Welfare Protection (Official Gazette of Montenegro 14/08) created a legal basis for adoption of regulations into which the EU notions can be incorporated, in accordance with the dynamics defined by the National Program of Integration of Montenegro into the EU.

Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07) is not in harmonized with the EU legislation, therefore the National Program for Integration of Montenegro into the EU (NPI) for the period 2008-2012 envisages drafting and adoption of the new Veterinary Law, which would lead to full compliance with the Acquis in this field and create a legal basis for adoption of regulations into which the EU notions can be incorporated.

Support of the TAIEX experts is important in preparation of the Law on Animal Welfare, secondary legislation in the field of animal health and welfare. During the project CARDS 2005-Development of the animal identification in Montenegro-phase I, the Law on Animal Identification and Registration and the Rulebook on the Method of Cattle Identification and Registration and Method of Keeping Registers and Electronic Database have been prepared. (Annex 46)

In August 2009 the I&R of sheep and goats project was initiated (IPA 2008, Project Implementation of an Animal Identification System / Phase II), during 2010 a Rulebook on Sheep and Goats Tagging will be adopted.

Within the IPA 2008 – Support to control and eradication of rabies and classical swine fever (beginning planed for the first quarter of 2010), legislation for control or rabies and classical swine fever will be prepared.

Phytosanitary policy

Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06), Law on Plant Protection Products (Official Gazette of Montenegro 51/08), Law on Agricultural Plants Seed Material (Official Gazette of the Republic of Montenegro 28/06), Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) and the Law on Plant Varieties Protection (Official Gazette of Montenegro 48/07 and 48/08) created a legal framework and basis for adoption of regulations which will be implemented and into which the EU notions can be incorporated, in accordance with the NPI defined dynamics.

Support of the TAIEX experts is important in preparation of phytosanitary legislation and secondary

legislation. Also, the IPA 2008-Project Development of the food safety services in Montenegro contains components for support of legislation harmonization. Strength of the Phytosanitary Directorate in Montenegro Project contains components for support of legislation harmonization. Strength of the Phytosanitary Directorate in Montenegro Project, which would help in evaluation of the legal framework and efficiency of organization in the phytosanitary field with the aim of ascertaining possible system weaknesses and proposal of measures for full harmonization, has been envisaged for 2010.

5. Please provide detailed information on the control activities and enforcement in the fields of food safety, veterinary and phytosanitary and feed legislation policy. Specification of the bodies that are (will be) in charge of control activities and enforcement and their respective responsibilities. Please describe mechanisms of co-ordination.

FOOD SAFETY

The Law on Food Safety (Official Gazette of Montenegro 14/07) lays down powers of state bodies in the field of food safety.

Division of competencies over composite food has been made between the Veterinary and Sanitary Inspectorates by the Decision on types of composite food and their classification.

The Ministry of Health is the body competent for carrying out activities and controls in the field of safety of food of plant origin following primary production and other food in production, international trade, wholesale trade, retail trade, as well as individually labelled and packed food of animal origin and composite food in retail trade.

Department for Food Safety performs technical affairs referring to preparation and implementation and performance of the following activities:

- Approval of the establishments for production and placement on the market of food of plant origin following primary production, and other food;
- Implementation of the pesticide residues monitoring program for food of plant origin following the primary production ;
- Keeping registers of the registered establishments.

Production and trade in food of plant origin following the primary production as well as other food can be performed only in establishments registered by the Ministry of Health and entered into the register of approved establishments. Operators in business with food of plant origin following the primary production and other food must not initiate performing of activities prior to receipt of a decision from the Ministry of Health.

Request for approval of an establishment for production and trade in food of plant origin following the primary production and other food and prescribed documentation are submitted to the Ministry of Health.

Compliance with the general and special hygiene requirements based on an on-the-spot check is determined by a decision of the Ministry of Health.

Exceptionally, an interim decision may be granted for the period of 180 days from the day of checking the production establishments fulfilling the general hygiene requirements concerning facilities, premises, equipment, water and power supply and waste disposal until fulfilment of the special hygiene requirements.

The establishment for which it has been established that it fulfils the prescribed requirements is entered into the register of approved establishments based on a decision on compliance with the requirements of the Ministry of Health, containing the following:

- Name and seat of the operator in business with food of plant origin following primary production and other food and the place where the approved establishment is located;
- Name, surname and residence of the operator in business with food of plant origin following primary production and other food, of the physical person as well as the place where the approved establishment is located;
- Type of activity for which the establishment has been approved;
- Establishment capacity and product range of the establishment;
- Control number of the establishment.

Register of establishments approved for production and trade in food of plant origin following the primary production and other food is kept by the Ministry of Health.

An establishment shall be deleted from the register of approved establishments by a decision of the Ministry of Health in the following cases:

- Upon request of the operator in business with food of plant origin following the primary production and other food;
- When it is established in the control procedure that the establishment ceased to fulfil the prescribed requirements, and in the period determined for removal of deficiencies the deficiencies have not been removed;
- Termination of performance of activities of the operator in business with food of plant origin following the primary production and other food, i.e. by change of property over the establishment;
- Pronouncing protective measures of permanent prohibition of performing the activities.

In Montenegro, precise records of operators in business with food of plant origin following the primary production and other food have not been established.

Setting-up of registers and revisions of previously issued approvals is planned.

Department for health-sanitary inspection affairs performs supervision over implementation of this law in accordance with the powers, through sanitary inspectors.

Department for food safety prepares the annual plan of establishment control and the plan of food sampling. While preparing the control plan, type of activity performed within it, production capacity, the condition of the establishment and previously determined irregularities, self-control systems in place etc. are taken into consideration.

Plan determines dynamics of controls, subject of check as well as method of performing the check. Chief sanitary inspector controls implementation of the control plan.

Adoption of food safety monitoring program (microbiological, chemical and biological contaminants in food of plant origin following the primary production and other food) is planned for the following period.

The **Veterinary Administration** is the body competent for carrying out activities and controls in the field of safety of food of animal origin, composite food and feed in production, international trade, wholesale trade, retail trade in meat, fish and other aquaculture products. Veterinary Administration, **Department for Veterinary Public Health** performs technical affairs related to preparation and implementation of the following activities:

- Approval of establishments for production and trade in products of animal origin and animal feed;
- Implementation of monitoring programs of food-borne zoonoses
- Implementation of residue monitoring programs for residues of veterinary medicinal products and other harmful substances in raw materials and products of animal origin;
- Implementation of pesticide residues monitoring program in feed and food of animal origin;

- Keeping registers of registered and approved establishments.

Production and trade in food of animal origin can be performed only in establishments approved by the Veterinary Administration and entered into the register of approved establishments. Operators in business with food of animal origin must not initiate performing of activities prior to receiving the approval from the Veterinary Administration.

Application for approval of an establishment for production and trade in food of animal origin and feed and prescribed documentation are submitted to the Veterinary Administration.

Compliance with the prescribed general and special hygiene requirements based on an on-the-spot check is determined by a decision of the Veterinary Administration.

Exceptionally, an interim decision can be granted for the period of up to 180 days from the day of the check performed for production establishments fulfilling the general hygiene requirements concerning the establishment, premises, equipment, water and power supply and waste disposal until special hygiene requirements are fulfilled.

The establishment for which it has been established that it fulfils the prescribed requirements is entered into the register of approved establishments based on a decision on compliance with the requirements of the Veterinary Administration, containing the following:

- name and seat of the food or feed business operator, and place where the approved establishment is located;
- name, surname and residence of the food or feed business operator, physical person as well as the place where the approved establishment is located;
- type of activities for which the establishment has been approved;
- establishment capacity and product range of the establishment;
- control number of the establishment.

Register of establishments approved for production and trade in food of animal origin and feed is kept by the Veterinary Administration.

Establishment is deleted from the register of approved establishments by a decision of the Veterinary Administration in following cases:

- upon request of a food and feed business operator;
- when it is established in the control procedure that the establishment ceased to fulfill the prescribed requirements, and deficiencies have not been removed in the period determined for removal of deficiencies;
- by termination of performing activities by the food or feed business operator, i.e. by change of property over the establishment;
- by pronouncing a protective measure of permanent prohibition of performing the activities.

According to the previously valid regulations in Montenegro, the following have been approved: 24 establishments for slaughter of cloven-footed animals (small-scale slaughtering capacity establishments up to 10 head per week for supply of their own retail establishments – butcher shops); 7 establishments for slaughter and cutting meat of cloven-footed animals; 3 establishments for slaughter of poultry and 3 establishments for slaughter and cutting poultry meat; 34 establishments for meat processing – production of meat products; 4 establishments for production of processed meat products; 1 establishment for treatment and processing of intestines and rennet production; 22 establishments for milk processing, 2 establishments for fish and fisheries products processing; 3 vessels for storage of fish over 24 hours; 3 establishments for storage of fish on land; 138 establishments for storage of animal origin food with a temperature regime; 221 establishments for retail trade in meat and 1 establishment – bivalve molluscs farm.

Pig slaughter is traditionally performed on agricultural holdings, where pigs, after being purchased in spring months, are kept until autumn and the meat is for private use. The rest of the production is slaughtered in approved slaughterhouses under supervision of an authorized veterinarian.

Following the slaughter, in most cases pig keepers submit samples for a trichinoscopic check performed by veterinary surgeries which have the equipment necessary for performing this check.

All pigs slaughtered in authorized slaughterhouses are subject to trichinoscopic check and this check is a part of check at the slaughter line.

In Montenegro, there are no establishments for slaughter of farmed game.

In accordance with the Veterinary Law, check at the slaughter line is entrusted to authorized veterinarians from veterinary surgeries. Authorization for this business is granted by the Director of the Veterinary Administration by a decision which defines the obligations and responsibilities of the authorized veterinarian.

Criteria for authorization include experience in performing these checks, evaluation of work from previous years, training as well as results of knowledge and skills check performed by the Veterinary Administration.

Authorized veterinarians are not authorized to undertake administrative measures and activities; it is done by veterinary inspectors following a notice on detected irregularities in work of authorized veterinarians.

A fee for work of authorized veterinarians is paid from the Budget of Montenegro, in accordance with the Decision on the amount of fee for veterinary-sanitary checks in internal trade.

The Veterinary Administration – **Department for Inspection Supervision** performs supervision over implementation of this law in accordance with powers through veterinary inspectors.

At the beginning of the year, the chief veterinary inspector adopts a plan of control of establishments. In preparation of the control plan, type of activity performed is taken into consideration, production capacity, condition of the establishment and previously detected irregularities, systems of self-control in place, etc.

The plan determines dynamics of controls, the subject of check as well as the method of performing the check. The chief inspector controls implementation of the control plan.

Activities and monitoring of residues of veterinary medicinal products and other harmful residues in food of animal origin and feed – Answer is given in question 14, Chapter 12, EC Questionnaire.

Activities and implementation of monitoring of zoonoses

With the aim of timely detection and prevention of salmonelosis occurrence in domestic poultry for the purpose of prevention of disease spreading and prevention of occurrence of the disease in humans, **salmonelosis monitoring** has been established by a systematic monitoring – sampling of domestic poultry whose products are used for public consumption from establishments registered with the Veterinary Administration.

Veterinary inspector takes samples of poultry eggs, faeces, blood and feed and submits them to the laboratory for bacteriological checks. The samples are taken from establishments for breeding and production of table eggs and poultry fattening. Frequency of sampling, type and number of samples by establishments from the Administration register, is determined by the chief veterinary inspector by a special instruction during the whole year.

With the aim of timely detection and control of listeriosis (Listeria monocitogenes) for the purpose of prevention of spreading of this disease to people, **monitoring of listeria** has been established through a systematic monitoring and sampling of products of animal origin which are placed on the market. Veterinary inspector takes samples of food and submits them to the laboratory for laboratory-bacteriological checks.

Frequency of sampling, type and number of samples by species and establishments from the register are determined by a special instruction of the chief veterinary inspector during the whole year.

Following the check of all establishments, approved according to the previously valid regulations, planned for 2010 and in accordance with the newly adopted rulebook on the method of entering, keeping and contents of registers, the Veterinary Administration will produce a register of

registered and approved establishments.

The **Phytosanitary Administration is the body competent for** carrying out activities, controls and coordination in the field of safety of food of plant origin at the level of primary production. It prepares professional basis for the annual control plan, monitoring plan and crisis management plan in the field of safety of food of plant origin at the level of primary production and prepares adoption of regulations under its competencies, determines fulfilment of prescribed requirements, performs control and inspection supervision over the safety of food of plant origin food at the level of primary production through the phytosanitary inspectors.

Department for Plant Protection products, Plant Nutrition Products and Food Safety performs technical affairs related to preparation and carrying out of the following activities:

- approval of establishments for production and trade in food of plant origin at the primary production level;
- implementation of the program of monitoring of pesticide residues for food of plant origin at the primary production level;
- keeping register of establishments.

Taking into account that the Phytosanitary Administration is a newly established authority with underdeveloped administrative capacities, the process of registration of establishments for production and trade in food of plant origin at the level of primary production has not yet started. It is planned that during the forming of this register, the existing Registers of Farmers are taken into account (register is in the Ministry of Agriculture, Forestry and Water Management) as well as the obligation of registration by the Law on Plant Protection Products, according to which plant producers may place plants and plant products on the market only if they are entered into the Register of plant producers kept by the local administration body competent for agricultural affairs.

Registration of producers of food of plant origin at the primary production level shall not apply to primary production of food for private consumption in a household and to direct supply of consumers with small quantities of primary products, while the rest of the production can take place only in establishments registered by the Phytosanitary Administration.

Phytosanitary Administration performs inspection supervision through phytosanitary inspectors. Inspectors perform supervision over the food of plant origin at the level of primary production. Inspection controls are carried using the control methods and techniques such as supervision and sampling commensurate with the subject of control. In accordance with powers from the Law on Inspection Supervision and the Law on Food Safety, the phytosanitary inspector is authorized to:

- check the establishment, surrounding area, premises, equipment and means of transport in primary production of food of plant origin;
- check and, where necessary, sample raw materials, matters and substances used for preparation of food of plant origin at the level of primary production;
- check and, where necessary, sample the materials, wrapping and objects coming in contact with food of plant origin at the level of primary production;
- control the process of cleaning, disinfection, disinfestation and rodent control, method of use and keeping of cleaning agents and products for disinfection, disinfestation and rodent control used in business with food of plant origin food at the primary production level;
- control the method of labelling, marking, presentation and advertising of food of plant origin at the primary production level.

When the phytosanitary inspector establishes that the Law on Food Safety or some other regulation has been violated, he/she is authorized to:

- order limitation and prohibition of trade in food of plant origin at the primary production level until removal of the hazard, i.e. suspicions regarding its safety;
- order destruction of unsafe food of plant origin at the primary production level;

- prohibit use of materials, wrappings and objects coming in contact with the food of plant origin at the primary production level which could endanger human health and lead to change in composition or its sensory characteristics under normal and envisaged conditions of transportation, handling and storage;
- undertake other measures in compliance with law.

The Phytosanitary Administration is carrying out the Program of monitoring of plant protection and nutrition products and food safety, with the aim of ensuring the production and trade in safe food of plant origin in Montenegro. Legal basis for this Program is contained in the Law on Plant Protection Products (Official Gazette of Montenegro, 51/08), Law on Plant Nutrition Products (Official Gazette of Montenegro, 48/07), Law on Food Safety (Official Gazette of Montenegro, 14/07) and other regulations governing this field. The Program also sets out task holders based on powers: University of Montenegro / Biotechnical Faculty / Centre for Plant Protection / Phytosanitary laboratory; Centre for Land and Melioration Research, Institute for Public Health / Centre for Eco-toxicological Research of Montenegro (CETI) / Extension Service in Plant Production. Activities from this Program are carried out by the following individual components:

- Component 2.1: In accordance with the Program of monitoring of pesticide residues in food of plant origin at the level of primary production for 2009, a systematic monitoring of pesticide residues in food of plant origin at the primary production level will be performed.
- Component 2.2: Post registration monitoring of plant protection products.
- Component 2.3: Plant nutrition products monitoring program.
- Component 2.4: Post registration monitoring of plant nutrition products program.
- Component 2.5: Measures in the field of safety of food of plant origin at the primary production level comprise: systematic monitoring of food of plant origin at the primary production level which is used for consumption at producers who are registered with the Phytosanitary Administration, by taking samples. Phytosanitary Inspectorate will be taking samples and submit them to the laboratory for checks. Samples of food of plant origin will be taken in primary production, storages for primary products, collection centres, markets (open sale places) and at border crossing at which phytosanitary inspection is organized. For the purpose of quick response in situations of unexpected and sudden occurrence of unsafe food of plant origin at the level of primary production, which can not be foreseen, and which demand immediate undertaking of urgent measures for protection of human and animal health, relevant technical activities will be carried out (frequency of sampling, type and number of samples, destruction of food) in the field as well as services of laboratory checks. The program comprises timely notification via media, provision of advice and publishing of technical publications, instructions and guides for carrying out of measures. Performance of these activities will depend on the situation itself and requests imposed by the situation, in line with instructions and orders of the Phytosanitary Administration.

Program of monitoring of pesticide residues in food of plant origin monitors pesticide residues levels in order to estimate the extent to which the population health is endangered. This program was adopted and published in the Official Gazette of Montenegro 57/09, and it was adopted in accordance with the Law on Food Safety (Official Gazette of Montenegro 14/07) and the Law on Plant Protection Products (Official Gazette of Montenegro 51/08).

The Program of monitoring of pesticide residues in food of plant origin determines persons in charge of performing monitoring, priority in sampling of food of plant origin, number of samplings and analyses and active substances to be analyzed for the purpose of monitoring the levels of pesticide residues with the aim of assessing the level of risk to the population health, in compliance with the prescribed pesticide residues level (Rulebook on quantities of pesticides, metals and metalloids and other poisonous substances, chemotherapeutics, anabolics and other substances which may occur in foodstuffs (Official Gazette of the Federal Republic of Yugoslavia 5/92, 11/92 and 32/02).

The Program lays down sampling and analyses of: fruit, vegetables, cereals, cereal-based beverages and products as well as baby food.

This Program is based on standard parameters and recommendations of the European Commission from February 4th, 2008, in relation to the coordinated monitoring program and national monitoring program for 2009 (2008/103/EC). Priorities of sampling food of plant origin food are determined by risk analysis on the basis of previous evidence on effects of pesticide residues on population health, in the following ranking system:

Low priority monitoring level

- there is no evidence of exceeded MRL/ Maximum Residue Levels or unauthorized pesticides on/in goods (source: previous monitoring, reports, Rapid Alert System for Food and Feed - RASFF's, or the monitoring data of other states);
- low number of expected pesticide residues on/in goods;
- goods are present in nutrition of any population group to a small extent.

Type of monitoring: Routine part, in the process of monitoring of the role of consumption. The aim of this monitoring type is to the check the legal harmonization and provision of the information needed.

Mid-priority monitoring level

- there is evidence of exceeded MRL or unauthorized pesticides in/on goods (source: previous monitoring, reports, Rapid Alert System for Food and Feed - RASFF's, or other monitoring data of other states);
- expected occurrence of residues on/in goods;
- goods are present in any population group consumption to a large extent;
- increasing popularity enhanced influx of goods from new sources.

Type of monitoring: Routine part of monitoring mostly for fresh types of goods. Aim of this monitoring type is monitoring of previous results.

High priority monitoring level

- recent evidence of exceeded MRL or unauthorized pesticides on/in goods (source: previous monitoring, reports, Rapid Alert System for Food and Feed - RASFF's, or other monitoring data of other states);
- evidence that ingestion might exceed the Acute Reference Dose;
- expected residues on/in goods of exceptional significance for a consumer group.

Type of monitoring: Annual monitoring of food with significant share in consumption and/or targeted monitoring for problems identified.

A special program of residues monitoring in animals, foodstuffs of animal origin and feed is carried out by the Veterinary Administration in accordance with the law.

Parameters taken into account during drafting of the program are the following:

- population by municipalities;
- statistical data on consumption of food of plant origin (presence in consumption);
- data on domestic production and importation of food of plant origin;
- data on residue levels from previous years;
- laboratories capacity, applied methods;
- registered pesticide preparations;
- number of storages, wholesale, importers and retail of food of plant origin.

*Phytosanitary Administration (PA) – performs monitoring in primary production, storages of primary plant products, at collecting centres, marketplaces (open sale premises) and at places

where plants are subject to customs clearance and at border crossings where phytosanitary service is organized;

**Ministry of Health (MH) – performs monitoring in production, in retail, wholesale premises and at the customs clearance post;

In accordance with the abovementioned, powers in Montenegro are divided among the Ministry of Agriculture, Forestry and Water management, Phytosanitary Administration, Veterinary Administration and the Ministry of Health, and separate funds are, in accordance with this division, allocated for analysis of the pesticide residues (each body, in its budget, in accordance with its powers).

VETERINARY POLICY

Veterinary Administration is the central body competent for the activities of control and implementation in the veterinary field.

Veterinary Administration is in charge of the animal I&R (Department for Animal Health and Welfare Protection). The obligation of identification and registration of animals and holdings has been prescribed by the Law on Identification and Registration of Animals. I&R of cattle has been established while tagging of other animals in accordance with the EU will be carried out in the following period. In August 2009, the I&R of sheep and goats has begun (IPA 2007, Project Implementation of an Animal Identification System / Phase II), with duration of 18 months and the plan is to complete tagging of sheep and goats by 2010.

The cattle I&R system and electronic databases are compatible with the EU requirements. All holdings where cattle is bred or kept have been entered into the database. All data are in the electronic database kept by the Veterinary Administration. All movements are recorded in the database.

Identification and registration of animals and holdings is carried out by veterinary surgeries which were assigned performance of these affairs by the Veterinary Administration, in accordance with the Veterinary Law. Identity of cattle is determined on the basis of eartags and movement documents.

Inspection supervision over implementation of rules set forth by the Law on I&R of animals is performed by the Veterinary Inspectorate, by checking data from the central base, in veterinary surgeries, holdings, at transporters and traders of animals.

In Montenegro, there are no precise records on holdings where pigs, sheep and goat are bred and kept. When carrying out of preventive measures, the veterinary surgeries keep mandatory records, containing name and surname of keeper and number of animals in a holding. There are separate records kept by the Livestock Selection Service for goat herds with more than 10 head, and for more than 20 sheep, used in allocation of funds from the Agro-budget – direct support to livestock production).

Measures for control of infectious diseases are regulated by the Veterinary Law. Department for animal health and welafre protection and is in charge of animal health control and preparation of the animal health protection program. Operational Program on Animal Health Protection is adopted by the end of the year for the following year. This program lays down measures, scope, laboratory diagnostics, time of carrying out, persons in charge of carrying out (veterinary surgery, laboratories) and control method. The funds for implementation of the Operational Program are provided from the Veterinary Administration budget.

Measures carried out have to be controlled and verified by the Veterinary Inspectorate. The veterinary inspector in charge must be timely informed at least 10 days prior to commencement of implementation of measures by a veterinary surgery, which must submit the measures implementation plan, including the dates and venues. The veterinary surgeries must submit to the veterinary inspector in charge, no later than by the 10th day in month for measures carried out in the previous month, the excerpts from the records (Report on measures carried out), containing the following data: name of the place, date of the measure implementation, name of the animal owner, number of the holding, identification of cattle, confirmation of performed diagnostic checks and results of diagnostic checks. Following the control, the veterinary surgery submits to the

Veterinary Administration a report on measures carried out, together with the inspector's minutes.

The Operational Program comprises the following measures for control of infectious diseases: epizootiological situation monitoring and diagnostics in case infectious diseases are suspected, measures for prevention and control of Bovine tuberculosis, bovine, caprine and ovine brucellosis, Enzootic Bovine Leucosis, Classical Swine Fewer, rabies, Newcastle disease, Avian Influenza, Anthrax, bee diseases (American foulbrood) and monitoring of the Bluetongue Disease.

The following checks shall apply to:

- tuberculosis to which all cattle older than 6 weeks are subject by application of intradermal tuberculin tests;
- brucellosis for all cattle older than 12 months, except for males intended for fattening, and sheep and goats older than six months by diagnostic testing of blood sera (method of fast serum agglutination test);
- enzootic leucosis of all cattle older than 24 months by a serological test.

From this year, a connection has been established between the veterinary surgeries and the central database and laboratories, marked coded test tubes are used so that number of the eartag is scanned first, then the test tube code, followed by blood taking. Following the receipt of the laboratory results, the results are entered into the central base.

Vaccination of dogs and cats against rabies is mandatory.

Vaccination of pigs against the classical swine fever – CSF is compulsory with the aim of constant maintenance of immunity against the CSF in all households where pigs are kept and bred, by vaccination prepared from the attenuated C virus strain.

In order to control the effectiveness of immunization of vaccinated pigs, the Veterinary Inspectorate performs sampling, by random sampling method, in order to check the presence of the specific antibodies against the CSF virus, checking the immunity status not earlier than 35 days following the vaccination.

With the aim of ascertaining the presence of the CSF virus in nature, among the wild boars population, veterinary surgeries submit to the laboratory the samples of lymph nodes, spleen, with the sample of a muscle (meat) of wild boars whose meat has been submitted for a thichinoscopic check, for checking the presence of the CSF virus in the wild boars population. Veterinary Administration bears the costs of the trichinoscopic meat check of the wild boars for hunters who submit to veterinary surgeries or laboratory the samples necessary for checking the presence of the CSF virus.

All poultry are subject to vaccination against the Newcastle disease by an inactivated vaccine prepared from a lentogenous strain. The control of effectiveness of immunization of vaccinated poultry is carried out by the Veterinary Inspectorate by the random sampling method, in accordance with the Veterinary Administration sampling plan.

Montenegro is a member of the World Organization for Animal Health since August 2007, the Director of the Veterinary Administration is the official delegate of Montenegro to the OIE. Montenegro is officially recognized by the OIE as free from the foot-and-mouth disease, without vaccination (2006) and as free from rinderpest, based on data from the past (2009).

Currently, contingency plans for certain diseases in accordance with the EU requirements have not been established yet. A Program for prevention, control and eradication of the Highly Pathogenic Avian Influenza in accordance with the EU regulations has been adopted.

The Veterinary Law prescribes the obligation of compensating the animal keepers the damage caused by control and eradication of infectious diseases, for diseases from the former A list (highly dangerous infectious diseases) and for other diseases determined by the Operational Program. Damages are paid out in the amount of market value of an animal on the day when the damage occurred.

In case of disease outbreak of larger scale, additional financial funds from the budget of Montenegro can be provided.

Measures for prevention of occurrence, detection, control and eradication are set forth by the Veterinary Law and Rulebooks for each disease separately.

Animal welfare

Veterinary Administration is the authority in charge of the control and implementation of activities in the field of animal welfare. The Law on Welfare lays down rules for animal welfare protection, which will be defined in more detail by secondary legislation.

Legal and physical persons dealing with transport of animals are not registered by the Veterinary Administration, i.e. no register of transporters has been established. Preparation of a rulebook for protection of animals during transport is underway and it will define in more detail the requirements for transport of animals which must be fulfilled by a transporter, transportation vehicle, contents of the route plan, registration method and manner of training the attendants accompanying animals, in accordance with the EU legislation.

Currently, transporters are not trained for fulfilling the welfare requirements during transportation. By adoption of new rules in accordance with the EU requirements, the continued training of persons transporting animals will be carried out, as well as establishing of the transporters register.

Most slaughterhouses are equipped by equipment for stunning animals and possess adequate premises for unloading and rest of animals (livestock depots).

By adoption of news rules in accordance with the EU requirements, the need for continued training of persons performing relocation, housing and care of animals in slaughterhouses, tethering, stunning and slaughter or killing of animals has been recognized.

Representatives of the Veterinary Administration participate in the program of training the trainers for animal welfare protection in slaughterhouse production (Training Trainers program Red Meat), carried out by the AWT training, University of Bristol, School of Clinical Veterinary Science, Department of Farm Animal Science, and organized by the Western Balkan University Network for Animal Welfare (this organization was established by the RSPCA and the Faculty of Veterinary Medicine Skopje). Training was initiated in March 2009, and it is envisaged to last until the end of 2010. The Program is aimed at training of the competent control authorities for the control of application of rules and fulfilment of requirements for animal welfare in slaughterhouses.

Fulfilment of requirements concerning animal welfare in slaughterhouses is an integral part of requirements that have to be fulfilled when approving slaughter establishments.

Veterinary Administration registers establishments where animals are bred in intensive keeping conditions. Animal welfare requirements for production in keeping and breeding have not been fully adopted. Adoption of a regulation by which this field would be harmonized with the EU legislation is planned, however, there are financial limitations at animal keepers for improvement of conditions in establishments and assistance in this segment is necessary.

PHYTOSANITARY POLICY

The Phytosanitary Administration is the central body competent for activities of control and implementation in the phytosanitary field.

The **Phytosanitary Administration is in charge of plant health (Department for Plant Health)**

Measures for control of harmful organisms are regulated by the Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06). Department for Plant Health and Department for inspection supervision are in charge of control of harmful organisms and preparation of a program for plant health protection.

The Program of Plant Health Protection is adopted within the Program of Phytosanitary Measures by the end of the year for the following year. This program comprises a reporting-forecasting program and monitoring of the health condition of plants, plant products and objects under supervision, Operational Program of continuous supervision over the quarantine harmful organisms, National Operational Program of continuous supervision over non-quarantine harmful

organisms and Urgent Phytosanitary Measures. The program is carried out with the aim of supervision over harmful organisms, it contains measures, comprises the necessary laboratory checks, time of check, persons performing checks (authorized laboratories), method of control and persons in charge. Funds for implementation of the Program of Phytosanitary Measures/ Program of Plant Health Protection have been provided in the budget of the Phytosanitary Administration.

Implementation of the Program by an authorized institution (Biotechnical Institute / Plant Protection Centre) and persons in charge and implementation of the Program on the basis of submitted reports, are controlled by the phytosanitary inspectorate. The aim of adoption of this Program is a stable health condition of plants on the entire territory of Montenegro, timely detection and control of occurrence of harmful organisms for plants, plant products and objects under supervision, timely, regular, effective and rational implementation of plant protection measures in practice, prevention or reduction of yield losses in plant production.

Border phytosanitary inspectors mostly deal only with **control activities** in the phytosanitary field and they spend full working hours at these affairs.

Phytosanitary inspectors working in internal units work on implementation of the phytosanitary policy, in addition to the control activities.

In accordance with the NPI, setting up of control through a PHYTO REGISTER is planned for the upcoming period, for the following:

- producers and importers of plants, plant products and objects under supervision /Commission Directive 92/90/EEC of 3 November 1992 establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration/
- setting up of a plant passport system / Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement/
- registration system of producers, wholesale dispatchers / Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register/

Taking into account that the Phytosanitary Administration is a newly established body with underdeveloped administrative capacities, the registration process has not commenced yet. Expected implementation in 2011.

The Phytosanitary Administration is in charge of pesticides and pesticide residues (Department for Plant Protection Products, Plant Nutrition Products and Food Safety).

The Phytosanitary Administration is the body in charge of control, implementation and coordination activities in the field of plant protection products and pesticide residues. The Law on Plant Protection lays down rules for control of plant protection products, which will be defined in more detail in the secondary legislation.

There is no pesticide production in Montenegro and it is allowed to import and use only the registered plant protection products in Montenegro in accordance with the List of plant protection products, which is published in the Official Gazette of Montenegro. Plant protection products may be placed on the market only if they are registered, classified, packaged, labelled and if they are accompanied by a label and instructions for use in accordance with the regulations governing the hazardous substances, chemicals.

A legally valid list of registered plant protection products has been taken from the former legal system which was valid for Serbia and Montenegro.

A list of active substances, which contains no active substances without an authorization for application in the EU, is published. This list is the list refined from the former system, from which all the active substances banned in the EU have been removed. These lists are the basis for

carrying out of controls, whether the administrative or inspection ones.

Control is multilayered and performed through: Register of Importers, Register of Wholesale Establishments, Register of Retail Establishments (working licenses through fulfilment of the prescribed conditions) and Register of Authorized Plant Protection Products and Active Substances.

Rounding up of the overall control of plant protection products will be completed by the planned registration of plant producers who may put plants and plant products on the market only if they are entered into the Register of Plant Producers kept by the local administration authority in charge of the agricultural affairs.

Plant producers who use plant protection products are obliged to keep records on use of products, to adequately keep the plant protection products and act with the plant protection products waste in accordance with the law governing waste. Plant protection products must be used in accordance with the decision on registration of plant protection products, i.e. instruction of use and the label and prepare the prescribed concentrations adhering to the principles of a Good Agricultural Practice for plant protection products, integrated plant protection and environment protection, in accordance with the prescribed principles of Good Agricultural Practice and integrated plant protection.

Only appliances guaranteeing the use of plant protection products safe for people, animals and environment, accompanied by a manufacturer's certificate may be used for application of plant protection products.

Owner of the appliance for application of plant protection products is obliged to keep the appliances in good repair. Owner of the appliance for application of plant protection products is obliged to keep technical documentation on the appliance (manufacturer's certificate, instructions for use, a proof on performed repair etc.).

Control is still not systematic; controls are performed from time to time.

Control is not fully established, local administration authorities have not set up plant producers registers yet and the Phytosanitary Administration as a newly established authority still does not have the administrative capacities developed enough, so the existing Registers are used. At this moment, control is more focused on control of imports than on the control in terms of the EU legislation.

Currently, plant keepers are not additionally trained for compliance with the requirements from the Law on Plant Protection Products; activities at preparation for education and training of plant keepers have been initiated.

Most of the establishments already registered for import, wholesale and retail are equipped in accordance with the requirements and they have adequate premises. A detailed revision and further training of both administration of the Phytosanitary Administration and local level administration and in the premises for sale of plant protection products are necessary.

Border phytosanitary inspectors mainly deal only with the **control activities** in the phytosanitary field and they spend full working hours on these affairs.

Phytosanitary inspectors working in internal units work on implementation of the phytosanitary policy, in addition to the control activities.

Program of Monitoring of Pesticide Residues in Food of Plant Origin monitors the pesticide residues levels in order to estimate the extent to which the population health is endangered. This program was adopted and published in the Official Gazette of Montenegro 57/09, and it was adopted in accordance with the Law on Food Safety (Official Gazette of Montenegro 14/07) and the Law on Plant Protection Products (Official Gazette of Montenegro 51/08).

The Program of Monitoring of Pesticide Residues in Food of Plant Origin determines persons performing monitoring, priority in sampling of food of plant origin, number of samplings and analyses and active substances to be analyzed for the purpose of monitoring the levels of pesticide residues with the aim of assessing the level of risk to the population health, in compliance with the prescribed pesticide residues level (Rulebook on quantities of pesticides,

metals and metalloids and other poisonous substances, chemotherapeutics, anabolics and other substances which may occur in foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 5/92, 11/92 and 32/02).

Program lays down taking samples and analyses of: fruit, vegetables, cereals, beverages and cereal-based products and baby food.

This Program is based on standard parameters and recommendations of the European Commission from February 4th, 2008 in relation to the coordinated monitoring program and national monitoring program for 2009 (2008/103/EC).

Border phytosanitary inspectors mostly deal only with **control activities** in the phytosanitary field and they spend full working hours at these affairs.

Phytosanitary inspectors working in internal units work on implementation of the phytosanitary policy, in addition to the control activities.

The Phytosanitary Administration is in charge of seed and planting material (Department for Agricultural Plants Seed Material, Planting Material and the GMO)

The Phytosanitary Administration is the competent body for the activities of control, implementation and coordination in the field of seed and planting material. The Law on Agricultural Plants Seed Material and the Law on Planting Material, as well as the activities of control, implementation and coordination referred to in the Law on Plant Health Protection lay down rules for control of seed and planting material which will be defined in more detail by secondary legislation.

The Law on Agricultural Plants Seed Material lays down conditions and method of production, processing, control, postcontrol, quality check, trade and import of cereal, industrial, forage, medicinal, aromatic and spice herbs, flowers, seed potatoes, bulbs, cloves, seedlings, rhizomes, edible and medicinal fungi (i.e. seed materials), recognition of agricultural plants varieties, entering of varieties into the Register of agricultural plants varieties and other issues of relevance for production and trade in seed material.

The Law on Planting Material lays down conditions and method of production, trade and import of planting material of fruit, grapevine, hop, decorative, medicinal and aromatic herbs, the procedure of recognition of varieties of planting material, entering of varieties and rootstocks into the Register of varieties and rootstocks of planting material and other issues of relevance for production and trade in planting material.

Administrative control activities are carried out through:

- control of categorization of seed and planting material
- registration process: entry into the Register of Producers of Seed and Planting Material where the Phytosanitary Administration establishes compliance with the requirements based on requirements prescribed for entry into the Register of Producers, and keeps the Register of Producers
- obligation of a producer to keep a book of records on production of seed and planting material
- Seed and planting material production is subject to the compulsory technical control with the aim of establishing: the origin of seed used, specie, variety and category, authenticity and purity of the specie and variety, spatial isolation, crop health condition, presence of weeds, general condition and growth of crops, preceding crop, application of agro-technical measures and expected yield of natural seeds, in the manner of and in accordance with the prescribed methodology for performing technical control.
- Register of processors and obligation that only a legal person or an entrepreneur may deal with seed material processing if they are entered into the Register of Seed Material Processors where the Phytosanitary Administration establishes compliance with the requirements based on requests prescribed for entry into the Register.

- Prescribed quality of the seed material which, in terms of this law – purity, humidity, germination and health condition
- accredited laboratory performs seed material analyses for the purpose of quality assessment
- seed and planting material in circulation must correspond to the declared specie and variety, prescribed quality norms, it must be originally packaged and contain a label with a waybill and tag (label on the wrapping).
- Seed and planting material in circulation must correspond to the quality marked on the label and the tag
- Trade in seed and planting material can be performed only by a legal entity, i.e. another legal entity and entrepreneur, if entered into the Register for Wholesale in Seed and Planting Material or into the Register of Retail Trade in Seed and Planting material, where the Phytosanitary Administration establishes the compliance with the requirements based on the requirements prescribed for entry into the Register
- import may be carried out by a legal entity, i.e. another legal entity and an entrepreneur, if entered into the Register of Importers, where the Phytosanitary Administration establishes the compliance with the requirements based on the requirements prescribed for entry into the Register
- Postcontrol checks of seed to which basic and certified seeds produced, processed and placed on the market is subject, whereby a standard sample of seed material is taken as a control sample. Postcontrol checks of seeds serve to check varietal aspects (originality), genetic purity, health condition and compliance with other requirements concerning the quality of seed of agricultural plants.

Border phytosanitary inspectors mostly handle only the **control activities** in the phytosanitary field and they spend full working hours at these affairs.

Phytosanitary inspectors working in internal units work on implementation of the the phytosanitary policy, in addition to the control activities.

Coordination between the competent bodies has not been fully established so information exchange and planning of joint activities is carried out at monthly meetings of chief inspectors, coordinators, laboratories. The plan is to make the evaluation of the existing safety system under the IPA 2008 Food Safety Project, which needs to be enhanced, especially in this part.

6. Implementation: For each of the following items of the food safety, veterinary, and phytosanitary policy, listed below please give details of the measures taken to ensure proper implementation of the legislation with reference as relevant to the following activities (indicative list):

- laboratories used in hygiene, veterinary, phytosanitary controls and food stuff analysis (chemical, microbiology, GMOs, etc): present or planned activities (with time-table) to comply with EU systems, timetable of accreditation according to EU law with name of accreditation body, methods of sampling and analysis (in general, for contaminates, for food contact materials, etc.;

Laboratories in charge of sanitary, veterinary, phytosanitary control and foodstuffs analysis

In Montenegro, the following laboratories are in charge of affairs from the field of sanitary, veterinary and phytosanitary control:

- **Institute of Public Health** in Podgorica (microbiological and physical-chemical examinations of food),
- **Diagnostic Veterinary Laboratory** in Podgorica (diagnostic examinations of animal diseases, microbiological examinations of food and feed of animal origin),
- **Center for Eco-Toxicological Researches** in Podgorica (physical-chemical examinations of food and feed),
- **Biotechnical Faculty of the University of Montenegro** within which the following function:
- **Phytosanitary Laboratory (Centre for plant protection in Podgorica)** (diagnostic examinations of harmful plant organisms and plant products and examination of biological efficiency of pesticides);
- **Laboratory for Seeds (Centre for Field Crops, Vegetables and Forage Crops)** (examination and quality assessment of planting material and agricultural plants material);
- **Laboratory for seeds material (Centre for Fruit and Vine Growing, Podgorica and Centre for Subtropical cultures in Bar)** (examinations and quality assessment of planting material).

In Montenegro, there is no laboratory for GMO examination, these examinations are carried out in laboratories in surrounding countries (laboratory must be an authorized and accredited one)

Institute of Public Health – IPH was established by a decision of the Government of Montenegro as a highly specialized health institution at the tertiary level of health protection, the activities of which are focused on maintenance and promotion of population health. Supervision over the work of the Institute is carried out by the Ministry of Health. In performing its activities the IPH, inter alia, proposes and implements measures concerning control of health safety of foodstuffs and objects in general use, controls hygienic safety of drinking water, surface and waste waters, and carries out microbiological and parasitological, chemical, biological, toxicological, biochemical and other laboratory analysis

Comprehensive reconstruction of the IPH building is under way, it is in its final phase, and laboratory room capacities will be significantly extended, observing all the principles of good laboratory practice. Under the same reconstruction project additional laboratory equipment will be supplied.

Laboratory examinations are carried out pursuant to national regulations which are partly harmonized with the EU. In the following period, in cooperation with other institutions in the country, the process of harmonization with the EU regulations will be enhanced, which will require introduction of new examination methods, and thereby acquisition of new equipment.

Special attention is attributed to further training of employees in the area of introduction of new methods and training for work with the equipment. The IPH policy is constant specialization of the employees and raising of the level of their competencies. To that aim, attendance is enabled at all educational seminars, scientific congresses etc. IPH participates in several international projects from different fields. In the field of food safety, the regional project FOCUS-BALKANS (Food consumer science in the Balkans) is under way, in which the IPH is a partner, as well as the Project of sustainable elimination of Iodine Deficiency Disorders (UNICEF) and the „Development of food safety services in Montenegro“ IPA 2008 Project, which will begin by the end of 2009.

Accreditation and participation at inter-laboratory comparative tests is the priority task of the IPH following termination of reconstruction. The IPH is in the process of preparation for obtaining of accreditation, during which documentation has been prepared with all the necessary procedures in accordance with requirements of the ISO 17025 standard. These procedures are already in implementation, although due to reconstruction of the IPH building, completion of the accreditation process is expected from the National Accreditation Body of Montenegro – ATCG.

Since April 2009, Accreditation Body of Montenegro is an associate member of the ILAC (International Laboratory Accreditation Cooperation), and since 2008, it is in a contract relation with the EA (European Cooperation for Accreditation).

Microbiological examinations of food – Institute of Public Health IPH

TYPE OF EXAMINATION	METHOD
Isolation and identification of salmonella species	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 8
Isolation and identification of coagulase-positive staphylococci	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 9
Isolation and identification of sulphite reducing clostridia	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 10
Isolation and identification of Proteus species	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 11
Isolation and identification of Escherichia coli	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method12
Determination of the number of microorganisms in g or ml	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 1
Determination of presence of microorganisms in sterilized milk and sterilized milk beverages	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 2
Determination of lipolytic bacteria	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 7
Determination of quantity of yeast and mold in g or ml	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 4
Determination of the number of Aerobic Sporogenous Bacteria in g or ml	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 3
Isolation and identification of coliform bacteria in fizzy non-alcoholic drinks	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 13
Isolation and identification of Enterococcus faecalis in fizzy non-alcoholic drinks	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method14

Isolation and identification of Proteus species in fizzy non-alcoholic drinks (in 100 ml)	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on the Method of Sampling and Methods for Laboratory Analyses of Drinking Water /Methods for Bacteriological, Virological, Biological and Parasitic Examination of Drinking Water / (Official Gazette of the Federal Republic of Yugoslavia, 33/87) method 5
Isolation and identification of Pseudomonas aeruginosa in fizzy non-alcoholic drinks (in 100 ml)	Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia, 26/93) Rulebook on the Method of Sampling and Methods for Laboratory Analyses of Drinking Water /Methods for Bacteriological, Virological, Biological and Parasitic Examination of Drinking Water / (Official Gazette of the Federal Republic of Yugoslavia, 33/87) method 7
Isolation and identification of Streptococcus β haemolyticus	Rulebook on Requirements in terms of Health Safety of Dietetic Foodstuffs which may be placed on the market (Official Gazette of the Socialist Federal Republic of Yugoslavia, 4/85) Rulebook on Methods of Performing Microbiological Analyses and Superanalysis of Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia, 25/80) II Procedure for Determination of Presence, Isolation and Identification of Microorganisms, method 15
Examination of presence of antibiotics residues	Method: “4 Plate Test”
Examination of presence of antibiotics residues	Method by Galeslot and Hassing

Physical-Chemical examination of food – Institute of Public Health - IPH

TYPE OF EXAMINATION	METHOD
DRINKING WATER	
Examination of odour	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -2
Examination of taste	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -3
Determination of temperature	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -1
Measuring of PH value (electrochemical method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -6/A
Determination of residue after evaporation at 105 °C	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -7
Determination of residue after evaporation at 180 °C	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -7
Determination of sediments after two hours	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -8
Determination of suspended solids	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -9
Determination of Electrolytic Conductivity (conductometric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV -11
Determination of potassium-permanganate consumption (metoda po Kübel-Tiemannu)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV-9a
Determination of oxygen by titrimetric Winkler method	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV-12
Determination of biochemical oxygen consumption– BOC (by Winler method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV-12
Determination of chemical oxygen consumption (volumetric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-IV-10
Determination of ammonium content (spectrophotometric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-2/ B
Determination of residual chlorine content (colorimetric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-18/ B
Determination of chloride content (volumetric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-19/ B
Determination of fluoride content (ion-selective electrode)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-15/ C

Determination of nitrate content (UV-spectrophotometric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-31/ C
Determination of nitrite content (spectrophotometric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-32/ A
Determination of aluminum content (spectrophotometric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-1/ B
Determination of anionic detergents (spectrophotometric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-13/ B
Determination of alkalinity (volumetric method)	Standard Methods for the Examination Water and Wastewater, 20th Edition, APHA, AWWA, WEF, 1998, method 2320
Determination of hardness (volumetric method)	Standard Methods for the Examination Water and Wastewater, 20th Edition, APHA, AWWA, WEF, 1998, method 2340
Determination of phosphates content (spectrophotometric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-16/ A
Determination of calcium content (volumetric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-22/ A
Determination of ammonium content (colorimetric method)	Drinking waters, Standard methods for examination of hygienic safety, FIFHP, 1990, method P-V-2/ A
CEREALS	
Examination of odour, taste and colour	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method I. 1
Determination of grain purity - extraneous impurities, - grains of other varieties, - yellowed grains, - discolored grains, - unpeeled grains, - grains with a red line, - broken grains, - grains affected by insects	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, methods I. 4 i I. 5
Determination of water (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method I. 8
MILL PRODUCTS	
Examination of odour, taste and colour	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method II. 1
Determination of nitrogen by Kjeldhal (volumetric method)	JUS ISO 1871:1992 JUS ISO 937:1992
Determination of water (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method I. 8
Determination of acidity (volumetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method I. 16
Determination of fat by Weibul Stoldt (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method I. 15
Determination of ash (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method I. 10
BAKERY PRODCUTS	
Examination of odour, taste and colour	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method II. 1
Determination of nitrogen content by Kjeldhal (volumetric method)	JUS ISO 1871:1992 JUS ISO 937:1992

Determination of fat by Weibul Stoldt (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method II. 4
Determination of water	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method II. 1
Determination of acidity (volumetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method II. 2
FAST FROZEN PASTRY	
Determination of fat by Weibul Stoldt (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method IV.4. (I.15)
Determination of water (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method II. 1
PASTRY AND RELATED PRODUCTS	
Examination of odour, taste and colour	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method III. 1
Determination of water (gravimetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method III. 5
Determination of acidity (volumetric method)	Rulebook on Methods of Physical and Chemical Analyses for Control of Cereals Quality, Mill and Bakery Products, Pastry and Fast Frozen Pastry, Official Gazette of the Socialist Federal Republic of Yugoslavia, 74/88, method III. 5
KITCHEN SALT AND SALT FOR FOOD INDUSTRY	
Determination of iodide content (volumetric method)	JUS E.Z8.002:2001
MILK	
Determination of milk fat by Gerber	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method I .3
Determination of acidity (volumetric method)	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method I .2
Determination of specific weight by lacto-densitometer	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method I .1
Determination of dry matter (gravimetric method)	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method I .4
CRÈME FRECHE	
Determination of dry matter without fat	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method II .4
Determination of pH value	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method V .2
POWDER MILK	
Determination of milk fat by Gerber	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method IV .2
Determination of acidity (volumetric method)	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method II .4
Determination of water (gravimetric method)	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method IV .11
CHEESE	

Determination of milk fat by Gerber	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method IV .2
Determination of pH value (electrochemical method)	Morris Kats: Methods of Air Sampling and Analysis, Second Edition, American Public Health Association, 1977.
Determination of water (gravimetric method)	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method IV .1
ICE CREAM	
Determination of milk fat by Gerber	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method V .1
Determination of water (refractometric method)	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method III .1
YOGHURT, SOUR MILK	
Determination of fat by Gerber	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method II.1
Determination of dry matter (gravimetric method)	Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products, Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83, method II.3
Determination of pH value (electrochemical method)	Morris Kats: Methods of Air Sampling and Analysis, Second Edition, American Public Health Association, 1977.
SOUPS, SAUCES, SEASONING PRODUCTS	
Determination of nitrogen content by Kjeldhal (volumetric method)	JUS ISO 1871:1992
Determination of Sodium Glutamate (volumetric method)	JUS E.Z8.018:1994
Determination of salt by Mohr (volumetric method)	JUS E.Z8.012:1994
Determination of water (gravimetric method)	JUS E.Z8.011:1993
Determination of fat by Weibul Stoldt (gravimetric method)	JUS E.Z8.015:1993
MEAT PRODUCTS	
Determination of nitrogen content by Kjeldhal (volumetric method)	JUS ISO 937:1992 JUS ISO 1871:1992
Determination of total phosphates (spectrophotometric method)	JUS ISO 13730:1999
Determination of nitrites content (spectrophotometric method)	JUS ISO 2918:1999
Determination of water (gravimetric method)	JUS ISO 1442:1998
Determination of hydroxyproline (spectrophotometric method)	JUS ISO 3496: 2002
FRUIT JUICE, FRUIT JUICE CONCENTRATE, FRUIT NECTAR, FRUIT JUICE POWDER, FRUIT AND VEGETABLES PRODCUTS	
Determination of acidity (volumetric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 18
Determination of acidity (volumetric method)	JUS ISO 750: 2003
Determination of pH value (electrochemical method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 6.
Determination of dry matter (refractometric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 1and method 2.
SPICES	
Determination of total ash (gravimetric method)	JUS ISO 928:2001

Determination of moisture content (gravimetric method)	JUS ISO 939:1997
Determination of evaporable oil content (gravimetric method)	JUS ISO 6571:2001
TEA	
Determination of water extract (gravimetric method)	JUS ISO 9768:1995
Determination of mass loss at 103°C (gravimetric method)	JUS ISO 1573:1995
Determination of total ash (gravimetric method)	JUS ISO 1575:1995
REFRESHING DRINKS, SYRUPS	
Determination of phosphates (spectrophotometric method)	Standard Methods for the Examination Water and Wastewater, 20th Edition, APHA, AWWA, WPCF, 2000. Modified standard method
Determination of coffeine (spectrophotometric method)	AOAC 17th edition, 2002. 962.13 (modified)
Determination of acidity (volumetric method)	JUS ISO 750: 2003
Determination of vitamin C (volumetric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 15.
Determination of dry matter (refractometric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 1 and method 2.
BEER	
Determination of carbon dioxide (gravimetric method)	Instructions of the equipment manufacturer. Measuring of gas pressure by a manometer.
Determination of alcohol content (pycnometer)	JUS E.M2.050:1959
Determination of pH value (electrochemical method)	Morris Kats: Methods of Air Sampling and Analysis, Second Edition, American Public Health Association, 1977.
COFFEE PRODUCTS	
Determination of extracts (gravimetric method)	AOAC, method 973.21
Determination of ash (gravimetric method)	M. Mirić, J. Trajković, J. Baras, S. Šiler: Analiza životnih namirnica, TMF, 1983. (M. Mirić, J. Trajković, J. Baras, S. Šiler: Analysis of Foodstuffs, TMF, 1983.)
Determination of water (gravimetric method)	M. Mirić, J. Trajković, J. Baras, S. Šiler: Analiza životnih namirnica, TMF, 1983. (M. Mirić, J. Trajković, J. Baras, S. Šiler: Analysis of Foodstuffs, TMF, 1983.)
COCOA PRODUCTS, CHOCOLATE, CREAM PRODUCTS	
Determination of lactose by Luff Shorll (volumetric method)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Cocoa-Grains, Chocolate-like Products, Bonbon Products, Cream Products and Biscuit-like Products, Official Gazette of the Socialist Federal Republic of Yugoslavia, 41/87, method II .13
Determination of fat by Weibul Stoldt (gravimetric method)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Cocoa-Grains, Chocolate-like Products, Bonbon Products, Cream Products and Biscuit-like Products, Official Gazette of the Socialist Federal Republic of Yugoslavia, 41/87, method II .9
Determination of ash (gravimetric method)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Cocoa-Grains, Chocolate-like Products, Bonbon Products, Cream Products and Biscuit-like Products, Official Gazette of the Socialist Federal Republic of Yugoslavia, 41/87, method II .5
Determination of sugar by Luff Shorll (volumetric method)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Cocoa-Grains, Chocolate-like Products, Bonbon Products, Cream Products and Biscuit-like Products, Official Gazette of the Socialist Federal Republic of Yugoslavia, 41/87, method II .13
Determination of theobromine (spectorphotometric method)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Cocoa-Grains, Chocolate-like Products, Bonbon Products, Cream Products and Biscuit-like Products, Official Gazette of the Socialist Federal Republic of Yugoslavia, 41/87, method II .7
Determination of water (gravimetric method)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Cocoa-Grains, Chocolate-like Products, Bonbon Products, Cream Products and Biscuit-like Products, Official Gazette of the Socialist Federal Republic of Yugoslavia, 41/87, method II .1
Determination of fat by Weibul Stoldt (gravimetric method)	JUS E.K8. 050:1997

Determination of phospate content (spectrophotometric method)	JUS E K8. 049:1997
Determination of methanol (spectrophotometric method)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Alcohol Beverages, Official Gazette of the Socialist Federal Republic of Yugoslavia 70/87, method 5
Determination of alcohol (by a picnometer)	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Alcohol Beverages, Official Gazette of the Socialist Federal Republic of Yugoslavia 70/87, method 1
Determination of total acids (volumetric method)	Rulebook on Honey and other Bee Products and Methods for Honey and other Bee Products Quality Control, Official Gazette of the Socialist Federal Republic of Yugoslavia, 4/85 and 7/92., method V. 7
Determination of Hydroxymethylfurfural content (spectrophotometric method)	Rulebook on Honey and other Bee Products and Methods for Honey and other Bee Products Quality Control, Official Gazette of the Socialist Federal Republic of Yugoslavia, 4/85 and 7/92., method V. 9
Determination of water (refractometric method)	Rulebook on Honey and other Bee Products and Methods for Honey and other Bee Products Quality Control, Official Gazette of the Socialist Federal Republic of Yugoslavia, 4/85 and 7/92., method V. 4
MUSHROOM PRODUCTS	
Determination of sodium chloride (volumetric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 10
Determination of ash insoluble in hydrochloride acid (gravimetric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 5
Determination of total acids (volumetric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 18
Determination of sodium benzoates (spectrophotometric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 7
Determination of pH value (electrochemical method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 6
Determination of dry matter (refractometric method)	Rulebook on Methods of Sampling and Chemical and Physical Analyses for Control of Fruit and Vegetables Products Quality, Official Gazette of the Socialist Federal Republic of Yugoslavia, 29/83, method 2
Determination of sulphur dioxide content (volumetric method)	JUS EN 13196:2003
Determination of mycotoxins (method of thin layer chromatography)	AOAC, 17th edition, 2002.968.22, 971.22, 975.37, 978.15
UTENSILS, KIT AND WRAPPING FOR FOODSTUFFS	
Examination of colour and appearance	Rulebook on the Method of Performing Analyses and Superanalyses for Determination of the Quantity of Heavy Metals (lead, copper, iron and nickel) in Foodstuffs – oils, fats and margarine, Official Gazette of the Socialist Federal Republic of Montenegro, 33/84

In addition to the aforementioned analyses, the Institute performs other food safety analyses, as well (additives, mycotoxins, heavy metals, pesticides...).

Diagnostic Veterinary Laboratory - DVL is established by the Veterinary Law (Official Gazette of the Republic of Montenegro 11/04, 27/07) to perform the laboratory diagnostics of animal diseases, laboratory examination of animal products and laboratory examination of feed. Diagnostic Veterinary Laboratory was founded by the Government of Montenegro in 2004, as a public institution performing activities of public interest, and the decision on fulfilment of requirements for work of the laboratory was made by the Veterinary Administration of Montenegro in 2005 and 2006. Supervision over the Laboratory's work is carried out by the Ministry of Agriculture, Forestry and Water Management. The premises of the DVL were built by the EU donor funds in 2004 under the project "Strengthening of Veterinary and Phytosanitary Services in Montenegro" (EAR 03MTG01/02/001, CARDS 2003) in the amount of around EUR 550 000. During implementation of the project "Strengthening of fisheries sector in Serbia and Montenegro" (CARDS 2005 FWC) additional equipment was supplied to the DVL in 2007 in the form of laboratory equipment worth around EUR 115 000.

Currently the equipment level of the DVL does not fully satisfy all the requirements of modern laboratory diagnostics and modern methods of examination of food and feed of animal origin.

Additional equipping of the DVL as well as additional education of staff should enable upgrade of all laboratory examinations procedures.

DVL, as the only laboratory of that kind in Montenegro is regularly included in the TAIEX programs aimed at promotion of laboratory examination methods in accordance with the EU regulations, and it also attends meetings of national reference laboratories of the EU for certain animal diseases.

DVL is actively pursuing the activities aimed at accreditation by the international ISO/IEC 17025 standard. The activities are carried out with the aim of implementation of complete documentation, procedures and processes, adoption and implementation of quality standards in all segments of the DVL work, with acquisition of necessary additional laboratory equipment and continuous education of laboratory staff, as well as participation in inter-laboratory comparative tests. Completion of these activities and accreditation of the DVL with the National Body – Accreditation Body of Montenegro (ATCG) is expected during 2010.

IPA 2008 Project: „Development of food safety services in Montenegro“, which will start at the end of 2009, will provide additional education of the SVL staff in the field of contemporary methods of laboratory examination of food.

During 2010, the DVL is planning to further continue development of the newly-introduced molecular techniques of animal disease diagnostics. Efforts will be primarily focused to the additional training concerning development and further improvement of the Real-Time PCR technique in Avian Influenza (bird flu) diagnostics, as well as Classical Swine Fever, Newcastle disease and other. To that sense, the DVL will in the period 2009-2011 actively participate in the regional project of the International Atomic Energy Agency based in Vienna, Austria (IAEA) – RER 5015 “Supporting Early Warning and Surveillance of Avian Influenza Infection in Wild and Domestic Birds and Assessing Genetic Markers for Bird Resistance“, as the representative of Montenegro along with 12 Eastern Europe countries.

Also, during the period 2009-2013, the DVL will be involved in implementation of the World Bank MIDAS project, under which additional equipping of the DVL is planned for the purpose of modernization of microbiological examination methods and introduction of examinations for TSEs worth EUR 210 000.

Microbiological examinations of food and feed – Diagnostic Veterinary Laboratory - DVL

TYPE OF EXAMINATION	METHOD
Determination of microorganisms count in 1 gr or 1 ml	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Determination of yeast and mold count	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Determination of lipolytic microorganisms count in food	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Isolation and identification of Salmonella	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Isolation and identification of coagulase-positive staphylococci	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Isolation and identification of sulphite reducing clostridia	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Isolation and identification of Proteus species	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Isolation and identification of E.coli	Rulebook on Methods of Performing Microbiological Analyses and Superanalises of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia, 25/80)
Isolation and identification of Listeria monocytogenes	ISO 11290-1 :1996 Microbiology of food and animal feedingstuffs – Horizontal method for the detection and enumeration of Listeria monocytogenes – Part 1: Detection method ISO 11290-2 :1998 Microbiology of food and animal feedingstuffs – Horizontal method for the detection and enumeration of Listeria monocytogenes – Part 2: Enumeration method

Determination of total count of saprophytic microorganisms in feed	Rulebook on Methods of Sampling, Physical-Chemical Examinations and Microbiological Examinations of Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia, 15/87)
Determination of total fungi and mould count in feed	Rulebook on Methods of Sampling, Physical-Chemical Examinations and Microbiological Examinations of Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia, 15/87)
Isolation and identification of Salmonella in feed	Rulebook on Methods of Sampling, Physical-Chemical Examinations and Microbiological Examinations of Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia, 15/87)
Isolation and identification of sulphite reducing clostridia in feed	Rulebook on Methods of Sampling, Physical-Chemical Examinations and Microbiological Examinations of Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia, 15/87)

Diagnostic examinations of animal diseases – Diagnostic Veterinary Laboratory - DVL

TYPE OF EXAMINATION	METHOD
Rabies	Direct immunofluorescence
Brucellosis	Rose Bengal (RB- test) iELISA cELISA
Enzootic Bovine Leucosis	iELISA
IBR / IPV	iELISA
Q fever	iELISA Indirect Immunofluorescence assay (IFA-test)
Bovine Virus Diarrhoea (BVD)	iELISA
Paratuberculosis	iELISA
Neospora caninum	iELISA
Bluetongue	cELISA
Foot-and-mouth disease	iELISA
Classical Swine Fever	Direct immunofluorescence iELISA AgELISA
Aujeszky`s disease	iELISA
PRRS	iELISA
Mycoplasmosis (Mycoplasma hyopneumoniae)	iELISA
Swine flu (H1N1)	iELISA
Caprine Encephalitis/Arthritis Virus	cELISA
Avian infectious bronchitis	iELISA
Infectious bursal disease (Gumboro bolest)	iELISA
Atypical fowl plague (Newcastle disease)	iELISA
Infection by Mycoplasmae gallinarum/synoviae	iELISA
Avian influenza	iELISA Real-Time PCR
Listeria (monocitogenes)	Isolation on nutritive media and identification
Staphylococcus spp.	Isolation on nutritive media and identification
Streptococcus spp.	Isolation on nutritive media and identification
Corynebacterium spp.	Isolation on nutritive media and identification
E.coli	Isolation on nutritive media and identification
Erysipelotrix rhusiopathie	Isolation on nutritive media and identification
Bacillus anthracis	Isolation on nutritive media and identification Ascoli precipitation
Campylobacter spp.	Isolation on nutritive media and identification
Clostriduim perfrigens	Isolation on nutritive media
Gas-Gangrene Clostridia caused by C.chaovei	Isolation on nutritive media
Salmonella spp.	Isolation on nutritive media
Yersinia enterocolitica	Isolation on nutritive media
Actinobacillus pleuropneumoniae	Isolation on nutritive media
Haemophillus spp.	Isolation on nutritive media
Pasteurella spp.	Isolation on nutritive media
Tuberculosis	Isolation on nutritive media and identification
Antimicrobial susceptibility test	Disc diffusion method
Trichinosis	Artificial digestion method
canine leishmaniosis	Indirect immunofluorescence assay (IFA-test)
American foulbrood	Microscopy
Nosemosis	Microscopy

Centre for Eco-toxicological Researches of Montenegro - CETI was founded by a decision of the Government of Montenegro in 1996 as a public institution for performing activities of public interest. Centre is the institution authorized for control and safety of food and objects in general use as of 1998, for control of agricultural and food products in foreign trade since 1999, as well as for examination of physical-chemical characteristics of pesticides. Supervision over the work of the Centre is carried out by the Ministry in charge of environmental protection affairs.

By the end of 2009, the Centre is planning expansion of the scope of accreditations with the standard EU-recognized methods in the field of dioxin examination in samples from the environment in accordance with the IAEA no. MNE8002 Project - "Upgrading a Persistent Organic Pollutant Laboratory towards Accreditation for Environmental Monitoring". In addition to study visits and schooling in this field at the NRL in Maribor, Slovenia, IAEA donated GCMSMS to the Centre for carrying out of these activities.

IAEA no. MNE2007002 Project - "Upgrading Capabilities to Establish Effective Monitoring Systems for Residues in Food and Air Quality" entails extension of the existing scope of accreditations with the standard EU-recognized methods of determination of veterinary medicinal products in foodstuffs of animal origin. In addition to important schooling which will be carried out through internship in a NRL in an EU Member State, this project envisages equipment donation of LCMSMS as one of the most important instrument for achieving the adequate detection limits for certain components.

CETI possesses: ISO 9001:2000 – Certified by TUV SUD Management Service GmbH, introduced standard JUS ISO/IEC 17025 – Accredited by JUAT-a (accreditation body of the former state union of Serbia and Montenegro) no. 01-107 in 2005 as well as MEST ISO/IEC 17025:2006 – Accredited by the Accreditation Body of Montenegro (ATCG) in 2008 (no. Li 08.03).

In accordance with the needs of Montenegro for certain fields of examination, the scope of CETI accreditation has been established, therefore, certain methods from the following fields of examination have been accredited so far:

- physical-chemical examinations: drinking water and ice, foodstuffs of animal origin, waters and waste waters, air, soil, sediments and sludge;
- examination of radioactivity in the samples of: waters, air, soil, food, construction material;
- examination of the level of external radiation;
- examination of the source of ionizing radiation;
- acoustic examination of noise;
- sampling of: surface waters and drinking water, liquids and flammable liquids, soil, sediments and sludge.

Physical-chemical examinations of food and feed - CETI

TYPE OF EXAMINATION	METHOD
Examination of meat and meat products quality: - water - fat - ash - salt - pH - nitrites - nitrates - phosphates	 ISO 1442, 1997 ISO 1444, 1997 ISO 936, 1998 ISO1841-1, 1998 ISO11289, 1997 ISO 2918, 1999 ISO 3091, 1998 ISO 13730, 1996
Examination of milk and dairy products quality	Rulebook on Methods of Sampling and Methods of Physical and Chemical Analyses of Milk and Dairy Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83)
Methods for examination of eggs and egg products quality	Rulebook on Methods of Examination of Eggs and Egg Products Quality (Official Gazette of the Socialist Federal Republic of Yugoslavia 72/87)

Methods for examination of honey and other bee products quality	Rulebook on Honey and other Bee Products Quality and Methods for Control of Honey and other Bee Products Quality (Official Gazette of the Socialist Federal Republic of Yugoslavia, 04/85) and Rulebook on Amendments of the Rulebook on Honey and other Bee Products Quality and Methods for Control of Honey and other Bee Products Quality (Official Gazette of the Socialist Federal Republic of Yugoslavia 7/92)
Methods for examination of feed quality	Rulebook on Methods of Sampling and Methods of Physical, Chemical and Microbiological Analyses of Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia 15/87)
Method for determination of fat in fish and fish products	AOAC Method 948.15, 948.16
Method for determination of ash in fish and fish products	AOAC Method 938.08
Method for determination of salt in fish and fish products	AOAC Method 937.09
Method for determination of total dry matter in fish and fish products	AOAC Method 952.08
Method for determination of total nitrogen fish and fish products	Handbook for Kjeldahl digestion-a recent review of the classical method with improvements, Developed by Tecator, 2nd edition, May 2006.
AAS/FL method for determination of metal content in foodstuffs and feed of animal origin (Pb, Cd, Cu, Zn, Fe, Cr, Ni, Mn, Co, Na, K)	AOAC method 972.23 i 973.34
AAS/HVG method for determination of arsenic content in foodstuffs and feed of animal origin	AOAC method 986.15
AAS/Hg-analyser method for determination of mercury content in foodstuffs and feed of animal origin	AMA.114 – Determination of mercury in animal tissue, Leco corporation, Form. No. 203-821-114
GC-ECD method for determination of organochlorine pesticides in meat and meat products, milk and dairy products, eggs	AOAC Method 970.52
GC-ECD method for determination of organophosphorous pesticides in meat and meat products, milk and dairy products, eggs	AOAC Method 970.52
GC-ECD method for determination of polychlorinated biphenyls in meat and meat products, milk and dairy products	AOAC Method 970.52
LCMS method for determination of Malachite green and Leuco-malachite green in fish	Quantitative and Confirmatory Analyses of Malachite Green and Leucomalachite Green Residues in Fish and Shrimp, No. 4363, Food and Drug Administration, Animal Drugs Research Center, Denver, Wendy C.Andersen, Sherri B.Turnipseed and Jose E. Roybal (with modifications)
LCMS method for determination of other pharmacologically active substances in urine	Quantitative, Highly Sensitive Liquid Chromatography-Tandem Mass Spectrometry method for detection of synthetic corticosteroids, Robert L.Taylor, Stefan K.Grebe and Ravinder J.Singh (with modifications)
LCMS method for determination of non-steroid anti-inflammatory medicinal products in a kidney	Confirmation of Phenylbutayone in bovine kidney, United States Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science (with modifications)
LCMS method for determination of carbamates in honey	Assessment of Pesticide residue in honey samples from Portugal and Spain, Cristina Blasco, Monica Fernandez, Angelina Pena, Celeste Lino, Irene Silveira, Guillermina Font and Yolanda Pico (with modifications)
LCMS method for determination of beta lactams in milk	PREVALENCE OF MOLECULES OF ß-LACTAM ANTIBIOTICS IN BOVINE MILK IN LOMBARDIA AND EMILIA ROMAGNA (ITALY), Ghidini S., Zanardi E., Varisco G., Chizzolini R., Ann. Fac. Medic. Vet. di Parma (Vol. XXII, 2002) - pag. 245 - pag. 252 (with modifications)
LCMS method for determination of beta lactams in tissue	Screening and Confirmation of β-Lactam Antibiotics by HPLC-MS/MS, CLG-BLAC.02 United States Department of Agriculture Food Safety and Inspection Service, Office of Public Health Science (with modifications)
LC/MS method for determination of stilbene in urine	Analysis of anabolic steroids in bovine urine by GC-MS, National Institute of Public health and the Environment,SOP-ARO/479, Netherlands (with modifications)
LC/MS method for determination of stilbene in tissue	Simultaneous Determination of Residual Veterinary Drugs in Bovine, Porcine, and Chicken Muscle using Liquid Chromatography Coupled with Electrospray Ionization Tandem Mass Spectrometry, Ryoji Yamada, Masaki Kozono, Takashi Ohmori, Fumiki Marimatsu, Masahiko Kitayama, Biosci. Biotechnol. Biochem. 70(1), 54-65, 2006 (with modifications)
LC/MS method for determination of thyrostatics in tissue	CLG-TST 2.00:Confirmation of Thyreostats by HPLC/MS/MS, United States Department of Agriculture, Food Safety and Inspection Service, Office of Public Health Science (with modifications)
LC/MS method for determination of thyroostatics in urine	Determination of Thyreostats in thyroid and Urine Using High-performance Liquid Chromatography-Atmospheric Pressure Chemical Ionization Mass Spectrometry, W.John Blanchflower, Peter J.Hughes, Andrew Cannavan, Maurice A.McCoy and D.Glenn Kennedy, Analyst, September 1997, Vol.122(967-972) (with modifications)
LC/MS method for determination of zeranol in tissue and urine	Determination of resorcylic acid lactones in biological samples by GC-MS. Discrimination between illegal use and contamination with fusarium toxins, M.H.Blokland, S.S. Sterk, R.W.Stephany, F.M.Launay, D.G.Kennedy and L.A.vanGinkel, Analytical and Bioanalytical Chemistry, 10.1007/s00216-005-0274-4 (with modifications)

LC/MS method for determination of beta agonists in urine and liver	Gas Chromatography-Mass Spectrometric Confirmatory Method for the determination of clenbuterol residues in animal urine and liver samples, Tomasz Sniegocki, Jan Zmudzki, Andrzej Posyniak and Stanislaw Semeniuk, Bull.Vet.Inst.Pulawy 47,139-144,2003 (with modifications)
LC/MS method for determination of chloramphenicol in meat	Confirmation of chloramphenicol residue in crab by electrospray LC/MS, Allen Pfenning, Sherri Turnipseed, Jose Roybal,Mark Madson, Rebecca Lee, Joseph Storey, Food and Drug Administration, LIB 4294 (with modifications)
LC/MS method for determination of chlorampenicol in milk	Validation of the gas chromatography-mass spectrometry method for the determination of chloramphenicol residues in milk, Tomasz Sniegocki, Jan Zmudzki and Andrzej Posyniak, Bull.Vet.Inst.Pulawy 50,353-357,2006 (with modifications)
LC/MS method for determination of chloramphenicol in honey	A confirmatory method for the determination of chloramphenicol, thiamphenicol and florfenicol in honey, Peter Hancock,Waters Corporation (with modifications)
LC/MS method for determination of nitroimidazola in meat	Confirmation of Nitroimidazols by ESI-LC/MS/MS, CLG-NIMZ 2.00, Food Safety and Inspection Service, Office of Public Health (with modifications)
LC/MS method for determination of nitroimidazole in milk	Determination of nitroimidazoles and their metabolites in milk using GC/MS-NCI, S. Constantinou, P. Kanari, C. Papachrysostomou, M. Hadjigeorgiou (with modifications)
LC/MS method for determination of nitroimidazole in eggs	Determination of Dimetridazole in Poultry Tissues and Eggs Using Liquid Chromatography-Thermospray Mass Spectrometry, Andrew Cannavan and D.Glenn Kennedy, Analyst, September 1997, Vol.122 (963-966) (with modifications)
LC/MS method for determination of nitrofuran metabolite in crustaceans and bivalve molluscs	Detection of nitrofuran Metabolites in Shrimp,U.S.Food and Drug Administration (with modifications)
LC/MS method for determination of metabolite nitrofuran in honey	LC/MS/MS determination of nitrofuran metabolites residues in honey, Kevin M.Jenkins, Michael S.Young,Waters Corporation (with modifications)
LC/MS method for determination of metabolite nitrofuran in milk	Determination of Nitrofuran metabolites in milk powder by High Performance Liquid Chromatography-Tandem Mass Spectrometry, Tao Peng (Tao Peng); Chu Xiaogang (Xiao-Gang Chu); Yang Qiang (Qiang Yang); Li Gang (Gang Li); Li Jianzhong (Jian-Zhong Li); Li Chongjiu (Chong - Jiu Li), Analytical Chemistry, 33 vol 8(2005/08),p.1073-1076 (with modifications)
HPLC Method for determination of aflatoxin M_1 in milk and cheese	AOAC Official Method 980.21- Aflatoxin M_1 in Milk and Cheese
HPLC Method for determination of aflatoxin B1 and M_1 in meat	AOAC Official Method 982.24- Aflatoxin B1and M_1 in liver
HPLC method for determination of chinolones in meat	Method for the Determination of Fluoroquinolones in Meat acc.35 and 64-Application- Macherey-Nagel, No 304060 (with modifications)
HPLC method for determination of chinolones in milk and eggs	(Validation of a multi-quinolone, multi-matrix, multi-species method for determination of quinolone residues by HPLC with fluorescence detection) poster i 27 Euroresidues V, Noodwijkerhout, The Netherlands, May 10-12.2004 E.Verdon, P.Couedor, P.Sanders, AFSSA-LERMVD, French Agency for Food Safety (with modifications)
HPLC method for determination of sedatives in meat and urine	Analytical procedure for the determination of chlorpromazine in muscle tissue and urine of food-producing animals-N.Kozuh Erzen (with modifications)
HPLC method for determination of sulphonamides in milk	Solid Phase Extraction by Matrix Solid Phase Dispersion (MSPD) and HPLC Determination of 6 Sulfonamides in Milk-MERCK Application
HPLC method for determination of tetracyclines in milk and eggs	-JTBAKER APPLICATION NOTE–FF-505-Extraction of Tetracyclines from Animal Tissue and Eggs
HPLC method for determination of antihelmintics in meat	Validation and robustness testing of a HPLC method for the determination of avermectins and moxidectin in animal liver samples using an alumina column clean-up-The Analyst-full paper Martin Danaher, Michael O´Keeffe and Jeremy D.Glennon (with modifications)
HPLC method for determination of steroids in urine	Merck Application 956 Solid Phase Extraction from Bovine Urine
HPLC method for determination of histamines	AOAC Official Method 977.13 Histamine in Seafood
GC-ECD method for determination of organochlorine pesticides in feed	AOAC Method 970.52
GC-ECD method for determination of organophosphorous pesticides in feed	AOAC Method 970.52
GC-ECD method for determination of polychlorinated biphenyls in feed	AOAC Method 970.52
GCMS method for determination of trichathecenes in cereals for feed	17 Mycotoxin Screen by GCMS, North Dakota State University, Department of Veterinary&Microbiological Sciences, Howard H.Casper
LCMS method for determination of zearalenone in cereals for feed	17 Mycotoxin Screen by GCMS, North Dakota State University, Department of Veterinary&Microbiological Sciences, Howard H.Casper (with modifications)
HPLC method for determination of aflatoxins in corn for feed	AOAC Official Method 990.33 – Aflatoxins in Corn and Peanut Butter

HPLC method for determination of ochratoxins in corn for feed	AOAC Official Method 991.44-Ochratoxin A in Corn and Barley
AAS/FL method for determination of metal content in foodstuffs of plant origin (Pb, Cd, Cu, Zn, Fe, Cr, Ni, Mn, Co, Na, K)	AOAC method 972.23, 973.34 i 985.01
AAS/HVG method for determination of arsenic content in foodstuffs of plant origin	AOAC method 986.15
AAS/Hg-analyser method for determination of mercury content in foodstuffs of plant origin	AMA.113 – Determination of mercury in plant tissue (vegetable food), Leco corporation, Form. No. 203-821-113
GC-MS method for determination of organophosphorous pesticides in fruit and vegetables	Foods of plant origin-Determinations of pesticides residues using GCMS following acetonitrile extraction/partitioning and cleanup by dispersive SPE-QuEChERS method, prEN 15662:2007
GC-MS method for determination of organochlorine pesticides in fruit and vegetables	Foods of plant origin-Determinations of pesticides residues using GCMS following acetonitrile extraction/partitioning and cleanup by dispersive SPE-QuEChERS method, prEN 15662:2007
GC-MS method for determination of pyrethroids in fruit and vegetables	Foods of plant origin-Determinations of pesticides residues using GCMS following acetonitrile extraction/partitioning and cleanup by dispersive SPE-QuEChERS metod, prEN 15662:2007
Methods of fruit and vegetables quality examination	Rulebook on the Method of Sampling and Performing Chemical and Physical Analyses for Quality Control of the Fruit and Vegetables Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 29/83)
Methods of cocoa and cocoa products quality examination	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Cocoa Grains, Cocoa Products, Chocolate like Products, Bombons, Biscuits and Biscuit like Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 41/87)
Methods of protein products examination	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Protein Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 41/85)
Methods of examination of cereals, mill and bakery products, pastry and fast frozen pastry quality	Rulebook on Methods of Physical and Chemical Analyses for Quality Control of Cereals, Mill and Bakery Products, Pastry and Fast Frozen Pastry (Official Gazette of the Socialist Federal Republic of Yugoslavia 74/88)
Methods of examination of alcohol beverages quality	Rulebook on Methods of Sampling and Performing Chemical and Physical Analyses of Alcoholic Beverages (Official Gazette of the Socialist Federal Republic of Yugoslavia, 70/87)
Methods of vinegar quality examination	Rulebook on Methods of Physical and Chemical Analyses for Quality Control of Vinegar and Diluted Vinegar Acid (Official Gazette of the Socialist Federal Republic of Yugoslavia, 26/89)

Phytosanitary laboratory (Biotechnical Faculty – Centre for Plant Protection) is authorized by the Phytosanitary Administration in accordance with the Law on Plant Health Protection (Official Gazette of the Republic of Montenegro, 28/06) for carrying out activities of plant health protection: laboratory examinations of harmful organisms, professional and technical affairs and other activities of public interest in plant health protection. The authorization defines the activities of public interest and requirements for delegation of public activities performance to the Phytosanitary laboratory. The Centre for Plant Protection is authorized for examination of biological efficiency of pesticides, as well.
Phytosanitary laboratory is the integral part of the Biotechnical Faculty in Podgorica – Centre for Plant Protection (University of Montenegro). Phytosanitary laboratory was additionally equipped with laboratory equipment through donation funds of the EU in 2004 under the project „Strengthening of Veterinary and Phytosanitary Services of Montenegro“ (EAR 03MTG01/02/001, CARDS 2003).

Currently, the level of the Phytosanitary laboratory equipment satisfies the requirements of modern laboratory diagnostics and modern methods of examination of harmful organisms, plants, plant products and objects under supervision. Additional equipping, as well as additional staff education should enable promotion of all laboratory examinations procedures.

Phytosanitary laboratory, as the only laboratory of that kind in Montenegro, is regularly included in the TAIEX programs which are aimed at promotion of laboratory examination methods in compliance with the EU regulations. Phytosanitary laboratory carries out activities aimed at accreditation by the international ISO 9001 standard. Activities are carried out with the aim of implementation of procedures and processes, adoption and implementation of quality standards in all segments of work, with acquisition of the necessary laboratory equipment and continuous staff education.

IPA 2008 Project: „Development of food safety services in Montenegro“, which is to commence by the end of 2009, will ensure additional education of the Phytosanitary Laboratory staff in the field of laboratory examination methods.

Phytosanitary laboratory consists of:

- Laboratory for phytopathology:
    a) Laboratory for mycology and bacteriology – 2 PhD phyto-pathologists employed – mycologists;
    b) Laboratory for virology – 1 MA phyto-pathologist virologist;
- Laboratory for entomology – 2 PhD entomologists employed;
- Laboratory for nematodes – 1 MA employed.

In addition to the abovementioned professional staff, there are 1 graduate in Agriculture and 2 technicians employed in the Phytosanitary laboratory.
Methods used for diagnostic examinations of harmful organisms for plant and plant products are: methods prescribed by the EU regulations for certain harmful organisms, EPPO methods or own laboratory methods.

Methods for examination of harmful plant and plant products organisms

TYPE OF EXAMINATION	METHOD
Mycological examinations	EPPO methods Visual examination Classical filter paper method Method of isolation on nutritive mediums Microscopy
Bacteriological examinations	EPPO methods Visual examination Method of isolation on nutritive and selective mediums
Virological examinations	EPPO methods Biological methods (biotest, plant indicator) Serological methods Lateral-flow test (DAS-ELISA test); Molecular methods (Polymerase chain reaction - PCR)
Entomological and acarological examinations	EPPO methods Visual examination Determination of insects and acarina by determination keys with use of steromicroscopes and microscopes
Nematological examinations	EPPO methods Isolation of active nematodes from plant material – procedure of use of mixer, centrifuge, and Baermann funnels, funnel-spray; Extraction of free living nematodes from soil - Oostenbrink elutriator; Extraction of cysts from wet soil – Kort elutriator Examination of extracted material under stereomicroscope and microscope and determination by determination keys

Measures which should be undertaken with the aim of improvement of the condition:

- Phytosanitary Laboratory must be clearly recognized through internal organization of the Biotechnical Faculty, with established hierarchy and responsibility levels;
- establish accreditation in compliance with the ISO 9001 standard;
- additional employment of professional and technical staff;
- form a herbology laboratory;
- introduce protocols for examination methods;
- introduce a good laboratory practice.

Laboratory for Seeds (Biotechnical Faculty – Centre for Crop, Vegetable and Forage Growing) is authorized by the Phytosanitary Administration in accordance with the Law on Agricultural Plants Seeds Material (Official Gazette of the Republic of Montenegro 28/06) for performing activities concerning seeds material: laboratory examinations and seed material quality, technical and professional affairs (certification) and other activities of public interest in this field. The authorization defines the activities of public interest and conditions for delegation of performance of public activities to the Seeds Laboratory. The Centre for Crop, Vegetable and

Forage Growing, authorized by the Phytosanitary Administration performs certification of agricultural plants seeds material.
The Laboratory for Seeds is the integral part of the Biotechnical Faculty in Podgorica – Centre for Crop, Vegetable and Forage Growing (University of Montenegro). The Laboratory for Seeds has been additionally equipped with laboratory equipment, through donor funds under the ,,SEEDNET" project.

Currently, the extent of equipment of the Seeds Laboratory does not fully satisfy the requirements of modern methods of examination of the quality of agricultural plants seeds material quality. Additional equipping as well as further staff training should enable upgrade of the procedures.

The Laboratory for Seeds, as the only laboratory of that kind in Montenegro, is included in education under the "SEEDNET" and in the TAIEX programs in this field. The Laboratory for Seeds carries out activities of accreditation by the international ISO 9001 standard and ISTA.

There are 4 PhDs employed in the Laboratory for Seeds (for crops, vegetables, forage and mechanization) and one technician with the degree of Secondary School of Agriculture; employment of technical staff is envisaged.

The need for upgrade of the existing equipment is evident, so that the laboratory could efficiently carry out the seeds quality checks.
Methods prescribed by national legislation or own methods of the laboratory are used for examination of agricultural seeds quality.

Methods for testing the quality of the seeds material of agricultural plants

TESTING	METHOD
Seeds quality	ISTA methods Rulebook on the Quality of Seed Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89, 16/92, 8/93, 21/93, 30/94, 43/96, 10/98, 15/01 and 58/02) Rulebook on Quality Norms, Packaging, Sealing and Labelling of Planting Material (Official Gazette of the Socialist Federal Republic of Yugoslavia, 45/75 and 26/79)

Measures which should be undertaken for improvement of the situation:

- The Laboratory for Seeds has to be clearly recognized through internal organization of the Biotechnical Faculty, with hierarchy and responsibility levels established;
- establish accreditation in accordance with the ISO 9001 standard and ISTA;
- Further employment of professional and technical staff;
- Introduction of protocols for testing methods;
- Introduction of Good Laboratory Practice.

The Laboratory for Planting Material (Biotechnical Faculty - Centre for Fruit and Vine Growing and Centre for Subtropical Cultures, Bar) is authorized by the Phytosanitary Administration in accordance with the Law on Planting Material (Official Gazette of the Republic of Montenegro, 28/06) to perform activities in the field of planting material, professional and technical affairs (certification) and other activities of public interest in this field. Authorization defines the activities of public interest and requirements for delegation of performance of activities of public interest. Laboratory for Planting Material, Centre for Fruit and Vine Growing, authorized by the Phytosanitary Administration, performs certification of planting material of agricultural plants.

Currently, the equipment of the Laboratory for Planting Material does not fully satisfy the requirements of contemporary methods of testing the quality of seed material. Supply of additional equipment and delivery of additional training to staff should make possible improvement of the procedures.

The Laboratory for Planting Material as the only laboratory of the kind in Montenegro is included in education through TAIEX projects in this field. The Laboratory for Planting Material works on accreditation in accordance with the ISO 9001 standard and ISTA.

The Laboratory for Planting Material employs 4 PhDs and one technician who completed Secondary School of Agriculture, further employment of technicians is planned.

Upgrade of the existing equipment is necessary so that the laboratory would be able to efficiently check the quality of the planting material.

The methods prescribed by the national legislation or laboratory's own methods are used in testing the quality of planting material of agricultural plants.

Methods for testing the quality of planting material

TESTING	METHOD
Planting material quality	ISTA methods Rulebook on Quality Norms, Packaging, Sealing and Labelling of Planting Material (Official Gazette of the Socialist Federal Republic of Yugoslavia, 45/75 and 26/79)

Measures which should be undertaken for improvement of the situation:

- The Laboratory for Planting Material has to be clearly recognized through internal organization of the Biotechnical Faculty, with hierarchy and responsibility levels established;
- establish accreditation in accordance with the ISO 9001 standard and ISTA;
- Further employment of professional and technical staff;
- Introduction of protocols for testing methods;
- Introduction of Good Laboratory Practice.

- management of crisis;

Crisis management

of food safety

The Law on Food Safety (Article 18 – the Precautionary Principle) defines the obligation of all competent bodies to undertake provisional measures of risk management until acquisition of the scientifically founded opinions necessary for clarifications of scientific dilemmas and carrying out of a comprehensive risk assessment when the possibility of harmful effect of food and feed on human and animal health is established following the assessment of information available, but there are scientific dilemmas concerning provision of the highest levels of human health protection possible.

The Law on Food Safety (Article 19 – Principle of Transparency) defines the obligation of competent bodies to, if there is a hazard that certain food or feed might pose a risk for human or animal health, immediately, via media with national coverage, inform the public on the type of food or feed, the risk it poses, as well as on measures which have been or will be undertaken for prevention, reduction or removal of that risk.

Risk management in the field of food safety, feed and animal origin by-products is carried out by the competent bodies by undertaking measures, performing supervision and control. Measures undertaken, supervision and control must be timely and commensurate with the ascertained or expected hazard (physical, microbiological, chemical and radioactive contamination).

When the competent body ascertains that food or feed pose a serious risk for human health, animal health or environment, and that the risk can not be satisfactorily removed, one or several measures are undertaken depending on the severity of situation:

When the crisis originates from Montenegro:

- restriction or prohibition of trade in food or feed, i.e. food or feed withdrawal from trade until removal of the hazard, i.e. suspicions in its safety;
- determination of measures of safe disposal of unsafe food or feed;

- other appropriate provisional measures.

When the crisis originates outside of Montenegro:

- temporary prohibition of food or feed importation from a country or part of an exporting country or the country of transit;
- determination of special measures for the mentioned food or feed from a country or part of an exporting country or the country of transit;
- setting forth of measures of safe disposal of the mentioned food or feed;
- other appropriate provisional measures.

Measures of restriction and prohibition of trade in food or feed are laid down by an order of the Ministry of Agriculture, i.e. the Ministry of Health.

The Law on Food Safety (Article 71) lays down adoption of a Plan for crisis management in the field of food and feed safety in 2010, for crisis situations management, when there are direct or indirect human health, animal health or environmental risks, caused by food and feed and the occurrence of which it is impossible to foresee, prevent, remove or reduce to an acceptable level.

This plan would precisely determine the following: crisis situations, general plan implementation procedures, establishment of a crisis coordinators network, practical crisis situations management procedures, crisis units roles, practical functioning of the crisis units, link between the crisis units and decision making units, crisis resolution, communication strategy and transparency principle.

Veterinary

Risk management in the veterinary field is carried out by the competent body through undertaking measures, performing supervision and control. Measures undertaken, supervision and control must be timely and commensurate with the established or expected hazard (animal diseases, natural disasters)

When the crisis originates outside of Montenegro;

The Veterinary Law (Article 17) defines that, when presence of an infectious disease in Montenegro is established, and for as long as it poses a hazard, the Ministry orders restriction or prohibition of trade in animals and according to the nature of the infectious disease and hazard level, establishes boundaries of the infected and endangered area and determines measures which are undertaken in the infected i.e. endangered area.

The Veterinary Law (Article 11) defines that with the aim of preventing outbreak, prevention of spreading and eradication of infectious diseases, the Ministry of Agriculture, Forestry and Water Management adopts programs for certain infectious diseases.

Montenegro has a Plan for eradication of the highly pathogenic avian influenza.

There are no contingency plans drafted for certain infectious animal diseases in accordance with the EU requirements.

When the crisis originates outside of Montenegro:

- temporary prohibition of animal importation from a country or part of an exporting country or the country of transit
- determination of special measures for animals from a country or part of an exporting country or the country of transit
- determination of safe animal disposal measures
- other appropriate temporary measures.

When there is a reasonable hazard from introduction of infectious diseases by imported animals, the Ministry adopts an order by which it determines one or more of the abovementioned measures.

Phytosanitary field

Crisis management in the phytosanitary field is carried out by the competent bodies through undertaking measures, performing supervision and control. Measures undertaken, supervision and control must be timely and commensurate with the established or expected hazard.

Urgent measures for prevention of outbreak, control and eradication of harmful organisms are determined by the Law on Plant Health Protection and secondary legislation.

Currently, there are no contingency plans established for certain harmful organisms in accordance with the EU requirements.

In 2010, the Operative program for urgent phytosanitary measures will be adopted, and it will be a basis for a rapid adoption of specific programs for urgent phytosanitary measures. The Operative program for urgent phytosanitary measures will contain the following chapters: General information and the program planning process; Assessment of the Report on hazard from harmful organisms; Contingency plans; Obligation of notification and information exchange; System of decision making on carrying out the eradication program; Program initiation; Harmful organism identification; Assessment of the current and potential distribution of a harmful organism, Inception Study; Data from places of detection/outbreak of harmful organisms; Geographic origin, Patterns of harmful organism spreading; Overview of distribution; Prognosis of a harmful organism spreading; Justifiability of the eradication program implementation; Biological and economic information; Analysis of the eradication program advantages and shortcomings; Eradication program; Forming of a management team; Eradication program implementation; Supervision, Isolation; Treatment and/or control measures; Eradication check, Documentation and Program Revision.

Law on Plant Protection prescribes the obligation of compensation of damages to plant keepers for the damage caused by control and eradication of quarantine harmful organisms. Damages are paid out in the amount of their market value on the day of occurrence.

The phyotsanitary measures program also envisages the urgent phytosanitary measures undertaken for the purpose of reduction of the extent of damage caused on agricultural crops and preservation of potential yields of important agricultural crops which demands, in addition to application of the control measures (treatment by plant protection products), monitoring and prognosis of the harmful organisms population growth, reporting-forecasting program contributing to the rational plant health protection (signalization of the appropriate moment for treatment with recommendation of the adequate plant protection products).

Program comprises monitoring of occurrence as well as the proposal of measures for harmful organisms control, assessment of possible damage on plants, plant products and establishments under supervision with the analysis of taken samples, timely information via media, advice and publishing of technical publications on outbreak, spreading and method of harmful organisms control and instructions and guides for undertaking urgent phytosanitary measures and expenses of international cooperation.

For the purpose of rapid responding in situations of an unexpected and sudden outbreak of quarantine and regulated harmful organisms of plants, plant products and objects under supervisions, which can not be predicted, and which demands immediate implementation of urgent phytosanitary measures for the purpose of protection of plant health and prevention of significant economic damage, urgent acquisition of the necessary equipment and material will be carried out, the corresponding technical activities in the field as well as the services of laboratory checks will be performed. Carrying out of these activities will depend on the situation and requirements set by the situation, upon instructions and orders of the Phytosanitary Administration.

- the setting up of the Rapid Alert System for Food and Feed (RASFF).

Setting up of the Rapid Alert System for Food and Feed (RASFF)

There is no Rapid Alert System for Food and Feed – RASSF established in Montenegro.

At the conference in Brussels (16-21 July 2009) on the occasion of the RASSF 30th anniversary, attended by representatives of the competent bodies of Montenegro, we obtained more knowledge of the system itself, of its advantages and we are acquainted with how we can, for the beginning, be the RASFF information users. Activities aimed at accession have been undertaken (Rapid Alert System for Food and Feed - RASFF).

II. VETERINARY POLICY

7. General

a) Please provide information on general architecture of the legal basis; organisation and powers of different institutions involved.

General structure of the legal basis

Veterinary field is governed by the following framework legal acts:

- Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07) governs the veterinary field: internal market trade (in live animals), importation, exportation and transit, animal diseases, preventive measures in domestic animals reproduction, veterinary medicinal product and other harmful residues, animal by-products as well as organization of the veterinary service and it contains basis for adoption of secondary legislation in veterinary field;
- Law on Animal Welfare (Official Gazette of Montenegro 14/08) governs the field of animal welfare and contains basis for adoption of secondary legislation in this field;
- Law on Animal Identification and Registration (Official Gazette of the Republic of Montenegro 48/07) governs the field of animal identification and registration and contains basis for adoption of secondary legislation in this field;
- Law on Food Safety (Official Gazette of Montenegro 14/07) governs general food safety rules and requirements for placing on the market of food and feed and it contains basis for adoption of secondary legislation in this field;
- Law on Genetically Modified Organisms (Official Gazette of Montenegro 7/08) governs general rules for placing on the market and labeling of the GMO products;
- Law on Measures for Livestock Breeding Development (Official Gazette of Serbia and Montenegro 59/92) represents a legal basis for the field of zootechnics.

Institutions in charge of drafting laws:

The Ministry of Agriculture, Forestry and Water Management is the policy-maker in the veterinary field, prepares proposals of laws, which are adopted by the Parliament following a procedure (described in detail in answer 4 of this chapter).

Institutions in charge of secondary legislation

The Ministry of Agriculture, Forestry and Water Management adopts regulations for enforcement of laws under their competency – rulebooks, orders, instructions as well as animal diseases programs and plans, zoonosis monitoring, residues monitoring, crisis management plan etc. from the veterinary field.

The Veterinary Administration prepares technical bases for regulations – laws, rulebooks, orders, instructions, animal diseases programs and plans for animal diseases, zoonosis monitoring, residues monitoring, crisis management plan etc. from the veterinary field.

b) Please provide information on respective fields of responsibilities of competent authorities concerned in particular regarding rules on control.

Respective fields of responsibilities of competent authorities

The Veterinary Administration implements the following laws: Veterinary Law, Law on Animal Welfare, Law on Animal Identification and Registration, Law on Food Safety, Law on Measures for Livestock Breeding Development, Law on Genetically Modified Organisms, as well as secondary legislation adopted based on these laws in the veterinary field and performs inspection supervision through veterinary inspectors.

Competent body and competency

Field		Framework legal act	Competent body implementation	control	note
Internal market control system	Live animals	Veterinary Law	VA	Veterinary Inspectorate	Described in detail in answer 8 of this chapter
	Animal origin products	Veterinary Law Law on Food Safety	VA	Veterinary Inspectorate, authorized veternarians	Described in detail in answer 8 of this chapter
	Financing	Veterinary Law			Described in detail in answer 8 of this chapter
	Protective measures	Veterinary Law Law on Food Safety	MAFWM, VA	Veterinary Inspectorate	Described in detail in answer 8 of this chapter
Import control system	Live animals	Veterinary Law	VA- Department for vetrinary public health	Border veterinary inspectorate	Described in detail in answer 9 of this chapter
	Animal origin products	Veterinary Law Law on Food Safety	VA- Department for vetrinary public health	Border veterinary inspectorate	Described in detail in answer 9 of this chapter
	Border inspection posts	Veterinary Law Law on Food Safety			Described in detail in answer 9 of this chapter
	Financing Control	Veterinary Law			Described in detail in answer 9 of this chapter
	Protective measurs	Veterinary Law Law on Food Safety	MAFWM, VA	Border veterinary inspectorate	Described in detail in answer 9 of this chapter
Animal identification and registration and movement registration		Law on Animal Identification and Registration	VA – Department for Animal health	Vetrerinary Inspectorate	Described in detail in answer 10 of this chapter
Animal diseases		Veterinary Law	VA – Department for animal health	Vetrerinary Inspectorate	Described in detail in answer 11 of this chapter
Trade in living animals, semen, ova and embryos		Veterinary Law	VA – Department for animal health	Vetrerinary Inspectorate	Described in detail in answer 12 of this chapter
Noncommercial movement of pets		Veterinary Law	VA – Department for animal health	Vetrerinary Inspectorate	Described in detail in answer 13 of this chapter
Monitoring of illicit substances and residues		Veterinary Law	VA – Department for vetrinary public health	Vetrerinary Inspectorate	Described in detail in answer 14 of this chapter
Requirements for imortation of living animals and animal origin food		Veterinary Law Law on Food Safety	VA – Department for vetrinary public health	Border veterinary inspectorate	Described in detail in answer 15 of this chapter
Animal Welfare		Law on Animal Welfare Protection	VA – Department for animal health	Veterinary Inspectorate	Described in detail in answer 17 of this chapter
Zootechnical regulatins		Law on Measures for Livestock	MAFWM, Livestock Selection Service	Agricultural Inspectorate,	Described in detail in answer 18 of this

	Breeding Development		Veterinary Inspectorate	chapter
Veterinary expenditures	Veterinary Law			Described in detail in answer 19 of this chapter

c) Please provide a clear table of all the framework acts that cover or impinge upon the veterinary domain with an explanation of their coverage as far as the EU veterinary acquis is concerned. Please indicate whether you envisage adopting new framework acts.

Framework legal acts in the veterinary field

Framework legal act	field	note
Veterinary Law	Internal market control system	Described in detail in answer 8 of this chapter
Veterinary Law Law on Food Safety	Imports control system	Described in detail in answer 9 of this chapter
Law on Animal Identification and Registration	Animal identification and registration and movement registration	Described in detail in answer 10 of this chapter
Veterinary Law	Animal diseases	Described in detail in answer 11 of this chapter
Veterinary Law	Trade in live animals, semen, ova and embryos	Described in detail in answer 12 of this chapter
Veterinary Law	Non-commercial movement of pet animals	Described in detail in answer 13 of this chapter
Veterinary Law	Monitoring of banned substances and residues	Described in detail in answer 14 of this chapter
Veterinary Law Law on Food Safety	Requirements for importation of living animals and animal origin food	Described in detail in answer 15 of this chapter
Law on Animal Welfare Protection	Animal Welfare	Described in detail in answer 17 of this chapter
Law on Measures for Livestock Breeding Development	Zootechnical regulations	Described in detail in answer 18 of this chapter
Veterinary Law	Veterinary expenditures	Described in detail in answer 19 of this chapter

The Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07) is not harmonized with the EU legislation. The National Program for Integration of Montenegro into the EU (NPI) for the period 2008-2012 envisages drafting and adoption of the new Veterinary Law by which full harmonization with the Acquis would be achieved in this field, and which would create a legal basis for adoption of regulations into which the EU notions could be incorporated.

It is necessary to regulate the field of animal by-products in a manner it has been regulated by the EU legislation; adoption of the Law on Animal By-products Management in accordance with the Regulation 1774/2002 is planned.

Adoption of new rulebooks, instructions and guides in compliance with the EU regulations from these fields is planned, by dynamics determined by the NPI 2008-2012.

d) Please provide information for each item listed below.

8. Control system in the internal market:

- live animals; semen, ova and embryos

Internal market control system

Living animals, semen, ova and embryos

Legislation

Framework legal acts defining control rules for placing live animals, semen, ova and embryos on the market of Montenegro are:

- Veterinary Law,
- Law on Animal Identification and Registration,
- Law on Animal Welfare Protection
- and secondary legislation adopted on the basis of these laws.

Competent body

The Veterinary Administration is the body competent for animal health control, identification, registration and animal welfare protection.

Through the veterinary inspectors, the Veterinary Administration carries out supervision over implementation of the prescribed animal health, identification and welfare requirements.

Diagnostic Veterinary Laboratory is the laboratory in charge of animal disease control and establishing of the health condition of semen, fertilized ova and embryos.

Veterinary surgeries perform the following affairs in accordance with the obligations and responsibilities laid down by the abovementioned laws:

- monitor health condition of animals, propose and undertake measures for prevention, detection, control and eradication of infectious animal diseases and carry out basic field and laboratory diagnostics for testing infectious and other animal diseases;
- carry out preventive measures (diagnostic testing vaccination) prescribed by the Operational Program on Animal Health Protection, based on the Contract concluded with the Veterinary Administration;
- implement measures for prevention, detection treatment and control of animal diseases beyond the Operative Program, as well as treating of injuries, and carrying out surgical interventions on animals;
- perform veterinary checks for the purpose of issuing animal health certificate and veterinary referral forms;
- take care of health of breeding animals, reproductive ability, implement measures for prevention and treatment of infertility, as well as insemination;
- provide veterinary first aid;

- veterinary surgeries authorized for checks at slaughterhouses carry out animal welfare protection during killing and slaughtering;
- apply rules prescribed for handling animals while performing interventions on animals, during transport and experimenting with animals;
- carry out identification (tagging) of animals and keep the register of animals in compliance with the regulations;
- issue census forms for registration of a holding and a certificate on performed identification of domestic and other animals and submit one copy of the census form to the Veterinary Administration for the purpose of entering the data into the Central register;
- submit the data on births, deaths, slaughter, sale, movement of domestic and other animals, as well as data on transfer of ownership and registration of new households;
- keep the ear tags assigned and keep records on assigned and applied ear tags and issued temporary passports, as well as records on certified movement documents (moving to mountain pastures).

During treatment of an animal, veterinarians use only medicinal products and medical devices approved for placing on the market in Montenegro.

Animal health control

A veterinary inspector carries out supervision over the compliance with the prescribed requirements concerning animal health, and in accordance with the legal powers to:

- order measures for prevention of outbreak, detection, control and eradication of infectious animal diseases;
- control of issuance of veterinary certificates and veterinary referral forms;
- monitor and control implementation of the Operational Program of Animal Health Protection;
- examine records on results of diagnostic tests, etc.

When he/she ascertains that a law or other regulations have been violated and when prescribed animal health requirements have not been complied with, the veterinary inspector:

- prohibits loading of animals, raw materials and waste;
- prohibits issuing of veterinary certificates when an infectious animal disease has occurred or its occurrence is suspected, or when an animal originates from an establishment with unverified or suspicious epizootiological conditions;
- orders the removal of shortcomings in production, trade in animals, semen, fertilized ova and embryos;
- determines boundaries of the infected and endangered area when an infectious animal disease occurs,
- prohibits the use of establishments for breeding of animals, stations and ports intended for loading, reloading and unloading of animals;
- orders the removal of shortcomings in relation to acquisition, storage and trade in animal semen, ova and fertilized ova;
- prohibits trade in animal semen, ova and fertilized ova unsafe in terms of health;
- destroys animal semen, ova and fertilized ova unsafe in terms of health;
- order disposal of animal carcasses, and other waste of animal origin.

While implementing measures from the Operativonal Program of Animal Health Protection, veterinary surgeries notify the veterinary inspectors in charge on time and place of carrying out a

preventive measure. The inspector performs direct controls on the spot during the performance or by method of random holding selection, upon receipt of reports submitted by veterinary surgeries.

Control of animal welfare protection

Veterinary inspector performs supervision over the compliance with the prescribed requirements referring to animal welfare and in accordance with the powers:

- checks and controls establishments and premises where animals are kept i.e. where they are reproduced;
- controls trade, transport, method of killing and slaughtering of animals, carrying out of experiments, organization of exhibitions, competitions, circus shows and other shows with animals;
- controls whether the conditions for animal keeping and breeding have been provided;
- controls the compliance with the conditions in pet day-care centers and shelters;
- controls the compliance with other conditions concerning the welfare protection.

When he/she ascertains that a law or other regulations have been violated and when prescribed requirements for animal welfare protection are not fulfilled, a veterinary inspector:

- orders measures for removal of irregularities identified within the specified period of time;
- prohibits animal fights or fights of animals and humans;
- prohibits carrying out of interventions on animals which are not performed by a veterinarian;
- prohibits killing of animals by a person who is not qualified for that;
- prohibits loading, reloading, unloading and transport of animals;
- prohibits slaughter performed without stunning animals;
- orders removal of irregularities in work of a pension or shelter with the specified period of time;
- temporarily seizes documentation and objects which can serve as evidence in a misdemeanor procedure;
- temporarily puts under surveillance an animal in a condition on the basis of which it may be concluded that the animal suffers from pain, distress, or great fear, that it is injured or that continuation of its life under the same conditions would entail irrelievable pain, until removal of irregularities;
- imposes the termination of an experiment or prohibits an experiment with animals carried out in contravention of the law or if the shortcomings regarding the carrying out have not been eliminated within the period of time prescribed;
- imposes remedying the irregularities in the work of zoos within the period of time specified;
- imposes and undertakes other measures ensuring the elimination of the established irregularities.

Control of the animal welfare protection requirements during killing and slaughter is performed by authorized veterinarians during slaughter in authorized slaughterhouses. Veterinary inspectors control animal keeping conditions on farms 4 times per year (registered larger-scale capacity establishments). Veterinary inspectors perform controls at all animal exhibitions on the basis of a notification sent by exhibition organizers.

Animal identification and registration control

Veterinary inspector performs supervision over the compliance with the requirements prescribed for identification and registration of animals and performs check and control of the following:

- proper application of ear tags and check of animal identification;

- proper keeping of the household register;
- documents for movement of animals on a holding;
- submission of prescribed data to the Veterinary Administration;
- changes in a household, in comparison to the previous year;
- assigned and applied ear tags.

When he/she ascertains that a law or other provisions have been violated and when prescribed requirements for animal identification and registration have not been fulfilled, the veterinary inspector:

- prohibits movement of all animals to and from a holding, if one or several animals have not been identified, do not possess movement documents and if the household register has not been kept in accordance with the law;
- orders slaughter and safe disposal of an animal at the expense of keeper, if the animal keeper can not prove identity of the animal in the course of two working days from the day of the performed control;
- temporarily prohibits movement only of animals not been entered into the household register or that have not been identified, i.e. do not possess movement documents, until removal of irregularities;
- temporarily prohibits movement of all animals in case 20% of animals in a household have not been entered into the household register or have not been identified or do not possess movement documents, while for households with 10 animals and less, if two or more animals have not been entered into the household register or have not been identified or do not possess movement documents;
- temporarily prohibit movement of animals to and from a household, if the animal keeper fails to notify the Veterinary Administration on animal movement.

The I&R control is performed in coordination of the Veterinary Inspectorate and Department for animal health and welfare protection – Service for animal identification and registration, by checking the status in the central database, with a special emphasis on households which did not report movement changes in the previous period, the newborn calves, etc.

In Montenegro, there is a high percentage of small households keeping 1-5 head of cattle. This information, as well as geographic characteristics of the terrain, especially in the northern part of Montenegro, where there is the cattle population is the highest, resulted in control of a number of households smaller than prescribed.

A large number of animals from Serbia are imported in Montenegro for the purpose of slaughter. The central database is linked with the border crossings with Serbia and with slaughterhouses thereby ensuring tracing of these animals.

- animal products

Products of animal origin

Legislation

Framework legal act defining the rules for placing products of animal origin on the market of Montenegro is:

- Law on Food Safety,
- secondary legislation from this field (hygiene rules, special hygienic rules for products of animal origin , microbiological requirements, harmful substances, trichinosis, residues...)

Competent body

Veterinary Administration is the body competent for safety of products of animal origin.

Department for veterinary public health prepares monitoring programs for food-borne zoonoses and monitoring program for residues of veterinary medicinal products and other harmful substances.

Department for inspection supervision performs supervision over the implementation of requirements prescribed for safety of products of animal origin, through veterinary inspectors.

Veterinary inspectors perform inspection supervision in all approved and registered establishments for production and trade in products of animal origin and in addition to sampling when inconsistencies are suspected, they take samples for monitoring of – listeriosis, salmonella, residues, according to the sampling plan prescribed by the Department for public health, at the annual level.

Chief veterinary inspector adopts the annual control plan for all municipal units of the Veterinary Inspectorate. The control plan is based on the condition of establishments, type of activities carried out in an establishment, previously established irregularities, system of self-control in place, etc. The plan defines the following: establishment (activities), frequency of control and subject of control.

Veterinary inspectors submit to the chief veterinary inspector the monthly reports on controls carried out.

It is envisaged that during 2010 instructions for veterinary inspectors be prepared for the purpose of a more efficient implementation of the newly adopted regulations in this field.

Veterinary Diagnostic Laboratory carries out microbiological analyses of products of animal origin.

Institute of Public Health of Montenegro carries out microbiological, physical and chemical analyses of products of animal origin.

Centre for Eco-toxicological Researches of Montenegro carries out physical and chemical analyses of products of animal origin and radioactivity control and it is the laboratory authorized for monitoring of residues.

Rulebook on the method of carrying out veterinary control of animals for slaughter, establishments and products of animal origin lays down the control procedure as follows:

Control of establishments

Establishments for slaughter of cloven-footed animals and poultry, cutting of the meat of cloven-footed animals and poultry, production and trade in processed meat, mechanically separated meat (MSM) and meat products, intestines and stomachs, milk and dairy products, bivalve molluscs and fisheries products, snails, frogs, eggs and egg products, honey as well as establishments and equipment for their storage are subject to the veterinary control.

Veterinary inspector controls the compliance with the hygienic requirements in an establishment (premises, equipment, staff, water, water supply and waste water drainage, transport of products, heat treatment, food waste and other requirements prescribed).

Compliance with the special hygiene requirements for products of animal origin (physical, chemical and microbiological criteria, consistency of temperature regimes with requirements in specific phases of production and trade, maintenance of the cold chain, sampling, consistency with the producer specification, labeling, materials and wrappings coming in contact with products etc.) is also checked by control in the establishment.

Meat of domestic ungulates

System of veterinary control and check of ungulates prior to slaughter is as follows:

- notification of slaughter at least 24 hours prior to the slaughter (an animal health certificate is submitted along with the notification – information on food chain);
- animal check during unloading into the slaughterhouse lairage, during the stay in the lairage and immediately prior to dispatching for slaughter;

- establishing the identity, animal health condition and animal welfare;
- prohibition of slaughter of animals not accompanied with the animal health certificate upon arrival to the lairage, of an animal which has not been identified, which is dirty, tired, distressed or hurt, animals showing symptoms of a disease, animal in the last trimester of pregnancy or if eight days have not elapsed since the parturition, an animal which was treated or was administered substances with pharmacological effect for prophylactic or nutritional purposes, and the period of time necessary for their excretion from the animal's body has not yet elapsed in accordance with the manufacturer's instructions for their use (withdrawal period);
- animal slaughter (stunning, bleeding, treatment – preparation for postmortem examination);
- examination of carcass and organs (inspection, palpation, incision, and, if necessary, laboratory examination – trichinella, residues, radioactivity, microbiology);
- making a decision and its assessment following the examination performed:
    - hygienically fit for public consumption;
    - hygienically unfit for public consumption (mark, separate, safely dispose of);
    - conditionally hygienically fit for public consumption (heat treatment);
- marking of meat;
- storage of meat (cooling, freezing, cutting, processing).

Poultry and lagomorphs meat

System of veterinary control and check of poultry and lagomorphs is as follows:

- notification on slaughter at least 24 hours prior to slaughter (an animal health certificate is submitted along with the notification – information on food chain – it must not be fed at least 8 hours prior to loading);
- animal check prior to unloading into a slaughterhouse lairage, during their stay in a lairage and immediately prior to dispatching for slaughter;
- establishing the identity, animal health condition and animal welfare;
- prohibition of slaughter of animals not accompanied with the animal health certificate upon arrival to the lairage, of an animal which is dirty, tired, distressed or hurt, animals showing symptoms of a disease, animal which was treated or was administered substances with pharmacological effect for prophylactic or nutritional purposes, and the period of time necessary for their excretion from the organism has not yet elapsed in accordance with the manufacturer's instructions for their use (withdrawal period)
- animal slaughter (stunning, bleeding, treatment – preparation for postmortem examination);
- examination of body and organs (inspection, palpation, incision, and laboratory examination if needed – residues, microbiology)
- making a decision and assessments following the examination performed:
    - hygienically fit for public consumption;
    - hygienically unfit consumption (mark, separate,);
    - conditionally hygienically fit for public consumption (heat treatment);
- marking of meat;
- storage of meat (cooling, freezing, cutting, processing).

Wild game meat

Veterinary control and examination system for of wild game comprises:

- notification of the veterinary inspector of hunting not later than 12 hours after hunting;
- examination of carcass and organs and marking in an establishment for handling wild game;
- making a decision and assessment following the examination performed.

Immediately after hunting, the hunters are obliged to eviscerate and correctly mark thoracal and abdominal organs of the wild game and to deliver as soon as possible (within 10 hours, if there is no cooling) the wild game to an establishment for examination.

Live bivalve molluscs and fisheries products

Live bivalve molluscs and fisheries products are safe for human consumption when it is ascertained by an examination that:

- bivalve molluscs are alive (firmly closed shell);
- prescribed microbiological and other hygiene and health requirements are complied with.

Only raw material assessed as safe may be used for processing fisheries products. After catch of crustaceans or fish, all damaged, dead products and all foreign bodies must be removed from the shell and they must be rinsed from impurities.

Crustaceans aimed at freezing must be frozen not later than 12 hours from catch.

Only live snails with undamaged shells or those preserved by freezing may be used for human consumption.

Examination of eggs and egg products comprises:

- visual examination, for assessment of cleanliness of the shell surface;
- examination of eggs under lamplight;
- breaking eggs, if needed, and a laboratory check for salmonella and residues in accordance with the set rules.

Milk and dairy products

Veterinary control and examination system for milk and dairy comprises:

- hygiene control during milking and collecting (of buckets, tanks, milk pipes in a collection station by taking swabs for a microbiological check);
- control of raw milk (total microorganisms count, total somatic cells count, MPP test);
- control of raw milk for residues;
- control of dairy products for checking the compliance with the prescribed hygienic requirements;
- control of efficiency of dairy products heat treatment;
- control of marking, labeling, transportation, storage.

When a veterinary inspector ascertains during examination, at any phase of production and trade, the inconsistencies which, based on a risk assessment, do not represent a public health hazard he/she orders taking of corrective measures is ordered.

Corrective measures comprise:

- inspector's decrees referring to irregularities which can be removed in the course of 7 days;
- decisions on removal of irregularities referring to established irregularity which should be removed within the period of time determined by the inspector. Should the control subject not act upon the decision, the inspector takes repressive measures due to failure of acting upon the decision (fine, misdemeanor procedure).

Sanctions

Should irregularities established in an establishment be such that they immediately (directly) endanger product safety or represent an immediate hazard for human or animal health, the veterinary inspector takes sanctions in accordance with law (adopts a decision on a temporary ban on operation of an establishment, a decision on withdrawal of unsafe products out of market, a decision on destruction of unsafe products etc.).

- certification

Law on Food Safety (Article 65) and the Veterinary Law (Article 31) lay down that consignments of animals, semen, ova and embryos, products of animal origin and feed during importation must be accompanied by a prescribed international certificate or other prescribed documentation, unless otherwise laid down by an international agreement.

Certificate must be: original, marked with a serial number, filled and signed by the competent body of the exporting country (official veterinarian).

For consignments which are imported, the certificate must be written both in Montenegrin and the language of the exporting country.

A special rulebook lays down in more detail conditions for importation of food, types and quantities of food of animal origin, composite food, pet food and plants and plant products, serving for supply of crew and passengers in international means of transportation, food used during traveling in the means of transportation, food or feed ordered via cash on delivery.

Veterinary Administration prepares a certificate on a printed form in compliance with the model issued by international organizations, OIE and the European Union Commission or in compliance with the form prescribed by the importing country.

Veterinary inspectors are in charge of signing the certificate. Copies of the certificates issued are returned to the Veterinary Administration.

Animals traded on the territory of Montenegro are accompanied by the health certificates issued by authorized veterinary surgeries. For products of animal origin in trade on the territory of Montenegro, accompanying documentation (declaration of safety) issued by the food business operator is obligatory.

- mutual assistance

These rules are not applicable in Montenegro until the day of the EU accession.

- safeguard measures

Safeguard measures

Veterinary Law (Article 17) defines that, when occurrence of an infectious disease is established in Montenegro, and as long as it poses a hazard, the Ministry of Agriculture, Forestry and Water Management adopts an order by which it restricts or prohibits trade in animals, and according to the nature of the infectious disease and the level of hazard, sets boundaries of the infected and endangered area and determines measures which are carried out in an infected i.e. an endangered area.

When it is established that animal origin products pose a serious risk for human health, animal health or the environment and that the risk can not be satisfactorily eliminated, the Veterinary Administration takes one or several measures depending on the gravity the situation:

- restricts or prohibits trade in products of animal origin, i.e. orders withdrawal of products of animal origin from trade until the removal of the hazard.
- orders destruction and safe disposal of unsafe products of animal origin;
- takes other appropriate temporary measures, as well.

Measures of restriction and prohibition of trade in products of animal origin are laid down by an order of the Ministry of Agriculture, Forestry and Water Management.

Informing of public on measures of restriction and prohibition of trade in products of animal origin via media with national coverage is obligatory.

- computer system (TRACES)

The TRACES system has not been established in Montenegro.

At all border inspection posts, infrastructure and technical conditions have been provided (computers, internet access).

Submission of an application for access to the TRACES system and training of the BIP staff is envisaged as soon as possible.

Internal market control system - overview of the condition with respect to the EU legislation

EU legislation		National legislation of Montenegro				
field	**EU legislation**	**National legislation**	**Legal basis for adoption**	**Current condition planned**	**Expected date of adoption implementation**	**TOC Table of correspondence**
Live animals	Council Directive **90/425/EEC** and corresponding application texts	List of regulations in the Annex	Veterinary Law			Not yet prepared
Animal origin products	Council Directive **89/662**/EEC and corresponding application texts	List of regulations in the Annex	Law on Food Safety			Not yet prepared
Certification	Council Directive 96/93/EC	List of regulations in the Annex	Veterinary Law	In preparation	2010	Not yet prepared
Mutual assistance	Council Directive 89/608/EEC	None	Veterinary Law		Not applicable until the day of the EU accession	Not yet prepared
Safeguard measures	Commission Decision 2005/731/EC	Orders VPAI program	Veterinary Law	Planned preparation of contingency plans	2011	Not yet prepared
	Commission Decision 2005/734/EC	None	Law on Food Safety	Planned preparation of contingency plans	By the day of accession	

9. Control system for imports:

- live animals

Legislation

Framework legal acts defining the control system for importation of live animals, semen, ova, embryos and products of animal origin are:

- Veterinary Law,
- Law on Animal Identification and Registration,
- Law on Animal Welfare Protection,
- Law on Food Safety
- and secondary legislation adopted on the basis of these laws.

Competent body

Veterinary Administration is the body competent for importation of live animals, semen, ova, embryos and products of animal origin.

Veterinary Administration performs supervision over the implementation of the prescribed requirements for health, identification, animal welfare and safety of food animal origin, through veterinary inspectors.

Control of consignments of live animals, semen, ova, embryos and animal origin products is carried out by the Veterinary Administration through border veterinary inspectors exclusively at approved border inspection posts (BIPs).

Live animals, semen, ova and embryos importation control system

All consignments of live animals, semen, ova and embryos imported in Montenegro are subject to veterinary check by a border veterinary inspector.

A border veterinary inspector is notified in advance of a consignment of animals, semen, ova and embryos for a check at least 24 hours prior to arrival of the consignment at the border inspection post.

Upon arrival of the consignment of animals, semen, ova and embryos, which has been properly announced, at the border inspection post, the importer or his/her authorized representative submits an application for consignment check to the veterinary inspector on a form prescribed by the Veterinary Administration. Veterinary certificate and other documentation such as invoices, bills of lading and a list with animal identification numbers are submitted together with the application.

Aiming at an efficient control and receipt of information on a consignment, the border veterinary inspector can request information from responsible persons, i.e. an insight into a ship or airplane cargo manifest for the purpose of certain checks.

Check of consignments of live animals, semen, ova and embryos which are imported into Montenegro

Documentation check

Every consignment of animals, semen, ova and embryos which is imported into Montenegro must be subject to a documentation check for the purpose of establishing compliance with the regulations. The certificate must be on a printed form, original, marked with a serial number, prepared on the day of the consignment dispatch, certified and signed by the competent authority.

The certificate must be in Montenegrin and in the exporting country language. A specification of identification marks of animals the certificate refers to must be submitted together with the certificate accompanying the animal consignments.

Incomplete, unclear, crossed, corrected, faxed, unsigned certificates can not be considered appropriate and importation will not be allowed in these cases. A consignment of animals, semen, ova and embryos is withheld at the border inspection post until the appropriate documentation is submitted.

Identification check

Identification check of every consignment is carried out for the purpose of establishing correspondence of information stated in documentation and a consignment of animals, semen, ova and embryos to be imported. This entails visual inspection of official marks, indicating the country and the institution of origin of the consignment, control and veterinary numbers of establishments, identification marks on animals.

Physical check

Physical check is carried out on each consignment in order to establish the compliance with the prescribed health, identification and welfare requirements. This entails check of means of transportation, animals, semen, ova and embryos.

Laboratory checks are carried out in accordance with the measures laid down in the quarantine order.

When laboratory check is carried out, the consignment must not be placed on the market until receipt of the laboratory test results and it is under supervision of the customs service and border veterinary inspectorate.

Following the receipt of the quarantine report, the border veterinary inspector makes a decision on the consignment – allows or prohibits importation.

Should the consignment of animals, semen, ova and embryos not fulfill the prescribed requirements, the border veterinary inspector takes the following actions:

1) prohibits importation;
2) temporarily prohibits importation, when shortcomings on a consignment and accompanying documentation should be eliminated;
3) prohibits use of vehicles for transportation of consignments, if these do not fulfill the conditions prescribed.

Border veterinary inspector decides on return or destruction of a consignment at the importer's request.

The consignment must be under supervision of the customs service and border veterinary inspectorate pending the final decision on handling the consignment.

Costs incurred in the procedure of re-dispatch or destruction of the consignment are borne by the importer.

Check of consignments of live animals, semen, ova and embryos through the territory of Montenegro (transit)

Based on previous checks, epizootiological situation in the country of origin, or the exporting country, as appropriate, a border veterinary inspector allows transit of consignments of animals, semen, ova and embryos through the territory of Montenegro, only if:

- consignments arrive from a state or part of a state from which importation, or transit into Montenegro is not prohibited;
- prescribed documentation is attached with the consignment;
- the consignment is subject to a documentation and identification check.

Consignments of animals, semen, ova and embryos which are transported via airplane or maritime transportation can be identified and documentation check can be performed on the basis of a plane or ship cargo manifest, as appropriate, only when consignments are not unloaded.

In exceptional situations, when there are information that consignments pose a hazard to public health or animal health, physical checks of such consignments must be carried out, as well.

As regards road and railway transportation of consignments of animals, semen, ova and embryos through the territory of Montenegro, it must be transported without unloading after leaving the border entry inspection post and it must leave the territory of Montenegro in three days at the latest.

Border veterinary inspector approving transportation, informs the border veterinary inspector at the exit border crossing via the existing means of communication.

- animal products

Importation control system for products of animal origin

All consignments of products of animal origin imported into Montenegro are subject to veterinary control by a border veterinary inspector.

A consignment of animal origin products is announced to the border veterinary inspector for the check at least 24 hours prior to arrival of the consignment to the border inspection post.

Upon arrival of the properly announced consignment of products of animal origin to the border inspection post, importer or his/her authorized representative submits an application for consignment check to the authorized veterinary inspector on a form prescribed by the Veterinary Administration.

Veterinary certificate and other documentation are submitted along with the application.

Aiming at a more efficient control and obtaining of information on the consignment, the border veterinary inspector may request an information from responsible persons, i.e. an insight into a ship or plane cargo manifest for certain checks.

Check of consignments of products of animal origin imported into Montenegro

Documentation check

Each consignment of products of animal origin imported into Montenegro must be subject to a documentation check for the purpose of establishing the compliance with the regulations. The certificate must be on a printed form, original, marked with a serial number, prepared on the day of the consignment dispatch, certified and signed by the competent authority.

The certificate must be in Montenegrin and in the exporting country language. Incomplete, unclear, crossed, corrected, faxed, unsigned certificates can not be considered appropriate and importation will not be allowed in these cases.

A consignment of animal origin products is withheld at the border inspection post until the suitable documentation is submitted.

Identification check

Identification check of each consignment is carried out for the purpose of establishing correspondence of information stated in documentation and the products of animal origin. This includes visual inspection of the stamp, official marks, lots, control veterinary numbers of establishments, declarations etc.

In order to perform an efficient check of animal origin products identity, it is necessary to open the packaging. While doing so, it must be taken care that products of animal origin are hygienically handled.

In cases of container consignments, the container number is also identified.

Physical check

In order to establish the extent of compliance with the prescribed safety requirements, defined by regulations applicable in Montenegro, and in order to confirm the accuracy of the guarantees from the certificate, physical check of each consignment is carried out, as well.

Physical check comprises:

- sensorial check (odour, colour, taste, consistency);
- simple, fast and physical tests (chopping, cutting, unfreezing, boiling or roasting);
- check of the means of transportation for the purpose of establishing whether the cold chain has been maintained or possibly broken, by checking the list of thermographs and by measuring temperature deep in the product;
- check of wrappings and all marks (imprints, labels, veterinary control numbers) for the purpose of establishing the compliance with the regulations;
- comparison of the actual consignment weight with the weight indicated in the certificate, by checking a certain number of packages or by weighing the consignment, if necessary.

Check must be performed on a series of different samples from the entire consignment, on at least 1% of items or packages in the consignment (at least 2, at most 10 products, i.e. packages). However, depending on the products and circumstances, more samples can be taken.

In case of a product in bulk, it is necessary to take at least 5 samples from different parts of the consignment.

During work, all actions are taken to eliminate the risk from contamination through handling.

Laboratory examination of consignments at the place of unloading is carried out according to an established plan of sampling of consignments of products of animal origin from imports. Sampling is carried out always when there are justified reasons for suspicion, whether that the situation in terms of harmful substances cannot be correctly established or when the guarantees provided are not specific enough.

In case when laboratory check is carried out, the consignment must not be placed on the market until the receipt of the laboratory test results and it is under supervision of the customs service and border veterinary inspectorate.

Should the consignment of animal origin products not fulfill the prescribed requirements, the border veterinary inspector takes the following actions:

4) prohibits importation;
5) temporarily prohibits importation, when shortcomings on a consignment and accompanying documentation should be eliminated;
6) prohibits use of vehicles for transportation of consignments, if these do not fulfill the conditions prescribed.

Border veterinary inspector decides on return or destruction of a consignment at the importer's request.

The consignment must be under supervision of the customs service and border veterinary inspectorate pending the final decision on handling the consignment.

Costs incurred in the procedure of re-dispatch or destruction of the consignment are borne by the importer.

If the laboratory check results are positive, an enhanced laboratory check of the following 10 successive consignments of that product is carried out.

Check of consignments of products of animal origin through the territory of Montenegro (transit)

Based on previous checks, epizootiological situation in the country of origin, or the exporting country, as appropriate, a border veterinary inspector allows transit of consignments of products of animal origin through the territory of Montenegro, only if:

- consignments arrive from a state or part of a state from which importation i.e. transit into Montenegro is not prohibited;
- the consignment is accompanies by the prescribed documentation;
- the consignment is subject to a documentation and identification check.

Consignments of products of animal origin which are transported via airplane or maritime transportation can be identified and documentation check can be performed on the basis of a plane i.e. ship cargo manifest only when consignments are not unloaded.

In exceptional situations, when there are information that consignments pose a hazard to public health or animal health, physical checks of such consignments must be carried out, as well.

As regards road and railway transportation of consignments of products of animal origin through the territory of Montenegro, it must be transported without unloading after leaving the border entry inspection post and it must leave the territory of Montenegro in three days at the latest.

Border veterinary inspector approving transit, informs the border veterinary inspector at the exit border crossing via the existing means of communication.

- safeguard measures

Measures of restriction and prohibition of trade in products of animal origin are laid down by an order of the Ministry of Agriculture, Forestry and Water Management.

When it is established that food or feed pose a serious risk for human health, animal health or the environment, and that the risk can be satisfactorily eliminated, the competent body carries out one or several measures, depending on gravity of the situation:

- temporarily prohibits imports of products of animal origin from an exporting country or a part of an exporting country;
- lays down special measures and requirements for importation and transit;
- orders a safe disposal of products of animal origin.

Measures of restriction and prohibition of trade in animals, semen, ova and embryos are laid down by an order of the Ministry of Agriculture, Forestry and Water Management.

When importation of infectious diseases by animals from imports poses a reasonable hazard, the Ministry adopts an order setting forth one or several measures:

- temporarily prohibits importation of animals from an exporting country or a part of an exporting country;
- lays down special measures and requirements for importation and transit;
- orders a safe removal of animals, semen, ova and embryos;
- other appropriate temporary measures.

- Border Inspection Posts (BIPs)

Border inspection posts (BIPs)

Border inspection posts in Montenegro at which border veterinary inspection is organized are the following:

Border inspection	Type of crossing	country	Working hours

post				
1.	Bar	port	international	07-15h and at call
2.	Debeli Brijeg	road	Croatia	07 -15h
3.	Podgorica	airport	international	at call
4.	Božaj	road	Albania	07-15 and at call
5.	Ilino Brdo	road	Bosnia	at call
6.	Kula	road	Kosovo	at call
7.	Dračenovac	road	Serbia	07-15h and at call
8.	Ranče	road	Serbia	at call
9.	Dobrakovo	Road	Serbia	7h - 21h

border inspection posts

Border veterinary inspection is organized at 9 border inspection posts.

Working hours are adjusted with the competent bodies of the border veterinary inspectorates of the neighbouring countries, as well as with the volume of trade at certain crossings.

Border inspection posts are located in immediate vicinity of the point of entry into Montenegro, in an area designated by the body competent for border crossings management.

At border inspection posts where veterinary control is not organized, all conditions necessary for carrying out checks in compliance with the EU requirements are not provided, save for the newly built border crossings Debeli Brijeg and Božaj (and these do not fulfill requirements for trade in live animals and destruction of unsafe consignments of animal origin). Border veterinary inspection has not yet been organized at the newly built border crossing Sukobin (with Albania), although conditions for work have been provided.

At all border inspection posts, basic equipment for sampling for routine checks has been provided, as well as appropriate equipment for rapid information exchange with other border veterinary posts (direct phone lines, faxes, computers, internet access) which has not yet been networked into the central information system.

For certain border inspection posts, reconstruction or building of the new ones has been planned, in accordance with the EU BIPs requirements.

Montenegro adopted a Strategy for Integrated Border Management, as well as the Action Plan for its implementation. Networking of border inspection posts with the Department for Inspection Supervision in the Veterinary Administration has been planned, as well as development of a computer program for monitoring consignments at importation, exportation and transit.

Computer movement control system (TRACES)

TRACES system has not been established in Montenegro.

Infrastructure and technical conditions (computers, internet access) have been provided at all border inspection posts.

Filing of an application to the European Commission for access to the TRACES system and for training of staff employed at BIPs is planned, as soon as possible.

Imports control system, overview of situation when compared to the EU

EU Legislation		National legislation of Montenegro				
Field	EU text	National text	Legal basis for adoption	Current state planned	Expected date of adoption implementation	TOC
Live animals	Council Directive 91/496/EEC Commission Decision 97/794/EC Commission Regulation (EC) No 282/2004 Commission Regulation (EC) No 318/2007	Veterinary Law Rulebook on the method of carrying out checks of animals in foreign trade of Montenegro	Veterinary Law	Draft in preparation	November 2009	Not prepared
	Commission Decision No 275/2007	Rulebook on laying down a list of animals and products subject to veterinary control at entry into Montenegro	Veterinary Law Law on Food Safety	Draft in preparation	November 2009	Not prepared
Animal origin products	Council Directive 97/78/EC Council Directive 2002/99/EC Regulation (EC) No 882/2004 Commission Decision 94/360/EC Commission Regulation (EC) No 136/2004 Commission Decision 2000/25/EC Commission decision 2000/571/EC Commission Regulation (EC) No 136/2004 Commission decision 2005/34/EC Commission decision 2005/92/EC Commission Regulation (EC) No 206/2009	Rulebook on the method of carrying out checks of animals in trade across the border of Montenegro	Law on Food Safety	Draft in preparation	October 2009	Not prepared

	Commission Decision 2000/208/EC on fish products Commission Decision 93/352/EEC of 1 June 1993 laying down derogations from the conditions of approval for border inspection posts located in ports where fish is landed	No national regulation	Law on Food Safety	Not planned		
Safeguard measures		Orders of the Ministry on prohibition of importation	Veterinary Law Law on Food Safety	Adoption planned in accordance with the EU		
Border inspection posts (BIPs)	Council Directive 91/496/EEC Council Directive 97/78/EC Regulation (EC) No 882/2004 Decision 2001/812/EC	no	Veterinary Law Law on Food Safety	Draft in preparation	November 2009	Not prepared
Computer movement control system (TRACES)	Council Decision 92/438/EEC	Not established	SAA Agreement	Filing of the application planned	As soon as possible	

10. Identification of animals and registration of their movements:

Legislation

Identification of animals and registration of their movement is governed by the following legal acts:

- Veterinary Law (Official Gazette of the Republic of Montenegro, 11/04 and 27/07)
- Law on Animal Identification and Registration (Official Gazette of Montenegro, 48/07) which is largely harmonized with the EU regulations and adjusted to local conditions of animal breeding. The Law created a basis for adoption of a series of secondary legislation acts, whereby the adequate level of legal harmonization in the field of animal identification and registration and marking of beef will be achieved. Aiming at a full transposition, amendments to the Law on Animal Identification and Registration have been envisaged.
- Rulebook on Method of Cattle Identification and Registration and Keeping the Register and Electronic Database (Official Gazette of the Republic of Montenegro, 58/07), which lays down the form, contents and material for manufacturing ear tags and the method of application of ear tags for cattle identification, the form and method of keeping the register of a holding and reporting on cattle movement, the form for method of issuing a passport and temporary passport, method of keeping registers, method and procedure of keeping the Central register of holdings, a more detailed contents of the Electronic database, form of the registry sheet and the certificate of cattle identification as well as the method of keeping records.

Holding registration is obligatory for all holdings where animals are bred or kept. Animal identification is obligatory for domestic animals bred at holdings.

During the CARDS 2005 Project Development of the animal identification in Montenegro-phase I, the Law on Animal Identification and Registration and the Rulebook on Method of Cattle Identification and Registration and Method of Keeping the Electronic Database Register have been prepared.

In August 2009, the goat and sheep I&R commenced (IPA 2007, Project Implementation of an Animal Identification System / Phase II); a Rulebook on sheep and goats tagging will be adopted during 2010.

Competent body

Veterinary Administration is the body competent for identification and registration of animals and their movement.

Veterinary Administration carries out supervision over implementation of requirements prescribed for identification and registration of animals and their movement, through veterinary inspectors.

Animal identification and registration are carried out by veterinary surgeries which these affairs are delegated to, following the procedures established and implemented by the Veterinary Law. A contract between the Veterinary Administration and veterinary surgeries specifies obligations of those in charge of these activities.

In case of noncompliance with the contract provisions, Veterinary Administration terminates the contract with a veterinary surgery.

- bovine animals (including central bovine database)

Cattle identification and registration

Cattle identification and registration system has been established in Montenegro with support of the CARDS Project 2005 - Development of the animal identification in Montenegro. The project was initiated in March 2006, and campaign of the first cattle identification and registration and registration of holdings commenced in September 2007, and ended on March 12, 2008.

Cattle I&R is free of charge for animal keepers, funds for the I&R are provided from the Budget of Montenegro.

All movements are recorded in the database so that by entering an animal's identification number from the database, animal can be traced back to the holding of origin.

Owner is obliged to register and update all cattle movements in his/her register and inform the veterinary surgery i.e. Veterinary Administration thereof, so that movement changes could be registered in the database.

Aiming at an efficient implementation of the Law on Animal Identification and Registration and the I&R system, public campaign for cattle keepers has been implemented, as well as training of the Veterinary Administration and veterinary surgeries staff, Instructions for the inspection control of the I&R system have been prepared as well as the Manual for Border Inspection Posts.

- ovine and caprine animals

Identification and registration of sheep and goats

Aiming at establishing of the I&R system of other animals under the IPA 2007, the Project Implementation of an Animal Identification System / Phase II commenced in August 2009 and it will last 18 months; I&R of small ruminants (sheep and goats) will be carried out within it. One of the Project components is also introduction of a single veterinary information system.

- porcine animals

Identification and registration of porcine animals

Identification and registration of porcine animals have not been established in Montenegro.

- equidae

Horse identification and registration

Horse identification and registration have not yet been established in Montenegro.

Animal identification and registration of their movement – overview in relation to the EU legislation

EU Legislation		Montenegrin national legislation				
Description	**EU texts**	**National text**	**Legal basis**	**Current stage of transposition**	**Date (expected) of transposition/ implementation**	**TOC availability**
Bovine animals	Regulation (EC) No 1760/2000 Commission Regulation (EC) No 911/2004 Commission Regulation (EC) No 1082/2003 Commission Regulation (EC) No 494/98	Rulebook on identification and registration of bovine animals, keeping registers and computerised database	Law on animal identification and registration	Adopted	October 2007	Law on animal identification and registration- yes Rulebook on identification and registration of bovine animals, keeping registers and computerised database - Not yet
	Commission Decision 2001/672/EC Commission Regulation (EC) No 644/2005	Amendments to the Rule book on identification and registration of bovine animals, keeping registers	Law on animal identification and registration	Not yet drafted	2012	
	Commission Decision 2006/28/EC Commission Regulation (EC) No 509/1999					
Porcine animals	Council Directive 64/432/EEC Council Directive 2008/71/EC Commission Decision 2000/678/EC	Rulebook on identification and registration of porcine animals	Law on animal identification and registration	Not yet drafted	2012	
Ovine and caprine animals	Council Regulation (EC) No 21/2004 Commission Regulation (EC) No 1505/2006	Rulebook on identification and registration of ovine and caprine animals	Law on animal identification and registration	Under consideration	2010	
Equidae	Council Directive 90/426/EEC	Rulebook on identification and registration of	Law on animal identification	Not yet drafted	2012	

	Council Directive 90/427/EEC Commission Decision 93/623/EEC Commission Regulation (EC) No 504/2008	equidae	and registration			

11. Animal disease control measures:

Animal diseases notification

Legislation

Notification of suspected and occurrence of an infectious animal disease is governed by the following legislation:

- Veterinary law (Official Gazette of the Republic of Montenegro 11/04 and 27/2007);
- Rulebook on classification of animal diseases, method of reporting and informing on infectious animal diseases (Official Gazette of Montenegro 5/08) (Annex 47)

Veterinary Law governs infectious animal diseases; prevention of outbreak, control and eradication of infectious animal diseases; preventive veterinary measures; obligatory scope of animal health protection; animal welfare protection; financing of animal health protection; organization of legal entities for carrying out veterinary activities; ensuring of performance of activities of public interest, as well as other issues of relevance for carrying out of veterinary activities.

Rulebook on classification of animal diseases, method of reporting and notification of infectious animal diseases, the integral part of which is the List of notifiable diseases, which is fully harmonized with the OIE list of notifiable diseases, method of notifying and informing on suspected, confirmed case, termination of a disease and classification of animal diseases and forms for notification of suspected, confirmed and termination of a disease are prescribed.

Competent body

Veterinary Administration is the body competent for animal health protection.

Veterinary Administration, through veterinary inspectors, performs supervision over the implementation of measures laid down by the law and secondary legislation in the field of prevention of occurrence, control and eradication of infectious animal diseases.

Disease notification

Notification of suspected and of occurrence of an infectious animal disease is the obligation of the animal owner and the veterinarian.

When an infectious disease or signs causing suspicion that an animal is diseased or died from an infectious disease, the animal owner is obliged to immediately inform the nearest veterinary surgery, i.e. a veterinarian or a veterinary inspector.

It is considered that an infectious disease is suspected in case when, among the animals of the same backyard, pen, herd, flock or apiary, there are two or more consecutive cases of a disease with the same or similar sings, or when animals suddenly die without a visible cause.

Upon receipt of a notification on suspicion of the disease by the animal owner or keeper, the veterinarian is obliged to issue a written instruction on the prescribed veterinary measures and to notify the veterinary inspector in case of suspicion in an infectious disease subject to the obligation of notifying the suspicion. The veterinarian must notify a confirmed case of a notifiable disease to the competent veterinary inspector, in the prescribed manner.

The veterinary inspector must notify the competent health institution on suspected or existing zoonosis.

The competent veterinary inspector must submit a report on disease occurrence to the Veterinary Administration by the 15th day in month, for the previous month.

When presence of an infectious disease is confirmed on the basis of results of diagnostic examinations, the laboratory is obliged to notify in the prescribed manner the Veterinary Administration and the competent veterinary inspector of confirmation of the presence of the infectious disease.

In case of outbreak of an OIE listed disease, the OIE Headquarters are informed via telegram, fax or electronically, within 24 hours in the cases of:

- first occurrence of a disease and/or infection from the OIE list of diseases in a country, zone or area;
- re-occurrence of a disease and/or infection from the OIE list of diseases in a country, zone or area, following a report declaring the disease outbreak as terminated;
- first occurrence of a new strain of a pathogen of the disease from the OIE list in a country, zone or area;
- sudden and unexpected increase in distribution, incidence, morbidity or mortality of an OIE listed disease in a country, zone or area;
- emerging diseases with a significant morbidity or mortality or zoonotic potential;
- evidence of a change in epidemiology of an OIE listed disease (including the type of host, pathogenicity, strain), especially in case of a zoonotic impact.

Weekly informing of the OIE Headquarters on evolution in the abovementioned cases is obligatory, for as long as the disease is not eradicated or becomes endemic, so that the six-month reporting fulfills the obligation of a country to the OIE, with an obligatory final reporting on every case.

Informing of the competent veterinary authorities of the neighboring countries within 24 hours is obligatory in the following cases:

- primary outbreak of certain diseases prescribed by the rulebook, confirmed in Montenegro;
- abolishment of all prohibition measures following eradication of the last disease outbreak.

Disease termination

An infectious disease is terminated when the period of time that elapsed after the last diseased animal recovers, dies or is killed, and after the final disinfection elapses the longest incubation period for that infectious disease, unless otherwise provided by the professional veterinary standards.

Veterinary inspector terminates an infectious disease with the Veterinary Administration on a prescribed form.

By termination of an infectious disease, the competent veterinary inspector confirms that after eradication of the last case, prohibition measures introduced in relation to the occurrence of the infectious disease have been abolished.

Measures of animal diseases control

Legislation

The Veterinary Law (Official Gazette of the Republic of Montenegro, 11/04 and 27/2007) is the framework legal act laying down measures for prevention of occurrence, detection, control and eradication of infectious animal diseases.

A number of secondary legislation acts regulating measures for prevention of occurrence, detection, control and eradication of individual animal diseases (list of regulations provided in the Annex I to this chapter) are in force. A part of these regulations is harmonized with the EU

legislation, while further harmonization is envisaged by the National Program of Integration of Montenegro into the EU (NPI) for the period 2008/2012.

Rulebooks on tuberculosis, brucellosis and enzootic bovine leucosis are harmonized with the Council Directive 78/52/EEC (control and eradication) and Directive 64/432/EEC (diagnostics). Also, the following regulations:

- Rulebook on Measures for Control and Eradication of Rabies in Animals (Official Gazette of Montenegro, 17/07);
- Order on undertaking measures for prevention of introduction of the infectious animal disease of Bovine Spongiform Encephalopathy (BSE) into the Republic of Montenegro (Official Gazette of Montenegro 44/08);
- Order on undertaking measures for prevention of introduction of the infectious animal Foot-and-mouth disease into Montenegro (Official Gazette of Montenegro, 44/08)

are harmonized with the EU legislation.

Program for prevention, control and eradication of the Highly Pathogenic Avian Influenza (HPAI), was adopted at the sitting of the Government of the Republic of Montenegro from October 13th, 2005, is harmonized with the Council Directive 92/40 EC and Commission Decision 2005/464/EC.

At this moment there are no contingency plans established for certain diseases in accordance with the EU requirements.

The following approach will be used in preparation of contingency plans for other diseases: measures in case of suspicion, immediate danger, outbreak, prevention of spreading and eradication of a disease.

Veterinary Law prescribes:

- Obligatory general preventive measures carried out by animal owners (Article 10);
- Special preventive health protection measures (Article 11);
- Special preventive measures against zoonoses (Article 12);
- Control and eradication of infectious animal diseases (Articles 14 and 15);
- Measures undertaken by the Ministry of Agriculture, Forestry and Water Management in crises (Articles 17, 18, 19 and 20, 28 and 94).

Montenegro is a member of the World Organization for Animal Health – OIE since August 2007, Director of the Veterinary Administration is the official delegate of Montenegro to the OIE.

Montenegro was officially recognized free from Foot-and-Mouth Disease by the OIE, without vaccination (2006) as well as from rinderpest, based on historical data (2009).

Reports on animal health condition are sent electronically to the WAHID.

Montenegro is user of the ADNS system of the European Commission for notification of animal diseases, therefore it has the obligation of notifying a disease outbreak in accordance with the ADNS requirements, and it receives regular reports on outbreak and movement of a disease in other member countries of this organization via this system.

Veterinary Administration of Montenegro prepares regular monthly reports which can be accessed at the website of the Veterinary Administration: http://www.gov.me/vet

Program of Animal Health Protection Measures (hereinafter: Operational Program)

For the purpose of early detection and prevention of outbreak of infectious animal diseases, the

Ministry of Agriculture, Forestry and Water Management adopts the Operational Program and

other programs of animal health protection at the end of every year, for the following year:

Operational program lays down:

- type of preventive vaccination;
- diagnostic and other examinations;
- scope (species and number of animals);
- deadlines for implementation ;
- task holders (veterinary surgeries, Diagnostic Veterinary Laboratory, Veterinary Inspectorate);
- methods of reporting on measures carried out;
- method of financing;
- other requirements for carrying out measures from the Operational Program, as well.

Operational Program is published in the Official Gazette of Montenegro.

Preventive measures prescribed by the Operational Program are carried out by veterinary surgeries, to which these activities have been delegated following the procedures established and implemented by the law. A contract between the Veterinary Administration and veterinary surgeries precisely defines obligations of entities in charge of these activities.

In case of noncompliance with the contract provisions, Veterinary Administration terminates the contract with a veterinary surgery.

Veterinary Administration provides diagnostic means, vaccines, antihelmintics and other consumables to veterinary surgeries for the purpose of implementation of the Operational Program.

Diagnostic Veterinary Laboratory performs laboratory diagnostics of infectious animal diseases.

Operational Program comprises the following activities:

- **Control and eradication of tuberculosis** in all cattle older than six weeks by application of intradermal tuberculin tests, with the aim of eradication of this disease and establishing of status of a cattle herd free from tuberculosis on the entire territory of Montenegro;
- **Control and eradication of enzootic leucosis** in all cattle older than 24 months, by serological examination with the aim of establishing the status of a cattle herd free from this disease on the territory of Montenegro;
- **Control and eradication of brucellosis** in all cattle older than 12 months, except for males for fattening, and sheep and goats older than six months, with the aim of establishing the status of a cattle herd free from brucellosis on the territory of Montenegro;
- **Monitoring of Bluetongue disease in cattle, sheep and goats** in Montenegro;
- **Bee diseases diagnostics** (clinical examination, sampling, laboratory examinations);
- **Prevention and control of the Classical Swine Fever** – vaccination of pigs and wild boars monitoring;
- **Prevention and control of rabies in dogs and cats** by vaccination with an inactivated vaccine;
- **Prevention and control of Echinococcosis,** by dog dehelmintization;
- **Prevention and control of Anthrax** by vaccination with a vaccine containing the suspension of live spores of Bacillus anthracis;
- **Prevention and control of Newcastle Disease** by vaccination with a vaccine produced from lentogenous strains;
- **Prevention of Avian Influenza** in wild birds and domestic poultry (sampling and laboratory examinations);

- **Monitoring of zoonoses – Salmonellosis and Listeriosis** of domestic poultry (sampling and laboratory examinations).

Financing of measures from the Operational Program

The following is financed from the Veterinary Administration budget:

- monitoring of the epizootiological situation;
- supply of vaccines, diagnostic kits, antihelmintics, consumables (vacutainer tubes, needles and holders);
- vaccination of pigs against CSF and cattle against anthrax;
- vaccination of domestic animals, if needed, against rabies, expenses of dog and cat vaccination are borne by their owners;
- blood sampling for checking the presence of Brucellosis, Enzootic Leucosis, Avian Influenza, Bluetongue and Swine Influenza;
- blood sampling for the purpose of control of immune status of poultry and pigs;
- laboratory examinations;
- autopsy, sampling, serological and diagnostic examination of the pathological material;
- zoohygienic and biosafety measures in infected holdings;
- awards to hunters for foxes and wolves shot;
- trichinoscopic examination of wild boars for hunters who, in addition to samples for trichinoscopic examination, submit samples for the analysis for Classic Swine Fever and residues monitoring.
- clinical and laboratory check of bee communities;
- monitoring of salmonella and listeria;
- clinical examination, sampling and laboratory examination of farmed freshwater fish for diseases (parasitological and bacteriological examination).

For the purpose of a more efficient and safer updating, control and filing of data on measures carried out from the Operational Program of Animal Health Protection (TBC, Brucellosis and Enzootic Bovine Leucosis) changes have been introduced into the central database this year (central register of cattle).

Changes are reflected in exclusive use of PDAs during tuberculinization of cattle and blood sampling, so the data on the abovementioned measures are directly fed into the central database. During blood extraction, marked coded tubes are used; primarily, the ear tag number is scanned, then the tube code is scanned and blood is extracted. Following the receipt of the laboratory results, the results of the analyses are entered into the central base.

Compensation of damage

Animal keepers are compensated in the amount of market value of an animal on the day of occurrence of damage, for the damage resulting from control and eradication of highly dangerous infectious diseases and other diseases (set forth by the Operational Program).

Funds for damages are established by the Veterinary Administration budget.

In case of a disease outbreak of larger proportions, additional financial funds from the Budget of Montenegro may be provided.

Procedures for control and eradication of infectious animal diseases

General provisions for control and eradication of infectious animal diseases are laid down by the Veterinary Law (Articles 14 and 15, 17, 18, 19 and 20 and 94).

Detailed rules for control and eradication of diseases are laid down by rulebooks for all diseases separately.

The Ministry of Agriculture, Forestry and Water Management, depending on the nature of an infectious disease and the hazard level, adopts an order establishing an infected and endangered area as well as measures to be undertaken in an infected and endangered area.

In state of emergency or state of war, in natural and other disasters, causing a larger number of diseased animals or if epizootics occur, the Ministry of Agriculture, Forestry and Water Management may order urgent implementation of special technical measures and tasks to legal entities and veterinarians.

In state of emergency (war, epizootics, natural disasters causing a larger number of diseased animals), the Ministry of Agriculture, Forestry and Water Management proposes to the Government of Montenegro the adoption of the following measures:

- mobilization of veterinarians and citizens for carrying out prescribed animal health protection measures;
- mobilization of equipment, medicinal products and means of transport, in compliance with special regulations, and temporary use of land and buildings for implementation of the prescribed measures of animal health protection;
- use of land and buildings for the purpose of safe disposal of carcasses of killed or dead animals, foodstuffs, litter, waste and other infected material by burying, incineration or otherwise;
- special duties to all veterinary organizations, and, if necessary, to other legal persons and state bodies in order to implement the prescribed measures of animal health protection.

Sector for emergency situations and civil security operates to the Ministry of Interior and Public Administration; it is in charge of actions in the abovementioned cases. The Veterinary Administration participated in preparation of the National Emergency Situation Plan.

An infectious disease is terminated when the period of time that elapsed after the last diseased animal recovers, dies or is killed, and after the final disinfection the longest incubation period for that infectious disease elapses, unless otherwise provided for by the professional veterinary standards.

Foot-and-Mouth Disease

There has been no occurrence of Foot-and-Mouth Disease in Montenegro.

Measures for control and eradication of Foot-and-Mouth disease are prescribed by the Rulebook on Method, Procedure and Measures for Control and Eradication of Foot-and-Mouth Disease.

When an infectious disease is established or suspected, a veterinary inspector:

- orders blocking of a backyard where infection i.e. suspected infection occurred. Blocking of a backyard lasts until the final disinfection is carried out,
- informs all interested bodies and organizations on the occurrence of the infection
- marks with visibly displayed panels the infected backyards i.e. infected places or infected areas, depending on the extent to which the infection has spread,
- establishes channels by which an infection could have been introduced and routes of diseased animals movement,
- checks measures undertaken by an animal owner or keeper and orders other measures prescribed.

Animal owner or keeper is obliged to undertake the following measures in an infected backyard:

- to prevent entering into, i.e. exiting from an infected backyard to persons without a veterinary inspector pass,

- to enclose all animals happened to be in an infected backyard,
- to collect the manure in a separate place and to pack it (compost) or daily spray it with a mixture of 2% sodium hydroxide and slaked lime,
- to put disinfection barriers in front of the entrance into an infected backyard,
- to provide assistance to the competent authority during infection control.

If an infectious disease occurred with a legal entity registered for breeding and keeping animals, it is obliged to undertake the following measures, in addition to the previously mentioned ones:

- to prohibit entrance into premises with diseased animals to persons who do not work in such premises,
- to prohibit transfer of animals from one establishment into another,
- to perform daily observation and examination of animal health condition,
- to put disinfection barriers in front of entrances into every establishment with animals.

An infected backyard means all establishments directly connected with the establishments with diseased animals.

The following measures are undertaken in an infected backyard:

- enclosure of animals and prohibition of movement of animals,
- killing and safe disposal of all animals diseased from Foot-and-Mouth Disease, or suspected of the disease, as well as other animals susceptible to Foot-and-Mouth Disease who happened to be with the diseased animals
- prohibition of entrance into an infected backyard, i.e. exit from an infected backyard without a veterinary inspector pass,
- carrying out of daily disinfection,
- prohibition of taking out from an infected backyard the products and raw material of animal origin and other objects that may transmit the infection.

Daily disinfection in an infected backyard comprises disinfection of premises with diseased animals, disinfection of a backyard and housing premises. Daily disinfection is carried out every day until the last slaughtering i.e. killing of animals in an infected backyard. Daily disinfection is carried out for two more days after that, and the final disinfection is carried out on the third day (disinfection of all premises and places where infected animals or animals suspected of a disease were situated as well as disinfection of objects which were in contact with such animals).

The final disinfection must be carried out following rodent control of stables where animals were staying and rodent control of premises where grain feed is kept.

The final disinfection is performed with a 2% solution of NaOH, by thermal means (dry, wet and overheated steam), formalin and other efficient means.

If feed can not be disinfected, it must be destroyed.

If hay is on a haystack, it must be sprayed with a 3% solution of lactic acid. Sprayed surface layer of hay must not be used in the course of 14 days since the day of spraying.

Exceptionally, if there is a slaughterhouse where animals may be slaughtered and meat may be processed at a temperature exceeding 70°C, slaughter of clinically healthy animals from an infected backyard may be allowed, on condition that they are transported to a slaughterhouse by a transportation means from which falling out of manure and leak of liquid manure is impossible.

In an infected area, the following is ordered:

- clinical examination of ruminants and pigs, for the purpose of establishing the extent to which infection has spread and preventive vaccination of animals not suspected of infection,

- daily examination of ruminants and pigs in the course of eight days from the day of preventive vaccination, and then checks on the third, sixth, thirteenth and twentieth day upon expiry of that period,
- enclosure of ruminants and pigs into stables, pens and folds,
- prohibition of transportation of ruminants and pigs by means of road transport, i.e. prohibition of withholding these means of transport if they are moving in an infected area by roads determined for ruminants and pig transportation,
- prohibition of ruminants and pig crossing on foot over the infected area,
- prohibition of transporting forage and litter for animals by means of road transportation across an infected area,
- prohibition of retention in an infected area of the railway means of transportation carrying ruminants and pigs,
- prohibition of transportation of people by motor vehicles beyond the determined roads (with an obligatory disinfection on exiting from an infected area),
- prohibition of holding livestock markets and exhibitions,
- destruction of stray dogs and stray cats,
- keeping dogs on a rein and enclosure of cats,
- prohibition of use of unboiled swill,
- prohibition of natural and artificial insemination of ruminants and pigs,
- prohibition of dispatching of ruminants and pigs, as well as meat, meat products and feed from an infected area,
- prohibition of storage of meat and meat products which have been delivered from an uninfected area,
- prohibition of mass gatherings of people (in schools, cinemas, at meetings), if so required by the epizootiological situation,
- prohibition for households of slaughtering animals without a previous examination by a veterinary inspector,
- temporary termination of a work in a slaughterhouse, if so required by the epizootiological situation,
- prohibition of animal castration.

The following is ordered in an endangered area:

- prohibition of holding livestock markets and exhibitions,
- prohibition of trade in ruminants and pigs, as well as meat and other foodstuffs by which the infection can be transmitted,
- prohibition of delivering ruminants and pigs, except for slaughter,
- prohibition of movement of ruminants and pigs outside the backyard,
- preventive vaccination of all ruminants and pigs,
- observing the animals for infection with Food-and-Mouth Disease every three days until the ninth day, and the final check is carried out on the fifteenth day. Should it be determined during that check that there are no signs of infection, movement and joint pasture of animals may be allowed,
- prohibition of natural insemination of ruminants and pigs,

- prohibition of dispatching skins, wool, feet, horns and other raw materials outside the endangered area if these have not previously been disinfected, i.e. heat treated at a temperature not lower than 70°C,
- prohibition of dispatching meat products if these have not been heat treated at the temperature exceeding 70°C in the depth of the product and if these are dispatched in a wrapping which has not been disinfected prior to packaging,
- prohibition of mass gathering of people coming from an uninfected area.

Should Foot-and-Mouth Disease occur, the prescribed measures are undertaken in the infected area, in the diameter of 5 km, and in an endangered area in the diameter of 10 km – from the disease source. Geographical position (configuration) of land, transportation communications etc. must be taken into consideration, so that such an area makes an epizootiological economic entity.

If there is a hazard from Foot-and-Mouth disease spreading outside the borders of the infected and endangered area, preventive vaccination of animals even outside these areas may be ordered, especially in areas where there is a higher concentration of animals.

Infection is considered terminated if at least 21 days have elapsed since the last case of killing, i.e. slaughtering of infected animals.

For prevention of re-occurrence of Foot-and-Mouth Disease in a backyard which was infected:

- newly acquired animals must not be introduced in the course of 45 days from the day of termination of an infection if the animals have been previously vaccinated, i.e. in the course of 90 days from the day of termination of infection, if the animals have not been preventively vaccinated,
- manure must not be taken out to fields, in the course of 30 days in summertime, and 90 days in wintertime, respectively – since the day of termination of disease,
- grain feed found in a backyard which was infected must not be taken out from the backyard in the course of 60 days from the day of termination of the infection.

Should Foot-and-Mouth Disease occur in a border area in a neighboring country in all territories of municipalities bordering the respective country, undertaking of following measures is ordered:

- prohibition of holding livestock markets and exhibitions,
- prohibition of gathering and pasture of ruminants and pigs in the diameter of 5 km from the border,
- preventive vaccination of all ruminants with a vaccine of the virus occurring in the neighboring country.

Owners/keepers of ruminants and pigs in municipalities bordering a country where occurrence of Foot-and-Mouth Disease has been registered, are obliged to undertake the following measures:

- persons working with animals must use overalls and footwear on work, they must carry out a daily disinfection of hands upon exit from premises with animals,
- prohibit entry into premises with animals to persons who do not work with animals,
- prohibit keeping of newly acquired and other animals at the same place before the newly acquired animals stay in quarantine in separate premises. Persons dealing with the newly acquired animals must not come in touch with the animals found,
- observe, on daily basis, the animals in relation to the Foot-and-Mouth disease.

In municipalities where preventive vaccination of ruminants and pigs has been carried out, trade in ruminants and pigs will be prohibited in the course of 14 days from the day of vaccination and reaction of vaccinated animals will be controlled during that period.

Classical Swine Fever

Rulebook on Measures for Control and Eradication of Classical Swine Fever lays down measures of control and eradication of the Classical Swine Fever.

When Classical Swine Fever is confirmed in a backyard or when Classical Swine Fever is suspected, the following measures are ordered:

- prohibition of movement of pigs outside an infected backyard or establishment or the one suspected of infection;
- prohibition of taking out and trade in pigs, products, raw material and waste originating from pigs, feed and other object the Classical Swine Fever Virus can be carried out with from an infected backyard or establishment or the one suspected of infection;
- stamping out of pigs in an establishment where Classical Swine Fever has been established;
- safe disposal of carcasses of dead and killed pigs;
- confiscation and safe disposal of products, raw materials and waste originating from pigs diseases or suspected of Classical Swine Fever;
- restriction of movement for persons who came in contact with animals diseased from or suspected of Classical Swine Fever, i.e. with products, raw materials and waste originating from diseased animals;
- prohibiting workers who stayed in an infected backyard or establishment to come in contact with healthy animals prior to disinfection;
- disinfection of stables, outlets for pigs, backyards and equipment used in an infected backyard or an establishment with a specific disinfectant;
- packaging and disposal of manure and prohibition of taking out and use of manure and liquid manure at least 40 days prior to carrying out the ordered measures in a backyard or an establishment;
- quarantine of dogs and cats in an infected backyard;
- rodent control, disinfestation and disinfection in an infected backyard or establishment.

In a municipality where Classical Swine Fever has been established, the following measures are ordered:

- establishing of the epizootiological situation, origin of the infection and routes of its transmission;
- prohibition of issuance of health certificates for pigs from the area of infected municipalities or places;
- listing and protective vaccination of all pigs which have not been vaccinated;
- protective vaccination of all vaccinated swine if they were younger than three months during the previous vaccination;
- prohibition of holding fairs, all types of gathering pigs and holding livestock markets in the territory of a municipality where Classical Swine Fever has been established;
- prohibition of use of unboiled swill for feeding animals.

Classical Swine Fever is considered terminated in an infected backyard if all measures ordered have been carried out and if at least six weeks have elapsed since then.

Avian Influenza

So far, there has been no Avian Influenza in Montenegro.

The Government of Montenegro adopted in 2005 the Program for prevention, control and eradication of the Highly Pathogenic Avian Influenza (HPAI), which represents the legal act for

acting in case of hazard of occurrence or in case of the occurrence of the Highly Pathogenic Avian Influenza in Montenegro.

The program of activities is divided in five phases, with respect to the level of hazard, i.e. outbreak of an infection:

- Phase I – hazard from occurrence in Montenegro, considering the spread of HPAI in many Asian countries and occurrence of the highly pathogenic virus in migratory birds,
- Phase II – Immediate hazard from the HPAI outbreak,
- Phase III – Suspected HPAI in Montenegro,
- Phase IV – Confirmation of HPAI on the territory of Montenegro,
- Phase V – Control and eradication of the HPAI in Montenegro.

Confirmation of the HPAI on the territory of Montenegro:

When the HPAI is officially confirmed, the Veterinary Administration declares the holding (establishment, farm or location) infected, the infected area with the diameter of at least 3 kilometers and the endangered area with the diameter of at least 10 kilometers, established by the Ministry of Agriculture, Forestry and Water Management upon a proposal from the Veterinary Administration. When determining the area, geographic, administrative, environmental and epizootiological factors concerning the HPAI must be taken into account.

Measures applied in an infected holding comprise:

- marking of an infected holding with poles and tapes and marking and supervision of the controlled entrance and exit posts;
- all poultry in a household will immediately be killed on the spot, poultry died or killed, as well as all eggs, shall be destroyed. Destruction of carcasses by incineration on the spot;
- incineration of carcasses to be done in burial pit at least 2m deep, incinerated carcasses to be covered with a layer of quicklime, followed by a layer of soil of approximately 0.4-0.5 meters. All objects, feed, litter or manure will be destroyed or adequately treated.
- carry out disinfection of establishments with disinfectants in concentrations approved by the Veterinary Administration, including the equipment and food silos. Following the disinfection, the establishment should be at least twice sprayed within an interval of at least two weeks between the sprayings.
- tracing and safe removal under official supervision of the poultry meat from animals slaughtered in the period between the probable introduction of the HPAI agent in backyards / farms

Measures implemented in an infected area comprise:

- identification of all holdings keeping poultry within the area,
- periodic visits to holdings where poultry is kept, clinical testing of the poultry, including, if necessary, collecting of samples for laboratory examination; records of visits and findings must be kept;
- keeping all poultry in their housing establishments or at other places where it can be isolated;
- use of appropriate disinfectants at entrances into and exits from households;
- control of movement of persons handling poultry, poultry carcasses, eggs and vehicles transporting poultry, carcasses and eggs within the zone, in general;
- prohibition of poultry transportation;
- prohibition of removing poultry and hatching eggs from the holding where they are kept, save for in case that the competent body has authorized transportation (under supervision of a veterinary inspector):

(i) of poultry for direct slaughter to a slaughterhouse which is, if possible, located in an infected area, or, if that is not possible, to a slaughterhouse which the Veterinary Administration has chosen outside of the infected area;

(ii) of day-old chicks or pullets to a holding within the endangered area where there is no other poultry. This holding must be placed under official control;

(iii) of hatching eggs to the incubation station determined by the Veterinary Administration. Prior to dispatching, eggs and their wrappings must be disinfected.

- prohibition of relocation or spreading of a used poultry litter or waste without approval;
- prohibition of holding fairs, exhibitions or other poultry and other birds gathering.

Measures applied in an infected area will be carried out during at least 21 days following the preliminary cleaning and disinfection activities on an infected holding.

An infected holding will then become a part of an endangered area.

Measures applied in an infected area comprise:

- identification of all holdings keeping poultry within the endangered area;
- control of movement of poultry and hatching eggs within the endangered area;
- prohibition of poultry movement outside the area during the first 15 days, save for movement directly to the slaughterhouse chosen by the Veterinary Administration outside the infected area.
- special health mark must be placed on poultry meat;
- prohibition of movement of hatching eggs outside of endangered area save for the incubation station determined by the Veterinary Administration and which have previously been disinfected;
- prohibition of relocation or spread of a used poultry litter or waste outside of the endangered area;
- prohibition of organizing fairs, exhibitions or other poultry and other birds gathering.

Measures applied in an endangered area will be implemented during at least 30 days following the preliminary cleaning and disinfection activities on an infected holding.

All persons involved in carrying out the activities must preventively take medicinal products against the flu (Tamiflu) and must be previously vaccinated against influenza – to be defined in cooperation with the Ministry of Health. All persons implementing the actions must not come in touch with other poultry, birds and pigs in the following 72 hours.

In case of HPAI occurrence, during implementation of the mentioned measures, the Veterinary Administration may seek assistance from a public administration body in charge of police affairs and an authority in charge of defence affairs in accordance with Article 17 of the Veterinary Law.

Adoption of a rulebook for prevention of occurrence, control and eradication of the Highly Pathogenic Avian Influenza is envisaged.

Newcastle Disease

Rulebook on measures for control and eradication of the Newcastle Disease defines measures for control and eradication of the Newcastle Disease.

All poultry must be immune against Newcastle Disease.

In poultry flocks with individual keepers in extensive breeding conditions, maintenance of immunity against Newcastle Disease is obligatory by protective vaccination of poultry, which is performed at least twice in these flocks.

If the Newcastle Disease is established, the following measures will be ordered in infected establishments, backyards and populated places:

- closing of infected establishments, backyards and settlements;
- prohibition of trade in poultry, poultry meat and products, eggs and feathers from infected establishments, backyards and populated places;
- killing of poultry diseased from the Newcastle Disease in an establishment or a backyard and safe removal of carcasses of dead and killed poultry;
- prohibition of slaughtering poultry from an infected establishment and an infected backyard;
- prohibition of holding markets, fairs, exhibitions and other public gatherings in infected places;
- destruction or sterilization of feed intended for poultry, found in an infected establishment;
- disinfection, disinfestations and rodent control of infected establishments and immediate surroundings;
- packing farmyard manure from infected establishments and prohibition of use of such farmyard manure for at least a month from the day of termination of packaging;
- prohibition of operation of incubators in populated places in commercial and individual production of one-day chicks, if these incubators serve for placing the one-day chicks on the market.

Newcastle Disease is considered terminated in an infected flock, i.e. infected area, when at least 30 days have elapsed from the last death or killing of poultry in that flock or backyard, on condition that all other ordered measures have been implemented.

Fish and bivalve molluscs diseases

Rulebook on measures for control and eradication of trout furunculosis and Rulebook on measures for control and eradication of trout whirling disease lay down measures for control of these fish diseases.

The following measures are ordered in a trout farm where trout furunculosis is established or where there is trout furunculosis suspected:

- prohibition of landing trout and their relocation from that farm to another, i.e. to other water courses;
- prohibition of letting trout out or prohibition of their leaving from a farm, i.e. from other open water establishments;
- prohibition of issuing an animal health certificate;
- safe disposal of severely diseased and dead trout;
- prohibition or restriction of access of outsiders and visitors to a trout farm;
- treatment with an appropriate medicinal product;
- disinfection of spawn following fertilization with an appropriate disinfectant;
- mechanical cleaning of trout farms, outlets, channels and objects used for work on a farm and their disinfection.

It is considered that there is no trout furunculosis in an infected farm if all ordered measures have been implemented, and if three weeks from then have elapsed.

The following measures are ordered in a trout farm where trout whirling disease is established:

- prohibition of landing trout and their relocation from that farm to another, i.e. to other water courses;
- prohibition of letting trout or prohibition of their leaving from a farm, i.e. from other open water establishments;
- prohibition of issuing an animal health certificate;

- safe disposal of severely diseased and dead trout;
- prohibition or restriction of access of outsiders and visitors to a trout farm;
- diagnostic examination of trout in a water course, upstream and downstream from the farm;
- mechanical cleaning of trout farms, outlets, channels and objects which serve for work on a farm and their disinfection.

It is considered that there is no whirling disease in trout in an infected farm, if all ordered measures, cleaning and disinfection have been carried out, and if, there is no whirling disease in newly introduced young trout, based on the clinical features and laboratory examination.

Bluetongue Disease

Measures for prevention of occurrence, control and eradication of the infectious Bluetongue Disease are laid down by the Rulebook on measures for prevention of occurrence, control and eradication of the infectious Bluetongue Disease − Febris catarhalis ovium.

When Bluetongue Disease is established or suspected, the following measures are ordered:

- blocking of the disease source;
- separating healthy from diseased ruminants;
- recording of ruminants and their marking;
- sampling and diagnostic examination in accordance with the program;
- killing by a bloodless method of all diseased ruminants with manifested characteristic clinical features;
- safe disposal of carcasses of dead and killed ruminants;
- control of wild ruminants and diagnostic examination in accordance with the program;
- control of disease carriers in accordance with the program;
- carrying out disinfestation in an infected and endangered area for the purpose of destruction of disease carriers in accordance with the program;
- disinfestation, disinfection and rodent control in establishments where ruminants are kept, as well as disinfection of means for transportation of ruminants.

When presence of Bluetongue Disease is established, the infected and endangered areas are determined:

Infected area comprises:

- disease source;
- area where a carcass of a dead or shot wild ruminant with Bluetongue Disease established;
- areas of populated places in the diameter of 50 km from the epizootiological source.

Endangered area comprises the area in the diameter of 100 km from the infected area.

Size of an infected and endangered area can be changed depending on: geographic position and environmental factors, meteorological conditions, presence and dispersion of disease carriers and results of epizootiological examination, as well as laboratory examination.

In addition to the abovementioned measures, the following measures are also implemented in an infected and endangered area:

- prohibition of movement and trade in ruminants from an infected and endangered area;
- Establishing the origin of the disease and its transmission routes, as well as a epizootiological examination;
- prohibition of holding fairs, markets and all forms of ruminant gathering;

- clinical examination of ruminants in an infected and endangered area in accordance with the program;
- diagnostic examination of ruminants in accordance with the program;
- control of disease carriers for the purpose of epizootiological and entomological examination in accordance with the program;
- prohibition of hunting wild ruminants in the diameter of 10 km from an endangered area;
- and other preventive, protection and control measures laid down by law.

Measures laid down by this rulebook cease to be implemented in an infected and endangered area by termination of the Bluetongue Disease, and when all ordered measures are implemented, and at least two longest incubation periods have elapsed since then.

For the following diseases: African Swine Fever; African Horse Sickness; other fish and bivalve moluscs diseases, Transmissible Spongiform Encephalopathy there is no specific legal regulation, but in case of their occurrence, general measures prescribed by the Veterinary Law are applied.

Projects in this area

Veterinary Administration of Montenegro is the beneficiary of the IPA 2008 Project "Support to control and eradication of rabies and Classical Swine Fever in Montenegro", the commencement of which is expected at the beginning of the next year. The project duration will be 2 years. The aim of this project is eradication of rabies in wild animals, and an interruption of the disease transmission chain in potentially infected wild boars to the population in domestic breeding, as well as harmonization of regulations from this field with the European requirements.

Project should provide for:

- assistance in harmonization of national legislation from the field of Classical Swine Fever and rabies with the European Union legislation;
- strengthening of the veterinary service capacities for diagnostics, monitoring and control of the mentioned diseases;
- monitoring of oral and parenteral vaccination of animals against rabies and Classical Swine Fever.

Animal health- overview when compared to the EU legislation

EU Legislation		Montenegrin national legislation				
Description	EU texts	National text	Legal basis	Current stage of transposition	Date (expected) of transposition/ implementation	TOC availability
Notification of animal diseases	Council Directive 82/894/EEC	Rulebook on notification of animal diseases	Veterinary Law	Animal Diseases Notification System (ADNS) in place	2008	
Foot and Mouth Disease	Council Directive 2003/85/EC	Rulebook on eradication of foot and mouth disease (existing national legislation)	Veterinary Law	To be reviewed (adoption of a new text)	2010	
Classical Swine Fever	Council Directive 2001/89/EC 2002/106/EC: Commission Decision Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever	Rulebook on eradication of classical swine fever (existing national legislation)	Veterinary Law	Adoption of a new text	2010	

African Swine Fever	Council Directive 2002/60/EC 2003/422/EC: Commission Decision African swine fever diagnostic manual		Veterinary Law	Not yet drafted	2012	
African horse sickness	Council Directive 92/35/EEC		Veterinary Law	Not yet drafted	2012	
Avian Influenza	Council Directive 2005/94/EC Commission Decision 2006/437/EC Commission Decision 2007/268/EC Commission Decision 2007/598/ EC	National programme of prevention and eradication of High Pathogenic Avian Influenza	National programme of prevention and eradication of High Pathogenic Avian Influenza	Not yet drafted	2011	
Newcastle disease	Council Directive 92/66/EEC	Rulebook on eradication of Newcastle disease (existing national legislation)	Veterinary Law	Adoption of a new text	2010	
Fish and Mollusc diseases	Council Directive 2006/88/EC Commission Decision 2004/453/EC	Rulebook on Mahomatosis salmonis Rulebook on Furunculosis salmonis (existing national legislation)	Veterinary Law	Adoption of a new text	2012	
Bluetongue disease	Council Directive 2000/75/EC Commission Regulation (EC) No 1266/2007	Rulebook on eradication of bluetongue (existing national legislation)	Veterinary Law	Adoption of a new text	2011	
Transmissible Spongiform Encephalopathies	Regulation (EC) No 999/2001 Commission Regulation (EC) No 546/2006 Commission Decision 2007/453/EC	Decree on measures for prevention of import of Transmissible Spongiform Encephalopathies in Montenegro (Existing national legislation)	Veterinary Law	Adoption of the suppression and eradication of TSE	2010	
Zoonoses	Regulation (EC) No 2160/2003 Directive 2003/99/EC Commission Regulation (EC) No 1003/2005 Commission Regulation (EC) No 1168/2006 Commission Regulation (EC) No 1177/2006 Commission Regulation (EC) No 646/2007 Commission Decision 2007/407/EC	Rulebook on eradication of salmonelosis (existing national legislation) Rulebook on eradication of Typhus Avium (Salmonella galinarum Salmonella pullorum) (existing national legislation)	Veterinary Law Food Safety Law	Adoption of a new text	2010	
Other Diseases	Council Directive 92/119/EEC Commission Decision 2000/428/EC		Veterinary Law	Not yet drafted	2012	

12. Trade in live animals, semen, ova and embryos

Trade in live animals, semen, ova and embryos

Legislation

Framework legal acts governing the field of trade in live animals, semen, ova and embryos are:

- Veterinary Law (Official Gazette of the Republic of Montenegro, 11/04 and 27/07),
- Law on Animal Identification and Registration (Official Gazette of the Republic of Montenegro, 48/07),
- Law on Animal Welfare Protection (Official Gazette of Montenegro, 14/08),
- and secondary legislation (list of legal acts is provided in Annex I to this chapter).

Internal trade in live animals, semen, ova and embryos

Animals in trade must be identified (marked) in an appropriate manner and must be accompanied with a health certificate, certifying the animal health condition and guaranteeing that in the place of origin of that animal, no presence of infectious animal diseases transmitted by that species of animals has been established, as well as other prescribed requirements.

The Animal Health Certificate contains data on the owner – animal keeper, obligatory animal identification and origin and it can be issued only for the animals:

- included in the Program of Mandatory Preventive Measures (Operational Program of Animal Health Protection Measures);
- for slaughter, which have not been treated or which have been treated and whose withdrawal period for used medicinal products has expired;
- which have not been treated with banned veterinary medicinal products and hormone preparations;
- if no existence of an infectious disease transmissible by that species of animal has been established in the place of origin of the animal.

The certificate is valid for the period of ten days since the day of issuance, i.e. from the day of its renewal.

The Health Certificate is issued by veterinarians employed in veterinary surgeries which are authorized for implementation of measures from the Operational Program of Animal Health Protection (contract with the Veterinary Administration).

Rulebook on health requirements for trade in cattle and swine lays down detailed requirements which cattle and swine in trade on the territory of Montenegro must fulfill. The Rulebook is harmonized with the Council Directive 64/432 in the part referring to definitions, Articles 3,4,5,6 (paragraphs 1, 2 and 3), Articles 7 and 8 (paragraph1) of the Directive, and Annexes B, C and D.

Herd statuses are established by a veterinary inspector's decision.

A provision of the Rulebook referring to the obligation of swine identification will be applicable following establishment of the swine identification and registration system in Montenegro.

Breeding, keeping and trade in animals may be performed by legal entities, other legal entities and entrepreneurs only in establishments fulfilling the prescribed conditions in terms of equipment, construction, veterinary-sanitary and other requirements, depending on the activities carried out in them, and which are entered into the Veterinary Administration's register.

Rulebook on organization of livestock markets, fairs, exhibitions and assemblies lays down requirements for establishments where livestock markets, fairs, exhibitions and assemblies are held (collection sites and collection stations).

The competent bodies of the local government issue licenses for organization of exhibitions, zoos, animal evaluation and competitions, for various events involving travelling animals (circuses, travelling zoos, etc.), and for the organized sale of animals and products outside business premises, with prior approval of the Veterinary Administration.

Trade in animals, semen, ova and embryos is allowed only following the veterinary check at the place of production, i.e. origin and if their identification and traceability are enabled, as well as other prescribed conditions fulfilled.

Animal owners and transporters of animals, semen, ova and embryos must provide the transportation conditions prescribed and enable performance of inspection check.

Means of transportation by which consignments of animals, semen, ova and embryos are transported must be cleaned and disinfected in a prescribed manner in accordance with the rulebook on the method of disinfection of means of transportation used for transporting consignments of animals, products, raw materials and animal origin waste.

As regards railroads, water, air and road means of transportation, loading, reloading and unloading of consignments of animals, semen, ova and embryos is permitted only at places which fulfill the prescribed conditions.

Establishments for breeding of breeding animals must be free from certain infectious animal diseases. Owner of the establishment for breeding animals must provide systematic monitoring of health condition and reproductive ability of breeding animals, as well as acquisition, production, storage and trade in animal semen, ova and fertilized ova in accordance with the prescribed conditions, as well as the minimum conditions for preservation of reproductive ability.

There are no establishments for breeding of breeding animals in Montenegro.

Acquisition, storage and placing on the market of animal semen, ova and fertilized ova may be performed only by legal entities fulfilling the conditions prescribed and which are registered for performing that activity. They must keep the prescribed records on acquisition, storage and placing on the market of animal semen, ova and fertilized ova.

International trade in live animals, semen, ova and embryos

Importation of animals, semen, ova and embryos is permitted only if the prescribed conditions regarding health protection, protection against torture and transportation of animals have been fulfilled.

Transportation of animals, semen, ova and embryos in international transport must be carried out exclusively at border crossings with veterinary control organized.

Prior approval of the Ministry competent for environmental protection affairs must be obtained by the importer for importation of foreign (allochtonous) live animal species.

During importation of animals, semen, ova and embryos, the prescribed veterinary checks and examinations must be carried out, in accordance with the risk analysis. Following the import, the imported animals must be kept in quarantine by the importer, for the purpose of examination. Location of the quarantine, type of examination and requirements regarding keeping animals in the quarantine are determined by the Veterinary Administration.

In accordance with the Rulebook on conditions and duration of quarantine for imported animals, the quarantine for imported horses, cattle, sheep, goats, pigs and big wild animals lasts 30 days, quarantine for decorative birds, poultry, dogs, cats, fish, crustaceans and bivalve molluscs lasts 21 days, while the quarantine for imported semen for artificial insemination and fertilized ova lasts until completion of the diagnostic examinations ordered, as a rule, not longer than 21 days.

For animals imported for the purpose of participation in sport events of up to 15 days and for exhibitions and fairs, as well as for ungulates, poultry and rabbits imported for immediate slaughter, the administration body may decide not to place them in the quarantine in case the epizootiological situation in the exporting country is such as to pose no risk of introduction of infectious animal diseases.

For consignments of animals, semen, ova and embryos which are exported, a certificate is issued, on a form prescribed for the importing country, on the occasion of loading in the place of origin of the consignment, and the veterinary inspector stamps it at the border on the occasion consignment’s exit across the border crossing.

Trade in live animals, semen, ova and embryos – overview in relation to the EU legislation

EU Legislation	Montenegrin national legislation				
EU texts	**National text**	**Legal basis**	**Current stage of transposition**	**Date (expected) of transposition/ implementation**	**TOC availability**
Council Directive 64/432/EEC Commission Decision 2002/598/EC Commission Decision 2003/886/EC Commission Decision 2004/226/ EC Commission Decision 2007/846/EC Commission Decision 2008/185/E	Rulebook on eradication of bovine tuberculosis	Veterinary Law	Adopted Transposition of : Annex B of the directive only chapter concerning the diagnosis tests	October 2008	Not yet
	Rulebook on eradication of Bovine brucellosis	Veterinary Law	Adopted Transposition of : Annex C of the directive only chapter concerning the diagnosis tests		
	Rulebook on eradication of Bovine leucosis	Veterinary Law	Adopted Transposition of : Annex D of the directive only chapter concerning the diagnosis tests		
	Rulebook on health conditions of bovine and porcine animals in trade inside Montenegro:	Veterinary law	In preparation. Will be included: Definitions, and conditions of trade with adaptation of Art 3,4, 5 6 (only first indent of par 1 and par. 2 and 3) , Art. 7, Art 8 (first par.) of the Directive and Annex B, C D chapters concerning the status of animals and holdings.	December 2009	
Council Directive 91/68/EEC Commission Decision 2007/846/EC	Rulebook on health conditions of sheep and goats in trade inside Montenegro	Veterinary law	In preparation. Will be included large parts of the EU directive with adaptations to the national conditions	2010	
Council Directive 90/426/EEC Commission Decision 95/329/EC Commission Decision 2007/846/EC			Not yet drafted	2012	
Council Directive 90/539EEC Commission Decision 94/327/EC Commission Decision 2003/644/EC Commission Decision 2004/235/EC			Not yet drafted	2012	
Council Directive 2006/88/EC			Not yet drafted	2011	
Council Directive 89/556/EEC			Not yet drafted	2012	
Council Directive 88/407/EEC			Not yet drafted	2010	
Council Directive 90/429/EEC			Not yet drafted	2012	
Council Directive 92/65/EEC Commission Decision 94/274/EC	(Notification of diseases already in place according to Montenegrin	Veterinary Law	Not yet drafted	2012	

Commission Decision 94/275/EC Commission Decision 95/294/EC Commission Decision 95/307/EC Commission Decision 95/388/EC Commission Decision 95/483/EC Commission Decision 2004/233/EC Commission Regulation (EC) No 1739/2005 Commission Decision 2007/846/EC	regulation)				

13. Non-commercial movements of pet animals

Non-commercial movement of pet animals

Legislation

The field of non-commercial movement of pet animals is governed by the following legal acts:

- Veterinary Law (Official Gazette of the Republic of Montenegro, 11/04 and 27/07),
- Law on Animal Identification and Registration (Official Gazette of the Republic of Montenegro, 48/07)
- Law on Animal Welfare Protection (Official Gazette of Montenegro 14/08).

Law on Animal Identification and Registration prescribes the obligation of registration for all animals. In Montenegro, the system of dogs identification has not been established yet. Adoption of a regulation which will regulate in more detail movement of pet animals is planned for 2011.

Documentation with data on animal owner, the animal itself, breed, sex, age, vaccinations, accompany the movement of pet animals within Montenegro.

Rulebook on measures for determination of presence, control and eradication of rabies in animals (Official Gazette of Montenegro, 17/07) prescribes the obligation of vaccination of dogs and cats with an inactivated vaccine against rabies, once a year. Dogs and cats older than three months are subject to vaccination. Concurrently, dehelmintization of dogs older than three months against Echinococcus granulosus is carried out.

Only vaccinated dogs and cats for which a certificate of the competent veterinary surgery has been issued may participate at exhibitions and other forms of gathering of cats and dogs, if the time of immunity development elapsed from the vaccination, according to the instruction of vaccine producer, i.e. 15 days at least.

International transport of pet animals is governed by the Veterinary Law. On the occasion of entrance into Montenegro, corresponding documentation must accompany the pet. On the occasion of movement from Montenegro into other states, the Veterinary Administration issues a certificate, based on data from veterinary surgeries records.

Competent body

Veterinary Administration is the body competent for non-commercial movement of pet animals.

Veterinary Administration performs supervision over implementation of prescribed requirements for non-commercial movement of pet animals, through veterinary inspectors.

Vaccination of dogs and cats is carried out by veterinary surgeries and they keep prescribed records on vaccinated animals.

Non-commercial movement of pet animals – overview in relation to the EU legislation

EU Legislation		Montenegrin national legislation				
Description	EU texts	National text	Legal basis	Current stage of transposition	Date (expected) of transposition/ implementation	TOC availability
Non commercial movements of pet animals	Regulation (EC) No 998/2003 Commission Decision 2003/803/EC Commission Decision 2004/824/EC Commission Decision 2004/839/EC Commission Decision 2005/91/EC Commission Decision 2007/25/EC	Rulebook on eradication of rabies	Veterinary Law	Obligation of vaccination already stated and implemented in December 2007 The provisions concerning sampling and detection of antibodies not yet drafted	2011	

14. Prohibition of substances and residue monitoring

Monitoring of unauthorized substances and residues

Legislation

Field of monitoring of unauthorized substances and residues is governed by the following framework legal acts:

- Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07),
- Law on Food Safety (Official Gazette of Montenegro 14/07).

Rules from this field are laid down in more detail by the following secondary legislation:

- Rulebook on monitoring of residues in animals, foodstuffs of animal origin and feedingstuffs (Official Gazette of the Republic of Montenegro 46/06),
- Rulebook on maximum allowed concentrations of residues of pharmacologically active substances of veterinary medicinal products in foodstuffs of animal origin (Official Gazette of the Republic of Montenegro 51/07),
- Rulebook on quantities of pesticides, metals and metalloids and other poisonous substances, chemotherapeutics, anabolics and other substances which might occur in foodstuffs (Official Gazette of the Federal Republic of Yugoslavia 5/92,11/92 and 32/02)
- Instruction for implementation of the Residues monitoring Program.

Competent body

Agency for Medicines and Medical Devices of Montenegro is in charge of issuing approvals for placing veterinary medicinal products on the market (marketing authorization), as well as for issuing approvals for veterinary medicinal products importation.

The Agency for Medicines and Medical Devices of Montenegro is in charge of preparation and update of the list of all medicinal products with active substances marketed in Montenegro. At request of the Veterinary Administration, the Agency submits an updated list of medicinal products to the Administration, which is used during drafting of the residues monitoring program.

Veterinary Administration is the body competent for preparation and carrying out of monitoring of unauthorized substances and residues. Department for Veterinary Public Health prepares the annual residues monitoring program, issues orders to veterinary inspectors for sampling and

monitors program implementation. Ministry of Agriculture, Forestry and Water Management adopts the monitoring program, by 31st March for the current year.

Veterinary Administration, through veterinary inspectors, carries out sampling and delivery to the laboratory and it also undertakes measures in case of positive results.

Funds for implementation of the Residues monitoring program are provided from the Veterinary Administration budget. The Veterinary Administration submits the annual report on result of the monitoring to the Ministry of Agriculture, Forestry and Water Management and the EU Commission - DG SANCO by 31st March of the current year for the previous year.

Residues monitoring is carried out in establishments where animals are bred and kept, i.e. establishments for slaughter, dairies, establishments for fish farming and processing, establishments for honey, establishments for collecting and packing eggs.

The aim of the Residues Monitoring Program is to achieve the following through a systematic control of an appropriate number of samples predetermined by the plan:

- ensure efficient monitoring of residue levels in excrements and body liquids of live animals, organs and tissues of slaughtered animals, meat, eggs, honey and feed;
- detect unauthorized treatment of animals for therapeutical purposes or zootechnical treatment, using unauthorized substances or products, or using allowed substances or products for purposes other than those permitted or under the conditions different from the prescribed ones.
- control of whether the maximum permitted concentrations of residues in excretions and body liquids of live animals, organs and tissues of slaughtered animals and meat, eggs and honey are in line with the maximum permitted quantities prescribed.

Results obtained should enable timely and preventive undertaking of measures necessary for ensuring the safety of food of animal origin and public health protection.

Rulebook on monitoring of residues in animals, foodstuffs of animal origin and feed lays down the measures of systematic control of pharmacologically active substances and their metabolites as well as residues of other substances in animals, foodstuffs of animal origin and feed. Annex I of this rulebook lays down substances which have anabolic effect and unauthorized substances (group A), and veterinary medicinal products and contaminants (group B). Annex II of this rulebook prescribes groups of substances which should be determined in animal species and food of animal origin, Annex III prescribes the scope and frequency of sampling, Annex IV prescribes the appropriate confirmation methods for organic residues and contaminants and chemical elements.

Rulebook on the maximum permitted concentrations of residues of pharmacologically active substances of veterinary medicinal products in foodstuffs of animal origin prescribes the maximum permitted concentrations (MRLs) of residues of pharmacologically active substances of veterinary medicinal products in excrements and body liquids of live animals, organs and tissues of slaughtered animals, meat and foodstuffs of animal origin.

Medicinal products for veterinary use containing the substances Furezolidone and Nitrofurazone were withdrawn from the market in 1992 (by a decision published in the Official Gazette of the Socialist Federal Republic of Yugoslavia 22/92 and 25/92).

Official Gazette of the Socialist Federal Republic of Yugoslavia 64/89 contains a list of off-the-counter medicinal products for veterinary use by which certain animal species whose products are used in human consumption are excluded from indications because they contain chloramphenicol.

Instruction for implementation of the residues monitoring program defines the basic principles of sampling; criteria for selection of samples; quantities and types of samples taken; division of samples; taking and packaging of samples in slaughterhouses; taking and packaging of samples in holdings and other primary production establishments; storage and transportation of samples; wrappings for sampling; form of the minutes on taking samples for residues analysis; an laboratory referral form; report on results of the analyses and a positive test result – more intensive sampling.

Veterinary inspectors take samples upon received orders for sampling. Sampling is carried out at different intervals throughout the entire year. Sampling is sudden, unpredictable, unexpected and carried out at a different time of day, in different days of the week.

Authorized laboratory (by the Veterinary Administration) for residues analysis in Montenegro is the Centre for Eco-toxicological Researches of Montenegro.

Veterinary inspector submits samples together with the accompanying act which does not indicate information on owner and origin of sample (blind sample).

After completing the sample examination, the authorized laboratory submits the results to the veterinary inspector who carried out the sampling and to the Department for Veterinary Public Health of the Veterinary Administration.

In addition to the sampling according to the program, a veterinary inspector may perform sampling if he/she suspects use of unauthorized substances, i.e. presence of residues in quantities exceeding the permitted ones.

Montenegro is included in the list of countries which have the residues monitoring plans approved (Annex of the Commission Decision 2004/432/EC) for cattle, sheep, swine, poultry, aquaculture, eggs and honey.

Monitoring of unauthorized substances and residues – overview of condition in comparison with the EU legislation

EU Legislation		Montenegrin national legislation				
Description	**EU texts**	**National text**	**Legal basis**	**Current stage of transposition**	**Date (expected) of transposition/ implementation**	**TOC availability**
Prohibition of substances	Council Directive 96/22/EC Council Decision 99/879/EC		Veterinary Law			Not yet
Residues controls	Council Directive 96/23/EC Commission Decision 97/747/EC Commission Decision 98/179/EC Commission Decision 2002/657/EC	Rule book on residues monitoring in live animals food of animal origin and feedingstuffs Manual for implementing the residues monitoring programme	Veterinary law Food Safety Law	Adopted Provisions of 96/23/EC are mostly transposed as well as those of 97/747/EC Confirmative methods for residues, contaminants and heavy metals are transposed from 2002/657/EC The Manuals is ordering the measures for the sampling methods laid down in Commission Decision 98/179/EC	July 2006	Not yet
	Council Regulation (EEC) No	Rule book on maximum permitted residues concentration of pharmacologically active	Veterinary Law	Adopted Transposing Annexes I and	August 2007	Not yet

	2377/90	substances of veterinary medicines in food of animal origin		IV of the Regulation (EEC) No 2377/90 and Annex II of Commission Decision 2002/657/EC		

15. Import requirements for live animals and animal products

Legislation

Field of importation of live animals and products of animal origin products is governed by the following framework legal acts:

- Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07),
- Law on Food Safety (Official Gazette of Montenegro 14/07),
- and secondary legislation in this field.

Rulebook on conditions and duration of quarantine for imported animals (Official Gazette of the Federal Republic of Yugoslavia, 6/88) prescribes requirements concerning necessary examinations and period of duration of quarantine for certain animal species.

A separate rulebook regulates detailed requirements for importation of food, type and quantity of food of animal origin, composite food, pet food and plants and plant products, serving for supplying crew and passengers in international means of transportation, food used during travel in the means of transportation, food or feed ordered via cash-on-delivery.

Competent body

Veterinary Administration is the body competent for imports of live animals and products of animal origin products - Department for veterinary public health.

Veterinary Administration carries out checks of all consignments of live animals, products of animal origin and feed across the approved border inspection posts through border veterinary inspectors.

Customs Administration – customs officers are in charge of controlling food in use during travel in means of transportation (personal consumption-luggage).

Importation of live animals and products of animal origin is approved following previous checks in order to establish absence of veterinary impediments for importation.

In making decision on authorizing importation from a certain country or part of a country, epizootiological situation of the exporting country is taken into account (on the basis of the OIE information) in relation to the disease which can be transmitted by that animal species or product of animal origin.

Importation is approved from establishments included in the list of approved establishments registered for exportation into the EU. Importation from other establishments, for which it is confirmed that regulations, standards and veterinary control system in the exporting country are equivalent to the prescribed national requirements, is authorized as well.

As regards live animals importation, conditions for their quarantine must be ensured in the preliminary procedure in accordance with the regulations. Location of quarantine, type of examination and requirements concerning animal keeping in the quarantine are established by the Veterinary Administration.

Previous approval of the ministry in charge of environmental protection is necessary for importation of foreign (allochtonous) animal species.

For animals imported for the purpose of participation in sport events of up to 15 days and for exhibitions and fairs, as well as for ungulates, poultry and rabbits imported for immediate slaughter,

the Veterinary Administration may decide not to place them in the quarantine in case the epizootiological situation in the exporting country is such as to pose no risk of introduction of infectious animal diseases.

Requirements for live animals and animal origin products importation – overview in relation to the EU legislation

EU Legislation		Montenegrin national legislation				
Description	**EU texts**	**National text**	**Legal basis**	**Current stage of transposition**	**Date (expected) of transposition/ implementation**	**TOC availability**
Bovine, Porcine, and Ovine Animals	Council Directive 2004/68/EC Regulation (EC) No 999/2001 Council Directive 96/23/EC Commission Decision 2007/453/EC		Veterinary Law Food safety Law	System under revision to adopt the European Union principles (lists of countries and establishments, models of certificates)	Expected 2010	
Equidae	Council Directive 90/426/EEC Council Directive 96/23/EC					
Poultry and Hatching Eggs and Specified Pathogen-Free Eggs	Council Directive 90/539/EEC Regulation (EC) No 2160/2003					
Aquaculture Animals - Fish	Council Directive 2006/88/EC Council Directive 96/23/EC					
Embryos of Bovine Animals	Council Directive 89/556/EEC					
Semen of Bovine Animals	Council Directive 88/407/EEC					
Semen of Porcine Animals	Council Directive 90/429/EEC					
Equine semen, ova and embryos	Council Directive 90/426/EEC					
Semen ova and embryos of the ovine and caprine species and ova and embryos of the porcine species	Council Directive 92/65/EEC Regulation (EC) No 999/2001					
Other Animals, Semen, Ova and Embryos	Council Directive 92/65/EEC Commission Decision 2005/64/ EC Commission Decision 2003/881/EC					
Animal products for human consumption	Council Directive 2002/99/EC Regulation (EC) No 854/2004 Council Directive 96/23/EC Commission Decision 2007/777/EC Commission Regulation (EC) No 2074/2005 Directive 92/118/ EEC					
Animal by-products not intended for human consumption	Regulation (EC) No 1774/2002 Commission Regulation (EC) No 2007/2006					

16. Bilateral veterinary international agreements with EU Member States, candidate countries and other third countries (if any)

Bilateral agreements in the veterinary field with the EU Member States, EU candidate countries and third countries

Montenegro has concluded the following bilateral agreements:

Agreement on veterinary cooperation between Montenegro and the Republic of Croatia, signed on October 18th, 2005.

Protocol on veterinary cooperation between Bosnia and Herzegovina and Montenegro, signed on February 26th, 2004.

17. Animal welfare:

Legislation

Field of animal welfare is governed by the Law on Animal Welfare (Official Gazette of Montenegro, 14/08). This Law regulates rights, obligations and responsibilities of physical and legal persons for animal welfare protection in relation to animal protection from torture, during keeping and breeding, killing and slaughter, performing of surgeries on animals, transportation and carrying out of experiments, rules of animal treatment, as well as other issues relevant for animal welfare protection.

The Law sets forth general provisions for transposition of the EU legislation into secondary legislation for the purpose of full harmonization of this field with the EU legislation.

Competent body

Veterinary Authority is body competent for animal welfare – Department for Animal Health and Welfare protection.

Veterinary Administration carries out supervision over the extent of compliance with the prescribed requirements referring to animal welfare, through veterinary inspectors.

- Farm animals, laying hens including information on conditions of production, chickens kept for meat production, calves, pigs

Protection of producing animals during keeping and breeding is governed by the Law on Animal Welfare (Official Gazette of Montenegro, 14/08) - Chapter IV (Articles 11,12,13,14 and 15). these provisions prescribe:

- obligations of an animal keeper concerning provision of feed, water, care, housing with enough light, heat and adequate clean space, in accordance with needs of animals, protection from bad weather, natural enemies and other animal health hazards; interval of control of animals kept in enclosed space must be at least once a day; lower age limit for an animal keeper is 16 years (Article 11);
- method of construction and equipping of an establishment i.e. materials used for construction must be safe for animal health and must be easy to clean and disinfect, and equipment and space where animals are staying must not be constructed so as to result in animals hurting themselves; interval of control of equipment used for animal keeping must be at least once a day (Article12);

- animals must be provided with the space adequate for their physiological and ethological functions; animals that have been deprived of their freedom must be provided with sufficient space in which they can lie down and stand up, stretch the forelegs and rear legs without difficulties, i.e. stretch themselves freely out, as well as which enables the animals to use the same area and the same space to turn around their longitudinal centre lines when standing and lying, without bending their bodies and heads (Article 13).
- method of animal feeding and watering must be in line with the animal species and category; animals must be provided with sufficient quantities of water of adequate quality, (Article 14);
- sufficient number of persons experienced in working with animals must take care of animals; in case of disease or injury, keeper is obliged to take care of the animal in accordance with its needs (Article 15);

Certain provisions of the Rulebook on veterinary-sanitary requirements for construction and equipping of an establishment for animal production and keeping (Official Gazette of the Republic of Montenegro 39/95 and 56/00) and Rulebook on organization of cattle markets, fairs, exhibitions and assemblies (Official Gazette of the Republic of Motnenegro 39/95) refer to provision of adequate conditions for housing and keeping animals for production in mentioned spaces.

These national regulations are not harmonized with the EU legislation.

Preparation of the **rulebook for protection of producing animals during keeping and breeding** which will define detailed requirements for welfare protection of producing animals, requirements which the establishments and equipment for animal keeping and breeding of producing animals must fulfil, as well as detailed requirements for welfare protection of calves, swine, laying hens and fattening chicken in compliance with the EU legislation, is under way. Pending the adoption of this rulebook for protection of calves, swine, laying hens and fattening chicken, provisions of the abovementioned rulebooks are in force.

- Animals during transport

Animal protection during transportation is governed by the Law on Animal Welfare Protection (Official Gazette of Montenegro, 14/08) - Chapter VII (Articles 30, 31 and 32). These provisions prescribe:

- loading, reloading, unloading and transportation of animals must be carried out in a manner which will not inflict pain, injury, unnecessary suffering or death of an animal and animals must not be deprived of their basic living needs during these activities; it is prohibited to carry out transportation of animals which are not fit for being transported, in inadequate means of transportation, if they do not have a permit for transportation (in accordance with provisions of Article 30 of this Law);
- control of a vehicle and method of use of equipment and devices for loading and unloading must be such as to avoid the unnecesary injury and suffering of animals and to protect their safety; transporter is obliged to make a route plan prior to the commencement of transporataion, which must be in the vehicle during transportation (Article 31);
- animal transportation can be carried out by commercial entities and entrepreneurs registered for that activity, and means of transportation must fulfil the veterinary-sanitary requirements; transporter must provide an attendant accompanying animals and minimize the duration of transport (Article 32).

Rulebook on requirements for transportation of animals in public transport and air transport (Official Gazette of the Federal Republic of Yugoslavia 42/88) prescribes requirements for transportation of animals by an aircraft used for transportation of persons in public air transport, and Rulebook on

requirements for incubator poultry production and requirements for packaging in poultry trade and transportation (Official Gazette of the Republic of Montenegro 16/93) contains provisions referring to transportation of incubated poultry.

These national regulations are not fully harmonized with the EU legislation.

Preparation of the rulebook for **animal protection in transport** which will define in more detail requirements for carrying out of transportation of animals to be fulfilled by the transporter, means of transportation, contents of the route plan and method of training of the animal attendant in accordance with the EU legislation, is under way.

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- Animals at the time of slaughter or killing

Protection of animals at the time of killing and slaughter is governed by the Law on Animal Welfare Protection (Official Gazette of Montenegro, 14/08) - Chapter V (Articles 16,17,18,19, 20 and 21). These provisions prescribe:

- reasons for which an animal may be killed (paragraph 2); procedures which must not be used in killing animals (paragraph 3); prohibition of killing animals in public places, save for in hunting grounds in accordance with the relevant regulations; animal killing may be performed only by a veterinarian or a veterinary technician under supervision of a veterinarian, save for in determined cases, prescribed by this law; animal killing is obligatorily performed following previous stunning (Article 16); animal who suffers from an intense and irrelievable pain must be immediately killed by its keeper (Article 17);
- method of animal stunning, i.e. it must be carried out prior to bleeding out, save for in cases envisaged by this law and it must lead to a momentary loss of consciousness; carrying out of procedures and means for stunning which inflict unnecessary pain, suffering, injury and fear to an animal is prohibited (Articles 18 and 19);
- manner of treatment, feeding, watering and housing conditions of animals in slaughterhouses; persons working with animals in a slaughterhouse must be trained for relocation, housing and care of animals in a slaughterhouse, containment, stunning and slaughtering or killing; equipment used in a slaughterhouse must be regularly maintained and controlled;
- slaughter is prohibited unless a veterinary check has been performed prior to slaughter and unless an animal has been stunned in a prescribed and professional manner.

Program of training the animal welfare protection trainers for production in slaughterhouses (TT Red Meat), in which representatives of the Veterinary Administration participate, carried out by the AWTraining, University of Bristol, School of Clinical Veterinary Science, Division of Farm Animal Science, and which is organized by the Western Balkan University Network for Animal Welfare (this organization is established by the RSPCA and the Faculty of Veterinary Medicine Skopje) is under way.

Drafting of the **rulebook for animal protection at slaughter and killing** which will define in detail welfare protection of animals for production during slaughtering and killing, methods and means of stunning and killing of animals, as well as the method of training persons for performing relocation, housing and care of animals in a slaughterhouse, restraining, stunning and slaughter or killing of animals in accordance with the EU legislation is under way.

Pending adoption of this rulebook, provisions referring to animal protection in slaughterhouses from the rulebook on method of performing veterinary-sanitary check and control of animals prior to slaughter and control of products of animal origin (Official Gazette of the Socialist Federal Republic of Yugoslavia, 68/89 and Official Gazette of Serbia and Montenegro, 10/03) are in force.

Animal welfare – overview in relation to the EU legislation

EU Legislation		Montenegrin national legislation				
Description	**EU texts**	**National text**	**Legal basis**	**Current stage of transposition**	**Date (expected) of transposition/ implementation**	**TOC availability**
Protection of animals kept for farming purposes (general)	Council Directive 98/58/EC Commission Decision 2006/778/ EC	Rulebook on protection of animals kept for farming purposes	Law on animal welfare	Final stage of drafting Includes Council Directives 98/58/EC, 99/74/EC 2007/43/EC, 1991/629/EEC and 91/630/EEC	End of 2009	
Laying hens	Council Directive 99/74/EC Commission Directive 2002/4/EC Commission Decision 2006/778/ EC					
Chickens kept for meat production	Council Directive 2007/43/EC					
Calves	Council Directive 1991/629/EEC					
Pigs	Council Directive 91/630/EEC					
Animals during transport	Council Regulation (EC) No 1/2005 Council Regulation (EC) No 1255/97	Rulebook on animal protection during transport.	Law on animal welfare	Drafted	End of 2009	
Animals at the time of slaughter or killing	Council Directive 93/119/EC	Rulebook on protection of animals at the time of slaughter	Law on animal welfare	Drafted	End of 2009	

18. Zootechnical legislation

Legislation

Basic regulation governing the field of livestock breeding, i.e. zootechnics, in Montenegro is the Law on Measures for Livestock Breeding Development (Official Gazette of the Republic of Montenegro, 4/92, 59/92 and 27/94).

Livestock breeding, in the sense of this law, comprises breeding of: cattle, sheep, goats, swine, horses, poultry and rabbits, and it prescribes certain measures for beekeeping promotion.

Competent authority

Authority competent for zootechnics is the Ministry of Agriculture, Forestry and Water Management.

In 2000, the Livestock Selection Service was established in Montenegro, as the technical service of the Ministry of Agriculture, Forestry and Water Management financed from the funds of the Ministry of Agriculture, Forestry and Water Management, through the Agrobudget, for the current year.

The Livestock Selection Service carries out:

- breeding control, or "Z" control – represents the most general form of control in selection and it comprises keeping records for a certain number of head identified. This type of control comprises all imported head and most of artificially inseminated cows fulfilling the requirements concerning the breed and the phenotypic quality;
- control of cow lactation performance, so called "A" control – The Selection Service carries out the so-called AT control of lactation performance which is official for Montenegro. AT

control consists of controlling the milk milked monthly, one month during morning, and the next month during evening milking;

- Artificial insemination program and control of implementation of this measure; the Livestock Selection Service prepares a plan of acquisition of semen and insemination control in the field;
- Selection of bulls and stallions for natural breeding – Selection Service, together with the veterinary and municipal extension service, works in the committee for licensing bulls for natural breeding. This measure is implemented in accordance with the Law on Livestock Breeding Development. Selection of bulls and stallions is carried out in accordance with several criteria. Bulls selected should be between one and two years old, to be purebred in the lineage of imported brown cows, as well as from the domestic population of brown and gray Tyrolean breed. Bulls must be in a good breeding condition;
- Breeding cattle exhibition – aiming at promotion of livestock breeding and the breed composition in cattle, sheep and goat keeping in Montenegro, the Livestock Selection Service organizes exhibitions of breeding cattle for breeds reared in Montenegro. Exhibitions are of regional character. Exhibitions are financed from the Budget of the Ministry of Agriculture, Forestry and Water Management.

Adoption of the new Law on Livestock Breeding, which is now in the draft form, is under way, which will be harmonized with the basic EU guidelines. Adoption of this Law is expected by the end of 2009.

This Law lays down method and requirements for breeding domestic animals, implementation of the breeding-selection program, preservation of genetic variability, trade in breeding animals, semen and other genetic material, rights and obligations of livestock operators and other issues important for livestock breeding.

This Law will apply to breeding of: cattle, buffalos, sheep, goats, horses, donkeys, swine, poultry, fur animals, rabbits and bees.

Pursuant to this Law, affairs in livestock breeding are performed by: public administration body competent for agricultural affairs (the Ministry), farmers, organizations of livestock farmers (breeder organizations), scientific-research institutions and other legal entities authorized by the Ministry (authorized institutions).

A number of new rulebooks should derive from this Law, upon its adoption, which will result in full harmonization with the EU legislation in the field of zootechnics.

For the purpose of accomplishing the goals in livestock breeding in accordance with this Law, the Government of Montenegro adopts the breeding-selection program for certain species and breeds of domestic animals which are important for Montenegrin livestock farming, for the period of five years.

Breeding-selection program will be implemented by authorized institutions as well as recognized breeder organizations fulfilling the requirements prescribed. Breeding-selection program is implemented in the entire territory of Montenegro, with provision of transparency and availability of results of the program implementation.

Zootechnics – overview in relation to the EU legislation

EU Legislation		Montenegrin national legislation				
Description	**EU texts**	**National text**	**Legal basis**	**Current stage of transposition**	**Date (expected) of transposition/ implementation**	**TOC availability**
Bovine animals	Council Directive 77/504/EEC Commission Decision 84/247/EEC Commission Decision 84/419/EEC Council Directive 87/328/EEC Commission Decision 2005/379/EC Commission Decision 2006/427/EC		Law on livestock breeding (existing legislation)	New Law on livestock breeding under drafting Rule books will be issued after adoption of the law	End of 2009 or beginning of 2010 for the issuing of the new law	
Porcine animals	Council Directive 88/661/EEC Commission Decision 89/501/EEC Commission Decision 89/502/EEC Commission Decision 89/503/EEC Commission Decision 89/504/EEC Commission Decision 89/505/EEC Commission Decision 89/506/EEC Commission Decision 89/507/EEC Council Directive 90/118/EEC Council Directive 90/119/EEC					
Ovine and Caprine animals	Council Directive 89/361/EEC Commission Decision 90/254/EEC Commission Decision 90/255/EEC Commission Decision 90/256/EEC Commission Decision 90/257/EEC Commission Decision 90/258/EEC					
Equidae	Council Directive 90/427/EEC Commission Decision 92/353/EEC Commission Decision 92/354/EEC Commission Decision 93/623/EEC Commission Decision 96/78/EC Commission Decision 96/79/EC Council Directive 90/428/EEC Commission Decision 92/216/EEC					
Other pure-bred animals	Council Directive 91/174/EEC					
Imports from third countries	Council Directive 94/28/ EC Commission Decision 96/509/EC Commission Decision 96/510/ EC					

19. Expenditure in the veterinary field

Expenditure in the veterinary field

On the basis of the Law on the Budget of Montenegro for 2009 (Official Gazette of Montenegro, 82/08 and 51/09) Veterinary Administration (functional classification 41102) is allocated, as a special budgetary unit, the funds in the amount of € 2,442,976.62, from which 592,976.62 € have been allocated for the costs of work of the Veterinary Administration and €1,850,000.00 for implementation of preventive animal health protection measures for 2009. These funds are at disposal of the Veterinary Administration and are used upon an order of the Director of the Veterinary Administration.

Pursuant to Article 59 of the Veterinary Law (Official Gazette of Montenegro, 11/04 and 27/07), funds for implementation of the mandatory scope of animal health protection referred to in article 55 of this law are provided from the Budget of Montenegro.

Ministry of Agriculture, Forestry and Water Management adopts the Operational Program on Animal Health Protection for each budgetary year, pursuant to Article 11 of the Veterinary Law. This program sets forth preventive measures for ensuring animal health protection, monitoring of epizootiological situation, carrying out of laboratory diagnostics of infectious and parasitic animal diseases, residues monitoring, zoonoses monitoring, plan of funds utilization and requirements for implementation of measures laid down by law.

Funds envisaged by this program are allocated from the Budget of Montenegro for 2009, in the amount of 1,850,000.00€. Veterinary Administration is responsible for implementation of the program.

In the course of implementation of this program, the Veterinary Administration may change the purpose of funds utilization and reallocate funds from one program to another, up to the amount of total funds. Aiming at prevention of occurrence, early detection, prevention of spreading, control and eradication of infectious and parasitic animal diseases, systematic monitoring of animal health condition is obligatory as well as undertaking of measures in the entire epizootiological area of Montenegro.

Operational Program on Animal Health Protection for 2009 (Official Gazette of Montenegro 5/09) comprises the following programs:

1	Monitoring of epizootiological situation and diagnostics of diseased animals suspected of infectious diseases.	86,325.00€
2	Provision of health protection in municipalities where there is no health protection organized.	21,000.00€
3	Control and eradication of bovine tuberculosis.	568,260.00€
4	Control and eradication of enzootic bovine leucosis.	218,950.00€
5	Control and eradication of ovine, bovine and caprine brucellosis	535,385.00€
6	Monitoring of bluetongue disease	7,400.00€
7	Diagnostics of bee diseases	29,700.00€
8	Prevention and control of the classical swine fever	94,515.00€
9	Prevention and control of dog and cat rabies, epizootiological situation and other domestic animals	27,825.00€
10	Control of echinococcosis	1,680.00€
11	Prevention and control of anthrax	1,425.00€
12	Prevention and control of atypical fowl plague	16,290.00€
13	Prevention of avian influenza	14,245.00€
14	Cattle identification and registration	131,600.00€
15	Residues monitoring	60,000.00€
16	Monitoring of zoonosis - salmonellosis	15,600.00€
17	Monitoring of zoonosis - listeria	13,800.00€
18	Monitoring of bovine spongiform encephalopathy –BSE	6,000,00€
	T O T A L :	**1,850,000.00€**

Veterinary Administration performs supervision over implementation of the Operational Program through monitoring and control of the method of implementation of measures, deadlines, scope of animals, keeping records and method of reporting on measures undertaken, in the course of the very implementation or afterwards, by checking the authenticity of submitted documentation, in the field, at animal keepers where measures from this Program have been carried out. Entities in

charge of implementation of measures by this program on animal health protection in 2009 must keep the prescribed records, registers and databases in accordance with the Veterinary Law, Law on Animal Identification and Registration and secondary legislation. Veterinary legal entities are obliged to issue a receipt on performed measures of diagnostic examinations and/or vaccinations to the owner, i.e. animal keeper where these were performed. Invoices for performed affairs submitted to the Veterinary Administration must be certified by the legal entity and controlled and certified by the Veterinary Inspectorate.

Records are kept in written and electronic form.

Expenditure in the veterinary field– overview in relation to the EU legislation

EU Legislation		Montenegrin national legislation				
Description	**EU texts**	**National text**	**Legal basis**	**Current stage of transposition**	**Date (expected) of transposition/ implementation**	**TOC availability**
Expenditure in the veterinary field	Council Decision 90/424/EEC	Programme on health protection of animals	Veterinary Law	Drafted each year	Budget of the programme adopted each year	

III. PLACING ON THE MARKET OF FOOD, FEED AND ANIMAL BY-PRODUCTS

20. General:

a) General architecture of the legal basis; organisation and powers of different institutions involved.

Marketing of food, feed and animal by-products is governed by the following framework legal documents:

- The Law on Food Safety (Official Gazette of Montenegro 14/07) lays down the general food safety rules, requirements for placing food and feed on the market and provides a basis for adoption of secondary legislation in this field;
- The Law on Genetically Modified Organisms (Official Gazette of Montenegro 7/08) lays down the general rules for placing on the market and marking of GMO products;
- The Veterinary Law (Official Gazette of Montenegro 11/04 and 27/07) is a framework legal document governing the field of by-products of animal origin and contains a basis for adoption of secondary legislation in the field of animal by-products;
- Decision on types of composite food and classification thereof (Official Gazette of Montenegro 20/09) defining the powers of sanitary and veterinary inspectorates over the composite food.

Institutions in charge of law development

The Ministry of Agriculture, Forestry and Water Management and the Ministry of Health are policy makers in the field of food and feed safety and they prepare the proposals of laws to be passed by the Parliament, following the appropriate procedure (described in detail in answer 4 of this Chapter).

The Ministry of Agriculture is the policy maker in the veterinary field (animal by-products) as well as in the field of GMOs, prepares proposals of laws to be passed by the Parliament, following the appropriate procedure (described in detail in answer 4 of this Chapter).

Institutions in charge of secondary legislation

The Ministry of Agriculture, Forestry and Water Management adopts regulations for implementation of laws under its competences – rulebooks, orders, instructions, monitoring plans, crisis management plan, etc.

The Veterinary Administration prepares technical basis for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan concerning the safety of food of animal origin and feed.

The Phytosanitary Administration prepares technical basis for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan concerning the safety of food of plant origin at the primary production level.

b) Respective fields of responsibilities of competent authorities concerned.

The Ministry of Health implements the Law on Food Safety and secondary legislation adopted on the basis of that law as regards food of plant origin after primary production, composite food, food

of animal origin in retail sale packaged and labelled in individual packaging, and other food. The Ministry of Health carries out inspectional supervision through the sanitary inspectors.

The Veterinary Administration implements the Law on Food Safety, the Veterinary Law and secondary legislation adopted based on the said laws as regards food of animal origin in all phases of production and wholesale, as well as of meat, fish and aquaculture products in retail sale, composite food, feed and animal by-products. The Veterinary Administration carries out inspection supervision through the veterinary inspectors.

The Phytosanitary Administration implements the Law on Food Safety and secondary legislation adopted based on that law as regards food of plant origin at the primary production level. The Phytosanitary Inspectorate carries out inspection supervision through phytosanitary inspectors.

c) Please provide a clear table of all the framework acts that cover or impinge upon the food, feed and animal by-products domain with an explanation of their coverage as far as the EU acquis is concerned. Please indicate whether you envisage adopting new framework acts.

Framework legal acts in the field of marketing of food, feed and animal by-products

Framework legal act	Field	Plans for adoption of new framework acts
Law on Food Safety	Marketing of food and feed	Amendments to the Law on Food Safety
Law on Genetically Modified Organisms	Marketing and marking of GMO products	
Veterinary Law	Animal by-products	Law on Animal By-products

Annex I to this Chapter provides a list of all the regulations applicable to marketing of food, feed and animal by-products.

In addition to the laws mentioned above, the marketing of food, feed and animal by-products is also laid down in more detail by a large number of secondary legislation from the previous legal system (Federal Republic of Yugoslavia, Serbia and Montenegro).

Adoption of new rulebooks, instructions and guidebooks in accordance with the EU regulations in this field is planned at the pace set by the NPI for 2008-2012.

Adoption of amendments to the Law on Food Safety is planned with a view to providing the best basis possible for the transposition of EU legislation into the national legislation related to the field of safety of food and feed.

The field of animal by-products needs to be regulated as the EU legislation regulates it. Adoption of the Law on Animal By-product Management, in accordance with the Regulation 1774/2002, is planned.

d) Please provide information for each item listed below.

• Hygiene rules

The Law on Food Safety lays down the obligation of compliance with the general food requirements for operators in business with food of animal origin in all phases of production and trade, as well as in primary production of food of animal and plant origin, together with accompanying activities.

The Rulebook on Hygiene Requirements for Food of Animal or Plant Origin (Official Gazette of Montenegro 14/09), which is harmonized with the Regulation EC 852/04, lays down more detailed requirements for the following:

- Establishments, premises and equipment for production and trade in food (location, the establishment area, access roads, layout, technological cycle in the establishment, maintenance of premises, lighting requirements, ventilation requirements, requirements for wardrobes);
- Sanitary premises;
- Premises where employees take meals;
- Premises for sanitation of equipment;
- Food washing premises;
- Interior of the premises;
- Food transport;
- Hand-washing facilities;
- Water supply and wastewater discharge;
- Hygiene and personal hygiene of staff;
- Training of staff;
- Heat treatment of products;
- Products and raw materials;
- Packaging and wrapping;
- Food waste.

The Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia 26/93 and 53/95) lays down the microbiological criteria for the food placed on the market. The count of micro-organisms in 1g, or 1ml of a foodstuff, as appropriate, in terms of this Rulebook, is the count of micro-organisms cultivated on a nutritive agar medium in accordance with the methods prescribed for microbiological analyses and super analysis of foodstuffs.

Foodstuffs on the market must not contain:

1) bacteria of Salmonella spp. in 25g (ml),

2) coagulase-positive staphylococci in 0.01g (ml),

3) sulphite-reducing clostridia in 0.01g (ml),

4) Proteus spp. in 0.001g (ml).

Adoption of a new Rulebook on Microbiological Criteria, in accordance with the EC Directive 2073/2005, is planned for 2010.

Montenegro does not have a national regulation for Listeria, the Veterinary Administration has, in the past two years, under the preventive measures for control of food-borne diseases, set up a sub-program –**Listeria monitoring.**

In the course of 2008, 261 samples of food of animal origin were tested for Listeria presence (according to the risk analysis, the heat-treated products of meat, cut meat products, milk products – cheeses, and other, are most frequently sampled).

The Veterinary Administration, in accordance with the preventive measures laid down by the Rulebook Measures for Control and Eradication of Salmonellosis (Official Gazette of the Federal Republic of Yugoslavia 6/88), also set up the sub-program – **Salmonella monitoring** and in the course of 2008, 749 samples were tested.

The following is subjected to diagnostic testing for salmonellosis:

- All raw materials of animal origin used in preparing feed for poultry prior to using them for the feed preparation;
- Facilities and premises for poultry egg incubation, packaging and equipment used for incubation – at least four times a year;
- Fertilized eggs from which, during incubation, no chickens were hatched, dead and weak chickens;
- One-day chicken that die during transport and chicken that die within three days from the day when the transport ended;
- Establishments for production of eggs and meat of poultry and poultry-breeding establishments – during production, by taking swabs;
- A bulk sample of faeces of young chicken and laying hens – twice a year (in breeding and exploitation);
- Bodies of dead chicken from breeding farms and laying hens farms used for production of table eggs – once a month,
- Skin, meat and parenchymal organs of poultry slaughtered – on one bulk sample from at least 10 animals, taken at the slaughterhouse at the beginning and at the end of the daily slaughter.

The newly adopted rules on food hygiene have been in force from the day of the publishing, in February 2009, and they apply to the establishments that are yet to begin with the operations.

The establishments registered according to the old regulations are obliged to harmonize their operations with the newly introduced requirements by the end of 2011.

Evaluation of the current situation in all establishments producing food of animal origin, registered in accordance with the old regulations, is underway, carried out through controls of a team of inspectors that are announced in advance. Check lists made by the DG SANCO model are used in evaluation of the situation. For inconsistencies established, the inspectors issue a decision ordering the removal of deficiencies, and deadlines for the removal are set.

In addition to pronounced incompliance as regards infrastructure requirements in establishments of a smaller production capacity, the inadequate level of training of persons handling food is most frequently perceived.

Provision of continuous training to business operators dealing with food of animal origin, in co-operation with producer associations, the Chamber of Commerce and expert institutions, is planned in order to familiarize them with the newly adopted hygiene rules. The training will be delivered through seminars and workshops (with support from IPA Food safety, GTZ, TAIEX) by sectors – meat, fish, milk, eggs.

Development of guides for these sectors is planned as well.

• Specific rules for animals products including information on the situation concerning agri-food establishments and the microbiological quality of raw milk

The Law on Food Safety lays down the obligation of food business operators to meet, in addition to general ones, also the special hygiene requirements for products of animal origin in all phases of production and trade.

The Rulebook on Special Hygiene Requirements for Food of Animal Origin (Official Gazette of Montenegro 14/09), which is harmonized with the Regulation EC 853/04, lays down more detailed requirements as regards the following:

- Physical, chemical and microbiology criteria;
- Temperature regimes in specific phases of production and trade;
- Cold chain maintenance;
- Sampling and testing, etc.;

Food of animal origin may be produced and stored only in approved establishments meeting the requirements prescribed, and which are under the supervision of veterinary inspectors.

The Veterinary Administration approves of the establishments for the following: slaughter of cleft-footed animals, poultry and lagomorphs, farmed game, handling game after hunting, cutting of meat of cleft-footed animals, poultry, production of meat, production and collecting of bivalve molluscs, storage and processing of fish and other fishery products, frogs, snails, milk production, production of eggs, and enters them into the register of approved establishments, in accordance with a special regulation.

Establishments for retail sale of meat are subject to approval, where cutting and preparation of processed meat products takes place in such establishments.

The Veterinary Administration keeps records of all approved establishments for production and trade in food of animal origin.

The Rulebook on the contents of the application, registration and approval procedure, method of entry into the register, content and method of keeping of registers of approved and registered establishments is in the phase of adoption.

The revision of approvals issued in accordance with the old regulations is planned for 2010, as well as allocation of veterinary control numbers and entry into the registers.

Approved establishments for production and trade in products of animal origin in Montenegro

establishment - activity	market Montenegro	market neighbouring countries	EU market	HACCP	2012 situation
Cleft-footed animal slaughter	24	5	-		
Slaughter and cutting of meat of cleft-footed animals	7	7	-	1	

Poultry slaughter	3	3	-		
Slaughter and cutting of meat of poultry	3	3	-		
Meat processing – meat products	34		-	3	
Processed meat products	4		-		
Intestines treatment and processing	1	1	-	1	
Milk processing – cheese production	22		-	4	
Ships for storage of fish for more than 24 hours	3		3		
On-land storing of fresh fish	3		3	1	
Fishery products processing	2	2	-	1	
Bivalve molluscs	1	1			
Storages for food of animal origin	138		-		
Retail sale of meat	221	-	-		

The rules laid down by the Law on Food Safety and by the rulebooks on general and special hygiene requirements for food of animal origin do not apply to the following:

- Primary production of food or feed for domestic use in a household;
- Preparation, handling or storing of food intended for domestic use in a household;
- Direct supply of consumers with small quantities of food through local retail sale outlets or by sale at the holding.

A special national regulation, basis for which is provided by the Law on Agriculture and Rural Development, shall lay down the general and special requirements for production of small quantities of food of animal origin for the purpose of trading it at the holding or through local retail sale outlets, with some minor derogations permitted in terms of infrastructure, but in the extent that does not affect the product safety.

The Rulebook on Special Requirements for Products of Animal Origin (Official Gazette of Montenegro 14/09) lays down the criteria for raw milk, in Article 87, stating that „criteria from that Article shall apply unless the criteria stated are laid down by a special regulation on the quality“.

The Rulebook on the Quality and Other Requirements for Milk, Milk Products and Starter Cultures (Official Gazette of the Federal Republic of Yugoslavia 26/02), in force in Montenegro, lays down the quality and other requirements that have to be met in production and trade in milk, dairy products and starter cultures.

The provisions of this Rulebook also apply to individual producers.

Milk, in terms of this Rulebook, means a product of mammary glands, obtained by continuous and complete milking of healthy, properly fed and regularly milked cows at least 15 days prior to and 5 days after calving, to which nothing must be added or taken away.

The milk must meet the following criteria:

- That the total micro-organism count is not higher than 1000000 in one millilitre of milk;
- That the total somatic cell count is not higher than 400000 in one millilitre of milk.

• Control rules including implementation of HACCP (Hazard Analysis and Critical Control Points) by food operators

The Law on Food Safety provides for establishing, maintaining and implementation of a system based on HACCP principles in all food business establishments by 2010 (except at the primary production level).

The food business operator in primary production and accompanying activities is obliged to establish the procedure for implementation of Good Hygiene Practice, Good Producer Practice and Good Farming Practice.

Currently, the HACCP system in Montenegro is established in a number of establishments for: slaughter of cleft-footed animals, cutting the meat of cleft-footed animals, intestine processing and rennet production, milk processing, treatment and processing of fishery products, production of non-alcoholic beverages, production of bakery products, hotels and a number of establishments is currently in the process of putting this system in place.

A special manual has been developed for the meat processing industry sector, facilitating the establishing and understanding the HACCP procedures. In most cases, business operators hire consultants for introduction of HACCP.

The Agri-budget sets the program of financial support to food business operators when putting in place this system.

• Specific control rules for animal products

The Rulebook on Method of Performing Veterinary Control of Animals before Slaughter lays down the rules for control of products of animal origin and establishments for production and trade in products of animal origin (described in more detail in answer 8 of this Chapter).

The official controls of products of animal origin are carried out by veterinary inspectors, in accordance with the powers laid down by the Law on Inspection and the Law on Food Safety.

Thirteen veterinary inspectors are in charge of control of products of animal origin (who also carry out veterinary controls) and 25 authorized veterinarians are in charge of examination at the slaughter line (ante-mortem and post-mortem).

The Veterinary Administration entrusts examination at the slaughter line to doctors of veterinary medicine, employed in veterinary surgeries.

Veterinary inspectors control the work of authorized veterinarians.

Establishments registered and approved by the Veterinary Administration are subject to veterinary control.

A veterinary inspector controls compliance with the hygiene requirements in an establishment (premises, equipment, staff, water supply and waste water discharge, transport of products, heat treatment, food waste and other requirements prescribed).

The control in the establishment also serves for checking the compliance with special hygiene requirements for products of animal origin (physical, chemical and microbiological criteria; harmonization of temperature regimes with requirements in specific phases of production and trade; maintaining of the cold chain; sampling and testing; compliance with the producer specification, etc.).

The controls are carried out by a plan of control based on the condition of the establishment, type of activity of the establishment, irregularities identified before, self-control systems established, etc.

With a view to harmonization with the Regulation 854/2004, as regards control of products of animal origin, as well as harmonization with the Regulation 882/2004, development of a

comparative analysis of control-related national legislation (the Law on Inspection, the Veterinary Law, the Rulebook on Methods of Performing Veterinary Control, the Law on Sanitary Inspectorate) is necessary for the future.

• Rules for animal by-products including information on the system of collection of cadavers and materials and situation of establishments

The Veterinary Law (Official Gazette of Montenegro 11/04 and 27/07), Articles 52, 53 and 54, lays down the general rules for collection and destruction of animal by-products not intended for human consumption.

The Rulebook on Method for Safe Disposal of Animal Carcasses and Animal Waste and Conditions that Must be Met by Establishments and Equipment for Collection, Safe Disposal and Establishing of the Cause of Death and Means of Transport for Animal Carcasses and Animal Waste (Official Gazette of Federal Republic of Yugoslavia 53/89) lays down in more detail the method for treatment, collection, transport and destruction of animal by-products.

Animal by-products intended for industrial use (raw hides, fur, wool, hair, bristles, toes, horns) are subjected to veterinary examination.

Premises where raw hides are stored and processed have to meet the requirements prescribed for that establishment type.

In Montenegro, there are 9 establishments for processing and conservation of raw, wet salted bovine hide and 1 establishment for wool collecting and processing (all establishments are registered also for exports to the markets of countries of the region).

Animal by-product management in Montenegro is done as follows:

- Operators in slaughter or other activities producing animal by-products have the obligation to sign contracts with municipal utility services in Montenegro that are in charge of collecting, transport and destruction of wastes in sites designated for that purpose;
- Carcasses of dead animals are destroyed on the holdings and under supervision of veterinary inspectorate, by burying.
- Where establishments do not have the conditions for proper keeping of by-products at the temperature of up to +4C, they have to be dispatched every day to the site for safe disposal.

There are no rules in place in Montenegro for SRM (Specified Risk Material) – SRM is disposed of and destroyed in the same way as other animal by-products.

The plan is to regulate this field with adoption of the Law on Animal By-product Management and thus harmonize it with the Regulation EC 1774/02 and other applicable texts in this area.

Development of a feasibility study is planned under the MIDAS Project (World Bank), which would, following an analysis of types and quantities of animal by-products, define the most acceptable way for animal waste management in Montenegro.

• Funding of checks

Inspectors in charge of controls are paid from the public budget.

The fees collected from the examination at slaughter line and veterinary checks of consignments traded across the border of Montenegro are set by decisions, made based on the Veterinary Law:

- Decision on the amount of the fees for veterinary checks in trade across the border (Official Gazette of Montenegro 51/2005)
- Decision on the amount of the fees for checks made in internal control (Official Gazette of Montenegro 55/2007).

The amount of the fees has been harmonized with the Regulation 882/2004 and the fees are the revenues of Montenegro's budget.

• Specific rules for feed hygiene

The Law on Food Safety (Official Gazette of Montenegro 14/07) lays down the general rules for safety of feed, the obligations of feed business operators and provides the basis for adoption of bylaws in this field;

The Law on Genetically Modified Organisms (Official Gazette of Montenegro 7/08) lays down the general rules for placing on the market and marking of GMO product;

The Ministry of Agriculture, Forestry and Water Management adopts regulations for implementation of the law – rulebooks, orders, instructions, monitoring plans, crisis management plans concerning the feed.

The Veterinary Administration implements the Law on Food Safety and the secondary legislation adopted based on this law, with regard to feed, and carries out inspection supervision through the veterinary inspectors.

In accordance with the provisions of the Law on Food Safety, the feed business operators have to be approved by the Veterinary Administration.

The Rulebook on the Quality and Other Requirements for Feed (Official Gazette of Montenegro 20/00 and 38/01) lays down the quality and other requirements for feed that must be met in production and trade.

All products placed on the market in original packaging must have on the wrapping, container or label for individual packaging, a label with the following information:

1) name of the product and its trade name, if any;

2) name and address of the head office of the producer;

3) production date and shelf life, or just the information "use by";

4) product net quantity (weight or volume);

5) main groups of nutrients of the product in the descending order of quantities, unless otherwise provided for by this Rulebook;

6) additives used and names thereof, for example: antioxidant (VNT), as well as their quantities in relative or absolute units;

7) method of use;

8) method of keeping;

9) type and quantity of denaturing agents;

10) other information of interest to consumers.

For products placed on the market in bulk, the information about the product must be put on the container and on the documents accompanying the consignment in transport. The label must be visible, clear, legible and indelible.

The products in production and trade must be stored, transported and kept in the way that ensures the preservation of their quality till opening within its shelf life, as prescribed by this rulebook.

The Rulebook on Maximum Quantities of Harmful Substances and Ingredients in Feed (Official Gazette of Socialist Federal Republic of Yugoslavia 2/90 and 27/90) lays down that feed and raw material used for production of compound feeds must not contain harmful substances in quantities higher than those maximum permitted or prescribed ones.

Feed must not contain hormones, sedatives and thyrostatics.

The Rulebook also prescribes the maximum quantities of pesticide residues or metabolites thereof in feed, maximum quantities of inorganic substances in feed, maximum permitted quantity of sodium chloride in compound feeds intended for poultry, the maximum quantities of antibiotics added into the compound feeds for stimulation purposes, by animal specie and category, the maximum permitted quantity of ammonium in protein feed, maximum quantities of poisonous herbs in feed, maximum quantities of natural organic poisons, maximum quantities of toxins of toxigenic fungi of moulds, and other requirements.

Compound feeds must not contain resorptive antibiotics in quantities that can be proved by methods prescribed or recognized.

Compound feeds must not contain sulphonamides.

The maximum count of saprophytic micro-organisms in feed is as follows:

Feed	Bacterial count in 1 g	Count of mould fungi in 1 g
Compound feed of plant origin	100.000.000	300.000
Compound feed of animal origin	50.000.000	10.000
Compound feed for young animals	10.000.000	50.000
Compound feed for adult animals	10.000.000	300.000

The maximum count of pathogenic micro-organisms in feed is as follows:

Micro organism	Feed	Count
Pathogenic micro-organisms	Feed and compound feed	0 in 50 g
Salmonellae	Feed and compound feed	0 in 50 g
Sulphite-reducing clostridia	Feed and compound feed	1000 in 1 g

Feed and compound feed must not contain toxins of toxigenic bacteria in 1g (Clostridium botulinum, Clostridium perfringens and Staphylococcus pyogenes).

The veterinary-sanitary control of feed is a set of procedures determining: organoleptic characteristics, type and quantity of nutrients that feed contains, hygienic safety and quantity of harmful substances in feed (antibiotics, hormones, pesticides, heavy metals and radioactive substances).

The veterinary-sanitary control also covers establishments where feed is produced, with regard to conditions that ensure hygienic safety of feed.

There are two laboratories in Montenegro analysing the feed (Veterinary Diagnostic Laboratory VDL – authorized for analyses of microbiological safety of feed and the Centre for Eco-toxicological Researches of Montenegro (CETI) – authorized for testing the quantities of nutrients in feed, additive content, the content of harmful substances, radioactivity, etc.)

Adoption of a rulebook that will, in more detail, lay down the requirements with regard to feed safety is planned for 2010, in accordance with the Regulation 183/2005 EC and other EU regulations in this field.

The Rulebook on Methods for Veterinary-Sanitary Control of Feed and Establishments in which Feed is Produced and Conditions that must be met by Laboratories for Super Analysis of Feed Samples (Official Gazette of Socialist Federal Republic of Yugoslavia 22/93 and 24/93) lays down the procedure for veterinary-sanitary control.

In order to provide the best possible basis for transposition of EU legislation into the national one in the field of food and feed safety, amending of the Law on Food Safety is planned.

Placing on the market of food, feed and animal by-products – overview in comparison with the EU legislation

EU legislation		Montenegrin national regulations				
Field	**EU text**	**National regulation**	**Basis for adoption**	**Current situation Plans**	**Adoption/implementation date**	**TOC**
HYGIENE RULES	Regulation (EC) No 852/2004 of the European Parliament and of the Council	Rulebook on hygienic requirements for food of plant and animal origin	Law on Food Safety	Passed in February 2009	On the day of publishing	Law on Food Safety – Not done Rulebook on hygiene requirements for food of plant and animal origin –Not done
	Commission Regulation (EC) No 2073/2005 Commission Regulation (EC) No 2074/2005	Rulebook on microbiology criteria	Law on Food Safety	Draft is being developed	At the end of 2009	
SPECIAL RULES FOR PRODUCTS OF ANIMAL ORIGIN	Regulation (EC) No 853/2004 of the European Parliament and of the Council	Rulebook on special hygiene requirements for food of animal origin Rulebook on quality and other requirements for milk and dairy products (existing legislation from the former legal system)	Law on Food Safety	Passed in February 2009		Not done
	Directive 92/118/ EEC	No national legislation	Law on Food Safety Veterinary Law	Not planned		
	Council Directive 2002/99/EC	No national regulation	Veterinary Law	Planned	2010	
	Commission Decision 96/77/EC Commission Decision 2002/226/EC	Rulebook on harmful and unauthorized substances in food (existing legislation	Law on Food Safety	Planned	2011	

		from the former legal system)				
RULES FOR CONTROL OF FOOD INDUSTRY OPERATORS, INCLUDING THE IMPLEMENTATION OF HACCP SYSTEM	Regulation (EC) No 882/2004 of the European Parliament and of the Council	Rulebook on method of veterinary control of animals before slaughter and of products of animal origin (existing legislation from the former legal system)	Law on Food Safety		Comparative analysis of national legislation with the EU legislation in the field of control is planned	
	Commission Regulation (EC) No 2074/2005		Law on Food Safety	Planned	2010	
	No 853/2004 of the European Parliament and of the Council	Rulebook on special hygiene requirements for products of animal origin HACCP mandatory in establishments by 2010 (Annex III 853/02)	Law on Food Safety	Passed February 2009 Development of instructions for HACCP planned	On the day of publishing 2010	Not done
	Commission Decision 2006/677/EC Commission Regulation (EC) No 401/2006	Rulebook on harmful and unauthorized substances in food (existing legislation from the former legal system)	Law on Food Safety Veterinary Law	planned	2010-2011	
SPECIAL RULES FOR CONTROL OF PRODUCTS OF ANIMAL ORIGIN	Regulation (EC) No 854/2004 of the European Parliament and of the Council Commission Regulation (EC) No 2074/2005 i (EC) No 2075/2005	Rulebook on method of veterinary control of animals before slaughter and of products of animal origin (existing legislation from the former legal system) Rulebook on meat control for trichinosis (existing legislation from the former legal system)	Law on Food Safety Veterinary Law	Planned	Comparative analysis of national legislation with the EU legislation in the field of control is planned 2011	
RULES FOR ANIMAL BY-PRODUCTS AND ESTABLISHMENTS FOR ANIMAL BY-PRODUCTS	Regulation (EC) No 1774/2002 of the European Parliament with application texts	Rulebook on safe disposal of animal by-products (existing legislation from the former legal system)	Veterinary Law	Adoption of the Law on Animal Waste Management is planned	2011	
FINANCING OF CONTROLS	Regulation (EC) No 882/2004 of the European Parliament and of the	Decision on the amount of the fee for veterinary examinations in trade across	Veterinary Law	Partly harmonized with 882/04 EC Adoption of new	2010	

	Council	the border (Official Gazette of Montenegro 51/2005) Decision on the amount of the fee for examinations in internal control (Official Gazette of Montenegro 55/2007)		decisions is planned		
FEED HYGIENE RULES	Regulation (EC) No 183/2005 of the European Parliament and of the Council	Rulebook on quality and other requirements for feed (existing legislation from the former legal system)	Law on Food Safety	Adoption of a rulebook on feed hygiene is planned	2011	

IV. FOOD SAFETY RULES

21. General:

a) Please provide information on general architecture of the legal basis; organisation and powers of different institutions involved.

Food safety rules are laid down by the following framework legal documents:

- The Law on Food Safety (Official Gazette of Montenegro 14/07) lays down the general food safety rules, requirements for placing on the market of food and feed and provides a basis for adoption of secondary legislation in this field;
- The Law on Genetically Modified Organisms (Official Gazette of Montenegro 7/08) lays down the general rules for placing on the market and marking of GMO products;

Institutions in charge of law development

The Ministry of Agriculture, Forestry and Water Management and the Ministry of Health are policy makers in the food safety field and prepare the proposals of laws to be passed by the Parliament, following the appropriate procedure (described in detail in answer 4 of this Chapter).

Institutions in charge of development of secondary legislation

The Ministry of Health and the Ministry of Agriculture, Forestry and Water Management adopt regulations for implementation of laws within their scope of authority – rulebooks, orders, instructions, monitoring plans, crisis management plan, etc.

The Veterinary Administration prepares technical basis for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan as regards safety of food of animal origin.

The Phytosanitary Administration prepares technical basis for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan as regards safety of food of plant origin at the primary production level.

b) Please provide information on respective fields of responsibilities of competent authorities concerned.

The Ministry of Health implements the Law on Food Safety and secondary legislation adopted on the basis of the Law as regards food of plant origin after primary production, composite food, food of animal origin in retail sale, in individual packaging and labelled, and other food. The Ministry of Health also carries out inspection supervision through the sanitary inspectors.

The Veterinary Administration implements the Law on Food Safety and the Veterinary Law and secondary legislation adopted on the basis of these laws in the field of food of animal origin in all phases of production and wholesale, as well as for meat, fish and aquaculture products in retail sale, composite food. The Veterinary Administration carries out the inspection supervision through veterinary inspectors.

The Phytosanitary Administration implements the Law on Food Safety and secondary legislation adopted based on that law in the field of food of plant origin at the primary production level. The

Phytosanitary Inspectorate carries out the inspection supervision through the phytosanitary inspectors.

c) Please provide a clear table of all the framework acts that cover or impinge upon the food safety domain with an explanation of their coverage as far as the EU acquis is concerned. Please indicate whether you envisage adopting new framework acts.

Framework legal acts in food safety field

Framework legal act	Field	Adoption of new framework acts planned
Law on Food Safety	Placing of food and feed on the market	Amendments to the Law on Food Safety
Law on Genetically Modified Organisms	Placing on the market and labelling of GMO products	
Law on Plant Protection Products	Pesticides	

The list of all pieces of legislation applied in the food safety field is enclosed in Annex I to this Chapter. The rules in the food safety field are laid down, in addition to the laws mentioned above, also by a large number of secondary legislation from the former legal system (Federal Republic of Yugoslavia, Serbia and Montenegro).

Adoption of new rulebooks, instructions and guides is planned in accordance with the EU legislation in this field, at the pace as set by the NPI 2008-2012.

With a view to providing the basis for the best possible transposition of the EU legislation into the national legislation in the food safety field, amending of the Law on Food Safety is planned.

d) Please provide information for each item listed below.

• Labelling, presentation and advertising of foodstuffs including nutrition and health claims and nutritional labelling

The Law on Food Safety (Official Gazette of Montenegro 14/07), Articles 29 and 30, lay down the labelling, marking, presentation and advertising. More detailed requirements for labelling, marking, presentation and advertising are laid down by a regulation of the Ministry of Health, with previous opinion from the Ministry of Agriculture.

The existing Rulebook on labelling and marking of packaged foodstuffs (Official Gazette of Serbia and Montenegro 4/04, 12/04 and 48/04) covers the method of labelling, the contents of the label and indication of the foodstuffs nutritive values. The label must not include the information ascribing healing properties to food. The Rulebook on labelling of packaged food for infants and small children (Official Gazette of Serbia and Montenegro 4/05) lays down that labelling of packaged foodstuffs for nutrition of infants and small children, which are intended for consumers and public eating establishments without further processing, as well as of general use items for packaging, transport, serving and use of this food.

These rulebooks are to a large extent harmonized with the EU legislation in this field, but it is necessary to revise them, while development of new regulations is planned by the end of 2012.

• Additives authorised and purity criteria

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 32, defines the food additives. More detailed requirements that additives should satisfy as regards safety, use and maximum permitted quantities are laid down by a regulation of the Ministry of Health, upon the previous opinion from the Ministry of Agriculture.

The Rulebook on the quality and conditions for use of additives in foodstuffs and on other requirements for additives and mixtures thereof (Official Gazette of Serbia and Montenegro 56/03 and16/05) lays down the quality, the conditions for use of additives in foodstuffs and other requirements for additives and mixtures thereof that must be met in production and trade. This rulebook also includes a positive list of additives, the marking system (E numbers), categories, the quality conditions for additives (synonym, definition, identification, purity), maximum permitted quantities in certain foodstuffs, restrictions in use of additives in certain foodstuffs, substances that, according to this rulebook, do not belong to additives. This rulebook is, in its major part, harmonized with the EU regulations, but further harmonization is planned by the end of 2012, upon the previous opinion from the Ministry of Agriculture. The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 32, defines food additives. More detailed requirements that should be met by additives in terms of safety, use and maximum permitted quantities are laid down by a regulation of the Ministry of Health upon the previous opinion from the Ministry of Agriculture.

• Food enzymes

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 32, defines the food additives. More detailed requirements that additives should satisfy as regards safety, use and maximum permitted quantities are laid down by a regulation of the Ministry of Health, upon the previous opinion from the Ministry of Agriculture.

The Rulebook on Quality and Other Requirements for Enzyme Preparations for Food Products (Official Gazette of Serbia and Montenegro 12/02) lays down the requirements for food enzymes. The rulebook provides the definitions of enzymes and enzyme preparations, the positive list of enzyme preparations which includes: ordinal number, trivial name, the classification name, the systematic name, EC number and origin, special quality conditions enzyme preparations such as: sources, active principles, systematic name and number, catalyzed reactions, characteristics, use and testing. Adoption of a new regulation is planned by 2012.

• Extraction solvents

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 32, defines the food additives. More detailed requirements that additives should satisfy as regards safety, use and maximum permitted quantities are laid down by a regulation of the Ministry of Health, upon the previous opinion from the Ministry of Agriculture.

The Rulebook on the Quality and Other Requirements for Auxiliary Products in Production of Food Products (Official Gazette of Serbia and Montenegro 60/02) provides the main definitions, prescribes the quality and other requirements for auxiliary products in food production. The rulebook classifies the auxiliary products into categories and includes a positive list of axuliary products in production. Adoption of a new regulation is planned by 2012.

• Flavourings

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 32, defines the food additives. More detailed requirements that additives should satisfy as regards safety, use and maximum permitted quantities are laid down by a regulation of the Ministry of Health, upon the previous opinion from the Ministry of Agriculture.

The Rulebook on the Quality and Other Requirements for Flavourings for Food Products (Official Gazette of Serbia and Montenegro 52/01) lays down in more detail the quality and other requirements that must be satisfied by flavourings in production and trade. The Rulebook provides the definitions for flavourings, flavouring substances, flavouring preparations, heat treatment flavouring, smoke flavouring and mixtures thereof, maximum permitted quantities of substances originating from flavourings or other ingredients with flavouring characteristics in food products (Annex I), Positive list of flavouring substances (Annex II) and the List of plants that cannot be used for production of flavourings for food products (Annex III).

The Rulebook has been partly harmonized with the EU legislation, but its revision is planned by the end of the 2012.

• Food contact materials

The Law on Food Safety (Official Gazette of Montenegro 14/07), Articles 29 and 30, defines the materials, packaging and items coming into contact with food. More detailed requirements that should be met by materials, packaging and items coming into contact with food are laid down by a regulation of the Ministry of Health, upon the previous opinion from the Ministry of Agriculture. Adoption of a rulebook that would lay down these requirements in accordance with the EU regulations is planned.

The Rulebook on conditions that, with regard to health safety, must be satisfied by general use items lays down the field of materials, packaging and items coming into contact with food (ceramics, porcelain, glass, stainless steel, plastic, etc.). Adoption of a new regulation is planned in 2010, for the purpose of harmonization with the EU requirements.

• Food supplements

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 34, defines the general requirements for food intended for the nutrition of persons for whom it is necessary to achieve certain effects by controlled use of food and of food supplements. More detailed requirements that should be met by these foods and supplements in terms of safety and nutritive composition are laid down by a regulation of the Ministry of Health.

The Rulebook on Conditions as Regards Health Safety of Dietetic Foodstuffs that may be Placed on the Market (Official Gazette of the Socialist Federal Republic of Yugoslavia 4/85 and 69/91) governs the field of dietetic products, while the Rulebook on the Quality and Conditions for Use of Additives in Foodstuffs and on Other Requirements for Additives and Mixtures Thereof give a definition of dietetic supplements. Adoption of a new rulebook, that will lay down in more detail these requirements in accordance with the EU legislation, is planned.

• Food for particular nutritional uses

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 34, defines the general requirements for food intended for the diet of persons for whom it is necessary to achieve certain effects by controlled use of food and of food supplements. More detailed requirements that should be met by these foods and supplements in terms of safety and nutritive composition are laid down by a regulation of the Ministry of Health.

The Rulebook on Conditions as Regards Health Safety of Dietetic Foodstuffs that may be Placed on the Market (Official Gazette of the Socialist Federative Republic of Yugoslavia 4/85 and 69/91) governs the field of food for particular nutritional uses. Adoption of a new rulebook, that will lay down in more detail these requirements in accordance with the EU legislation is planned.

• Quick-frozen Foodstuffs

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 33, lays down the general requirements for quick-frozen food. More detailed requirements that should be met by quick-frozen food are laid down by the Ministry of Agriculture for food of animal origin and composite food, and by the Ministry of Health for food of plant origin after primary production, composite food and other food. Adoption of a rulebook, for the purpose of harmonization with the EU requirements, is planned in 2010.

• Contaminants

The Law on Food Safety (Official Gazette of Montenegro 14/07) defines the following:

The food is considered unsafe for human consumption if:

- It contains micro-organisms, parasites, bacterial toxins and histamines above the values prescribed;
- It contains natural toxins or other natural toxic substances above the values prescribed;
- It contains heavy metals, metalloids, residues of pesticides, veterinary medicinal products, mycotoxins and other substances above the values prescribed;
- It includes substances that have not been toxicologically evaluated, checked and safe for human consumption;
- It includes mechanical impurities;

The Rulebook on Quantities of Pesticides, Metals, Metalloids and Other Toxic Substances, Chemotherapeutics, Anabolics and Other Substances that may be Found in Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia 5/92 and 32/02) sets the maximum levels for residues of pesticides, heavy metals and non-metals, anabolics, mycotoxins, PCBs, PAHs, and other contaminants in food. Adoption of a rulebook, for the purpose of harmonization with the EU requirements, is planned in 2012.

• Novel foods and genetically modified foodstuffs and feedstuffs (GMOs)

The Law on Food Safety (Official Gazette of Montenegro 14/07), Articles 35 and 36, defines the general requirements for novel food and genetically modified foodstuffs and feedstuffs (GMOs). More detailed requirements that should be met by novel food are laid down by the Ministry of Health, upon previous opinion from the Ministry of Agriculture.

More detailed requirements that should be met by genetically modified food or feed in terms of safety are laid down by the Ministry of Agriculture, upon the previous opinion from the Ministry of Health.

The Law on Genetically Modified Organisms, the Rulebook on restricted use of GMOs, the Rulebook on marketing of GMOs, products made of GMOs, governs the conditions for placing on the market of genetically modified organisms and products that contain, consist of or are obtained from GMOs, their use in closed systems and deliberate introduction into the environment, as well as placing on the market, handling, transport, packaging, transit, marking, processing and measures for the prevention and removal of harmful effects. Adoption of secondary legislation, for the purpose of harmonization with the EU requirements in this field, is planned by 2012.

• Ionising radiation

The field concerning the preservation of food by ionising radiation is governed by the Rulebook on Conditions for Preservation of Foodstuffs by Ionising Radiation. More detailed requirements concerning the safety of food subjected to ionising radiation are laid down by the Ministry of Health, upon the previous opinion from the Ministry of Agriculture. Adoption of secondary legislation is planned in 2011, for the purpose of harmonization with the EU legislation in this field.

• Mineral waters

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 11, defines the general requirements for water. Natural mineral water, in terms of this law, means water of a special mineral composition with traces of elements or compounds thereof.

More detailed requirements that should be satisfied by mineral water in terms of safety are laid down by the Ministry of Health, upon the previous opinion from the Ministry of Agriculture.

The Rulebook on the Quality and Other Requirements for Natural Mineral Water, Spring and Table Water (Official Gazette of Serbia and Montenegro 53/05) lays down the requirements in terms of mineral composition and safety of mineral water. Adoption of a new rulebook, for the purpose of harmonization with the EU requirements, is planned in 2010.

• Bilateral international agreements with EU Member States, candidate countries and other third countries (if any)

Montenegro signed the following bilateral agreements:

The Agreement on Veterinary Co-operation between Montenegro and the Republic of Croatia, signed on October 18, 2005.

The Protocol on Veterinary Co-operation between Bosnia and Herzegovina and Montenegro, signed on February 26, 2004.

Rules in food safety – overview made in comparison with the EU legislation

EU legislation		Montenegrin national legislation				
Field	**EU text**	**National legislation**	**Basis for adoption**	**Current situation/ planned**	**Adoption/implementation date**	**TOC**
RULES IN THE FIELD OF FOOD SAFETY	Directive 2000/13/ EC of the European Parliament and of the Council Council Directive 90/496/EEC of 24 September 1990 Council Directive 89/396/EEC Commission Directive 87/250/EEC Regulation (EC) No 1924/2006	Rulebook on Labelling and Marking of Packaged Foodstuffs and Rulebook on Marking of Packaged Foodstuffs Intended for Infants and Small Children (regulations from the former legal system)	Law on Food Safety	Planned	2010	Not done
	Council Directive (EEC) 89/107 Council Directive (EC) 94/35 Council Directive(EC) 94/36 Council Directive(EC) Council Directive(EC) 95/2	Rulebook on the Quality and Conditions for Use of Additives in Foodstuffs and Other Requirements for Additives and Mixtures Thereof (regulation from the former legal system)	Law on Food Safety	Planned	2012	
	Regulation (EC) No 1331/2008 of the European Parliament and of the Council Regulation (EC) No 1332/2008 of the European Parliament and of the Council	Rulebook on the Quality and Other Requirements for Enzyme Preparations for Food Products (regulation from the former legal system)	Law on Food Safety	Planned	2012	
	Directive 2009/32/EC of the European Parliament and of the Council	Rulebook on the Quality and Other Requirements for Auxiliary Products in Production of Food Products (regulation from the former legal system)	Law on Food Safety	Planned	2012	
	Council Directive 88/388/EEC Regulation (EC) No 2232/96	Rulebook on Quality and Other Requirements for Flavourings and Other Requirements for Flavourings for Food Products (regulation from the former legal system)	Law on Food Safety	Planned	2012	
	Regulation 1935/2004/EC Commission Directive 2002/72/EC Council Directive ~~84/500/EEC~~ Commission Directive EEC 93/10	Rulebook on conditions which in terms of health safety governs the ~~field of materials~~, packaging and items coming into contact with food (regulation from the	Law on Food Safety	Planned	2010	

		former legal system)				
	Directive 2002/46/EC of the European Parliament and of the Council Regulation (EC) No 1925/2006 of the European Parliament and of the Council	Rulebook on Conditions with regard to Health Safety of Dietetic Foodstuffs that may be placed on the Market (regulation from the former legal system)	Law on Food Safety	Planned	2012	
	Commission Directive EC 89/398 Directive 2009/39/EC of the European Parliament and of the Council Commission Directive 1999/21/EC Commission Directive EC 1999/539 Commission Directive EC 2006/82 Commission Directive EC 2006/181	Rulebook on Conditions with regard to Health Safety of Dietetic Foodstuffs that may be placed on the Market (regulation from the former legal system)	Law on Food Safety	Planned	2012	
	Council Directive 89/108/EEC Commission Directive 92/2/EEC Commission Regulation (EC) No 37/2005	No national piece of legislation on quick-frozen food	Law on Food Safety	Planned	2010	
	Council Regulation (EEC) No 315/93 Commission Regulation (EC) No 1881/2006 Commission Regulation (EC) No 401/2006 Commission Regulation (EC) No 333/2007 Council Directive 76/895 EEC, 86/362 EEC, 91/414 EEC	Rulebook on Quantities of Pesticides, Metals and Metalloids and Other Toxic Substances, Chemotherapeutics, Anabolics and Other Substances that may be Found in Foodstuffs (regulation from the former legal system)	Law on Food Safety	Planned	2012	
	Regulation (EC) No 258/97 Regulation (EC) N° 1829/2003 Regulation (EC) N° 1830/2003 of the European Parliament and of the Council EC 2000/195 Regulation EC 2001/17 Regulation EC 2001/122 Regulation EC 2001/424	Law on Genetically Modified Organisms. Rulebook on Placing on the Market of GMOs, GMO products and the Rulebook on Restricted Use of GMOs (regulations from the former legal system) No piece of legislation on novel food	Law on Food Safety and Law on Geneticall y Modified Organisms	Law on Genetically Modified Organisms adopted in 2008. Adoption of a piece of legislation on novel food planned	2012	
	Directive 1999/2/EC of the European Parliament and of the Council Directive 1999/3/EC of the European Parliament and of the Council Commission Decision 2002/840/EC	Rulebook on conditions for preservation of food by ionising radiation (regulation from the former legal system)	Law on Food Safety	Planned	2011	

	Commission Directive 98/83EC Directive 2009/54/EC of the European Parliament and of the Council Commission Directive 2003/40/EC	Rulebook on Quality and Other Requirements for Natural Mineral Water, Spring and Table Water (regulation from the former legal system)	Law on Food Safety	Planned	2010	

V. SPECIFIC RULES FOR FEED

22. General:

a) Please provide information on general architecture of the legal basis; organisation and powers of different institutions involved.

a) General structure of legal basis

Feed is governed by the following framework legal documents:

- The Law on Food Safety (Official Gazette of Montenegro 14/07) lays down the general feed safety rules, obligations of feed business operators and provides a basis for adoption of secondary legislation in this field;
- The Law on Genetically Modified Organisms (Official Gazette of Montenegro 7/08) lays down the general rules for placing on the market and marking of GMO products;

Institutions in charge of development of laws:

The Ministry of Agriculture, Forestry and Water Management and the Ministry of Health are policy makers in the field of food and feed safety and they prepare a proposal of a law to be passed by the Parliament, following the procedure (described in detail in answer 4 of this Chapter).

Institutions in charge of secondary legislation

The Ministry of Agriculture, Forestry and Water Management adopts regulations for implementation of laws – rulebooks, orders, instructions, monitoring plans, crisis management plan concerning feed.

The Veterinary Administration prepares technical basis for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan concerning feed.

The Phytosanitary Administration prepares technical basis for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan concerning the safety of food of plant origin at the primary production level.

b) Please provide information on respective fields of responsibilities of competent authorities concerned.

The Veterinary Administration implements the Law on Food Safety and the secondary legislation adopted on the basis of this law concerning the feed and carries out the inspection supervision through the veterinary inspectors.

The Phytosanitary Administration implements the Law on Food Safety and the secondary legislation adopted based on this law concerning the food of plant origin at the primary production level and carries out the inspection supervision through phytosanitary inspectors.

c) Please provide a clear table of all the framework acts that cover or impinge upon the feed domain with an explanation of their coverage as far as the EU acquis is concerned. Please indicate whether you envisage adopting new framework acts.

Framework legal acts on feed

Framework legal act	field	Adoption of new framework acts planned
Law on Food Safety	Feed Safety	Amendments to the Law on Food Safety

Law on Genetically Modified Organisms	Placing on the market and marking of GMO products	

A list of all pieces of legislation applied in the feed area is given in Annex I to this Chapter.

The feed area is governed in more detail with a large number of secondary legislation from the previous legal system (Federal Republic of Yugoslavia, Serbia and Montenegro) which define the safety and qualitative requirements for feed.

Adoption of new rulebooks in accordance with the EU regulations in this field is planned, at the pace as set by the NPI 2008-2012.

Amendments to the Law on Food Safety are planned in order to provide the best possible basis for transposition of EU legislation into the national legislation in the field of food and feed safety.

d) Please provide information for each item listed below.

• Authorised additives in feedingstuffs

The Rulebook on the Quality and Other Requirements for Feedingstuffs (Official Gazette of Montenegro 20/00 and 38/01) lays down the quality and other requirements for feed. Feedingstuffs, in terms of this rulebook, means products obtained by an established technological procedure from appropriate raw materials in the following forms:

- feeds;
- premixes;
- mixes;
- authorized additives.

This Rulebook lays down the feedingstuffs additives added to feedingstuffs in quantities prescribed.

The feedingstuffs additives means substances added to feedingstuffs in order to improve their biological nutritive value and quality, for better utilization and longer shelf life, for simpler technological procedures in preparation of mixes and colouring of animal meat and poultry eggs, which include the following:

1) vitamins and provitamins;

2) microelements and minerals;

3) nonprotein nitrogen compounds;

4) amino acids;

5) other authorized additives.

Use of organically linked microelements is authorised in feedingstuffs and feedingstuffs additives.

Other authorised additives include antioxidants, preservatives, flavourings, flavouring enhancers, emulsifiers, stabilizers, thickeners, binders, gelling agents, dyes, agents that prevent curdling,

lubricants, acids, bases, salts, enzymes and sweeteners, antibiotics, coccidiostats, micro-organisms and other organic substances.

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 32, defines the additives for feedingstuffs. More detailed requirements that should be met by additives in terms of safety, use and maximum permitted quantities in feedingstuffs shall be laid down by a regulation of the Ministry of Health, upon the previous opinion from the Ministry of Agriculture. Adoption of a rulebook in accordance with the EU legislation in this field is planned for 2011.

• Marketing of compound feedingstuffs

The Rulebook on the Quality and Other Requirements for Feedingstuffs (Official Gazette of Montenegro 20/00 and 38/01) lays down the quality and other requirements for feedingstuffs. The feedingstuffs, in terms of this rulebook, means products obtained by an established technological procedure from appropriate raw materials in the following forms:

- Feeds (fish meal, feeds with non-protein nitrogen compounds added, mineral feeds intended to supply animals with adequate quantities of calcium, phosphorus, sodium, potassium, magnesium, sulphur and chlorine);
- premixes;
- mixes;
- authorized additives.

Mixes, in terms of this rulebook, means products obtained by mixing feeds and feedingstuffs additives in such a ratio that they may serve as complete feedingstuffs or supplementary feedingstuffs.

The Law on Food Safety (Official Gazette of Montenegro 14/07) lays down the general rules for feed safety and obligations of food business operators. Adoption of a regulation that will lay down in more detail the requirements for feedingstuffs hygiene, in accordance with the EC Regulation 183/2005, is planned for 2010.

In accordance with the provision of the Law on Food Safety, the establishments in feed business have to be approved by the Veterinary Administration. In Montenegro, there are two establishments approved for feed production (feed manufacturing plants).

There are two laboratories in Montenegro that analyze feed (Veterinary Diagnostic Laboratory - VDL– authorised for analysis of microbiological safety of feedingstuffs, and the Centre for Eco-Toxicological Researches of Montenegro (CETI) – authorised for analysing the quality of nutrients in feedingstuffs, the additive content, the quantity of harmful substances, radioactivity, etc.

Circulation of feed materials

The Law on Food Safety (Official Gazette of Montenegro 14/07), Article 31 defines the materials, packaging and items coming into contact with food and feed. More detailed requirements that should be met by materials, packaging and items coming into contact with food and feed are laid down by a regulation of the Ministry of Health, upon the previous opinion from the Ministry of Agriculture. Adoption of a rulebook that will, in more detail, govern the requirements for materials coming into contact with feed in accordance with the EU legislation in this field is planned.

• Circulation of feed materials

The Law on Food Safety (Official Gazette of Montenegro 14/07), in Article 25, lays down the prohibition of production and putting into circulation of feed that is not safe, as well as a ban on feeding animals used for food production with such feed. In Article 27 of this Law closer parameters for determining unsafe feed are defined.

This Law lays that the feed materials in production and trade must be label and marked (Article 29). Data from the declarations and tags must match the information specified in the production specification and requirements established by this Law and regulations adopted pursuant to this Act. The Rulebook on the Quality and Other Requirements for Feedingstuffs (Official Gazette of Montenegro 20/00 and 38/01) lays down the provisions that define closer how to label and mark feed.

• Undesirable substances in animal feed

The Law on Food Safety (Official Gazette of Montenegro 14/07) defines that feed is considered unsafe if:

- it has a harmful effect on animal or human health;
- the products obtained from food-producing animals are unsafe for human consumption.

Where feed, established to be unsafe, is a part of a production lot, series or a consignment of the same type of feed by description and category, all feed in that production lot, series or consignment is considered unsafe, unless proved otherwise.

Feed is considered unsafe if:

- It contains micro-organisms, parasites, bacterial toxins and histamines above the values prescribed;
- It contains natural toxins or other natural toxic substances above the values prescribed;
- It contains heavy metals, metalloids, residues of pesticides, veterinary medicinal products, mycotoxins and other substances harmful to human and animal health above the values prescribed;
- It contains additives that must not be used in a specific type of feed or the content of authorised additives is above the values prescribed;
- It contains radionuclides above the values prescribed or is irradiated above the threshold allowed;
- Packaging, materials and items coming into contact with feed do not comply with the requirements prescribed;
- Its sensorial characteristics are altered (odour, colour, appearance, consistency and other) due to physical, chemical, microbiological or other processes;
- It contains substances that have not been toxicologically evaluated, tested and safe for feeding animals;
- It contains mechanical impurities;

- The packaging is damaged so microbiological and chemical alterations are possible;
- It has not been produced, treated, packaged, stored or distributed as prescribed;
- It has not been labelled and marked as prescribed;
- It fails to meet the requirements prescribed in terms of nutritive composition.

The Rulebook on Maximum Permitted Quantities of Harmful Substances and Ingredients in Feedingstuffs (Official Gazette of Federal Republic of Yugoslavia 2/90 and 27/90) lays down that feed must not include hormones, sedatives, thyrostatics, that compound feed must not contain sulphonamides and resorptive antibiotics in quantities that may be proved by methods prescribed or recognized.

This rulebook also prescribes the maximum quantities of residues of pesticides or metabolites thereof in feed, maximum quantities of inorganic substances, maximum quantities of antibiotics added to compound feed for stimulation purposes, maximum values of indicators of chemical decomposition in feed, maximum counts of saprophyte and pathogenic micro-organisms, maximum quantities of toxins of toxigenic mould fungi, natural organic poisons, poisonous herbs and parasitic fungi. Adoption of a new regulation that will be harmonized with the EU legislation is planned in 2011.

The following are in force in Montenegro, as well:

- Order on prohibition of feeding bone meal to animals, as of 2001,
- Order on undertaking of measures for prevention of introduction of infectious animal disease TSE (Official Gazette of Montenegro 44/08)
- Order on prohibition of circulation of consignments of feed containing ingredients of animal origin (Official Gazette of the Republic of Montenegro 3/01)

• Feedingstuffs intended for particular nutritional purposes

In Montenegro, there are no national regulations governing the field of feedingstuffs intended for particular nutritional purposes. For the purpose of harmonization with the EU requirements, adoption of a rulebook in this field is planned by 2012.

• Certain products used in animal nutrition (Bioproteins)

In Montenegro, there are no national regulations governing the field of certain products used in animal nutrition (bioproteins). For the purpose of harmonization with the EU requirements, adoption of a rulebook in this field is planned by 2012.

• Conditions governing the preparation, placing on the market and use of medicated feedingstuffs

The Rulebook on Quality and Other Requirements for Feedingstuffs (Official Gazette of Montenegro 20/00 and 38/01) lays down the quality and other requirements for feedingstuffs. The Rulebook lays down that medicated feedingstuffs may be produced in establishments issued with approval from the Veterinary Administration. The rules on method of prescribing and issuing of medicinal products for veterinary use are laid down by a special regulation adopted based on the

Law on Medicinal Products. For the purpose of harmonization with the EU requirements, adoption of a rulebook is planned by 2012.

• Bilateral international agreements with EU Member States, candidate countries and other third countries (if any)

The Agreement on Veterinary Co-operation between Montenegro and the Republic of Croatia, signed on October 18, 2005.

The Protocol on Veterinary Co-operation between Bosnia and Herzegovina and Montenegro, signed on February 26, 2004.

Special rules for feed – tabular overview of the situation in comparison with the EU legislation

EU legislation		Montenegrin national legislation				
Field	**EU text**	**National legislation**	**Basis for adoption**	**Current situation/ planned**	**adoption/implementation date**	**TOC**
SPECIAL RULES FOR FEED	Council Directive 96/25/EC	Rulebook on the quality and other requirements for feed (regulation from the former legal system)	Law on Food Safety	planned	2010	
	Council Directive 79/373/EEC	Rulebook on the quality and other requirements for feed (regulation from the former legal system)	Law on Food Safety	planned	2010	
	Council Regulation (EC) No 1831/2003 Council Directive 1999/29/EC	Rulebook on the quality and other requirements for feed (regulation from the former legal system) Rulebook on maximum permitted quantities of harmful substances and ingredients in feed (regulation from the former legal system)	Law on Food Safety	planned	2010 2011	
	Commission Directive 93/74 EEC Commission Directive 94/39/EC	No special national regulation for this kind of food in our national legislation, although such food is used in nutrition of pets and is mainly imported from the EU (Hills, Royal Canine).	Veterinary Law	planned	2012	
	Council Directive 90/167/EEC	Rulebook on the method of prescribing and issuing of medicinal products for veterinary use Rulebook on the quality and other requirements for feed (regulation from the former legal system)	Law on Food Safety Law on Medicinal Products	planned	2012	
	Council Directive 70/373/EEC	Rulebook on methods of sampling and methods of physical, chemical and microbiological analyses of feed	Law on Food Safety	planned	2011	

		(regulation from the former legal system)				
	Council Directive 95/53/EC Commission Directive 98/68/EC	Rulebook on the method of carrying out veterinary-sanitary control of feed and establishments manufacturing feed and conditions that must be satisfied by laboratories carrying out super analysis of feed samples (regulation from the former legal system)	Law on Food Safety	planned	2011	
	Council Directive 2002/32 on undesirable substances in feed	Rulebook on maximum permitted quantities of harmful substances and ingredients in feed (regulation from the former legal system)	Law on Food Safety	planned	2012	
	Council Directive 82/471 concerning certain products used in animal nutrition	Rulebook on maximum permitted quantities of harmful substances and ingredients in feed (regulation from the former legal system)	Law on Food Safety	planned	2012	

Chapter 12 – FOOD SAFETY, VETERINARY AND PHYTOSANITARY POLICY

ANNEX I

List of regulations applied in Montenegro in veterinary and food safety field

TRADE

Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07)

Rulebook on Organizaiton of Livestock Markets, Fairs and Exhibitions (Official Gazette of the Republic of Montenegro 39/95)

Rulebook on Conditions that Must be Met by Stations and Ports for Loading, Reloading and Unloading of Animal Consignments (Official Gazette of the Socialist Federal Republic of Yugoslavia 6/88)

Rulebook on More Detailed Conditions for Issuing, Contents and Form of the Animal Health Certificate (Official Gazette of the Republic of Montenegro 13/2006)

Rulebook on Method for Disinfection of Means of Transport for Transport of Consignments of Animals, Products, Raw Materials and Waste of Animal Origin (Official Gazette of the Socialist Federal Republic of Yugoslavia 22/89)

Rulebook on Conditions and Duration of Quarantine for Imported Animals (Official Gazette of the Socialist Federal Republic of Yugoslavia 6/88)

Rulebook on Conditions that Must be Met by Establishments for Housing of Animals and Warehouses for Storage of Products, Raw Materials and Wastes of Animal Origin on Border Crossings (Official Gazette of the Socialist Federal Republic of Yugoslavia 6/88)

Decision on Amount of the Fee for Veterinary-Sanitary Examinations Carried Out in Internal Trade (Official Gazette of Montenegro 55/07)

Decision on Amount of the Fee for Veterinary-Sanitary Examinations in Trade across the Border of Montenegro (Official Gazette of the Republic of Montenegro 50/2005)

Rulebook on Measures for Establishing the Presence, Control and Eradication of Brucellosis (Official Gazette of Montenegro 64/08)

Rulebook on Measures for Establishing the Presence, Control and Eradication of Bovine Tuberculosis (Official Gazette of Montenegro 64/08)

Rulebook on Measures for Establishing the Presence, Control and Eradication of Enzootic Bovine Leucosis (Official Gazette of Montenegro 64/08)

Rulebook on Health Requirements in Trade in Bovine and Porcine Animals.

ANIMAL IDENTIFICATION AND REGISTRATION

Law on Animal Identification and Registration (Official Gazette of the Republic of Montenegro 48/07)

Rulebook on Method of Identification and Registration of Cattle and Keeping of Registers and Electronic Database (Official Gazette of the Republic of Montenegro 58/2007) (Annex 46)

ANIMAL DISEASES

Veterinary Law (Official Gazette of the Republic of Montenegro 11/04)

Rulebook on classification of animal diseases, method of reporting and informing on infectious animal diseases (Official Gazette of Montenegro 5/08)

Rulebook on Methods, Procedure and Measures for Control and Eradication of Food-and-Mouth Disease (Official Gazette of the Federal Republic of Yugoslavia 5/70, 32/70 i 40/77)

Order on Undertaking of Measures for Prevention of Introduction of the Infectious Foot-and-Mouth Disease into Montenegro (Official Gazette of Montenegro 44/08)

Rulebook on Measures for Control and Eradication of Classical Swine Fever (Official Gazette of the Socialist Federal Republic of Yugoslavia 6/88)

Program for Eradication of Highly Pathogenic Avian Influenza

Rulebook on Measures for Control and Eradication of Newcastle Disease (Official Gazette of the Socialist Federal Republic of Yugoslavia 39/88)

Rulebook on Measures for Control and Eradication of Trout Furunculosis (Official Gazette of the Socialist Federal Republic of Yugoslavia 72/91)

Rulebook on Measures for Control and Eradication of Whirling Disease in Trouts (Official Gazette of the Socialist Federal Republic of Yugoslavia 72/91)

Rulebook on Prevention of Occurrence, Detection, Control and Eradication of Infectious Bluetongue Disease (Official Gazette of the Republic of Montenegro 56/2001)

Order on Undertaking of Measures for Prevention of Measures for Introduction of Infectious Disease of Bovine Spongiform Encephalopathy (BSE) into Montenegro (Official Gazette of Montenegro 44/08)

Order on Prohibition of Trade in Consignments of Feed Containing Ingredients of Animal Origin (Official Gazette of the Republic of Montenegro 3/2001)

Rulebook on Measures for Control and Eradication of Salmonellosis in Poultry (Official Gazette of the Socialist Federal Republic of Yugoslavia 6/88)

Rulebook on Measures for Control and Eradication of Fowl Typhoid (Official Gazette of the Socialist Federal Republic of Yugoslavia 6/88)

Rulebook on Measures for Control and Eradication of Rabies in Animals (Official Gazette of Montenegro 17/07)

Rulebook on Measures for Establishing the Presence, Control and Eradication of Bovine Tuberculosis (Official Gazette of Montenegro 64/08)

Rulebook on Measures for Establishing the Presence, Control and Eradication of Bovine Brucellosis (Official Gazette of Montenegro 64/08)

Rulebook on Measures for Control and Eradication of Brucellosis in Bovine, Ovine, Caprine and Porcine Animals (Official Gazette of the Socialist Federal Republic of Yugoslavia 34/89)

Rulebook on Measures for Establishing the Presence. Control and Eradication of Enzootic Bovine Leucosis (Official Gazette of Montenegro 64/08)

Rulebook on Measures for Control and Eradication of Anthrax in Animals (Official Gazette of the Federal Republic of Yugoslavia 39/88)

Rulebook on Measures for Control of Trichinellosis in Animals (Official Gazette of the Federal Republic of Yugoslavia 20/95)

Rulebook on Measures for Control and Eradication of Leptospirposis in Animals (Official Gazette of the Federal Republic of Yugoslavia 6/88)

Rulebook on Measures for Control and Eradication of Equine Infectious Anaemia (Official Gazette of the Federal Republic of Yugoslavia 39/88)

Rulebook on Measures for Control and Eradication of Infectious Bovine Rhinotracheitis and Infective Pustular Vulvovaginitis - IBR/IPV (Official Gazette of the Federal Republic of Yugoslavia 63/89)

Rulebook on Laboratory Tests and Methods and on Conditions that Must be Met by Veterinary Organizations Checking Results of Laboratory Testing in the Fields of Diagnostics of Infectious Animal Diseases and Veterinary-Sanitary Safety of Raw Materials and Products of Animal Origin (Official Gazette of the Socialist Federal Republic of Yugoslavia 37/88)

RESIDUES

Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07)

Law on Food Safety (Official Gazette of Montenegro 14/07)

Rulebook on Residue Monitoring in Animals, Foodstuffs of Animal Origin and Feed (Official Gazette of the Republic of Montenegro 46/06),

Rulebook on Maximum Permitted Concentrations of Residues of Pharmacologically Active Substances of Veterinary Medicinal Products in Foodstuffs of Animal Origin (Official Gazette of the Republic of Montenegro 51/07)

Instructions for Implementation of the Residue Monitoring Program in accordance with the Commission Decision 98/179/EC

ANIMAL WELFARE

Law on Animal Welfare Protection (Official Gazette of Montenegro 14/08)

Rulebook on Conditions for Transport of Animals in Public and Air Transport (Official Gazette of the Socialist Federal Republic of Yugoslavia 42/88)

Rulebook on Conditions for Poultry Production in Incubators and Conditions for Packaging in Trade in Transport of Poultry (Official Gazette of the Republic of Montenegro 16/93),

Rulebook on Arranging of Livestock Markets, Fairs, Exhibitions (Official Gazette of the Republic of Montenegro 39/95),

Rulebook on Veterinary-Sanitary Conditions for Construction and Equipment of Establishments for Production and Keeping of Animals (Official Gazette of the Republic of Montenegro 39/95 and 56/00),

Rulebook on Method of Carrying Out Veterinary-Sanitary Examination and Control of Animals Before Slaughter and Products of Animal Origin (Official Gazette of the Federal Republic of Yugoslavia 68/98)

ZOO-TECHNICS

Veterinary Law (Official Gazette of the Republic of Montenegro 11/04)

Law on Measures for Livestock Breeding Development (Official Gazette of the Republic of Montenegro 59/92)

PLACING ON THE MARKET OF FOOD, FEED AND ANIMAL BY-PRODUCTS

Law on Food Safety (Official Gazette of Montenegro 14/07)

Veterinary Law (Official Gazette of Montenegro 11/04 and 27/07))

Decision on Types of Composite Foods and Classification Thereof (Official Gazette of Montenegro 20/09),

Law on Genetically Modified Organisms (Official Gazette of Montenegro 7/08)

Rulebook on Hygiene Requirements for Food of Animal or Plant Origin (Official Gazette of Montenegro 14/09) (Annex 48)

Rulebook on Special Hygiene Requirements for Food of Animal Origin (Official Gazette of Montenegro 14/09) (Annex 45)

Rulebook on Method of Carrying Out Veterinary-Sanitary Examination and Control of Animals Before Slaughter and Products of Animal Origin (Official Gazette of the Federal Republic of Yugoslavia 68/98)

Rulebook on Conditions of Health Safety of General Use Items, Materials, Packaging and Items Coming into Contact with Food (Official Gazette of the Socialist Federal Republic of Yugoslavia 26/83 and 19/91)

Rulebook on Hygiene Safety of Drinking Water (Official Gazette of the Socialist Federal Republic of Yugoslavia 33/87)

Rulebook on Sampling Method and Methods for Laboratory Analysis of Drinking Water (Official Gazette of the Socialist Federal Republic of Yugoslavia 33/87)

Rulebook on Microbiological Safety of Foodstuffs in Trade (Official Gazette of the Federal Republic of Yugoslavia 26/93 and 53/95)

Rulebook on Methods for Carrying Out Microbiological Analyses and Super-analyses of Foodstuffs (Official Gazette of the Socialist Federal Republic of Yugoslavia 25/80)

Rulebook on Quantities of Pesticides, Metals and Metalloids and Other Toxic Substances, Chemotherapeutics, Anabolics and Other Substances that may be Found in Foodstuffs (Official Gazette of Federal Republic of Yugoslavia 5/92 and 32/02)

Rulebook on Labelling and Marking of Packaged Foodstuffs (Official Gazette of Serbia and Montenegro 4/2004 and 48/04

Rulebook on Marking of Packaged Foodstuffs Intended for Infants and Small Children (Official Gazette of Serbia and Montenegro 4/2005)

Instructions on Method of Sampling for Analyses and Super-analyses of Foodstuffs and General Use Items (Official Gazette of the Socialist Federal Republic of Yugoslavia 60/78)

Rulebook on Conditions in Terms of Qualified Staff, Premises and Equipment that must be met by Health and Other Organizations for Carrying Out Analyses and Super-Analyses of Foodstuffs and General Use Items (Official Gazette of the Federal Republic of Yugoslavia 4/92 and 7/01 and 60/02)

Decision on Health and Other Organizations of Associated Labour Meeting the Conditions for Carrying Out Super-Analyses of Foodstuffs and General Use Items (Official Gazette of the Socialist Federal Republic of Yugoslavia 25/80, 4/83)

Rulebook on Methods of Sampling and Methods of Physical, Chemical and Microbiological Analyses of Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia 15/87)

Rulebook on Quality and Other Requirements for Flavourings (Official Gazette of Serbia and Montenegro 52/01)

Rulebook on Quality and Conditions for Use of Additives in Foodstuffs and Other Requirements for Additives and Mixtures Thereof (Official Gazette of Serbia and Montenegro 56/03, 4/04 and 16/05)

Rulebook on Quality and Other Requirements for Enzyme Preparations for Food Products (Official Gazette of the Federal Republic of Yugoslavia 12/02)

Rulebook on Quality and Other Requirements for Auxiliary Means in Production of Food Products (Official Gazette of the Federal Republic of Yugoslavia 62/02)

Rulebook on Conditions in Terms of Health Safety of Dietetic Foodstuffs that may be Placed on the Market (Official Gazette of the Socialist Federal Republic of Yugoslavia 4/85 and 69/91)

Rulebook on Conditions in Terms of Health Safety that must be met by General Use Items in Trade (Official Gazette of the Socialist Federal Republic of Yugoslavia 26/83)

Rulebook on Restricted Use of GMOs (Official Gazette of the Federal Republic of Yugoslavia 62/02)

Rulebook on Placing on the Market of GMOs, GMO Products (Official Gazette of the Federal Republic of Yugoslavia 62/02)

Rulebook on Radioactive Contamination Limits for Food and Environment (Official Gazette of the Federal Republic of Yugoslavia 9/99)

Rulebook on Quality and Other Requirements for Natural Mineral Water, Spring and Table Water (Official Gazette of Serbia and Montenegro 53/05)

Rulebook on Maximum Permitted Quantities of Harmful Substances and Ingredients in Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia 2/90 and 27/90)

Rulebook on Methods for Carrying Out Veterinary-Sanitary Control of Feed and Establishments Manufacturing Feed and Conditions that must be met by Laboratories Carrying Out Super-Analysis of Feed Samples (Official Gazette of the Federal Republic of Yugoslavia 72/91 and 24/93)

Rulebook on Minimum Technical Conditions for Equipping the Business Premises for Trade in Raw Hides, Skin, Wool, Hair and Animal Waste (Official Gazette of the Republic of Montenegro 2/81)

Rulebook on Methods for Safe Disposal of Animal Carcasses and Wastes of Animal Origin and on Conditions that must be met by Establishments and Equipment for Collecting, Safe Disposal and Establishing of the Cause of Death and Means for Transport of Animal Carcasses and Wastes of Animal Origin (Official Gazette of the Socialist Federal Republic of Yugoslavia 53/89)

FOOD AND FEED QUALITY

Law on Standardization (Official Gazette of Montenegro 13/08)

Law on Technical Requirements for Products and on Evaluation of Compliance of the Product with the Requirements Set (Official Gazette of Montenegro 14/08)

Rulebook on Quality of Meat of Animals, Poultry and Wild Game for Slaughter (Official Gazette of the Socialist Federal Republic of Yugoslavia 34/74 and 13/78)

Rulebook on Quality of Meat Products (Official Gazette of the Federal Republic of Yugoslavia 32/2004)

Rulebook on Quality of Fish, Crustaceans, Shellfish, Frogs, Snails and Products Thereof (Official Gazette of the Socialist Federal Republic of Yugoslavia 65/79 and 48/84)

Rulebook on Quality of Poultry Meat (Official Gazette of the Socialist Federal Republic of Yugoslavia 1/81 and 51/88)

Rulebook on Quality of Poultry Meat Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 55/91)

Rulebook on Quality and Other Requirements for Milk, Dairy Products, Composite Milk Products and Starter Vultures (Official Gazette of the Federal Republic of Yugoslavia 26/2002)

Rulebook on Methods of Sampling and Methods of Chemical and Physical Analyses of Milk and Dairy Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 32/83)

Rulebook on Quality of Slaughtered Pigs and Pork Categorization (Official Gazette of the Socialist Federal Republic of Yugoslavia 2/85 and 24/86)

Rulebook on Quality of Honey and other Bee Products and Methods for Control of the Quality of Honey and other Bee Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 4/85 and 7/92)

Rulebook on Quality of Eggs and Egg Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 55/89)

Rulebook on Methods for Testing the Quality of Eggs and Egg Products (Official Gazette of the Socialist Federal Republic of Yugoslavia 72/87)

Rulebook on Methods and Procedure for Control of the Quality of Agricultural and Food Products in Foreign Trade (Official Gazette of the Federal Republic of Yugoslavia 13/96)

FEED

Law on Food Safety (Official Gazette of Montenegro 14/07)

Rulebook on Methods for Sampling and Methods of Physical, Chemical and Microbiological Analyses of Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia 15/87)

Rulebook on Maximum Quantities of Harmful Substances and Ingredients in Feed (Official Gazette of the Socialist Federal Republic of Yugoslavia 2/90 and 27/90)

Rulebook on Methods for Carrying Out Veterinary-Sanitary Control of Feed and Establishments Manufacturing Feed and Conditions that must be met by Laboratories Carrying Out Super-Analysis of Feed Samples (Official Gazette of the Federal Republic of Yugoslavia 72/91 and 24/93)

VI. PHYTOSANITARY POLICY

23. General

a) Please provide information on general architecture of the legal basis; organisation and powers of different institutions involved.

b) Please provide information on respective fields of responsibilities of competent authorities concerned.

c) Please provide a clear table of all the framework acts that cover or impinge upon the phytosanitary domain with an explanation of their coverage as far as the EU acquis is concerned. Please indicate whether you envisage adopting new framework acts.

d) Please provide information for each item listed below.

Ministry of Agriculture, Forestry and Water Management is the public administration body in charge of policy making for the field of phytosanitary policy and for supervision over the legality and appropriateness of the work of the Phytosanitary Administration.

The Phytosanitary Administration was established by the Decree on Amendments to the Law on Organization and Method of Work of the Public Administration (Official Gazette of Montenegro 43/08), establishing the ministries and other administration bodies, lays down the method of work of public administration and governs other issues of relevance for work of the public administration.

Legal basis and powers delegated:

- Law on Plant Health Protection, Articles 4 and 5 (Official Gazette of the Republic of Montenegro 28/06) transposes Article 1 paragraph 4 of the Directive (Celex No. 32000L0029);
- Law on Plant Protection Products Article 6 (Official Gazette of Montenegro 51/08);
- Law on Seed Material of Agricultural Plants Article 4 (Official Gazette of the Republic of Montenegro 28/06);
- Law on Planting Material Article 6 (Official Gazette of the Republic of Montenegro 28/06);
- Law on Plant Variety Protection Article 11 (Official Gazette of Montenegro 48/07 and 48/08);
- Law on Food Safety Article 8 (Official Gazette of Montenegro 14/07);
- Law on Plant Nutrition Products Article 8 (Official Gazette of Montenegro 48/07); (Annex 42)
- Law on Genetically Modified Organisms Article 10 (Official Gazette of Montenegro 22/08).(Annex 44)

The Phytosanitary Administration is in charge of direct implementation of regulations and of administrative and other related technical and inspectorial activities and is in charge of co-ordination and contacts related to phytosanitary field.

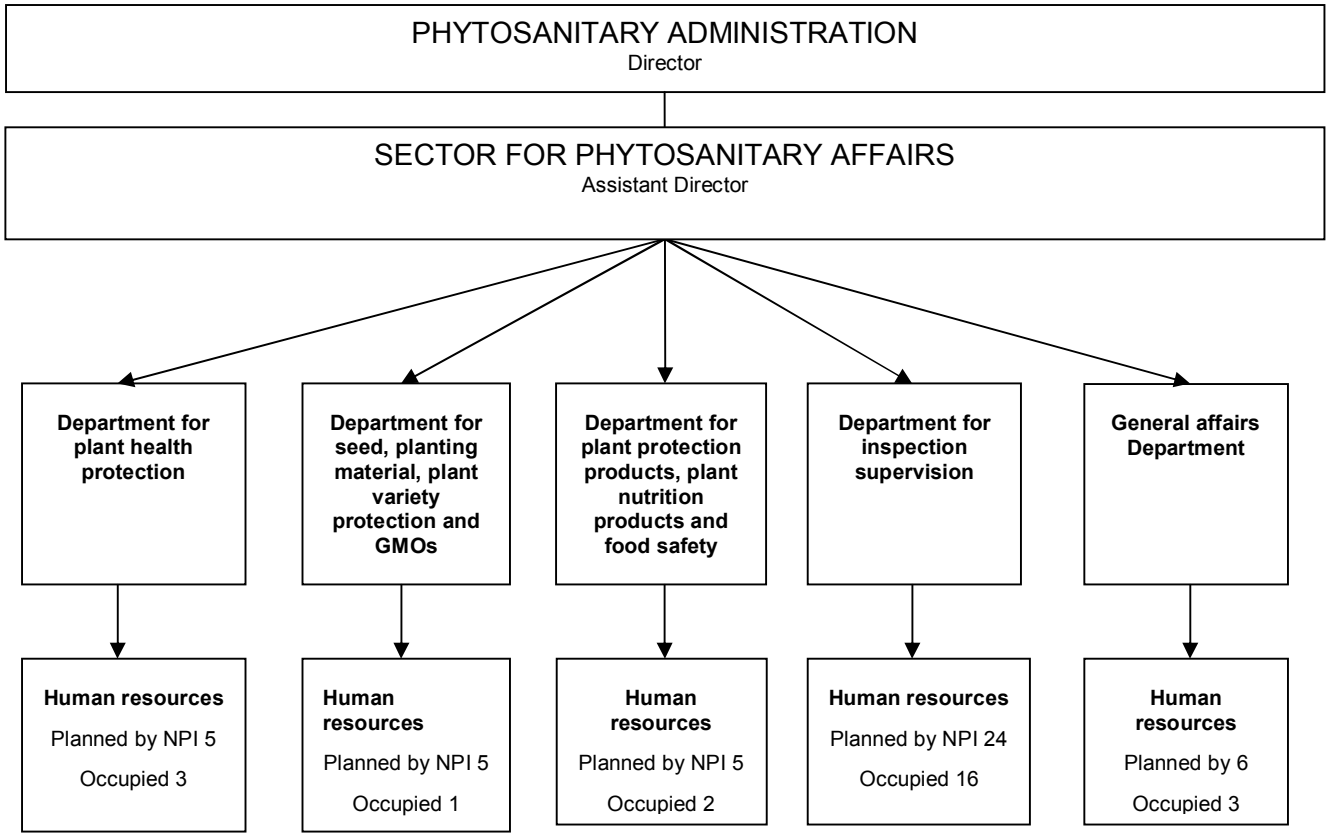
Adoption of the Law on Budget of Montenegro for 2009 (Official Gazette of Montenegro 82/08) provided the conditions for commencement of work of the Phytosanitary Administration and funds in the amount of 780,918.51 € have been earmarked for its activities.

The Rulebook on Internal Organization and Systematization of Phytosanitary Administration was adopted by the Government at the sitting on February 26, 2009.

According to the Rulebook, the activities of the Phytosanitary Administration are systematized into 38 jobs for officers and employees.

The work of the Phytosanitary Administration is organized in accordance with the Rulebook on Internal Organization and Systematization of Phytosanitary Administration, by the following organigram:

Phytosanitary Administration Organigram



Human Resources Total

Planned: 47

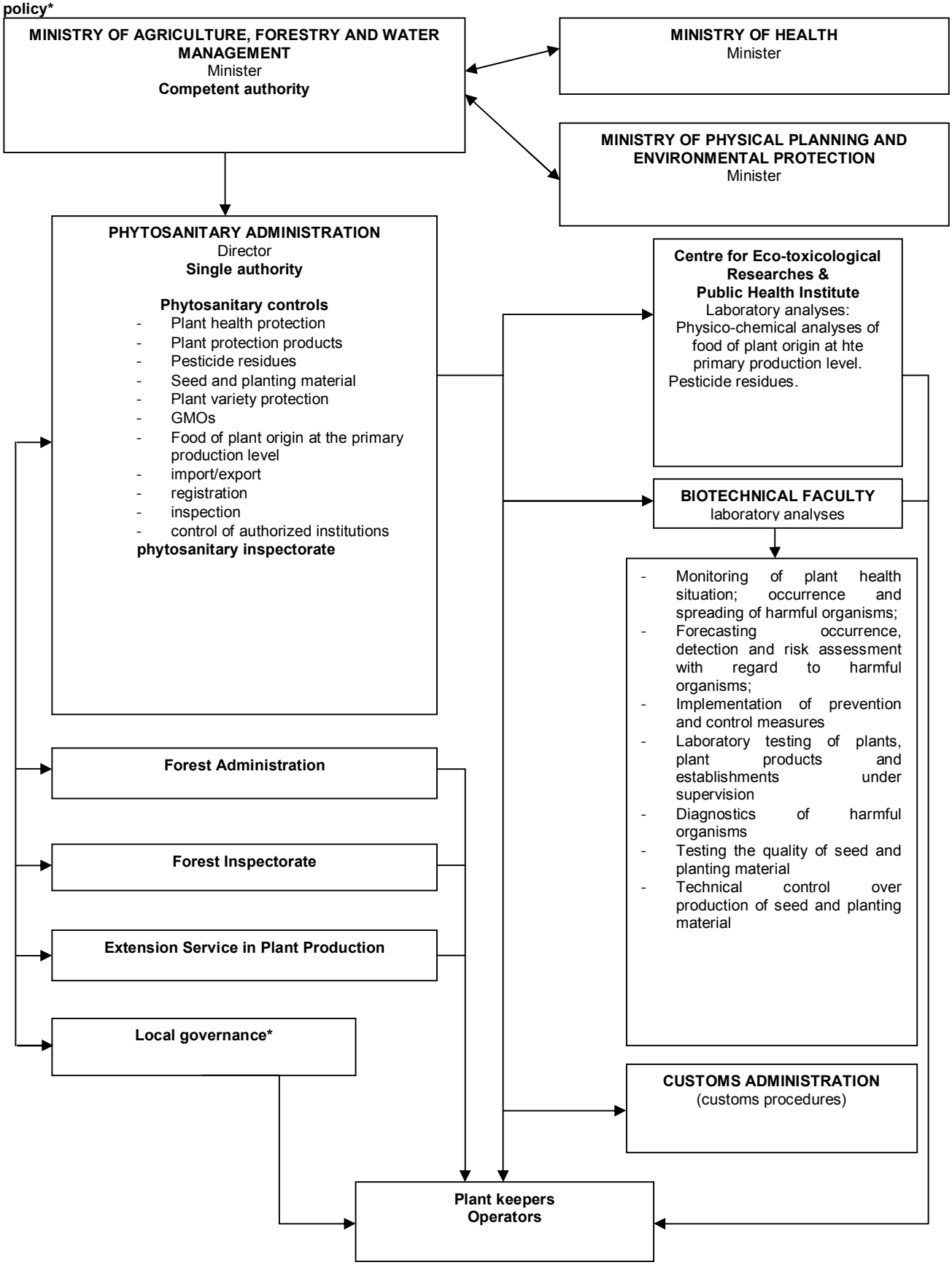
Currently: 27

Human resources overview by NPI*:

Institution	Existing / planned	2007	Planned number of staff				
			2008	2009	2010	2011	2012
Sector of the Plant Health Protection		1	3	3	5	5	5
Sector of the Seed and Propagating and Planting Material and of the Plant Variety Protection, and GMO		1	3	3	5	5	5
Sector of the Plant Protection and Nourishment Products and Food Safety		0	3	3	5	5	5
Phytosanitary inspection		20	22	22	24	24	24

*the staff of administrative and general affairs not included

Flow chart - competence levels - line of management of services in charge of phytosanitary policy*



*All institutions in charge of phytosanitary filed are at the central level, only the Register of Plant Producers who place their products on the market would be kept by local governance bodies.

24. Plant health, harmful organisms:

- General control measures; Specific control measures; Protected zones; Registration of operators (plant passports); Imports; Inspections and notification of interceptions; Expenditure in the phytosanitary field; Status of harmful organisms listed in the EU acquis.

The Ministry of Agriculture, Forestry and Water Management is a public administration body in charge of policy making for the field of plant health protection and of supervision of legality and appropriateness of the work of the Phytosanitary Administration.

The Phytosanitary Administration, public administration body in charge of direct implementation of regulations and related technical affairs, is also in charge of co-ordination and contacts concerning the plant health protection as a single and central body, in accordance with Articles 4 and 5 of the Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) and Article 1 paragraph 4 of the Directive, Celex No. 32000L0029 and powers delegated in accordance with the Decree on Amendments to the Decree on Organization and Method of Work of Public Administration (Official Gazette of Montenegro 43/08).

The Rulebook on internal organization and systematization of the Phytosanitary Administration, the Department for Plant Health Protection was established within the Sector for Phytosanitary Affairs.

The Department for Plant Health Protection is in charge of direct implementation of regulations and activities concerning the plant health protection, measures for prevention of introduction and spread of harmful organisms, measures for control of harmful organisms on plants, plant products and objects under supervision, organization and implementation of continuous supervision over harmful organisms, evaluation of plant health condition with a view to determining the occurrence and spread of harmful organisms, risk assessment in cases of occurrence and determination of new harmful organisms, issuing of technical instructions and measures, notification on plant consignments detained as a result of failure to comply with the phytosanitary requirements, control and implementation of restrictions or prohibitions of imports into Montenegro and transit of certain plant species through the territory of Montenegro, providing technical basis for setting the limits of areas where extraordinary health supervision needs to be established, setting up and keeping of registers, records, preparation of the program of preventive measures that are undertaken in order to prevent the introduction and spread of harmful organisms and taking care that these are implemented, proposing implementation of measures for prevention, control and eradication of harmful organisms and harmonization of their implementation, supervision over the work of persons with authorizations, notification on occurrence, massive occurrence and spread of harmful organisms, providing information related to plant health protection to the public, setting up and maintenance of the information system in plant health protection, development of technical basis for control plan, monitoring plan and crisis management plan, issuing of approvals, entry into registers, keeping registers and records, implementation of international conventions, contracts and exchange of information, participation in international bodies and organizations, setting up of information system, data collecting, processing and keeping; development of reports, analyses, briefing notes and other materials, in accordance with the regulations and international contracts and agreements and other activities placed under its scope of authority.

In case presence of harmful organisms from List I A and List II A is established, the Phytosanitary Administration will order implementation of appropriate phytosanitary measures in order to prevent the spread or in order to control the harmful organisms, such as treating, destruction or any other removal of harmful organisms, plants, plant products or objects under supervision, where presence of harmful organisms has been established, while orders for implementation of measures are adopted by the Ministry of Agriculture, Forestry and Water Management.

Phytosanitary measures are implemented for the purpose of plant health protection and they are based on the principles of risk assessment and management.

The following shall be taken into account in the risk assessment process:

- Scientific information available;
- Production processes and methods;
- Methods of inspection, sampling and testing;
- Distribution of certain harmful organisms;
- Existence of areas without harmful organisms;
- Environmental conditions;
- Quarantine or other procedure.

Risk management includes taking into account economic feasibility in terms of loss in production or sale in case of introduction and spread of harmful organisms, costs of control or eradication thereof, as well as cost-effectiveness of alternative approaches to risk reduction.

The extent of the presence of harmful organisms is established by the Phytosanitary Administration.

The Phytosanitary Administration notifies plant keepers and persons authorized of occurrence of and risk from harmful organisms and informs them of the measures for prevention of spreading of harmful organisms.

In case of presence of harmful organisms, the plant keeper has the obligation to protect the plants, plant products and objects under the supervision against harmful organisms and to prevent the contact with other plants, plant products and objects under supervision that the harmful organisms might be spread to.

The plant keeper has the following obligations:

- In order to detect the occurrence and prevent the spread of harmful organisms, the keeper has to check the plants grown in areas where they are grown (field, plantation, nursery, garden, greenhouse, etc.), wild herbs, as well as plant products and objects under supervision, regardless of whether these are his/her ownership or are used and handled in any other way;
- To notify the administration body or other persons carrying out plant health protection activities of all the new and unusual occurrences or suspected presence of harmful organisms;
- To undertake, without delay, the measures set by the Phytosanitary Administration in order to prevent the spread, or to control or eradicate the harmful organisms;
- To keep records on plant health protection measures undertaken.

In case the plant keeper fails to implement the measures ordered, the administration authority shall implement these measures at the expense of the plant keeper.

Reporting-forecasting activities are undertaken for the purpose of providing timely alerts to plant keepers on occurrence of harmful organisms and recommendations for control thereof.

The Department for Inspection Supervision carries out the activities of inspection supervision with regard to ensuring the implementation of laws and secondary legislation, adoption of decisions in administrative procedures, submits requests for initiation of misdemeanour proceedings, reports on commercial offence proceedings and on crime, initiates amendments to the legal documents implementation of which it controls, prepares briefing notes and reports on the situation in this field as well as other activities in accordance with the law.

The powers of the phytosanitary inspectorate are based on implementation of the Law on General Administrative Procedure (Official Gazette of the Republic of Montenegro 60/03), the Law on Inspection Supervision (Official Gazette of the Republic of Montenegro 39/03) and implementation of the Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06), rulebooks, orders, decrees, programs, instructions, etc.

The Phytosanitary Inspectorate carries out:

Inspection supervision over phytosanitary border inspection posts

The border phytosanitary inspectorate carries out the health supervision over the consignments of plants, plant products and objects under supervision in trade (import, export, re-export, transit) across the border of Montenegro, issues certificates on plant health condition (phyto-certificate), undertakes phytosanitary measures for the purpose of preventing the introduction, spread, and for the purpose of eradication of harmful organism in accordance with the law.

Import of consignments of plants, plant products and objects under supervision

Checks of consignments, which are the subject of phytosanitary supervision, by phytosanitary inspectors are mandatory at the border crossing of entry.

A plant consignment may be imported only through the designated border crossings, were customs and phytosanitary inspection supervision is in place.

Importers and authorised representatives thereof have the obligation to submit to the border phytosanitary inspector a written application for health check of plants for which the check is mandatory.

The application is submitted in writing, stating all the documents accompanying the consignment.

The application is to be registered and issued with a protocol number which consists of: the procedure mark; year mark; inspectorate mark; identification number of the inspector and the ordinal number of the protocol and the date when the application was submitted.

The importer or the authorised representative has to give the phytosanitary inspector a notice on arrival of the consignment no later than 24 hours prior to the expected arrival of the consignment to the border crossing.

The plant consignment that is subjected to the phytosanitary examination remains under customs supervision until the phytosanitary inspector confirms that the phytosanitary check is completed.

The phytosanitary checks at imports of consignments of plants, plant products and objects under the supervision at the border inspection post include:

- Documentation check;
- Identity check;
- Physical checks.

Documentation check

Phytosanitary inspector checks whether the consignment is accompanied by the following:

- original of the phytocertificate (for plant consignment for which the certificate is prescribed), which ensures that the consignment complies with the specific requirements;
- approval from the Phytosanitary Administration (where prescribed);
- waybill or bill of lading;
- invoice, packing list, and
- other documents accompanying the consignment of plants, plant products and objects under supervision, where prescribed.

In documentation check, the phytosanitary inspector checks the following:

- whether the original of the phytocertificate is enclosed and whether it is issued in accordance with the International Plant Protection Organization (IPSM 12);
- the date on which the phytosaniary certificate was issued (whether it is older than 14 days) and compares it with the date on which the packing list was issued (in order to check the date when phytocertificate was issued);
- whether the goods were marked with an appropriate botanical name;
- whether the contents of the goods indicated on the phytocertificate matches the contents of

the waybill;

- whether plants, plant products or objects under supervision indicated in the documents are subject to prohibitions, restrictions, or whether an additional declaration is requested, whether there are some temporary prohibitions concerning a region, country or plants, etc;
- if prescribed, the phytocertificate with the additional declaration which should include the clause „seed originates from plants that were not infected with quarantine harmful organisms and production in the vegetation period was controlled by the competent authority for plant health of the country of origin“;
- in addition to the additional declaration, the phytocertificate for consignments of fruit and vine planting material must also include the additional declaration: "Parent plants were tested by a laboratory method and agents of quarantine viroses and mycoplasmas were not found";
- phytocertificate for consignments of live plants and parts thereof (other than fruit and seed) from genuses Amelanchier, Chaenomeles, Cotoneaster, Crataegus, Cydonia, Eriobotrua, Malus, Mespilus, Pyracantha, Pyrus, Robus, Sorbus and Strenvaesia must include the additional declaration: "Plants originate from plants cultivated in the field that has for the past two years been controlled by the competent authority for plant health of the country of origin and *Erwinia amylovora* has not occurred in the field of production and within the distance of 5 km from that field";
- phytocertificate for consignments of live plants and parts thereof and for pot plants (other than seed and fruit), of genuses and species Apium graveolens, Capsicum spp., Chrysanthemum spp., Cucumis spp., Dendranthema spp., Dianthus caryophilus, Gypsophila spp., Gerbera spp., Lactuca spp., Lycopersicon esculentum and Senecio X hibridum originating in countries of Southern, Central and Northern America must include the following additional declaration: "The plants originate from healthy plants, and there were no occurrences of Amaromyza sativa, *Liriomyza sativa* and *Liriomyza huidobrensis* in the place of production, and three months prior to dispatch of the consignment, at least once a month, the competent authority of the exporting country examined the plants cultivated, during the vegetation period";
- plant consignments imported must be cleaned from soil. Where presence of soil is established in a plant consignment, the consignment must include the following additional declaration: "The soil has been tested for the presence of quarantine nematode species and for the presence of *Synchitrium endobioticum*";
- phytocertificate for consignments of edible fungi must include the date when the production of the crop completed the bolting phase and the following additional declaration: "The edible fungi crop (species) has been produced and kept in sterile conditions";
- for potato consignments, a clause which should include the following „the consignment originates from the soil where *Synchitrium endobioticum* has never been found. The soil has been tested for absence of *Globodera pallida* and *Globodera rostochiensis*. The consignment is not infected with *Clavibacter michiganenensis spp.sepedonicus*, *Pseudonomas solanacearum*, Potato spindle tuber viroid, non-European potato viruses and other quarantine harmful organisms“;
- in case disinfestation and disinfection of lumber with or without bark has been done, it has to be certified in the phyto-certificate, or marked on the lumber, or on the packaging, as appropriate, with "Kilndried" (K.D.) or some other international mark.

In case the documentation is incomplete or has some deficiencies, the importer or its authorized representative has the obligation to provide the missing documentation and the consignment is detained pending the completion of the documentation.

In case the documentation is complete and complies with all the conditions, the phytosanitary inspector shall proceed to identity and physical checks.

At border inspection posts where there are no conditions for this segment of the health check

(identity and physical checks), the phytosanitary inspector shall issue a decision on redirection of the consignment under customs supervision to the phytosanitary inspector in the place of customs clearance or some other place designated in accordance with the law.

Identity and physical checks

The phytosanitary inspector makes identity and physical checks of the consignment at the border crossing if there are conditions for such checks or in the bonded warehouse or another officially designated place under the customs supervision.

The consignment of plants, plant products and objects under supervision is opened in the presence of the phytosanitary inspector, who commences the identity check of the commodities (origin, breeder, purpose of the commodities, packaging) making the comparison with the information indicated in the phytocertificate, in terms of quality, commodity type, packaging and all the marks (tags, etc.), and actual weight of the consignment with the weight indicated in the phytocertificate or another document by checking the number of packages or, if necessary, by weighing the consignment, the checks are made in several different samples taken from the entire consignment in order to establish the compliance with all the conditions prescribed as well as whether the consignment is fit for use for the purposes indicated in the accompanying phyto-certificate or another document.

The phytosanitary inspector appraises the level of risk from introduction of quarantine harmful organisms and possible derogations from the conditions prescribed for the type of commodity in the consignment in order to establish the method of physical check (setting the number of packages from which samples are to be taken, the number and the size of the samples, examination method, frequency and experiences with the importer, preventive measures, etc). Available scientific and technical information on previous analyses, information on quarantine harmful organisms on certain host plant species, on origin of the consignment, reliability of the phytocertificate and other accompanying documents are used for checking the risk level.

The physical check – health check - implies:

- visual check for the presence of harmful organisms of the consignment and the wooden packaging material;
- simple laboratory analyses, and
- checking the means of transport.

Laboratory checks are done in accordance with the risk analysis, previous experience or information on introduction of harmful organisms, where there are justified reasons for suspicion, whether the condition cannot be established exactly on the basis of accompanying documents or the physical checks made. The laboratory checks are done in authorized accredited laboratories.

The consignments sent to laboratory checks are under the customs or quarantine supervision and must not be placed on the market pending the receipt of the results of laboratory testing.

In case the plant consignment or the packaging is infected with a quarantine or certain economically harmful organisms above the percentages set, and it cannot be fully controlled by disinfection or disinfestation at the point of import, or in case the consignment is exposed to a higher level of secondary infections, biological or mechanical impurities and for that reason does not match the name declared, the phytosanitary inspector will undertake one of the measures prescribed and issue a decision prohibiting the import and order the consignment to be returned to the consignor and destroyed, and in case such plant consignment is introduced by a natural person, the consignment will be seized and destroyed. The phytosanitary inspector puts the declaration **"Import prohibited. The consignment infected with_____"** (name of the quarantine harmful organism, or an economically harmful organism) on accompanying documentation.

In case it is established through the health checks of the plant consignment that the plant consignment is not infected with a quarantine harmful organism or an economically harmful organism above the percentage set, or in case the consignment is not exposed to a higher level of secondary infections, the phytosanitary inspector will confirm that the health check of the plant

consignment has been made, by placing on the customs declaration or the document accompanying the consignment the following declaration: **"The consignment checked. Import allowed"**.

In order to check the shipping consignments in sea ports, the ship has to be berthed at the port and consignments have to be onboard, or, with approval from the phytosanitary inspector, in a bonded warehouse where conditions for a phytosanitary check are provided.

In case the plant consignment is imported by containers over the border crossing where containers are not examined, the phytosanitary inspector checks documentation only. In case it is established that the consignment in the container is supplied with the appropriate phytocertificate and that the certificate is not mandatory, the phytosanitary inspector approves of the transport of the container under customs supervision to the designated place for health check of the container, where opening of the container may take place. In case it is established that the plant consignment imported in containers is not supplied with a phytocertificate where it is prescribed, or where it can be established from the documentation that it contains plants import of which is prohibited, or restricted, as appropriate, the phytosanitary inspector will order the consignment to be returned to the consignor.

The consignments transported by railway are checked at railway stations designated by the Phytosanitary Administration.

Airmail, general cargo and mail consignments are checked in the bonded warehouse in the space designated for that purpose.

The phytosanitary inspectors also control the requests for plant quality in imports.

In imports of planting material that transmits or may transmit the quarantine harmful organisms, presence of which cannot be established by health check at the border crossing (hidden infections) the phytosanitary inspector issues a decision ordering monitoring of the health condition of the planting material at the end user's (at the planting site). The following types of planting material are subjected to the monitoring of health condition of planting material at end user's:

No.	Planting material type	Quarantine harmful organisms
1	2	3
1.	Rosaceae : Malus – originating in all countries	Gymnosporangium spp. (non-European) Monilinia fructicola (Winter) Honey Phylosticta solitaria Ell. et Ev. Apple proliferation MLO Cherry rasp leaf virus
2.	Prunus - originating in all countries from Australia and North and South America and Asia.	Monilinia fructicola (Winter) Honey Cherry rasp. leaf virus Peach American mosaic disease Peach phoney bacterium RLO Plum American line pattern virus Apricot chlorotic leafroll MLO Peach rosette MLO Peach yellows MLO Peach X disease MLO Apple proliferation MLO Plum pox virus Apricot chlorotic leafroll MLO
3.	Chaenomeles - originating in Australia and countries of North and South America and Asia.	Monilinia fructicola (Winter) Honey
4.	Crataeagus - originating in Australia and countries of North and South America and Asia.	Gymnosporangium spp: (non-European) Phyllosticta solitaria Ell. et Ev. Monilinia fructicola (Winter) Honey
5.	Cydonia - originating in non-European countries	Gymnosporangium spp. (non-European) Monilinia fructicola (Winter) Honey
6.	Pyrus - originating in non-European countries	Gymnosporangium spp. (non-European) Monilinia fructicola (Winter) Honey Phyllosticta solitaria Ell. et Ev. Conotrachelus nenuphar (Hbst.)
7.	Photinia - originating in North and South America and Asia.	Gymnosporangium spp (non-European)
8.	Rubus - originating in Germany and non-European countries.	Apple mosaic virus in Rubus (strain USA) Raspberry leaf curl virus

9.	Rutaceae: Citrus, Fortunella, Poncirus, Aeglopsis, Afraegle, Pamburus, Clausena and hybrids of genuses Citrus, Fortunella and Poncirus - originating in Italy, Spain and non-European countries.	Citrus greening bacterium Xanthomonas axonopodis pv. citri (Hasse) Vauterin et al. Citrus tristeza virus Diaphorina citri (Kuway) Toxoptera citricida (Kirk.) Tryoza erytreae (Del G.) Radopholus citrophilus Huettel et al. R. similis (Cobb) Thorne
10.	Umbelliferae : Arracacia - originating in Italy, Spain and non-European countries	Citrus tristeza virus
11.	Passifloraceae : Passiflora - originating in Italy, Spain and non-European countries	Citrus tristeza virus
12.	Solanaceae : Solanum tuberosum - potato (basic, elite and superelite) originating in all countries	Globodera pallida (Stone) Behrens Globodera rostochiensis (Wollenweber) Behrens Nacobbus aberrans (Thorne) Thorne et Allen
13.	Vitaceae : Vitis - originating in all countries	Grapevine flavescence doree MLO Hylophylus ampelinus (Panagopoulos) Willems et al. Xylella fastidiosa Wells et Raju Xiphinema americanum Cobb Xiphinema index Thorne et Allen

Transit

Consignments of plants in transit through the territory of Montenegro and reloaded into other means of transport are subject to mandatory health checks at the border crossing. Where such a consignment arrives at the border crossing where reloading is not done, the phytosanitary inspector checks the documents only.

Reloading

In case reloading takes place and the documentation complies with the conditions prescribed as well as with other regulations, the phytosanitary inspector approves of the transit under customs supervision to the place where reloading and health check of plants would take place.

Reloading must not commence in absence of a phytosanitary inspector. In case the consignment arrived without a phyto-certificate, the phytosanitary inspector will prohibit the entry of the consignment and order the consignment to be returned to the consignor. The phytosanitary inspector will place the following declaration **"Transit prohibited. Consignment arrived without a phyto-certificate" on** the documentation. The inspector will order the same in case it is established by the health check that the consignment is infected with a quarantine harmful organism. The following declaration will be placed on the accompanying documents: **Transit prohibited (consignment infected, name of the plant pest)**.

Export

Health checks of consignments in exports and re-exports includes checking the means of transport, packaging and plants. Where it is established during the health check that the consignment is not infected with a harmful organism for which its introduction into the importing country or the country of transit would be prohibited, the phytosanitary inspector issues phyto-certificates.

For consignments intended for export and re-export a phytocertificate is issued and the consignment has to cross the border of Montenegro within the period of 14 days.

Where it is established during the health check that the consignment or a part of the plant consignment is infected with a harmful organism for which its introduction into the importing country or the country of transit would be prohibited, the phytosanitary inspector will not issue a phytocertificate for export of such a consignment and would order the measures necessary.

The phytosanitary inspector on the border crossing co-operates with the customs, veterinary inspectorate and administration bodies in charge of implementation of CITES list, etc.

Inspection supervision in internal trade

Inspection procedures in internal trade include the following:

- inspection procedures at the place of production:

- monitoring of inspection;
- supervision.

Phytosanitary inspectors supervise plants, plant products and objects under supervision in production, storage and trade:

- check plants, plant products and objects under supervision and order measures for prevention of the occurrence, control and eradication of harmful organisms;
- supervise and check plants, plant products and establishments under supervision;
- take samples of plants, plant products and objects under supervision in order to establish the presence of harmful organisms;
- check whether producers, processors, importers, exporters, storage operators and distributors of prescribed plant species and plant products are entered in the register;
- check imports, growing or use of organisms for biological plant health protection;
- check whether the persons entered in the register meet the conditions for entry in the register;
- check whether the persons entered in the register meet their obligations:
    1) keep detailed records on production, processing and trade in plant, plant products and objects under supervision, which they buy for storage, planting on the farm, processing or moving to another place;
    2) keep and regularly update the plan of sites where plants, plant products and objects under supervision are grown, processed, stored, kept and used;
    3) carry out regular visual health checks as prescribed;
    4) notify the Phytosanitary Administration or the phytosanitary inspector of all unusual occurrences and increased volume of harmful organisms, symptoms or other changes on plants as well as on production and occurrence of prohibited plant species;
    5) notify the Phytosanitary Administration of all the changes of the data kept in the register;
    6) inform the Phytosanitary Administration, i.e. the competent inspector of the volume and place of production or processing of plants and plant products;
    7) co-operate with the Phytosanitary Administration and the phytosanitary inspector in implementation of plant health protection;
    8) store records for at least one year.

With a view to preventing the introduction and spread of harmful organisms, the phytosanitary inspector implements continuous supervision over the plants, plant products and other objects under supervision and orders phytosanitary measures laid down by the law.

In case the plant keeper or other person notices on plant, plant products or objects under supervision a new and unusual occurrence of harmful organisms or suspects the presence of harmful organisms from the lists of quarantine harmful organisms List I A and List II A he/she has the obligation to immediately notify the phytosanitary inspector, or the Phytosanitary Administration.

In case presence of harmful organisms is suspected, the phytosanitary inspector takes a sample and delivers it for the laboratory analysis in order to establish the presence of harmful organisms.

Laboratory analyses are carried out by an accredited laboratory.

Following the receipt of the results of analyses, the phytosanitary inspector shall order some of the measures prescribed (destruction of plants, disinfection, disinfestations, etc.) and control the implementation of measures ordered.

The Forest Administration and the Forest Inspectorate of the Ministry of Agriculture, Forestry and Water Management are in charge of plant health protection activities in the forestry field. The Forestry Inspectorate is not involved in exports/imports.

Inspection supervision of the authorized institutions

Phytosanitary inspector monitors and controls implementation of annual programs of phytosanitary measures, programs of reporting-forecasting activities, program of the biological plant protection, annual programs of special technical supervision and carrying out of public duties based on the authorizations given.

Phytosanitary inspector supervises the activities of public interest in plant health protection entrusted to the Biotechnical Faculty – Plant Protection Centre, as follows:

- monitoring of plant health condition, including wild herbs in order to collect the information on occurrence, intensity of infestation, population dynamics and spread of harmful organisms for plants, plant products and record keeping;
- collecting of biological, meteorological and other information for forecasting the occurrence of harmful organisms;
- forecasting the occurrence of harmful organisms, their development and population dynamic and definition of optimal timeframes for control thereof;
- detection of harmful organisms;
- laboratory testing of plants, plant products and objects under supervision for the purpose of diagnosing the harmful organisms;
- development of bases, including the human resources and material preconditions, in order to set the borderline of protected area and areas under special supervision;
- reporting on occurrence, presence and spread of harmful organisms;
- assessment of risk from harmful organisms;
- assessment of the need to implement the preventive measures and measures for control of harmful organisms;
- research activities in plant health protection field;
- providing technical instructions in the field of plant health protection for plant keepers;
- training of plant keepers, service providers and other stakeholders on harmful organisms, phytosanitary measures and methods for carrying out the activities in the field of plant health protection;
- preparation, organization and implementation of the program of professional development of persons in the plant health protection field;
- taking part in preparations and implementation of the program of reporting-forecasting service and special supervision;
- data supply for the information system.

In case it is established during the supervision that the tasks entrusted are not carried out in accordance with the public authorization or in case it is established that they fail to meet some of the conditions prescribed, the phytosanitary inspector shall intitiate the procedure for termination of authorization.

Border phytosanitary inspectors are engaged in activities of control in phytosanitary field and they work full time on these activities.

In addition to control activities, the phytosanitary inspectors who work in internal units also work on implementation of phytosanitary policy.

The List of Montenegro Border Inspection Posts designated as official points of entry
Phytosanitary Administration
Montenegro

Phytosanitary Inspectorate Address: Bratstva i jedinstva bb, 81000 Podgorica Tel:+382 20 621 111 Fax:+382 20 621 008 Chief Phytosanitary Inspector: Popovic Spaso mobile phone +382 67 207 104 E-mail: spasop@t-com.me			
BIP	**Means of transportation**	**Contacts**	**Working hours**
BIP Bozaj Border country Albania	 Road	**Tel +382 20 621 007 Fax +382 20 621 008 Contact: Medenica Srbijanka Tel +382 67 215 229 Mijovic Gordana Tel +382 67 218 819 E-mail:fitopg@t-com.me**	**Every day (on request) winter 08:00-13:00 h 15:00-18:00 h summer 08:00-13:00 h** 16:00 – 20:00 h
BIP Podgorica – Railway Border country Albania	 Railway	**Tel +382 20 621 007 Fax +382 20 621 008 Contact: Medenica Srbijanka Tel +382 67 215 229 Mijovic Gordana Tel +382 67 218 819 E-mail:fitopg@t-com.me**	**Every day (on request) 08:00-15:00 h**
BIP Podgorica – Post&DHL Border country - international	 Post & DHL	**Tel +382 20 621 007 Fax +382 20 621 008 Contact: Medenica Srbijanka Tel +382 67 215 229 Mijovic Gordana Tel +382 67 218 819 E-mail:fitopg@t-com.me**	**Every day (on request) 08:00-15:00 h**
BIP Podgorica – Airport Border country - international	 air port	**Tel +382 20 621 007 Fax +382 20 621 008 Contact: Medenica Srbijanka Tel +382 67 215 229 Mijovic Gordana Tel +382 67 218 819 E-mail:fitopg@t-com.me**	**Every day (on request) 08:00-15:00 h**
BIP Port of Bar Border country international	 See Port	**Tel +382 30 311 844 Fax +382 30 311 844 E-mail:fitobar@t-com.me Contact: Scepanovic Radojka Tel +382 67 215 229**	**Every day 07:00-19:00 h**
BIP Dobrakovo Border country Serbia	 Road	**Tel +382 50 478 102 Fax +382 50 478 102 E-mail:mpsvdobrakovo@t-com.me abcd123@t-com.me Contact: Vojinovic Milutin Tel +382 67 218 805 Rakonjac Gordana Tel +382 67 545 604 Bakic Vukadin Tel +382 67 238 773**	**Every day winter 07:00-12:00 h 15:00-18:00 h summer 07:00-12:00 h 15:00-20:00 h**
BIP Dobrakovo Border country Serbia	 Railway	**Tel +382 50 478 102 Fax +382 50 478 102 E-mail:mpsvdobrakovo@t-com.me abcd123@t-com.me Contact: Vojinovic Milutin Tel +382 67 218 805 Rakonjac Gordana Tel +382 67 545 604 Bakic Vukadin Tel +382 67 238 773**	**Every day winter 07:00-12:00 h 15:00-18:00 h summer 07:00-12:00 h 15:00-20:00 h**
BIP Metaljka Border country BiH	 Road	**Tel +382 82 621 007 Fax +382 82 621 008 E-mail:c.zarko@t-com.me Contact: Cacic Velinka Tel +382 67 218 807**	**Only Tuesday and Thursday 08:00-13:00 h**

BIP Rance Border country Serbia		**Tel +382 82 621 007** **Fax +382 82 621 008** **E-mail:fitosanitarnarance@yahoo.com** **Contact:** **Cvorovic Ljiljana** **Tel +382 67 221 134** **Tel +382 89 321 190**	**Every day excluding Sunday** **(on request)** **winter** **08:00-12:00 h** **15:00-17:00 h** **Summer** **08:00-12:00 h** **18:00-20:00 h**
BIP Dracenovac Border country Serbia		**Tel +382 51 273 139** **Fax +382 51 273 139** **E-mail:fitokula@t-com.me** **Contact:** **Kalac Sefik** **Tel +382 67 221 136**	**Every day excluding Sunday** **(on request)** **08:00-11:00 h** **Winter 15:00-18:00 h** **Summer** **08:00-12:00 h** **16:00-20:00 h**
BIP Kula Border country Kosovo		**Tel +382 51 273 139** **Fax +382 51 273 139** **E-mail:fitokula@t-com.me** **Contact:** **Kalac Meta** **Tel +382 67 218 813**	**Every day excluding Sunday** **(on request)** **winter** **08:00 - 11:00** **15:00 – 18:00** **Summer** **08:00 - 11:00** **17:00 – 20:00**
BIP Ilino Brdo Border country BiH		**Tel +382 40 213 098** **Fax +382 40 213 098** **E-mail:fitoilinobrdo@t-com.me** **Contact:** **Cupic Milica** **Tel +382 67 221 137** **Gojkovic Danijela** **Tel +382 67 571 137**	**Every day** **on request** **08:00-15:00 h.**
BIP Debeli Brijeg Border country Croatia		**Tel +382 31 688 236** **Fax +382 31 688 236** **E-mail:fitodb@t-com.me** **Contact:** **Jovanovic Valentina** **Tel +382 67 288 022**	**Every day excluding Sunday** **winter** **08:00-12:00 h** **15:00-17:00 h** **Summer** **08:00-12:00 h** **19:00-20:30 h**

The Customs Administration, too, takes part in control of plants by controlling personal baggage in passenger transport, in order to establish that:

- there are no more than 5 plants;
- there are no more than 2kg of bulbs, corms, tubers (other than potato, which must not be introduced) and rhizomes;
- there are no more than 2kg of fruit and vegetables (other than potato, which must not be introduced);
- one bunch of cut flowers or other plant parts; and
- no more than 5 commercial packages of seed (other than potato seeds).

All quantities of plant above the limits prescribed shall be taken and destroyed as prescribed by the Customs Administration.

The plan is to have the customs take part in control of wooden packaging material containing commodities other than plants.

LOCAL LEVEL

Extension Service for Plant Production provides advisory and technical support, provides information to agricultural producers and acts as a link between producers and phytosanitary administration.

Advisory Services in municipalities provide advisory and technical support, provide information to agricultural producers and act as a link between producers and phytosanitary administration.

PROJECTS

In the past few years, significant financial means have been earmarked by the EU through the EAR (implementation of the project «Technical Assistance to Strengthening of Veterinary and Phytosanitary Services») for building and strengthening of the phytosanitary sector by strengthening the capacity of phytosanitary laboratory (entomology; virology; mycology; bacteriology; nematology) as well as the capacity of phytosanitary inspectorate and the future Phytosanitary Administration. With EU expert technical assistance and adequate logistic co-operation of local experts, technical support and implementation have been provided. Technical, thematic seminars organized by TAIEX play an important role.

FUTURE ACTIVITIES

Plant health protection activities are combined, in accordance with the Directive (Celex No. 32000L0029) which clearly defines existence of a responsible official body in charge of plant health protection. The Phytosanitary Administration which was established as a *single authority,* will build the institutional capacity through work of the Department for Plant Health Protection with clear definition of administrative and inspectorial activities, allocation of clear competences and powers with the process of co-operation strengthening, better knowledge and exchange of information within the system itself (administration, inspectorate, laboratory) and with other institutions.

It is necessary to establish an appropriate system of training for the whole administration, phytosanitary inspectors and laboratory staff in terms of implementation, to improve the rapid communication system and exchange of data and to supply additional equipment.

Powers of various institutions in plant health protection field

Centre for Plant Protection – Phytosanitary Laboratory of the Biotechnical Faculty of the University of Montenegro **(**diagnostics of harmful organisms in plants and plant products), based on the authorization of the Phytosanitary Administration, is authorized for plant health protection activities: laboratory testing, technical activities and other activities of public interest in plant health protection.

The authorization was issued in accordance with the Law on Plant Health Protection, which defines the activities of public interests and conditions for delegating the activities of public interests to persons that satisfy the conditions prescribed.

The phytosanitary laboratory consists of the following:

- Laboratory for Phytopathology:
    c) Laboratory for Mycology and Bacteriology – employs two PhDs phytopathologist – mycologist;
    d) Laboratory for Virology – employs 1 MSc, phytopathologist virologist;
- Laboratory for Entomology – employs 2 PhDs entomologists;
- Laboratory for Nematodes – employs 1 MSc.

Laboratory staff – 1 graduate in agriculture and 2 technical assistants

Methods used in diagnosing harmful organisms of plants and plant products are: methods prescribed by EU regulations for certain harmful organisms, EPPO methods or the laboratory's own methods.

Mycology methods:

- Visual check
- Classical method on filter paper
- Method of isolation on nutritive media, and
- Microscopy method.

Bacteriology methods:

- Visual check;
- Isolation on nutritive and selective media

Virology methods:

- Biological methods (biotest, plant indicator)
- Serological methods (Lateral-flow test, DAS-ELISA test);
- Molecular methods (Polymerase chain reaction - PCR)

Entomological and acarological methods:

- Visual check
- Determination of insects and mites by determination keys, using stereomicroscopes and microscopes

Nematological methods:

- For separation of active nematodes from plant material – procedures for use of mixers, centrifuge and Baermann funnel, funnel-spray;
- For extraction of free-living nematodes from land Oostenbrink elutriator;
- For extraction of cysts from wet soil Kort elutriator and
- Examination of material extracted under the stereomicroscope and microscope and determination of species by determination keys.

The Phytosanitary laboratory is equipped for diagnostics of harmful organisms for plants and plant products.

The control of the quality of work within the Centre for Plant Protection/Phytosanitary laboratory, is carried out by a written scheme and the head of the Centre is responsible for implementation.

The laboratory has the obligation to handle the sample so as to ensure the identity of the sample and conditions for prevention of the risk from spread of harmful organisms. The laboratory has the obligation to keep the records of samples, to keep and supply information on analyses carried out as prescribed.

In plant health field, several checks are applied: scientific – research work in different projects, identification of harmful organisms, routine diagnostic procedures on samples taken in internal and external control in the country, health control of seed and planting material, biological evaluation of pesticides etc. Work on national researches is funded from the Program of Phytosanitary Measures, in accordance with the contracts signed.

The staff has all the necessary IT equipment (computers, cameras, photocopiers, fax and permanent internet access, etc.).

Under the project “Capacity Building of Veterinary and Phytosanitary Services in Montenegro” implemented from October 2003 till the end of March 2005, appropriate equipment for research activities in various plant health protection fields was supplied: in mycology – microscopes, autoclavs, driers, laminar chamber, for bacteriology – fluorescence microscope, virology ELISA technique, as well as for all mentioned research fields PCR apparatus and electrophoresis set; for entomology – magnifying glasses, insect boxes, deep freezers, for nematology – magnifying glasses, filters, etc.

Nevertheless, there is a need for further capacity building. There are no premises with controlled external conditions. It is also important to mention the lack of a glasshouse, which is necessary for various research activities.

Measures that need to be taken in order to improve the situation:

- Internal organization of the Biotechnical Faculty has to recognize the Phytosanitary Laboratory with internal hierarchy in order to recognize the responsibility;

- The Phytosanitary Laboratory, as well as all other laboratories must be accredited in accordance with the ISO 17025 standard or general ISO 9001 standard;
- Obvious lack of technical staff for carrying out the checks;
- Establishing of a laboratory for herbology is necessary as well as completion of the Laboratory for Mycology and Bacteriology;
- Within the phytosanitary laboratory, it is necessary to employ a bacteriologist;
- Protocols for testing methods should be introduced;
- Introduction of a Good Laboratory Practice (as a part of the accreditation procedure) is necessary, which includes laboratory hierarchy, that is, the recognized responsibility of both the head of the laboratory and the staff in order to ensure the quality of the laboratory's work.

LEGAL BASIS

The Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) establishes a legal framework for the plant health protection system, harmonized with the EU acquis, which adopts the EU plant health protection concept (in accordance with the Directive, Celex No. 32000L0029).

The Law governs the protection of plant health and plant products against harmful organisms, measures for prevention of introduction and spread, as well as measures for control of harmful organisms, health supervision over plants and plant consignments in trade, ensuring the carrying out of activities of public interest as well as other issues of relevance for this field. The law provides general provisions for transposition of the EU legislation into the secondary legislation that will fully harmonize this filed with the EU legislation.

The Law on Ratification of the International Convention on Plant Protection was passed in 2008 (December, 2008) and in August 2009, Montenegro became a member of the IPPC (International Plant Protection Organization).

As regards bilateral international agreements in phytosanitary field, Montenegro concluded a bilateral agreement on co-operation in plant health protection field with Croatia. This agreement was signed on October 18, 2005 in Podgorica.

Pending the adoption of other secondary legislation, the following national regulations adopted before are applied, in accordance with the Law on Plant Health Protection:

- Decree on Carrying Out of Forecast-reporting Activities in Plant Protection (Official Gazette of the Federal Republic of Yugoslavia 65/99);
- Rulebook on Health Checks of Crops and Objects for Production of Seed, Seedlings and Planting Material and Health Checks of Seeds, Seedlings and Planting Material (Official Gazette of the Federal Republic of Yugoslavia 66/99, 13/02, Official Gazette of Serbia and Montenegro 10/03, 13/03);
- Criteria for Determining the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material;
- Rulebook on Health Checks of Plant Consignments in Trade Across the State Border (Official Gazette of the Federal Republic of Yugoslavia 69/99, 59/01);
- Rulebook on Conditions that Must be Satisfied by Quarantine Establishments for Checks of Health Condition of Plants and Plant Quarantine (Official Gazette of the Federal Republic of Yugoslavia 68/01);
- Rulebook on Method of Destruction of Plants for which Destruction Measures Were Ordered (Official Gazette of the Federal Republic of Yugoslavia 67/01);
- Order on Prohibition and Restriction of Imports and Transit of Certain Plant Species in order to Prevent the Introduction of Fire blight (Erwinia amylovora) of Apple and Pear Trees (Official Gazette of the Socialist Federal Republic of Yugoslavia. 40/91, 53/91);

- Order on Undertaking of Measures for Prevention of Spread of Quarantine Plant Pest - Diabrotica virgifera Le Conte (Official Gazette of the Federal Republic of Yugoslavia 23/94);
- Rulebook on Provision of Services in Plant Protection Field (Official Gazette of the Federal Republic of Yugoslavia 42/99);
- Order on Types of Planting Materials from Imports and Monitoring of Health Condition at End User's (Official Gazette of the Federal Republic of Yugoslavia 8/99);
- Order on Prohibition of Imports and Transit of Certain Plant Species and Deciding Upon Quarantine Supervision over certain Plant Species Imported for Cultivation Purposes (Official Gazette of the Federal Republic of Yugoslavia 8/99);
- List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03);
- List of Economically Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 65/99 and 67/99);
- Instructions on Publishing Information on Occurrence and Distribution of Newly-Discovered Quarantine Harmful Organisms, December 01,1999.

PRIORITY AND TENTATIVE PLAN OF HARMONIZATION WITH THE EU ACQUIS – CLEAR TABLE

I general control measures

EU	MNE
Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) **Status:** TOC not made **In future:** after TOC are made, in case of discrepancies, the process of making amendments to the law will be commenced
Annex I Annex II Annex III Annex IV Annex V Annex VI Annex VII Annex VIIIa	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) articles 8 and 9 **Legal act in force:** - List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) - List of Economically Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 65/99 and 67/99) - Order on Prohibition of Imports and Transit of Certain Plant Species and Deciding Upon Quarantine Supervision over Certain Plant Species Imported for Cultivation Purposes (Official Gazette of the Federal Republic of Yugoslavia 8/99) - Order on Types of Planting Material from Import and Monitoring of Health Condition at End User's (Official Gazette of the Federal Republic of Yugoslavia 8/99) – Rulebook on Heath Checks of Plant Consignments in Trade across the State Border (Official Gazette of the Federal Republic of Yugoslavia 69/99, 59/01) – Order on Prohibition and Restriction of Imports and Transit of Certain Plant Species in order to Prevent introduction of Fire Blight of Apple and Pear trees (Official Gazette of the Federal Republic of Yugoslavia 40/91, 53/91) – Order on Undertaking of Measures for Prevention of Spread of Quarantine Plant Pest - *Diabrotica virgifera* Le Conte (Official Gazette of the Federal Republic of Yugoslavia 23/94) **Status:** in the procedure of adoption by the Government of Montenegro: Rulebook on Measures for Prevention of Introduction and Spread of Organisms Harmful for Plant and Plant Products and Objects under Supervision in Accordance with the Annexes of the Council Directive 2000/29/EC
Commission Regulation (EC) No 1756/2004 of 11 October 2004 specifying the detailed conditions for the evidence required and the criteria for the type and level of the reduction of the plant health checks of certain plants, plant products or other objects listed in Part B of Annex V to Council Directive 2000/29/EC	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 31 paragraph 2 **Legal act in force:** **Status:** **In future:** Rulebook on Conditions and Method of Checks and Species of

	Plants, Plant Products and Objects under Surveillance / on the day of accession to the EU.
Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) - article 26 paragraph 6 **Legal act in force:** Rulebook on Health Checks of Plant Consignments in Trade across the State Border (Official Gazette of the Federal Republic of Yugoslavia 69/99, 59/01) part 3 article 35 – **Status:** TOC not made, Draft Rulebook on Minimum Conditions for Phytosanitary Checks of Plants, Plant Products and Establishments under Supervision is finished (Celex 32004L0103) **In future:** To be adopted by the end of 2010.

II specific control measures

EU	MNE
Council Directive 69/464/EEC of 8 December 1969 on control of *Potato Wart Disease*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** Rulebook on Health Examination of Crops and Objects for Production of Seeds, Seedlings and Planting Material and Health Checks of Seeds, Seedlings and Planting Material (Official Gazette of the Federal Republic of Yugoslavia 66/99, 13/02, Official Gazette of Serbia and Montenegro 10/03, 13/03); Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** TOC not made, Draft Rulebook on Protective Measures against *Potato Wart Disease – Synchitrium endobioticum* is finished (Celex No. 31969L0464) **In future:** To be adopted by the end of 2010.
Council Directive 69/465/EEC of 8 December 1969 on control of *Potato Cyst Eelworm*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** Rulebook on Health Examination of Crops and Objects for Production of Seeds, Seedlings and Planting Material and Health Checks of Seeds, Seedlings and Planting Material (Official Gazette of the Federal Republic of Yugoslavia 66/99, 13/02, Official Gazette of Serbia and Montenegro 10/03, 13/03); Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** Directive will be repealed as of 01/06/2010 to be harmonized with Celex No. 32007L0033 Draft Rulebook on Protective Measures against *Potato Cyst Eelworom–Globodera Palida and Globodera Rostochiensis* is finished (Celex No. 32007L0033) **In future:** To be adopted in 2010.
Council Directive 2007/33/EC of 11 June 2007 on the control of *potato cyst nematodes* and repealing Directive 69/465/EEC (from 01/06/2010)	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** Rulebook on Health Examination of Crops and Objects for Production of Seeds, Seedlings and Planting Material and Health Checks of Seeds, Seedlings and Planting Material (Official Gazette of the Federal Republic of Yugoslavia 66/99, 13/02, Official Gazette of Serbia and Montenegro 10/03, 13/03); Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** TOC not made, Draft Rulebook on Protective Measures against *Potato Cyst Eelworom–Globodera Palida and Globodera Rostochiensis* is finished (Celex No. 32007L0033) **In future:** To be adopted in 2010.
Council Directive 74/647/EEC of 9 December 1974 on control of carnation leaf-rollers	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** TOC not made, Draft Rulebook on Protective Measures against carnation leaf-roller (Celex 31974L0647) is finished

	In future: To be adopted by 2012.
Council Directive 93/85/EC of 4 October 1993 on control of *Potato Ring Rot*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Current Status:** in the harmonization process- Draft Rulebook on Protective Measures against *Potato Ring Rot-Clavibacter Michiganensis Sepedonicus* (Celex 31993L0085) is finished **In future:** To be adopted in 2010.
Council Directive 98/57/EC of 20 July 1998 on the control of *Ralstonia solanacearum (Smith) Yabuuchi et* al.	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** in the harmonization process Draft Rulebook on Protective Measures against *Potato Brown Rot-Ralstonia Solanacearum* (Celex 31998L0057) is finished **In future:** To be adopted in 2010.
Council Directive 2006/91/EC of 7 November 2006 on control of *San José Scale*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** in the harmonization process Draft Rulebook on Protective Measures against *Quadraspidiotus perniciosus* (Celex 31969L0466) is finished **In future:** To be adopted in 2010-2011.
Commission Decision 2002/757/EC of 19 September 2002 on provisional emergency phytosanitary measures to prevent the introduction into and the spread within the Community of *Phytophthora ramorum Werres, De Cock & Man in 't Veld sp. Nov*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** Rulebook on Health Examination of Crops and Objects for Production of Seeds, Seedlings and Planting Material and Health Checks of Seeds, Seedlings and Planting Material (Official Gazette of the Federal Republic of Yugoslavia 66/99, 13/02, Official Gazette of Serbia and Montenegro 10/03, 13/03); Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** TOC not made, **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Phytophtora ramorum* (Celex 32002D0757) To be adopted in 2010.
Commission Decision 2003/766/EC of 24 October 2003 on emergency measures to prevent the spread within the Community of *Diabrotica virgifera Le Conte*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) Order on undertaking measures for the prevention of spread of quarantine plant harmful organism - *Diabrotica virgifera* Le Conte (Official Gazette of the Federal Republic of Yugoslavia 23/94) Criteria for Establishing the Health Condition of Crops and Objects, Seeds, Seedlings and Planting Material **Status:** TOC not made **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Diabrotica virgifera* (Celex 32003D0766) To be adopted in 2010-2011.
Commission Decision 2004/200/EC of 27 February 2004 on measures to prevent the introduction into and the spread within the Community of Pepino mosaic virus	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** There is no act related to this Regulation **Status:** TOC not made, **In future:**

	Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Pepino mosaic virus* (Celex 32004D0200) To be adopted in 2010-2011.
Commission Decision 2006/133/EC of 13 February 2006 requiring Member States temporarily to take additional measures against the dissemination of *Bursaphelenchus xylophilus* (Steiner et Buhrer) Nickle et al. (the pine wood nematode) as regards areas in Portugal, other than those in which it is known not to occur	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Status:** TOC not made, **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Pinewood nematode* (Celex 32006D0133) To be adopted in 2010-2011.
Commission Decision 2006/464/EC of 27 June 2006 on provisional emergency measures to prevent the introduction into and the spread within the Community *of Dryocosmus kuriphilus Yasumatsu*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** There is no act related to this Regulation **Status:** TOC not made, **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Dryocosmus kuriphilus;* To be adopted in 2010-2011.
Commission Decision 2007/365/EC of 25 May 2007 on emergency measures to prevent the introduction into and the spread within the Community of *Rhynchophorus ferrugineus (Olivier)*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** There is no act related to this Regulation **Status:** TOC not made **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Rhynchophorus ferrugineus (Olivier);* To be adopted in 2010-2011.
Commission Decision 2007/410/EC of 12 June 2007 on measures to prevent the introduction into and the spread within the Community of *Potato spindle tuber viroid*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Status:** TOC not made **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Potato Spindle Tuber Viroid;* To be adopted in 2010-2011.
Commission Decision 2007/433/EC of 18 June 2007 on provisional emergency measures to prevent the introduction into and the spread within the Community of *Gibberella circinata Nirenberg*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** There is no act related to this Regulation **Status:** TOC not made, **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Gibberella circinata Nirenberg;* To be adopted in 2010-2011.
Commission Decision 2008/840/EC of 7 November 2008 on emergency measures to prevent the introduction into and the spread within the *Community of Anoplophora chinensis (Forster)*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Status:** TOC not made **In future:** Rulebook on Urgent Measures on Case of Occurrence or Introduction of *Anoplophora chinensis (Forster);* To be adopted in 2010-2011.

III Protected zones

EU	MNE
Commission Directive 92/70/EEC of 30 July 1992 laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones in the Community	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 15 paragraph 4 **Current situation:** There is no act related to this Regulation **Status:** TOC not made **In future** Rulebook on more detailed conditions for recognition and proclamation of protected areas and implementation of systemic researches in protected areas To be adopted by the end of 2012.
Commission Directive 93/51/EEC of 24 June 1993 establishing rules for movements of certain plants, plant products or other objects through a protected zone, and for movements of such plants, plant products or other objects originating in and moving within such a protected zone	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 15 paragraph 4 **Current situation:** There is no act related to this Regulation **Status:** TOC not made **In future** Rulebook on movements of certain plants, plant products and objects under supervision across protected areas and within them (Celex 31993L0051) To be adopted by the end of 2012.
Commission Regulation (EC) No 690/2008 of 4 July 2008 recognising protected zones exposed to particular plant health risks in the Community	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 15 paragraph 4 **Current situation:** There is no act related to this Regulation **Status:** TOC not made **In future** Rulebook on recognition of protected areas exposed to special risks for plant health To be adopted by the end of 2012.

IV Registration of operators – plant passports

EU	MNE
Commission Directive 92/90/EEC of 3 November 1992 establishing obligations to which producers and importers of plants, plant products or other objects are subject and establishing details for their registration	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 42 **Current situation:** **Status:** TOC not made **In future** Rulebook on Conditions for Entry in the Register of Producers, Importers, Warehouse Operators and Distributors of Certain Plants, Plant Products and Other Objects (Celex 31993L0050) To be adopted by the end of 2011 -2012.
Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 42 **Current situation:** **Status:** TOC not made **In future** The Rulebook on Establishing of Standard Plant Passports for Movement of Plants, Plant Products and Other Objects under Supervision To be adopted by the end of 2011 -2012.
Commission Directive 93/50/EEC of 24 June 1993 specifying certain plants not listed in Annex V, part A to Council Directive 77/93/EEC, the producers of which, or the warehouses, dispatching centres in the production zones of such plants, shall be listed in an official register	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 42 **Current situation:** **Status:** TOC not made **In future** The Rulebook on Certain Plants whose Producers, Warehouse Operators, Dispatch Centres in Production Zones must be registered To be adopted by the end of 2011 -2012.

V Imports, inspections and notification of interceptions

EU	MNE
Commission Decision 91/261/EEC of 2 May 1991 recognizing Australia as being free from Erwinia amylovora (Burr.) Winsl. et al.	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** There is no act related to this Regulation **Status:** **In future:** On the day of accession
Commission Decision 98/109/EC of 2 February 1998 authorising Member States temporarily to take emergency measures against the dissemination of *Thrips palmi Karny* as regards Thailand	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Current situation:** **Status:** **In future** Order on Urgent Measures for *Thrips palmi Karny* for Thailand To be adopted by the end of 2010.
Commission Decision 2002/360/EC of 13 May 2002 establishing the amendments to be made to the measures taken by Austria to protect itself against the introduction *of Anoplophora glabripennis (Motschulsky)*	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Status:** **In future:** On the day of accession
Commission Decision 2004/4/EC of 22 December 2003 authorising Member States temporarily to take emergency measures against the dissemination of *Pseudomonas solanacearum (Smith) Smith* as regards Egypt	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** **Status:** **In future:** On the day of accession
Commission Directive 2004/105/EC of 15 October 2004 determining the models of official phytosanitary certificates or phytosanitary certificates for re-export accompanying plants, plant products or other objects from third countries and listed in Council Directive 2000/29/EC	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 33 paragraph 7 **Legal act in force:** **Status**: **In future:** On the day of accession
Commission Decision 2004/416/EC of 29 April 2004 on temporary emergency measures in respect of certain citrus fruits originating in Argentina or Brazil	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** **Status**: **In future:** On the day of accession
Commission Decision 2006/473/EC of 5 July 2006 recognising certain third countries and certain areas of third countries as being free from Xanthomonas campestris (all strains pathogenic to Citrus), *Cercospora angolensis* Carv. et Mendes and Guignardia citricarpa Kiely	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraphs 5 and 6 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Status:** **In future:** On the day of accession
Commission Directive 94/3/EC of 21 January 1994 establishing a procedure for the notification of interception of a consignment or a harmful organism from third countries and presenting an imminent phytosanitary danger	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 12 paragraph 6 **Legal act in force:** **Status:** in the harmonization process **In future:** Development of a rulebook on notification of interception of consignments or harmful organisms representing phytosanitary danger (Celex 31994L0003) To be adopted in 2010-2011.
Commission Directive 95/44/EC of 26 July 1995 establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 19 paragraph 2 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Status:** in the harmonization process, Draft Rulebook on Conditions for Introduction of Harmful Organisms, Plants, Plant Products and Objects under Surveillance for Scientific Purposes has been finished (Celex 31995L0044)

	In future: To be adopted in 2010-2011.
Commission Directive 98/22/EC of 15 April 1998 laying down the minimum conditions for carrying out plant health checks in the Community, at inspection posts other than those at the place of destination, of plants, plant products or other objects coming from third countries	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) article 35 paragraph 5 **Legal act in force:** List of Quarantine Harmful Organisms (Official Gazette of the Federal Republic of Yugoslavia 42/01, 9/03) **Status:** in the harmonization process, Rulebook on Minimum of Conditions for Phytosanitary Checks of Plants, Plant Products and Establishments under Supervision (Celex 31998L0022) **In future:** To be adopted in 2010-2011.

VI Expenditure in phytosanitary field

EU	MNE
Commission Regulation (EC) No 1040/2002of 14 June 2002 establishing detailed rules for the implementation of the provisions relating to the allocation of a financial contribution from the Community for plant-health control and repealing Regulation	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) Articles 6, 14, 54, 55 Law on the Budget of Montenegro for 2009 (Official Gazette of Montenegro 82/08) **Legal act in force:** The Programme of Phytosanitary Measures for 2009 (Official Gazette of Montenegro 20/09) **Status:** postponed until accession to the EU **In future:** a rulebook on conditions for implementation of financial support in plant health protection filed will be adopted To be adopted by the end of 2010.
Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community	**Legal basis:** Law on Plant Health Protection (Official Gazette of the Republic of Montenegro 28/06) Articles 6, 14, 54, 55 **Legal act in force:** Decision on the Amount of the Fee for Health Check Carried out on Plant Consignments and Control of Pesticides and Fertilizers in Trade across the Border of FRY (Official Gazette of the Federal Republic of Yugoslavia 71/2000) The Programme of Phytosanitary Measures for 2009 (Official Gazette of Montenegro 20/09) **Status:** postponed until accession to the EU **In future:** a rulebook on conditions for implementation of financial support in plant health protection filed will be adopted To be adopted by the end of 2010.

In accordance with the Law on Plant Health Protection, the Programme of Measures of Plant Health Protection for 2008 was implemented, and the Programme of Phytosanitary Measures for 2009, implementation of which falls within the responsibility of the Phytosanitary Administration, adopted (Official Gazette of Montenegro 20/09).

Funds in the amount of 150,000 € (earmarked by the Budget of Montenegro for 2009) were earmarked for implementation of the Program of Phytosanitary Measures for 2009.

The Program of Plant Health Protection is adopted under the Program of Phytosanitary Measures, at the end of the current year for the next year.

This program includes four basic programs:

- Reporting-forecasting program and monitoring of health condition of plants, plant products and objects under supervision;
- Operational program of continuous supervision over quarantine harmful organisms;
- National Operational program of continuous supervision over non-quarantine harmful organisms and
- Urgent phytosanitary measures.

The program is implemented for the purpose of supervision over the harmful organisms, it includes the measures, the scope, the laboratory analyses necessary, the implementation period, the implementing institutions (authorized laboratories), control methods and persons responsible.

Funds for implementation of the Program of Phytosanitary Measures / Program of Plant Health Protection are provided in the budget of the Phytosanitary Administration.

The persons responsible submit the measure implementation plan, by specific measures, and have the obligation to present reports to the Phytosanitary Administration at least once a month, and in case of occurrence or detection of a quarantine harmful organisms, without delay, together with excerpts from records which include the following information:

- Name of the location,
- Number of the cadastral parcel,
- date,
- name of the plant keeper,
- records on diagnostic testing carried out, and
- results of testing.

Implementation of the Program by the authorized institution (Biotechnical Faculty / Centre for Plant Protection) and persons responsible and implementation of the Program based on the reports submitted is controlled by the phytosanitary inspectorate.

The purpose of adoption of the program is a stable plant health situation on the whole territory of Montenegro, timely detection and control of occurrence and spread of harmful organisms of plants, plant products and objects under supervision, timely, appropriate, successful and rational implementation of plant health protection measures in practice, prevention or reduction of yield losses in plant production.

The institutions in charge are the Phytosanitary Administration, the University of Montenegro / Biotechnical Faculty / - Centre for Plant Protection / Phytosanitary laboratory, Extension Service in Plant Production.

Activities are implemented by components, as follows:

Component 1.1:

With a view to ensuring the completion of tasks of reporting and forecasting of occurrence and movement of harmful organisms of plants, plant products and objects under supervision and timely notification of a plant keeper of occurrence of harmful organisms and provision of recommendations for control thereof the University of Montenegro / Biotechnical Faculty / Centre for Plant Protection / Phytosanitary Laboratory will monitor the health condition of plants, plant products and establishments under supervision and reporting – forecasting activities and at least once a month will present to the Phytosanitary Administration the report on activities on this program. The report includes, in particular, the most important issues in plant health protection on the territory of Montenegro, the main bio-climatic characteristics that were favourable for the occurrence, development and spread of harmful organisms, for harmful organisms specified the time, place and duration of the occurrence is to be stated, the species of affected plants, plant products and objects under supervision, the extent to which harmful organisms are present, the volume/area of the affected plants, plant products and objects under supervision, the intensity of the infestation and damage in percentages, the proposal of measures for control. Based on the report, the Phytosanitary Administration notifies the plant keepers of the occurrence and risk of harmful organisms and undertakes measures for prevention of spread and measures for control of harmful organisms. The responsibility for timeliness, effects and implementation lies with: University of Montenegro / Biotechnical Faculty / Centre for Plant Protection / Phytosanitary Laboratory – head of the Centre for Plant Protection, Extension Service in Plant Production – head of the Service.

Component 1.2:

Operational program of monitoring over harmful organisms is an activity clearly defined in accordance with the legal obligations and relevant regulations of the European Union, procedures of the European and Mediterranean Plant Protection (EPPO) and standards of the International Plant Protection Convention (IPPC), i.e. phytosanitary measures, particularly in specific crops (potato seed production, etc) which are of major significance for Montenegro. The University of Montenegro / Biotechnical Faculty / Centre for Plant Protection / Phytosanitary Laboratory will

monitor the health condition of plants, plant products and objects under supervision and will present to the Phytosanitary Administration the report on activities, in accordance with the laws. The responsibility for timeliness, effects and implementation lies with: University of Montenegro / Biotechnical Faculty / Centre for Plant Protection / Phytosanitary Laboratory – head of the Centre for Plant Protection.

Component 1.3:

The National operational program of monitoring over non-quarantine harmful organisms contributes to production of food safe in terms of health; first of all, program beneficiaries, farmers and phytosanitary service, have a clearer picture on harmful organisms and methods of fighting them, which contributes to reduction in number of treatments, or use of pesticides, as appropriate. The responsibility for timeliness, effects and implementation lies with: University of Montenegro / Biotechnical Faculty / Centre for Plant Protection / Phytosanitary will carry out the testing for the presence of harmful organisms for plants, with particular emphasis on:

- olive fly (Bactrocera oleae Gmel.),
- fruit fly (Ceratitis capitata Wiedemann),
- silverleaf whitefly (Bemisia tabaci Gennadius),
- grapevine cicada – phytolasma vectors,
- grapevine disease (ESCA),
- prevention of infestation of plant pests,
- invasive insect species in greenhouses,
- phytoparasitic nematodes in greenhouses, and
- viruses*.

** (Potato leaf roll virus; Potato virus Y; Potato virus X; Potato virus A; Potato virus M; Potato virus S; Tomato spotted wilt virus; Impatiens necrotic spot virus; Pepino mosaic virus; Tomato yellow leaf curl virus)*

The responsibility for timeliness, effects and implementation of the program lies with: University of Montenegro / Biotechnical Faculty / Centre for Plant Protection / Phytosanitary Laboratory – head of the Centre for Plant Protection, Extension Service in Plant Production – head of the Service.

Component 1.4:

Urgent phytosanitary measures are implemented in order to reduce the scope of damage in agricultural crops and in order to preserve the potential yield of important agricultural crops which requires, in addition to implementation of control measures (treatments with plant protection products) also the monitoring and forecasts on increase in number of populations of harmful organisms, the reporting-forecast program which contributes to a rational plant health protection (signalling the proper moment for application of the treatment, together with a recommendation on appropriate plant protection products).

The program includes monitoring of occurrence as well as the estimate of potential damage on plants, plant products and establishments under supervision, together with the analysis of samples taken, timely provision of information through the media, advice and publishing of technical publications on occurrence and the spread and the method of control of harmful organisms and instructions and guides for implementation of urgent phytosanitary measures and expenses of international co-operation.

With a view to prompt reactions in cases of unexpected and sudden outbreak of quarantine and regulated harmful organisms of plants, plant products and establishments under supervision, which cannot be forecasted, but which require immediate implementation of urgent phytosanitary measures in order to protect the plant health and prevent more extensive economic damage, urgent supply of equipment and materials necessary would take place, and appropriate technical activities would be implemented in the field, as well as laboratory testing services. Implementation of these activities would depend on the situation and requirements that the emergency imposes, in

line with instructions and orders from the Phytosanitary Administration.

At this moment, contingency plans for certain harmful organisms, in accordance with the EU requirements, are not in place. In 2010, the Operational Program for Urgent Phytosanitary Measures will be adopted, which will provide a platform for prompt adoption of specific programs for urgent phytosanitary measures.

According to the plans, the Operational Program for Urgent Phytosanitary Measures will include and elaborate the following:

- General information and program planning process;
- Appraisal of the report on danger from harmful organisms;
- Emergency plans;
- Obligation of reporting and exchange of information;
- System of decision-making as regard eradication program;
- Program launch;
- Identification of a harmful organism;
- Appraisal of the current and potential distribution of the harmful organism,
- Starting analysis;
- Data from the location of detection/occurrence of harmful organisms;
- Geographic origin,
- Ways of spreading of harmful organism;
- Distribution overview;
- Forecasts on spreading of a harmful organism;
- Justification for implementation of eradication program;
- Biological and economic information;
- Strengths and weakness analysis for eradication program;
- Eradication process;
- Establishing of a management team;
- Implementation of an eradication program;
- Supervision, isolation;
- Treatment and/or control measures;
- Eradication check;
- Documentation, and
- Program revision.

The Law on Plant Health Protection lays down the obligation of compensating the plant keepers the damage caused by control and eradication of quarantine harmful organisms. The damage is paid in the amount equal to the market value on the day the damage was caused, in accordance with a decision of the Committee on Damages.

Program of Phytosanitary Measures for 2009 (Official Gazette of Montenegro 20/09)

	Plant health protection program	**Value in €**
1.1	Reporting-forecasting program and monitoring of plant health condition	5,000.00
1.2	Operational program of monitoring over quarantine harmful organisms	49,000.00
1.3	National Operational Program of Monitoring over non-quarantine harmful organisms	

	Olive fly - *Bactrocera oleae Gmel*	10,000.00
	Mediterranean fruit fly - *Ceratitis capitata Wiedemann*	5,000.00
	Silverleaf whitefly - *Bemisia tabaci Gennadius*	8,000.00
	Grape vine cicada – phytoplasm vectors	10,000.00
	Grape vine disease - ESKA	5,000.00
	Prevention of plant pest infestations	5,000.00
	Invasive insect species in greenhouses	5,000.00
	Phytoparasitic nematodes in greenhouses	10,000.00
	Viruses*	10,000.00
1.4	Urgent in Phytosanitary Measures and Damages	28,000.00
	Total:	150,000.00

* *(Potato leaf roll virus; Potato virus Y; Potato virus X; Potato virus A; Potato virus M; Potato virus S; Tomato spotted wilt virus; Impatiens necrotic spot virus; Pepino mosaic virus; Tomato yellow leaf curl virus)*

STATUS OF HARMFUL ORGANISMS FROM THE EU ACQUIS LISTS COMPARED TO THE STATUS OF HARMFUL ORGANISMS IN MONTENEGRO BEFORE THE GOVERNMENT OF MONTENEGRO ADOPTED THE RULEBOOK ON MEASURES FOR PREVENTION OF INTRODUCTION AND SPREAD OF ORGANISMS HARMFUL TO PLANTS AND PLANT PRODUCTS AND OBJECTS UNDER SUPERVISION IN ACCORDANCE WITH THE ANNEXES OF THE COUNCIL DIRECTIVE 2000/29/EC

(a) Insects, mites and nematodes, at all stages of their development

EU status I/AI	MNE status
1.*Acleris spp.* (non-European species)	*Acleris gloverana and variana* **A1**
2.*Amauromyza maculosa* (Malloch)	**A1**
3.*Anomala* (*Blitopertha*) *orientalis* Waterhouse	**A1**
4.*Anoplophora chinensis* (Thomson)	**A1**
4.1. *Anoplophora glabripennis* (Motschulsky)	**A1**
5. *Anoplophora malasiaca* (Forster)	**A1**
6. *Arrhenodes minutus* Drury	**A1**
7.*Bemisia tabaci* Genn. (non-European populations), vectors of viruses such as: (a) Bean golden mosaic virus (b) Cowpea mild mottle virus (c) Lettuce infectious yellows virus (d) Pepper mild tigré virus (e) Squash leaf curl virus (f) Euphorbia mosaic virus (g) Florida tomato virus	*Bemisia tabaci* (non-European) **A1**
8. Cicadellidae (non-European species) known as vectors of Pierce disease (agent Xylella fastidiosa), such as: (a) *Carneocephala fulgida* Nottingham (b) *Draeculacephala minerva* Ball (c) *Graphocephala atropunctata* (Signoret)	**A1**
9. *Choristoneura spp*. (non-European species)	*Choristoneura conflictana,* **A1** *Choristoneura fumiferana* **A1** *Choristoneura occidentalis* **A1** *Choristoneura rosaceana* **A1**
10. *Conotrachelus nenuphar* (Herbst)	**A1**
10.0 *Dendrolimus sibiricus* Tschetverikov **Directive 2009/7/EC of 10 February 2009**	**not regulated**
10.1. *Diabrotica barberi* Smith et Lawrence	**A1**
10.2. *Diabrotica undecimpunctata howardi* Barber	*Diabrotica undecimpunctata* **A1**
10.3. *Diabrotica undecimpunctata undecimpunctata* Mannerheim	
10.4. *Diabrotica virgifera zeae* Krysan & Smith **Directive 2009/7/EC of 10 February 2009**	**not regulated**
11. *Heliothis* (*Helicoverpa*) *zea* (Boddie**)**	**A1**
11.1. *Hirschmanniella* spp., except *Hirschmanniella gracilis* (de Man) Luc et Goodey	*Hirschmanniella* spp **A1**
12. *Liriomyza sativae* Blanchard	**A1**
13. *Longidorus diadecturus* Eveleigh et Allen	**not regulated**
14. *Monochamus spp.* (non-European species)	**A1**
15. *Myndus crudus* Van Duzee	**A1**
16. *Nacobbus aberrans* (Thorne) Thorne et Allen	**A1**

16.1.	*Naupactus leucoloma* Boheman	**A1**
17.	*Premnotrypes* spp. (non-European species)	**A1**
18.	*Pseudopityophthorus minutissimus* (Zimmermann)	**A1**
19.	*Pseudopityophthorus pruinosus* (Eichhoff)	**A1**
19.1. *Rhynchophorus palmarum* (L.) **Directive 2009/7/EC of 10 February 2009**		**not regulated**
20.	*Scaphoideus luteolus* (Van Duzee)	**A1**
21.	*Spodoptera eridania* (Cramer)	**A1**
22.	*Spodoptera frugiperda* (Smith)	**A1**
23.	*Spodoptera litura* (Fabricius)	**A1**
24.	*Thrips palmi* Karny	**A1**
25.	Tephritidae (non-European species), such as:	
(a)	*Anastrepha fraterculus* (Wiedemann)	
(b)	*Anastrepha ludens* (Loew)	
(c)	*Anastrepha obliqua* Macquart	
(d)	*Anastrepha suspensa* (Loew)	
(e)	*Dacus ciliatus* Loew	
(f)	*Dacus cucurbitae* Coquillet	*Dacus* (*Bactrocera*) *cucurbitae* Coquillet
(g)	*Dacus dorsalis* Hendel	*Dacus* (*Bactrocera*) *dorsalis* Hendel
(h)	*Dacus tryoni* (Froggatt)	*Dacus* (*Bactrocera*) *tryoni* (Froggatt)
(i)	*Dacus tsuneonis* Miyake	*Dacus* (*Bactrocera*) *tsuneonis* Miyake
(j)	*Dacus zonatus* Saund.	
(k)	*Epochra canadensis* (Loew)	
(l)	*Pardalaspis cyanescens* Bezzi	
(m)	*Pardalaspis quinaria* Bezzi	
(n)	*Pterandrus rosa* (Karsch)	*Pterandrus* (*Ceratitis*) *rosa* (Karsch)
(o)	*Rhacochlaena japonica* Ito	
(p)	*Rhagoletis cingulata* (Loew)	**Synonyms for species given in brackets**
(q)	*Rhagoletis completa* Cresson	
(r)	*Rhagoletis fausta* (Osten-Sacken)	
(s)	*Rhagoletis indifferens* Curran	
(t)	*Rhagoletis mendax* Curran	
(u)	*Rhagoletis pomonella* Walsh	
(v)	*Rhagoletis ribicola* Doane	**All Tephritidaea from the EU list included in the MNE A1 list**
(w)	*Rhagoletis suavis* (Loew)	
26.	*Xiphinema americanum* Cobb *sensu lato* (non-European populations)	**A1**
27.	*Xiphinema californicum* Lamberti et Bleve-Zacheo	**A1**

(b) Bacteria

1.	*Xylella fastidiosa* (Well et Raju)	**A1**

(c) Fungi

1.	*Ceratocystis fagacearum* (Bretz) Hunt	**A1**
2.	*Chrysomyxa arctostaphyli* Dietel	**A1**
3.	*Cronartium spp.* (non-European species)	*Cronartium coleosporioides* *Cronartium comandrae* *Cronartium comptoniae* *Cronartium fusiforne* **A1** *Cronartium hilamayense* *Cronartium kamtschhaticum* *Cronartium qurcum*
4.	*Endocronartium* spp. (non-European species)	*Endocronartium harknessii* **A1**
5.	*Guignardia* (*botryosphaeria*) *laricina* (Saw.) Yamamoto et Ito	**A1**
6.	*Gymnosporangium* spp. (non-European species)	*Gymnosporangium asiaticum* *Gymnosporangium clavipes* *Gymnosporangium globosum* **A1** *Gymnosporangium juniperi-virginianae* *Gymnosporangium yamadae*
7.	*Inonotus weirii* (Murril) Kotlaba et Pouzar	*Phellinus weirii* **A1**
8.	*Melampsora farlowii* (Arthur) Davis	**A1**
9.	*Monilinia fructicola* (Winter) Honey	**A1**
10.	*Mycosphaerella larici-leptolepis* Ito et al.	**A1**
11.	*Mycosphaerella populorum* G. E. Thompson	**A1**

12.	*Phoma andina* Turkensteen	**A1**
13.	*Phyllosticta solitaria* Ell. et Ev.	**A1**
14.	*Septoria lycopersici* Speg. var. malagutii Ciccarone et Boerema	**A1**
15.	*Thecaphora solani* Barrus	**A1**
15.1.	*Tilletia indica* Mitra	**A1**
16.	*Trechispora brinkmannii* (Bresad.) Rogers	*Phymatotrichopsis omnivore* **A1**

d) Virus and virus-like organisms

1.	Elm phlöem necrosis phytoplasma (mycoplasm)	Prokaryots **A1**
2.	Potato viruses and virus-like organisms, such as:	
(a)	Andean potato latent virus	Potato Andean latent tymovirus
(b)	Andean potato mottle virus	Potato Andean mottle comovirius
(c)	Arracacha virus B, oca strain	Arracacha potato nepovirus B
(d)	Potato black ringspot virus	Potato black ringspot nepovirus **A1**
(e)	Potato spindle tuber viroid	Potato spindle tuber viroid
(f)	Potato virus T	Potato trichvirus
(g)	Non-European isolates of potato virus A, M, S, V, X and Y (including Yo, Yn and Yc) and Potato leafroll virus	on list **A1** (Official Gazette of Federal Republic of Yugoslavia 8/99)
3.	Tobacco ringspot virus	Tobacco ringspot nepovirus **A1**
4.	Tomato ringspot virus	on list **A1** (Official Gazette of Federal Republic of Yugoslavia 8/99)
5.	Viruses and virus-like organisms on plants from genuses *Cydonia* Mill., *Fragaria* L., *Malus* Mill., *Prunus* L., *Pyrus* L., *Ribes* L., *Rubus* L. and *Vitis* L., such as:	
(a)	Blueberry leaf mottle virus	Blueberry leaf mottle nepovirus
(b)	Cherry rasp leaf virus (American)	Cherry rasp leaf nepovirus
(c)	Peach mosaic virus (American)	Peach mosaic closterovirus (American)
(d)	Peach phony rickettsia	Peach phony rickettsia
(e)	Peach rosette mosaic virus	Peach rosette mosaic nepovirus
(f)	Peach rosette phytoplasma (mycoplasm)	Peach rosette phytoplasma – prokaryots
(g)	Peach X-disease phytoplasma (mycoplasm)	Peach X-disease phytoplasma – prokaryots
(h)	Peach yellows phytoplasma (mycoplasm)	Peach yellows phytoplasma – prokaryots
(i)	Plum line pattern virus (American)	Plum line pattern ilarvirus (American)
(j)	Raspberry leaf curl virus (American)	Raspberry leaf curl luteovirus **A1**
(k)	Strawberry latent »C« virus	Strawberry latent »C« rhabdovirus
(l)	Strawberry vein banding virus	Strawberry vein banding caulimovirus
(m)	Strawberry witches' broom phytoplasma (mycoplasm)	Strawberry witches' broom phytoplasma – prokaryots **A1**
(n)	Non-European viruses and virus-like organisms coming on plants from genuses *Cydonia* Mill., *Fragaria* L., *Malus* Mill., *Prunus* L., *Pyrus* L., *Ribes* L., *Rubus* L. and *Vitis* L.	Non-European viruses and virus-like organisms on list **A1** (Official Gazette of Federal Republic of Yugoslavia 8/99)
6.	Viruses carried by *Bemisia tabaci* Genn., such as:	
(a)	Bean golden mosaic virus	Bean golden mosaic bigemivirus **A1**
(b)	Cowpea mild mottle virus	Cowpea mild mottle carlavirus **A1**
(c)	Lettuce infectious yellows virus	Lettuce infectious yellows closterovirus A**1**
(d)	Pepper mild tigré virus	Pepper mild tigré begomovirus **A1**
(e)	Squash leaf curl virus	Squash leaf curl begomovirus **A1**
(f)	Euphorbia mosaic virus	Euphorbia begomovirus on A1 list (Official Gazette of Federal Republic of Yugoslavia 8/99)
(g)	Florida tomato virus	on list **A1** (Official Gazette of Federal Republic of Yugoslavia 8/99)

I/All

(a) Insects, mites and nematodes at all stages of their development

EU status		**MNE status**
0.1	*Diabrotica virgifera* Le Conte	**A2**
1.	*Globodera pallida* (Stone) Behrens **	**A2**
2.	*Globodera rostochiensis* (Wollenweber) Behrens **	**A2**
– – –		
6.1.	*Meloidogyne chitwoodi* Golden et al. (all populations) **	**A2**
6.2.	*Meloidogyne fallax* Karssen**	**A2**
7.	*Opogona sacchari* (Bojer)	**A1**
8.	*Popillia japonica* Newman **	**A1**

8.1. *Rhizoecus hibisci* Kawai et Takagi **	**A1**
9. *Spodoptera littoralis* (Boisduval) **	**A1**

(b) bacteria

1. *Clavibacter michiganensis* (Smith) Davis *et al*. ssp. *sepedonicus* (Spieckermann and Kotthoff) Davis *et al*.	**A1**
2. *Pseudomonas solanacearum* (Smith) Smith	Ralstonia *solanacearum* (Smith) Yabuuchi et al. **A1**

(c) Fungi

1. *Melampsora medusae* Thümen	**A1**
2. *Synchytrium endobioticum* (Schilbersky) Percival	**A1**

(d) Viruses and virus-like organisms

1. Apple proliferation mycoplasm	**A1**
2. Apricot chlorotic leafroll mycoplasm	**A1**
3. Pear decline mycoplasm	**A1**

** for harmful organisms marked with asterisks, there are no data on their presence in Montenegro

List II
AI

(a) Insects, mites and nematodes, at all stages of their development

		EU status / MNE status
Species	**Subject of infection**	
1. *Aculops fuchsiae* Keifer	Plants of *Fuchsia* L., intended for planting	**A1**
1.1. *Agrilus planipennis* Fairmaire	Plants of intended for planting in culture of tissue and seed, wood and bark of *Fraxinus* L., *Juglans mandshurica* Maxim., *Ulmus davidiana* Planch., *Ulmus parvifolia* Jacq. and *Pterocarya rhoifolia* Siebold & Zucc., originating in Canada, China, Japan, Mongolia, Republic of Korea, Russia, Taiwan and USA	**not regulated**
2. *Aleurocanthus* spp.	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	*Aleurocanthus spiniferus* *Aleurocanthus woglumi* **A1**
3. *Anthonomus bisignifer* (Schenkling)	Plants of *Fragaria* L., intended for planting	**A1**
4. *Anthonomus signatus* (Say)	Plants of *Fragaria* L., intended for planting	**A1**
5. *Aonidiella citrina* Coquillet	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**
6. *Aphelenchoides besseyi* Christie [1]	Seeds of *Oryza* spp.	**not regulated**
7. *Aschistonyx eppoi* Inouye	Plants of *Juniperus* L., other than fruits and seeds, originating in non-European countries	**not regulated**
8. *Bursaphelenchus xylophilus* (Steiner et Buhrer) Nickle *et al*.	Plants of *Abies* Mill., *Cedrus* Trew, *Larix* Mill., *Picea* A. Dietr., *Pinus* L., *Pseudotsuga* Carr. and *Tsuga* Carr., other than fruits and seeds i coniferous tree wood *(Coniferales)* originating in non-European countries	**A1**
9. *Carposina niponensis* Walsingham	Plants of *Cydonia* Mill., *Malus* Mill., *Prunus* L. and *Pyrus* L., other than seeds, originating in non-European countries	**A1**
10. *Diaphorina citri* Kuway	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids and *Murraya* König, other than fruits and seeds	**A1**
11. *Enarmonia packardi* (Zeller)	Plants of *Cydonia* Mill., *Malus* Mill., *Prunus* L. and *Pyrus* L., other than seeds, originating in non-European countries	**not regulated**
12. *Enarmonia prunivora* Walsh	Plants of *Crataegus* L., *Malus* Mill., *Photinia* Ldl., *Prunus* L. and *Rosa* L., intended for planting, and fruits of plants *Malus* Mill. And *Prunus* L., originating in non-European countries	**not regulated**
13. *Eotetranychus lewisi* McGregor	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**A1**

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15. *Grapholita inopinata* Heinrich	Plants of *Cydonia* Mill., *Malus* Mill., *Prunus* L. and *Pyrus* L., other than seeds, originating in non-European countries	*Cydia inopinata* Heinrich **A1**
16. *Hishomonus phycitis* (Distant)	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**
17. *Leucaspis japonica* Ckll.	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	*Lopholeucaspis japonica* Ckll. **A2**
18. *Listronotus bonariensis* (Kuschel)	Seeds of *Brassicaceae (Cruciferae), Poaceae (Gramineae)* i *Trifolium* spp. originating in Argentina, Australia, Bolivia, Chile, New Zealand and Uruguay	**A1**
19. *Margarodes*, non-European species, such as: (a) *Margarodes vitis* (Phillipi) (b*) Margarodes vredendalensis* de Klerk (c) *Margarodes prieskaensis* Jakubski	Plants of *Vitis* L., other than fruits and seeds	**A1**
20. *Numonia pyrivorella* (Matsumura)	Plants of *Pyrus* L., other than seeds, originating in non-European countries	**A2**
21. *Oligonychus perditus* Pritchard et Baker	Plants of *Juniperus* L., other than fruits and seeds, originating in non-European countries	**A1**
22. *Pissodes* spp. (non-European species)	Conifers *(Coniferales),* other than fruits and seeds, wood of conifers *(Coniferales)* with bark and isolated bark of conifers *(Coniferales),* originating in non-European countries	*Pissodes nemorensis* *Pissodes strobe* *Pissodes terminalis* **A1**
23. *Radopholus citrophilus* Huettel Dickson et Kaplan	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, other than fruits and seeds, and plant *Araceae, Marantaceae*, *Musaceae, Persea* spp., *Strelitziaceae*, rooted or together with growing substrate attached or associated	**A1**
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25. *Scirtothrips aurantii* Faure	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than seeds	**A1**
26. *Scirtothrips dorsalis* Hood	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**A1**
27. *Scirtothrips citri* (Moultex)	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than seeds	**A1**
28. Scolytidae spp. (non-European species)	Conifers (*Coniferales*), over 3 m in height, wood of conifers (*Coniferales*) with bark and isolated bark of conifers (*Coniferales*), originating in non-European countries	**A1**
28.1. *Scrobipalpopsis solanivora* Povolny	Tubers of *Solanum tuberosum* L.	**not regulated**
29. *Tachypterellus quadrigibbus* Say	Plants of *Cydonia* Mill., *Malus* Mill., *Prunus* L. i *Pyrus* L., other than seeds, originating in non-European countries	**not regulated**
30. *Toxoptera citricida* Kirk.	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**A1**
31. *Trioza erytreae* Del Guercio	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, and *Clausena* Burm. f., other than fruits and seeds	**A1**
32. *Unaspis citri* Comstock	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**A1**

[1] Species not present on seeds of *Oryza spp* in EU

b) Bacteria

Species	Subject of infection	
1. Citrus greening bacterium	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**A1**
2. Citrus variegated chlorosis	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**

3. *Erwinia stewartii* (Smith) Dye	Seeds of *Zea mays* L.	*Pantoea stewartii subsp. stewartii* (Smith) Mergaert et al. **A1**
4. *Xanthomonas campestris* (all strains pathogenic to *Citrus genus*)	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than seeds	*Xanthomonas axonopodis pv. citri* (Hasse) Vauterin et al **A1**
5. *Xanthomonas campestris* pv. *oryzae* (Ishiyama) Dye and pv. *oryzicola* (Fang. *et al*.) Dye	Seeds of *Oryza* spp.	**not regulated**

(c) Fungi

Species	**Subject of contamination**	
1. *Alternaria alternata* (Fr.) Keissler (non-European pathogenic isolates)	Plants of *Cydonia* Mill., *Malus* Mill. and *Pyrus* L. intended for planting, originating in non-European countries	**not regulated**
1.1. *Anisogramma anomala* (Peck) E. Müller	Plants of *Corylus* L. intended for planting, originating in Canada and USA	**A1**
2. *Apiosporina morbosa* (Schwein.) v. Arx	Plants of *Prunus* L. intended for planting	**A1**
3. *Atropellis* spp.	Plants of *Pinus* L., other than fruit and seeds, isolated bark and wood of *Pinus* L.	*Atropellis pinicola* *Atropellis piniphila* **A1**
4. *Ceratocystis virescens* (Davidson) Moreau	Plants of *Acer saccharum* Marsh., other than fruits and seeds, originating in USA and Canada; wood of *Acer saccharum* Marsh., including wood that has not kept its natural round surface, originating in USA and Canada	**not regulated**
5. *Cercoseptoria pini-densiflorae* (Hori et Nambu) Deighton	Plants of *Pinus* L., other than fruits and seeds, and wood of *Pinus* L.	*Mycosphaerella gibsonii* **A1**
6. *Cercospora* (*Phaeoramularia*) *angolensis* Carv. et Mendes	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than seeds	**not regulated**
7. *Ciborinia camelliae* Kohn	Plants of *Camellia* L., intended for planting, originating in non-European countries	**not regulated**
8. *Diaporthe vaccinii* Shaer	Plants of *Vaccinium* spp., intended for planting	**A1**
9. *Elsinoe* spp. Bitanc. et Jenk. Mendes	Plants of *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds; Plants of *Citrus* L. and their hybrids, other than seeds and fruit, except fruits of *Citrus reticulata* Blanco and *Citrus sinensis* (L.) Osbeck originating in South America	**A1**
10. *Fusarium oxysporum* f. sp. *albedinis* (Kilian et Maire) Gordon	Plants of *Phoenix* spp., other than fruits and seeds	**not regulated**
11. *Guignardia citricarpa* Kiely (all strains pathogenic for *Citrus genus*)	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than seeds	**A1**
12. *Guignardia piricola* (Nosa) Yamamoto	Plants of *Cydonia* Mill., *Malus* Mill., *Prunus* L. and *Pyrus* L., other than seeds, originating in non-European countries	**not regulated**
13. *Puccinia pittieriana* Hennings	Plants of *Solanaceae family,* other than fruits and seeds	**A1**
14. *Scirrhia acicola* (Dearn.) Siggers	Plants of *Pinus* L., other than fruits and seeds	**not regulated**
14.1. Stegophora ulmea (Schweinitz: Fries)	Plants of *Ulmus* L. and *Zelkova* L., intended for planting, other than seed	**not regulated**
15. *Venturia nashicola* Tanaka et Yamamoto	Plants of *Pyrus* L., intended for planting, originating in non-European countries	**not regulated**

(d) Virus and virus-like organisms

Species	Subject of infection	
1. Beet curly top virus (non-European isolates)	Plants of *Beta vulgaris* L., intended for planting	Beet curly top hybrigeminivirus **A1**
2. Black raspberry latent virus	Plants of *Rubus* L., intended for planting	Black raspberry latent ilarvirus **A1**
3. Blight and blight-like organisms (Citrus blight disease)	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**
4. Cadang-cadang viroid	Plants of *Arecaceae (Palmae),* intended for planting, originating in non-European countries	**not regulated**
5. Cherry leafroll virus[2]	Plants of *Rubus* L., intended for planting	Cherry leaf roll nepovirus **A1**
5.1. Chrysanthemum stem necrosis virus Plants of *Dendranthema* (DC.) Des Moul. and	Plants of *Dendranthema* (DC.) Des Moul. I *Lycopersicon lycopersicum* (L.) Karsten ex Farw., intended for planting, other than seeds	**not regulated**
6. Citrus mosaic virus	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf., and their hybrids, other than fruits and seeds	Citrus mosaic badnavirus **A1**
7. Citrus tristeza virus (non-European isolates)	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	Citrus tristeza closterovirus **A1**
8. Leprosis	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	Citrus leprosies rhabdovirus **A1**
9. Little cherry pathogen (non-European isolates)	Plants of *Prunus cerasus* L., *Prunus avium* L., *Prunus incisa* Thunb., *Prunus sargentii* Rehd., *Prunus serrula* Franch., *Prunus serrulata* Lindl., *Prunus speciosa* (Koidz.) Ingram, *Prunus subhirtella* Miq., *Prunus yedoensis* Matsum., and hybrids and cultivars thereof, intended for planting	Cherry little cherry 'virus' **A1**
10. Naturally spreading psorosis	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	Citrus ringspot virus **A1**
11. Palm lethal yellowing mycoplasm	Plants of *Arecaceae* (*Palmae),* intended for planting, originating in non-European countries	**A1**
12. Prunus necrotic ringspot virus[3]	Plants of *Rubus* L., intended for planting	Apple mosaic ilarvirus **A1**
13. Satsuma dwarf virus	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	Satsuma dwarf nepovirus **A1**
14. Tatter leaf virus	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	Citrus tatter leaf capillovirus **A1**
15. Witches' broom (MLO)/	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**

[2]Cherry leafroll virus not present on *Rubus* L. in the EU

[3]Prunus necrotic ringspot virus not present in *Rubus* L. in the EU

II/AI

(a) Insects, mites and nematodes at all stages of their development

Species	Subject of contamination	
1. *Aphelenchoides besseyi* Christie	Plants of *Fragaria* L., intended for planting	**A2**
2. *Daktulosphaira vitifoliae* (Fitch)	Plants of *Vitis* L., other than fruits and seeds	*Viteus vitifolie* **A2**
3. *Ditylenchus destructor* Thorne	Flower bulbs and corms of *Crocus* L., miniature cultivars and their hybrids of the genus *Gladiolus* Tourn. ex L., such as *Gladiolus callianthus* Marais, *Gladiolus colvillei* Sweet, *Gladiolus nanus* hort., *Gladiolus ramosus* hort., *Gladiolus tubergenii* hort., *Hyacinthus* L., *Iris* L., *Tigridia* Juss., *Tulipa* L., intended for planting and potato tubers (*Solanum tuberosum* L.), intended for planting	**not regulated**

4. *Ditylenchus dipsaci* (Kühn) Filipjev	Seeds and bulbs of *Allium ascalonicum* L., *Allium cepa* L. and *Allium schoenoprasum* L., intended for planting and plants of *Allium porrum* L., intended for planting, bulbs and corms of *Camassia* Lindl., *Chionodoxa* Boiss., *Crocus flavus* Weston 'Golden Yellow', *Galanthus* L., *Galtonia candicans* (Baker) Decne, *Hyacinthus* L., *Ismene* Herbert, *Muscari* Miller, *Narcissus* L., *Ornithogalum* L., *Puschkinia* Adams, *Scilla* L., *Tulipa* L., intended for planting and seed of *Medicago sativa* L.	**A2**
5. *Circulifer haematoceps*	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**
6. *Circulifer tenellus*	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**
6.1.*Eutetranychus orientalis* Klein	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**A1**
6.2. *Helicoverpa armigera* (Hübner) Plants of *Dendranthema* (DC.) Des Moul	*Dianthus* L., *Pelargonium* l'Hérit. ex Ait. and *Solanaceae* family intended for planting other than seeds	**A2**
6.3. *Parasaissetia nigra* (Nietner) Plants of *Citrus* L., *Fortunella* Swingle,	*Poncirus* Raf., and its hybrids, except fruit and seeds	not regulated
7. *Radopholus similis* (Cobb) Thorne	Plants of *Araceae, Marantaceae, Musaceae, Persea* spp.*, Strelitziaceae*, rooted or together with growing substrate attached or associated	**A2**
8. *Liriomyza huidobrensis* (Blanchard)	Cut flowers, foliage vegetables *Apium graveolens* L. and plants of herbaceous plant species intended for planting, other than: – bulbs, – corms, – plants from the family of *Poaceae (Gramineae)*	**A1**
9. *Liriomyza trifolii* (Burgess)	Cut flowers, foliage vegetables *Apium graveolens* L. and plants of herbaceous plant species, intended for planting, other than: – bulbs, – corms, – plants from the family *Poaceae (Gramineae)*	**not regulated**

(b) Bacteria

Species	**Subject of infection**	
1. *Clavibacter michiganensis* spp. *insidiosus* (McCulloch) Davis *et al*.	Seeds of *Medicago sativa* L.	**A1**
2. *Clavibacter michiganensis* spp. *michiganensis* (Smith) Davis *et al*.	Plants of *Lycopersicon lycopersicum* (L.) Karsten ex Farw., intended for planting	**A2**
3. *Erwinia amylovora* (Burr.) Winsl. et al.	Plants of *Amelanchier* Med., *Chaenomeles* Lindl., *Cotoneaster* Ehrh., *Crataegus* L., *Cydonia* Mill., *Eriobotrya* Lindl., *Malus* Mill., *Mespilus* L., *Photinia davidiana* (Dcne.) Cardot, *Pyracantha* Roem., *Pyrus* L. and *Sorbus* L., intended for planting	**not regulated**
4. *Erwinia chrysanthemi* pv. *dianthicola* (Hellmers) Dickey	Plants of *Dianthus* L., intended for planting	*Erwinia chrysanthemi* Burkholder et al **A2**
5.*Pseudomonas caryophylli* (Burkholder) Starr i Burkholder	Plants of *Dianthus* L., intended for planting	**not regulated**
6. *Pseudomonas syringae* pv. *persicae* (Prunier *et al.*) Young *et al*.	Plants of *Prunus persica* (L.) Batsch and *Prunus persica* var. *nectarina* (Ait.) Maxim, intended for planting	**A1**
7. *Xanthomonas campestris* pv. *phaseoli* (Smith) Dye	Seeds of *Phaseolus* L.	**not regulated**
8. *Xanthomonas campestris* pv. *pruni* (Smith) Dye	Plants of *Prunus* L., intended for planting	Xanthomonas arboricola pv. pruni (Smith) Vauterin et al. **A2**
9. *Xanthomonas campestris* pv. *vesicatoria* (Doidge) Dye	Plants of *Lycopersicon lycopersicum* (L.) Karsten ex Farw. i *Capsicum* spp., intended for planting	**not regulated**

10. *Xanthomonas fragariae* Kennedy et King	Plants of *Fragaria* L., intended for planting	**A1**
11. *Xylophilus ampelinus* (Panagopoulos) Willems *et al.*	Plants of *Vitis* L., other than fruits and seeds	**A1**

(c) Fungi

Species	**Subject of infection**	
1. Ceratocystis fimbriata f. sp. *platani* Walter	Plants of *Platanus* L., intended for planting, wood of *Platanus* L., including wood which has not kept its natural round surface	**A1**
2. *Colletotrichum acutatum* Simmonds	Plants of *Fragaria* L., intended for planting	**not regulated**
3. *Cryphonectria parasitica* (Murrill) Barr	Plants of *Castanea* Mill. i *Quercus* L., intended for planting, and wood and isolated bark of *Castanea* Mill.	**not regulated**
4. *Didymella ligulicola* (Baker, Dimock et Davis) v. Arx	Plants of *Dendranthema* (DC.) Des Moul., intended for planting	**not regulated**
5. *Phialophora cinerescens* (Wollenweber) van Beyma	Plants of *Dianthus* L., intended for planting	**not regulated**
6. *Phoma tracheiphila* (Petri) Kanchaveli et Gikashvili	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than seeds	**not regulated**
7. *Phytophthora fragariae* Hickmann var. *fragariae*	Plants of *Fragaria* L., intended for planting	**not regulated**
8. *Plasmopara halstedii* (Farlow) Berl. et de Toni	Seeds of *Helianthus annuus* L.	**not regulated**
9. *Puccinia horiana* Hennings	Plants of *Dendranthema* (DC.) Des Moul., intended for planting	**not regulated**
10. *Scirrhia pini* Funk et Parker	Plants of *Pinus* L., intended for planting	**not regulated**
11. *Verticillium albo-atrum* Reinke et Berthold	Plants of *Humulus lupulus* L., intended for planting	**not regulated**
12. *Verticillium dahliae* Klebahn	Plants of *Humulus lupulus* L., intended for planting	**not regulated**

(d) Viruses and virus-like organisms

Species	**Subject of infection**	
1. Arabis mosaic virus	Plants of *Fragaria* L. i *Rubus* L., intended for planting	**not regulated**
2. Beet leaf curl virus	Plants of *Beta vulgaris* L., intended for planting	Beet leaf curl virus **A1**
3. Chrysanthemum stunt viroid	Plants of *Dendranthema* (DC.) Des Moul., intended for planting	**A1**
4. Citrus tristeza virus (European isolates)	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**A1**
5. Citrus vein enation woody gall	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**
6. Grapevine flavescence dorée MLO	Plants of *Vitis* L., other than fruits and seeds	**A1**
7. Plum pox virus	Plants of *Prunus* L., intended for planting	**not regulated**
8. Potato stolbur phytoplasma	Plant from the family of *Solanaceae*, intended for planting	**not regulated**
9. Raspberry ringspot virus	Plants of *Fragaria* L. i *Rubus* L., intended for planting	**A2**
10. *Spiroplasma citri* Saglio *et al.*	Plants of *Citrus* L., *Fortunella* Swingle, *Poncirus* Raf. and their hybrids, other than fruits and seeds	**not regulated**
11. Strawberry crinkle virus	Plants of *Fragaria* L., intended for planting	**not regulated**
12. Strawberry latent ringspot virus	Plants of *Fragaria* L. i *Rubus* L., intended for planting	**not regulated**
13. Strawberry mild yellow edge virus	Plants of the genus *Fragaria* L., intended for planting	**not regulated**
14. Tomato black ring virus	Plants of *Fragaria* L. i *Rubus* L., intended for planting	**A1**
15. Tomato spotted wilt virus	Plants of *Apium graveolens* L., *Capsicum annuum* L., *Cucumis melo* L.,	

	Dendranthema (DC.) Des Moul., all varieties of New Guinea hybrids from the genuses *Impatiens*, *Lactuca sativa* L., *Lycopersicon lycopersicum* (L.) Karsten ex Farw., *Nicotiana tabacum* L., for which there is evidenced that they are intended for sale to professional tobacco growers, *Solanum melongena* L. and *Solanum tuberosum* L., intended for planting	**not regulated**
16. Tomato yellow leaf curl virus	Plants of *Lycopersicon lycopersicum* (L.) Karsten ex Farw., intended for planting	**A1**

Harmful organisms from lists I and II part B have not been addressed

Harmful organisms included in MNE lists A1 and A2, but are not in EU lists I and II:

A1

Insects and mites

16. *Anthonomus eugenii*
17. *Anthonomus grandis*
20. *Bactrocera cucumis*
23. *Bactrocera minax*
27. *Blitopertha orientalis*
28. *Cacyreus marshalli*
29. *Callosobruchus analis L.*
30. *Callosobruchus chinensis (L.)*
31. *Callosobruchus maculatus (F.)*
34. *Cecidophyopsis ribis (Westwood)*
48. *Dendroctonus adjunctus*
49. *Dendroctonus brevicomis*
50. *Dendroctonus frontalis*
51. *Dendroctonus ponderosae*
52. *Dendroctonus pseudotsugae*
53. *Dendroctonus rufipennis*
58. *Dryocoetes confusus*
59. *Gnathotrichus sulcatus*
61. *Echinothrips americanus Morgan*
66. *Eutetranychus orientalis*
68. *Heteronychus arator*
70. *Ips calligraphus*
71. *Ips confusus*
72. *Ips grandicollis*
73. *Ips lecontei*
74. *Ips pini*
75. *Ips plastographus*
79. *Malacosoma americanum*
80. *Malacosoma disstria*

84. *Megastgmus spp.*

90. *Orgyia pseudotsugata*

120. *Steneotarsonemus laticeps (Halbert)*

121. *Sternochetus mangiferae*

125. *Trogoderma granarium Everts*

Nematodes:

3. *Heterodera glycines Ichinoche*

7. *Xiphinema bricolense Ebsary, Vrain et Graham*

Prokaryotes:

3. *Acidovorax avenae ssp. Citrulli (Schaad et al.) Willems et al.*

4. *Burkholderia caryophylli (Burkholder) Yabuuchi et al.*

16. Potato purple-top wilt phytoplasma

20. *Xanthomonas arboricola pv. Populi (ex de Camm) Vauterin et al.*

22. *Xanthomonas axonopodis pv. Dieffenbachiae (Mc Cull. & Pirone) Vaut. Et al.*

24. *Xanthomonas translucens pv. Translucens (Jones et al.) Vauterin et al.*

Fungi

5. *Bipolaris maydis Drechsler*

8. *Cercospora zeae – maydis Tehon et Daniels*

32. *Ophiostoma wageneri*

36. *Phytophtora cambivora (Petri) Buisman*

38. *Pseudopityophthorus pruinosus*

41. *Stenocarpella maydis (Berk.)*

44. *Tilletia controversa Kuhn*

Viruses and virus-like organisms:

9. Cherry necrotic rusty mottle disease

19. Impatiens necrotic spot tospovirus

22. Peach latent mosaic viroid

30. Potato yellow dwarf nucleorhabdovirus

31. Potato yellow vein crinivirus

32. Potato yellowing alfamovirus

37. Squash mosaic comovirus

42. Tomato mottle begomovirus (and other American *Geminiviridae* of capsicum and tomato)

44. Watermelon silver mottle tospovirus

Weeds:

1. *Acroptilon repens D.C.*

2. *Ambrosia psilostachya D.C*.

3. *Solanum rostratum Dunn*.

4. *Solanum triflorum Nutt.*

Parasitic flowering plants:

2. *Arceuthobium abietinum*
3. *Arceuthobium americanum*
4. *Arceuthobium compylopodum*
5. *Arceuthobium douglasii*
6. *Arceuthobium laricis*
7. Arceuthobium minutissimum
8. *Arceuthobium occidentale*
9. *Arceuthobium pusillum*
10. *Arceuthobium tsugense*
11. *Arceuthobium vaginatum*
12. *Striga spp.*

A2

Insects and mites

1. *Cacoecimorpha pronubana Hubner*
2. *Cecidophyopsis hendersoni (K.)*
3. *Ceratitis capitata (Wiedemann)*
5. *Frankliniella occidentalis*
6. *Gonipterus scutellatus*
7. *Epichoristodes acerbella Walker*
10. *Liriomyza bryoniae (Kaltenbach)*
14. *Polyphagotarsonemus latus (Banks)*
15. *Taeniothrips simplex Morison*

Nematodes:

2. *Ditylenchus dipsaci (Kuhn) Filipjev*
8. *Xiphinema rivesi Dalmasso*

Prokaryots

2. *Curtobacterium flaccumfaciens pv. Flaccumfaciens (Hedges) Collins et Jones*
3. *Xanthomonas arboricola pv. Corylina (Miller et al.) Vauterin et al.*

Fungi

1. Phytophtora fragarie var. Rubi

Virus and virus-like organisms

3. Tomato ringspot nepovirus

Weeds:

1. *Ambrosia artemisifolia L.*
2. *Ambrosia trifida L.*
3. *Asclepias syriaca L.*
4. *Galisoga ciliata Ruiz et Pav.*
5. *Iva xantifolia Null.*

Parasitic flowering plants

1. *Cuscuta spp. L.*
2. *Orobanche spp.*

Some of harmful organisms listed on A1 and A2 MNE list are included in the list of organisms harmful to protected zones.

25. Plant health, plant protection products:

PLANT PROTECTION PRODUCTS

COMPETENT BODIES / POWERS

The Ministry of Agriculture, Forestry and Water Management, the Ministry of Health and the Ministry of Physical Planning and Environmental Protection are public administration bodies in charge of policy making and adoption of regulations concerning plant protection, while supervision over the legality and purposefulness of the Phytosanitary Administration work lies with the Ministry of Agriculture, Forestry and Water Management.

The Phytosanitary Administration was established by the Decree on Amendments to the Decree on Organization and Method of Work of the Public Administration (Official Gazette of Montenegro 43/08), establishing the ministries and other public administration bodies, lays down the method of work of public administration and governs other issues of relevance for work of the public administration. Authorizations laid down by the Law on Plant Protection Products, Official Gazette of Montenegro 51/08 are placed under its scope of authority.

The Phytosanitary Administration is the public administration body in charge of direct implementation of regulations and of related administrative activities and is in charge of co-ordination and contacts, development of legislation, inspection activities and international relations concerning the issues related to plant protection products.

The Rulebook on Internal Organization and Systematization of Phytosanitary Administration, adopted by the Government at the sitting on February 26, 2009, establishes the **Department for Plant Protection Products, Plant Nutrition Products and Food Safety,** under the Sector for Phytosanitary Affairs.

Department for Plant Protection Products, Plant Nutrition Products and Food Safety is in charge of direct implementation of regulations and activities concerning the following:

- Registration of plant protection products;
- Evaluation of active substances and plant protection products;
- Program of monitoring of post-registration control of plant protection products;
- Recognition of plant protection product registration;
- Preparation of technical basis for development of legislation concerning the plant protection products;
- Monitoring of situation as regards trade in plant protection products;
- Preparation and implementation of safeguard measures;
- Preparation, co-ordination and supervision of programs concerning the measures and proper use of plant protection products as well as program implementation;
- Introduction of the principle of Good Agriculture Practice and integrated plant protection;
- Establishing of specific conditions for production, placing on the market and application of plant protection products;

- Implementation of procedures in selection and undertaking of protection measures concerning the plant protection products;
- Preparation of technical basis for annual control plan, monitoring plan and crisis management plan;
- Issuing of approvals, entry into registers, keeping of records and registers:
    a) Register of wholesale of plant protection products;
    b) Register of retail sale of plant protection products;
    c) Register of plant producers (kept by local government bodies, data from the register are submitted to the Phytosanitary Administration);
    d) Register of plant protection products;
    e) List of registered plant protection products;
    f) List of authorized active substances;
    g) List of banned active substances;
    h) Register of persons engaged in control and eradication of harmful organisms in agriculture and forestry using plant protection products;
    i) Register of importers;
- Implementation of international conventions, agreements and exchange of information;
- Participation in international bodies and organizations;
- Setting up of information system, data collecting, processing and storage;
- Preparation of reports, analyses information and other materials in accordance with the regulations and international contracts and agreements and other activities placed within its scope of authority.

Department for Inspection Supervision carries out the activities of inspection supervision with regard to ensuring the implementation of laws and secondary legislation, adoption of decisions in administrative procedures, submits requests for initiation of misdemeanour proceedings, reports on commercial offence proceedings and on crime, initiates amendments to the legal documents implementation of which it controls, prepares briefing notes and reports on the situation in this field as well as other activities in accordance with the law.

The powers of the phytosanitary inspectorate are based on implementation of:

- Law on General Administration Procedure (Official Gazette of the Republic of Montenegro 60/03),
- Law on Inspection Supervision (Official Gazette of the Republic of Montenegro 39/03) and
- Law on Plant Protection Products - Official Gazette of Montenegro 51/08 – rulebooks, orders, decrees, programs, instructions, etc.

The Phytosanitary Inspectorate carries out:

Inspection supervision in foreign trade

The Phytosanitary Inspectorate carries out the inspection of the consignments of plant protection products in trade (import and transit) across the border of Montenegro.

The Phytosanitary Inspectorate controls whether the companies or other legal persons and entrepreneurs are registered in the Register of importers of plant protection products.

The Phytosanitary Inspectorate controls whether the persons engaged in imports of plant protection products supply the plant protection products to persons registered in the Register for wholesale trade in plant protection products and the Register for retail sale of plant protection products.

Imports of plant protection products may take place over the border crossings where phytosanitary checks are organized.

Phytosanitary inspector controls the plant protection products at the border crossing of entry. Importers, transit operators, transporters and authorized representatives thereof announce the arrival of consignments and present application for check within the periods of time set. The application is submitted in writing, stating all the documents accompanying the consignment. The customs services cannot commence the customs clearance procedure before the phytosanitary inspector completes the check.

Checks of plant protection products on the border inspection post include:

- Checking the documents accompanying the consignments in order to identify them with the marks on the wrapping, packaging and contents of the consignment and to check the compliance with the conditions laid down by the law:
  a) Approvals of the Phytosanitary Administration (if prescribed);
  b) Certificate on quality;
  c) waybill / bill of lading;
  d) invoices, packing lists and other documents accompanying the consignment.
- Physical check includes:
  a) Visual check;
  b) Checks of means of transport;
  c) Wrappings and all marks (tags, seals, etc.);
  d) Comparison of actual consignment weight with the weight in accordance with the approval for import, other document, by checking a number of items or, if necessary, by weighing the consignment; checks are made on several different species taken from the whole consignment.

The phytosanitary inspector checks the consignment in order to establish whether the conditions prescribed are satisfied, whether the consignment is fit for use for the purposes indicated in the accompanying document.

The phytosanitary inspector appraises possible derogations from the conditions prescribed in order to establish the method of check and the need for taking samples for laboratory analyses (setting the number of packages from which samples are to be taken, the number and the size of the samples, examination method, preventive measures, etc).

Where the phytosanitary inspector establishes the condition based on the check of accompanying documents and physical checks and where there are no justified reasons for suspicion or derogation, in accordance with the risk analysis, the phytosanitary inspector will approve of the import by a decision and will put the clause **”Import allowed“** onto the accompanying documentation.

Where the phytosanitary inspector cannot determine the situation based on the check of accompanying documents or where there are justified reasons for suspicion or derogation, samples will be taken for the purpose of laboratory analyses, in accordance with the risk analysis.

The samples are sent to authorized accredited laboratories for laboratory analyses.

The consignments sampled by the phytosanitary inspector, samples of which were sent for laboratory analyses, are placed under customs supervision and must not be placed on the market pending the receipt of the results.

In case a plant protection product, sent for analysis, does not match the quality declared, which is confirmed by laboratory analyses, the phytosanitary inspector will issue a decision prohibiting the import and order the consignment to be returned to the consignor, and in case the consignment was imported by a natural person, the consignment will be seized and destroyed in accordance with the regulations. The inspector will place the clause: **”Import prohibited“** on the

accompanying documentation.

In case that the plant protection product sent for analysis is in accordance with the quality labelled, which is confirmed by laboratory analyses, the phytosanitary inspector will issue a decision allowing the import. The inspector will place the clause: **"Import allowed"** on the accompanying documentation.

In order to check the shipping consignments in ports, the ship has to be berthed at the port and consignments have to be onboard, or, with approval from the phytosanitary inspector, in a bonded warehouse where conditions for a phytosanitary check are provided.

In case of consignments imported by containers over the border crossing where containers are not examined, the phytosanitary inspector checks accompanying documents only and in case it is established that the consignment in the container is supplied with the appropriate approval and documentation, phytosanitary inspector approves of the transport of the container under the customs supervision to the place designated for checking of the container, where opening of the container may take place. In case it is established that the consignment imported in containers is not supplied with the documents prescribed, or where it can be established from the documentation that it contains a consignment import of which is prohibited, or restricted, as appropriate, the phytosanitary inspector will order the consignment to be returned to the consignor.

The consignments transported by railway are checked at railway stations designated by the Phytosanitary Administration.

Airmail, general cargo and mail is checked in the bonded warehouse in the space designated for that purpose, where the conditions for check are in place.

Consignments in transit over the territory of Montenegro are subjected to mandatory checks at the border crossing.

Inspection supervision in internal trade

The phytosanitary Inspectorate controls plant protection products in internal trade in Montenegro.

During the control, the phytosanitary inspector:

- Checks whether the plant protection product is registered in the Register of Plant Protection Products, or whether the decision on registration was issued for the product in question;
- Checks the documentation accompanying the plant protection product in trade;
- Controls keeping of registers and records;
- Checks compliance with the conditions for placing the plant protection product on the market, packaging, marking, trade in and use of plant protection products;
- Checks carrying out of technical activities and tasks of authorized legal persons and activities performed by service providers, in accordance with this law;
- Establishes the identity of the offender when he/she suspects that this law has not been applied, by photographing or recording, where necessary;
- Takes samples for post-registration control of plant protection products;
- Takes samples of plants, plant products, plant growth substrates, solution mixtures, plant protection products or other samples necessary in order to check the prescribed conditions for use of a plant protection product (eg. crop damage, failure to comply with the waiting period, etc);
- Issues temporary prohibitions, pending the removal of irregularities, of trade in plant protection product in case the company or other legal person and entrepreneur is not registered in the Register for trade in plant protection products, or fails to comply with the conditions prescribe and notifies the Phytosanitary Administration of that;
- Checks whether plant protection products are used in accordance with the decision on registration of plant protection products, or, the instructions for use and the label, as

appropriate, and prepared in accordance with the concentration prescribed, observing the principles of Good Agricultural Practice for plant protection products, integrated plant protection and environmental protection;

- Checks whether the plant protection products are used so as not to cause pollution of housing, business and other establishments accommodating humans and animals, or pollution of water and surrounding soil;
- Checks whether residues of plant protection products exceed the level prescribed and where it is established that the residues of plant protection products are above the maximum residue levels (MRL) for plant protection products, the phytosanitary inspector orders destruction of such plants, plant products, food, or in some other way prevents their use for nutrition of animals or humans;
- Checks compliance with the conditions prescribed of persons registered in the Register of Phytosanitary Administration for carrying out the activities of control and eradication of harmful organisms in agriculture and forestry;
- Checks devices used for application of plant protection products, or whether the owner of the device used for application of plant protection products keeps it in good repair and whether technical documentation on the device is retained (manufacturer's certificate, leaflets, evidence on repairs made, etc.)
- Checks whether the plant protection products placed on the market and used on the territory of Montenegro are registered, classified or categorized, packaged, marked, and whether they are accompanied by a label and the instructions for use in accordance with the regulations governing hazardous substances, chemicals, and in accordance with the law, as well as the expiry period for that plant protection product;
- Checks whether the information on the packaging of the plant protection product are printed clearly and legibly in Montenegrin language, so as to prevent their deletion or removal;
- Checks whether the person registered in the Register for wholesale trade in plant protection products and the Register for retail sale of plant protection products satisfies the conditions set, such as whether it:
    a) Employs, on full-time basis, a person responsible for supply, trade, accommodation, storage and issuing of plant protection products with postgraduate specialist studies, or faculty of agriculture (department – plant protection), or postgraduate specialist studies or faculty of agriculture (plant production department), who completed the specialist course for plant protection products;
    b) Has adequate equipment and space for storage, or sale, as appropriate, of plant protection products;
    c) stores records within the periods of time prescribed and keeps records on the quantity of:
        - Plant protection products supplied;
        - Plant protection products sold, which includes:
            - Information on user, or registered plant producer (name and address, or the name and head office address of the producer, information on entry in the register of plant producers, the name of the plant protection product and active substances, date of sale);
            - Information on producer of plants for domestic purposes (name, address, personal identification number, name of the plant protection product, date of sale);
        - Plant protection products stored;
            - Plant protection products withdrawn from the market;
        - Presents the information from the records to the Phytosanitary Administration in accordance with the periods of time prescribed;
        - For chemicals classified into the plant protection products marked with T+,

also keep the records which include:

- Information on the plant protection product (trade name, purpose, shelf life);
- Date of sale, or delivery of the plant protection product;
- Quantities of a plant protection product sold or delivered;
- Information on the buyer or user (for legal persons: name, head office and registration number, for natural persons: first name and the last name, address and personal identification number);
- Signatures of the supplier and the recipient.

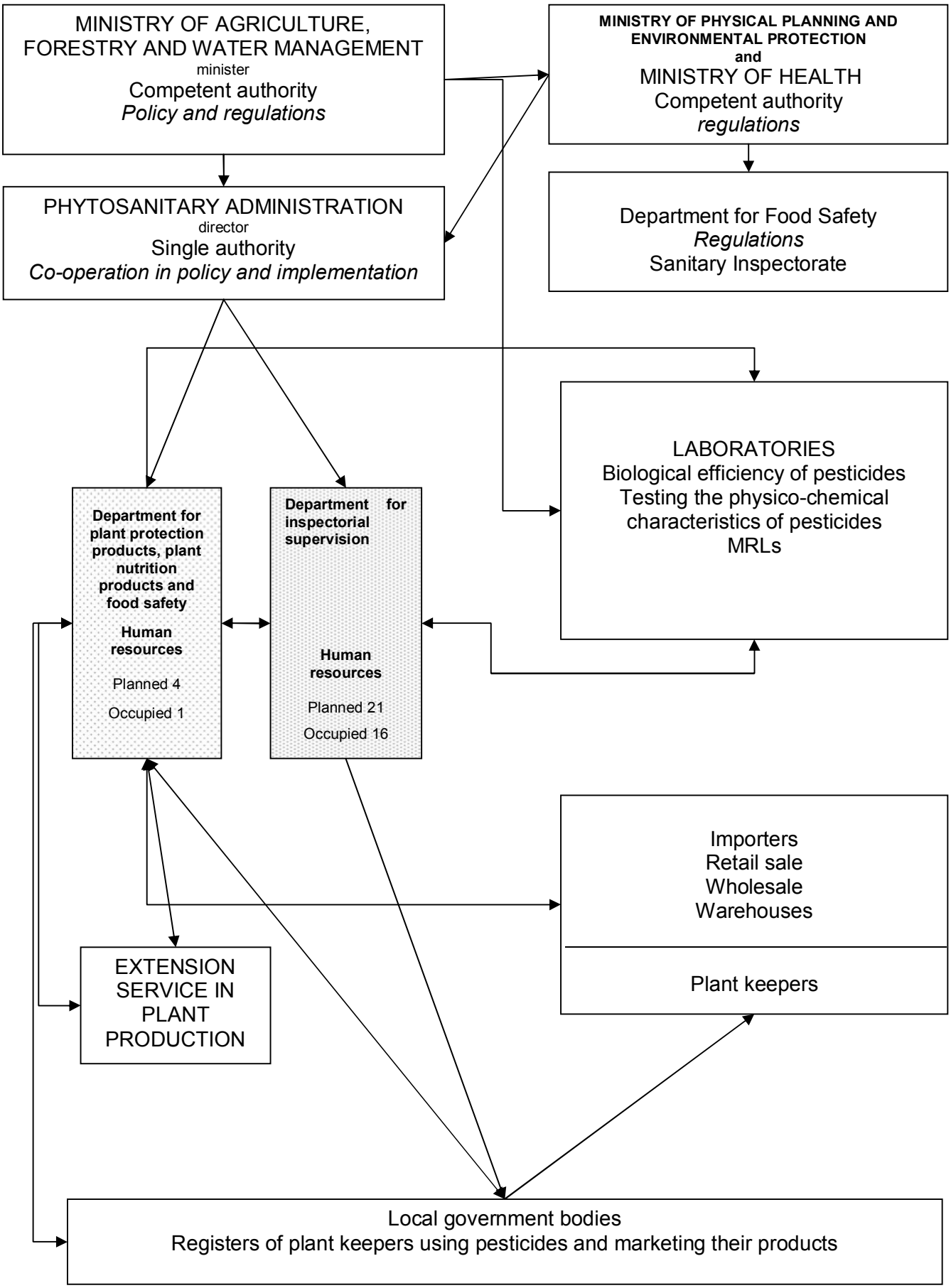
AUTHORITIES OF DIFFERENT INSTITUTIONS IN THIS FIELD

University of Montenegro/Biotechnical Faculty Podgorica/Centre for Plant Protection / Podgorica – is authorized by the Ministry of Agriculture, Forestry and Water Management for analysis of biological efficiency of pesticides, field trials, other professional and technical activities of public interest concerning the plant protection field.

University of Montenegro/Biotechnical Faculty Podgorica/Centre for Subtropical Cultures / Bar – is authorized by the Ministry of Agriculture, Forestry and Water Management for analysis of physico-chemical characteristics of pesticides: laboratory analyses, other professional and technical activities of public interest concerning the plant protection field.

Public Institution Centre for Eco-toxicological Research of Montenegro/Podgorica/ – is authorized by the Ministry of Agriculture, Forestry and Water Management for analysis of physico-chemical characteristics of pesticides: laboratory analyses, other professional and technical activities of public interest concerning the plant protection field.

Flowchart – plant protection products, residues



LEGAL BASIS

Law on Plant Protection Products (Official Gazette of Montenegro 51/08) is a framework law, that is, a legal framework for the plant protection products field, harmonized with the EU acquis, adopting the EU concept in accordance with the Directive, Celex No. 31991L0414.

The Law governs the method of classification, registration, trade in and use of plant protection products and active substances, maximum permitted levels of plant protection products residues, the method of keeping the registers and records, exchange of data and other issues of relevance for plant protection products.

This law provides a legal basis for development of secondary legislation, which will be harmonized with the EU legislation.

Pending the adoption of secondary legislation in accordance with this Law, the following national legislation adopted previously will be applied:

Regulations within the scope of authority of the Ministry of Agriculture, Forestry and Water Management:

- Rulebook on Pesticide Analysis (Official Gazette of the Federal Republic of Yugoslavia 63/00 and 65/00);
- Rulebook on Pesticide Analysis Methods (Official Gazette of the Federal Republic of Yugoslavia 11/99);
- Rulebook on Conditions for Production Line, Marketing, Import and Sampling of Pesticides and Fertilizers (Official Gazette of the Federal Republic of Yugoslavia 12/99);
- Rulebook on Pesticide Production Line (Official Gazette of the Federal Republic of Yugoslavia 68/01);
- Rulebook on Types of Packaging for Pesticides and Fertilizers and on Destruction of Pesticides and Fertilizers (Official Gazette of the Federal Republic of Yugoslavia 35/99);
- List of organizations authorized for testing plant protection products (pesticides) and plant nutrition products (fertilizers) (Official Gazette of the Federal Republic of Yugoslavia 4/2000);
- Rulebook on Trade in, Import and Sampling of Pesticides (Official Gazette of the Federal Republic of Yugoslavia 59/01);
- List of small crops and plantations (Official Gazette of the Federal Republic of Yugoslavia 24/03);
- Decree on Forecasting-Reporting Activities in Plant Protection Field (Official Gazette of the Federal Republic of Yugoslavia 65/99);
- Rulebook on Conditions for Performing the Activities of Disinfection, Disinfestation and Rodent Control in the Field of Protection of Plants and Plant Products (Official Gazette of the Federal Republic of Yugoslavia 12/99).

Legislation within the scope of authority of the Ministry of Health:

- List of poisons classified into groups (Official Gazette of the Federal Republic of Yugoslavia 12/00);
- Decision on conditions that must be met by legal persons and entrepreneurs engaged in production, trade and control of poisons (Official Gazette of the Federal Republic of Yugoslavia 30/96);
- Decision on marking the poisons in trade (Official Gazette of the Federal Republic of Yugoslavia 38/97);
- Rulebook on Criteria for Classification of Poisons into Groups and on Methods for Determining the Toxicity Level of Certain Poisons (Official Gazette of the Federal Republic of Yugoslavia 79/91);
- Rulebook on Methods for Destruction of Unused Poisons and Packaging Used for Poison Packing and on the Method of Withdrawal of Poisons from the Market (Official Gazette of

the Socialist Federal Republic of Yugoslavia 7/83).

- Placing on the market of plant protection products;

Only registered plant protection products, in accordance with the List of Plant Protection Products published in the Official Gazette of Montenegro, may be imported and used in Montenegro.

The List of Registered Plant Protection Products has been valid so far, taken over from the previous legal system of Serbia and Montenegro.

The List of Active Substances which are alowed for use in plant protection products has been published, and this list does not include the active substances not authorized for use in the EU (Official Gazette of Montenegro 70/09). This list is a refined list from the previous system.

The List of Authorized Plant Protection Products, will be published in 2010.

This list will extend all the existing registrations for plant protection products for the period of one year, after which the re-registration, based on applications, would commence. This list does not include plant protection products banned based on the Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances.

The responsible public administration body for the initial phase of registration of plant protection products is the Ministry of Physical Planning and Environmental Protection and Ministry of Health, which implements the procedure in accordance with the Law on Chemicals (Official Gazette of Montenegro 11/07); Rulebook on Criteria for Classification of Poisons into Groups and on Methods for Determination of the Toxicity Level for Certain Poisons (Official Gazette of Federal Republic of Yugoslavia 79/91); Decision on Marking of Poisons in Circulation (Official Gazette of the Federal Republic of Yugoslavia 38/97); Rulebook on Criteria for Classification of Poisons into Groups and on Methods for Determination of the Toxicity Level for Certain Poisons (Official Gazette of Federal Republic of Yugoslavia 79/91);

Prior to adoption of the Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Montenegro had registered neither the active substances, nor the plant protection products – this activity took place at the level of the former state union with Serbia.

SYSTEM PLANNED:

The application for registration of a plant protection product is submitted to the Phytosanitary Administration in accordance with the Article 23 of the Law on Plant Protection Products, Official Gazette of Montenegro 51/08. For a plant protection product containing an active substance or active substances included in the List of Authorized Active Substances, the applicant may request recognition of a registration on the basis of a registration done in another country, provided that the product had been registered in accordance with the uniform principles for evaluation of a plant protection product (Article 14 paragraph 5, Law on Plant Protection Products Official Gazette of Montenegro 51/08) and provided that, for the proposed use of the product on the territory of Montenegro, the conditions in agricultural production, plant protection and the environment, including the climatic conditions of importance for the application of the product, are comparable with the conditions in other countries belonging to the same climatic zone.

Together with the request for recognition of a registration, the following information is included: identity of the active substance, plant protection product, evidence and report on registration of a plant protection product in another state, translated into Montenegrin language and certified photocopy of the original and the summary (article 16 paragraph 2 of the Law on Plant Protection Products Official Gazette of Montenegro 51/08).

Biological testing is done by field testing during 1 or 2 vegetation seasons.

Prior to the administrative issuance of the licence, i.e. the registration, the sitting of the Commission for Plant Protection Products (Commission members are prominent public figures, scientists and professionals in plant protection, plant health protection, veterinary field,

environmental protection, chemistry, biochemistry, toxicology and other professionals in fields of relevance for plant protection products) takes place.

The Commission eventually considers the application and provides its opinion in the registration procedure to the administrative unit in the Phytosanitary Administration. It is followed by the administrative procedure of licence issuing by the Phytosanitary Administration.

The phytosanitary Administration registers the plant protection product for the period of no longer than ten years.

The information on the packaging of a plant protection product for sale on the territory of Montenegro is written clearly and legibly in Montenegrin language so as to prevent their deletion or removal (Article 5 of the Law on Plant Protection Products (Official Gazette of Montenegro 51/08).

More detailed conditions and method for recognition of registration and assessment of comparability of circumstances and climatic conditions will be prescribed in the course of 2010.

ACTIVITIES AND PLANS

Activities currently implemented in the field of plant protection products are analysis of the current situation and work and activities of existing institutions involved in this field.

The most important step is to build the capacity of the recently established plant protection product service of the Phytosanitary Administration for the following:

- Authorization, or recognition of authorization and issuing of approvals for plant protection products;
- Co-ordination, exchange of information and international relations in the field of plant protection products;
- Reporting in the field of plant protection products;
- Further development of legislation and taking care of its implementation;
- Requirements related to equipment for application of plant protection products;
- Monitoring of conditions for placing on the market and use of plant protection products and co-operation in preparation of appropriate measures;
- Co-operation in programs concerning the measures for proper use of plant protection products, including the monitoring of residues in plants and plant products;
- Introduction of the principle of good practice in plant protection and integrated plant protection;
- Co-ordination of the system of training the producers for use of plant protection products;
- Setting up of an information system in this field;
- Setting up of registers, databases and lists;
- Writing reports, analyses and other materials.

In this sector, it is necessary to do the following:

- Train staff for full transposition and implementation of EU legislation;
- Train staff on procedures of sampling for the purpose of control following the registration process;
- Working visits to the EU Member States with conditions similar to those in Montenegro in order to check the structure and organization established;
- Development of the strategy of transposition, implementation and enforcement of the EU legislation;
- Transposition of the EU legislation;

- Establishing of an appropriate structure and organization for implementation and enforcement;
- Monitoring of the efficiency and the quality of the system established.

Considering that Montenegro is a small country with limited human resources, it is natural that it is not able to develop the full capacity as regards evaluation of plant protection products (PPPs).

The preliminary evaluations of the situation in this field show that Montenegro would most probably rely on evaluations of the EU countries and opt for the system of recognition of authorizations.

Regardless of these preliminary evaluations, establishing of institutional capacity for an efficient European system is necessary, with the structure that is the most acceptable for Montenegro, in order to accomplish the objectives set in the EU.

*Note: Plant protection products are not produced in Montenegro

PRIORITY AND TENTATIVE PLAN OF HARMONIZATION WITH THE EU ACQUIS – CLEAR TABLE

EU	MNE
Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) **Legal acts in force:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) **Status:** TOC table not made **In future:** after TOC are made, in case of discrepancies, the process of making amendments to the law will be started
Annex I Active substances authorised for use in plant protection products	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Article 30 **Legal acts in force:** List of Authorized Active Substances **Status:** in the harmonization process **In future:** Continuous monitoring of the list of active substances authorized for application in the EU and revision of the national list in accordance with the European one.
Annex II Requirements for the dossier to be submitted for the Inclusion of an active substance in annex I	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Article 14-33 **Legal acts in force:** **Status:** in the harmonization process **In future:** Adoption of a Rulebook on Requirements for Inclusion of Active Substances in the List of Authorized Ones Adoption by the end of 2012.
Annex III Requirements for the dossier to be submitted for the Authorization of a plant protection product	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Article 14-33 **Legal acts in force:** **Status:** in the harmonization process **In future:** Adoption of a Rulebook on Requirements for Dossiers for Authorization of Plant Protection Products Adoption by the end of 2012.
Annex IV Standard phrases for special risks for humans or the Environment as referred to in article 16	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Article 5 **Legal acts in force:** **Status:** in the harmonization process **In future:** Adoption of a Rulebook on Standard Phrases Pointing to Special Hazards and Safety Measures Concerning the Plant Protection Products Adoption by the end of 2012.
Annex V Standard phrases for safety precautions for the Protection of humans or the environment as Referred to in article 16	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Article 5 **Legal acts in force:**

	Status: in the harmonization process **In future:** Adoption of a Rulebook on Standard Phrases Pointing to Special Hazards and Safety Measures Concerning the Plant Protection Products Adoption by the end of 2012.
Annex VI Part I Uniform principles for evaluation and authorisation of chemical plant protection products Part II Uniform principles for evaluation and authorisation of plant protection products containing micro-organisms	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Article 14 **Legal acts in force:** **Status:** in the harmonization process **In future:** Adoption of a Rulebook on uniform principles for evaluation of plant protection products Adoption by the end of 2012.
Application texts Programme of Work Recognition of the completeness of the dossier Possible Inclusions – Provisional Authorisations Protective measures Renewal of the inclusion Continued use Non authorised substances Banned substances	**Legal basis:** Law on Plant Protection Products (Official Gazette of Montenegro 51/08) Article 14 **Legal acts in force:** **Status:** in the harmonization process **In future:** List on prohibition of placing on the market and use of plant protection products containing certain active substances (Celex No. 31979L0117)

*** the regulations stated above will be consolidated in the mid-term and amend the following directives: (Celex No. 31076L0895, 31986L0362, 31986L0363, 31990L0642).

- Setting up an controls of maximum residue levels.

In accordance with the Law on Food Safety (Official Gazette of Montenegro 14/07) and the Law on Plant Protection Products (Official Gazette of Montenegro 51/08) the powers in the field of residues of plant protection products are divided between the Ministry of Agriculture, Forestry and Water Management (Phytosanitary Administration, Veterinary Administration) and the Ministry of Health.

Adoption of the Law on Food Safety provides a general, i.e., the horizontal legal framework for further harmonization of this field, and the Law on Plant Protection Products adopted will govern the issue of pesticide residues by adoption of secondary legislation on the basis of that law, and in accordance with special, i.e., the vertical EU legislation.

Overview of Montenegro's legislation – pesticide residues:

- Law on Plant Protection Products (Official Gazette of Montenegro 51/08);
- Law on Food Safety (Official Gazette of Montenegro 14/07);
- Rulebook on Quantities of Pesticides, Metals, Metalloids and Other Poisonous Substances, Chemotherapeutics, Anabolics and Other Substances that may be found in Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia 5/92, 11/92 and 32/02);
- Rulebook on Conditions concerning the Health Safety of Dietetic Foodstuffs that may be placed on the Market (Official Gazette of the Socialist Federal Republic of Yugoslavia 4/85, 70/86, 69/91, Official Gazette of Serbia and Montenegro 56/03);
- Instructions on the Method of Sampling for Analyses and Super-analyses of foodstuffs and General Use Objects (Official Gazette of the Socialist Federal Republic of Yugoslavia 60/78).

According to the Article 22 of the Law on Plant Protection Products (Official Gazette of Montenegro 51/08), a product may not be issued with an authorization unless MRL and waiting period is set for it, for each intended use and the application method separately.

The Ministry of Health, in cooperation with the Ministry of Agriculture, Forestry and Water Management sets MRL on plants or plant products or in plants and in plant products, food or feed.

COMPETENT PUBLIC BODIES AND CONTROL

The Law on Food Safety published in the Official Gazette of Montenegro 14/07 classifies the food

by origin into food of animal origin; food of plant origin; composite food and other food. In accordance with this classification, the division of competences for monitoring of pesticide residues is made by the Law on Plant Protection Products (Official Gazette of Montenegro 51/08):

- Ministry of Agriculture
- Ministry of Health
- Veterinary Administration
- Phytosanitary Administration

Sample analysis is carried out by legal persons authorized for monitoring of plant protection product residues in accordance with the Law on Plant Protection Products and the Law on Food Safety.

By 1998, the only institution analyzing foodstuffs of plant and animal origin in accordance with the Law on Health Safety of Foodstuffs and General Use Objects (Official Gazette of the Socialist Federal Republic of Yugoslavia 53/91 and Official Gazette of the Federal Republic of Yugoslavia 24/94, 28/96, 37/02) as well as the Rulebook on Quantities of Pesticides, Metals, Metalloids and Other Poisonous Substances, Chemotherapeutics, Anabolics and Other Substances that may be found in Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia 5/92, 11/92 and 32/2002) had been the Institute for Health Protection, which was, later on, named the Institute of Public Health. As of 1998, in addition to the Institute of Public Health, the analyses are performed by the Centre for Eco-toxicological Research of Montenegro (CETI).

At the end of the year, all annual results of analyses of samples of plant origin of the institutions stated above are statistically processed in the Institute for Public health by the following categories:

- cereals, leguminous plants and flour;
- bread, pasta, biscuits;
- fruit and fruit products;
- vegetables and vegetable products;
- coffee, cocoa and teas;
- fats and oils.

The reports of authorized laboratories on analyses of food of plant origin by active substances are delivered to the Phytosanitary Administration and the Ministry of Health.

LABORATORIES

- **Institute of Public Health** - (laboratory analyses of foodstuffs for plant protection product residues)
- **Centre for Eco-toxicological Research of Montenegro** (CETI) - (laboratory analyses of foodstuffs on plant protection products residues).

The main requirements for laboratories will be overview of the current situation, accreditation (ISO/IEC 17025) and setting up of the Quality control procedures for pesticide residues analysis.

Inspection is carried out by phytosanitary, veterinary and sanitary inspectors, in accordance with their respective powers from the law.

PESTICIDE RESIDUES MONITORING PROGRAM

The pesticide residues monitoring program in food of plant origin monitors the pesticide residue levels in order to estimate the risk for the population health. The Program was adopted and published in the Official Gazette of Montenegro 57/2009, and was adopted in accordance with the Law on Plant Protection Products (Official Gazette of Montenegro 51/2008). The Program of monitoring of pesticide residues for food of plant origin will be adopted every year, and it includes monitoring of pesticide residues in accordance with the residue levels prescribed (MRL/Maximum Residue Levels). The proposal of the pesticide residues monitoring program for 2009 was

developed in accordance with the Commission Recommendation of 4 February 2008 concerning a coordinated Community monitoring programme for 2008 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin and national monitoring programmes for 2009 (2008/103/EC). The monitoring includes fruits, vegetables, cereals, cereal-based beverages and products as well as food for children. A separate program of residues monitoring in animals, foodstuffs of animal origin and feed is implemented by the Veterinary Administration. The monitoring is based on representative samples of goods, intelligence-based and traceable monitoring system. The number of samples is set on the basis of the presence in nutrition, with particular emphasis on the food intended for children.

The samples are taken by trained phytosanitary inspectors: at the place of plant production, storages primary plant products, collecting sites, markets (open market spaces), border crossings and sanitary inspectors: in retail and wholesale outlets and in border crossings.

The monitoring includes the goods produced in the country as well as imported goods and it has the priorities:

- Checks whether pesticide residues exceed the MRLs (Maximum Residue Level) set;
- Checks whether certain types of food of plant origin contain unexpected pesticide residues, in accordance with the law;
- Checks whether the ingestion of pesticide residues through food is at an acceptable level.

The priorities are based on risk analysis, current evidence of effects of pesticide residues on the health of population in Montenegro and beyond Montenegro, and in accordance with the European and other international harmonized obligations and recommendations.

Prioritising system	
Monitoring	**Monitoring type**
Low priority level – No evidence on MRL exceeded or non-authorized pesticides on/in the commodity (source: monitoring done so far, reports, Rapid Alert System for Food and Feed–RASFF, or other data of other countries' monitoring) – A low number of expected pesticide residues on/in the commodity – The commodity's presence in nutrition of any population group is low	Routine segment in the process of monitoring of the nutrition role in order to check the harmonization with the law and ensure the information necessary. Such commodity types are monitored at least once in four years.
Medium priority level – There is evidence on MRL exceeded or non-authorized pesticides on/in the commodity (source: monitoring done so far, reports, Rapid Alert System for Food and Feed–RASFF, or other data of other countries' monitoring) – Expected occurrence of residues on/in the commodity – The commodity is significantly present in nutrition of any population group – Increasing popularity promoted the inflow of commodities from new sources	Routine segment of the monitoring, mainly for fresh commodities, done once in two or three years. The objective of this monitoring type is follow up on past results.
High priority level – More recent evidence on exceeded MRL or non-authorized pesticides on/in the commodity (source: monitoring done so far, reports, Rapid Alert System for Food and Feed–RASFF, or other data of other countries' monitoring) – Evidence that ingestion might exceed the Acute Reference Dose – Expected residues on/in the commodity of very high significance for a consumer group	Annual monitoring of commodities with significant presence in the nutrition and/or targeted monitoring for problems identified.

Criteria used in development of the monitoring plan:

- Population by municipalities;
- Statistical data on consumption of food of plant origin;
- Data on domestic production and imports of food of plant origin;
- Data on residue levels from past years;
- Capacity of laboratories, methods used (multi –residue methods-MRMs);

- Assessment of risk from pesticides;
- Registered pesticide preparations for certain commodity types;
- Number of warehouses, wholesale facilities, importers and retail outlets of food of plant origin.

In accordance with the abovementioned, the competences in Montenegro are divided among the Ministry of Agriculture, Forestry and Water Management, the Phytosanitary Administration, the Veterinary Administration and the Ministry of Health and allocation of separate funds for analyses of pesticide residues is made accordingly (the bodies allocate the funds in their respective budgets, in accordance with their respective competences).

	Program of monitoring of plant protection products, plant nutrition products and food safety	Value in €
2.1	Monitoring of pesticide residues in food of plant origin at the primary production level	30,000.00

* Program of phytosanitary measures for 2009 (Official Gazette of Montenegro 20/09)

PRIORITY AND TENTATIVE PLAN OF HARMONIZATION WITH THE EU ACQUIS RESIDUES OF PLANT PROTECTION PRODUCTS– CLEAR TABLE

EU	MNE
Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC	**Legal basis:** Law on Plan Protection Products (Official Gazette of Montenegro 51/08) and Law on Food Safety (Official Gazette of Montenegro 14/07) **Legal act in force:** Rulebook on Quantities of Pesticides, Metals and Metalloids and Other Poisonous Substances, Chemotherapeutics, Anabolics and other Substances that may be found in Foodstuffs (Official Gazette of the Federal Republic of Yugoslavia 5/92, 11/92 and 32/2002); **Status:** not harmonized **In future:** Adoption of a rulebook on maximum residue levels in and on food and feed of plant and animal origin Adoption by the end of 2012.
Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC	**Legal basis:** Law on Plan Protection Products (Official Gazette of Montenegro 51/08) and Law on Food Safety (Official Gazette of Montenegro 14/07) **Legal act in force:** Instructions on method of sampling for analyses and super analyses of foodstuffs and general use objects (Official Gazette of the Socialist Federal Republic of Yugoslavia 60/78). **Status:** not harmonized **In future:** Adoption of a rulebook on methods of sampling for implementation of official control of pesticide residues in and on products of plant and animal origin Adoption by the end of 2012.
Commission Regulation (EC) No 1213/2008 of 5 December 2008 concerning a coordinated multiannual Community control programme for 2009, 2010 and 2011 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin	**Legal basis:** Law on Plan Protection Products (Official Gazette of Montenegro 51/08) and Law on Food Safety (Official Gazette of Montenegro 14/07) **Legal act in force:** Program of monitoring of pesticide residues in food of plant origin for 2009 (Official Gazette of Montenegro 57/09) **Status:** harmonized **In future:** Continuous adoption and implementation of residue monitoring program in food of plant origin
Commission Recommendation of 4 February 2008 concerning a coordinated Community monitoring programme for 2008 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin and national monitoring programmes for 2009	**Legal basis:** Law on Plan Protection Products (Official Gazette of Montenegro 51/08) and Law on Food Safety (Official Gazette of Montenegro 14/07) **Legal act in force:** Program of monitoring of pesticide residues in food of plant origin for 2009 (Official Gazette of Montenegro 57/09) **Status:** harmonized **In future:** Continuous adoption and implementation of residue monitoring program in food of plant origin

26. Quality of seeds and plant propagating material regarding the marketing of seed and propagating material of agricultural crops and vegetables, vine, forestry, ornamentals and fruit plants:

Competent bodies:

- Ministry of Agriculture, Forestry and Water Management;
- Phytosanitary Administration:
    - Department for seed and planting material, protection of plant varieties and GMO;
    - Department for inspection supervision.

The Ministry of Agriculture, Forestry and Water Management is the public administration body in charge of policy making and adoption of regulations in the field of seed and planting material and it supervises the legality and appropriateness of the activities of the Phytosanitary Administration.

The Phytosanitary Administration was established by the Decree on Amendments to the Decree on Organization and Method of Work of Public Administration (Official Gazette of Montenegro 43/08), establishing the ministries and other administration bodies, and which determines the method of work of the public administration and governing other issues of relevance for the work of the public administration. Powers from the Law on Seed Material of Agricultural Plants (Official Gazette of Montenegro 24/06) (Annex 43) and from the Law on Planting Material (Official Gazette of the Republic of Montenegro 24/06) were transferred to its scope of authority.

The Phytosanitary Administration is a public administration body, in charge of direct implementation of regulations and related technical affairs, and is in charge of co-ordination and contacts, development of legislation, inspection activities and international relations concerning the seed and planting material.

In accordance with the Rulebook on Internal Organization and Systematization of the Phytosanitary Administration that the Government of Montenegro adopted at the sitting on February 26, 2009, a Department for Seed and Planting Material, Plant Variety Protection and GMOs was established within the Sector for Phytosanitary Affairs.

Department for Seed and Planting Material, Plant Variety Protection and GMOs is in charge of direct implementation of legislation and activities concerning the following:

- Establishing the compliance with the conditions and methods of production, processing, control, post-control, quality testing, trade and import of seed material of agricultural plants;
- Approval of production for lower categories of seed material;
- Issuing of certificates for seed material;
- Control and testing of seed material;
- Recognition of results of DUS tests;
- Processing of results of variety testing in a trial field;
- Setting up of a technical committee for the purpose of appraising the value for commercial use as well as distinctness, uniformity and stability of the variety of seed material of agricultural plants;
- Establishing the compliance with the conditions and method of production, trade in and imports of planting material;
- Authorizes a legal person for technical control of production of planting material;
- Issuing the certificates on recognition of production of planting material;

- Control and testing of varieties of planting material;
- Recognition of results of DUS tests, processing of results of variety testing in a trial field, setting up of a technical commission for the purpose of evaluation of the value for commercial use as well as distinctness, uniformity and stability of the variety of seed material;
- Control of reproductive GMO plant material or products containing, consisting of or obtained from GMOs intended for placing on the market;
- Development of technical basis for the plan of control, monitoring plan;
- Issuing of approvals, entry in the registers, keeping records and registers:
    - Register of Agricultural Plants Varieties;
    - Register of Seed Material Producers;
    - Register of Seed Material Processors;
    - Register for Wholesale of Seed Material;
    - Register for Retail Trade in Seed Material;
    - Register of Seed Material Importers;
    - Register of Varieties and Rootstocks of Planting Material;
    - Register of Planting Material Producers;
    - Register for Wholesale of Planting Material;
    - Register for Retail Trade in Planting Material;
    - Register of Importers of Planting Material;
- Implementation of international conventions, agreements and exchange of information;
- Participation in international bodies and organizations;
- Setting up of the information system, data collecting, processing and keeping;
- Preparation of reports, analyses, briefing notes and other materials in accordance with the regulations and international treaties and agreements and other activities placed under its scope of authority.

Department for Inspection Supervision carries out the activities of inspection supervision with regard to ensuring the implementation of laws and secondary legislation, adopts decisions in administrative procedures, submits requests for instigation of misdemeanour proceedings, reports on commercial offence proceedings and on crime, initiates amendments to the legal documents implementation of which it controls, prepares briefing notes and reports on the situation in this field as well as other relevant activities.

The powers of the phytosanitary inspectorate are based on implementation of the following:

- Law on General Administrative Procedure (Official Gazette of the Republic of Montenegro 60/03);
- Law on Inspection Supervision (Official Gazette of the Republic of Montenegro 39/03) and implementation of the laws, rulebooks, orders, decrees, programs, instructions, etc. in the phytosanitary field.

The Phytosanitary Inspectorate carries out:

Inspection supervision over phytosanitary border inspection posts

The border phytosanitary inspectorate carries out the examination of the consignments of seed and planting material in trade (import, export, re-export, transit) across the border of Montenegro, with regard to checking the quality requirements, varietal aspects and health condition, issues the certificates on plant health condition (phyto-certificate), undertakes measures for the purpose of

preventing the introduction, spread, and for the purpose of eradication of harmful organisms in accordance with the law.

Import of consignments of seed and planting material

Checks of consignments of seed and planting material, which are the subject of phytosanitary supervision, by phytosanitary inspectors are mandatory at the border crossing of entry.

A consignment of seed and planting may be imported only through the designated border crossings, were customs and phytosanitary inspectorial supervision is in place.

Only the importers registered with the Phytosanitary Administration may engage in imports of seed and planting material.

Prior to importing the seed or planting material, the importers or their authorised representatives have the obligation to address the Phytosanitary Administration for approval of the conditions for imports of seed or planting material.

Upon obtaining the approvals with import conditions, the importer or its authorized representative submits to the phytosanitary inspector an application in writing for examination of seed and planting material as regards compliance with the quality requirements prescribed, varietal aspects and health safety.

The application is submitted in writing, stating all the documents accompanying the consignment.

The application is to be registered and issued with a protocol number which consists of: the procedure mark; year mark; inspectorate mark; identification number of the inspector and the ordinal number of the protocol and the date when the application was submitted.

The importer or the authorised representative has to give the phytosanitary inspector a notice on arrival of a consignment of seed and planting material no later than 24 hours prior to the expected arrival of the consignment to the border crossing.

The consignment of seed and planting material that is subject to the examination remains under the customs supervision until the phytosanitary inspector confirms that the examination is completed.

The phytosanitary checks at imports of consignments of seed and planting material at the border inspection post include:

- Documentation check;
- Identity check;
- Physical checks.

Documentation check

Phytosanitary inspector checks whether the consignment of seed and planting material is accompanied by the following:

- original of the phytocertificate (for plant consignment for which the certificate is prescribed),
- approval from the Phytosanitary Administration;
- certificate of varietal aspect of seed and planting material (OECD);
- for imports of seed and planting material not included by the OECD certification system, the consignment must be accompanied by a document on varietal aspect issued by the competent body of the exporting country;
- certificate of quality of seed and planting material (ISTA);
- a declaration issued by the competent body of the exporting country, which must be marked in accordance with the national requirements prior to marketing;
- waybill or bill of lading;
- invoice, packing list, and

- other documents, where prescribed.

In documentation check, the phytosanitary inspector checks the following:

- whether the companies or other legal persons or entrepreneurs are registered in the Register of Seed and Planting Material Importers;
- whether they have ownership over or contract of lease for a registered bonded warehouse;
- whether the importer imports seed and planting material in accordance with the prescribed categories of seed and planting material;
- whether seed and planting material is imported in the original packaging;
- whether the seed and planting material is imported from producers satisfying the production conditions, i.e., who are registered with and are under control of the competent body of the exporting country;
- whether the quality of the seed and planting material satisfies the requirements set;
- the varietal aspects of the seed and planting material;
- whether the original of the phytocertificate is enclosed and whether it is issued in accordance with the International Plant Protection Organization (IPSM 12);
- the date on which the phytosanitary certificate was issued and compares it with the date on which the packing list was issued (in order to check the date when phytocertificate was issued);
- whether the goods were marked with an appropriate botanical name;
- whether the contents of the goods indicated on the phytocertificate matches the contents of the waybill;
- whether plants, plant products or objects under supervision indicated in the documents are subjected to prohibitions, restrictions, and
- whether an additional declaration is requested from the viewpoint of plant health protection;
- whether there are any temporary prohibitions concerning a region, country or plants, etc.

In case the documentation is incomplete or has some deficiencies, the importer or its authorized representative has the obligation to provide the missing documentation and the consignment is detained pending the completion of the documentation.

In case the documentation is complete and complies with all the conditions, the phytosanitary inspector shall proceed to identity and physical checks.

At border inspection posts where there are no conditions for examination (identity and physical checks), the phytosanitary inspector shall issue a decision on redirection of the consignment under customs supervision to the phytosanitary inspector in the place of customs clearance or some other place designated in accordance with the law.

Identity and physical checks

The phytosanitary inspector performs identity and physical checks of the consignment of the seed and planting material at the border crossing if there are conditions for such checks either in the bonded warehouse or another officially designated place in bond.

The consignment of seed and planting material is opened in the presence of the phytosanitary inspector, who commences the check of the quality, varietal aspects, identity of the goods, comparing the information indicated in the phyto-certificate, the certificate on varietal aspects of the seed and planting material (OECD); the certificate of quality of seed and planting material (ISTA); the declaration issued by the competent body of the exporting country in terms of the quantity, commodity type, packaging and all the marks (tags, etc.), and actual weight of the consignment with the weight indicated in the documentation by checking the number of packages or, if necessary, by weighing the consignment. The checks are made in several different samples taken from the entire consignment in order to establish the compliance with all the conditions prescribed

as well as whether the consignment is fit for use for the purposes indicated in the documentation.

During the control of seed and planting material, the phytosanitary inspector appraises, in addition to the quality and varietal aspects, also the level of risk from introduction of quarantine harmful organisms and possible derogations from the conditions prescribed for the seed and planting material in the consignment in order to establish the method of examination (setting the number of packages from which samples are to be taken, the number and the size of the samples, examination method, preventive measures, etc). Available scientific and technical information on previous analyses, information on quarantine harmful organisms on certain host plant species, on origin of the consignment, reliability of the phytocertificate and other accompanying documents are used for checking the risk level.

The physical check, that is, the examination, implies:

- visual check;
- simple laboratory analyses, and
- checks of the means of transport.

Laboratory checks are done in accordance with the risk analysis, where there are justified reasons for suspicion, whether the condition cannot be established accurately on the basis of accompanying documents or the physical checks done. The laboratory checks are done in authorized laboratories accredited for the quality of seed and planting material and authorized laboratories accredited for diagnostics of harmful organisms.

The consignments sent to laboratory checks are under the customs or quarantine supervision and must not be placed on the market pending the receipt of the results of laboratory testing.

In case the consignment of seed and planting material fails to meet the conditions prescribed by the Law on Plant Health Protection and the conditions from the Law on Planting Material and the Law on Seed Material of Agricultural Plants, and it cannot be fully controlled by disinfection or disinfestation, or in case the consignment is exposed to a higher level of secondary infections, or does not meet the varietal aspects or is not in accordance with the quality declared, the phytosanitary inspector will issue a decision prohibiting the import and order the consignment to be returned to the consignor or destroyed, and in case such consignment of seed and planting material is introduced by a natural person, the consignment will be seized and destroyed. The clause: **"Import prohibited"** will be placed on the accompanying documentation.

In case the consignment of seed and planting material complies with the prescribed conditions from the Law on Plant Health Protection and the conditions from the Law on Planting Material and the Law on Seed Material of Agricultural Plants, the phytosanitary inspector will confirm that the health check of the consignment of seed and planting material was done by placing on the customs declaration or the document accompanying the consignment the following declaration: **"The consignment checked. Import allowed"**.

In order to check the shipping consignments in ports, the ship has to be berthed at the port and consignments have to be onboard, or, with approval from the phytosanitary inspector, in a bonded warehouse where conditions for a phytosanitary check are provided.

In case the consignment of seed and planting material is imported by containers over the border crossing where containers are not examined, the phytosanitary inspector checks documentation only. In case it is established that the consignment in the container is supplied with the appropriate phyto-certificate, the approval of the Phytosanitary Administration (where prescribed), the certificate on varietal aspects of the seed and planting material (OECD), the certificate of quality of seed and planting material (ISTA), the declaration of quality, the phytosanitary inspector approves of the transport of the container under customs supervision to the designated place for the container check, where opening of the container may take place. In case it is established that the consignment of seed and planting material imported in containers is not supplied with a phyto-certificate, the approval of the Phytosanitary Administration (where prescribed), the certificate on varietal aspects of the seed and planting material (OECD), the certificate of quality of seed and planting material (ISTA), the declaration of quality, or where it can be established from the documentation that it contains seed and planting material in contravention of the prescribed

prohibition of import or restriction of import, as appropriate, the phytosanitary inspector will order the consignment to be returned to the consignor.

The consignments transported by railway are checked at railway stations designated by the Phytosanitary Administration.

Airmail, general cargo and mail are checked in the bonded warehouse in the space designated for that purpose.

In imports of those types of seed and planting material that transmit or may transmit quarantine harmful organisms presence of which cannot be established during the health checks at the border crossing (hidden infections), the quarantine supervision at the end user's (at the planting site) is imposed, in accordance with the regulations of plant health protection (Order on Types of Planting Material from Imports and Monitoring of Health Condition at End User's, Official Gazette of the Federal Republic of Yugoslavia 8/99). During the check of health condition of planting material, the material must not be propagated or taken from the designated isolated plot of land, or moved to another plot of land without approval from the phytosanitary inspector.

Transit of consignments of seed and planting material

Consignments of seed and planting material in transit through the territory of Montenegro and reloaded to other means of transport are subject to mandatory health checks at the border crossing. When such consignment arrives to the border crossing where reloading does not take place the phytosanitary inspector checks documents only.

Reloading of consignments of seed and planting material

In case reloading takes place and the documentation complies with the conditions prescribed as well as other regulations, the phytosanitary inspector approves of the transit under the customs supervision to the place where reloading and health check of the seed and planting material would take place.

Reloading must not commence in absence of a phytosanitary inspector. In case the accompanying documentation is not in accordance with the conditions prescribed, the phytosanitary inspector will prohibit the entry of the consignment of seed and planting material and order the consignment to be returned to the consignor. The same shall be ordered in case it is established by the health check that the consignment is infected with a quarantine harmful organism. The following declaration will be placed on the accompanying documents: **Transit prohibited (consignment infected, name of the quarantine harmful organism)**.

Export and re-export of consignments of seed and planting material

The check of consignment of seed and planting material in export and re-export includes the following:

- means of transport;
- packaging;
- where necessary, warehouses, preparation establishments and holdings that the consignment originates from;
- health examination;
- documentation check (certificate of health condition, certificate of varietal aspects issued by the authorized institution and the declaration issued by the producer of planting material, in accordance with the prescribed requirements of the country the consignment is exported to).

Following the health check of the consignment of seed and planting material and the accompanying documentation and in case the requirements prescribed by the country the consignment is exported to are met, the phytosanitary inspector will allow the export and issue a phyto-certificate.

Where it is established during the health check that the consignment of seed and planting material does not meet the requirements prescribed by the country that the consignment is to be exported

to or that it is infected with a harmful organism for which its introduction into the importing country or the country of transit would be prohibited, or in case the means of transport and the packaging do not meet the conditions for export, the phytosanitary inspector will not allow the export nor issue a phytocertificate for such consignments.

Inspection control in internal trade

During the control in internal trade, the phytosanitary inspector performs inspection supervision over the registered producers, importers, retail and wholesale establishments for seed and planting material, as follows:

- whether they are entered into the registers prescribed, and for natural person, whether he/she concluded a contract on co-operation with the registered producer;
- whether they meet the conditions prescribed for entry in the register;
- whether the seed and planting material in accordance with the categories laid down by the law is marketed;
- whether records on production of and trade in seed and planting material are kept, as well as on imported quantities of seed and planting material;
- whether the varieties produced and placed on the market are registered in the Register of varieties and rootstocks and exercising of rights of use of protected varieties and rootstocks.

The phytosanitary inspector also controls the producers registered in the Register of Producers in terms of the conditions prescribed, as follows:

- whether they have land necessary for production of seed and planting material;
- whether they employ, on full-time basis, a person responsible for production of seed and planting material, with prescribed qualifications and minimum three years of professional working experience;
- whether they reported to the Phytosanitary Administration all the changes of conditions for production;
- whether they keep the records on production of seed and planting material, and in particular the following:
    - the plan of the nursery and nuclear stock (object) with clearly marked area where planting material is produced, the species or variety and the year of production of the planting material used in setting up of the production;
    - distribution of seed crops, or object, with clearly marked area where seed material is produced, the species or variety and the year of production of the seed material used in setting up of the production;
    - total quantity of seed and planting material;
    - data on production method;
    - type and date of works;
    - total quantities of seed and planting material received, produced, sold and destroyed;
- whether seed and planting material produced originates from varieties and rootstocks registered in the Register of Varieties and Rootstocks of Seed and Planting Material;
- whether they submit every year the application on production of seed and planting material to the Phytosanitary Administration;
- whether they have production plan defining the critical points for specific types of seed and planting material that might affect the quality, health condition and yield of seed and planting material, as well as methods for monitoring and control of critical points;

- whether they perform the checks for the purpose of monitoring and control of critical points in accordance with the methods; implement measures in order to prevent the occurrence or spread of harmful organisms; take and deliver the samples to the authorized laboratory for the purpose of monitoring of the quality of the production; keep minutes on monitoring and records of critical points as well as on measures implemented in order to ensure the compliance of the seed and planting material with the standards prescribed;
- whether they notify the Phytosanitary Inspectorate, i.e., the phytosanitary inspector, on occurrence or suspected occurrence of harmful organisms at the place of production;
- whether they made possible the supervision and identification of every lot of seed and planting material in all phases of production, processing, storage in trade and supply of seed and planting material;
- whether they keep records and documents on maintenance of the variety, or of supply and origin of seed and planting material used for reproduction;
- whether they perform other activities as laid down by the law;
- whether producers of planting material retain documentation for at least five years, and producer of seed material for at least one year for annual crops and three years for perennial plantations;
- whether seed and planting material on the market is stored and kept by methods and under the conditions ensuring the preservation of its quality;
- whether trade in seed material is performed only in the sales establishment.

POWERS OF DIFFERENT INSTITUTIONS IN THIS FIELD

Biotechnical Faculty of the University of Montenegro, within which the following institutions operate:

- Laboratory for Seed (Centre for Field Crops, Vegetable and Fodder Production) (testing and determination of the quality of seed material of agricultural plants);
- Laboratory for Planting Material (Centre for Fruit Growing and Viticulture, Podgorica and Centre for Subtropical Cultures, Bar) (testing and determination of the quality of planting material).

The Laboratory for Seed (Biotechnical Faculty - Centre for Field Crops, Vegetable and Fodder Production) is authorized by the Phytosanitary Administration, in accordance with the Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) for the following activities concerning the seed material: laboratory testing and determination of the quality of seed material, VCU TESTS for establishing of the value for cultivation and use of a variety; professional and technical activities (certification) and other activities of public interest in this field. The authorization defines the activities of public interests and conditions for delegating the performing of public activities to the Laboratory for Seed. The Centre for Field Crops, Vegetable and Fodder Production, authorized by the Phytosanitary Administration, certifies the seed material of agricultural plants.
The Laboratory for Seed is a unit of the Biotechnical Faculty in Podgorica – Centre for Field Crops, Vegetable and Fodder Production (University of Montenegro). The Laboratory for Seed has received additional laboratory equipment supplied from donor funds under the SEEDNET Project.

Currently, the equipment of the Laboratory for Seed does not fully satisfy the requirements of modern methods of testing the quality of seed material of agricultural plants. Supply of additional equipment and delivery of additional training to staff should make possible improvement of the procedures.

The Laboratory for Seed as the only laboratory of the kind in Montenegro, is included in the education under the SEEDNET project as well as in the TAIEX projects in this field. The Laboratory for Seed works on accreditation in accordance with the ISO 9001 standard and ISTA.

The Laboratory for Seed employs 4 PhDs (for crop production, vegetable production, fodder and mechanization) and one technician who completed a Secondary School of Agriculture, employment of technicians is planned.
Upgrade of the existing equipment is necessary so that the laboratory would be able to efficiently check the seed quality.
The methods prescribed by the national legislation or laboratory's own methods are used in testing the quality of seed material of agricultural plants.

Methods for testing the quality of seed material of agricultural plants

TESTING	METHOD
Seed quality	ISTA methods Rulebook on the Quality of Seed Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89, 16/92, 8/93, 21/93, 30/94, 43/96, 10/98, 15/01 and 58/02) Rulebook on Norms of Quality, Packaging, Sealing and Labelling of Seed Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 55/75)

Measures that need to be implemented in order to improve the situation:

- The Laboratory for Seed has to be clearly recognized through internal organization of the Biotechnical Faculty, with hierarchy and responsibility levels established;
- Establish accreditation in accordance with the ISO 9001 standard and ISTA;
- Further employment of professional staff and technicians;
- Introduction of protocols for testing methods;
- Introduction of Good Laboratory Practice.

Laboratory for Planting Material (Biotechnical Faculty - Centre for Fruit Growing and Viticulture, Podgorica and Centre for Subtropical Cultures) is authorized by the Phytosanitary Administration, in accordance with the Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) for the following activities concerning the planting material: laboratory testing and determination of the quality of planting material, VCU TESTS for establishing of the value for cultivation and use of a variety or a rootstock; professional and technical activities (certification) and other activities of public interest in this field. The authorization defines the activities of public interests and conditions for delegating the performing of public activities to the Laboratory for Planting Material. The Centre for Fruit Growing and Viticulture, authorized by the Phytosanitary Administration, certifies the planting material of agricultural plants.

Currently, the equipment of the Laboratory for Planting does not fully satisfy the requirements of contemporary methods of testing the quality of planting material. Supply of additional equipment and delivery of additional training to staff should make possible improvement of the procedures.

The Laboratory for Planting Material, as the only laboratory of the kind in Montenegro, is included in the education under the TAIEX projects in this field. The Laboratory for Planting Material works on accreditation in accordance with the ISO 9001 standard and ISTA.

The Laboratory for Planting Material employs 4 PhDs and one technician who completed Secondary School of Agriculture, employment of technicians is planned.
Upgrade of the existing equipment is necessary so that the laboratory would be able to efficiently check the quality of planting material.
The methods prescribed by the national legislation or laboratory's own methods are used in testing the quality of planting material.

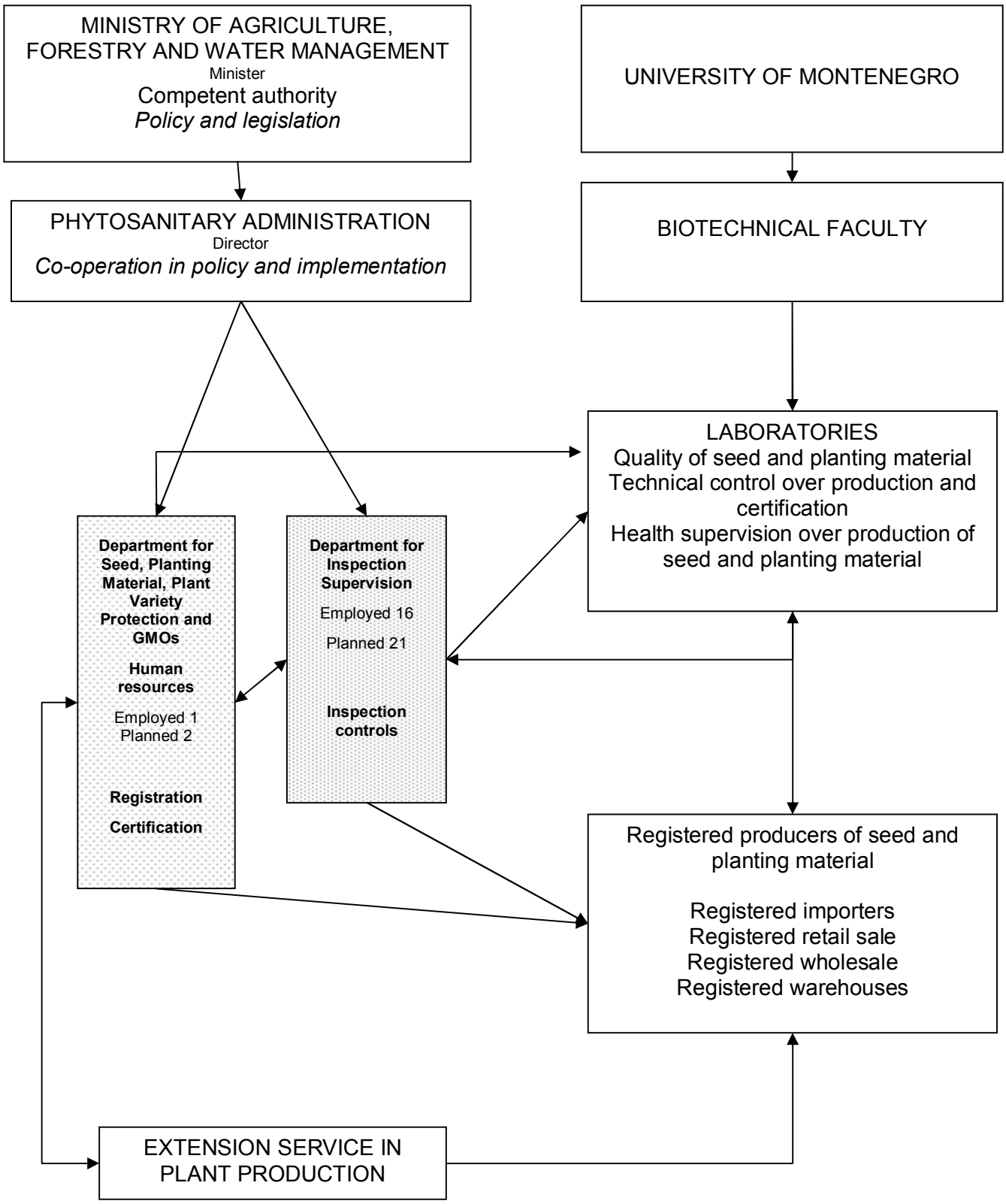
Methods for testing the quality of planting material

TESTING	METHOD
Planting material quality	ISTA methods Rulebook on Norms of Quality, Packaging, Sealing and Labelling of Planting Material (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79)

Measures that need to be implemented in order to improve the situation:

- The Laboratory for Planting Material has to be clearly recognized through internal organization of the Biotechnical Faculty, with hierarchy and responsibility levels established;
- Establish accreditation in accordance with the ISO 9001 standard and ISTA;
- Further employment of professional staff and technicians;
- Introduction of protocols for testing methods;
- Introduction of Good Laboratory Practice.

Flow chart- Quality of Seed and Planting Material



- **Registration of varieties, catalogues;**

The procedure for entry of varieties into the Register/Catalogue of varieties of agricultural plants

The procedure for registration of varieties and setting up of a catalogue/register of varieties of agricultural plants is governed by the Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06), the Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) and the Law on Protection of Plant Varieties (Official Gazette of the Republic of Montenegro 48/07 and 48/08) which is harmonized with the UPOV requirements. In this way, the legal framework concerning the intellectual property in the field of protection of plant varieties has been established in Montenegro for the first time, and it governs the method and procedure for acquiring the breeder's rights.

Prior to adoption of these laws, the procedure for approval and introduction into production of allochthonous newly selected varieties (already approved and tested) had been very complicated. As a result of lack of technical and financial capacity for checking a large number of new quality varieties continuously created throughout the world, their introduction into production was very difficult, which , to a large extent, hindered the modernization of, first of all, vegetable production. Through the list of approved varieties and protection of rights secured, these laws made possible for the producers to set up the production based on international experiences. With setting up of a list of recommended varieties, the protection has been provided to producers who want to set up production on an assortment tested by competent institutions in agro-environmental conditions of Montenegro.

The Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) lays down the *Register of varieties of agricultural plants*, kept by Phytosanitary Administration, which includes, in particular, the information on:

- Newly created domestic varieties;
- Foreign varieties approved by the competent body of a foreign country;
- Domestic and domesticated varieties;
- Varieties with temporary approval.

In order to be included in the List of recommended varieties, a variety entered into the Register of Varieties of Agricultural Plants may be tested for the value for cultivation and use (VCU TEST) in accordance with the methods prescribed. The testing is performed by authorized institutions in Montenegro.

DUS TEST, establishing the distinctness, uniformity and stability of a variety are not performed in Montenegro; thus the results of DUS tests performed in a UPOV (International Union for Protection of Varieties) member state are recognized.

The Phytosanitary Administration sets the list of varieties entered, or deleted, as appropriate, from the Register of Agricultural Plants, and sets the List of recommended varieties.

The List of recommended varieties of agricultural plants is published in the »Official Gazette of Montenegro«.

The Register of varieties of agricultural plants is a list of varieties officially accepted for certification and marketing on the territory of Montenegro. The List of domestic and domesticated varieties, taken from the legal system of the state union (the List of approved domestic newly created varieties of agricultural and forest plants, foreign varieties of agricultural and forest plants for which introduction into production in FRY is authorized, and of domestic and domesticated foreign varieties of agricultural and forest plants, Official Gazette of the Federal Republic of Yugoslavia 56/02) is a part of this Register.

For every variety included in the list, the following is indicated: plant species, variety denomination, origin, year of the approval, name of the breeder, representative. This list was made in 2002, and has not been updated since.

The Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) lays down the *Register of Varieties and Rootstocks*, kept by the Phytosanitary Administration, includes in particular the information on the following:

- Newly created domestic varieties;
- Foreign varieties approved by the competent authority of a foreign country;
- Domestic and domesticated varieties.

The planting material of a variety may be marketed for the period of time for which the variety is registered in the Register of Varieties and Rootstocks.

The Register of Varieties and Rootstocks includes the data on newly created domestic and approved foreign varieties, varieties entered in the EU catalogue, domestic and domesticated varieties.

Domestic and foreign varieties approved in the procedure of approval of a variety, in terms of this Law are recommended varieties, and varieties entered in the catalogue of EU Member States are approved varieties, in terms of this Law.

Domestic and domesticated varieties not complying with all the conditions for entry in the Register of Varieties and Rootstocks as laid down by this Law may be registered in the Register of Varieties and Rootstocks, and they are marked differently.

Approval of varieties, in terms of this Law, is approval of a newly created domestic variety, in case it is a result of hybridization or selection, or if it is biologically different from another approved variety, which served as a standard variety in the approval process.

In the procedure of approval of a variety, the quality and other essential characteristics - based on which a variety may be approved - are determined, while seed or planting material of that variety may be reproduced or marketed on the territory of Montenegro as varietal.

A variety is approved in case it is established that:

- It is distinct, uniform and stable (DUS test);
- It has a favourable value for cultivation and use (VCU test);
- The denomination of the variety is determined in accordance with the law.

The procedure of approval of the variety is initiated based on an application, with documentation on activities carried out in creating of a variety, submitted by the variety breeder or his authorized representative. The information and documentation concerning the origin of original material and the description of the process of creating a variety is business secret.

Based on results of testing of a variety, at proposal of an expert committee, the Phytosanitary Administration adopts a decision on approval of the variety or on rejection of the application, as appropriate.

Based on the decision on approval of the variety, the Phytosanitary Administration enters the variety in the Register of Varieties of Agricultural Plants. During the period of time for which the variety is registered in the Register of Varieties of the Agricultural Plants, the seed, or the planting material of the variety, as appropriate, may be marketed as varietal.

- Seed certification

The Phytosanitary Administration is a public administration body in charge of direct implementation of regulations and certification of seed in Montenegro. Strengthening of its administrative capacity will be continued in order to achieve the best possible quality in implementation of the EU legal framework in the field of seed material

The Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro

28/2006) is a framework law for the field of seed material and seed certification. This law provides a legal framework for harmonization with the EU legislation in the field of production, packaging, marking, control and trade in seed material, introduction of the quality of seed material in accordance with the ISTA standards and varietal aspects of the seed material in accordance with the OECD, acceptance of the UPOV standards in the process of approval of varieties, setting up of registers that enable keeping records and more intensive control of all participants in the process of production and trade in seed material, as well as setting up of a single information system. This law is a legal basis for development of secondary legislation that will be aligned with the EU legislation.

Pending the adoption of secondary legislation in accordance with this Law, the following national pieces of legislation, adopted before, will be applied:

- Order on Authorized Mixtures of Different Varieties and Species of Agricultural Seed that may be Placed on the Market (Official Gazette of the Republic of Montenegro 3/83);
- Rulebook on Technical Control over the Seed Production (Official Gazette of the Republic of Montenegro 28/94);
- Decision on the Amount of the Fee for Control and Mandatory Checks in Production of Agricultural Seed and Planting Material (Official Gazette of the Republic of Montenegro 54/00);
- Order on Authorized Mixtures of Different Varieties and Species of Agricultural Seed that may be Placed on the Market (Official Gazette of the Republic of Montenegro 3/83)
- Rulebook on the Form and Method of Keeping the Register of Seed Producers and Processors and Register of Producers of Planting Material (Official Gazette of the Republic of Montenegro 24/82);
- Rulebook on Technical Control over the Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/1994);
- Rulebook on the Quality of Seed of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89; Official Gazette of the Federal Republic of Yugoslavia16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02);
- and a set of set of regulations in plant health protection field.

The only seed material production in Montenegro is the seed potato production.

There are eight seed potato producers registered in the Register of seed material producers.

Certified seed, in terms of this Law, is seed produced from seed of known genetic origin, production of which is controlled, and which is tested, processed and labelled in accordance with this Law.

The purpose of seed certification is to encourage the production of high quality seed of varieties and hybrids cultivated and placed under the best of conditions in order to ensure the genetic identity and purity of the varieties and hybrids.

A registered producer of seed material may produce only the seed material of varieties entered in the Register/catalogue of varieties of agricultural plants and has the obligation to provide, from the owner of the variety, the approval for reproduction of seed material, for cultivation of the protected varieties.

Under special conditions approved by the Phytosanitary Administration, a producer may produce, process and test imported seed material of varieties not entered in the Register of varieties of agricultural plants for a foreign client, based on a contract signed with a foreign client, according to which the foreign client is to take over the total quantity of natural or processed seed material produced.

A registered producer of seed material in the certification process has to submit to the Phytosanitary Administration an application for production, in a prescribed from and within the

period of time prescribed. The producer has the obligation to submit the application for technical control within the period of 15 days from the day of completion of the sowing, and no later than:

- December 31, for autumn sowing;
- June 30 for spring sowing.

The producer may submit the application for production provided that:

- He/she is registered in the Register of Producers;
- The variety is entered in the Register of agricultural plants;
- He/she obtained the approval for reproduction of seed material of a protected variety from the variety owner.

The application is to be registered and issued with a protocol number which consists of: the procedure mark; year mark; sector mark; ordinal number of the protocol and the date when the application was submitted, in two copies with the accompanying documents enclosed.

The application must indicate, in particular, the following:

- Name and the head office address, or the first and the last name of the applicant;
- Application number of every location, in case there are several;
- Information on the producer (fist name and the last name, address or the name and the head office address, the number of the decision on registration), in case there are several producers, the application is submitted for each producer separately;
- Information on production:
    - Plant species produced;
    - variety, category, quantity and producer of the seeds used, name and head office address of the authorized institution that issued the declaration of quality of the seeds used;
    - total production area;
    - area by locations, as follows:
        - elite, super elite – minimum area of 0.5 ha;
        - original and first variety reproduction – minimum area 1 ha;
    - settlement, parcel (name, cadastral number and area);
    - altitude:
        - seed potato crops may be set up as follows:
            - super elite above 1200m asl;
            - elite above 1000m asl;
            - original above 900m asl;
            - first variety reproduction above 800m asl;
    - previous crops (crop rotation);
    - isolation strip width:
        - super elite minimum 500m;
        - elite minimum 300m;
        - original minimum 200m;
        - first variety reproduction minimum 100m;
- name of the institution authorized for technical control.

In case production takes place at several different locations, the application is submitted for every location separately.

Together with the application for production, the following documents are to be submitted:

- decision on entry in the Register of seed material producers;
- contract on performing the technical control concluded with an authorized institution;
- evidence of employment, on full-time basis, of a person responsible for production;
- evidence on origin of seed used for production:
    - for seed material from domestic production (for potato, category original) a certificate on recognition of the crop, issued by the Phytosanitary Administration is to be submitted;
    - for imported seed material, the phytocertificate and the certificate on varietal aspects and quality, issued by the authorized body of the exporting country.
- For processing, the contract with a registered processor is to be enclosed;
- Evidence of ownership over or contract of lease for land necessary for production of seed material;
- A framework plan of production with information on:
    - Defined critical points, which might affect the quality, health condition and yield of seed material, with methods for monitoring and control of these critical points;
    - Measures planned in order to prevent the occurrence or spread of harmful organisms;
    - Production method;
    - Type and date of works performed;
- Scheme of distribution of seed crops, or objects, as appropriate.

A seed material producer, applying for production, has the obligation to ensure all the conditions necessary for technical control, for all aspects (eg. for seed potato production, it is necessary to ensure, within a prescribed period of time, sampling of soil for the purpose of laboratory analyses for the presence of nematodes).

Technical control over the production of pre basic seed material is performed by a variety maintainer, while for other categories of seed material, it is performed by a legal person authorized by the Phytosanitary Administration, provided that conditions as regards human resources and equipment are met.

Technical control over the production of seed material of agricultural plants is performed by the Biotechnical Faculty in Podgorica, Centre for Crop, Vegetable and Fodder Production, based on the authorization of the Phytosanitary Administration.

During the vegetation period, as a part of the technical control, the mandatory checks of crops are performed (3-6 checks) in accordance with the Rulebook on Technical Control over Production of Agricultural Seed (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for performing the control over the production of agricultural seed and the Rulebook on health examination of crops and objects for production of seed, seedlings and planting material and health checks of seed, seedlings and planting material (Official Gazette of the Federal Republic of Yugoslavia 66/99, 13/02, Official Gazette of Serbia and Montenegro 10/03, 13/03) with Criteria for determining the health condition of crops and objects, seed and seedlings and planting material.

The authorized legal person, that is, the Centre for Crop, Vegetable and Fodder Production:

- Controls producers in terms of whether the producer acts in accordance with the procedures prescribed and established, implemented during the vegetation period;
- Checks documentation on the origin of the seed used;

- Performs technical examinations during the vegetation period in terms of checking the origin of the seeds used,
- Check authenticity and purity of the variety produced, during the vegetation period, when morphological, phenological and other characteristics of the specie and the variety are the most pronounced;
- Controls spatial isolation of crops, that is, determines the distance of seed crops from other crops of the same or other species or varieties of plants with which free cross breeding may take place;
- Controls the crop rotation, establishes whether the duration (four years or three years) prescribed has been observed;
- Controls the presence of weed in the seed crop, establishing the weediness, and particularly the presence of weed that affects the quality of the seed in terms of genetics (biology), health and mechanics;
- Controls general condition and development of the seed crop, in terms of determining the appearance and uniformity of crop, its growth and other characteristic features of the plants of that particular specie and variety;
- Estimates the expected yield of unprocessed seed based on the entire quantity of seed yield from the area it is produced on;
- Health condition of crops,
- Implementation of measures for preservation of biological and economic features of the seeds.

A crop is recognized as a seed crop only after performing all the mandatory checks, depending on the type of the crop.

The health certificate for seed is issued by the Biotechnical Faculty in Podgorica, the Centre for Plant Health Protection, which is authorized for monitoring of the health condition of seed material during the vegetation period, issued based on the analyses done, when it is established that the seed material is not infected with quarantine plant pests or pests of economic significance above the percentage permitted by the criteria for determining the health condition of seeds.

Basic and certified seed produced, process and placed on the market is subject to post-control checks of seed, where control sample is a standard sample of seed material.

The post-control checks of seed are used to check the varietal aspects (originality), genetic purity, health condition and compliance with other criteria concerning the quality of seed of agricultural plants.

The post-control checks of seed are carried out by an authorized legal person.

Minutes are made on each technical control carried out over the seed crops for each location, which is signed by the person responsible at the producer's and by the person performing the technical control. On the basis of these minutes, the authorized legal person presents to the Phytosanitary Administration a report on the technical control performed. On the basis of that report, the Phytosanitary Administration issues a certificate of recognition of seed crops.

After obtaining this certificate, the processor submits to the authorized legal person an application for issuing of a declaration of quality of seeds. The application is, at the same time, the application for checking the seed prior to placing it on the market.

The authorized legal person issues a declaration in accordance with the contents, methods and appearance prescribed for specific seed material categories. The authorized legal person keeps records of declarations issued and used.

The seed material on the market must be in accordance with the species and variety declared, with the quality standards prescribed, must be in the original packaging and with a declaration accompanying the packing list and the tag (label on the packaging). The seed material in trade must be in accordance with the quality marked in the declaration and on the tag.

The method of marking (labelling) of seed material is laid down by articles 4 and 37 of the Law on Seed Material of Agricultural Plants. Printing of tags is entrusted to the authorized legal person (Biotechnical Faculty in Podgorica, Centre for Crop, Vegetable and Fodder Production), while control of the number of tags issued is provided, in accordance with the quantities of seeds processed, with a view to preventing abuse.

Seed material in lots must be in original packaging, marked in a prescribed manner, which ensures the originality of the packaging and preservation of is quality. In case the seed material of agricultural plants is treated with chemicals or phyto-pharmacological preparations, the products used must be indicated on the label.

Depending on the type and category of the seed material, the label and the tag must be uniform by content, size, colour and must have a serial number. The label for small packaging of seed material is issued by the processor, or importer, as appropriate. Packaging and labelling of seed material is carried out by the processor, at the place of processing, in presence of representatives of the authorized legal person. The records on labels, or tags, issued, are kept by the legal person (Biotechnical Faculty in Podgorica, Centre for Crop, Vegetable and Fodder Production).

It is prohibited to re-pack seed material in original packaging from domestic production and import. By way of exception, with approval from the Phytosanitary Administration, a processor, or importer, as the case may be, may re-pack seed material. The application for re-packing of seed material is submitted by the processor, or importer, as appropriate, to the administration body, together with the declaration or certificate on varietal aspects of seed (OECD), the certificate of quality for seed (ISTA) and phyto-certificate.

The quality of seed material has to be established for each lot of the seed, prior to marketing. The authorized quantity of seed in a lot for certain types of seed material and mixtures thereof is governed by the Rulebook on the Quality of Seed of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87).

Testing and establishing the quality and categorization of seed material is done prior to marketing. The Laboratory for Seed (Biotechnical Faculty - Centre for Crop, Vegetable and Fodder Production) is authorized by the Phytosanitary Administration for testing and determining the quality of seed material.

The processor, or importer, as appropriate, is responsible for the quality of seed material.

The categories of the seed material are as follows:

- pre-basic;
- basic;
- certified seed of the first generation;
- certified seed of the second generation;
- non-varietal.

Pre-basic seed is elite of self-pollinated plant species, self-pollinated lines, super elite potato and seed of parent components, produced and maintained by the maintainer and used for production of basic seed.

The basic seed is the original of self-pollinated plant species, components of potato hybrids and elites, produced under the control of the Phytosanitary Administration and used for production of certified seed of the first generation.

The certified seed of the first generation is the first variety reproduction of self-pollinated plant species, the first generation of the hybrid and original potato, used for production of seed of the second generation and produced under the control of the Phytosanitary Administration.

The certified seed of the second generation is the second variety reproduction of self-pollinated plant species and the first variety reproduction of potato, produced under the control of Phytosanitary Administration.

Non-varietal seed is seed of flowers, aromatic, medicinal herbs and spices for which there are no approved varieties, but satisfies the conditions in terms of authenticity and purity of the species and is produced under the control of the producer.

- Approval of propagating material

Phytosanitary Administration is a public administration body in charge of direct implementation of regulations and approval of planting material in Montenegro. Administrative capacity building of the Administration will be continued for the purpose of achieving the best possible quality of implementation of the EU legal framework concerning the planting material.

The Law on Planting Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/2006) is the framework law for the field of planting material and approval of the planting material. This law provided the legal basis for alignment with the EU legislation in the field of production, packaging, marking, control and trade in planting material, introduction of the quality categories for the planting material in accordance with the ISTA standards and varietal aspects of the planting material in accordance with the OECD, acceptance of the UPOV standards in the process of approval of varieties, setting up of registers that enable the recording and better control of all participants in the process of production and trade in planting material, as well as setting up of a single information system. This law provides a legal basis for development of secondary legislation that will be harmonized with the EU legislation.

Pending the adoption of the secondary legislation in accordance with this Law, the following pieces of national legislation adopted previously shall apply:

- Rulebook on Contents and Methods of Keeping Records on Planting Material Produced, Supplied, Sold and Used for Private Purposes (Official Gazette of the Republic of Montenegro 24/82);
- Rulebook on Technical Control over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94);
- Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79);
- Rulebook on Methods of Selection of Parent Trees, Varieties and Rootstocks, i.e. Selection of Fruit Trees, Grape Vine and Hop as well as Method of Keeping the Book of Parent Trees (Official Gazette of the Republic of Montenegro 9/83);
- Rulebook on Methods and Procedures of Selection and Rootstocking of Trees, Plantations of Fruit Trees, Grape Vine, Hop and Roses, as well as on the Contents and Methods of Keeping the Book of Parent Trees (Official Gazette of the Republic of Montenegro 26/97).

A registered producer of planting material may produce only the planting material of varieties registered in the Register of Varieties and Rootstocks and has to obtain approval from the variety owner for propagation of varieties of planting material in case the producer grows protected varieties.

Under special conditions to be approved by the Phytosanitary Administration, a foreign producer may, for the needs of a domestic customer, produce planting material in another state based on a contract signed by the domestic customer and the foreign producer.

Under special conditions to be approved by the Phytosanitary Administration, a domestic producer, too, may, for a foreign customer, produce from imported reproduction material the planting material of varieties or rootstocks not registered in the Register of Varieties and Rootstocks, based on a contract signed with the foreign customer according to which the foreign customer would take over the whole quantity of the planting material produced. Marketing of this material on the territory of Montenegro is not allowed.

In the process of approval, a registered producer of planting material must submit to the Phytosanitary Administration the application for production in a prescribed form and within the period of time prescribed.

Every year, the producer of a planting material has the obligation to submit the application for technical control over the material produced no later than April 30 of the current year for the planting material produced as well as for the reproduction material to be used for production of the planting material.

The producer of the planting material may submit the application for production provided that:

- He/she is registered in the Register of Producers;
- the variety is registered in the Register of Varieties and Rootstocks;
- he/she secured approval of the variety owner for reproduction of planting material of a protected variety.

The application is registered and given a protocol number, consisting of: procedure mark; year mark; sector mark; ordinal number of the protocol and the date when the application was submitted, in two copies with the accompanying documents attached.

The contents of the application have to include in particular the following:

- name and address of the head office, or the first and the last name of the applicant;
- number of the application for each location, in case there are several locations;
- data on the producer (first name and the last name, address or name and address of the head office, the number of the decision on registration), in case there are several producers, the application is submitted for every producer separately;
- data on production:
    - plant variety produced;
    - variety, category, quantity, name and address of the head office of the authorized institution that issued the declaration of quality for the planting material used;
    - plan of the nursery and nuclear stock (establishment with clearly marked area where the planting material is produced, the specie or variety and the year of production of the planting material used in setting up of the production);
    - isolation strip width:
        - for parent seedlings of stone fruits 1000 m;
        - for planting material of stone fruits 500 m;
        - for planting material of berries 300 m from the six-needle pine;
- name of the authorized legal person for carrying out of technical control.

In case production takes place in several different locations, the application is submitted for each location separately.

Together with the application for production, the following documentation is to be submitted:

- decision on entry into the Register of producers of planting material;
- a contract concluded with the authorized institution for carrying out of technical control;
- evidence that the producer employs on full-time basis a professional in charge of production;
- evidence on origin of planting material used for production:
    - for planting material from domestic production, a certificate on approval of production of planting material, issued by the Phytosanitary Administration is to be submitted;

- for imported planting material, the phytocertificate and the certificate on varietal aspects and quality is to be presented, issued by the competent authority of the exporting country;

- evidence of ownership over or contract on lease for land necessary for production of the planting material;
- a framework production plan with information on:
  - critical points defined, which might affect the quality, the health condition and yield of the planting material with methods for monitoring and control of these critical points;
  - measures planned in order to prevent the occurrence or spread of harmful organisms;
  - production method;
  - type and dates of the work done;
- scheme of arrangement of parent plants, planting material used, or objects, as appropriate.

Production of planting material and parent trees used in production of planting material subject to mandatory technical control.

Parent plants are selected and marked based on the Rulebook on Methods and Procedures of Selection and Rootstocking of Trees, Plantations of Fruit Trees and Grape Vine, Hop and Roses, as well as on the Contents and Methods of Keeping the Book of Parent Trees (Official Gazette of the Republic of Montenegro 26/97).

The technical control over the production of planting material is done by an authorized legal person, which is authorized for these activities by the Phytosanitary Administration.

The conditions, in terms of staffing, premises and equipment, that should be met by an authorized legal person, the method and methodology of carrying out the technical examination of the planting material, the content and deadlines for submitting the report of the technical examination performed are set by the Rulebook on Technical Control over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94).

The authorized legal person, that is, the Centre for Fruit Growing and Viticulture, Podgorica and the Centre for Subtropical Cultures, Bar:

- controls producers as regards whether the producer acts in accordance with the procedures laid down by the law and the procedures set, implemented during the vegetation period;
- checks documents on the origin of the planting material;
- carries out technical examinations at least twice during the vegetation period as regards checking the origin of the planting material;
- the first examination takes place when characteristics of the species, variety or selection are most distinct, no later than August 1, while the second examination takes place when uniform development and general appearance of the planting material is pronounced, and no later than December 1 of the current year;
- checking the authenticity and purity of the variety produced in the vegetation period, when morphological, phenological and other characteristics of the species and the variety are the most distinct;
- controls spatial isolation, that is, establishes the distance from others of the same or other species
- controls the presence of weed;
- controls the general condition and development in terms of determining the appearance and uniformity, growth and other distinct characteristics of the plants of that species and variety;

- estimates the expected yield;
- health condition;
- implementation of measures for preservation of biological and economic characteristics.

Minutes are made on every technical examination of the production of planting material for each location; the minutes are signed by the producer's responsible person and the person performing the technical examination. Based on these minutes, the authorized legal person submits to the Phytosanitary Administration a report on technical examination done. On the basis of the report, the Phytosanitary Administration issues the certificate on approval of production of the basic, certified and standard planting material.

In case it is established during the technical control that the planting material does not correspond with the genuineness and purity of the species, variety or selection and category, the commission will establish the number of the planting material, mark it visibly and state the quantity in the minutes. The producer must separate and destroy this quantity within the period of time prescribed, in the presence of a phytosanitary inspector.

Upon receipt of the certificate on approval of the basic, certified and standard planting material, the producer applies, in a prescribed form, to the authorized legal person for issuing of declarations of quality of the planting material. This application is at the same time the application for examination of planting material before placing it on the market.

The authorized legal person issues a declaration in accordance with the contents, methods and appearance prescribed for the specific planting material categories. The authorized legal person keeps records of declarations issued and used.

The planting material on the market must be in accordance with the species and variety declared, with the quality standards prescribed, must be in the original packaging and with a declaration accompanying the packing list and the label (tag) on the seedlings separately, or in a group. The planting material in trade must be in accordance with the quality marked in the declaration and on the tag. Depending on the type and category of the planting material, the declaration and the tag must be uniform by content, size, colour and have the serial number.

Packing and labelling of planting material is done by the producer of the planting material at the place of production.

The categories of the planting material are as follows:

- pre-basic;
- basic;
- certified;
- standard.

Pre-basic planting material is a reproduction material produced under the control of the keeper, tested for the presence of diseases and pests and is used for production of basic planting material.

The basic planting material is the reproduction material obtained from pre-basic planting material, free from viruses, intended for production of certified planting material, produced in nuclear stocks (objects) under technical control and is marked in trade with a white label.

The certified planting material is the reproduction planting material obtained from the basic planting material, intended for production of certified seedlings or for production of standard planting material and is marked in trade with a blue label.

The standard planting material is the reproduction planting material obtained by propagation of planting material from certified seedlings or standard parent plants, shrubs or vines identity, purity of the variety and health condition of which has been established, which is used for production of standard seedlings, setting up of plantations and is marked in trade with a yellow label and sign S-A.

Only the abovementioned categories of planting materials may be used for production of planting material.

PRIORITY AND TENTATIVE PLAN OF HARMONIZATION WITH THE EU ACQUIS – CLEAR TABLE

Fodder plant

EU	MNE
Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a Rulebook on marketing of fodder plant seeds (Celex 31966L0401) by the end of 2010.

Cereals

EU	MNE
Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production Rulebook on the quality of seeds of agricultural plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89 ; Official Gazette of the Federal Republic of Yugoslavia 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02); **Status:** In the harmonization process **In future:** Development of a Rulebook on marketing of cereal seeds (Celex 31966L0402, 32006L0055) by the end of 2010.
Commission Directive 2006/55/EC of 12 June 2006 amending Annex III to Council Directive 66/402/EEC as regards the maximum weight of seed lots	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production Rulebook on the quality of seeds of agricultural plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89 ; Official Gazette of the Federal Republic of Yugoslavia 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02); **Status:** In the harmonization process **In future:** I Development of a Rulebook on marketing of cereal seeds (Celex 31966L0402, 32006L0055) by the end of 2010.

Vine

EU	MNE
Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** Rulebook on Technical Control Over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94); Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for the grape vine (Celex 31968L0193, 32005L0043)by the end of 2010.

Commission Directive 2005/43/EC of 23 June 2005 amending the Annexes to Council Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** - Rulebook on Technical Control Over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94); - Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for the grape vine (Celex 31968L0193, 32005L0043)by the end of 2010.

Vegetable propagating and planting material

EU	MNE
Council Directive 2008/72/ECof 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production Rulebook on the quality of seeds of agricultural plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89 ; Official Gazette of the Federal Republic of Yugoslavia 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.
Council Directive 92/33/EEC of 28 April 1992 on the marketing of vegetable propagating and planting material, other than seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production Rulebook on the quality of seeds of agricultural plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89 ; Official Gazette of the Federal Republic of Yugoslavia 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.

Fruit plants

EU	MNE
Council Directive 92/34/EEC of 28 April 1992 on the marketing of fruit plant propagating material and fruit plants intended for fruit production	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** - Rulebook on Technical Control Over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94); - Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for fruit species (Celex 31992L0034, 32008L0090, 31993L0048, 31993L0064, 31993L0079) by the end of 2010.
Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of

intended for fruit production	Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** Rulebook on Technical Control Over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94); Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for fruit species (Celex 31992L0034, 32008L0090, 31993L0048, 31993L0064, 31993L0079)by the end of 2010.

Ornamental plants

EU	MNE
Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** Rulebook on Technical Control Over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94); Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for ornamental plants (Celex 31998L0056, 31993L0049, 31999L0066, 31999L0068)by the end of 2010.

Forest reproductive material

EU	MNE
Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material	**Legal basis:** Law on Reproductive Material of Forest Trees (Official Gazette of the Republic of Montenegro 37/07) **Legal act in force:** Law on Reproductive Material of Forest Trees (Official Gazette of the Republic of Montenegro 37/07) **Status:** In the implementation process **In future:** after TOC are made, in case of discrepancies, the process of making amendments to the law will be started

Catalogue of varieties of agricultural plants

EU	MNE
Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 65 Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06)Article 49 **Legal act in force:** The list of national newly produced, foreign and domesticated varieties of agricultural and forest plants (Official Gazette of the Federal Republic of Yugoslavia 12/98 and 37/02) **Status:** Harmonized, since the EU common catalogue of varieties of agricultural plant species is approved **In future:** Inclusion of the national variety list into the common catalogue of varieties of agricultural plant species into the EU common catalogue

Beet

EU	MNE
Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production Rulebook on the quality of seeds of agricultural plants (Official

	Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89 ; Official Gazette of the Federal Republic of Yugoslavia 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of beet seed (Celex 32002L0054, 32004L0117) by the day of accession to the EU.

Vegetable seed

EU	MNE
Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.
Council Directive 92/33/EEC of 28 April 1992 on the marketing of vegetable propagating and planting material, other than seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.

Seed potatoes

EU	MNE
Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of seed potato (Celex 32002L0056, 31993L0017, 32004D0003) by the end of 2010.godine.

Oil and fibre plants

EU	MNE
Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of seed of oil and fibre plants (Celex 32002L0057, 31997D0125, 32004D0266, 32008L0124) by the day of accession to the EU.

Application texts

EU	MNE
Dispensing certain Member States from the obligations for certain species	**Legal basis:** **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.

Authorising certain Member States to restrict the marketing of certain varieties	**Legal basis:** **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.
More stringent provisions as regards Avena fatua	**Legal basis:** **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.

Agricultural plant species

EU	MNE
Commission Decision 81/675/EEC of 28 July 1981 establishing that particular sealing systems are 'non-reusable systems' within the meaning of Council Directives 66/400/EEC, 66/401/EEC, 66/402/EEC, 69/208/EEC and 70/458/EEC	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 37 **Legal act in force:** Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); Rulebook on the quality of seeds of agricultural plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89 ; Official Gazette of the Federal Republic of Yugoslavia 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02); **Status:** In the harmonization process **In future:** Development of a rulebook on implementation of a packing system that does not make possible reuse of packaging (Celex 31981D0675) by the end of 2010.godine.
Council Decision 2003/17/EC of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and on the equivalence of seed produced in third countries	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 13 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** In the harmonization process.
Council Decision 2005/834/EC of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries and amending Decision 2003/17/EC	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 13 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process. **In future:** In the harmonization process.
Commission Regulation (EC) No 217/2006 of 8 February 2006 laying down rules for the application of Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards the authorisation of Member States to permit temporarily the marketing of seed not satisfying the requirements in respect of the minimum germination	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 4 **Legal act in force:** **Status:** In the harmonization process. **In future:** Applicable on the day of accession to the EU.

Fodder Plants

EU	MNE
Commission Decision 80/512/EEC of 2 May 1980 authorizing the Kingdom of Denmark, the Federal Republic of Germany, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands and the United Kingdom not to apply the conditions laid down in Council Directive 66/401/EEC on the marketing of fodder plant seed, as regards the weight of the sample for determination of seed of Cuscuta	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) **Legal act in force:** **Status:** not applicable **In future:** Applicable on the day of accession to the EU.
Commission Decision 85/370/EEC of 8 July 1985 authorizing the Netherlands to assess the satisfaction of the varietal purity standards laid down in Annex II to Council Directive 66/401/EEC for seed of apomictic uniclonal varieties of Poa pratensis, also on the basis of the results of seed and seedling testing	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) **Legal act in force:** **Status:** not applicable **In future:** Applicable on the day of accession to the EU.
Commission Decision 2004/371/EC of 20 April 2004 on conditions	**Legal basis:**

for the placing on the market of seed mixtures intended for use as fodder plants	Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) **Legal act in force:** Order on authorized mixtures of various varieties and species of agricultural seeds that may be placed on the market (Official Gazette of the Republic of Montenegro 3/1983); **Status:** In the harmonization process **In future:** Applicable on the day of accession to the EU.
Commission Directive 2008/124/EC of 18 December 2008 limiting the marketing of seed of certain species of fodder plants and oil and fibre plants to seed which has been officially certified as 'basic seed' or 'certified seed'	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** **Status:** In the harmonization process **In future:** Development of a rulebook on limited marketing of seed of certain species of fodder plants, oil and fibre plants (Celex 32008L0124) by the end of 2012.
Commission Decision 2009/109/EC of 9 February 2009 on the organisation of a temporary experiment providing for certain derogations for the marketing of seed mixtures intended for use as fodder plants pursuant to Council Directive 66/401/EEC to determine whether certain species not listed in Council Directives 66/401/EEC, 66/402/EEC, 2002/55/EC or 2002/57/EC fulfil the requirements for being included in Article 2(1)(A) of Directive 66/401/EEC	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.

Cereals

EU	MNE
Commission Decision 80/755/EEC of 17 July 1980 authorizing the indelible printing of prescribed information on packages of cereal seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on the quality of seeds of agricultural plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 47/87, 60/87, 55/88, 81/89 ; Official Gazette of the Federal Republic of Yugoslavia 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01 and 58/02); **Current status:** In the harmonization process; **In future:** Development of a rulebook on indelible printing of prescribed information for cereal packages (Celex 31980D0755) by the end of 2012.

Vine

EU	MNE
Commission Directive 2004/29/EC of 4 March 2004 on determining the characteristics and minimum conditions for inspecting vine varieties	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 14 **Legal act in force:** Rulebook on Technical Control Over Production of Agricultural and Forest Planting Material (Official Gazette of the Republic of Montenegro 28/94); **Current status:** In the harmonization process **In future:** Development of a rulebook on determination of characteristics and minimum conditions for control of vine varieties (Celex 32004L0029) by the end of 2011.

Vegetable propagating and planting material

EU	MNE
Commission Directive 93/61/EEC of 2 July 1993 setting out the schedules indicating the conditions to be met by vegetable propagating and planting material, other than seed pursuant to Council Directive 92/33/EEC	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Current status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.

Commission Directive 93/62/EEC of 5 July 1993 setting out the implementing measures concerning the supervision and monitoring of suppliers and establishments pursuant to Council Directive 92/33/EEC on the marketing of vegetable propagating and planting material, other than seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Current status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.

Fruit plants

EU	MNE
Commission Directive 93/48/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by fruit plant propagating material and fruit plants intended for fruit production, pursuant to Council Directive 92/34/EEC	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for fruit species (Celex 31992L0034, 32008L0090, 31993L0048, 31993L0064, 31993L0079) by the end of 2010.
Commission Directive 93/64/EEC of 5 July 1993 setting out the implementing measures concerning the supervision and monitoring of suppliers and establishments pursuant to Council Directive 92/34/EEC on the marketing of fruit plant propagating material and fruit plants intended for fruit production	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for fruit species (Celex 31992L0034, 32008L0090, 31993L0048, 31993L0064, 31993L0079) by the end of 2010.
Commission Directive 93/79/EEC of 21 September 1993 setting out additional implementing provisions for lists of varieties of fruit plant propagating material and fruit plants, as kept by suppliers under Council Directive 92/34/EEC	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 paragraph 4 **Legal act in force:** Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of planting material for fruit species(Celex 31992L0034, 32008L0090, 31993L0048, 31993L0064,31993L0079) by the end of 2010.

Ornamental plants

EU	MNE
Commission Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 **Legal act in force:** Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** Development of a Rulebook on marketing of planting material of ornamental plants (Celex 31998L0056, 31993L0049, 31999L0066, 31999L0068)by the end of 2010.
Commission Directive 1999/66/EC of 28 June 1999 setting out requirements as to the label or other document made out by the supplier pursuant to Council Directive 98/56/EC	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10

	Legal act in force: Rulebook on Norms of the Quality, Packaging, Sealing and Labelling of Planting Material of Agricultural Plants (Official Gazette of the Socialist Federal Republic of Yugoslavia 45/75 and 26/79); **Status:** In the harmonization process **In future:** I Development of a Rulebook on marketing of planting material of ornamental plants (Celex 31998L0056, 31993L0049, 31999L0066, 31999L0068) by the end of 2010.
Commission Directive 1999/68/EC of 28 June 1999 setting out additional provisions for lists of varieties of ornamental plants as kept by suppliers under Council Directive 98/56/EC	**Legal basis:** Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 10 **Legal act in force:** **Status:** In the harmonization process **In future:** I Development of a Rulebook on marketing of planting material of ornamental plants (Celex 31998L0056, 31993L0049, 31999L0066, 31999L0068) by the end of 2010.

Forest reproductive material

EU	MNE
Commission Regulation (EC) No 1597/2002 of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the format of national lists of the basic material of forest reproductive material Commission Regulation (EC) No 1598/2002 of 6 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the provision of mutual administrative assistance by official bodies Commission Regulation (EC) No 1602/2002 of 9 September 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the authorisation of a Member State to prohibit the marketing of specified forest reproductive material to the end-user Commission Regulation (EC) No 2301/2002 of 20 December 2002 laying down detailed rules for the application of Council Directive 1999/105/EC as regards the definition of small quantities of seed Commission Regulation (EC) No 69/2004 of 15 January 2004 authorising derogations from certain provisions of Council Directive 1999/105/EC in respect of the marketing of forest reproductive material derived from certain basic material Commission Decision 2004/678/EC of 29 September 2004 authorising Member States to permit temporarily the marketing of seed of the species Cedrus libani, Pinus brutia and planting stock produced from this seed not satisfying the requirements of Council Directive 1999/105/EC Commission Decision 2005/853/EC of 30 November 2005 authorising France to prohibit the marketing to the end user, with a view to seeding or planting in certain regions of France, of reproductive material of Pinus pinaster Ait. of Iberian Peninsula origin, which is unsuitable for use in such territories under Council Directive 1999/105/EC Commission Decision 2005/871/EC of 6 December 2005 releasing Denmark and Slovenia from certain obligations for marketing of forest reproductive material under Council Directive 1999/105/EC Commission Decision 2006/665/EC of 3 October 2006 temporarily authorising Spain to approve for marketing seed of the species Pinus radiata and planting stock produced from this seed imported from New Zealand which does not satisfy the requirements of Council Directive 1999/105/EC in respect of identification and labelling Commission Decision 2007/527/EC of 25 July 2007 authorising Bulgaria and Romania to derogate from Council Directive 1999/105/EC on the marketing of forest reproductive material with regard to the stocks accumulated from 1 January 2003 to 31 December 2006 Council Decision 2008/971/EC of 16 December 2008 on the equivalence of forest reproductive material produced in third countries Commission Decision 2008/989/EC of 23 December 2008 authorising Member States, in accordance with Council Directive 1999/105/EC, to take decisions on the equivalence of the guarantees afforded by forest reproductive material to be imported from certain third countries	**Legal basis:** Law on Reproductive Material of Forest Trees (Official Gazette of the Republic of Montenegro 37/07) **Legal act in force:** Law on Reproductive Material of Forest Trees (Official Gazette of the Republic of Montenegro 37/07) **Status:** In the harmonization process **In future:** Applicable on the day of accession to the EU.

Catalogue of varieties of agricultural plants

EU	MNE
Commission Regulation (EC) No 930/2000 of 4 May 2000 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 54 Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 34 **Legal act in force:** **Status:** In the harmonization process **In future:** Applicable on the day of accession to the EU.
Commission Directive 2003/90/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/53/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06)Article 54 Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 34 **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.
Commission Decision 2004/842/EC of 1 December 2004 concerning implementing rules whereby Member States may authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of varieties of agricultural plant species or vegetable species has been submitted	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 65 Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 49 **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.
Council Decision 2005/834/EC of 8 November 2005 on the equivalence of checks on practices for the maintenance of varieties carried out in certain third countries and amending Decision 2003/17/EC	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 65 Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 49 **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.
Commission Decision 2006/10/EC of 10 January 2006 concerning the provisional prohibition in Greece of the marketing of seeds of maize hybrids with the genetic modification MON 810 inscribed in the common catalogue of varieties of agricultural plant species, pursuant to Directive 2002/53/EC	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 65 Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 49 **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.
Council Decision 2006/545/EC of 18 July 2006 on the equivalence of the official examination of varieties carried out in Croatia	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 65 Law on Planting Material (Official Gazette of the Republic of Montenegro 28/06) Article 49 **Legal act in force:** **Status:** **In future:** Applicable on the day of accession to the EU.

Vegetable seed

EU	MNE
Commission Directive 89/14/EEC of 15 December 1988 determining the groups of varieties of spinach beet and beetroot referred to crop isolation conditions of Annex I to Council Directive 70/458/EEC on the marketing of vegetable seed	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.
Commission Directive 2003/91/EC of 6 October 2003 setting out implementing measures for the purposes of Article 7 of Council Directive 2002/55/EC as regards the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of vegetable species	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of

	Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of vegetable seedlings (Celex 32008L0072, 31992L0033, 32003L0091, 31993L0061, 31989L0014, 31993L0062, 32005D0055) by the end of 2010.

Seed potatoes

EU	MNE
Commission Directive 93/17/EEC of 30 March 1993 determining Community grades of basic seed potatoes, together with the conditions and designations applicable to such grades	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of seed potatoes (Celex 32002L0056, 31993L0017, 32004D0003)by the end of 2010.godine.
Commission Decision 2004/3/EC of 19 December 2003 authorising, in respect of the marketing of seed potatoes in all or part of the territory of certain Member States, more stringent measures against certain diseases than are provided for in Annexes I and II to Council Directive 2002/56/EC	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of seed potatoes (Celex 32002L0056, 31993L0017, 32004D0003)by the end of 2010.godine.

Oil and fibre plants

EU	MNE
Commission Decision 97/125/EC of 24 January 1997 authorizing the indelible printing of prescribed information on packages of seed of oil and fibre plants and amending Decision 87/309/EEC authorizing the indelible printing of prescribed information on packages of certain fodder plant species	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of seed of oil and fibre plants (Celex 32002L0057, 31997D0125, 32004D0266, 32008L0124) by the day of accession to the EU.
Commission Decision 2004/266/EC of 17 March 2004 authorising the indelible printing of prescribed information on packages of seed of fodder plants	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Current status:** In the harmonization process **In future:** Development of a rulebook on marketing of seed of oil and fibre (Celex 32002L0057, 31997D0125, 32004D0266, 32008L0124) by the day of accession to the EU.
Commission Directive 2008/124/EC of 18 December 2008 limiting the marketing of seed of certain species of fodder plants and oil and fibre plants to seed which has been officially certified as 'basic seed' or 'certified seed' (Codified version)	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** Rulebook on Technical Control over Agricultural Seed Production (Official Gazette of the Republic of Montenegro 28/1994) with Uniform methods for control over the agricultural seeds production **Status:** In the harmonization process **In future:** Development of a rulebook on marketing of seed of oil and fibre (Celex 32002L0057, 31997D0125, 32004D0266, 32008L0124) by

	the day of accession to the EU.

Agricultural landraces and varieties

EU	MNE
Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties	**Legal basis:** Law on Seed Material of Agricultural Plants (Official Gazette of the Republic of Montenegro 28/06) Article 5 paragraph 3 **Legal act in force:** **Current status:** In the harmonization process **In future:** Applicable on the day of accession to the EU.

27. Plant variety rights

The Law on Protection of Plant Varieties (Official Gazette of the Republic of Montenegro 48/07 and 48/08) (Annex 41) provided a legal framework for the protection of plant varieties, it governs the methods and procedures for acquiring the breeder's rights and it is in accordance with the Regulation (Celex No. 31994R2100).

On October 25, 2007, at the 41st session of the UPOV Council, the law had for the first time been considered in terms of conformity. The Council discussed the Law and recommended Montenegro to make further amendments to the Law.

Prior to adoption of the revised and amended Law on Protection of Plant Varieties, Montenegro sent the text to the UPOV for re-examination of the conformity with the UPOV Convention.

Prior to adoption in the Parliament of Montenegro, the text of the amended Law was discussed at the 25th extraordinary UPOV Council sitting, on April 11, 2008.

At this sitting, the UPOV Council made a positive decision stating: "that amendments are to be made in articles 19 and 44 and once the law thus amended is passed in the Parliament, Montenegro may deposit the instrument of accession to the 1991 Act".

Amendments to the Law on Protection of Plant Varieties (Official Gazette 48/07 and 48/08) were adopted in August 2008 and the application for membership was submitted in 2009.

The system of plant variety protection set by this law is one of newer systems of protection of this kind in Montenegro and it allows protection of intellectual rights guaranteed for protection of plant varieties, as well. A variety may be protected in accordance with the law if it is new, distinct, uniform, stable and meets the conditions for granting it a protected variety denomination.

The period of variety protection is 25 years and for trees and grape vine 35 years from the day of recognition of the breeder's right.

DUS-TESTS establishing distinctness, uniformity and stability of a variety are not performed in Montenegro, but results of DUS tests done in an UPOV (International Union for the Protection of New Varieties of Plants) member state are recognized, while VCU TEST for establishing of value for cultivation and use of a variety is carried out by authorized institutions.

The body in charge of direct implementation of regulations and activities in this field is the Phytosanitary Administration, within which the Department for Seed, Planting Material, Plant Variety Protection and GMO operates, which is in charge of administrative activities, development of legislation and international relations in the plant variety protection field.

ACTIVITIES PLANNED

Meeting of obligations planned in this field requires further strengthening of administrative capacity of the Phytosanitary Administration.

Further harmonization with and implementation of related EU regulations will be continued, with emphasis placed on strengthening of administrative capacity for assuming of new obligations.

The breeder's rights will be acquired in an administrative procedure run by the Phytosanitary Administration.

PRIORITY AND TENTATIVE PLAN OF HARMONIZATION WITH THE EU ACQUIS – CLEAR TABLE

Basic texts

EU	MNE
Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of Montenegro 48/07 and 48/08) **Legal act in force:** Law on Protection of Plant Varieties (Official Gazette of the Republic of Montenegro 48/07 and 48/08) **Status:** In the implementation process **In future:** after TOC are made, in case of discrepancies, the process of making amendments to the law will be started

Application texts

EU	MNE
Council Regulation (EC) No 2470/96 of 17 December 1996 providing for an extension of the terms of a Community plant variety right in respect of potatoes	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of the Republic of Montenegro 48/07 and 48/08) **Legal act in force:** **Status:** In the harmonization process **In future:** Adoption 2010 -2011.
Commission Regulation (EC) No 1238/95 of 31 May 1995 establishing implementing rules for the application of Council Regulation (EC) No 2100/94 as regards the fees payable to the Community Plant Variety Office	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of Montenegro 48/07 and 48/08) Article 29, 45 paragraph 2 **Legal act in force:** **Status:** In the harmonization process **In future:** Adoption 2010 -2011.
Commission Regulation (EC) No 1768/95 of 24 July 1995 implementing rules on the agricultural exemption provided for in Article 14 (3) of Council Regulation (EC) No 2100/94 on Community plant variety rights	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of Montenegro 48/07 and 48/08) Article 29 **Legal act in force:** **Status:** In the harmonization process **In future:** Development of a rulebook on relations between variety owner and farmer / Adoption 2010 -2011.
Code of good administrative behaviour in the Community Plant Variety Office	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of Montenegro 48/07 and 48/08) **Legal act in force:** **Status:** In the harmonization process **In future:** Development of a Code of Good Administrative Practice for Variety Protection / Adoption 2010 -2011.
Council Decision 2006/551/EC of 24 July 2006 appointing the President of the Community Plant Variety Office	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of Montenegro 48/07 and 48/08) **Legal act in force:** **Status:** **In future:**
Council Decision 2007/168/EC of 22 February 2007 appointing the Vice-President of the Community Plant Variety Office	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of Montenegro 48/07 and 48/08) **Legal act in force:** **Status:** **In future:**
Council Decision 2007/858/EC of 17 December 2007 appointing the Chairperson of the Board of Appeal of the Community Plant Variety Office and his Alternate	**Legal basis:** Law on Protection of Plant Varieties (Official Gazette of the Republic of Montenegro 48/07 and 48/08) **Legal act in force:** **Current status:** **In future:**

28. Bilateral phytosanitary international agreements with EU Member States, candidate countries and other third countries (if any)

As regards bilateral international agreements in the phytosanitary field, Montenegro concluded a bilateral agreement with Croatia on co-operation in the plant health protection field.

This agreement was signed on 18 October 2005, in Podgorica.

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