

Chapter 12: Food safety, veterinary and phytosanitary policy

This chapter reflects the EU's integrated approach aiming to assure a high level of public health, animal health, animal welfare and plant health within the European Union through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. In this domain a Candidate Country is requested to ensure the transposition of the EU *acquis* and its progressive implementation by a properly structured and trained administration.

Implementation requires appropriate administrative structures to be able to carry out inspection and control including appropriate laboratory capacity. Coordination between different authorities in charge of the transposition and/or implementation is crucial. In addition, training of the various control inspectors, food- and feed business operators is necessary.

I. GENERAL

For each of the following points, please describe the current status and the foreseen evolution with a precise timetable.

1. Please provide flowcharts/organisation charts 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).

Pursuant to The Law on Food Safety (Official Gazette RS No. 41/2009) competencies in the field of food safety have been divided between the Ministry of Agriculture, Forestry and Water Management and the Ministry of Health.

In the field of food safety, competencies of the Ministry of Agriculture, Forestry and Water Management are following:

- 1) in the primary production stage:
 - of food of animal origin – veterinary inspection,
 - of food of plant origin – phytosanitary inspection;
- 2) in the production, processing and wholesale stage:
 - of food of animal origin – veterinary inspection,
 - of food of plant origin and non-alcoholic beverages – agricultural inspection,
 - of composite food – veterinary and agricultural inspections;
- 3) in the import and transit stage:
 - of food of animal origin – border veterinary inspection,
 - of food of plant origin – phytosanitary inspection;
 - of composite food – border veterinary and phytosanitary inspections;
- 4) in the export stage:
 - of food of animal origin – veterinary inspection,
 - of food of plant origin – phytosanitary inspection;
 - of composite food – veterinary and agricultural inspections;
 - of wines and spirits – agricultural inspection;
- 5) Control of genetically modified food in all stages of production, processing and placing on the market shall be conducted by phytosanitary inspection, and the veterinary inspection regarding genetically modified feed;
- 6) In the retail stage, food of animal origin in the facilities registered or approved by the Ministry, as well as retail of fresh meat, milk, eggs, honey, fish and game in specialized facilities (butcheries, fisheries and similar) shall be conducted by veterinary inspection, and regarding wines and spirits by agricultural inspection.

In the food safety field, Ministry of Health is competent for: control of novel food, dietary products, infant formulas – substitute for mother's milk, dietary supplements and salts for human consumption and production of additives, flavourings, enzymatic preparations of non-animal origin and supplementary agents of non-animal origin, as well as drinking water in original packaging (table water, mineral water, spring water), and water from the public water supply system in all stages of production, processing and placing on the market (wholesale, retail, imports at the customs points and exports) – sanitary inspection.

In the field of feed safety, competencies of the Ministry of Agriculture, Forestry and Water Management are following:

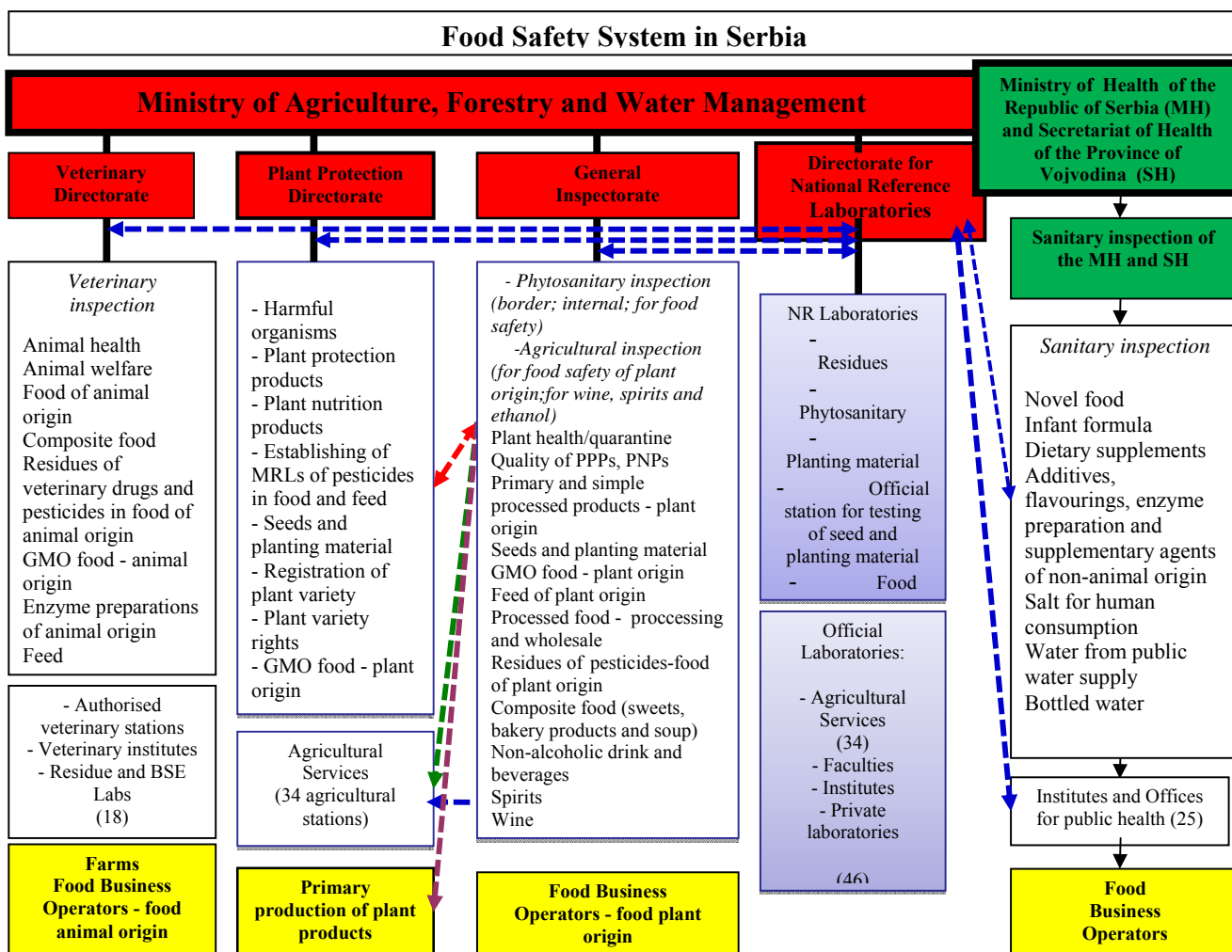
- 1) in the primary production stage:
 - of feed of animal origin – veterinary inspection,
 - of feed of plant origin – phytosanitary inspection;
- 2) in the production, processing and circulation stage – veterinary inspection;
- 3) in the import, transit and export stage:
 - of feed of animal origin and composite feed – veterinary inspection,
 - of feed of plant origin – phytosanitary inspection.

Veterinary, phytosanitary and agricultural inspections are centrally-managed but distributed territorially so as to cover the entire territory of the Republic of Serbia.

In Autonomous Province of Vojvodina tasks related to food safety falling under the competency of the Ministry of Health have been conferred to the Secretariat for Health of the Province of Vojvodina; control over the conferred tasks is carried out by the Ministry of Health.

Organisation charts of all competent authorities along with the description of their tasks are given in answer to question 3, Section I / General, Chapter 12.

Flow diagram – levels of competence – management lines of competent authorities for food safety, veterinary and phytosanitary policy



2. Please indicate resources and planned resources (human, material and financial) allocated to each sector.

Number of employees in public administration must not exceed 28,400 permanently employed civil servants, in accordance with the Law on maximum number of employees in public administration and the Decision on maximum number of employees in public administration bodies, public agencies and organisations for compulsory social security.

Ministry of Agriculture, Forestry and Water Management (MAFWM) may have 947 employees maximum, out of which 383 in the Veterinary Directorate, 33 in the Plant Protection Directorate, 280 in the General Inspectorate, and 55 in the Directorate for National Reference Laboratories. Ministry of Health (MH) may have maximum of 311 employees, out of which 184 in the Division for sanitary inspection of the Inspection Department, and 74 in the Division for sanitary supervision of the Secretariat for Health of the Province of Vojvodina.

Human resources in both MAFWM and MH are defined by Rulebooks on internal organisation and systematisation of job positions.

Salaries and other financial assets required for implementation of regular activities of both MAFWM and MH are allocated from the budget of the Republic of Serbia. Financial resources are projected through a multi-annual programme budget and annually in coordination with the Ministry of Finance. For the Veterinary Directorate, Plant Protection Directorate, General Inspectorate and Directorate for National Reference Laboratories funds are allocated as independent budget units.

1) Ministry of Agriculture, Forestry and Water Management

1.1. Veterinary Directorate

Human Resources

Present situation

In accordance with the current Rulebook on internal organisation and systematisation of job positions, 383 civil servants (executives and appointees) are employed in the Veterinary Directorate (VD). All job positions are filled. Due to the increased workload for certain activities, and also as replacements, additional 25 operators (secondary school qualifications) and 20 executives (university qualifications) have been hired on contract.

Veterinary Directorate	Number of employees	
	Veterinarians (university degree)	Other employees
Director	1	1 secretary (SSQ)
Advisor for food safety, economy and project management	-	1 economist (UD)
Assistant Director	1	-
Central level	31	1 economist (UD) 1 lawyer (UD) 2 administrative officers (SSQ) 2 appointees (SSQ)
Veterinary inspection – central level	13+1	-
Veterinary inspection – regional level	25	-

Veterinary inspection – local level	274	-
Border veterinary inspection	29	-
Total	375	8

UD - university degree

SSQ - secondary school qualifications

Future situation

According to the Decision on maximum number of employees in public administration bodies, public agencies and organisations for compulsory social security and the Law on maximum number of employees in public administration, total number of employees in VD must be 383. In order to meet harmonisation and implementation requirements in the field of veterinary policy and food safety, for certain tasks additional staff must be hired.

Material resources

Present situation

VD has material resources that meet the needs of the employees, namely: necessary IT equipment, including internet connection, central data base for cattle and VetUp data base for registered veterinary stations and practices, and their fields of work related to the implementation of Programme of measures for the protection of animal health and control of infectious diseases trends, direct phone and fax lines, business mobile phones, vehicles and necessary office equipment.

At all border crossings where veterinary inspection is organised infrastructural and technical conditions are provided (computers and internet connection) with a view to network the border crossings with the VD and to develop a computer programme for tracking consignments during import and transit, as well as to join TRACES system of the EU.

Offices located outside VD seat (regional offices under lease) are equipped with: direct phone and fax lines and have continued internet access. IT equipment is obsolete, office capacities and furniture do not meet the needs of the employees, and part of the equipment required for inspection control is also lacking. All veterinary inspectors have business mobile phones, but they do not have sufficient number of vehicles whilst certain number of vehicles are very old.

Not all border crossings meet prescribed infrastructural and other requirements needed by the veterinary inspection, except border crossing Horgoš that was constructed and equipped within the Project of refurbishment of border crossings supported by the EU. In other border crossings existing offices are inadequate in terms of space and office equipment. All border inspectors have business mobile phones, but the number of vehicles as well as sampling equipment is insufficient.

Part of the existing equipment (computers, vehicles and professional equipment for veterinary inspectors) was procured through projects supported by the EU and other donors over the past 5 years.

Future situation

It is planned for an integrated veterinary information system to be established and connected with the existing cattle, sheep and goat identification and registration system, as well as with the registration system for pigs and poultry and other animal species, with a possibility for extension in relation to the needs of VD; establishment of an IT system for border veterinary inspection is also planned, as well as linking of operators and slaughterhouses.

In the forthcoming period procurement of the missing equipment and equipment of veterinary inspection offices and border crossings will be planned, depending on the allocated budget funds.

Financial resources for 2010 (in EUR)

VETERINARY DIRECTORATE				
760 Health care not classified in other place		Budget funds	Expenses from additional income	Total funds
413	Benefits in kind	10		10
414	Social benefits	10		10
416	Compensations to the employees and other expenditures	10		10
421	Standing expenses	118.476	38.095	156.571
422	Travel expenses	81.905	19.047	100.954
423	Contracted services	391.667	47.619	439.286
424	Specialized services	1.905	10	1.915
425	Current repairs and maintenance	42.381	9.524	51905
426	Material	100.762	47.619	148.381
451	Subsidies to public non-financial companies and organisations; Allocation and use of this appropriation will be carried out in accordance with the special government enactment	11.961.904	10.476.191	22.438.095
462	Grants to international organisations	19.057	4.762	23.819
482	Taxes, compulsory fees and fines	13.334	9.524	46.677
483	Fines and penalties by Court decisions	10	10	20
485	Indemnity due to injuries or compensation of damages caused by			
	public authorities	10	476	486
512	Machinery and equipment	4.762	4.762	9.524
515	Intangible assets	19.047	10	19.057
	Sources of funding:			
01	Revenues from the budget	12.755.248		12.755.248

04	Own revenues of budgetary beneficiaries		10.657.64 8	10.657.64 8
	Total:	12.755.24 8	10.657.64 8	23.412.89 6
	Programme 2601			
	First component of the IPA pre-accession programme – Transition Assistance and Institution building 2601-08			
	project 06			
	Support for the control/ eradication of classical swine fever and rabies in the Republic of Serbia	1.339.048		1.339.048
	Sources of funding for Chapter 16.1:			
01	Revenues from the budget	14.094.29 5		
04	Own revenues of budgetary beneficiaries		10.657.64 8	
	Total:	14.094.29 5	10.657.64 8	24.751.94 2

Subsidies are used to fund the activities in accordance with the Programme on allocation and use of subsidies in the veterinary field adopted by the Government.

1.2. Plant Protection Directorate

Human Resources

Present situation

In accordance with the current Rulebook on internal organisation and systematisation of job positions, 33 civil servants are envisaged for the Plant Protection Directorate (PPD). Two positions are vacant. Due to the increased workload for certain activities, additional staff have been hired on contract (in total of 3 persons).

Human resources of the Plant Protection Directorate

Plant Protection Directorate	Number of employees	Education
Director of the Plant Protection Directorate	1	ScD
Administrative staff	2	UD, lawyer and economist
Section for Plant Health and Plant Quarantine	6 + 1 vacancy	UD, 5 plant protection engineers and 1 agricultural machinery engineer
Department for plant protection products and plant nutrition products	8	UD, plant protection engineers
Group for seeds and planting material	4	UD, 3 field crop engineers, 1 pomiculture engineer
Section for plant variety registration	6 + 1 vacancy	UD, 4 field crop engineers, 1 agro-economy engineer, 1 pomiculture

		engineer, one High school
Group for plant variety protection and biological safety	4	UD, 2 field crop engineers, one pomiculture engineer, one technology-biotechnology engineer

UD - university degree

Future situation

In order to fully meet the requirements related to harmonisation and implementation of legislation in the fields of plant health, seeds and planting material, establishment of a large number of registers and records as well as development of electronic data bases, further capacity building and professional development of PPD and Phytosanitary Inspection staff is required.

Law on plant protection products provides for an assessment of plant protection products, establishment of registers of distributors, importers and service providers, keeping records of the placing on the market and use of plant protection products, as well as development of electronic data bases. To this end it is required to build the capacities and improve professional skills of PPD and Phytosanitary Inspection staff.

As plant variety protection system (protection of plant breeders' rights) is being established in Serbia for the first time, and taking into consideration specific legal provisions and keeping of required registers and data bases, new staff has to be recruited. New staff is also required for biological safety (genetically modified organisms).

According to the Decision on maximum number of employees in public administration bodies, public agencies and organisations for compulsory social security and the Law on maximum number of employees in public administration, total number of employees in PPD must not exceed 33. In order to meet harmonisation and implementation requirements in the field of phytosanitary policy, for certain tasks additional staff must be hired on contract.

Material resources

Present situation

The PPD has material resources that meet the needs of its employees, namely: necessary IT equipment, including internet connection, direct phone and fax lines, business mobile phones, vehicles and necessary office equipment.

Future situation

It is required to set up an information system, given the fact that PPD is responsible for establishment of a large number of registers and a central data base in the phytosanitary field, which calls for additional material and financial resources.

Funding of the PPD and activities related to the implementation of programme of measures are funded from the budget and from own revenue. In the forthcoming period, under the new phytosanitary legislation, levels of fees that PPD shall have at its disposal with the purpose of improving and developing the phytosanitary system should be defined.

Financial resources for 2010 (in eur)

PLANT PROTECTION DIRECTORATE				
Agriculture, forestry, hunting and fishing		Budget funds	Expenses from additional income	Total funds
413	Benefits in kind	1,867		1,867
414	Social benefits	938		938
416	Remuneration for the employees and other expenses	9.5		9.5
421	Standing expenses	9,479	9,479	18,958
422	Travel expenses	9,479	37,915	47,394
423	Contracted services	14,218	94,788	109,006
424	Specialized services	14,218	366,821	381,039
425	Current repairs and maintenance	938	1,896	2,834
426	Material	3,791	18,960	22,751
451	Subsidies to public non-financial companies and organisations	284,365	284,365	568,730
	These funds are earmarked for plant protection programmes, allocation and use of this appropriation will be carried out in accordance with the special government enactment			
462	Grants to international organisations		18,960	18,960
482	Taxes, compulsory fees and fines	948	4,740	5,688
483	Fines and penalties by Court decisions		474	474
512	Machinery and equipment	3,820	9,479	13,299
	Sources of funding for function 420:			
01	Revenues from the budget	344,072		344,072
04	Own revenues of budgetary beneficiaries		847,872	847,872
	Total for function 420:	344,072	847,872	1,191,944
	Sources of funding for Chapter 16.2:			
01	Revenues from the budget	344,072		344,072
04	Own revenues of budgetary beneficiaries		847,872	847,872
	Total:	344,072	847,872	1,191,944

1.3 General Inspectorate

Human Resources

Present situation

In accordance with the current Rulebook on internal organisation and systematisation of job positions, 280 executive officers and appointees have been envisaged for the General Inspectorate (GI). All job positions are filled. Due to the increased workload for certain activities, additional workforce is hired on fixed-term contract.

Human resources of the General Inspectorate for the fields of phytosanitary inspection and food safety

General Inspectorate	Number of employees
General Inspectorate – central level	3
Phytosanitary inspection	55
Border phytosanitary inspection	33
Phytosanitary inspection for food safety	18
Agricultural inspection for food safety	26
Wine, rakija, alcoholic and non-alcoholic beverages	25

All employees of the GI have university degrees of different profiles (agriculture, technology, veterinary medicine, law).

Material resources

Present situation

In its seat (Belgrade), GI has material resources that meet the needs of its employees, namely: necessary IT equipment, including internet connection, direct phone and fax lines, business mobile phones, vehicles and necessary office equipment.

Offices of phytosanitary and agricultural inspections located outside GI seat are equipped with direct phone and fax lines, and have continued internet access, but IT equipment is obsolete. Office space and equipment do not meet the needs of the employees, and additional equipment is required in order to improve inspection controls. All inspectors have business mobile phones and vehicles (certain number of vehicles is very old).

Not all border crossings meet prescribed infrastructural and other requirements for the operation of the border phytosanitary inspection, except border crossing Horgoš that was constructed and equipped within the Project of refurbishment of border crossings supported by the EU. In other border crossings existing offices are inadequate in terms of space and office equipment. All border inspectors have business mobile phones, but number of vehicles and sampling equipment is insufficient.

Part of the existing equipment (computers, vehicles and professional equipment for phytosanitary inspectors) was procured through projects supported by the EU and other donors over the past 5 years, as well as from the budget.

Future situation

Establishment of an integrated information system that will cover all levels is planned: central, regional and local levels, including laboratories and border crossings. This will enable quality risk analysis and establishment of a rapid communication and alert system.

Depending on the allocated budget funds in the following years, procurement of the missing equipment and improvement of other border crossings will be planned.

Financial resources for 2010 (in EUR)

GENERAL INSPECTORATE OF AGRICULTURE, FORESTRY AND WATER MANAGEMENT				
Agriculture, forestry, hunting and fishing		Budget funds	Expenses from additional income	Total funds
414	Social benefits	4.673,06		4.673,06
421	Standing expenses	160.192,3	11.848,54	172.040,85
422	Travel expenses	75.830,68	4.739,417	80.570,095
423	Contracted services	86.257,4	8.6257,4	90.048,93
424	Specialized services	104.267,2	246.449,7	350.716,88
425	Current repairs and maintenance	56.873,01		56.873,01
426	Material	165.879,6	47.394,17	213.273,78
482	Taxes, compulsory fees and fines	35.071,69	18.957,67	5.4029,35
483	Fines and penalties by Court decisions	9.478,835	9.478,835	18.957,66
511	Buildings and building structures	33.175,92		33.175,92
512	Machinery and equipment	105,49		33.175,92
515	Intangible assets	18.957,67		18.957,67
	Sources of funding for function 420:			
01	Revenues from the budget	75.0762,9		75.0762,9
04	Own revenues of budgetary beneficiaries		425.125,73	425.125,73
	Total for function 420:	75.0762,9	425.125,73	1.126.493,15
	Sources of funding for Chapter 16.5:			
01	Revenues from the budget	75.0762,9		750.762,9
04	Own revenues of budgetary beneficiaries		425.125,73	425.125,73
	Total:	75.0762,9	425.125,73	1.126.493,15

1.4 Directorate for National Reference Laboratories

Human resources

Present situation

In accordance with the current Rulebook on internal organisation and systematisation of job positions, total number of job positions envisaged for the Directorate for National Reference Laboratories (DNRL) is 55. Current number of employees is 19, out of which 9 with permanent employment contract, while others are hired on contract basis.

Human resources of the Directorate for National Reference Laboratories

Directorate for National Reference Laboratories	Number of employees	Education
Director	1	Doctor of veterinary medicine
Administrative staff	1	UD, mechanical engineer
Reference phytosanitary laboratory	2	UD, plant protection engineers
Reference laboratory for residues	1	UD, plant protection engineers
Plant gene bank	3	UD, 1 biologist, 1 crop husbandry engineer, 1 SSQ technician
Reference laboratory for food and feed safety and milk	1	doctor of medical science

UD - university degree SSQ – secondary school qualifications

Future situation

It is expected that the job positions envisaged will be filled as soon as possible.

Directorate for National Reference Laboratories	Number of employees
Director of the Directorate for National Reference Laboratories	1
Managers of reference laboratories and administration	7
Administrative staff	15
Department – Reference phytosanitary laboratory	8
Department – Reference laboratory for residues	6
Department – Plant gene bank	4
Department - Reference laboratory for food and feed safety and milk	6
Department – Official testing station for seed and planting material	4
Section - organic production	4

Operational plan for full operation of DNRL was devised under CARDS 2005 Project 'Institutional capacity building for the Food Chain laboratories administration' and it envisages 222 staff.

Material resources

Present situation

DNRL complex consists of 3 laboratory buildings and a main building. The complex is situated in Zemun – Gornji grad. Laboratories are currently undergoing refurbishment in line with the food chain laboratories standards. Laboratory equipment procured during 2003 was turned over to the official laboratories in the field of food safety, veterinary and phytosanitary controls.

DNRL has at its disposal material resources that meet the needs of the employees in the laboratory complex, namely: necessary IT equipment, including internet connection, direct phone and fax lines, business mobile phones, vehicles and necessary office equipment. Currently equipment for the Plant gene bank procured through the Seednet project is in place.

Future situation

Refurbishment of the existing laboratories will be finished at the beginning of 2011. Procurement procedure for laboratory equipment is in its final stage and full operation is expected in the first half of 2011.

Equipment will be procured through the Twinning project 'Institutional capacity building of the Directorate for National Reference Laboratories' within IPA 2010 programme cycle. The rest will be funded from the budget of the Republic of Serbia.

Financial resources for 2010 (in Serbian dinars and EUR)

DIRECTORATE FOR NATIONAL REFERENCE LABORATORIES				
Agriculture, forestry, hunting and fishing		Budget funds	Expenses from additional income	Total funds
421	Standing expenses	2.840.000 (26.883 €)		2.840.000 (26.883 €)
422	Travel expenses	3.300.000 (31.238€)		3.300.000 (31.238 €)
423	Contracted services	7.600.000 (71.941€)		7.600.000 (71.941 €)
424	Specialized services	3.000.000 (28.398 €)	50.000.000 (473.299 €)	53.000.000 (501.697 €)
425	Current repairs and maintenance	3.000.000 (28.398 €)		3.000.000 (28.398 €)

426	Material	5.500.000 (52.063 €)		5.500.000 (52.063 €)
482	Taxes, compulsory fees and fines	3.000.000 (28.398 €)		3.000.000 (28.398 €)
512	Machinery and equipment	1.000.000 (9.466 €)		1.000.000 (9.466 €)
515	Intangible assets	2.000.000 (18.932 €)		2.000.000 (18.932 €)
	Sources of funding for function 420:			
01	Revenues from the budget	31.240.000 (295.717 €)		31.240.000 (295.717 €)
04	Own revenues of budgetary beneficiaries		50.000.000 (473.299 €)	50.000.000 (473.299 €)
	Total for function 420:	31.240.000 (295.717 €)	50.000.000 (473.299 €)	81.240.000 (769.016 €)
	Sources of funding for Chapter 16.6:			
01	Revenues from the budget	31.240.000 (295.717 €)		31.240.000 (295.717 €)
04	Own revenues of budgetary beneficiaries		50.000.000 (473.299 €)	50.000.000 (473.299 €)
	Total for Chapter 16.6	31.240.000 (295.717 €)	50.000.000 (473.299 €)	81.240.000 (769.016 €)

2) Ministry of Health

Human Resources

Present situation

In accordance with the current Rulebook on internal organisation and systematisation of job positions, currently there are 184 civil servants and executive officers in the Division for sanitary inspection of the Ministry of Health (MH), and another 74 in the Secretariat for Health of the Province of Vojvodina (SH).

Human resources of the Ministry of Health and the Secretariat for Health of the Province of Vojvodina

Ministry of Health	Number of employees
Inspection Department	4
Inspection Department – Division for sanitary inspection	3
Inspection Division – Group for internal supervision over the holders of public authorisations regarding the delegated activities in the field of sanitary supervision	4

Division for sanitary inspection – sanitary inspectors	173
Secretariat for Health of the Province of Vojvodina – Division for sanitary supervision	74

Material resources

Present situation

MH does not have material resources that meet the needs of the employees. Necessary office equipment, direct phone and fax lines and vehicles are in place, but IT equipment is used by more inspectors, internet connection is available to few inspectors, while only 76 inspectors have mobile phones.

Future situation

According to the Decision on maximum number of employees in public administration bodies, public agencies and organisations for compulsory social security and Law on maximum number of employees in public administration, all job positions are filled and currently there is no possibility to increase the number of employees.

Financial resources 2010 (in Serbian dinars) (Ministry of Health only)

<i>1801-03 Sanitary Supervision</i>		Budget funds	Expenses from additional income	Total funds
411	Salaries, bonuses and benefits of the employees (earnings)	141.747.000		141.747.000
412	Social contributions paid by the employer	25.395.000		25.395.000
413	Benefits in kind	1.700.000		1.700.000
414	Social benefits to the employees	1.000.000		1.000.000
415	Cost recovery for employees	2.900.000		2.900.000
416	Remuneration for the employees and other expenses	1.000		1.000
421	Standing expenses	4.400.000		4.400.000
422	Travel expenses	1.850.000		1.850.000
423	Contracted services	5.000.000	85.000.000	90.000.000
424	Specialized services	73.000.000		73.000.000
425	Current repairs and maintenance	2.000.000		2.000.000
426	Material	11.350.000	17.000.000	28.350.000
482	Taxes, compulsory fees and fines	2.500.000		2.500.000
	Sources of funding for programme 1801-03:			
01	Revenues from the budget	272.843.000		272.843.000

04	Own revenues of budgetary beneficiaries		102.000.000	102.000.000
	Total:	272.843.000	102.000.000	374.843.000
411	Salaries, bonuses and benefits of the employees (earnings)	141.747.000		141.747.000
412	Social contributions paid by the employer	25.395.000		25.395.000

3. Please provide a description of the current structure, as well as of the evolution foreseen. Two sets of organisation charts: 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).

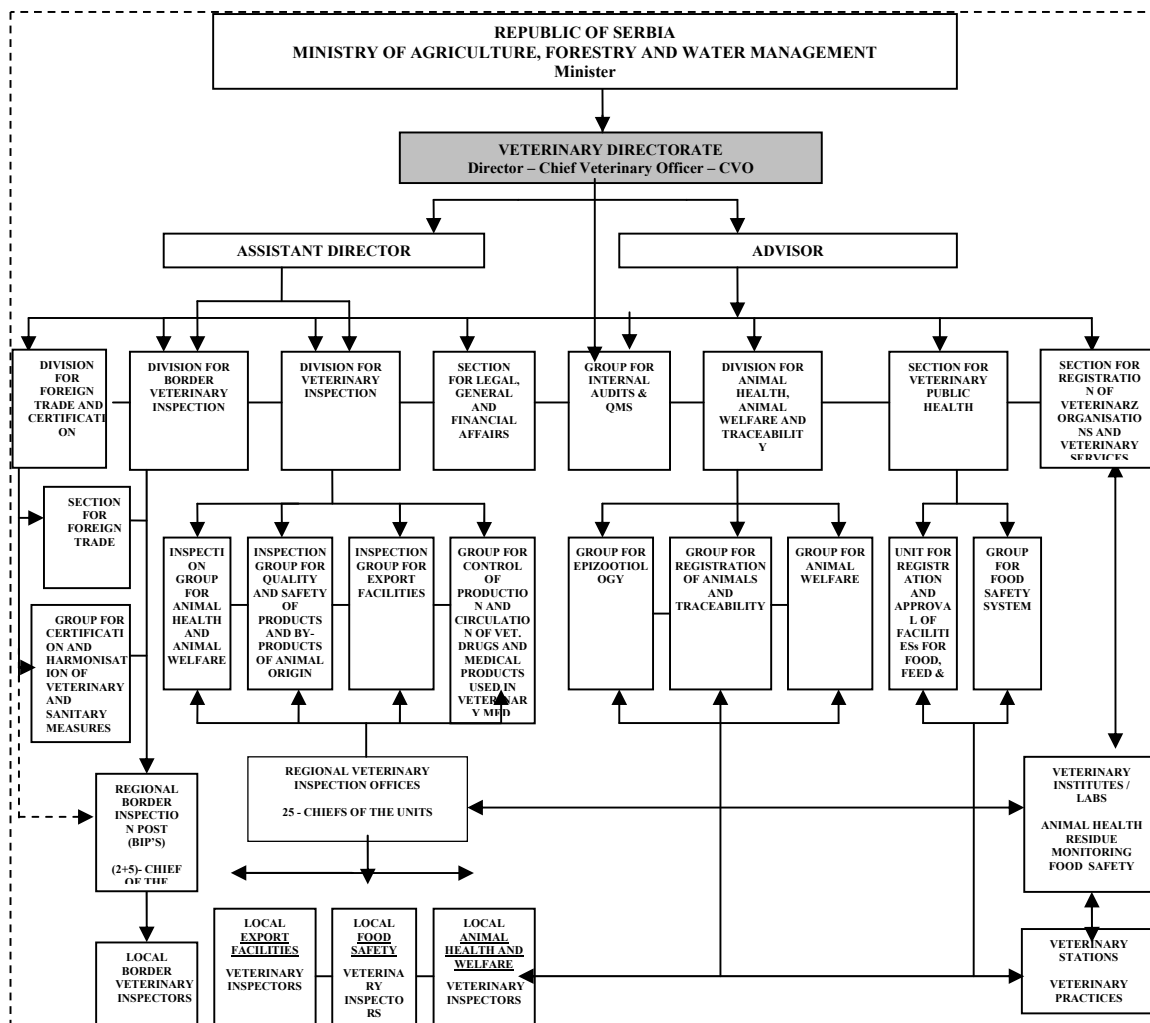
1) Ministry of Agriculture, Forestry and Water Management

Ministry of Agriculture, Forestry and Water Management (MAFWM) is responsible for veterinary, phytosanitary and food safety policies (safety of food of animal origin, composite food, food of plant origin and feed). The MAFWM is supervising the legality of work of the Veterinary Directorate, Plant Protection Directorate, General Inspectorate and Directorate for National Reference Laboratories.

1.1. Veterinary Directorate

According to the new rules on organisation, as of November 2010 current and future organisations have been consolidated as follows:

Organisation chart of the Veterinary Directorate



Veterinary Directorate (VD) as administrative authority within the MAFWM performs tasks related to: animal health and animal welfare, and veterinary public health; ensuring risk management systems in production and circulation of food and products of animal origin and of feed; veterinary and sanitary controls in production and circulation of animals, products, raw materials and by-products of animal origin, reproductive material and other organisms and objects by means of which an infectious disease could be transferred, feed and components for feed production; registration and control of facilities for production of food of animal origin; control of feed production facilities and safe disposal of carcasses and animal by-products, and control of processing facilities; control of production and circulation of veterinary drugs and medical products and items used in veterinary medicine; veterinary environmental protection; consolidation of databases, registers and veterinary information systems; international cooperation; certification and control in foreign trade; monitoring and harmonisation of national regulations in the field of veterinary medicine and food safety and other tasks envisaged by law.

VD is managed by the director, who reports to the minister of the MAFWM. Director also acts as Chief Veterinary Officer, and fosters implementation of all regulations in the

field of veterinary medicine and food safety, and has legal authority to prescribe all measures necessary for prevention of outbreak and spread, suppression or eradication of infectious diseases of animals, including the prohibition of production and circulation of goods, as well as movement of people to/from the infected field. Director coordinates the operation of the service through his deputy, assistants and heads of divisions.

Heads of divisions coordinate the operation of their divisions through heads of sections and group managers, and also cooperate with other divisions.

Heads of the sections of district veterinary inspection are responsible for supervision and coordination of operation of veterinary inspectors in the field. Head of the district section implements in the field the orders and work procedures received from the section head/division head at the central level (from the VD). Feedback/reports from local and regional levels are sent by the head of the district section to the VD.

Official control is carried out by veterinary inspectors in domestic trade and by border veterinary inspectors in foreign trade. Veterinary inspectors at the local level are divided in such way that at least one inspector performs tasks in the field of animal health, while the other performs administrative and supervisory tasks in the field of food safety (food of animal origin). In order to be able to work in a facility registered and approved for export, veterinary inspector must receive a special decision by which he is assigned to the tasks related to control and supervision in the exporting facility. Veterinary inspectors carry out inspection controls and submit reports to the head of the district section, and from him/her they receive instructions and official controls plan for the following period.

The VD consists out of the following smaller organisational units:

- Division for animal health, animal welfare and traceability;
- Section for registration of veterinary organisations and veterinary services;
- Section for veterinary public health;
- Division for foreign trade and certification;
- Section for legal, general and financial affairs;
- Division for veterinary inspection;
- Division for border veterinary inspection;
- Group for internal audit and quality management system.

Division for animal health, animal welfare and traceability performs tasks related to: preparation of a long-term strategy for animal health, programme of measures for animal health protection, special programmes for animal health protection against infectious diseases, certification programmes for farms free from infectious diseases; monitoring of the execution of animal health protection programme; monitoring of epizootic situation in Serbia and outside; monitoring of implementation of measures for prevention of outbreaks and spread and for eradication of infectious diseases; monitoring of animal health and welfare and preparation of guidelines in the field of welfare and good treatment of animals; laying down of veterinary and sanitary conditions for quarantine and facilities used for keeping, breeding and selling of animals; preparation of programmes for identification and registration of animals, their movement and

traceability as well as monitoring the execution of the said programmes; keeping central database of identified and registered animals, keeping registers of facilities used for keeping and breeding of animals; managing the animal health information system; establishment of a certification system for disease-free farms and monitoring the implementation of the programme with a view to obtain the disease-free status; participation in preparation and implementation of projects relating to animal health and welfare; participation in assessing the system effectiveness and preparation of proposals for corrective actions of veterinary and sanitary control, as well as development of procedures for introducing QMS for animal health and welfare; performs other tasks pertaining to this field.

Following smaller internal units are organised within the Division for animal health, animal welfare and traceability:

- Group for epizootiology;
- Group for animal welfare;
- Group for registration of animals and traceability.

Section for registration of veterinary organisations and veterinary services performs tasks related to: laying down veterinary and sanitary conditions for performance of veterinary activities in the appropriate facilities, namely: veterinary practices, veterinary stations, veterinary clinics, laboratories, animal breeding and artificial insemination centres, facilities for manufacture, storage and circulation of veterinary drugs and veterinary medical products, facilities for disinfection, disinsection and rodent control; laying down the conditions in line with the guidelines of Good Manufacturing Practice, Good Distribution Practice and Good Laboratory Practice for facilities for manufacture and circulation of veterinary drugs; keeping registers of legal entities and entrepreneurs performing veterinary activities; laying down and delegating certain expert tasks of the veterinary inspection to legal entities performing veterinary activities; laying down and conducting competition for selection of legal entities to be delegated with activities related to the Programme of Measures for Animal Health Protection; monitoring and payments to legal entities performing veterinary activities for tasks performed under the Programme of Measures for Animal Health Protection; analysing and monitoring of financial effects of the implementation of the Programme of Measures for Animal Health Protection and financial planning related to the said Programme; monitoring of results from national and international proficiency testing schemes; monitoring of side effects of veterinary drugs; participation in assessing system effectiveness and preparation of proposals for corrective actions in the field of veterinary and sanitary control of the facilities; development of procedures for introduction of QMS in the field of veterinary services; also performs other tasks within the scope of the Section.

Section for veterinary public health performs tasks related to: strategic planning and devising of the expert policy and development programmes in the field of food and feed safety; integration of animal health management system and safety certification system for food and products of animal origin; programme development and preparation of procedures and actions for ascertaining fulfilment of veterinary and sanitary conditions for operation, registration or approval of facilities for slaughter, production and

circulation of food and products of animal origin, production and circulation of feed, and of facilities for collection, storage, processing, using and disposing of animal carcasses and animal by-products; preparation of documents required for development, introduction and review of manufacturer's internal control system in the field of food and feed safety and animal by-products; preparation of regular and special programmes for systemic testing of food of animal origin and of feed; planning, preparation and participation in programmes for establishment and improvement of national food and feed safety system and system for collection, storage, processing, use and destruction of animal by-products; keeping Registers of facilities in the field of veterinary public health; participation in assessing system effectiveness and preparing proposals for corrective actions in the field of veterinary and sanitary control of the facilities and veterinary public health programmes; development of procedures for introduction of QMS in the field of veterinary public health; performs other tasks in this domain;

Following smaller internal units are formed within the Section for veterinary public health:

- Group for registration of facilities for production, processing, storage and circulation of food, feed, products and by-products of animal origin;
- Group for development, establishment and maintenance of the food safety system.

Division for foreign trade and certification performs tasks related to: laying down veterinary and sanitary conditions for import, transit and export of consignments of animals, food, feed and feed components, products of animal origin, animal by-products and reproductive material; monitoring epizootic situation in the exporting country and the transit country, as well as the equivalence of veterinary and sanitary control systems related to risk analysis in foreign trade; development of plans for systemic monitoring of import consignments; reporting changes of veterinary and sanitary measures implemented in the Republic of Serbia to the WTO and EU; participation in monitoring and removal of sanitary and phytosanitary barriers; preparation of platforms for bilateral cooperation; preparation of bilateral agreements for circulation of animals and other consignments subject to veterinary and sanitary control in foreign trade; participation in assessing system effectiveness and preparing proposals for corrective measures of veterinary and sanitary control in the field of certification of animals, food and products of animal origin, feed, feed components, animal by-products and reproductive material; preparing, issuing, recording and keeping of international veterinary certificates and development of procedures for introduction of QMS in this field; organising the implementation of staff trainings and keeping records thereof; performs other tasks pertaining to this domain;

In the Division for foreign trade and certification following smaller internal units are formed:

- Group for certification and harmonisation of veterinary and sanitary measures
- Section for foreign trade.

Section for legal, general and financial affairs performs tasks related to: preparing regulations in the field of veterinary matters, proposing amendments and

supplements to the regulations with a view to harmonisation with the EU regulations; preparing opinions regarding application of regulations from the respective scope of work; preparing proposals of the ministry's budget in the part relating to the VD; checking the soundness, completeness and accuracy of the payment documents, allocation to an account and posting of all changes related to material and financial operations of the VD; devising quarterly and annual reports on budget execution; assessment of revenues per respective types and monitoring of revenue generation; monitors the realization of the Programme on allocation and use of subsidies in the veterinary field, provision of professional assistance to other organisational units; preparing proposals and changes to contracts with budgetary beneficiaries; participation in preparation of the Rulebook on internal organisation and systematisation of job positions in the Ministry; preparing answers to claims, acting on complaints of citizens and legal entities, conducting public procurement procedures, assessing system effectiveness and preparing proposals for corrective measures in the veterinary field; developing procedures for introducing QMS in the veterinary field; performs other tasks pertaining to this domain.

Division for veterinary inspection performs tasks of veterinary and sanitary control implemented through supervision, inspection, monitoring, sampling and checking the application of the laws and regulations relating to animal health, animal welfare and breeding of animals, integrity and quality of food, products and by-products of animal origin, of feed, veterinary drugs and medical products used in veterinary medicine, and water; veterinary and sanitary control and fulfilment of requirements in the facilities for breeding and keeping of animals, for production and circulation of food of animal origin, feed, products and by-products of animal origin, reproductive material, veterinary drugs and medical products used in veterinary medicine, disinfection, desinsection and rodent control products and other poisons used in veterinary medicine; supervision and inspection of animals, food of animal origin and feed, supervision over animal testing, application of envisaged and ordered measures for the prevention of outbreak, detection, containment, control and eradication of infectious animal diseases; supervision and inspection of means of transport and transport conditions, of facilities, equipment, conditions and way of operation of the legal entities performing veterinary activities and veterinary organisations, of obtaining, production, and storage of reproductive material; of application of veterinary drugs and medical products used in veterinary medicine, as well as of other facilities, assets, objects and equipment that could be a source or carrier of infectious animal diseases or in other way compromise animal health or human health; performs other tasks from this domain.

In the Division for veterinary inspection following smaller organisational units are formed within the seat of the Ministry:

- Veterinary inspection group for animal health and animal welfare;
- Veterinary inspection group for quality and safety of food, products and by-products of animal origin not intended for human consumption;
- Veterinary inspection group for export facilities;
- Veterinary inspection group for control of production and circulation of veterinary drugs and medical products used in veterinary medicine, of feed and medicated feed.

Division for border veterinary inspection performs veterinary and sanitary control through inspection and supervision over the application of laws and other regulations relating to: import, export and transit of animals, food, products and by-products of animal origin, reproductive material, feed, feed components, veterinary drugs, medical products used in veterinary medicine, diagnostic preparations and other objects by means of which an infectious animal disease could be transferred over the state border; checking integrity and quality of products, food and waste of animal origin, control of conditions for transport of animal, food, products and waste of animal origin; performs other tasks pertaining to this domain.

In the Division for border veterinary inspection 4 groups and 2 sections are formed that cover border crossings mentioned in answer to the question 10, Import control system, Chapter II.

Group for internal audit and quality management system performs tasks related to: planning, implementation, monitoring and managing the internal audit system in the field of animal health and animal welfare and food and feed safety; organising and implementing QMS audits; checking the implementation of laws and prescribed procedures and processes related to the management of animal health, animal welfare and veterinary public health system; checking the implementation of prescribed procedures of veterinary and sanitary control; drawing up reports containing results and proposals for corrective actions; drawing up work programmes and annual internal audit plans; drawing up annual work report, periodic reports on implementation of the programme and annual internal audit plan; performs other tasks pertaining to this domain.

1.2. Plant Protection Directorate

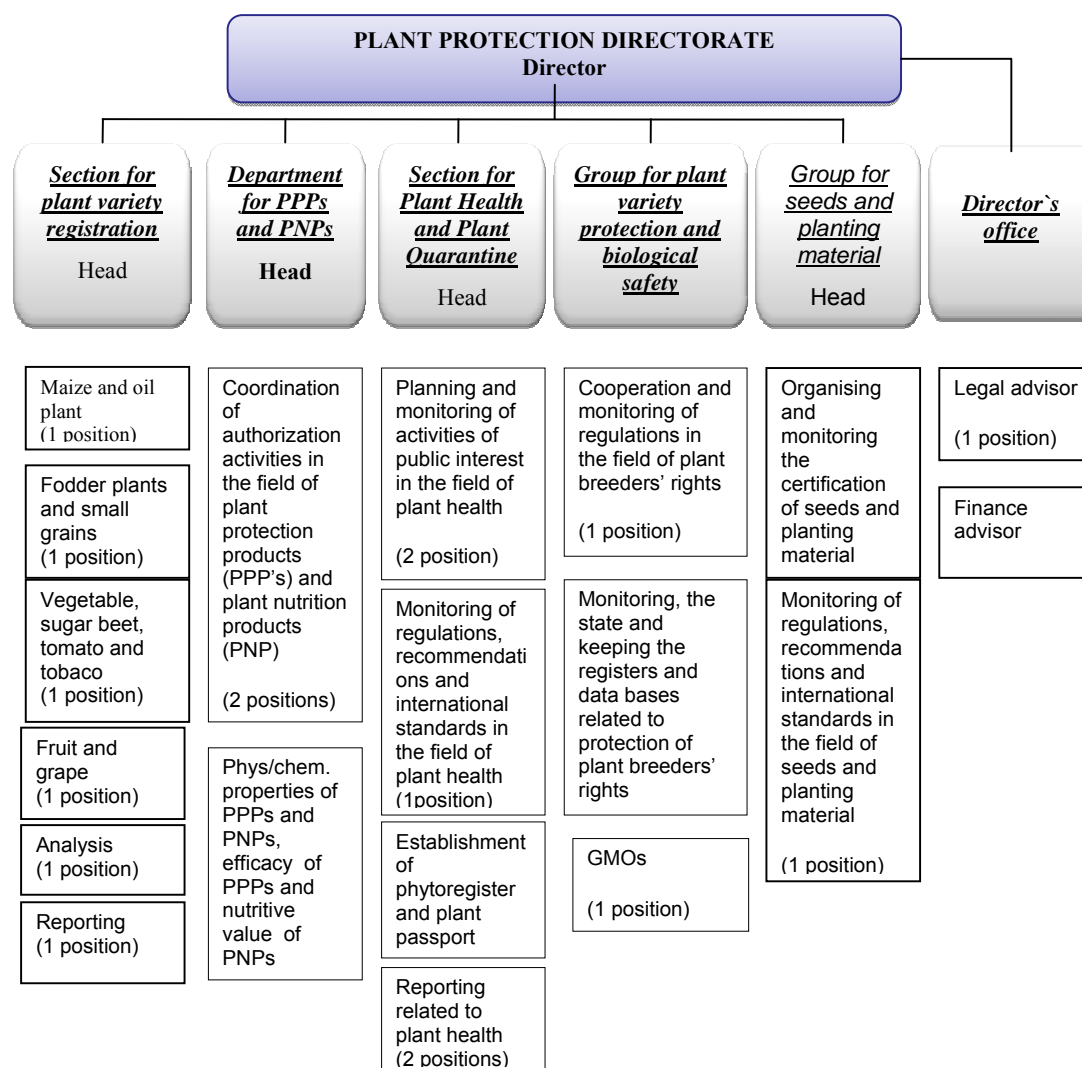
The Plant Protection Directorate (PPD) as administrative authority within the MAFWM performs tasks related to: protection of plants against harmful organisms; authorisation and control of plant protection products and plant nutrition products in manufacture, domestic and foreign trade; control of the use of plant protection products; registration of plant varieties, plant variety protection (plant variety rights), biological safety (genetically modified organisms) and performs other tasks in this field;

Following internal organisation units are formed within the PPD:

- Section for plant health and plant quarantine;
- Department for plant protection products and plant nutrition products;
- Section for plant variety registration;
- Group for plant variety protection and biological safety;
- Group for seeds and planting material.

The PPD is managed by the director, who reports to the minister of the MAFWM. Heads of internal organisational units coordinate the work in their respective units and also cooperate with other units.

Organisation chart of the Plant Protection Directorate



Section for plant health and plant quarantine: Performs administrative, regulatory and coordination-related tasks in the field of plant health pertaining to: monitoring national and international standards, and other documents needed for improvement of activities in the field of plant health and plant quarantine; issuing approvals for import of harmful organisms and plants; establishment of phytoregister and plant passport system; cooperation with international organisations and national services of other countries in the field of plant health and plant quarantine; monitoring and harmonising the laws and bylaws, regulations and recommendations with decisions, standards and recommendations of the international organisations in the field of plant health and plant quarantine; drawing up scientific basis for development of regulations in the field of plant health and plant quarantine; preparing elements related to pest monitoring (permanent and special monitoring) required for drawing up of the PPD's financial plan. Division is managed by the head who reports to the director of the Plant Protection Directorate.

Department for plant protection products (PPPs) and plant nutrition products (PNPs): Performs administrative, regulatory and coordination-related tasks in the field of plant

protection products and plant nutrition products pertaining to: authorisation and issuance of approvals for placing on the market of plant protection products and plant nutrition products; restriction and prohibition of placing on the market of PPPs and PNPs; monitoring resistance of harmful organisms to plant protection products; monitoring of manufacture, placing on the market and use of PPPs and PNPs; monitoring provision of services in the field of PPPs and control testing of devices for application of PPPs; monitoring residues of PPPs in food and feed of plant origin; keeping registers of distributors and importers of PPPs and PNPs, as well as registers of service providers in the field of plant protection products; preparation of scientific basis for drawing up draft laws and proposals for bylaws and their harmonisation with standards and recommendations of international organisations in the field of plant protection products and plant nutrition products; establishment and running of an information system in the field of PPPs and PNPs; collecting and sorting statistical data required for activities related to PPPs and PNPs. Department is managed by the head of the Department who reports to the director of the Plant Protection Directorate.

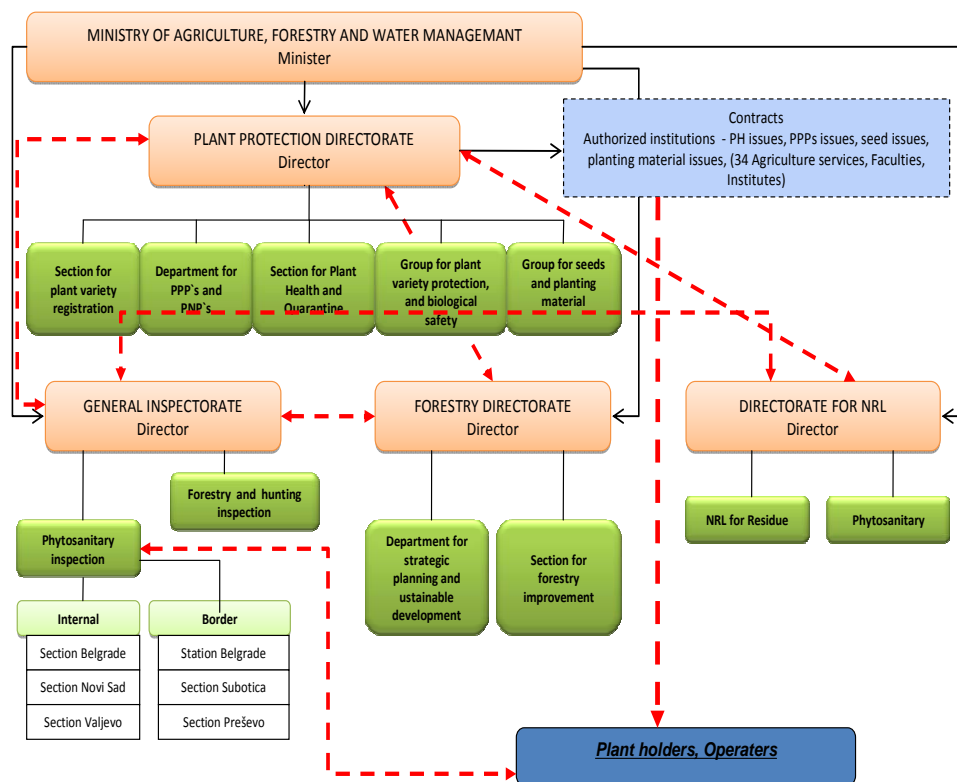
Group for seeds and planting material: Performs administrative, regulatory and coordination-related tasks in the field of seeds and planting material pertaining to: organisation and monitoring of seeds and planting material certification; monitoring of national and international standards and other documents required for improvement of activities in the field of seeds and planting material certification; cooperation with international organisations and national services of other countries, monitoring and harmonising the laws and bylaws, regulations and recommendations with decisions, standards and recommendations of international organisations in the field of seeds and planting material; drawing up scientific basis for preparation of regulations in the field of seeds and planting material; preparing elements relating to subsidies for seeds and planting material required for devising of the PPD's financial plan; keeping registers and records, drawing up analysis and balances related to seeds and planting material; performs other tasks in this field. Group is managed by the group manager who reports to the director of the Plant Protection Directorate.

Section for plant variety registration: Performs tasks related to: registration of new domestic varieties of agricultural plants; approvals for introducing into production foreign varieties of agricultural plants and entry into register of foreign varieties of fruit and grape vine; monitoring and drawing up scientific basis for development of proposals for regulations and other general documents in the field of registration of varieties of agricultural plants; drawing up methods for testing the varieties of a certain crop or group of crops in a trial field and in laboratory; monitoring the development of registration procedures in Europe and rest of the world; keeping of required registers related to the registration of varieties of agricultural plants; drawing up a list of recommended varieties of fruit and grape vine. Section is managed by the section head who reports to the director of the Plant Protection Directorate.

Group for plant variety protection and biological safety: Performs tasks related to: plant variety protection (plant breeders' rights) and biological safety (genetically modified organisms); monitoring and preparation of laws and bylaws in accordance with the

decisions, standards and recommendations of the European Union, UPOV and other international organisations in the field of plant breeders' rights and biological safety; cooperation with international organisations (UPOV, CPVO) and national services of other countries in the field of plant breeders' rights and biological safety; implementation of projects in the field of plant breeders' rights and biological safety; planning, preparing and implementing national and international projects for establishment and improvement of the plant breeders' rights and biological safety system; keeping of required registers in the field of plant breeders' rights and biological safety; coordinating the operation of the Expert Council for Plant Breeders' Rights and the Expert Council for Biological Safety; preparing data for development and updating of national databases for plant breeders' rights and biological safety; establishment and implementation of measures for biological safety, mechanisms for decision making and implementation of decisions relating to safe transfer, handling and use of GMOs with a view to prevent and reduce potential negative effects of GMOs to the environment and human and animal health. Group is managed by the Head of the Group who reports to the director of the Plant Protection Directorate.

Flow diagram – levels of competence – management lines of authorities competent for phytosanitary policy

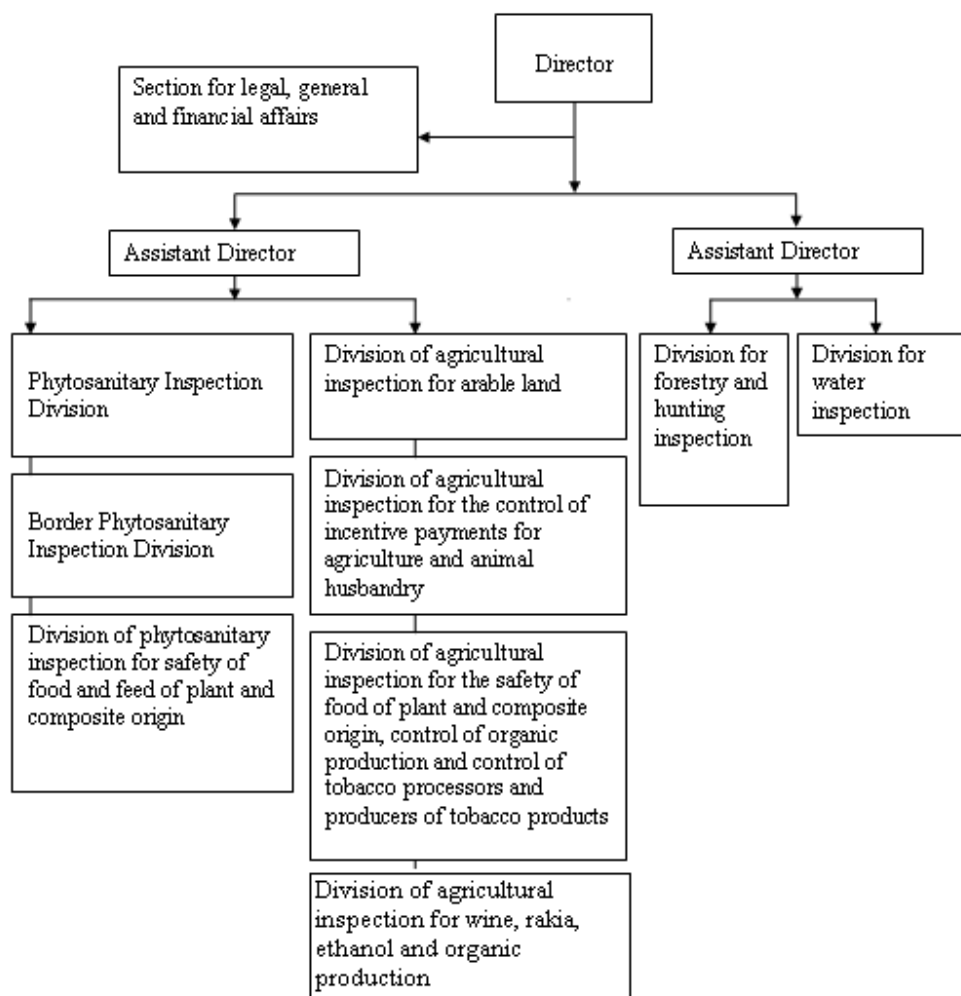


1.3. General Inspectorate

General Inspectorate (GI) performs tasks related to inspectorial supervision in the field of plant health, seeds and planting material; plant protection products; plant nutrition products; food safety of foodstuffs of plant and composite origin; feed safety of feed of plant origin; wine, rakija, alcoholic and non-alcoholic beverages and ethanol, as well as control in the field of organic production.

General Inspectorate is managed by the director who reports to the minister of the MAFWM. Two assistant directors are responsible for the operation of divisions within the GI. Heads of divisions and group managers coordinate the work in their respective divisions and groups, and also cooperate with other divisions and other groups.

Organisation scheme of the General Inspectorate



Phytosanitary Inspection Division performs tasks related to: plant inspection for the presence of harmful organisms; systemic supervision of plants for the presence of harmful organisms considered extremely dangerous to plant health; health inspection of imported plants for which post-quarantine supervision was ordered; official sampling for laboratory testing for the presence of harmful organisms and residues of PPPs; inspection of GMOs in all stages of production, processing and circulation; inspection of safety of food of plant origin in the primary production stage; inspection of safety of feed of plant origin in the primary production stage; inspection of manufacture, circulation and use of plant protection products and plant nutrition products; inspection of production, finishing, circulation and use of seeds of agricultural plants in both conventional and organic production; inspection of production, circulation and use of planting material of agricultural plants; inspection of operation of agricultural extension services.

Border Phytosanitary Inspection Division performs tasks related to: inspection of plant health at import, export and transit with trans-shipment; issuance of phytocertificates; inspection of safety of food of plant origin during import (primary produce and simply

treated products of plant origin); control of PPP and PNP import; inspection for the presence of GMOs; sets phytosanitary measures; prepares notifications for interception of harmful organisms during import.

Within the Border Phytosanitary Inspection Division there are three sections – Subotica, Belgrade and Preševo. Each section of border phytosanitary inspection covers certain number of border crossings out of 20 border crossings in total. Border crossings through which import, export or transit of plants, plant protection products and plant nutrition products may be performed are defined in the ordinance.

Division of agricultural inspection for the safety of food of plant and composite origin, control of organic production and control of tobacco processors and producers of tobacco products performs tasks related to: control in the field of safety of food of animal and composite origin in the production, processing and wholesale stages; inspection of business premises, facilities, plants, devices, objects and goods in production, processing and wholesale of food of plant and composite origin; ascertaining the fulfilment of conditions for starting the organic production of plants; control of methods, manufacturing processes during processing, storage, packaging and transport of organic products of plant origin; ascertaining the fulfilment of conditions for authorisation of certified organisations for organic production.

Division of phytosanitary inspection for safety of food and feed of plant and composite origin performs tasks related to: control in the field of safety of food of plant and composite origin and of feed of plant origin during import at 11 control points as well as during export.

Division of Agricultural Inspection for wine, rakija, alcoholic and non-alcoholic beverages and organic production performs tasks of inspectorial supervision over the implementation of laws and other regulations relating to: fulfilment of conditions for production of wine, rakija, other alcoholic beverages, ethanol, beer and non-alcoholic beverages; testing and determination of quality of these products and raw materials used for their production; control of production of grape, fruit, wine and rakija with protected geographical indication; ascertaining the fulfilment of conditions for starting the organic production of wine, rakija and other alcoholic beverages, beer and non-alcoholic beverages; control of inclusion into organic production of wine, rakija, other alcoholic beverages, beer and non-alcoholic beverages; control of methods, manufacturing processes in processing, storage, packaging and transport of wine, rakija, other alcoholic beverages, beer and non-alcoholic beverages; control of circulation and quality of wine, rakija, other alcoholic beverages, ethanol, beer and non-alcoholic beverages in domestic trade; inspection of operation of control organisations, authorised accredited laboratories; checking the safety of grape consignments intended for industrial processing, of wine, rakija, other alcoholic beverages, ethanol and beer after import.

1.4 Directorate for National Reference Laboratories

Directorate for National Reference Laboratories (DNRL), as the administrative authority within the MAFWM, performs tasks related to laboratory testing as well as other specific tasks in the food chain.

Directorate for National Reference Laboratories is managed by the director who reports to the minister.

Within DNRL following laboratories are established – reference phytosanitary laboratory, reference laboratory for residues and reference laboratory for food safety and milk. Apart from reference laboratories, Official testing station for seeds and planting material, Plant gene bank and Section for organic production are also found within the DNRL.

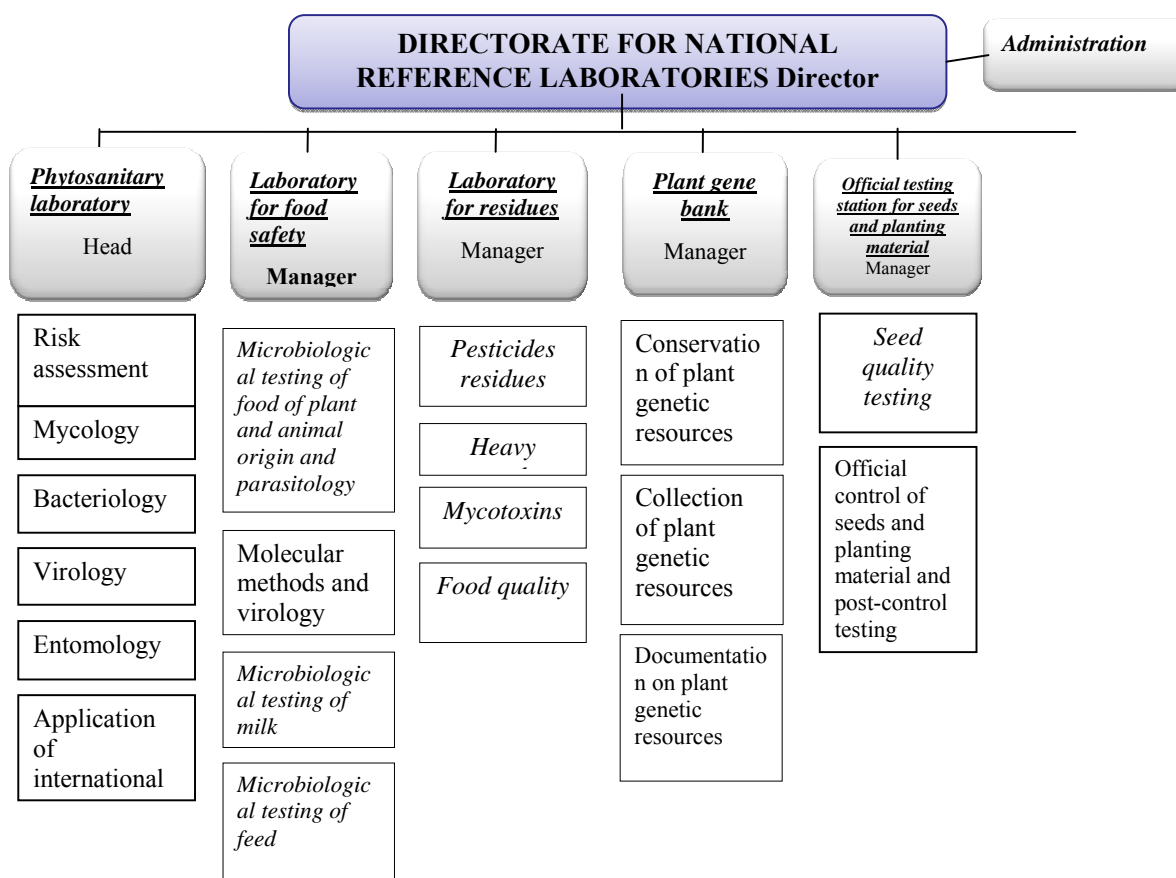
In line with The Law on Food Safety, the DNRL must be accredited against: EN ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories, EN 45002 – General criteria for the assessment of testing laboratories, EN 45003 – Calibration and testing laboratory accreditation systems. General requirements for operation and recognition.

At the moment, the DNRL is not operational in terms of performing laboratory testing. Once full operation is achieved, the DNRL will coordinate the operation of the authorised laboratories and enable forming of a functional network of authorised laboratories for the food chain control. Organisation units of the DNRL will perform following tasks:

- *Reference phytosanitary laboratory:* cooperation with national reference laboratories of other countries and exchange of information regarding official diagnostic activities; validation and standardisation of international diagnostic protocols for their implementation in authorised laboratories; monitoring the establishment of uniform criteria and methods and implementation of standards required for the operation of authorised laboratories; organisation of parallel testing or validation tests in cases when a harmful organism has been detected, and if allowed by international standards; organisation and supervision of seeds and planting material certification in part relating to health control; provision of professional and technical assistance to the Ministry for implementation of coordinated control plans; preparing national guidelines for phytosanitary controls, sampling and sample handling; organising trainings required in this field; preparing scientific frameworks for development of regulations from the scope of the group; preparation of programmes for professional development;
- *Reference laboratory for food and feed safety and milk:* cooperation with national reference laboratories of other countries in the field of food and feed safety and milk; monitoring the establishment of uniform criteria and methods and implementation of standards required for the operation of laboratories authorised for activities related to food safety and milk; exchange of information in the field

of food and feed safety and milk with national reference laboratories of other countries; provision of professional and technical assistance to the Ministry for implementation of the coordinated control plans in the field of food and feed safety and milk; development of testing methods in accordance with the international standards in the field of food safety and milk, with compulsory validation; laboratory testing in the field of food and feed safety and milk; establishment of a quality control system, not only for own use but for authorised laboratories as well; organising services of analysis validation and super analysis if relevant to the needs of authorised laboratories in the field of food safety and milk; organising proficiency testing for authorised laboratories with a view to having uniform methods implemented in the field of food and feed safety and milk; training of staff in authorised laboratories; preparing national guidelines for sampling and sample handling; preparation, maintenance, and distribution of reference material used for analysis in the field of food and feed safety and milk;

- *Reference laboratory for residues:* cooperation with national reference laboratories of other countries and exchange of information relating to the residues of pesticides, heavy metals and mycotoxins in food and chemical analysis of food; monitoring the establishment of uniform criteria and methods and implementation of laboratory standards in laboratories authorised for testing of pesticide residues, heavy metals and mycotoxins in food and chemical analysis of food; validation and standardisation of international protocols to be implemented in authorised laboratories; monitoring the establishment of uniform criteria and methods and implementation of standards for operation of authorised laboratories; organising super analysis or confirmatory testing; organisation and supervision over the operation of authorised laboratories; organising ongoing training for authorised and commercial laboratories, at their request.



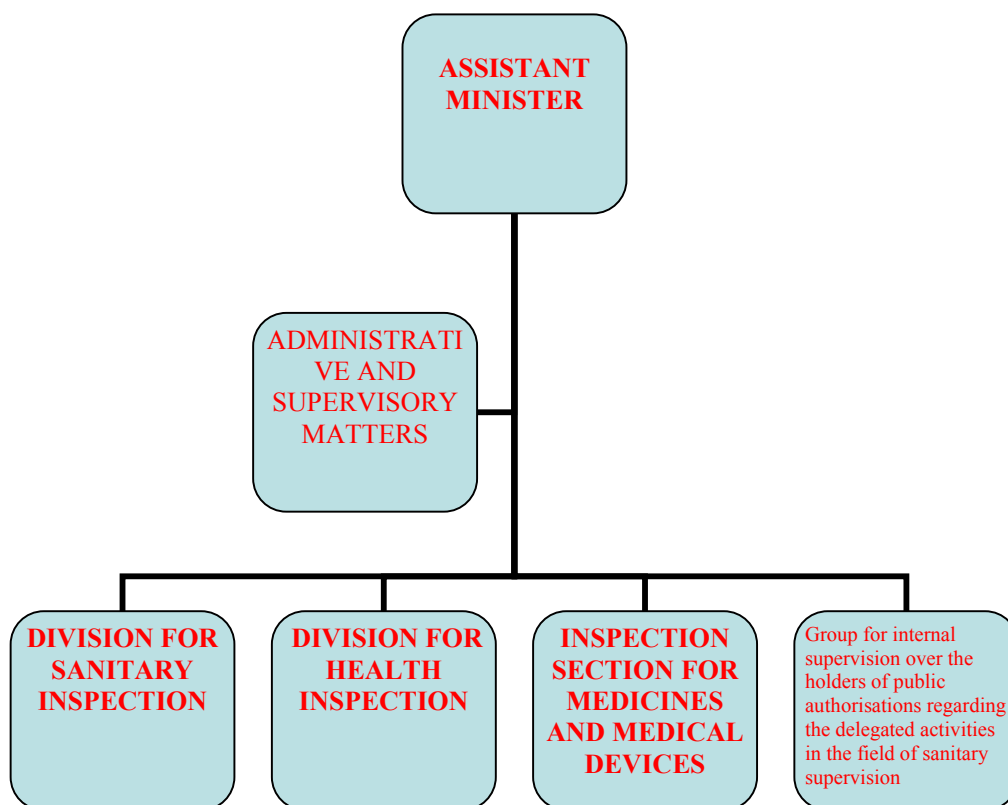
2) Ministry of Health

In the field of food safety, Ministry of Health (MH) performs tasks of the public administration relating to: control of novel food; dietary products; infant formulas – substitute for mother’s milk; dietary supplements and salts for human consumption; production of additives, aromatics, enzymatic preparations of non-animal origin and supplementary agents of non-animal origin, as well as drinking water in original packaging (table water, mineral water, spring water), and water from the public water supply system in all stages of production, processing and circulation (wholesale, retail, imports at the customs points and exports); control of sanitary and hygienic condition of facilities subject to sanitary supervision; sanitary supervision of persons placed under sanitary supervision by law, as well as supervision of plants, devices and equipment used in carrying out activities subject to sanitary supervision; laying down sanitary and hygiene requirements for facilities subject to sanitary supervision in construction or refurbishment stages and regular supervision thereof.

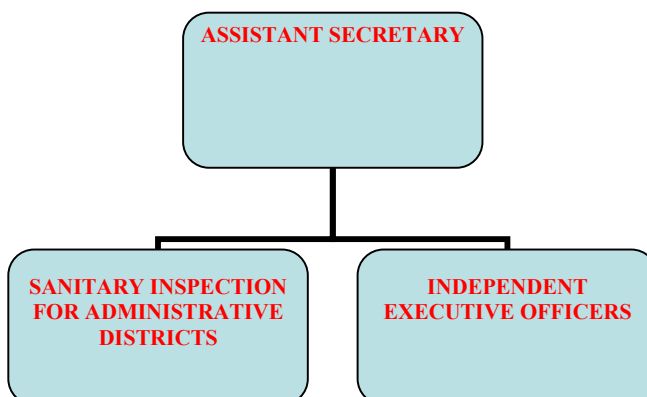
Pursuant to the Rulebook on internal organisation and systematisation of job positions in the MH, Sanitary Inspection Division of the Inspection Department is performing tasks in the field of food safety. There are 18 sections for sanitary supervision within the Division for sanitary inspection.

Within the Secretariat for Health of the Province of Vojvodina, Sanitary Inspection Division for administrative districts which consists of 7 sections is responsible for carrying out tasks related to food safety.

Organisation scheme of the Ministry of Health – Inspection Department



Organisation chart of the Secretariat for Health of the Province of Vojvodina (delegated tasks of sanitary supervision)



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 of decrees);**

The National Assembly of the Republic of Serbia is responsible for passing laws proposed by the Serbian Government. Type and dynamics of passing and adoption of legislation under Government authority are determined by the statutory guidelines of the Government Annual Work Programme.

Public administration authorities prepare draft laws, other legislative and general acts for the Government and propose to the Government development strategies and other measures which are instrumental in shaping the Government policy. In preparation of laws and other general acts, public administration authorities obtain opinions from those public administration authorities whose scope of work covers the issue being governed. Procedures related to preparation of laws and other general acts are prescribed by the Rules of Procedure of the Government.

The Government is responsible for passing regulations, decisions and conclusions upon proposal of competent ministries.

Ministries and special organisations adopt rulebooks, orders and guidelines for enforcement of laws and other regulations.

Administrative authorities of ministries are involved in shaping the Government policy through ministries and cannot independently adopt regulations.

Public administration authorities monitor and analyse situations in fields associated with their scope of work, examine consequences of analysed situations, prepare analyses, reports, information and other materials and, depending on the competence, undertake measures on their own initiative or propose legislation and measures to the Government for introduction.

Public administration authorities issue instructions directing the task organisation and work modes of employees in public administration authorities and holders of public authorisations in execution of conferred public administration tasks (province, municipalities, cities/towns, public companies, institutions, public agencies and other organisations).

Heads of public administration authorities may issue guidelines determining the work behaviour standards for employees in public administration authorities.

Preparation of food safety legislation falls within the competence of the Ministry of Agriculture, Forestry and Water Management and the Ministry of Health while the fields of veterinary and phytosanitary policy fall into the competence of the former.

Activities for preparing laws in the field of food safety, veterinary and phytosanitary policy :

- Establishment of a law-drafting working group, consisting of representatives of competent public administration authorities and outside experts in the fields in question: representatives of scientific institutions, laboratories, professional organisations, NGOs and others. The group is formed by the minister of the competent authority.
- Working group prepares and submits the text of the draft law to competent authorities and stakeholders for consideration (public debates).
- Upon completion of public debates, the working group finalises the text of the Draft Law.
- Following adjustments and receipt of positive opinions, the competent authority submits the text of the Draft Law to the Government for consolidation.
- The Government submits consolidated Draft Law to the National Assembly of the Republic of Serbia.
- The Draft Law and possible amendments are subject to further review by competent committees of the National Assembly along with the representatives of the proposer (the Government).
- The National Assembly of the Republic of Serbia adopts the Law.
- The President of the Republic of Serbia issues a decree promulgating the law.
- The Decree on promulgation of the Law and the text of the Law are published in the Official Gazette of the Republic of Serbia.

Drafting of legislation falling within the competence of the Government of the Republic of Serbia comprises the following activities:

- Establishment of a working group to provide draft legislation coming within the competence of the Government and enabling a detailed elaboration of the relationship governed by law or initiating measures and addressing the issues of common interest (regulations, decisions).
- Working group consists of representatives of competent public administration authorities and outside experts in the fields in question: representatives of scientific institutions, laboratories, professional organisations, NGOs and others.
- Working group finalises the text of legislation and, upon receipt of positive opinions of competent authorities and stakeholders, submits it to the Government for adoption.
- Following consideration, the Government adopts proposed legislation.
- Regulations and decisions are published in the Official Gazette of the Republic of Serbia.

Drafting of legislation falling into the competence of the ministries comprises the following activities:

- Establishment of a working group to provide draft legislation falling into the competence of ministries and enabling elaboration of specific legal provisions (rulebooks), ordering or prohibiting actions in a certain situation (orders – protective measures) or ascertaining work modes of public administration authorities and holders of public authorisations in execution of delegated and conferred public administration tasks (province, municipalities, cities/towns, public companies, institutions, public agencies and other organisations) (guidelines). The group is formed by the minister of the competent ministry.
 - Working group consists of representatives of competent ministries, holders of public authorisations and outside experts: representatives of scientific institutions, laboratories, professional organisations, NGOs and others.
 - Working group finalises the text of draft legislation and, upon receipt of positive opinions of competent authorities and stakeholders, submits it to the Minister for adoption.
 - The Minister submits the proposal for legislation to the Republic Secretariat for Legislation for consideration.
 - Following the receipt of positive opinion of the Republic Secretariat for Legislation, the legislation is published in the Official Gazette of the Republic of Serbia.
- 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 dynamics of the transposition of the EU food safety legislation into the national legislation is envisaged in detail by the National Programme for Integration of Serbia into the EU (NPI) for the period 2009–2012.

The Law on Food Safety (Official Gazette of RS, No. 41/09) envisages a division of competences of public administration authorities with regard to policy making, transposition and enforcement of food safety legislation to ensure coverage of the entire food chain, including phytosanitary issues and animal health and welfare.

The Ministry of Agriculture, Forestry and Water Management (MAFWM) is the competent authority for the policy and adoption of regulations governing the enforcement of laws in the field of food safety, veterinary and phytosanitary policy.

The Veterinary Directorate of the MAFWM is responsible for direct implementation of regulations and related expert tasks in the field of safety of food of animal origin, composite food and feed, animal health and welfare. Drafting of legislation and cooperation in policy making in these fields also fall under the competence of the Veterinary Directorate.

The Plant Protection Directorate of the MAFWM is responsible for direct implementation of regulations as well as administrative and related expert tasks (Single Authority) in the field of plant health, plant protection products and residues of plant protection products in food and feed, plant nutrition products and soil enhancers, seed and planting material of agricultural plants, registration of agricultural plant varieties, plant variety protection and biosafety.

The General Inspectorate of the MAFWM is responsible for the safety control of food of and feed of plant origin and composite food.

The Directorate for National Reference Laboratories of the MAFWM is responsible for laboratory testing issues and related expert tasks in food chain – with regard to the safety of food and milk, plant health, residues of plant protection products in food and feed, quality of seed and planting materials of agricultural plants and plant gene bank.

The Ministry of Health is the competent authority for the policy, adoption and implementation of regulations for enforcement of laws governing the fields of: novel food, dietary products, infant formulas – substitute for mother's milk, dietary supplements and salts for human ingestion, production of additives, flavourings, enzymatic preparations and supplements of non-animal origin, as well as drinking water in original packaging (table water, mineral water and spring water), and water from the public water supply system.

The Law on Food Safety provides for the establishment of the Expert Council for Risk Assessment in the Field of Food Safety. The Expert Council should continually monitor and carry out risk assessment relating to food and feed safety in order to protect human and animal health and life, propose decisions on professional issues and render scientific and expert assistance in decision-making and preparing food and feed safety regulations. Until its establishment, risk assessment and risk management in the field of food and feed safety are carried out by the ministries in conformity to the division of competences envisaged by The Law on Food Safety. In its operation the Expert Council shall apply and use recommendations, guidelines and information available through the European Food Safety Authority (EFSA).

Work tasks at the central level are coordinated by the mutual adjustment between the ministries responsible for food and feed safety, in accordance with the Law on Public Administration (Official Gazette of RS, No. 79/05). The ministries are bound to cooperate in all fields of common interest and submit to each other necessary data and information, establishing, if necessary, joint bodies to perform tasks requiring participation of several public administration authorities.

- **legal possibility to adopt legislation which will be implemented progressively and which can incorporate EU notions and cross-reference to another piece of EU legislation.**

Effective transposition of EU legislation is legally restricted to a certain extent as the EU legislation being transposed or harmonised with cannot be referred to in the national legislation due to existing legislative procedures.

Therefore it is necessary to find more effective modes of adoption and transposition of EU legislation into the national legislation, bearing in mind the extensiveness and complexity of EU legislation in the field of food safety, veterinary and phytosanitary policy.

Food Safety

The Law on Food Safety has provided a legal framework for the adoption of regulations allowing incorporation of the EU hygiene package rules in accordance with the dynamics defined by the National Programme for Integration of the Republic of Serbia into the EU (NPI) for the period 2009-2012. It is necessary to evaluate organisational effectiveness of the existing food safety system to identify its possible weaknesses and suggest measures to achieve full harmonisation of The Law on Food Safety through amendments, supplements and enactment of the regulations pursuant to the Law.

Veterinary Policy

The Laws on Veterinary Medicine (Official Gazette of RS, No. 91/05 and 30/10), Food Safety (Official Gazette of RS, No. 41/09), Animal Welfare (Official Gazette of RS, No. 41/09), and Drugs and Medical Products (Official Gazette of RS, No. 30/10) have established a legal framework for the adoption of regulations conforming to the EU *acquis*. Having in mind the limitations of the Serbian legal system in relation to full transposition of European legislation, the amended and supplemented Law on Veterinary Medicine has created additional opportunities for further harmonisation by adopting a larger number of bylaws transposed from the European legislation. Several bylaws in the fields of veterinary Medicine and food safety have been adopted in a prior period, partially or completely harmonised with particular EU legislation.

Phytosanitary policy

The Laws on Plant Health (Official Gazette of RS, No. 41/09), Law on Plant Protection Products (Official Gazette of RS, No. 41/09), Law on Plant Nutrition Products and Soil Enhancers (Official Gazette of RS, No. 41/09), Law on Agricultural Plant Seed (Official Gazette of RS, No. 45/05), Law on Planting Material of Fruit, Grape Vine and Hop (Official Gazette of RS, No. 18/05), Law on Protection of Plant Breeders' Rights (Official Gazette of RS, No. 41/09), Law on Genetically Modified Organisms (Official Gazette of RS, No. 41/09), and Law on Registration of Agricultural Plant Varieties (Official Gazette of RS, No. 30/10) have provided a legal framework and basis for the adoption of regulations to be implemented that will allow incorporation of the EU rules, in accordance with the dynamics defined in the NPI.

The project CARDS 2005 'Institutional Capacity Building within the Plant Protection Directorate of the MAFWM' rendered significant professional assistance in drafting legislation and bylaws in the field of plant health, seed and planting material, and the same is expected for the IPA 2008 project 'Harmonisation of national legislation with EU legislation for placing on the market and control of Plant Protection Products and implementation of new legal provisions', whose implementation began on 1 October 2010.

5. Please provide detailed information on the control activities and enforcement in the fields of food (and feed) safety, veterinary and phytosanitary policy, including details on the organisation of the controls as regards the frequency, the choice of establishments, the procedure for sampling and procedures in case of infringements. Please specify which bodies that are (will be) in charge of control activities and enforcement and their respective responsibilities. Please describe mechanisms of co-ordination.

The Law on Food Safety has laid down the competences of public authorities in the field of food safety, namely the Ministry of Agriculture, Forestry and Water Management (MAFWM) and Ministry of Health (MH).

General section of this Questionnaire, Chapter I, question 1, provides the competences of the ministries (MAFWM and MH), per competent services and per fields of control. Question 3 of the Questionnaire provides detailed description of tasks in organisational units of the Veterinary Directorate together with the fields of competence and scope of work as well as the interconnection of central, regional and local levels schematically illustrated in diagrams.

Several regulations regulating more closely the field of food safety have been passed in accordance with The Law on Food Safety, namely:

- According to the Rulebook governing the contents and method of keeping the Central Register of Facilities (Official Gazette of RS, No. 20/2010), all facilities related to food and feed business operation must be entered in the Central Register. The rulebook prescribes method of entry and linking of the existing registers and databases on food/feed facilities under the control of both the MAFWM and MH. The Central Register is kept by the MAFWM. It has been prepared pursuant to Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, and laying down procedures in matters of food safety; it is partially harmonised with Regulations 852/2004, 853/2004, 854/2004, 882/2004, 183/2005.

- The Rulebook on food hygiene (Official Gazette of RS, No. 73/2010) laying down detailed requirements of food hygiene for all food business operators across all stages of food production, processing and circulation. It has been prepared in line with the Regulation (EC) 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs;

- The Rulebook on general and specific requirements for food hygiene in all stages of production, processing and circulation (Official Gazette of RS, No. 72/2010), laying down detailed general and specific food hygiene requirements in all stages of production, processing and circulation, along with Annex 1 of this rulebook specifying microbiological criteria for foodstuffs in the following chapters: food safety criteria, process hygiene criteria (for meat and milk and products thereof, egg products, fish, other aquatic animals and products thereof, vegetables, fruits and products thereof), rules for sampling and preparation of test samples is due to become effective on 1 June 2011. This rulebook is partially harmonised with the Regulation (EC) 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and the Regulation EC 2073/2005 on microbiological criteria for foodstuffs.

Chapter XIV of The Law on Food Safety stipulates that the issuance of planning documents in the field of food and feed safety, monitoring, sampling and analysis falls under the competence of the Minister of the MAFWM and the minister responsible for public health. The planning documents contain the structure and organisation of food and feed control system, objectives, control priorities, method, time limits and funds for conducting official controls, coordination between official control authorities and preparation of food and feed safety monitoring programme in accordance with the competences established by this Law.

Two rulebooks are currently under consideration:

- The rulebook on official control implementation, prepared pursuant to Regulation 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, and
- The rulebook on implementation of official control for food of animal origin, prepared in accordance with Regulation 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

The above rulebooks shall completely define fields of competence of veterinary, phytosanitary and agricultural inspections of the MAFWM and sanitary inspection of the MH.

Veterinary Directorate

Pursuant to The Law on Food Safety, the Veterinary Directorate (VD) is the competent authority for implementation of actions and controls in the field of safety of food of animal origin, composite food and feed in production, international circulation, wholesale and retail of food of animal origin in facilities registered and approved by the MAFWM as well as retail of fresh meat, milk, eggs, honey, fish and game in specialized facilities (butcheries, fisheries and similar).

As regards veterinary issues, pursuant to the Laws on Veterinary Medicine, Animal Welfare, Food Safety and Drugs and Medical Products, the official control (inspection and supervision) comprises the following activities:

- to conduct direct inspection and supervision of the enforcement of laws and other regulations relating to animal health and welfare, animal identification and registration, food and feed safety;
- to ascertain the fulfilment of veterinary and sanitary requirements for registration or approval of animal breeding/keeping facilities, production and circulation of food of animal origin and feed;
- to determine whether animal owners and keepers and food/feed business operators implement measures prescribed by law;
- to conduct official controls in accordance with prescribed control plans and monitoring programme;
- to conduct systematic control of microbiological, chemical and biological contaminants in food and feed across all stages of production, processing and circulation;
- to conduct systematic control of official sampling method and requirements, sample record keeping and methods of laboratory analyses for specific microorganisms, chemical and biological contaminants in accordance with the division of competence;
- to initiate and conduct administrative proceedings;
- to order measures for elimination of deficiencies and to control execution thereof following the expiry of a specified time limit;
- to initiate proceedings before competent authorities against persons (legal and natural) committing criminal acts, economic offences and infringements;
- to handle and resolve petitions and complaints;
- to provide professionally documented basis and methodology for monitoring and implementation of inspection and supervision plan;
- to provide a professional basis for the annual control plan and food and feed safety monitoring programme;
- to prepare information and reports on control plan implementation, propose measures associated with their scope of work and other activities in accordance with legislation.

Production and circulation of food of animal origin can be carried out only in facilities approved by the VD and entered into the Register of approved facilities. Food business operators handling food of animal origin may not conduct any business activity prior to obtaining approval from the VD and their facility being entered in the Central Register. Applications for approval of facilities for production and circulation of food of animal origin and feed are submitted to the VD, along with other required documents. Following

direct examination, the Veterinary Directorate issues a decision verifying that designated general and specific hygiene requirements are met.

All veterinary inspectors work within the Division for Inspection and Supervision and are assigned to 25 Districts in the territory of the Republic of Serbia.

Having reasonably grounded suspicion with regard to veterinary and sanitary, health or qualitative safety of products of animal origin, food of animal origin, feed and animal drinking water or to veterinary and sanitary safety of reproductive material and not being able to ascertain it or at the explicit request of the producer or the client, veterinary inspectors submit the required number of samples taken in the prescribed manner to an authorised laboratory for testing (analysis). The party in question shall permit the taking of the required quantity of samples for laboratory testing purposes free of charge.

The party dissatisfied with the analysis report may request a super analysis of the sample taken at the same time and in the same manner within three days from the receipt of the analysis report.

The facility fulfilling prescribed requirements is entered in the Register of approved facilities pursuant to the decision on compliance with the VD requirements, containing the following information:

- name and seat of the food or feed business operator and location of the approved facility;
- first name, surname and address of the food or feed business operator, natural person as well as location of the approved facility;
- type of business activity referred to in the approval;
- capacity and product range of the facility;
- veterinary control number of the facility.

The Register of approved facilities for the production and circulation of food of animal origin and feed is kept by the VD.

The facility is deleted from the register of approved facilities pursuant to the decision of the VD in following cases:

- at the request of the food and feed business operator;
- if the control procedure shows that the facility has ceased to meet the prescribed requirements and that deficiencies have not been eliminated within the prescribed time period;
- on termination of the food or feed business operator's activities;

In accordance with the Law on Veterinary Medicine, slaughter inspection is carried out by veterinary inspectors or authorised veterinarians (permit issued by the MAFWM-VD). See Question 10, funding of checks, in this Chapter.

Authorised veterinarians do not have the power to impose administrative measures and activities. These actions are carried out by veterinary inspectors after receiving notification of an irregularity identified by the authorised veterinarian.

Facility control plan is prepared at the beginning of each year. In developing the control plan, following things are taken into consideration - type of business activity performed at a facility, production capacities, condition and previously identified irregularities, self-control systems established and similar. The plan lays down dynamics of control, inspection subjects as well as methods.

Monitoring activities related to testing of veterinary drug residues and other harmful residues in food of animal origin and feed are carried out in accordance with the Programme of systematic monitoring of residues of pharmacologically active substances, hormones and other harmful matters in live animals, products of animal origin, food of animal origin and animal feed harmonised with the Council Directives 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and 97/747/EC.

Chapter V of The Law on Food Safety describes general food safety requirements (prohibitions, requirements for determination of food safety, measures, restrictions and prohibition of food). Article 27 thereof sets out the procedure for implementation of measures, restrictions and prohibition in case of reasonably grounded suspicion that certain food is unsafe that falls within the competence the Ministry of Agriculture, Forestry and Water Management (MAFWM) and the ministry responsible for public health. Pursuant to Articles 11 and 12 of this Law, the MAFWM is the central authority whereas the Ministry of Health is responsible for supervision issues. In cases of food-borne disease threat, both ministries conduct supervision and inform each other of the outbreak and measures that have been undertaken.

Pursuant to Article 146 of the Law on Veterinary Medicine (Official Gazette of RS, No. 91/05 and 30/2010), veterinary inspectors have the powers and duties: to order measures for elimination, prevention, containment and eradication of infectious, parasitic or reproductive diseases of animals in holdings suspected to be or already infected; to impose a temporary ban on the construction or reconstruction of a facility or on the use of a constructed or reconstructed facility not complying with the prescribed veterinary and sanitary requirements and to establish compliance measures and deadlines; to prohibit production and circulation of animals, products of animal origin, food and waste of animal origin that can transmit infectious animal diseases and become a threat to human health; to order seizure, slaughter or killing of animals in circulation, destruction of products, food and waste of animal origin and feed in production and circulation or order a change of intended use; to order elimination of deficiencies or temporarily prohibit further use of premises, equipment and facilities and impose a ban on performing activities in registered and approved facilities until deficiencies have been eliminated; to order other measures and undertake other activities in accordance with the Law.

In carrying out veterinary supervision, border veterinary inspectors have the following powers and duties: to perform veterinary and sanitary control of consignments at import and transit of animals, products and food of animal origin, feed, veterinary drugs and medical products for veterinary use, waste of animal origin and related items; to inspect

the imported consignments of animals, products and food of animal origin, feed, waste and related items in order to evaluate their adequacy; to check international veterinary certificates on adequacy of imported consignments; to take samples, free of charge, from consignments of products and food of animal origin and feed in order to ascertain their veterinary and sanitary adequacy. (Article 150).

Authorised veterinarians

Veterinary station meeting all legal requirements may perform following professional activities pertaining to veterinary inspection: veterinary and sanitary inspection of animals, products and food of animal origin and feed in domestic circulation; veterinary and sanitary inspection of animals intended for slaughter, meat and products of animal origin prior to their placing on the market; veterinary and sanitary inspection of vehicles used in the transportation of animals, products and food of animal origin, feed and waste of animal origin in domestic circulation; issuing of certificates verifying the status of a disease-free agricultural holding. Veterinary stations may not perform the above mentioned professional activities on their own animals, products and food of animal origin, feed, animal by-products and their own vehicles.

The Minister ascertains the fulfillment of the requirements for performance of conferred tasks and renders the compliance decision published in the Official Gazette of the Republic of Serbia; a person performing professional activities of veterinary inspection must have a permit issued by the Ministry.

General Inspectorate (GI)

General Inspectorate is the competent authority for coordination and implementation of the control in the field of safety of foodstuffs of plant origin at primary production level, simply treated food of plant origin, processed food of plant origin, composite food, feed of plant and composite origin - through phytosanitary and agricultural inspectors.

Control plan is prepared at the beginning of each year and reviewed on a monthly and quarterly basis. In developing the control plan, following things are taken into consideration - type of business activity performed at a facility being inspected, production capacities, condition as well as previously identified irregularities.

The General Inspectorate Division of agricultural inspection for the safety of food of plant and composite origin, control of organic production and control of tobacco processors and producers of tobacco products

Checks are carried out as: regular, action and irregular.

Regular checks are carried out annually on the basis of statutory powers (with or without notice) within the framework of adopted work objectives for each inspector.

Action checks are carried out on the basis of annual and quarterly work plan defining the type of product, group of producers or part of the territory of the Republic of Serbia, in case of a large number of checks within a short period of time.

Irregular checks are conducted if there is reasonable doubt as to hazards to human health. These checks are carried out on the basis of written protocols and in cooperation with authorised accredited laboratories.

All checks are carried out through the following steps:

- check of documentation;
- physical check of the fulfilment of prescribed requirements;
- physical check of products (label, sensory inspection);
- sampling and forwarding of samples to accredited laboratories for testing purposes.

Objects of control are selected according to operational databases pertaining to territorial competence of each inspector. Frequency of checks is not prescribed; it depends on estimates of inspectors, consumer complaints, but first and foremost on the annual supervision plan. There is no documented classification of objects in relation to risk assessment and the plans ensure overall coverage, depending on the extent of irregularities identified in one producer, the whole branch or a product group in a prior period.

Sampling is carried out in the prescribed manner and the number of samples taken during regular control is envisaged by the general plan defined by work objectives for each inspector (defined on an annual basis and ranging from 2-5 samples per inspector for a period of one month).

Sampling methods and methods of food product analysis are prescribed by standards and rulebooks remaining in force until bylaws implementing The Law on Food Safety and governing the fields of sampling and testing have been passed (deadline is June 2011).

Agricultural inspector responsible for the safety of food of plant and composite origin, control of organic production and control of tobacco processors and producers of tobacco product – the authorised inspector, takes, in accordance with prescribed regulations, samples of food of plant and composite origin for the safety and quality analysis and super analysis. Sampling is carried out in the presence of the FBO (food of plant and composite origin). Two identical samples (sample and control sample/sample for analysis and super analysis) are taken for laboratory testing of food of plant and composite origin. At the request of the food business operator or in case the authorised inspector deems it necessary, the third sample is taken (for possible expertise) and along with a copy of sampling record given into the care of the owner of sampled food. Samples for analysis must represent to the greatest possible degree the average composition of the overall quantity of food sampled and are collected in quantities sufficient for analysis (defined by the List of recommended minimum quantity required for laboratory samples, prepared under Good Laboratory Practice).

Average samples of non-homogenous and bulk food of plant and composite origin are taken from several spots by mixing (quartering procedure). Samples of homogenous food (liquid, mash, etc.) in bags, crates or other similar large containers are taken from the top, middle and bottom of a packaging unit, whereas the average sample is formed in the prescribed manner, depending on the number of packaging units. The average sample of food in original packaging is formed in the designated manner, depending on the number of packaging units and packaging weight. Authorised inspectors may take samples for analysis according to random sample principle when it is certain that samples taken are representative of total sampling quantity.

Handling methods, packaging and sampling/packaging equipment should not have adverse effects on the sample composition and sensory, microbiological or other properties thereof. Microbiological analyses require the use of sterile packaging and sampling equipment. Each sample of food of plant and composite origin is appropriately packed and wrapped, marked indelibly and with official seal on the wrapping and sealed in a manner appropriate to prevent opening, unless the seal has been damaged. Sampling record is made during the sampling procedure. Samples for analysis are submitted to an accredited laboratory from the list of laboratories authorised for food safety testing and monitoring. Request for laboratory analysis, containing the sample itself and all necessary data on the conducted procedure, is prepared for each sample and submitted together with specific testing request to the accredited laboratory. Authorised inspectors are obliged to store the second control sample under proper conditions until the testing of the product safety has been completed and in case of product compliance to place it at the disposal of the relevant business operator.

If laboratory testing shows that the sampled food is unsafe, food business operator may request new testing in which case control sample is sent for super analysis to another accredited laboratory. The result of super analysis is final. Costs of analysis and super analysis are borne by the party from which the sample was taken if final test results show its non-conformity with prescribed properties. If the sample conforms to prescribed properties, costs of laboratory analyses and super analyses shall be funded through the budget of the Republic of Serbia.

In cases of non-compliance with legal norms, inspectors impose administrative measures (Decisions prohibiting production or circulation) and file requests for initiating infringement proceedings and charges for economic offences in court, depending on the type of infringement (penalties).

Inspectors of the *General Inspectorate Division of Agricultural Inspection for wine, rakija, non-alcoholic beverages and organic production* shall control the products (wine, rakija, ethanol, beer and soft beverages) within the scope of their work competence in the same manner and following the same procedures.

The General Inspectorate Division of Phytosanitary Inspection for the safety of food and feed of plant and composite origin

Control system for the food of plant and composite origin/feed of plant origin is based on written procedures. At import it covers the following activities:

- recording of consignments at border crossings carried out by border phytosanitary inspection for food and feed (consignments subject to inspection only pursuant to The Law on Food Safety are only recorded),
- control at one of 11 internal phytosanitary inspection posts for the safety of food of plant and composite origin and feed of plant origin.

Upon arrival of imported consignments of food and feed of plant and composite origin and returned export consignments of foodstuffs, border phytosanitary inspectors make record of the consignment, issue a record list with number, date and name of internal inspection post to which the consignment is sent.

Upon receipt of the importer's request, phytosanitary inspectors for the safety of food and feed of plant and composite origin:

- check documentation and identify the consignment,
- enter request data into computer and prepare records,
- determine the number, quantity and types of official sample analysis,
- issue a confirmation of performed sensory inspection and samples taken for laboratory testing,
- issue a decision on permit of import and placement on the market, production, finishing and processing of the product,
- issue a notification to the importer in case tested products are not safe, including a super analysis option,
- issue a decision prohibiting import and circulation, production,
- finishing and processing of the product if testing results confirm its unsafety.

Testing of safety of food and feed of plant and composite origin involve quality control and control of the presence of plant protection products and heavy metals as well as microbiological analyses.

Number of controls is directly related to the flow of requests submitted by importers in order to provide evidence of food safety. Records are made for every particular import, whereas the sampling is carried out according to established procedure to determine whether the food consignment is safe for the market of the Republic of Serbia.

With regard to requests for import of products without commercial value (products intended for trial production, market research, presentations; humanitarian aid, etc.), phytosanitary inspectors for the safety of food and feed of plant and composite origin perform the following procedures:

- check of documentation,

- verification of the request.

The General Inspectorate Division of Border Phytosanitary Inspection conducts activities related to the control of plants, plant products, prescribed facilities, plant protection products, plant nutrition products in circulation across the state border (import, export and transit with reloading).

Control of plants, plant products and regulated objects

Control of plants, plant products and designated regulated objects at import, export and transit with reloading is carried out at border crossings and include:

- control of plant health, plant products and regulated objects;
- issuance of phytocertificates and re-export phytocertificates;
- recording of consignments and forwarding to phytosanitary inspection for food safety at the inspection post;
- control of GMO presence;
- control of the presence of radioactive contamination;
- preparation of the notification on interception of harmful organisms at import.

Number of controls is directly related to the flow of requests submitted by importers in order to provide evidence of plant health. Records are made for every particular import, as well as sensory inspection, whereas the sampling is carried out according to established procedure to determine whether the consignment conforms to legal norms.

Import, transit and export of plants, plant products and regulated objects can be conducted through border crossings with organised phytosanitary inspection and corresponding hygienic and technical working conditions. Consignments packed in wooden materials which are not subject to phytosanitary inspection can be imported through border crossings at which a customs checkpoint has been established.

Article 67 of the Law on Plant Health (Official Gazette of RS, No. 41/09) defines the types of plant consignments subject to health control and inspection during the import, as well as mandatory requirements to be met.

Plants, plant products and regulated objects from List VB Part I and List VB Part II must be accompanied by a phytocertificate re-export phytocertificate.

Phytocertificate and re-export phytocertificate must be issued in conformity with the International Plant Protection Convention.

1. Check of documentation

Imported consignments should be accompanied by the following documentation:

- declaration of plant consignments subject to phytosanitary inspection
- international certificate on health status of plant consignments – phytocertificate or re-export health certificate – re-export phytocertificate. (This applies to

consignments of plants on List VB Part I of the Rulebook on lists of harmful organisms and lists of plants, plant products and regulated objects (Official Gazette of RS, No. 7/10)).

- a copy of Decision on entry into the Register of Importers (Phyto-Register)
- OECD and ISTA certificates for seed consignments – if pertaining to the accompanying documentation as well as certificate of production for planting material consignments.
- other documents accompanying the consignment - CMR, invoice, bill of lading, Border phytosanitary inspectors also check:
- whether the variety is listed in the Variety Register - for seed, seedling and planting material consignments.

2. Identification and inspection of the consignment

- Identification of consignments is carried out by comparing data from the accompanying documentation with the consignment markings (seed, seedling and planting material consignments must be labeled with appropriate labels).

3. Inspection

- vehicle inspection – first of all identification of the vehicle – of load section where the consignment is placed, containing the data from the accompanying documentation, and inspection of all parts of the vehicle to ascertain the presence of harmful organisms.
- packaging inspection – to ascertain the presence of harmful organisms on/in the packaging.
- plant inspection – inspection of the entire consignment and taking of samples, wherever necessary and possible, according to prescribed procedures.

Inspection of samples is carried out in laboratory at the border crossing.

In case available data give grounds for suspicion of the presence of harmful organisms which cannot be ascertained at the border crossing point (hidden infections) or require determination of the type of the identified pathogen or in case the analysis of the presence of genetic modification or gamma spectrometry analysis are prescribed pursuant to regulations, samples taken are properly packed, sealed and sent to an authorized institution.

4. Decisions upon completion of controls

If accompanied by proper documentation, analytical laboratory report are received and the vehicle, packaging and plants are identified and inspected at the border crossing, the consignment is deemed to have met the requirements prescribed by law and a Decision of allowing import and customs clearing is issued. At the same time phytosanitary certificate and re-export phytosanitary certificate, accompanying the consignment, are verified by the stamp ‘Consignment inspected - Import permitted’.

Thus verified original phytosanitary certificate accompanies the consignment, while the verified copy is retained in the case record.

If the consignment cannot be identified due to lack of proper documentation or labelling/declaration, border phytosanitary inspectors issue a decision prohibiting the import and order the return or destruction of the consignment.

If the inspection of vehicle, packaging and/or plant and the analytical laboratory report have ascertained that the consignment does not meet the requirements prescribed by regulations and/or that it is infested by harmful organism (organisms), border phytosanitary inspectors issue a decision on ban on the import and order measures prescribed by law - return, seizure, destruction of the consignment or disinfection treatment, depending on the identified harmful organism and plant type.

Measures of destruction or disinfection are, if possible, carried out at the same border crossing or the inspectors issue a provisional decision and, undertaking preventive measures, send the consignment to the nearest place where the imposed measures can be carried out under customs supervision.

In case of consignment return, phytosanitary certificate and re-export phytosanitary certificate are verified by the red triangular stamp stating 'certificate revoked'.

If appropriate phytosanitary measures are to be undertaken, Form 2 – Notification of interceptions, which is an integral part of the Rulebook on phytosanitary control of plants, plant products and regulated objects in international circulation (Official Gazette of RS, No. 32/10) – is, upon issuance of a final decision, filled out and forwarded to the Division of Plant Health and Plant Quarantine of the Plant Protection Directorate.

The Plant Protection Directorate notifies the exporting country of interceptions using the prescribed forms.

Upon completion of phytosanitary inspection of consignments of plants, plant products and regulated objects, a record list is issued for consignments inspected pursuant to The Law on Food Safety. Further inspection and supervision procedures are carried out by phytosanitary inspection for food safety.

Control of plant protection product import

Plant protection products can be imported through border crossings with organised phytosanitary inspection. The Customs Service cannot start customs clearance procedures unless phytosanitary inspection has not been completed. Importers, transit shippers and their authorised representatives are bound to notify the arrival of the consignment to border phytosanitary inspectors in due course and to submit the request for inspection. The request is submitted in writing, referencing all documents accompanying the consignment.

Number of controls is directly related to the flow of requests submitted by importers in order to provide evidence of compliance with declared quality in accordance with the

decision on placing of plant protection products on the market. Records are made for every particular import, whereas the sampling is carried out according to established procedures.

Inspection of plant protection product consignments at border crossings includes:

- check of documentation (documents) accompanying the consignment in order to identify markings on the packaging and established consignment contents and to ascertain the fulfilment of the requirements prescribed by law:
 - certificate of quality,
 - bill of lading/consignment note,
 - invoices, delivery notes and other documents accompanying the consignment,
 - decision on entry in the Register of Distributors and Importers,
 - decision on plant protection product registration (authorisation), and/or evidence that the active substance is on the list of approved substances;
- physical inspection of the consignment:
 - visual inspection,
 - vehicle inspection,
 - inspection of packaging and all markings (labels, trademarks, etc.);
- sampling.

To ascertain physical and chemical properties, samples are sent to institutions authorised by the MAFWM.

Sampling procedure of PPP consignments, list of authorised testing institutions and test methods are given in the answer to question No. 6, point 2, Plant Protection Products and Residues thereof, Section I – General Information, Chapter 12.

Consignments sampled by phytosanitary inspectors remain under customs supervision and may not be placed on the market prior to obtaining test results.

If it is established that PPP:

- do not conform to declared quality, as confirmed by laboratory tests, phytosanitary inspectors issue a decision to prohibit their import and order the return of the consignment to the sender;
- conform to declared quality, as confirmed by laboratory tests, phytosanitary inspectors issue a decision allowing the import.

With regard to the consignments imported in containers through the border crossing not designated for container inspection, phytosanitary inspectors only check the accompanying documentation. If the consignment is accompanied by appropriate documentation, phytosanitary inspectors allow transport of containers under customs supervision to the approved place of inspection where the containers can be opened.

Consignments transported by rail are inspected at railway stations designated by the MAFWM. Air and mail consignments and goods in lots are inspected at the customs warehouse in specified examination field that meets inspection requirements.

Consignments in transit through the territory of the Republic of Serbia, which are reloaded or split, are subject to compulsory examination at border crossings.

Import control of plant nutrition products and soil enhancers

Plant nutrition products and soil enhancers can be imported through border crossings with organised phytosanitary inspection. The Customs Service cannot start customs clearance procedures unless phytosanitary inspection has not been completed. Importers, transit shippers and their authorised representatives are bound to notify the arrival of the consignment to border phytosanitary inspectors in due course and to submit the request for inspection. The request is submitted in writing, referencing all documents accompanying the consignment.

Number of controls is directly related to the flow of requests submitted by importers in order to provide evidence of compliance with declared quality in accordance with the decision on placing of plant nutrition products and soil enhancers on the market. Records are made for every particular import, whereas the sampling is carried out according to established procedures.

Inspection of plant nutrition product and soil enhancer consignments at border crossings includes:

- check of documentation (documents) accompanying the consignment in order to identify markings on the packaging and established consignment contents and to ascertain the fulfillment of the requirements prescribed by law:
 - certificate of quality,
 - bill of lading/consignment note,
 - decision on entry in the Register of Distributors and Importers,
 - decision on entry in the Register of Plant Nutrition Products,
 - invoices, delivery notes and other documents accompanying the consignment;
- physical inspection of the consignment:
 - visual inspection,
 - vehicle inspection,
 - inspection of packaging and all markings (labels, trademarks, etc.);
- sampling.

To ascertain physical and chemical properties, samples are sent to institutions authorised by the MAFWM.

Sampling procedure is prescribed by the Rulebook governing requirements and manner of consignment inspection and sampling at import, method of arrival notification, forms and contents of the inspection request and mandatory requirements for phytosanitary inspection, method of sample delivery, number and size of samples for testing purposes as well as treatment of seized consignments (Official Gazette of RS, No. 86/2010) conforming to Annex IV of the Regulation (EC) No. 2003/2003 of the European Parliament and of the Council.

Consignments sampled by phytosanitary inspectors remain under customs supervision and may not be placed on the market prior to obtaining test results.

If it is established that plant nutrition products and soil enhancers:

- do not conform to declared quality, as confirmed by laboratory tests, phytosanitary inspectors issue a decision to prohibit their import and order the return of the consignment to the sender;
- conform to declared quality, as confirmed by laboratory tests, phytosanitary inspectors issue a decision allowing the import.

With regard to the consignments imported in containers through the border crossing not designated for container inspection, phytosanitary inspectors only check the accompanying documentation. If the consignment is accompanied by appropriate documentation, phytosanitary inspectors allow transport of containers under customs supervision to the approved place of inspection where the containers can be opened.

Consignments transported by rail are inspected at railway stations designated by the MAFWM. Air and mail consignments and goods in lots are inspected at the customs warehouse in specified examination field that meets inspection requirements.

PNP consignments in transit with reloading or splitting in the territory of the Republic of Serbia, are subject to compulsory examination at border crossings.

The General Inspectorate Division of Phytosanitary Inspection performs tasks related to:

- inspection of soil and plants for the presence of harmful organisms;
- regular and special supervision of plants to ascertain presence or absence of harmful organisms pursuant to the Rulebook establishing the programme of measures for protection of plant health on an annual basis;
- systematic supervision of plants to ascertain presence of harmful organisms considered particularly dangerous to plants;
- official sampling for laboratory testing to ascertain presence of harmful organisms;
- control of production, finishing, placing on the market and use of agricultural plant seed;
- control of production, finishing, placing on the market and use of agricultural plants of organic origin for the establishment of organic production;
- control of production, finishing, placing on the market and use of agricultural planting material;
- control of production, placing on the market and application of plant protection and plant nutrition products;
- control of work activities of holders of public authorisations.
- control of use in closed systems and deliberate release of GMOs into the environment
- control of plant protection product residues in foodstuffs of plant origin

Inspection controls are carried out on the basis of the annual work plan (broken down by months) and work objectives for each inspector - within regular, irregular and action checks. Checks include constant supervision, special supervision and sampling, implemented in accordance with the prescribed procedures.

Phytosanitary controls in the field of plant health

Phytosanitary inspectors perform constant and special supervision of harmful organisms in accordance with legal provisions and the Programme of Measures; they also monitor implementation of the Programme, presence of harmful organisms and risk assessment related thereto, conduct phytosanitary inspection and issue official and other documentation.

Objects that are controlled are set on the basis of the annual work plan and defined by the Programme of Measures. Inspection of objects comprises of the check of documentation, visual inspection, sampling and testing of plants, plant products and regulated objects to ascertain the presence of harmful organisms.

Special supervision of harmful organisms implemented within a specified time period is defined by the Rulebook establishing the Programme of measures for protection of plant health. The said Rulebook lays down special supervision of potatoes, pomaceous fruit, stone fruit, grape vine, strawberries, beans, tomatoes and peppers.

In any case of doubt as to the presence of quarantine harmful organisms, the holder of plants and authorised agricultural extension services are bound to immediately report the matter to phytosanitary inspector.

In accordance with their legal powers, phytosanitary inspectors take samples in order to examine plant health and ascertain the presence of harmful organisms (seed, planting material, commercial plants) according to the prescribed procedure. Samples taken are forwarded to authorised institutions for laboratory testing. In cases of any doubt as to the presence of quarantine harmful organisms, phytosanitary inspectors are obliged to take and send the sample marked URGENT for laboratory analysis and orders adequate preventive phytosanitary measures. Authorised institutions provide the inspectors with laboratory reports for further action.

In cases of non-compliance with legal norms, phytosanitary inspectors take administrative measures (Decisions imposing the measures, prohibiting production, finishing or circulation) and other phytosanitary measures.

Pursuant to identified irregularities, charges for economic offences and requests for initiating infringement proceedings are filed in court, depending on the status of the control subject as well as type of infringement (penalties).

Control of seed and planting material.

Production of seed and planting material is subject to compulsory professional and health control. Producers have a legal obligation to report the production for each vegetative season. Production reports are subject to control. Controls are carried out to ascertain: the origin of used seed, species, varieties and categories, authenticity and purity of species and varieties, spatial isolation, crop health, presence of weeds, general health, growth and development of crops, pre-crops, application of agro-technical measures and the expected yield for natural seed and quantity of planting material, pursuant to the prescribed manner and methods of professional and health control.

Phytosanitary inspection conducts controls on the basis of the annual work plan, evaluated and reviewed on a monthly and quarterly basis. In developing the control plans, following things are taken into consideration - type of business activity performed in facilities subject to control, capacities thereof, condition as well as previously identified irregularities.

Regular checks are carried out annually on the basis of statutory powers (with or without notice) within the framework of adopted work objectives for each inspector.

Action checks are carried out on the basis of annual and quarterly work plan defining the type of product, producers or part of the territory of the Republic of Serbia, in case of a large number of checks within a short period of time.

Phytosanitary inspectors carry out regular checks of production, finishing and placing on the market of agricultural plant seed and planting materials during vegetation periods and periodic checks of seed and planting material in finishing and circulation. They also constantly supervise work activities of agricultural extension services authorised to conduct professional and health controls of seed and planting material.

In any case of doubt as to the presence of quarantine harmful organisms, the holder of plants and agricultural extension services are bound to immediately report the matter to phytosanitary inspector.

In accordance with their legal powers, phytosanitary inspectors take samples in order to examine plant health and ascertain the presence of harmful organisms (seed and planting material). Samples taken are forwarded to authorised institutions for laboratory testing. In cases of any doubt as to the presence of quarantine harmful organisms, phytosanitary inspectors are obliged to take and send the sample marked URGENT for laboratory analysis and orders adequate preventive phytosanitary measures. Authorised institutions provide the inspectors with laboratory reports for further action.

In cases of non-compliance with legal norms, phytosanitary inspectors take administrative measures (Decisions imposing the measures, prohibiting production,

finishing or circulation) and other phytosanitary measures. Pursuant to identified irregularities, criminal charges, charges for economic offences and requests for initiating infringement proceedings are filed in court, depending on the status of control subjects as well as type of infringement (penalties).

In any case of doubt as to the presence of quarantine harmful organisms, the holder of plants and agricultural extension services are bound to immediately report the matter to phytosanitary inspector.

Control of food of plant origin at primary production stage and control of genetically modified food at all stages of production, processing and placing on the market

Pursuant to the annual plan covering the control of pesticide residues in food of plant origin (fruit and vegetables), phytosanitary inspectors select facilities to be inspected, conduct the control and take samples of agricultural products of plant origin in circulation. Sampling is carried out pursuant to prescribed procedures detailing sample formation method and procedure, sample size as well as handling methods. Samples are taken by accredited samplers in the presence of phytosanitary inspectors. Samples taken are forwarded to accredited laboratories. Accredited laboratories provide the inspectors with laboratory reports for further action.

Phytosanitary inspectors are authorised to:

- inspect facilities, environment, premises, equipment and vehicles in primary production of food of plant origin;
- inspect and, if necessary, take samples of raw materials, materials and substances used at primary production level of food of plant origin;
- inspect and, if necessary, takes samples of materials, packaging and items coming into contact with food of plant origin at primary production level.

In cases of non-compliance with The Law on Food Safety and The Law on Plant Protection Products, phytosanitary inspectors are authorised to:

- impose restrictive measures and ban the market of plant, plant products and food of plant origin at primary production level until hazards and doubts about its safety have been eliminated;
- order destruction of plant, plant products and food of plant origin at primary production level which is deemed unsafe;
- undertake other measures in accordance with the law;

Pursuant to identified irregularities, criminal charges, charges for economic offences and requests for initiating infringement proceedings are filed in court, depending on the status of control subjects as well as type of infringement (penalties).

Control of plant protection products (PPPs) and plant nutrition products (PNPs) on internal market

In accordance with the annual activity plan regular checks of producers, distributors and users of plant protection products are carried out. Selection of facilities is based on a review of control operators entered in the Register of Distributors and Importers. To determine physical and chemical properties, samples are sent to institutions authorised by the MAFWM. Sampling procedure of PPP consignments, list of authorised testing institutions and test methods are given in the answer to question No. 6, point 2, Plant Protection Products and Residues thereof, Section I - General Information, Chapter 12.

Sampling procedures of PNPs consignments, list of authorised testing institutions and test methods are given in the answer to question No. 35 Fertilizers point a), subpoint 2.2. General inspectorate and subpoint 2.4. Authorized institutions

During inspection, phytosanitary inspectors:

- check whether PPPs and PNPs are authorised and accompanied by label and directions for use and whether the shelf life of plant protection product has been displayed;
- check the fulfilment of the requirements for wholesale, retail and import of PPPs and PNPs, with the purpose of entry of legal entities and entrepreneurs in the Register of Distributors and Importers of PPPs and PNPs;
- check the fulfilment of the requirements for placing on the market of PPPs and PNPs, packaging, labeling, sale and application use thereof;
- check documentation accompanying PPPs and PNPs on the market;
- check professional tasks and duties of authorised legal entities and business activities of service providers;
- take samples of plants, plant products and regulated objects, water and soil so as to inspect the prescribed use of PPPs and PNPs (e.g., crop damage, non-observance of the waiting period, etc.);
- temporary ban, until irregularities have been eliminated, market of PPPs and PNPs if legal entities and entrepreneurs have not been entered in the Register of Importers and Distributors of PPPs and PNPs, or if they fail to meet the prescribed requirements;
- check whether the use of plant protection products conforms to the approval, or directions for use and label following the principles of good agricultural practice, integrated plant and environmental protection;
- check whether plant protection products are used in a manner that does not endanger human and animal health (pollution of residential, business and other facilities for human and animal habitation as well as of water and soil);
- check whether residues of PPPs exceed the prescribed level. In case residues are higher than the maximum residue level, phytosanitary inspectors in charge of such plants, plant products and food order appropriate measures (destruction or otherwise prevent their use for human or animal consumption).

A phytosanitary inspector checks the fulfillment of the conditions for wholesale and retail sale and import of PPPs, for the purpose of registration of legal persons and entrepreneurs in the Register of distributors and importers of PPPs. The conditions subject to the checks performed by a phytosanitary inspector have been prescribed by the Rulebook on the conditions with respect to facilities, equipment and professional qualifications of personnel that must be met by a distributor and importer to be registered within the register of distributors and importers, as well as on the requirements with respect to facilities, equipment and professional qualifications of staff to be met by distributors for placing on the market particularly dangerous PPPs ("Official Gazette of RS, No. 80/10).

In cases of non-compliance with legal norms, phytosanitary inspectors impose administrative (Decisions imposing the measures, prohibiting production, placing on the market and use of PPPs and PNPs), in accordance with the law order appropriate measures in case that the official tests have established that residues of plant protection products in and on plants, plant products and food have exceeded maximum residue levels as well as other measures. Pursuant to identified irregularities, criminal charges, charges for economic offences and requests for initiating infringement proceedings are filed in court, depending on the status of control of operators as well as type of infringement (penalties).

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, food- and feed-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 contaminants, for food contact materials etc);**
- **management of crisis;**
- **the setting up of the Rapid Alert System for Food and Feed (RASFF)**

Signing the Memorandum of Understanding in 2002 Accreditation Body of Serbia (ATS) became an associate member of the European Co-operation for Accreditation – EA. In 2007 Memorandum of Understanding was replaced by the Contract on cooperation with the EA, in accordance with changes relating to possible statuses of EA members. ATS representatives participate in the work of the General Assembly, technical committees and working groups of this cooperation.

On 17 February 2009 the ATS became an associate member of the International Laboratory Accreditation Cooperation – ILAC.

The ATS has contracts on bilateral cooperation related to accreditation with following bodies in the region: Hungarian Accreditation Body, Accreditation Institute of Bosnia and Herzegovina, Accreditation Body of Montenegro, and Accreditation Institute of the FYR of Macedonia.

Accreditation Body of Serbia grants accreditation on the basis of:

- Law on Accreditation (Official Gazette RS, No. 73/2010),
- Decision on Establishment of the Accreditation Body of Serbia (Official Gazette RS, No. 96/2006),
- Statute of the Accreditation Body of Serbia,
- The standards SRPS ISO/IEC 17011, 17020, 17021, 17024, 17025, SRPS ISO 15189, SRPS EN 45011 containing requirements related to the operation of a national accreditation body and competence assessment of conformity assessment bodies,
- Rulebook on accreditation,
- Rulebook of procedure related to quality,
- Procedures, instructions and guidelines of the EA – European Cooperation for Accreditation and/or ILAC – International Laboratory Accreditation Cooperation and/or IAF – International Accreditation Forum,
- sectoral laws and regulations laying down accreditation process and compulsory conformity assessment.

1. Food Hygiene

Pursuant to the open competition conducted by the General Inspectorate, a List of laboratories for laboratory tests in the field of food and feed safety and implementation of monitoring programme in the field of food and feed safety, with which a contract was signed was published by the Ministry of Agriculture, Forestry and Water Management in the Official Gazette of RS, No. 91/09.

List of laboratories:

- Bureau of Public Health Vranje, Vranje
- Bureau of Public Health Leskovac, Leskovac
- Bureau of Public Health Zrenjanin, Zrenjanin
- Bureau of Public Health Šabac, Šabac
- Bureau of Public Health, Sremska Mitrovica
- Bureau of Public Health Pomoravlje, Čuprija
- Bureau of Public Health Užice, Užice,
- Bureau of Public Health Čačak, Čačak,
- Bureau for Health Protection Pirot, Pirot
- Bureau of Public Health Valjevo, Valjevo,
- Bureau of Public Health Požarevac, Požarevac
- Bureau of Public Health, Kraljevo
- Bureau of Public Health Timok, Zaječar

- Bureau for Health Protection Subotica, Subotica
- Bureau of Public Health Kruševac, Kruševac
- City Institute of Public Health, Belgrade
- Institute of Public Health Kragujevac, Kragujevac
- Institute of Public Health Niš, Niš
- Public Health Institute of Vojvodina, Novi Sad
- Institute of Occupational Medicine Dr Dragomir Karajović, Belgrade
- Public Health Institute Dr Milan Jovanović Batut, Belgrade
- Faculty of Veterinary Medicine, Belgrade
- Veterinary Specialist Institute Subotica, Subotica
- Veterinary Specialist Institute Kraljevo, Kraljevo
- Veterinary Specialist Institute Sombor, Sombor
- Veterinary Specialist Institute Niš, Niš
- Institute of Meat Hygiene and Technology, Belgrade
- Scientific Veterinary Institute of Serbia, Belgrade
- Scientific Veterinary Institute Novi Sad, Novi Sad
- Scientific Institute of Food Technology, Novi Sad
- Institute for Field and Vegetable Crops, Novi Sad
- Centre for Food Quality Research CIN, Belgrade
- Faculty of Science, Novi Sad
- SP Laboratorija, Bečej
- Jugoinspekt a.d., Belgrade
- Jugoinspekt d.o.o., Novi Sad
- A Bio tech lab, Sremska Kamenica
- Eko-lab d.o.o., Padinska Skela
- SGS Beograd d.o.o., Belgrade
- Alfa lab, Aleksandrovac
- Enology Station, Vršac
- Knjaz Miloš a.d., Aranđelovac
- Anahem, Belgrade
- Ekolab, Novi Sad
- Research and Development Institute Tamiš, Pančevo
- Centre for Viticulture and Enology, Niš

See Annex I, Test methods

SAMPLING METHODS FOR FOOD AND FEED
<ul style="list-style-type: none"> • Rulebook on sampling methods and methods for chemical and physical analyses used in quality control of fruits and vegetables (Official Journal of SFRY, No. 29/83), • Rulebook on sampling methods and methods for chemical and physical analyses of milk and dairy products (Official Journal of SFRY, No. 32/83), • Rulebook on sampling methods and methods for chemical and physical analyses of protein products for alimentary industry (Official Journal of SFRY, No. 41/85), • Rulebook on sampling methods and methods for chemical analysis of cocoa pods,

cocoa products, chocolate-like products, candy products, cream desserts, biscuits and biscuit-like products (Official Journal of SFRY, 41/87),
<ul style="list-style-type: none"> • Rulebook on test methods for eggs and egg products (Official Journal of SFRY, No. 72/87), • Rulebook on methods for physical and chemical analyses used in quality control of cereals, milling products, pasta and deep freeze dough (Official Journal of SFRY, No. 74/88), • Rulebook on sampling methods and methods for chemical and physical analyses used in quality control of vinegar and diluted acetic acid (Official Journal of SFRY, No. 26/89), • SRPS ISO 3100-1:1992 - Meat and meat products, part I: taking primary samples • Rulebook on sampling methods and methods for physical, chemical and microbiological analyses of feed (Official Journal of SFRY, No. 15/87),

With entry into force of the Rulebook on general and specific requirements for food hygiene in all stages of production, processing and circulation governing the microbiological criteria for foodstuffs, as of 1 June 2011 all food testing laboratories will apply test methods in accordance with the Regulation 2073/2005:

Microorganisms	Reference test method
Salmonella	EN ISO 6579
Enterobacteriaceae	ISO 21528-1 21528-2
Total count of aerobic bacteria (Enumeration)	EN ISO 4833
<i>E. coli</i>	EN ISO 16649-1 or EN ISO 16649-2
<i>Listeria monocytogenes</i>	EN ISO 11290-1 and EN ISO 11290-2
Coagulase – Positive staphylococcus	EN ISO 6888-1 or EN ISO 6888-2
<i>Staphylococcal enterotoxins</i>	European screening method CRL Milk
<i>Histamine</i>	HPLC

2. Veterinary control

Veterinary laboratory network in the Republic of Serbia comprises:

- Veterinary scientific and veterinary specialist institutes,
- Laboratories established as public institutions,
- Laboratories of the Faculty of Veterinary Medicine
- Private laboratories.

Legal basis for operation of veterinary scientific and veterinary specialist institutes and other laboratories included in the laboratory network is provided by Laws on Veterinary Medicine and Food Safety.

Law on Veterinary Medicine defines the tasks of veterinary and specialist institutes, confirms the continuity of state laboratories (institutes) the founder of which is the

Republic of Serbia, lays down the tasks and responsibilities of the reference laboratories and the requirements for operation of laboratories, obligation with respect to accreditation of laboratories against international laboratory standard ISO 17025 and lays down the authorisation procedure of laboratories.

The Law on Food Safety defines the tasks of reference and authorised laboratories and provides the legal basis for establishment and operation of food safety reference laboratories and testing of veterinary drug residues in food, i.e. provides a legal basis for the establishment of the Directorate for National Reference Laboratories.

Requirements for the operation of laboratories of both types - public and laboratories established by legal entity or natural person (private laboratories) - are laid down by law and relate to staff, equipment and tools that laboratories must meet, as well as the obligation of applying the accredited methods established by international and Serbian standards, i.e. all laboratories must be accredited against ISO 17025.

In this respect all laboratories must apply standard operating procedures (SOPs) and methods of microbiological diagnostic of infectious animal diseases, microbiological analyses of safety of foodstuffs of animal origin and feed prescribed by international and national standards, as well as methods recommended by the OIE and EU reference laboratories. These procedures include standard procedures for handling infectious agents and biosafety procedures for handling these agents in authorised laboratories.

In the Republic of Serbia accreditation is granted by the Accreditation Body of Serbia.

State laboratories

Veterinary scientific and veterinary specialist institutes: For the purpose of performing microbiological analyses and diagnostic of causative agents of infectious animal diseases (bacteriological, serological, virological, mycological and parasitological tests), determination of the cause of death of animals, investigation of the cause of animal abortion, pathoanatomical tests, microbiological and chemical analyses of feed and safety of food of animal origin, i.e. laboratory testing of veterinary and sanitary, health safety and quality of products and raw materials of animal origin, TSE testing, determining the presence of animal protein in feed, and determining bovine protein in feed, in accordance with the Law on Animal Health (Official Gazette RS, No. 37/91 and other laws) following veterinary scientific and veterinary specialist institutes have been established as public veterinary services or continued working as such:

- Scientific Veterinary Institute of Serbia, New Belgrade;
- Scientific Veterinary Institute Novi Sad, Novi Sad
- Veterinary Specialist Institute Kraljevo, Kraljevo;
- Veterinary Specialist Institute Šabac, Šabac;
- Veterinary Specialist Institute Zaječar, Zaječar;
- Veterinary Specialist Institute Niš, Niš;
- Veterinary Specialist Institute Požarevac, Požarevac;
- Veterinary Specialist Institute Subotica, Subotica;

- Veterinary Specialist Institute Pančevo, Pančevo;
- Veterinary Specialist Institute Zrenjanin, Zrenjanin;
- Veterinary Specialist Institute Sombor, Sombor;
- Veterinary Specialist Institute Jagodina, Jagodina.

These institutes are distributed per epizootic fields of the Republic of Serbia, and each institute is responsible for performance of the above mentioned tasks in the epizootic field it covers.

Apart from regular, routine laboratory diagnostic and testing, certain veterinary institutes are authorised as reference laboratories for certain laboratory tests, i.e. diagnostic of certain infectious diseases in accordance with the Law on Veterinary Medicine. Supervision over the work activities of institutes is carried out by the Ministry of Agriculture, Forestry and Water Management - Veterinary Directorate.

Republic of Serbia is the founder and owner of capital of the veterinary institutes. Institutes present the support of the veterinary service in the part relating to management of particularly dangerous infectious diseases by providing the immediate support to the veterinary inspection in the field, in terms of expertise and opinions, risk assessments as well as the immediate actions of the infectious disease management teams in the field: animal euthanasia, disinfection of facilities and similar. Apart from the above mentioned, institutes are directly involved in monitoring the trends of infectious animal diseases and zoonoses, drawing up studies, planning the implementation of the Programme of Measures for monitoring of infectious animal diseases in their respective epizootic fields as well as implementation of different projects in this field. An important segment of the work of these institutes is the activities relating to animal health issues in the field of infertility pathology of domestic animals.

Another important activity of the institutes is the pathoanatomical diagnostic in cases of animal deaths and diseases where it is necessary to perform post mortem examination and establish the cause of death.

Another important segment of the activities of these institutes is the laboratory testing in the field of food and feed safety.

Institute of Meat Hygiene and Technology: In the field of food safety in the Republic of Serbia, the Institute of Meat Hygiene and Technology is authorised as the reference laboratory for microbiological analyses of foodstuffs of animal origin and testing of residues of pharmacological, hormonal and other harmful substances in animals, products of animal origin and feed. This institute was established in 1955, and now it operates within the system of public services whose founder is the Government of the Republic of Serbia.

Laboratories of the Faculty of Veterinary Medicine: In the network of veterinary laboratories included are the laboratories of the Faculty of Veterinary Medicine which operate within it, namely: Pathomorphology Department – Laboratory for TSE/BSE

testing in the field of animal health, as well as Radiation Hygiene Department - Radiology Laboratory for testing food and feed radioactivity.

Priorities were set and a list of laboratories (institutes) to perform diagnostic and laboratory testing within the network of reference and authorised laboratories with clearly determined status of 100% state capital was defined. Equipping of the state laboratories was laid down accordingly.

Institute of Dairy Farming, Belgrade: Institute of Dairy Farming is an accredited state owned laboratory established for testing of milk and dairy products.

Private laboratories

Next to the state owned laboratories the founder of which is the Republic of Serbia, significant are the authorised private laboratories performing tests in the field of food safety.

In total, two laboratories are included: Centre for Food Quality Research – Belgrade and SP Laboratorija d.o.o. – Bečej.

In order for laboratories to perform laboratory testing for the purpose of official control, apart from compulsory accreditation they must be authorised for certain tests by the Ministry of Agriculture, Forestry and Water Management.

Reference laboratories

Authorised reference laboratories participate regularly in annual ring trials and proficiency testing schemes with the EU reference laboratories. All laboratories meet the accreditation requirements and are accredited against ISO 17025. In their work they apply standard ISO methods, methods recommended by the OIE defined in European regulations, i.e. recommended by the EU reference laboratories. Until full capacities of the Directorate for National Reference Laboratories and its position within the laboratory network are established, the existing system of authorised and reference laboratories provides the services of laboratory diagnostic to the line ministry in the field of animal health and food safety.

List of the reference and authorised laboratories comprising the network of veterinary laboratories in the Republic of Serbia

Laboratories within the system of animal health and testing of food and feed safety the founder of which is the Republic of Serbia

Authorised reference laboratories for highly contagious and particularly dangerous infectious diseases

1) Scientific Veterinary Institute of Serbia, New Belgrade: authorised reference laboratory for diagnostic of following infectious diseases:

- Foot and Mouth Disease;
- Swine vesicular disease;
- Blue tongue;
- Classical swine fever;
- African swine fever;
- African horse sickness;
- Infectious horse anemia;
- Horse influenza;
- Dourine;
- Glanders;
- Anaerobic infections;
- Aujeszky disease;
- Enzootic bovine leucosis;
- Fish diseases.

Institute also performs routine diagnostic testing of following infectious animal diseases:

- Tuberculosis;
- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Leptospirosis,
- Listeriosis,
- Rabies;
- BSE;
- other viral, bacterial and fungous diseases of domestic and wild animals.

2) Scientific Veterinary Institute Novi Sad, Novi Sad Authorised reference laboratory for diagnostic of following infectious diseases:

- Leptospirosis,
- Listeriosis,
- Atrophic rhinitis;
- Transmissible gastroenteritis of swine;
- Gumboro disease,
- IBR/IPV;
- Mycoplasma infections.

Institute also performs routine diagnostic testing of following infectious animal diseases:

- Classical swine fever;
- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Leptospirosis,
- Listeriosis,
- Other viral, bacterial and fungous diseases of domestic and wild animals;

3) Veterinary Specialist Institute Kraljevo, Kraljevo: authorised reference laboratory for diagnostic of following infectious diseases:

- Influenza avian;
- New Castle Disease;
- Q fever;

Institute also performs routine diagnostic testing of following infectious animal diseases:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Leptospirosis,
- Listeriosis,
- Other viral, bacterial and fungous diseases of domestic and wild animals;

4) Faculty of Veterinary Medicine Belgrade – Pathomorphology Department: authorised laboratory for reference testing of TSE/BSE;

Authorised laboratories for performance of routine laboratory testing and diagnostic of infectious diseases

1) Veterinary Specialist Institute Šabac, Šabac: authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Listeriosis,
- other viral, bacterial and fungous diseases of domestic and wild animals;

2) Veterinary Specialist Institute Zaječar, Zaječar - authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Other viral, bacterial and fungous diseases of domestic and wild animals.

3) Veterinary Specialist Institute Niš, Niš: authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Other viral, bacterial and fungous diseases of domestic and wild animals.

4) Veterinary Specialist Institute Požarevac, Požarevac: authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Other viral, bacterial and fungous diseases of domestic and wild animals.

5) Veterinary Specialist Institute Subotica, of the address Segedinski put 88, 24000 Subotica - authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Other viral, bacterial and fungous diseases of domestic and wild animals.

6) Veterinary Specialist Institute Pančevo, Pančevo: authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;

- E.coli;
- Pasterellosis;
- Other viral, bacterial and fungous diseases of domestic and wild animals.

7) Veterinary Specialist Institute Zrenjanin, Zrenjanin: authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Other viral, bacterial and fungous diseases of domestic and wild animals.

8) Veterinary Specialist Institute Sombor, Sombor: authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- other viral, bacterial and fungous diseases of domestic and wild animals.

9) Veterinary Specialist Institute Jagodina, Jagodina: authorised laboratory for routine testing of:

- Enzootic bovine leucosis;
- Brucellosis;
- Salmonellosis;
- E.coli;
- Pasterellosis;
- Other viral, bacterial and fungous diseases of domestic and wild animals.

Laboratories within the Food Safety System

Reference laboratories

Institute of Meat Hygiene and Technology, Belgrade: authorised laboratory for performing the tasks of the reference laboratory for testing safety of foodstuffs of animal origin and residues of pharmacological, hormonal and other harmful substances in animals, products of animal origin and feed.

Authorised laboratories for food and feed safety

Routine control of food safety and physical and chemical analyses of foodstuffs of animal origin is carried out by laboratories within the above mentioned veterinary and specialist institutes.

Apart from veterinary and specialist institutes, services of following public (state owned) institutes and private laboratories are used:

- Public Agricultural Service, Institute of Dairy Farming, Laboratories Department, of the address Autoput 3, New Belgrade, established by Government's Decision - testing of milk (state owned laboratory);
- Centre for Food Quality Research, Belgrade – testing of foodstuffs of animal origin;
- SP Laboratorija a.d., of the address Industrijska zona bb, Bečej - testing of foodstuffs of animal origin.

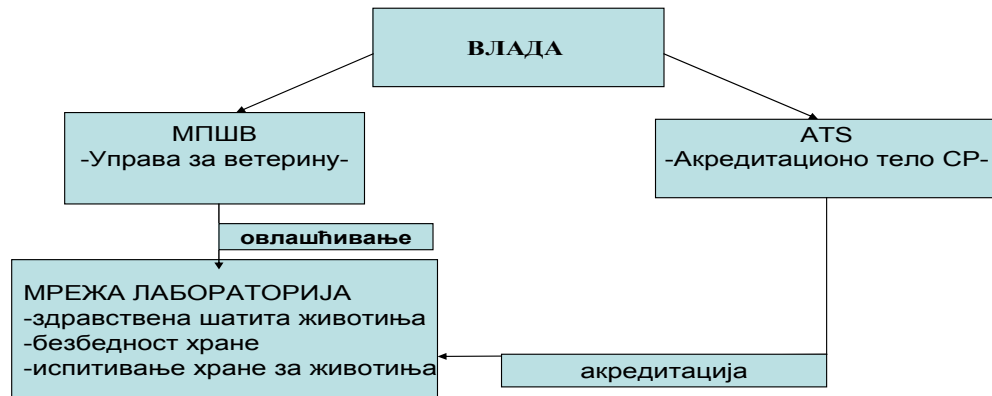
Status of the laboratories with respect to accreditation and introduction of ISO 17025

No.	NAME OF THE INSTITUTION	QMS 9001:2000	Animal Health	Food Safety	Feed Safety
1.	Scientific Veterinary Institute of Serbia, New Belgrade;	+	+	+	+
2.	Scientific Veterinary Institute Novi Sad, Novi Sad	+	+	+	+
3.	Veterinary Specialist Institute Kraljevo, Kraljevo;	+	+	+	+
4.	Veterinary Specialist Institute Šabac, Šabac;	+	+	+	+
5.	Veterinary Specialist Institute Zaječar, Zaječar;	+	+	+	+
6.	Veterinary Specialist Institute Niš, Niš;	+	+	+	+
7.	Veterinary Specialist Institute Požarevac, Požarevac;	+	+	+	+
8.	Veterinary Specialist Institute Subotica, Subotica;	+	+	+	+
9.	Veterinary Specialist Institute Pančevo, Pančevo;	+	+	+	+
10.	Veterinary Specialist Institute Zrenjanin, Zrenjanin;	+	+	+	+
11.	Veterinary Specialist	+	+	+	+

	Institute Sombor, Sombor;				
12.	Veterinary Specialist Institute Jagodina, Jagodina.	+	+	+	+
13.	Public Agricultural Service, Institute of Dairy Farming, New Belgrade;	+	+	+	+
14.	Institute of Meat Hygiene and Technology, Belgrade;	+		+	+
15.	Faculty of Veterinary Medicine – Laboratory for TSE/BSE		+		
16.	Faculty of Veterinary Medicine – Laboratory for radiation hygiene			+	+
17.	Centre for Food Quality Research d.o.o., Belgrade;	+		+	+
18.	SP Laboratorija a.d., Bečej	+		+	+

NETWORK OF LABORATORIES-legal basis and organizational structure

МРЕЖА ВЕТЕРИНАРСКИХ ЛАБОРАТОРИЈА-Законски основ и организациона структура



GOVERNMENT

**MAFWM -Veterinary Directorate-
accreditation**

**ATS – Accreditation Body of Serbia-
accreditation**

- animal health protection
- food safety
- testing of feed

3. Plant protection products and residues thereof

Following institutions are authorised by the MAFWM for testing of plant protection products (PPP) formulation for the purposes of authorisation (physical and chemical properties and efficacy) and inspection control (physical and chemical analyses):

Type of testing	Institution	Accreditation
Chemical and physical properties and efficacy of PPPs in agriculture	Institute for Pesticides and Environmental Protection, Zemun	SRPS/ISO/IEC 17025:2006 (ATS certificate)
	Institute for Field and Vegetable Crops, Novi Sad	<ul style="list-style-type: none"> – SRPS/ISO/IEC 17025:2006 (ATS certificate) – BS EN ISO 14001:2004 (BSI certificate) – ISO 9001:2000 (BSI certificate)
	Faculty of Agriculture, Department of phytomedicine and environmental protection Dr Pavle Vukasović, Novi Sad	SRPS/ISO/IEC 17025:2006 (ATS certificate)
	Faculty of Agriculture, Institute of phytomedicine, Zemun	Undergoing accreditation against SRPS/ISO/IEC 17025:2006
	Institute for plant protection and environment, Belgrade	
Chemical and physical properties	Zorka – Research Centre, Šabac	SRPS/ISO/IEC 17025:2006 (ATS certificate)
Efficacy (maize and soy bean)	Maize Institute Zemun Polje, Zemun	ISO 9001:2008 (TÜV certificate)
Efficacy of growth regulators using biotest methods	Institute of biological research Dr Siniša Stanković, Belgrade	-
Efficacy of PPPs in forestry	Faculty of Forestry, Belgrade	-
	Institute of Forestry, Belgrade	SRPS/ISO/IEC 17025:2006 (ATS certificate)
	Institute for lowland forestry and environment, Novi Sad	-

ATS – Accreditation Body of Serbia

BSI – The British Standard Institution
TÜV – TÜV Rheinland InterCert

Tasks and requirements for delegation of tasks are defined by the powers of MAFWM, in accordance with Article 51 of the Law on Plant Protection. However, since the Law on Plant Protection no longer applies in this part, in line with Article 87 of the new Law on Plant Protection Products, these institutions will perform tasks for which they were authorised until completion of the competition for performance of the tasks of public interest implemented in compliance with this Law.

Test methods for chemical and physical properties and efficacy of the plant protection products are defined by the Rulebook on pesticide testing methods (Official Journal of FRY, No. 63/2001 and 65/2001, Official Gazette of RS, No. 93/2005).

For testing of chemical and physical properties of the plant protection products CIPAC (Collaborative International Pesticides Analytical Council) or AOAC methods are applied, in line with the current Manual on development and use of FAO and WHO specifications for pesticides. In case that some other test methods have to be applied, detailed description thereof is provided in the test report.

The standards of the European and Mediterranean Plant Protection Organisation are applied for efficacy testing of plant protection products (Efficacy Evaluation of Plant Protection Products / PP1). Efficacy testing for which EPPO standards have not been laid down are carried out in analogy with these methods, by applying the methods in scientific work, and detailed description thereof is provided in the test report.

Sampling of the plant protection products for the purpose of testing chemical and physical properties thereof in the control procedure is defined by the Rulebook placing on the market, import and sampling of pesticides (Official Journal of FRY, No. 58/2001, Official Gazette of RS, No. 104/2005).

Individual original packagings are sampled, up to the defined quantity depending on the type of the formulation (e.g. liquid formulation - 0.5 litres, water soluble granules, water dispersible granules, microcapsules for suspensions, capsule suspensions – 0.1kg and similar), and per batches (up to three batches individual samples of each batch are taken – 4-10 batches individual samples of three randomly selected batches are taken etc.). If the original packaging is small, several packagings are sampled until prescribed quantity is reached, homogenisation by blending or agitating is compulsory if large packagings are in question.

Within the authorisation procedure of PPPs part of the tasks relating to the assessment of active substances and PPPs (toxicological profile, eco-toxicological profile, partly fate and behaviour in the environment, partly operator and consumer risk assessment) are performed by the institutions which were until 10 June 2009 conducting part of the active substances and PPP assessment in line with the authorisation of the Ministry of Environment and Spatial Planning, namely:

- Institute for Pesticides and Environmental Protection, Zemun,
- Institute of biological research Dr Siniša Stanković, Belgrade,
- Faculty of Agriculture, Institute of Phytomedicine, Zemun,
- School of Medicine, Belgrade,
- Medical Faculty, Novi Sad,
- Military Medical Academy, Belgrade,
- Faculty of Pharmacy, Belgrade

Pursuant to the public competition conducted under The Law on Food Safety, contract for tasks relating to PPP residue testing has been entered into with the following institutions: A Biotech, Sremska Kamenica; AOO 'Alfalab', Aleksandrovac; SP Laboratorija, Bečej; Anahem, Belgrade; Institute of Public Health Dr Milan Batut, Belgrade; Institute of Public Health, Niš; Bureau of Public Health Pomoravlje, Čuprija; Bureau of Public Health, Čačak. All of the above institutions are accredited against SRPS/ISO/IEC 17025:2006 (ATS certificate).

In all listed institutions special attention is paid to professional development of the employees related to the introduction of new methods and trainings on the use of the equipment. Policy of these institutions is professional development of the employees and raising the level of their competency. To that end, participation in workshops, scientific congresses and similar is enabled, and these institutions participate in a large number of domestic and international projects in different fields. Accreditation and participation in proficiency testing schemes represents their priority task.

Supervision over the operation of authorised institutions and contracted institutions is carried out by the MAFWM.

In the adoption procedure is the Rulebook on food sampling methods for determination of PPP residues in food and feed of plant and animal origin, fully aligned with the Commission Directive No. 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.

Until this regulation is adopted, phytosanitary inspectors of the General Inspectorate will take samples of food of plant origin for the purpose of testing PPP residues in accordance with the guideline adopted under the Project 'Pesticide residues in food of plant origin' funded by the Plant Protection Directorate in 2005 and 2006, which is in compliance with the Commission Directive No. 2002/63/EC.

4. Quality testing of agricultural plant seed

In accordance with Article 31 of the Law on Seeds, testing and determination of quality of agricultural plant seed is carried out by accredited laboratories. All laboratories (18) are accredited against SRPS/ISO/IEC 17025:2006 (ATS certificate), and two laboratories are accredited by the ISTA (International Seed Testing Association) (marked with *).

Institution	Type of testing
Maize Institute Zemun polje Zemun*	Chemical, physical and biological testing of seeds of field and vegetable crop varieties, seeds of grasses, flowers and medicinal plants and coated seed, sampling of seeds of agricultural plants
Institute for field and vegetable crops Novi Sad*	Testing of seeds of field and vegetable crops, medicinal plants, herbs, flowers, woody plants, shrubs, soy bean seed, maize seed and other
Institute Tamiš, Pančevo Laboratory Tamiš Agrolab Pančevo	Chemical, physical and sensory testing of soil, seed, nursery plants, planting material. Data on extension to scope of accreditation: chemical, physical and phytosanitary testing of agricultural plant seeds, sampling thereof
Ekolab d.o.o. Belgrade – Padinska Skela	Physical and biological testing of agricultural plant seeds, sampling thereof
PSS Sombor, Sombor	Physical, physical and chemical and biological testing of agricultural plant seeds, sampling thereof
PSS Kikinda, Kikinda	Physical, chemical and biological testing of agricultural plant seeds, sampling thereof
PSS Vrbas, Vrbas	
Agrolab d.o.o. Novi Sad	Physical, biological and biochemical testing of agricultural plant seeds, sampling thereof
Sirmium seme d.o.o. Sremska Mitrovica	
PSS Bačka Topola, Bačka Topola	
Jugoinspekt ad Belgrade	Physical, physical and chemical, biological and biochemical testing of agricultural plant seeds, sampling thereof
PSS Poljoprivredna stanica d.o.o., Novi Sad	
PSS Agrozavod DOO, Vršac Laboratory Agrozavod	
Agrolab DOO Subotica	
PSS Senta doo, LabS Senta	
PSS Zrenjanin d.o.o., Zrenjanin	
Institute for vegetable crops d.o.o. Smederevska Palanka	

PSS Sremska Mitrovica doo, Sremska Mitrovica	
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5. Plant health

In the field of plant health following laboratories have been authorised by the Plant Protection Directorate of the MAFWM to perform laboratory analyses for the presence of harmful organisms.

Routine laboratory analyses

<i>Routine laboratory analyses</i>	Authorised laboratories of agricultural extension services	Methods	Accreditation
Cereals, vegetables	AES Sombor	ELISA, PCR,IF	ISO 9001
Industrial crops	AES Sremska Mitrovica	ELISA, PCR,IF	ISO 9001
Grape vine, berries	AES Smederevo	ELISA, PCR,IF	in the procedure
Fruitc	AES Čačak	ELISA, PCR, IF	in the procedure
Potato, tomato, peppers	AES, Niš	ELISA, PCR,IF	ISO 9001

Expertise

Expertise	7 laboratories of the scientific institutes and faculties
<u>Mycology</u>	1. Institute of pomiculture and viticulture, Čačak: ISO 9001 2. Institute for Pesticides and Environmental Protection: ISO 9001, ISO 17025 3. Institute for Field and Vegetable Crops, Novi Sad: ISO 9001, ISO 17025 4. Faculty of Agriculture, Zemun
<u>Bacteriology</u>	1. Institute for Pesticides and Environmental Protection: ISO 9001, ISO 17025 2. Faculty of Agriculture, Zemun

<u>Viruses and phytoplasma</u>	1. Institute of pomiculture and viticulture, Čačak: ISO 9001 2. Institute for Pesticides and Environmental Protection: ISO 9001, ISO 17025 3. Institute for plant protection and environment, Belgrade: ISO 9001 4. Faculty of Agriculture, Zemun
<u>Entomology</u>	1. Institute for Pesticides and Environmental Protection: ISO 9001 2. Faculty of Agriculture, Novi Sad,
Nematology	1. Institute for plant protection and environment, Belgrade: ISO 9001 2. Faculty of Agriculture, Zemun 3. Institute Tamiš, Pančevo ISO 9001, ISO 17025

Methods

Expertise	Metode	Authorized laboratories of the scientific institutes and faculties
Fungi	<ul style="list-style-type: none"> ▪ Isolation ▪ Serological methods DAS-ELISA EBIA ▪ Molecular methods: PCR (conventional and nested) ▪ Sequencing 	<ul style="list-style-type: none"> • Institute for Pesticides and Environmental Protection: ISO 9001, ISO 17025 • Faculty of Agriculture, Zemun – in the procedure of accreditation
Bacteria	<ul style="list-style-type: none"> • Isolation on growth media • IF • PCR 	<ul style="list-style-type: none"> • Institute for Pesticides and Environmental Protection: ISO 9001, ISO 17025 • Faculty of Agriculture, Zemun – in the procedure of accreditation
<u>Viruses and phytoplasma</u>	<ul style="list-style-type: none"> ▪ BIOTEST - mech. inoculation test indicator plants ▪ Serological methods: DAS-ELISA EBIA ▪ Molecular methods: RT-PCR Sequencing 	<ul style="list-style-type: none"> • Institute of pomiculture and viticulture, Čačak: ISO 9001 • Institute for Pesticides and Environmental Protection: ISO 9001, ISO 17025 • Institute for plant protection and environment, Belgrade - in the procedure of accreditation

		<ul style="list-style-type: none"> • Faculty of Agriculture, Zemun - in the procedure of accreditation
Insects and mites	<ul style="list-style-type: none"> • visual inspection under appropriate magnification loupe • Berlezov funnel is used to extract the tiny insects from the bulk material • In addition to the manual extraction of individuals, sifting method according to De Lille is used, and to extract mites from leaves, brushing machine according to Henderson and McBurnieu is used. • determination to the species is done using appropriate morphological taxonomic keys, and if necessary in combination with molecular methods 	<ul style="list-style-type: none"> • Institute for plant protection and environment, Belgrade - in the procedure of accreditation • Faculty of Agriculture - Novi Sad
Nematodes	<ul style="list-style-type: none"> • To extract the moving form of nematodes decant method and sifting according to Kobb combined with Baerman funnel is used • To extract the cyst nematodes using the method of elutriation according to Fenwick 	<ul style="list-style-type: none"> • Institute for plant protection and environment, Belgrade - in the procedure of accreditation • Faculty of Agriculture Zemun - in the procedure of accreditation • Institute Tamiš, Pančevo ISO 9001, ISO 17025

	and flotation Souto • determination to the species is done using appropriate morphological taxonomic keys, and if necessary in combination with molecular methods	
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Tasks and requirements for delegation of tasks are defined by the powers of the MAFWM, in accordance with the Law on Plant Protection. However, since the Law on Plant Protection is repealed, in line with Article 105 of the new Law on Plant Health, these institutions will perform the tasks for which they were authorised until the competition for performance of tasks of public interest implemented in compliance with this Law is organised.

Sampling and methods for laboratory analyses are implemented in accordance with the EPPO standards, other diagnostic standards (ISTA) and Annexes of the EU Directives related to ring rot and brown rot of potato.

For GMO laboratories please see the answer in Section VII, question 34.

- management of crisis;

Food safety

The Law on Food Safety (Article 7, Precautionary principle) defines the obligation of the competent authorities to apply provisional risk management measures until new scientific information required for clarification of scientific dilemmas and implementation of a comprehensive risk assessment are obtained where, upon the assessment of available information, a possibility of a harmful effect of the food and feed on human and animal health is ascertained, but there are scientific dilemmas as to provision of the highest possible level of health protection.

The Law on Food Safety (Article 9, Principle of transparency) defines the obligation of the competent authorities, if there is a threat that certain food or feed may pose a risk to human or animal health, to notify immediately the general public of the type of food or feed, risk posed by it, as well as the measures being applied or to be applied towards preventing, abating or eliminating the risk.

Risk management in the field of food and feed safety and ABPs is carried out by competent authorities through undertaking measures, and implementing supervision and control. Measures undertaken, supervision and control must be timely and appropriate for

the ascertained or expected threat (physical, microbiological, chemical and radioactive contamination).

Once it is ascertained that food or feed pose a serious risk to human health, animal health or the environment, and that the risk can not be eliminated in a satisfactory way, depending on the gravity of the situation, the competent authority (General Inspectorate or Veterinary Directorate) shall take one or more measures.

If the food or feed is of domestic origin, following emergency measures may be undertaken:

- temporary prohibition of the circulation or use of food or feed;
- specifying special requirements for handling of the mentioned food or feed.

If the food or feed is imported, following emergency measures may be undertaken:

- temporary prohibition of import of food or feed from the country of export or a part thereof or the country of transit;
- specifying special requirements for handling the food or feed from the country of export or a part thereof or the country of transit.

The Law on Food Safety (Articles 42 and 43) stipulates the adoption of the Crisis Management Programme and crisis management plan in the field of food and feed safety in the event of direct or indirect risks to human health, animal health or the environment, the causes of which are the food or feed and the occurrence of which could not be foreseen, prevented, eliminated or abated to the acceptable level.

Programme is adopted by the Government, and it governs precisely:

- Type of situation in which direct or indirect risk to the human health caused by food or feed exists;
- Measures that have to be implemented without delay once it is established that food or feed is posing a serious threat to humans or animals, either directly or indirectly through the environment;
- Crisis management procedures which include the principle of transparency and communication;
- Plan of exercises and simulations for crisis management purposes.

Pursuant to the Programme, the Minister of Agriculture shall adopt, with the consent of the minister responsible for public health, a special crisis management plan depending on the types of risks and shall form a crisis team to implement the special plan.

Veterinary field

Risk management in the veterinary field is carried out by the competent authority through undertaking measures, implementing supervision and control. Measures undertaken, supervision and control must be timely and appropriate for the ascertained or expected threat (animal disease, natural disasters).

Law on Veterinary Medicine (Articles 63 and 64) stipulates that once the presence of an infectious disease in the Republic of Serbia is ascertained, and as long as it poses a threat, the MAFWM shall order restriction or prohibition of the circulation of animals and in accordance with the nature of the infectious disease and the level of threat, shall lay down boundaries of the infected field and field at risk, as well as measures to be undertaken in these fields.

Law on Veterinary Medicine (Articles 51 and 52) stipulates that for the purpose of preventing the outbreak, preventing the spread and eradication of infectious diseases the MAFWM shall adopt programmes for certain infectious diseases.

Republic of Serbia has a Plan for eradication of highly pathogenic avian influenza. Contingency plans for certain infectious diseases have not been devised in line with the EU requirements.

Measures undertaken when crisis is coming from outside Serbian territory:

- Temporary prohibition of the import of animals from the country of export or a part thereof or country of transit
- Laying down special measures for animals from the country of export or a part thereof or country of transit
- Laying down measures for safe disposal of animals
- Other appropriate provisional measures.

In case of a justified threat from infectious diseases to be introduced through imported animals, the MAFWM issues an order by which one or more of the above mentioned measures are ordered.

Phytosanitary field

Risk management in the field of plant health is carried out by the competent authority (Plant Protection Directorate and General Inspectorate) by undertaking measures, implementing supervision and control. Measures undertaken, supervision and control must be timely and appropriate for the ascertained or expected threat.

Programme of measures and guidelines for implementation thereof stipulate that in case of any doubt as to the presence of quarantine harmful organisms, phytosanitary inspectors of the General Inspectorate must be notified without delay. Phytosanitary inspector takes and sends the sample marked URGENT for laboratory analysis and orders adequate preventive phytosanitary measures. In the annex to the Guidelines to all holders of public authorisations, contact details are provided of all phytosanitary inspectors in the territory of the Republic of Serbia, as well as of the head of the Phytosanitary Inspection Division and the head of the Section for plant health and plant quarantine, along with contact persons and phone numbers of the authorised laboratories.

Law on Plant Health stipulates specific programmes for protection of plant health to be adopted in case emergency phytosanitary measures are implemented.

Plant Protection Directorate of the MAFWM has Contingency plans for certain harmful organisms, namely:

- Contingency plan for prevention of spread and control with a view to eradication of the potato ring rot;
- Contingency plan for prevention of spread and control with a view to eradication of the potato brown rot and bacterial wilt of potato and tomato;

For each concrete case, a working group for emergency interventions is formed, made up of representatives from the Plant Protection Directorate, General Inspectorate, Phytosanitary Laboratory, Directorate for National Reference Laboratories and authorized laboratories, and a contingency plan with implementing measures is established.

In case of genuine danger from the introduction of harmful organisms through imports the MAFWM can give an order through which one or more phytosanitary measures are taken:

- Temporary prohibition of the import of plants from the country of export or a part thereof or country of transit
- Laying down special measures for plants from the country of export or a part thereof or country of transit
- Other appropriate provisional measures.

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

Pursuant to The Law on Food Safety (Articles 38 to 41), the Ministry of Agriculture, Forestry and Water Management shall establish and manage the Rapid Communication and Alert System for Food and Feed (RASFF). National RASFF shall communicate any information of a serious risk to human health caused by food or feed at both national and international levels.

Apart from the MAFWM, RASFF shall also include: Ministry of Health, Expert Council for Food Safety, Directorate for National Reference Laboratories as well as laboratories authorised for testing of food safety.

The establishment of a National Contact Point, organisational structure and communication procedures of the RASFF is ongoing.

II. VETERINARY POLICY

General

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

The Law on Veterinary Matters (Official Gazette of the RS 91/2005 and 30/2010) regulates the protection and improvement of animal health and welfare, specifies contagious or infectious animal diseases and measures for the prevention of occurrence, detection, prevention of spread, suppression and eradication of contagious or infectious animal diseases and animal diseases that can be transmitted to humans, veterinary-sanitary control and requirements for production and marketing of animals, animal products, food of animal origin, feed and requirements for carrying out veterinary activities.

(Article 1)

Veterinary activity, in terms of this Law, includes:

- 1) monitoring, protection and improvement of animal health;
- 2) protection of animals against contagious or infectious and other diseases;
- 3) detection and diagnostics of diseases and treatment of sick animals;
- 4) implementation of the animal health protection measures;
- 5) protection of people against zoonoses;
- 6) control of safety of food of animal origin and animal products at the place of breeding, production and marketing of animal products, food of animal origin and feed;
- 7) marking of animals to control their movements and provision of monitoring animals, animal products and food of animal origin in their production and marketing;
- 8) water quality control to provide its health correctness to water animal;
- 9) control of breeding animal health and their reproductive aptitudes and implementation of the measures for the treatment of sterility and artificial insemination;
- 10) protection of the environment against pollution with contagious or infectious animal disease causes;
- 11) protection of animal from torturing and suffering and caring for animal welfare;
- 12) control in the production and marketing of veterinary medications and medicinal devices for use in veterinary medicine;
- 13) disinfection, disinsection, deratisation, deodorisation and decontamination activities;
- 14) veterinary education and information.

Veterinary activity can be performed by a legal entity registered as:

1. veterinary health centre
2. veterinary station
3. veterinary clinic
4. veterinary pharmacy
5. centre for animal reproduction and artificial insemination
6. centres for storage and distribution of semen for artificial insemination

7. laboratory

Legal entities and entrepreneurs meeting requirements with regard to expert personnel, facilities (establishment) with technically appropriate equipment can be entered in the register.

Apart from the above stated, veterinary activity can be performed by a veterinary-specialized institute, veterinary institute, and national reference laboratory for particularly serious contagious or infectious diseases on OIE and reference laboratory lists. Higher education institutes and higher education units deal with education of veterinarians.

The Veterinary Chamber was established to provide the protection and improvement of expertise, sustain professional ethics, raising the level of animal health protection, and the protection of professional interests of veterinary medicine doctors and graduate veterinarians and to achieve other objectives.

Supervision of the implementation of the Law is conducted by veterinary inspectors and border veterinary inspectors.

While conducting their inspection tasks, veterinary inspectors are entitled and responsible for the following: to check whether the owners and keepers of animals apply the prescribed measures in accordance with the Law, whether veterinary organisations are entered in the Register of legal entities for conducting veterinary activity; whether veterinary service within a business entity or other legal entity operating in the field of stock holding and livestock production meets the requirements in accordance with the Law, whether the working hours were provided by the operators performing veterinary activity in emergency situations and other urgent veterinary assistance and services; implementation of animal health protection measures by legal entities and owners and keepers of animals; implementation of special animal health protection programmes; whether there is HACCP programme; meeting veterinary-sanitary requirements in registered and approved establishments; entry of registered and approved establishments in the Register of establishments and in the Register of export establishments; registration of agricultural holdings and identifying animals and keeping records of animals in accordance with the provisions of this Law, and keeping records of buying and selling animals, notifying the change of location for the purpose of entering in and withdrawing from the Central Database; to monitor the work of approved veterinary station or health centre and veterinary service in the animal identifying procedure and keeping records of identified animals; production and marketing of animals, animal products, food of animal origin, feed and animal waste; issuing health certificates for animals and keeping records of the issued certificates; technical and hygienic requirements of means of transport where animals and animal products and animal waste are transported, and veterinary-sanitary requirements of facilities where loading, reloading and unloading of animals are carried out during transportation; whether quarantines satisfy requirements laid down in this Law; whether the veterinary-sanitary control of wild games after being caught or shot is conducted; animal health condition, safety of food of animal origin for human consumption and health-hygienic and quality correctness of food of animal origin and

feed; manner of keeping, storing and professional use of disinfection, disinsection and deratisation agents; whether veterinary-sanitary controls are carried out in establishments for collection, processing and disposal of carcasses and other waste; whether harmless disposal and transport of waste are performed from production place to establishments for collection, processing and disposal; keeping proper documentation in accordance with this Law; raw materials and production-technology process for products intended for export, in conformity with special requirements of importing countries; calculation of the fees for the performed veterinary-sanitary checks of consignments in the production process and marketing; application of measures in conformity with this Law. (Article 146) While performing the tasks referred to in Article 146 of the Law, veterinary inspector is responsible and entitled to: give orders for measures related to the prevention, suppression and eradication of contagious or infectious, parasitic diseases of breeding animals in a suspected or contaminated yard; give orders for the temporary suspension of building or reconstruction of establishment or the temporary suspension of use of the establishment that was not built and reconstructed in accordance with the veterinary-sanitary requirements and to determine the measures and time limit for works and establishment to be adjusted in accordance with these requirements; prohibit the production and marketing of animals, animal products, food of animal origin and animal waste that can transmit animal contagious or infectious diseases and endanger human health; give orders to take away such animals, slaughter or kill animals that are in circulation, to destroy animal products, food of animal origin, feed and animal waste that are in the production process and circulation or to give orders to use them for other purposes; give orders for remedying defects or imposing temporary ban on using facilities, equipment and establishment and may prohibit performing practice in the registered and approved establishments until certain defects are remedied; give orders for other measures and undertaking other actions in accordance with law.

A veterinary station meeting requirements provided by law may carry out certain professional activities of veterinary inspection as follows: veterinary-sanitary examination of animals, animal products, food of animal origin and feed in the internal trade; veterinary-sanitary examination of animals intended for slaughter, meat and animal products before placing on the market; veterinary-sanitary examination of means of transport that are used for transportation of animals, animal products, food of animal origin, feed and animal waste in the internal trade; issuing certificates of agricultural holding status that are free from certain contagious or infectious disease.

A veterinary station can not perform these professional activities for their own animals, animal products, food of animal origins, feed and animal waste, and for their own means of transport.

A person carrying out professional activities of veterinary inspection must have a licence issued by the Ministry.

While performing veterinary supervision, a border veterinary inspector is responsible and entitled to: conduct veterinary-sanitary control over consignments at import, transit and export of animals, animal products, food of animal origin, feed, medications and

medicinal devices for use in veterinary medicine, animal waste and accompanying things; carry out examinations of consignments of animals, animal products, food of animal origin, feed, waste and accompanying things that are imported to determine their health condition; conduct control on international veterinary certificates of health condition of consignments that are imported; take samples from consignments of animal products, food of animal origin and feed, with no fees charged, for testing of their veterinary-sanitary correctness. (Article 150)

While performing the tasks referred to in Article 150 of the Law, border veterinary inspector is responsible and entitled to: prohibit import, export or transit of consignments of animals, animal products, food of animal origin, feed and animal waste if each consignment is not in conformity with current requirements, if during the check it is determined that a consignment is contaminated, suspicious or if it originates from contaminated area or if he finds out that a consignment is not accompanied by the international veterinary certificate of its health condition; permit import, export or transit of consignments of animals, animal products, food of animal origin, feed, medications and medicinal devices for use in veterinary medicine, waste and accompanying things; temporarily prohibit the import, export or transit of consignments of animals, animal products, food of animal origin, feed, medications and medicinal devices for use in veterinary medicine, animal waste and accompanying things if defects on the consignment or accompanying document have to be remedied; give orders related to storing consignments of animals, animal products, food of animal origin, feed and animal products in case the health condition of consignment should be tested; take away or destroy animal products from the person crossing country border, if such measure is foreseen by special regulations; order undertaking animal protection measures in accordance with this Law and obligations under international agreements on animal health protection.

Chapter 5 of the Law on Food Safety defines the general food safety requirements (bans, requirements for determining safety, measures and restrictions and prohibition of food). In Article 27 of this Law, the procedure for implementing measures and restrictions and prohibition of food when there are reasonable grounds for suspecting that food is unsafe are laid down, and they shall be implemented by the Ministry of Agriculture, Forestry and Water Management (MAFWM) and the ministry responsible for public health. According to Article 11, the central competent authority is MAFWM, and the Ministry of Health is responsible for carrying out the supervision in accordance with Article 12 of the same Law. In the case of hazard identification associated with the occurrence of disease caused by food, both Ministries shall carry out supervision and interactively exchange information on the occurrence and measures that have been taken.

8. Please provide information on respective fields of responsibility of competent authorities concerned, in particular regarding rules on control.

In accordance with the Law on Veterinary Matters, Law on Ministries and Rules on Internal Organisation and Systematisation of Jobs in MAFWM of November 2010, the powers of official veterinary services in the Veterinary Directorate were specified.

The manner of conducting veterinary - sanitary controls and powers of veterinary inspectors are shown in Section XVI of the Law on Veterinary Matters. The Programme of monitoring of residues in animals and products of animal origin is shown in Article 83 of the Law on Veterinary Matters, and the Programme of good manufacturing and hygiene practice and HACCP principles are prescribed by Article 82 of the Law on Veterinary Matters and in Articles 47 - 54 of the Law on Food Safety, with the obligatory implementation as of 1st January 2009. Food business operators are responsible for the implementation of these programmes and they are responsible to ensure that, in all stages of production, processing and distribution of food that are under their control, requirements with regard to food and feed hygiene are met according to the Law on Food Safety, Law on Veterinary Matters and other administrative provisions regulating this field.

In accordance with the Law on Veterinary Matters, establishments can not be approved or registered if do not apply measures proscribed by these laws. All establishments registered and approved by the Veterinary Directorate must be entered in the Register of approved and registered establishments. At approval procedure, these establishments are assigned veterinary control number if they are approved for the internal marketing and export control number if they are approved for export purposes. These numbers are constituent part of a stamp for meat and identification mark on food and products of animal origin in accordance with the regulations of the Republic of Serbia, and in this way traceability in food chain is provided. According to the animal identification and marking system in R. Serbia, all domestic animals are marked in a proper manner and entered in the Central Database that is maintained by the Ministry (Art. 84 to 86 of the Law on Veterinary Matters, and the documents accompanying animals in trade are prescribed by Art. 87 to 97).

Veterinary-sanitary control conducted by veterinary inspectors at local level in R. Serbia is conducted in registered and approved establishments and depending on the type of establishment (permanent, periodical). Veterinary inspectors carry out verification of compliance with these programmes, and certified organisations and food business operators are responsible for introduction of these programmes.

9. 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.

See **the list of regulations adopted by the Veterinary Directorate**, Annex II

With regard to the Veterinary Directorate planned regulations, the following are shown:

- The list of planned regulations in the field of feed safety is shown in Chapter V of this Section. Special rules regarding feed hygiene are described in the answer to question 26;
- The list of planned regulations in the field of food safety is shown in Chapter IV in the answer to question 22;
- The list of planned regulations in the field of food and by-products of animal origin is shown in Chapter III in the answer to question 13;

10. Please provide information for each item listed below:

Control system in the internal market:

- **live animals; semen, ova and embryos;**
- **products of animal origin;**

Measures for animal and human health protection against diseases that can be transmitted from animals to people are prescribed by the Law on Veterinary Matters (Official Gazette of RS 91/2005 and 30/2010) and they are as follows:

- prevention of contagious or infectious animal disease occurrence;
- long-term strategy for animal health protection;
- Programme of measures for animal health protection;
- special programmes for animal health protection;
- the manner of delegating jobs from the Programme of measures for animal health protection;
- contracts on carrying out tasks of public interest;
- responsibilities of animal owners and keepers with regard to implementation of the Programme of measures for animal health protection;
- vaccination of dogs and cats against rabies;
- veterinary medication and medicinal devices for use in veterinary medicine required for implementation of the Programme of Measures;
- compulsorily notifiable contagious or infectious diseases;
- implementing measures for prevention of contagious or infectious disease occurrence;
- early disease detection and diagnostics;
- procedure in case of suspicion of contagious or infectious disease;
- contagious or infectious disease diagnostics;
- measures for the prevention of spread, suppression and eradication of contagious or infectious diseases;
- emergency veterinary-sanitary measures;
- compensation and the amount of compensation.

Procedures for approving and registering establishments and facilities for animal keeping, slaughtering, for food production and marketing, production and marketing of products of animal origin, feed, for collecting, processing and destroying animal by-products are defined in Articles 72 - 80 of the Law on Veterinary Matters.

Mandatory application of the HACCP programme in establishments is prescribed in Article 82 of the Law on Veterinary Matters and in Articles 47 - 54 of the Law on Food Safety, as well as the obligation to notify every change of activities they are performing. The Programme of monitoring residues in animals and products of animal origin is prescribed in Article 83 of the Law on Veterinary Matters, and for residues in food and feed in Article 69 of the Food Safety Law.

The Law on Veterinary Matters governs domains of veterinary activities, and they are:

- animal breeding, keeping and marketing (identifying and recording animals and maintaining the central database for animals and holdings, animal passports, official controls of animal identification and registration, marketing of animal, quarantine, permit for gathering animals) (Articles 84 - 100);
- animal slaughter, official control before and after animal slaughter and slaughterhouse record keeping (Articles 101 - 104);
- production and marketing of food of animal origin (official control on food of animal origin, food of animal origin that are not safe for human consumption, production and marketing of milk and milk products (Articles 105 - 108);
- products of animal origin for use in agriculture, industry, pharmacology or surgery - marketing of animal skins (Article 109);
- production and marketing of feed and establishments for feed production (Articles 110 - 112);
- production, storage, marketing and use of reproductive materials (monitoring health and reproductive aptitudes of animals intended for reproduction, and suspicion or detection of contagious or infectious diseases of animals intended for reproduction, and marketing of reproductive materials) (Article 112); production of disinfection, disinsection and deratisation agents (Article 116);
- collection, processing and destruction of carcasses and other animal waste (Articles 117 - 119);
- management of waste arising from veterinary organisations and establishments where veterinary activities are carried out (Article 119a);
- pharmaceutical waste management (Article 119b).

Veterinary-sanitary checks in the fields of veterinary medicine and food safety are carried out pursuant to the Law on Veterinary Matters, Law on Animal Welfare, Law on Medicines and Medicinal Devices, Food Safety Law and other accompanying regulations that closer regulate particular fields. Controls on standard implementation and food quality are performed in accordance with regulations governing this field.

By implementing these laws and by-laws that specify general and specific food hygiene requirements, the traceability principle is observed presenting the whole production process monitored from holding-to-table, i.e. from primary production through processing factories, conditions and storages up to wholesale and retail.

In other words, the Central Register was established, i.e. the central database for recording all places for animal keeping and breeding was created and animal identification was performed; as regards establishments for production of food of animal

origin and composite food products, they are registered and approved by the Veterinary Directorate and they are assigned veterinary control numbers. All food products are marked with an identification stamp, and the identification mark with the stated veterinary control number must be included in declaration. Live animals can be placed on the market only if they are marked and if they originate from establishments and holdings registered in the Central Database. Animals in trade must be accompanied by a health certificate issued by the veterinary service contracted by the Ministry of Agriculture, Forestry and Water Management on implementation of the Programme of Measures, issued on the basis of evidence of implemented preventive actions and conducted diagnostic tests. Animals in trade must be accompanied by appropriate identification documents, and animals leaving epizootic unit must be accompanied by health certificates of consignments in trade. The health certificate can be issued only if in the animal's place of origin no contagious or infectious disease communicable by that animal species is detected, and the health certificate of consignment in trade can be issued only if the veterinary-sanitary checks have been carried out in the place of loading, meaning that the means of transport are to be checked and all animal health and welfare requirements to be met. The health certificate presents information in the food chain and contains all data related to feeding, treatment and withdrawal time reported and signed by the animal holder and keeper in one part of the certificate; the other part of the certificate contains information about the diagnostic examination in accordance with the national Programme of Measures, treatment and withdrawal time and is signed by the veterinarian. All these documents that are required to accompany animals in trade are issued by the approved veterinary station, veterinary health centre or veterinary service which was delegated to carry out tasks of public interest. Tasks of public interest for which veterinary organisations are approved are assigned by a tender. The veterinary inspection is responsible for monitoring the work of approved veterinary organizations.

- Certification

In accordance with the amendments to the Law on Veterinary Matters, animal passports are issued as identification documents only for identified animals that shall accompany bovine, ovine, caprine and porcine animals, equidae, dogs, cats and as necessary other animals from their birth to death. For imported animals, a new passport is issued within 14 days of data entry in the Central Database. Animals in circulation are accompanied by animal health certificates that guarantee implementation of the measures prescribed by the Programme of measures for animal health protection. Passports are issued by approved veterinary organizations implementing this Programme. For marketing animals, health certificates of consignments are issued. In accordance with this Law, these certificates can be issued by the competent veterinary inspector or official veterinarian.

- Mutual assistance

See the first indent of question 10 in this Chapter.

- Safeguard measures

See question 10 in this Chapter under: **Animal disease control measures**

- Computer system (TRACES)

Available information systems

At present,

the Veterinary Directorate information system consists of:

- Central Database for bovine animals (data containing details of registered bovine animals, registered holdings and details of monitoring their movements);
- VetUp, databases of registered veterinarians, veterinary stations and veterinary health centres, with data on geo-competence for tasks carried out under the Contract with regard to carrying out tasks of the Programme of animal health protection measures; data related to the register containing details of identified and vaccinated dogs; data on registered and vaccinated porcine animals against classical swine fever; data related to the number of vaccinated animals and data related to notifying and monitoring contagious or infectious animal diseases that are compulsorily notifiable.

AIMCS (Animal Identification and Movement Control System) application includes possibilities for registering animals, searching animals, recording animal movements from and to holdings, recording movements on to pastures, issuing passports, searching passports, recording animal slaughter and searching their current movements, and management of eartags for bovine animal identification.

The system prevents wrong data entry by applying the rules for checking incoming data.

This application can show data on an animal, data on a passport, history of registration and movements, history of data entry and data on animal parents and descendants.

There is also a possibility of calculating fee amounts with regard to providing services in animal identification and registration by official veterinarians.

The system enables generating and printing certificates of implemented programme measures on bovine animals for each holding separately and for each populated place. While generating these certificates, each certificate is assigned its number from the system and it is further used for entering the same in the application.

Ordering of eartags duplicates is done through the database, enabling significantly better control of this process and reducing possibilities of abuse.

Integration of the existing information system and LIMS (Laboratory Information Management System) is planned, and thus the Rapid Alert System application in the animal health protection would start operating.

New applications relating to the registration and identification of equidae, and to beekeepers associations are being prepared.

Applications for monitoring movements of ovine, caprine and porcine animals, and for the system risk analysis and on the spot controls are being upgraded.

Data entry in the Vet up base on all registered and approved establishments for production and marketing of food, feed and by-products of animal origin is under the introduction and preparation process.

The next phase (depending on availability of funds) is the Programme for entering data on official controls carried out by the veterinary inspection, with findings and risk analysis programme, which will serve as a base for preparing the annual plan of official controls (by establishments and risks and by type of official controls).

- Funding of checks

The costs of analysis and super analysis of all samples shall be borne by the party from which the sample was taken if it is found in the final procedure that it does not conform with the prescribed properties.

For performed veterinary-sanitary checks on animals, raw materials and products of animal origin in slaughterhouses and establishments for production, applicants shall pay fees pursuant to the Decision on the fee rates for performed veterinary-sanitary checks on animals, animal products, raw materials and animal waste in production and marketing (Official Gazette of RS No 69/2001) amounting to:

in animal slaughter plants:

- for equidae and ungulates before slaughter, and for meat and offal meat after slaughter: 1% of the animal value;
- for poultry and rabbits before slaughter, and for meat and offal meat after slaughter: 1.2%;
- for meat products made from ungulates and equidae meat, from poultry and rabbit meat and wild game meat: 0.6% of the product value per 1 kg;

in the plants for cutting meat of ungulates, equidae, poultry and rabbits:

- for ungulate and equine meat: 0.6% of the value per 1 kg;
- for poultry and rabbit meat: 0.6% of the value per 1 kg;

in the plants for treating and cutting of wild game meat:

- for wild game meat and offal: 0.6% of the value per 1 kg;

in the plants for meat processing and manufacturing of meat products of ungulates, equidae, poultry and wild game:

- for raw materials of animal origin: 0.2% of the value per 1 kg;
- for meat products of equidae and ungulates: 0.6% of the value per 1 kg;
- for meat products of poultry and wild game: 0.6% of the value per 1 kg;

in the plants for treating, processing and manufacturing of milk products:

- for raw and pasteurized milk: 0.03% of the value of raw milk per 1 l; - for milk products: 0.02% of the value per 1 l / 1 kg; in the plants for the egg preparation and processing:

- for eggs: 0.025% of the value per piece;
- for egg products: 0.03% of the value per 1 kg;

in the plants for cutting and processing of fish meat:

- for freshwater and saltwater fish: 0.06% of the value per 1 kg;

- for fishery products: 0.03% of the value per 1 kg;
- in the plants for cutting and processing of crustaceans, shells, snails and frogs:
 - for live crustaceans, shells, snails and frogs: 0.06% of the value per 1 kg;
 - for crustacean, shell, snail and frog products: 0.03% of the value per 1 kg;
- in the plants for treating, processing and storage of honey:
 - for honey and other bees' products: 0.3% of the value per 1 kg;
 - for remedies made from honey and other bees products: 0.2% of the value per 1 kg;
- in the plants for treating, finishing, processing and storage of ungulate and equidae intestines:
 - for untreated intestines: 0.03% of the value per 1 kg;
 - for treated intestines: 0.06% of the value per 1 kg;
- in the plants for production of sausage wrapping made from animal raw materials:
 - for raw materials of animal origin: 0.03% of the value per 1 kg;
 - for wrapping made from animal raw materials: 0.06% of the value per 1 kg;
- in the plants for cheese rennet production:
 - for raw materials of animal origin: 0.03% of the value per 1 kg;
 - for cheese rennet: 0.06% of the value per 1 l;

Article No 3 of this Decision is repealed (it refers to paying fees for performed veterinary-sanitary checks at loading, reloading and unloading of consignments), since it is being harmonized with the Amendments to the Law of Veterinary Medicine (that provision of the Law - Article 95 is repealed).

The manner of charging fees for performed checks will be completely modified when the Rulebook on the manner of carrying out official controls enters into force (harmonization with Regulation (EC) No 882/2004).

Funds for implementation of the animal health protection measures shall be provided from:

- 1) animal health certificate fees;
- 2) fees for checks performed at loading consignment of animals out of epizootiologic units;
- 3) fees for performed veterinary-sanitary checks on facilities with regard to general and specific food and feed hygiene requirements;
- 4) fees for performed veterinary-sanitary checks on food of animal origin, feed of animal origin, feed and by-products of animal origin in production and marketing;
- 5) fees for identification, registration and monitoring of animal movements;
- 6) fees for identification and recording of dogs and recording cats;
- 7) fees for performed veterinary-sanitary checks on consignments in international circulation.

Funds for the prevention, suppression and eradication of contagious or infectious diseases shall be provided in the budget of the Republic of Serbia;

Funds accrued from the fees referred to in this Article (1) shall be revenue of the budget of the Republic of Serbia and shall be used for implementation of animal health protection measures, and 50% of the funds accrued from the fees referred to in points 1), 2), 4), 5) and 6) shall be used for implementation of animal health protection measures through approved veterinary stations. The fee rates shall be specified by the Government.

These funds shall be used for implementation of animal health protection measures.

Allocation of funds provided in the budget of the Republic of Serbia shall be specified by the Ministry in accordance with the Programme of measures and special programmes.

Applicants shall bear the costs of administrative procedure for the following:

- issuance of decision certifying that veterinary-sanitary requirements are met and determination of general and specific food and feed hygiene conditions;
- issuance of decision on determining veterinary-sanitary conditions for import or transit of consignments;
- entry in the Register of legal entities and entrepreneurs for carrying out veterinary activity;
- entry in the Register of approved establishments and control number assignment;
- entry in the Register of exporting establishments;
- entry of establishments in the Register and veterinary control number assignment.

Applicants shall make these payments to the appropriate account for the budget public revenue of the Republic of Serbia.

The amount of costs shall be specified in accordance with regulations on the amount of costs in administrative procedure.

Control system for imports:

- **live animals**
- **products including food, feed and animal by-products;**

Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management is the competent authority for veterinary-sanitary checks on the import of live animals, semen, ova and embryos, animal products, food of animal origin, animal by-products and feed.

Veterinary-sanitary checks on import/transit of these consignments are carried out by border veterinary inspectors at certain border inspection posts (BIP).

Legal acts defining the control system on imports of live animals, semen, ova and embryos, animal products, food of animal origin, animal by-products and feed are:

- Law on Veterinary Matters
- Law on Animal Welfare
- Food Safety Law
- Law on Medicines and Medicinal Devices.

By-Laws made on the basis of these laws are:

- 1) Rulebook laying down the technical and hygienic working conditions that must be satisfied by border inspection posts with organized veterinary sanitary controls (Official Gazette of RS No 30/2010); it specifies technical and hygienic working conditions that must be satisfied by border inspection posts with organized veterinary sanitary checks and where import, transit and export of animals, animal products, feed, veterinary medications and medicinal devices and accompanying things are carried out. This Rulebook is prepared on the basis of Commission Decision 2001/812/EC on the approval of border inspection posts responsible for veterinary checks on products introduced into the Community from third countries;
- 2) Rulebook on the types of consignments that are subject to veterinary checks and the methods of carrying out veterinary checks at border inspection posts (Official Gazette of the Republic of Serbia No 56/2010) specifies the types of consignments that are subject to veterinary checks, the manner of carrying out veterinary checks at border inspection posts with organized veterinary checks. This Rulebook has been prepared on the basis of Council Directive 91/496/EEC, Council Directive 97/78/EEC, Commission Decision 2007/275/EC concerning the lists of animals and products to be subject to controls at border inspection posts under Council Directive 91/496/EEC laying down the principles governing the organization of veterinary checks on animal entering the Community, with amendments 89/662/EEC, 90/425/EEC, 90/675/EEC and 97/78/EC laying down principles governing the organization of veterinary checks on animal entering the Community from third countries (and Commission Decision 2002/349 laying down the list of products of animal origin to be checked at border inspection posts in close cooperation with customs and in accordance with combined nomenclature from Council Regulation (EC) 2658/87 on the tariff and statistical nomenclature and the Common Customs Tariff);
- 3) Rulebook on the contents, form and the manner of issuing a common veterinary entry document (Official Gazette of RS No 70/2010) specifies the contents and form and the manner of issuing a common veterinary entry document. This Rulebook is prepared on the basis of Commission Regulation (EC) No 282/2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community and Commission Regulation (EC) 136/2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries.

Control system for imports of live animals, semen, ova and embryos

Consignments of live animals, semen, ova and embryos importing into the Republic of Serbia are subject to veterinary-sanitary check carried out by a border veterinary inspector.

Upon arrival of these consignments at the border veterinary post, the importer representative or authorized agent shall submit to the border veterinary inspector the application for check on the form prescribed by the Veterinary Directorate.

This application should be accompanied by the following documents:

- evidence that the fee for veterinary-sanitary check was paid;
- import certificate (issued on the basis of the previously issued decision on quarantine);
- original international veterinary certificate of the country of export;
- list of animal identification marks, and
- other documents (invoice, consignment note).

Checks of consignments of live animals, semen, ova and embryos importing into the Republic of Serbia

All consignments of live animals, semen, ova and embryos importing into the Republic of Serbia are subject to a **documentary check** with a view to verifying the compliance with the stated provisions.

The international veterinary certificate must be original, with identification serial number, issued on the day of dispatch of consignment, certified and signed by the competent authority, and should be written in the Serbian language and in the language of the country of origin.

Identity check (number of animals, identification number - eartag number, tattoo number or microchip number) is carried out in order to verify the equivalence of the data stated in the documentation with the consignment of live animals, semen, ova and embryos being imported.

Physical check of each consignment is carried out to assess the general condition and animal's fitness for further transport and to verify requirements regarding animal welfare in transport.

Laboratory analyses are conducted in accordance with the measures specified in the quarantine certificate. When laboratory tests are conducted, customs clearance and circulation are prohibited until the laboratory results are obtained.

Upon receiving the minutes on the completed quarantine period issued by the competent veterinary inspector, the border veterinary inspector makes decision on consignment - approves or prohibits importation.

When consignments of live animals, semen, ova and embryos do not meet prescribed requirements, the border veterinary inspector shall make:

- provisional decision on import prohibition, when deficiencies on accompanying documentation have to be eliminated, and
- decision on import prohibition.

At the importer's request, the border veterinary inspector makes decision on return or destruction of the consignment.

Check of consignments of live animals, semen, ova and embryos being in transit through the Republic of Serbia

On the basis of previous checks, epizootiological situation in the country of origin, i.e. country of export, the border veterinary inspector approves the transit of consignments of live animals, semen, ova and embryos through the territory of the Republic of Serbia, if:

- consignment is coming from the country or part of the country from which import into and transit through the Republic of Serbia is not prohibited;
- consignment is accompanied by all required documents;
- documentary and identity checks have been performed.

If, on the basis of information, a consignment is found to pose a threat to human or animal health, physical check of the consignment is carried out.

When road and railway transits through the territory of the Republic of Serbia are concerned, consignments of live animals, semen, ova and embryos must not be unloaded after leaving the entry border crossing and must leave the territory of the Republic of Serbia in 24 hours at the latest.

At the entry border crossing, the border veterinary inspector approves transit and informs the border veterinary inspector at the exit border crossing by telephone or by electronic means.

In the procedure of granting approval for import, there are certificates of determining veterinary-sanitary conditions for import that must be provided prior to arriving of consignments at border crossing and that are issued at the importer's request. The certificate is valid for three months, with possibility to be extended for another three months. This certificate does not limit the quantity of goods being imported.

- Products including food, feed and animal by-products

Control system for imports of animal products, food of animal origin, feed and animal by-products

Consignments of animal products, food of animal origin, feed and animal by-products being imported into the Republic of Serbia are subject to veterinary-sanitary controls by the veterinary-sanitary inspection.

Upon arrival of consignments of animal products, food of animal origin, feed and animal by-products at the border veterinary post, the importer representative or authorized agent shall submit to the border veterinary inspector the application for check on the form prescribed by the Veterinary Directorate.

This application should be accompanied by the following documents:

- evidence that the fee for veterinary-sanitary check was paid;
- import certificate;
- original international veterinary certificate of the country of export;
- other documents (invoice, specification of goods, consignment note).

Check of consignments of animal products, food of animal origin, feed and animal by-products

All consignments of animal products, food of animal origin, feed and animal by-products are subject to **documentary check** with a view to verifying the compliance with the stated provisions.

International veterinary certificate must be original, with identification serial number, issued on the day of dispatch of consignment, certified and signed by the competent authority, and should be written in the Serbian language and in the language of the country of origin. Prior to that, the certificates had to be harmonized between the two veterinary services, of the country of import and of the country of export.

All consignments of animal products, food of animal origin, feed and animal by-products are subject to **identity check** in order to ensure that the data stated in the documentation tally with the content of the consignment. This includes visual check of stamp, official marks, lots, control veterinary exporting numbers of establishments, declarations, packaging condition and other.

In order to verify compliance with safety requirements defined in the stated regulations of the Republic of Serbia and to verify accuracy from the international veterinary certificate, **physical check** is carried out, and it includes:

- sensor checks (conformation, colour, smell, taste, consistency);
- brief physical tests (boiling, baking, thawing, chopping, slicing, measuring temperature in the depth of the product);
- check of the means of transport and thermograph list to determine cold chain maintenance and measuring temperature in the depth of the product;
- check of the packaging and all relevant marks (stamps, veterinary control number, declaration);
- comparison of actual weight of the consignment with the weight specified in the certificate by checking the number of packages or, if needed, weighing the consignment.

Checks must be conducted on a number of different samples from the entire consignment to at least 1% of the products or packaging in the consignment (at least 2 and at most 10

products and packages in the consignment), and in case of a consignment containing products in bulk, the physical check includes at least 5 samples to be taken from different parts of the consignment.

As part of this check, the sampling for laboratory analysis can be performed. The sampling is performed whenever there are reasonable grounds for suspicion (when presence of hazardous substances can not be accurately determined or when the dates of guarantees are not precise).

Minimum and maximum sample quantities are specified in the Rulebook on the types of consignments that are subject to veterinary checks and methods of carrying out veterinary checks at border crossings.

When laboratory tests are conducted, circulation of the consignment is prohibited until the results from laboratory tests are obtained, and the consignment shall be under the supervision of the customs authority and the border veterinary inspection.

If the consignment of animal products, food of animal origin, feed and animal by-products does not comply with the prescribed requirements, the border veterinary inspector shall make:

- provisional decision on import prohibition, when defects on accompanying documentation have to be eliminated, or
- decision on import prohibition.

Upon the importer request, the border veterinary inspector makes decision on returning or destroying the consignment.

Check on consignments of animal products, food of animal origin, feed and animal by-products that are in transit through the territory of the Republic of Serbia

Border veterinary inspector, on the basis of the previously performed checks, epizootiological situation in the country of origin, i.e. country of export shall approve the transit through the territory of the Republic of Serbia for consignments of animal products, food of animal origin, feed and animal by-products if:

- consignment comes from the country or part of the country from which import and transit through the Republic of Serbia is not prohibited;
- consignment is accompanied by all required documents;
- documentary and identity checks of the consignment have been performed.

If, on the basis of information, the consignment is found to pose a threat to human or animal health, physical check of the consignment is carried out.

When road and railway transits through the territory of the Republic of Serbia are concerned, consignments of animal products, food of animal origin, feed and animal by-products must not be unloaded after leaving entry border crossing and must leave the territory of the Republic of Serbia within 72 hours at the latest.

At the entry border crossing, the border veterinary inspector approves transit and informs the border veterinary inspector at the exit border crossing by telephone or by electronic means.

- Safeguard measures

If there is any risk of introducing mandatory notifiable contagious or infectious diseases or their transmission by import or transit of consignments in the territory of the Republic of Serbia, the Minister can:

- order to prohibit or restrict the import or transit of animals, animal products, food of animal origin, feed and accompanying things;
- order control on circulation of animals, animal products, food of animal origin, feed and accompanying things at endangered border areas, including roads, bridges, ferries;
- order disinfection of persons and vehicles crossing the border of the Republic of Serbia.

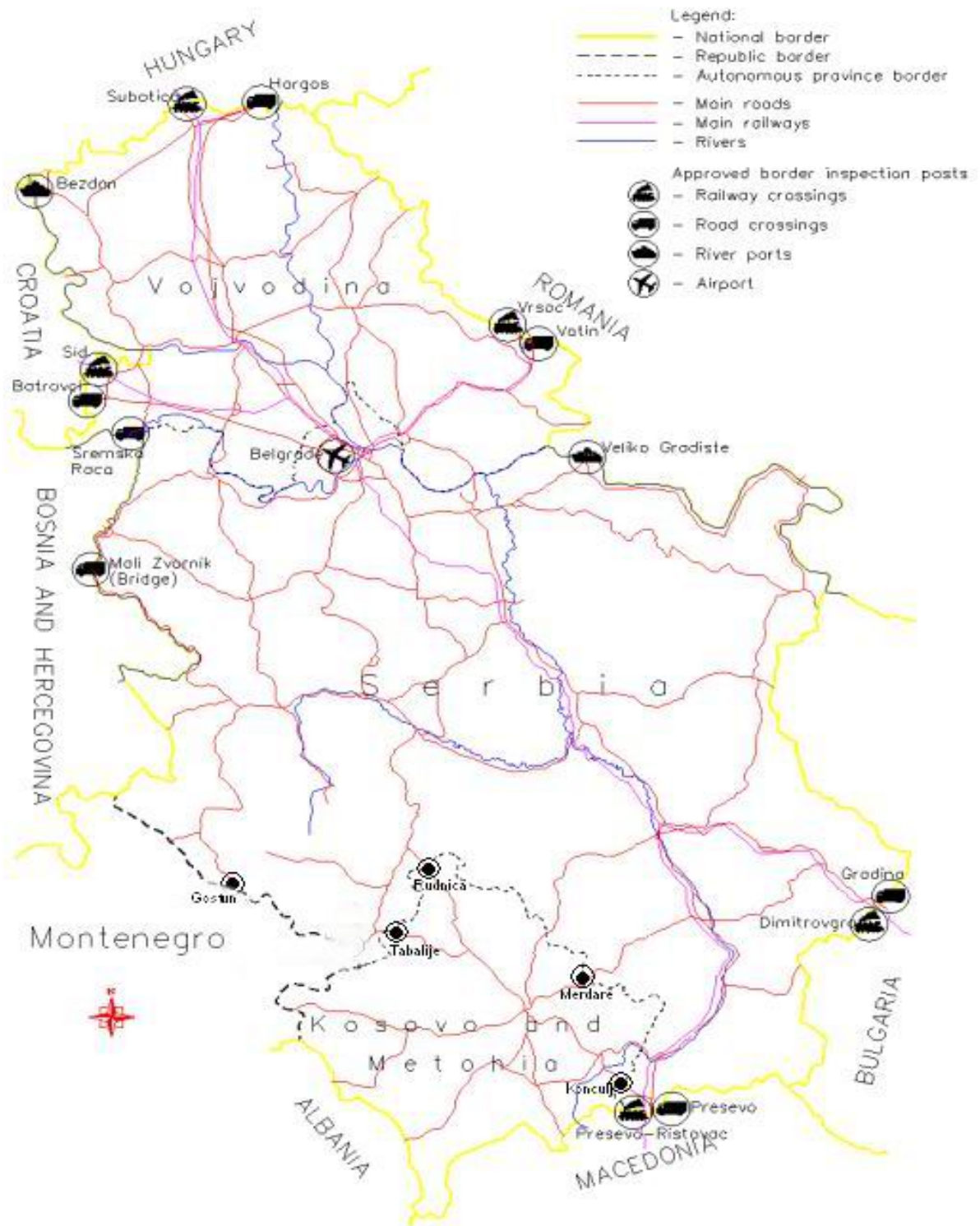
- Border Inspections Posts

The list of border inspection posts in the Republic of Serbia with organized veterinary-sanitary control and the map of border inspection posts:

Border inspection crossing		Type of crossing	Country	Working hours
1.	Belgrade	aerial	international	7:00 am - 7:00 pm.
2.	Subotica	railway	Hungary	7:00 am - 7:00 pm.
3.	Horgos	road	Hungary	00 - 24:00 h
4.	Bezdan	river	Hungary	at call
5.	Shid	railway	Croatia	7:00 am - 7:00 pm.
6.	Batrovci	road	Croatia	00 - 24:00 h
7.	Sremska Raca	road	B&H	7:00 am - 7:00 pm.
8.	Mali Zvornik	road	B&H	7:00 am - 7:00 pm.
9.	Vrsac	railway	Romania	at call
10.	Vatin	road	Romania	7:00 am - 7:00 pm.
11.	Veliko Gradiste	river	Romania	at call
12.	Dimitrovgrad	railway	Bulgaria	at call
13.	Gradina	road	Bulgaria	7:00 am - 7:00 pm.
14.	Presevo-Ristovac	railway	Macedonia	at call

15.	Presevo	road	Macedonia	00 - 24:00 h
16.	Prijepolje	railway	Montenegro	at call
17.	Gostun	road	Montenegro	7:00 am - 7:00 pm.
18.	Merdare - administrative inspection post	road	Kosovo and Metohija	at call
19.	Rudnica - administrative inspection post	road	Kosovo and Metohija	at call
20.	Tabanovci - administrative inspection post	road	Kosovo and Metohija	at call
21.	Konculj - administrative inspection post	road	Kosovo and Metohija	at call

BORDER INSPECTION POSTS



- Computer system (TRACES)

TRACES system has not been established in the Republic of Serbia. The application for access to the TRACES system is planned to be submitted to the European Commission as soon as possible and training of BIP personnel will be performed again. Infrastructural and technical conditions (computers and internet connections) are provided at all veterinary border crossings. Networking of border inspection posts is planned to be made with the Veterinary Directorate, and development of computer programmes for monitoring consignments at import and transit.

- Funding of checks

Fees for performed veterinary-sanitary checks at border crossings are charged in accordance with the Decision on the fee rates for performed veterinary-sanitary checks on consignments in international marketing (Official Gazette of RS No 8/2006).

In accordance with the Law on Veterinary Matters, fees for laboratory tests after taking samples for analysis are to be borne by importers.

Identification of animals and registration of their movements:

- bovine animals (including central bovine database)

Identification and registration of bovine animals and control of their movements are regulated in the following legal acts:

- Law on Veterinary Matters (Official Gazette of RS Nos 91/2005 and 30/2010), and Rulebook laying down the manner of bovine animal identification and registration of identified bovine animals (Official Gazette of RS Nos 57/09 and 14/10), which has been harmonized with Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97).

In accordance with these regulations, the Veterinary Directorate is the competent authority for carrying out animal marking, registration and identification and control of their movements, through authorized persons responsible for animal identification in veterinary stations and other veterinary services authorized for implementing the animal identification and registration procedures. The Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Management is responsible for granting authorization.

Supervision over implementation of the prescribed requirements and measures related to animal identification and registration and identification procedures is performed by the Veterinary Directorate veterinary inspectors.

Identification and registration of holdings are obligatory for all holdings where animals are bred, kept or sold.

Identification and registration of bovine, ovine, caprine and porcine animals and equidae are obligatory.

Identification and registration of bovine animals comprise the following elements:

- 1) central database;
- 2) register of holdings where bovine animals are bred, kept and sold (hereinafter referred to as: Register of holdings);
- 3) eartags for individual identification of bovine animals;
- 4) receipt of performed bovine animal identification and control of their movements;
- 5) holding registration receipt;
- 6) bovine animal passports;
- 7) bovine animal movement control;
- 8) records on bovine animal identification and movements in holding where bovine animals are kept (hereinafter referred to as: On holding register).

Central database contains data on:

- 1) holding where bovine animals are bred, kept and sold;
- 2) eartags for individual identification of bovine animals;
- 3) identified bovine animals;
- 4) ordered and used eartags;
- 5) annulled and issued eartags duplicates;
- 6) issued and annulled passports;
- 7) authorized veterinarians and persons responsible for animal identification;
- 8) imported bovine animals;
- 9) performed controls on bovine animal identification.

Control on the bovine animal identification and registration is carried out by the veterinary inspection according to the annual plan approved by the Ministry, on a sample of 10% of the total number of holdings. Veterinary inspectors shall print from the database the control lists for certain holdings, take them when visiting those holdings and upon the performed control shall enter the data in the system.

The Central database for bovine animals is within the information system AIMCS (Animal Identification and Movement Control System) of the Veterinary Directorate. The system prevents wrong data entry by applying the rules for incoming data check. This application can show data on an animal, data on a passport, history of registration and movements, history of data entry and data on animal parents and descendants. There is also a possibility of calculating fee amounts for authorized veterinarians with regard to providing services in animal identification and registration.

The system enables generating and printing certificates of implemented programme measures on bovine animals for each holding separately and for each populated place. While generating these certificates, each certificate is assigned its number from the system, which is further used for entering the same in the application. Ordering of

eartags duplicates is done through the database, enabling significantly better control of this process and reducing possible abuse.

- Ovine and caprine animals

Ovine and caprine animal identification started in 2006, based on the previously gained experiences in bovine animal identification.

The manner of ovine and caprine animal identification is specified by the Rulebook laying down the manner of porcine, ovine and caprine animal identification and keeping records on identified porcine, ovine and caprine animals (Official Gazette of RS No 11/06). The identification is compulsory for each animal older than 6 months or prior to leaving the holding where it was born.

Draft of the new Rulebook on the ovine and caprine animal identification was prepared and harmonized with the EU requirements, and a substantial financial assistance was received from the EU project implemented by Veterinary Directorate - *Technical Assistance to the Animal Identification and Registration System in the Republic of Serbia*. Database on identified ovine and caprine animals is also a part of AIMCS information system of the Veterinary Directorate.

Data contained in the receipt of performed ovine and caprine animal identification are recorded in AIMCS system.

Database for ovine and caprine animals contains individual identification numbers of animals, identification date and types of animals, as well as data on animal holdings, owner and/or keeper. Data on animal breed, date of birth and other data are currently recorded, but their entries are foreseen within the further development of the system. Ovine and caprine animal movements are not recorded at present, but the draft of new rulebook provides for control of ovine and caprine animal movements through the system, and implementation of inspection control on the ovine and caprine animal identification as well.

AIMCS for small ruminants includes animal registration, searching, and data on blood sampling and eartag ordering.

- Porcine animals

Porcine animal identification started in the year 2006. The campaign for porcine animal identification was conducted in parallel with the vaccination against classical swine fever.

The manner of porcine animal identification is specified in the Rulebook laying down the manner of identification and registration of porcine animals and of official controls on identification and registration of porcine animals (Official Gazette of RS No 94//10), which has been harmonized with Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs.

Each animal is identified by ear tags with an unique identification animal number. There is a possibility of electronic identification prescribed by new rulebook.

The identification is compulsory for each animal older than 45 days or prior to leaving the holding where it was born.

Within the EU project *Technical Assistance to the Animal Identification and Registration System in the Republic of Serbia*, the new rulebook on the porcine animal identification was prepared and harmonized with the EU requirements.

Database on the identified porcine animals is part of the VetUp information system. Data on the porcine animal identification are entered in the VetUp system together with data on preventive measures.

The database includes the number of porcine animals in the holding, the number of identified porcine animals and identification number series used for identification.

Porcine animal movements are not currently recorded in the database. Holding of origin is traceable from the database by way of using the animal identification number.

- Equidae

Identification of horses is specified in the Rulebook laying down the manner of identification and registration of equidae, and of official controls on identification and registration of equidae (Official Gazette of RS No 72/10).

Identification documents accompanying equidae during their life are introduced for the first time; this document contains 10 chapters.

Identification documents - PASSPORTS for equidae are issued by the Veterinary Directorate and records are also maintained by this Directorate.

The Rulebook and the form and contents of passport for equidae are fully harmonized with EU (European Commission Regulation (EC) No 504/2008 of June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae).

Passports for equidae contain the following information:

1) information on identification, Sections I and II;

In the case of registered horses, apart from unique identification number and UELN number, this section contains information from pedigree or herd-book that is entered according to the rules of the organization responsible for maintaining records for certain breed.

2) information on the owner, Section III;

2) records on checks conducted on equidae identity, Section IV

- 4) information on performed vaccinations against equine influenza, Section V;
- 5) information on other performed vaccinations (other than equine influenza), Section VI;
- 6) information on diagnostic tests for equine contagious or infectious diseases, Section VII;
- 7) document validity for circulation purposes, Section VIII;
- 8) information on veterinary medicine application, Section IX, containing Part I, Part II and Part III.
- 9) general requirements regarding the health protection of equidae, Section X.

Inspection control on at least 2% of registered equidae is carried out by official veterinary inspectors within their authority.

All equidae in the Republic of Serbia are subject to identification and registration. Identification is performed by microchips.

Development of software application for the registration of equidae is underway.

Animal disease control measures:

- **Notification of animal diseases; Foot and Mouth disease; Classical swine fever; African swine fever; African horse sickness; Avian influenza; Newcastle disease; Fish and mollusc diseases; Bluetongue disease; Transmissible spongiform Encephalopathies (TSE); Zoonoses and other diseases;**

Surveillance measures for contagious animal diseases are proscribed by the Law on Veterinary Matters (Official Gazette of RS, number: 91/2005, 30/2010) and the Rulebook on the List of Particularly Contagious Animal Diseases and the List of Compulsory Notifiable Compulsory Animal Diseases, as well as the notification procedure (Official Gazette of RS, number: 49/2006).

Compulsory animal diseases, according to this Law, are the diseases identified by the Zoosanitary Code of the World Organisation for Animal Health – Office International des Epizooties (in further text: OIE).

According to this Law, particularly dangerous contagious diseases are those that may spread fast, regardless of state borders, and that cause severe health problems accompanied with negative economic consequences for the country, as well as for the international trade in live animals, products of animal origin, food of animal origin and animal feed.

Compulsory Notifiable contagious animal diseases are diseases that carry a high risk to animal and public health:

- enzootic animal diseases, if the disease appears or spreads on the territory of Republic of Serbia;
- exotic diseases, if the disease is imported and spread on the territory of Republic of Serbia;

Measures for early identification and diagnostics for contagious diseases are:

- continuous surveillance of the animal health that includes monitoring of the epizootiological situation and diagnostic research;
- determine the cause of death or illness of the animals, in case of suspecting a contagious disease to be the cause of death or illness of the animals.

Suspecting a Contagious Disease

It is considered that there is a suspect contagious disease in cases when indicative clinical symptoms occur, when animals die suddenly for no apparent cause, or if two or more cases of the illness occur among the animals from the same facility, with identical or similar signs, or with a terminal outcome.

In case of suspecting a contagious disease, the owner or the keeper of the animal is obliged to:

- immediately notify the veterinarian, or the veterinary inspector;
- prevent others from approaching the animal, herd or the carcass before the arrival of the veterinarian or the veterinary inspector;
- isolate the animals or the carcass of the animal suspected to be diseased;
- keep the carcass of the animal suspected to have died from a contagious disease, until receiving instructions from the veterinarian or the veterinary inspector;
- provide the information required by the veterinarian or the veterinary inspector;
- enable the collection of materials necessary for testing;

The veterinarian is obliged to notify the veterinary inspector about the suspected contagious disease.

After receiving the suspicion on the presence of a contagious disease, the veterinary inspector conduct an epizootiological investigation and inform to the Ministry.

If a veterinary inspector suspects a contagious disease during the examination of animals before and after the slaughtering, or if a contagious disease is identified, the inspector must do the following:

- notify the Ministry;
- act according to the specific regulation;
- order the legal entity and the entrepreneur to take the necessary measures for prevention of the spreading of contagious diseases.

Diagnosing a Contagious Disease

In case of suspecting a contagious disease, the veterinary station and the veterinary clinic organises the collection and collects samples for laboratory testing and forwards them to an authorised laboratory for testing.

Organising the collection, collecting and sending the samples are performed under the surveillance of the veterinary inspector.

When the results of diagnostic testing confirm the presence of contagious disease, the minister defines the borders of the protection and surveillance zone as well as the measures for the prevention of the spreading, for suppressing and for eradicating the contagious disease.

Notification Procedure for Contagious Diseases

In case of a suspect contagious disease, the owner and the keeper of the animal is obliged to notify immediately the veterinarian or the veterinary inspector.

After receiving the suspicion on the presence of a contagious disease, the veterinary inspector conduct an epizootiological investigation and inform the Ministry in authorized for veterinary matters about the suspected contagious disease listed on the List of Notifiable Contagious Animal Diseases.

The veterinary inspector informs the Ministry about the suspect presence of a contagious disease within 24 hours by telephone – fax and by mail or e-mail.

When the presence of a transmissible disease is confirmed by the results of diagnostic testing, the authorised laboratory that has performed the testing is obliged to inform immediately, without delay, the Ministry and the competent veterinary inspector by telephone – fax or e-mail and confirm the presence of a contagious disease.

In case of presence of a contagious disease listed on the List of Compulsory Notifiable Contagious Animal Diseases, the veterinary inspector inform the Ministry.

In case of presence of a contagious disease listed in the List of Particularly Contagious Animal Diseases, the competent veterinary inspector inform the Ministry immediately, without delay, by telephone and fax or by e-mail, and by post within 24 hours.

The contagious disease is eradicated when the longest incubation period has expired from the day of recovering,, death or elimination of the last diseased animal and after the final disinfection has been performed, unless recommended otherwise by the OIE.

Veterinary inspector informs the Ministry about de-notification of the contagious disease in 24 hours after disease has been stopped by e-mail and by mail.

Serbia is a member of the World Organisation for Animal Health – Office International des Epizooties (OIE).

OIE has accepted the received evidence and documents and the General Assembly has assigned the Republic of Serbia the status of country officially free of Foot and Mouth disease (without applying vaccination) and free of Rinderpest. This status is confirmed every year, based on the monitoring and surveillance results provided by the Veterinary Directorate Republic of Serbia.

The animal health reports are sent electronically to the OIE information system (WAHID).

The Republic of Serbia uses the ADNS system for reporting animal diseases, upon the permission of the European Commission and on a voluntary base.

With the aim of preventing, early identification, monitoring, suppressing or eradicating contagious diseases, the minister impose a Program of Animal Health Protection Measures, at the latest by the end of January of the current year for which this Program has been applied.

The Program of Animal Health Protection Measures determined the measures for active and passive surveillance for particular contagious diseases, deadlines, way of conducting these measures, subjects responsible for conducting them, sources of funds and ways of reaching and using them, as well as implementation control measures.

The Program of Animal Health Protection Measures for 2010 included::

- identification and registering of animals, registration and keeping in records of holdingholdings and population of data on identified and registered animals and registered holdings in the central data base
- zoosanitary and biosafety measures and animal welfare
- active surveillance of animal health on holdings
- immunoprophylactic measures (Classical swine fever, Rabies, Newcastle disease)
- diagnostic testing for particularly dangerous contagious diseases
- diagnostic testing of cattle, sheep and goats for Brucellosis and Bluetongue disease, diagnostic testing of cattle for TBC and enzootic bovine leucosis
- diagnostic testing for Trichinellosis, Salmonellosis and Fowl typhoid, Avian influenza, Porcine influenza, Avian chlamydiosis, Infectious equine anaemia, Leptospirosis, Q fever, fish diseases, bee diseases and bovine and ovine infections of aerobic and anaerobic origin;
- diagnostic testing of abortions
- diagnostic testing in bovine and porcine artificial insemination centres and diagnostic testing of breeding bulls and boars used for natural insemination.

Contagious animal diseases are suppresses according to the Law on Veterinary Matters and by rulebooks that define suppression and eradication measures for contagious diseases.

FOOT AND MOUTH DISEASE

Suppression and eradication measures for the Foot and mouth disease are proscribed by the Rulebook on Defining the Measures for Early Identification, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Contagious Foot and Mouth Disease (Official Gazette of RS No. 15/2010);

Every suspect occurrence and every occurrence of foot and mouth must be notified, without any delay, to the Ministry competent for veterinary matters

Measures Taken in Case of Suspect Foot and Mouth at a Holding

When there are one or more animals at a holding that are suspected of having been infected or contaminated by the foot and mouth disease virus, an epizootiological investigation is performed immediately and laboratory samples are collected in order to confirm the presence or the absence of the foot and mouth disease.

The holding goes under surveillance immediately upon the notification on suspect Foot and mouth disease, and the following measures are taken:

- listing of all holding animals by categories of disease susceptible species, number of dead animals in each category, categories of animals suspect of having been infected or contaminated. The animal list must be regularly updated in order to include the newborn and dead animals in the period during the suspect presence of Foot and mouth disease at the holding; the data from the list must be made available at the request of the veterinary inspector and checked during every official control and monitoring visit;
- stock register for milk, dairy products, meat, meat products, carcasses, furs and leather, wool, semen, embryos, ova, manure and animal feed at the holding;
- ban of movement to or from the holding for any animal of the susceptible sort, except in case the holding consists of diverse epizootiological production units and when all susceptible animal species are kept in a place where they continuously live or in a place where they could be isolated;
- setting disinfectant barriers at the entries and the exits of the facility for susceptible animal species and at the entries and the exits of the holding. Every person entering or exiting the farm must take appropriate biosafety measures, necessary for decreasing the hazard of the spreading of the Foot and mouth virus. In addition to this, all transport vehicles must be disinfected before leaving the holding.

In addition to above mentioned measures, measures of transfer ban are also taken for moving to and from the holding suspect of hosting Foot and mouth disease, especially for:

- transfer of carcasses, meat and meat products, milk and dairy products, semen, ova or embryos of susceptible species, or of animal feed, equipment, or other products (wool, skin, fur, hair, waste of animal origin, manure) that could be a Foot and mouth disease transmitting agent;
- transfer of animals that are not susceptible to Foot and mouth disease;
- movement of people to and from the holdings;
- transfer of vehicles to and from the holdings.

Measures taken in case of a suspect incidence of Foot and mouth disease must be extended to other holdings in case there is a justified suspicion based on their location, settlement and distribution or contact with the animals from the suspect holdings.

When the epizootiological situation requires so, especially in cases of a high density population of the susceptible species and intensive movement and transfer of animals or of people who are in contact with the susceptible species and delayed notification on the suspect case of Foot and mouth disease, or in case of missing information on the potential source and the vectors that ways of spread the Foot and mouth disease, the Ministry may pronounce a temporary control zone.

Measures Taken in Case the Foot and Mouth Disease has been Confirmed at a Holding

Once the Foot and mouth disease has been confirmed, in addition to the measures taken when the disease is suspected, the following measures are ordered to be taken at the holding:

- immediate killing,, in a humane way, of all susceptible animal species. Under special circumstances, the susceptible animal species may be killing, at the closest appropriate place,, with the veterinary inspector present, in a way that prevents the spreading of the Foot and mouth disease during transport and the killing,;
- taking an adequate number of samples before or during the killing of susceptible animal species for further epizootiological testing;
- immediate safe removal of carcasses of susceptible animal species that have died, or have been killing without delay under the surveillance of the veterinary inspector, in order to prevent the hazard of spreading the foot and mouth disease virus. When special circumstances require for the carcasses to be burned or buried on the spot, or at some other location, the burning or burying is performed according to the contingency plan;
- the collection and isolation in a specific space of milk, dairy products, meat, meat products, carcasses, furs and skins, wool, semen, embryos, ova, manure and animal feed, until they are proven not to be contaminated, or until they have been processed under the surveillance of a veterinary inspector who will ensure a safe destroying of the foot and mouth disease virus.

After the slaughter and safe removal of susceptible animal species, the following is performed:

- cleaning and disinfection of all the facilities that have been used for the susceptible animal species, of the surrounding area, vehicles used for their transport and other facilities suspected to have been contaminated;
- disinfection of the living and work places at the holding, if there is a suspicion that they have been contaminated;
- re-stocking the animals to the holding.

Cleaning and disinfection are performed under the surveillance and instructions of the veterinary inspector, with the usage of approved disinfectant and an approved solution concentration.

Stocks of milk, dairy products, meat, meat products, carcasses, fur and skins, wool, semen, embryos, ova, manure and animal feed that derive from the susceptible animal species and have been collected at the holdings that have been confirmed to be infected with the foot and mouth disease, and semen, ova and embryos collected from the

susceptible animal species at that holdings in the period between the import of the causative agent to the holdings and the implementation of the proscribed measures must be discovered and processed, or in the case of other matter, except for semen, ova and embryos, processed under the supervision of the veterinary inspector in a way that ensures that the foot and mouth disease virus has been destroyed and that any hazard of its spreading has been eliminated.

Measures additional to kill and safe disposal may be taken at holdings that have been confirmed as foot and mouth disease positive, such as killing and processing of animal species unsusceptible to foot and mouth disease in a way that eliminates all hazard of spreading of the foot and mouth disease virus. These measures are not applied to those animal species that are not susceptible to foot and mouth disease and that can be isolated, under the condition that they have been identified, and in case of equidae, to enable the control of their movement.

The measure of immediate killing, in a humane way, of all susceptible animal species on the spot, can be ordered in epizootiological connected production units or in neighbouring/joined holdings, in case epizootiological data or other evidence raises suspicion that these holdings, have been contaminated.

Measures for Slaughterhouses, Border Crossings and Transport Vehicles

When the presence of foot and mouth disease is confirmed in a slaughterhouse, at a border crossing, or in a vehicle, the following measures will be taken:

- immediate killing of all susceptible animal species;
- safe disposal of carcasses, of animal origin waste, under the surveillance of the veterinary inspector;
- cleaning and disinfection of the manure, facilities, equipment and vehicles under the surveillance of the veterinary inspector;
- epizootiological investigation.

These measures are taken at contact holdings as well.

An animal may not be delivered to a slaughterhouse, border crossing, nor be transported until 24 hours have expired after the cleaning and disinfection.

A holdings is declared to be a contact holdings if it is found that the foot and mouth disease virus has been imported by the movement of people, animals, animal origin products, by vehicles or any other way.

The Protection and the Surveillance Zone

Once the presence of the foot and mouth disease has been confirmed for a holding, the Ministry defines the borders of the protection zone in a 3 km radius (at least) around the location where the disease occurred and the surveillance zone in a 10 km radius around the location of the foot and mouth disease. When defining the borders of the protection and surveillance zone administrative borders, natural barriers and the surveillance potential are taken into consideration. If necessary, borders can be moved.

The protection and surveillance zone should be marked with visible signs on all the roads in the area.

The following measures are taken in the protection zone:

- list of all holdings keeping susceptible animal species and lists of all holding animals and regular updating of these lists;
- regular control of all holdings keeping susceptible animal species in a way that prevents the spreading of the possibly present foot and mouth disease virus at the holding, including review of adequate documentation;
- ban of transfer of susceptible animal species from the farms where they are kept or bred.

The following cannot be done in the protection zone:

- transfer of animals from the holdings and transport of susceptible animal species;
- organizing fairs, exhibitions, markets and other events for gathering animals;
- artificial insemination, collecting of ova and embryos from susceptible animal species.

In addition to these, other measures can be taken:

- ban of transfer or transport of unsuitable animal species between holdings in the protection zone, and transfer or transport of susceptible animal species out of or to a protection zone;
- ban of transport of all animals through a protection zone;
- ban of gathering in places where people may come in contact with susceptible animal species and where there is a hazard of spreading the foot and mouth disease virus;
- artificial insemination, collecting of ova and embryos from animal species unsuitable to foot and mouth disease;
- ban of movement for vehicles used in animal transport;
- ban of slaughter of susceptible animal species on holding for personal needs;
- transport of animal feed, hay and straw to the holdings that keep susceptible animal species.

Raw meat, diced meat and meat products from the meat of susceptible animal species from the holdings in the contaminated area cannot be placed on the market.

Raw meat, diced meat and meat products from the meat of susceptible animal species produced in facilities in a protection zone cannot be placed on the market.

Milk from susceptible animal species that are from the protection zone and dairy products made from that milk cannot be placed on the market.

Milk and dairy products from susceptible animal species that produced in facilities in the protection zone cannot be placed on the market.

Semen, ova and embryos of susceptible animal species from a protection zone cannot be placed on the market.

The following measures are taken in the surveillance zone:

- list of all holdings keeping susceptible animal species and lists of all holding animals and regular updating of these lists;
- regular control of all holdings keeping susceptible animal species in a way that prevents the spreading of the possibly present foot and mouth disease virus at the holding, including review of adequate documentation;
- ban of transfer of susceptible animal species from the holdings where they are kept or bred.

Vaccination

There is no vaccination of animals for the foot and mouth disease and hyperimmune serum is given only in exceptional cases.

The manufacturing, storage, procurement, distribution and sale of the foot and mouth disease vaccine are under official surveillance.

The Contingency Plan and Centres for the Prevention of the Foot and Mouth Disease

The Ministry impose the Contingency Plan with measures in case of the occurrence of foot and mouth disease, which defines the way of securing the facilities, equipment, staff and other material necessary for quick and efficient eradication of the disease.

The Contingency Plan may be amended due to the development of the situation.

The Ministry updates the Contingency Plan every 5 years, taking into consideration simulation drills.

In case of occurrence of foot and mouth disease, the minister sets up a crisis centre with regional units organised at a county or municipal level.

CLASSICAL SWINE FEVER

Suppression and eradication measures for the classical swine fever are proscribed by the Rulebook on Defining the Measures for Early Identification, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Contagious Disease Classical Swine Fever (Official Gazette of RS No102/2009). The Ministry must be notified, without any delay about every suspected occurrence and every occurrence of classical swine fever.

Measures Taken in Case of Suspected Classical Swine Fever at a Holding

When one or more porcine animals at a holding are suspected of being infected with the classical swine fever virus, a veterinary inspector immediately performs an epizootiological investigation, places the holding under surveillance and orders the following measures:

- listing of all porcine animals at the holding, by category and the number of infected, dead or suspected to have the classical swine fever in each category, control of all vaccinations against the classical swine fever, the identification and the trade in

previous 12 months. The list must be regularly updated in order to include the newborn and dead animals in the period during the suspect presence of the classical swine fever at the holding; the data from the list must be made available at the request of the veterinary inspector and checked during every official control and monitoring visit;

- limited movement of the porcine animals at the holding, where they must be contained in their boxes or in a place where they could be isolated;
- banned transfer of porcine animals to and from the holding, and, if necessary, banned transfer of other animals from the holding;
- banned movement of porcine carcasses without a written order from the veterinary inspector;
- banned trade with meat and other porcine products, porcine semen, ova and embryos, animal feed, waste and equipment that could be a transmitting agent for the classical swine fever, without a written order from the veterinary inspector;
- banned movement of people to and from the holding without a written order from the veterinary inspector;
- banned movement of vehicles to and from the holding without a written order from the veterinary inspector;
- setting disinfectant barriers at the entries and the exits to the facility for susceptible animal species and at the entries and the exits to the holding. Every person entering or exiting the holding must take appropriate biosafety measures, necessary for decreasing the hazard of the spreading of the classical swine fever virus. In addition to this, all transport vehicles must be disinfected before leaving the holding.

Measures Taken in Case the Classical Swine Fever has been Confirmed at a Holding

If the classical swine fever has been officially confirmed at a holding, the veterinary inspector, performs epizootiological inspection, takes other measures at the contaminated holding and orders the following measures to be taken:

- immediate killing (euthanasia) of all porcine animals at the contaminated holding, under the surveillance of the veterinary inspection, in a way that ensures the prevention of spreading the classical swine fever virus during the destruction and transport of carcasses;
- taking a sufficient number of samples in accordance with the Diagnostic Manual to identify how the classical swine fever virus was imported to the holding and to identify how long was the virus present before the disease was reported;
- safe disposal of porcine carcasses, died or killed under the surveillance of the veterinary inspection;
- finding and safe disposal,, under the surveillance of the veterinary inspection, of porcine products, raw material and waste, originating from pigs that were slaughtered from the period between the probable import of the classical swine fever virus to the holding and the beginning of the implementation of ordered measures;
- finding and safe disposal,, under the surveillance of the veterinary inspection, of porcine semen, ova and embryos, which were taken from the period between the probable import of the classical swine fever virus to the holding and the beginning

of the implementation of ordered measures, in a way to prevent the spreading of the classical swine fever virus;

- processing of all material and waste that may have been contaminated (e.g. animal feed), in a way to destroy the classical swine fever virus;
- destruction, under the surveillance of the veterinary inspection, of all disposable material that may have been contaminated, especially the material used in the slaughtering process;
- cleaning and disinfection of facilities where the porcine animals were kept, of transport vehicles, equipment, litter and manure, after the porcine animals have been safely disposed

Measures Taken at Contact Holdings

When the veterinary inspector has justified doubt, or establishes after the epizootiological investigation that there is a suspected occurrence of classical swine fever at the contact holdings,, and if the epizootiological situation requires so, measures for the case of confirmed presence of classical swine fever at a holdings, will be ordered, and a sufficient number of samples shall be taken from killing pigs in order to confirm the presence or absence of the classical swine fever virus at the holdings,.

The Protection and the Surveillance zone

After the presence of the classical swine fever virus has been officially confirmed, the Ministry defines the borders of the protection and surveillance zone.

The borders of the protection zone are set in a 3 km radius around the location where the disease occurred. The protection zone is within the surveillance zone in a 10 km radius around the location where the disease occurred.

The following measures are taken in the protection zone:

- list of all holdings keeping and breeding porcine animals, at the shortest possible notice, vaccination of all porcine animals that have not been vaccinated, or have been vaccinated more than 6 months previous to the event, identification and registering of all non identified porcine animals, after which the veterinary inspector must carry out an inspection, within 7 days at the latest, of the protection zone,, clinically test the porcine animals, review the holding registers, vaccination and the identification processes;
- ban of trade and transfer of porcine animals, except in special cases. The veterinary inspector may make an exception and allow the porcine animals transport by road or rail through the protection zone, under the condition that the transport is without any stopping and with no unloading of animals. The permission is issued for the transport of porcine animals that are not from the protection zone and are sent for slaughter in a slaughterhouse located in the protection zone;
- cleaning and disinfection as soon as possible after contamination, of trucks and other vehicles and equipment used for the transport of porcine animals or other animals or materials that could be contaminated (carcasses, animal feed, manure

and similar). Not a single vehicle that has been used for porcine animals transport may leave the protection zone before it has previously been disinfected and inspected, and without having previously been approved of by a veterinary inspector;

- ban of movement to or from the holding for any domestic animal without the permit of the veterinary inspector;
- immediate notifying of the veterinary inspector about every porcine animal that died or is diseased at the holding; the veterinary inspector orders adequate testing, in accordance with the Diagnostic Manual;
- ban of transfer of porcine animals from the holding until at least 30 days expire from the cleaning and the first disinfection of the contaminated holdings, and at least 15 days after the animals at the holding have been vaccinated;
- ban of trade in porcine semen, ova and embryos from the holdings in the protection zone;
- compulsory conducton of biosafety measures necessary to minimise the risk of spreading of the classical swine fever virus by any person entering, or exiting from the holding.

Measures in the protection zone remain in force until the cleaning, first disinfection and the clinical testing of porcine animals have been performed, including laboratory testing if necessary.

The following measures are taken in the surveillance zone:

- listing of all holdings;
- vaccination of all porcine animals that have not been vaccinated, or have been vaccinated more than 6 months previous to the event;
- identification and registration of all non idetificated porcine animals;
- ban of movement and transport for all porcine animals, on all private and public roads, without the permission of the Ministry that can be obtained for the porcine animals transit by road or rail through the surveillance zone, under the condition that the transit is without any stopping and with no unloading of animals, as well as for porcine animals that are not from the surveillance zoneand are sent for immediate (urgent) slaughter in a slaughterhouse located in the contaminated area;
- cleaning and disinfection of trucks and other vehicles and equipment used in the transport of porcine animals or other animals or materials that could have been contaminated with the classical swine fever virus (i.e. carcasses, animal feed, manure), which is possible after the contamination. Vehicles used for porcine animals transport may not leave the surveillance zoneunless they have previously been cleaned and disinfected;
- ban of entering or leaving the holdings for all animals in the first 7 days from the day the surveillance zone borders have been set without the permit of a veterinary inspector;
- immediate reporting on , without delay, or diseased porcine animal;
- ban of trade in porcine animals from the holdings at least 21 after the cleaning and the final disinfection of the contaminated holdings have been performed, and 15 days after the vaccination of the porcine animals. After a 21-day period,

the Ministry may allow transfer of porcine animals from the holdings in special cases;

- ban of trade in porcine semen, ova and embryos within the surveillance zone;
- appropriate biosafety measures necessary to minimise the risk of spreading of the classical swine fever virus by any person entering, or exiting from the holding.

Measures for the surveillance zone remain in force until the cleaning, first disinfection and the clinical testing of porcine animals have been performed, including laboratory testing if necessary.

The clinical testing, vaccination control and the identification of porcine animals shall be performed 20 days after the cleaning and the first disinfection of the contaminated holdings have been undertaken.

Measures Taken in Case of a Suspected or Confirmed Classical Swine Fever in a Slaughterhouse or a Vehicle

In case of a suspected classical swine fever in a slaughterhouse or a vehicle the veterinary inspector immediately conduct an epizootiological investigation and proscribes other measures to confirm the presence or absence of the classical swine fever virus.

In case of a suspected classical swine fever in a slaughterhouse, the porcine animals will immediately be placed under surveillance until the test results return.

Once the classical swine fever in a slaughterhouse or a vehicle has been confirmed, the following will be performed:

- immediate slaughter without delay of all susceptible animals in the slaughterhouse or in the vehicle;
- safe desposal of carcasses, bodies, internal organs, slaughterhouse and animal waste, deriving from potentially contaminated animals, under the surveillance of a veterinary inspector;
- cleaning and disinfection of the facilities, equipment and the vehicle, under the surveillance of the veterinary inspector;
- epizootiological investigation;;
- genetic typisation of the isolated classical swine fever virus;
- implementing the rules from this Rulebook at the holding from which the contaminated porcine animals or carcasses originate, as well as at other contact holdings;
- ban of importing porcine animals for slaughter, or trade, until 24 hours have expired after the cleaning and the disinfection.

Measures Taken in Case of a Suspected and Confirmed Classical Swine Fever in Wild Boars

In case of a suspected classical swine fever in wild boars, the veterinary inspector immediately conduct the epizootiological investigation and proscribes other measures to confirm the presence or absence of the classical swine fever virus.

Veterinary inspector informs porcine animal owners and hunters about the suspected occurrence of classical swine fever virus in wild boars.

After the classical swine fever of wild boars has been confirmed, the Ministry defines the borders of the infected zones as well as the following measures for that area:

- list of all categories of porcine animals at the holdings in that area, regularly updated by the owners and controlled by the veterinary inspector;
- proper vaccination and identification;;
- keeping the animals at the holding in a way that ensures preventing direct or indirect contact with wild boars;
- ban of movement to or from the holding for all porcine animals without the permit of the veterinary inspector;
- setting disinfectant barriers at the entries and the exits to the facility for susceptible animal species and at the entries and the exits to the holding.
- adequate hygienic and biosafety measures for all persons who were in contact with wild boars, in order to minimise the risk of spreading the classical swine fever virus; these may include a temporary ban of entering the porcine holding;
- testing at the holding of all porcine animals that have died, or are showing clinical signs of the classical swine fever;
- ban of importing to the holding of any organ or tissue of a hunted or dead wild boar, as well as of supplies and equipment that could have been contaminated with the classical swine fever virus;
- a test of all hunted or dead wild boars in the infected zone in the presence of a veterinary inspector and their testing to the classical swine fever;
- safe disposal of carcasses of wild boars that were positive for the classical swine fever under the surveillance of a veterinary inspector;
- ban of trade in wild boars and boar meat that originates from the infected zone and their safe disposal under the surveillance of a veterinary inspector;
- safe disposal of wild boar parts that are not intended for human consumption, under the surveillance of a veterinary inspector;
- genetic typisation of the isolated classical swine fever virus;

After classical swine fever in wild boars has been confirmed, the Ministry presents a written Measures Plan (Plan) for eradicating the classical swine fever in wild boars and on the holdings in the infected zone.

Vaccination for the Classical Swine Fever

The classical swine fever is prevented and eradicated by strengthening the porcine immunity to classical swine fever at all holdings that keep and breed porcine animals throughout the year, by vaccinating all porcine animals with the vaccine containing attenuated K-strain virus, according to the manufacturer's recommendation as following:

- the first vaccination of piglets 45-60 days old, 15 days before they are places on the market, at the latest;
- vaccination of sows, 15 days before mating at the latest;
- vaccination of boars twice a year, every six months.

Porcine animals that are taken out to a common pasture, as well as wild boars in separate breeding establishments, must be vaccinated once a year, 15 day before letting out to the pasture at the latest.

The Ministry may approve porcine vaccination with marker vaccines at holdings with a closed production cycle, if appropriate diagnostics are ensured to enable the differentiation between the vaccine titre vs. marker vaccine from vaccine titre vs. conventional vaccine from the wild type virus.

Vaccine for the classical swine fever must be manufactured according to the latest OIE edition of the Manual of Standards for Diagnostic Tests and Vaccines.

Vaccination of Wild Boars

In case the classical swine fever has been officially confirmed in wild boars, with the goal of preventing the classical swine fever in wild boars, the Ministry may initiate the vaccination of wild boars and make a vaccination plan.

The Contingency Plan

The Ministry impose the Contingency Plan with measures to be taken in case of the occurrence of classical swine fever, which defines the way to secure the approach to the facilities, equipment, staff and material necessary for fast and efficient eradication of the disease.

The Contingency Plan may be amended, depending on the development of the situation.

The Ministry updates the contingency plan every five years.

AFRICAN SWINE FEVER

Eradication and suppression measures for African swine fever are proscribed by the Rulebook on Measures for Early Identification, Diagnostics, Prevention, Suppression and Eradication of African swine fever (Official Gazette of RS, No. 32/10).

The Ministry must be reported without any delay about every suspected occurrence and every occurrence of African swine fever.

Measures in Case of Suspected African Swine Fever

When one or more porcine animals at a holding are suspected of being infected with the African swine fever virus, a veterinary inspector immediately without delay, conducts an epizootiological investigation, places the holding under surveillance and orders the following measures:

- listing of all porcine animals at the holding, by category and the number of ill, dead or suspected to be infected with the African swine fever virus. The list must be regularly

updated in order to include the newborn and dead animals in the period during the suspect presence of the African swine fever at the holding the data from the list must be made available at the request of the veterinary inspector and checked during every official control and monitoring visit;

- orders to restrict movement of porcine animals on the holding and orders that they be kept in their pens, or separated in an isolated area in the facility;
- bans the transfer of porcine animals to and from the holding and, if necessary, bans the transfer of other animals from the holding, and orders appropriate measures to be taken for destroying insects or rodents;
- bans the movement of porcine carcasses without a written order from the veterinary inspector;
- bans the trade with meat and other porcine products, porcine semen, ova and embryos, animal feed, waste and equipment that could be a transmitting agent for the African swine fever, without a written order from the veterinary inspector;
- bans movement of people to and from the holding without a written order from the veterinary inspector;
- bans movement of vehicles to and from the holding without a written order from the veterinary inspector;
- orders disinfection barriers to be set at the entries and the exits of the facilities with porcine animals and at the entries and the exits of the holding. Every person entering or exiting the holding must take appropriate biosafety measures, necessary for decreasing the hazard of the spreading of the African swine fever virus. In addition to this, all transport vehicles must be disinfected before leaving the holding.

Measures in Case African Swine Fever has been Confirmed

If African swine fever has been officially confirmed at a holding, the veterinary inspector conducts an epizootiological investigation,, proscribes measures that are taken at holding suspected to be contaminated and also orders:

- immediate killing (euthanasia) of all porcine animals at the contaminated holding, under the surveillance of the veterinary inspector, in a way that ensures the prevention of spreading the African swine fever virus during the destruction and transport of carcasses;
- collection of a sufficient number of samples from the killing porcine animals, to identify how the African swine fever virus was imported to the holding and to identify how long was the virus present before the disease was reported;
- safe disposal of porcine carcasses, died and killed under the surveillance of the veterinary inspector;
- find and safe disposal, under the surveillance of the veterinary inspector, of products, raw material and waste from porcine animals slaughtered in the period between the probable import of the African swine fever virus to the holding and the beginning of the implementation of protection and prevention measures;
- find and safe disposal , under the surveillance of the veterinary inspector, of porcine semen, ova and embryos that were taken in the period between the probable import of the African swine fever virus to the holding and the beginning of the implementation of protection and prevention measures;

- processing of all matter and waste (i.e. animal feed) and the destruction of all disposable material that have probably been contaminated, especially those used for killing, in a way that will destroy the African swine fever virus;
- cleaning and disinfection, and disinsection if necessary, of facilities for keeping the porcine animals, of vehicles used for transport, of the equipment, litter and manure, after safe disposal of porcine carcasses.

The Protection and the Surveillance zone

After the disease has been officially confirmed, the protection zone is set in a 3 km radius within the surveillance zone in a 10 km radius around the outbreak.

Measures Taken in the Protection zone

In the protection zone:

- listing of all holding for keeping and breeding porcine animals, as soon as possible, identification and registration of all non identified porcine animals, after which the veterinary inspector inspects all holding in the contaminated area within 7 days, in order to clinically inspect the animals, review the porcine register at holding and inspect the identification of the animals;
- ban of transfer and transport of porcine animals on public and private roads, unless it is necessary to transport the animals on the holdings road, when such transfer and transport has been approved of by the veterinary inspector. This ban does not always apply to the transport of porcine animals that are not from the protection zone and are sent to a slaughterhouse located in the protection zone for an emergency slaughter;
- cleaning and disinfection, and disinsection if necessary, of trucks and other vehicles and equipment used for transport of porcine and other animals or matter that may be contaminated (i.e. carcasses, animal feed, manure and similar);
- ban of movement to or from the holding for any domestic animal without the permit of the veterinary inspector;
- mandatory immediate reporting to the veterinary inspector, on each ill or dead porcine animal from the holding, in order to enable the inspector to require the necessary tests;
- ban of transfer of porcine animals holding the farm where they are kept until at least 40 days have passed from the cleaning and the first disinfection, and disinsection if necessary, of the contaminated holdings;
- ban of trade in porcine semen, ova and embryos from the holding in the protection zone;;
- temporary biosafety procedures that must be taken by every person entering or exiting the holding in the contaminated area, with the goal of decreasing the risk of spreading the African swine fever virus.

Measures Taken in the Surveillance zone

The following measures are taken in the surveillance zone:

- list of all holdings that keep porcine animals;

- identification and registration of all non identified porcine animals;
- ban of transfer and transport of porcine animals on public and private roads, unless it is necessary to transport the animals on the holding roads, when such transfer and transport has been approved of by the veterinary inspector;
- cleaning and disinfection, and disinsection if necessary, of trucks and other vehicles and equipment used for transport of porcine and other animals or matter that may be contaminated (i.e. carcasses, animal feed, manure and similar) as soon as possible after the contamination;
- ban of entering and exiting the holdings for all animals in the first 7 days from the day the endangered area borders have been set without the permit of a veterinary inspector;
- mandatory immediate reporting to the veterinary inspector, on each ill or dead porcine animal from the holding,, in order to enable the inspector to require the necessary tests;
- ban of transfer of porcine animals from the holding, where they are kept until at least 30 days have passed from the cleaning and the first disinfection, and disinsection if necessary, of the contaminated holdings;
- ban of trade in semen, ova and embryos of the porcine animals from the holdings in the surveillance zone;
- temporary biosafety procedures that must be taken by every person entering or exiting the holding in the endangered area, with the goal of decreasing the risk of spreading the African swine fever virus.

Vaccination

Vaccination for African swine fever is forbidden.

The minister imposes a Contingency Plan with measures taken in case of African swine fever, taking into consideration the porcine population density and its potential effect on the spreading of the African swine virus spreading.

The Contingency Plan defines the way to secure the approach to the facilities, equipment, staff and material necessary for fast and efficient eradication of the disease.

AFRICAN HORSE SICKNESS

Measures for suppressing and eradicating the African horse sickness are defined in the Rulebook Defining the Measures for Early Identification, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Contagious African Horse Sickness and the Manner of their Implementation (Official Gazette of RS No. 6/2010).

The Ministry must be reported, without any delay about every suspected occurrence and every occurrence of African horse sickness.

Measures Taken in Case of Suspected Contagious African Horse Sickness

If there is a suspected case of African horse sickness, the holding is placed under surveillance, the epizootiological investigation is conducted and the following measures are taken:

- list of all equidae at the holding, with the number of equidae that have died, been infected and may have been infected and the number of new born foals in the period of suspected disease occurrence;
- clinical test of all equidae at the holding,, especially the equidae suspected of being diseased, post mortem of the dead equidae and totake samples necessary for laboratory tests;
- identifying the location where the vectors may remain and survive;
- confining of all equidae in facilities at the holding,, or isolating them in some other way at the holding,, in order to protect them from the vectors;
- ban of entry and exit from the holding, for all equidae;
- destroying insects in all the facilities where equidae are kept and in their surroundings;
- safe disposal incineration or burial of all equidae carcasses at the holding,, in a way to minimise the risk of potential spreading of the causative agent.

These measures can be taken at other holdings if their position, geographic location or contacts with the holding that is suspected of being host to African horse sickness indicate a potential contamination with the causative agent.

These measures are applied until the suspicion of the transmissible disease African horse sickness has been completely eradicated.

Measures in case African horse sickness has been confirmed

Once the African horse sickness has been officially confirmed, in addition to the measures taken in case there is a suspected occurrence, the following measures are taken as well:

- humane killing all equidae that have been infected, or are showing clinical signs of the diseases;
- safe disposal, incineration or burial of (stamped out) killing equidae carcasses, in a way to minimise the risk of potential spreading of the causative agent.
- systematic vaccination with an approved vaccine, of all equidae at holdings in a 20 km radius (including the contaminated area) with the centre in the contaminated holding and indelible marking of vaccinated equidae.

If the epizootiological, environmental or meteorological situation, or the movement of equidae to and from the holding that has been confirmed to have been contaminated with the African horse sickness, there is a suspicion that the disease has spread, systematic vaccination may be undertaken beyond the 20 km radius.

Exceptions from the systematic vaccination may be permitted for epizootiological, meteorological, geographic or climatic reasons.

Measures Taken in the Protection and Surveillance zone:

Once the contagious disease African horse sickness has been confirmed, the minister competent for veterinary matters sets the boundaries of the protection zone in a 100 km radius around the contaminated holding and in a radius of at least 50 km for the surveillance zone around the contaminated area, in which there has been no vaccination in the previous 12 months.

The boundaries of the protection and surveillance zone are set according to geographic, administrative, environmental and meteorological parameters related to the contagious disease African horse sickness, to the presence, spreading and type of vectors, to the results of the epizootiological investigation of the laboratory tests, as well as dependant on the potential to take the control measures, especially the measures of destroying insects.

Measures Taken in the Protection Zone:

- list of all holdings that keep equidae;
- regular control of all holdings that keep equidae;
- clinical inspection of all equidae, to take samples for laboratory tests if necessary, all of which must be registered;
- ban of movement of equidae from the holding, except in case of monitored transport to a slaughterhouse in the protection zone for emergency slaughtering,, or to a slaughterhouse in the surveillance zone that has been approved of by the Ministry, if there isn't one in the protection zone.

In addition to the above measures, systematic vaccination for African horse sickness and special identification of equidae may be organized in the protection zone

Measures Taken in the Surveillance zone:

- listing of all holdings that keep equidae;
- regular control of all holdings that keep equidae;
- clinical inspection of all equidae, to take samples for laboratory tests if necessary, all of which must be registered;
- ban of movement of equidae from the holding, except in case of monitored transport to a slaughterhouse in the surveillance zone for emergency slaughtering or to a slaughterhouse in the protection zone that has been approved of by the Ministry, if there isn't one in the surveillance zone.

Vaccination for the contagious disease African horse sickness in the surveillance zone is not permitted.

The Ministry decides when the measures shall take place and when they will end, for both the protection and surveillance zone.

If systematic vaccination was undertaken, measures may not last less than 12 months.

The Ministry shall take all necessary measures to inform the population of the protection and surveillance zone about the proscribed measures and enable their adequate implementation.

AVIAN INFLUENZA

Measures for suppressing and eradicating the avian influenza are proscribed in the Rulebook on Early Detection, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Contagious Disease Avian Influenza and their Implementation (Official Gazette of RS No. 7/2010).

In case of a suspected contagious disease AI - highly pathogenic avian influenza (in further text: highly pathogenic AI), an epizootiological investigation and to take samples for laboratory testing are undertaken, in order to confirm the disease and placement of the holding under official surveillance.

The Following Measures are Taken in Case of a Suspected Highly Pathogenic AI:

- listing of poultry, birds and domestic mammals, or, if necessary, estimated numbers of confined animals by species of poultry and bird;
- listing an approximate number of diseased, dead and probably infected animals (poultry, birds and domestic mammals) in each category at the holding. The list must be updated daily, taking into consideration the number of hatched, newborn and dead animals throughout the period of suspected highly pathogenic AI and it must be sent to the veterinary inspector at request;
- containment of poultry and birds at the holding.. If this is practically impossible for the reason of animal welfare, they may be contained in some other facility at the holding., in order not to come into contact with poultry and birds from other holding.s. Necessary measures are also taken to prevent their contact with wild birds;
- ban of importing and exporting poultry and birds to and from the holding.;
- ban of exporting poultry and bird bodies, poultry meat, including liver (poultry meat), poultry feed (feed), tools, material, waste, faeces, manure from contained poultry and birds (manure) slurry, used straw and anything else that could be an AI transmitting agent, without a written permission from the veterinary inspector, and in accordance with biosafety measures in order to minimize the risk of spreading the highly pathogenic AI;
- ban of export from the holding. and trade in eggs from poultry and birds;
- controlled movement of people, domestic mammals, vehicles and equipment to or from the farm;
- disinfection of entries and exits to the facilities for keeping poultry and birds, as well as of entries and exits to the holding., in line with the instructions of the veterinary inspector.

These measures are applied until the laboratory findings do not exclude the presence of the highly pathogenic AI virus.

The following additional protection measures may be taken at holdings in the area of intensive breeding and a high density of poultry population, based on the results of an epizootiological investigation:

- temporary ban of export and trade in poultry, birds, eggs, and movement restriction for vehicles used in poultry breeding at the territory of the area (region) if there is an epizootiological justification, on the territory of the Republic of Serbia. Such measures may be extended to domestic animal-mammals for 72 hours, and longer if the measure remains to be justified;
- if there is an epizootiological justification, after the measures have been proscribed, lab tests may be done on killed poultry and birds;

Around the holdings in the area of intensive breeding and a high density of poultry population, in case there is a suspected occurrence of AI, temporary control zone may be established and necessary measures may be taken.

The Following Measures are Taken in Case of a Confirmed Highly Pathogenic AI at a holding, in Addition to the Above Measures:

- epizootiological investigation;
- humane and immediate stamping out of poultry and birds on the spot;
- safe disposal of bodies and eggs of poultry and birds;
- destruction of rodents and insects;
- destruction and treatment that will destroy the causative agent, of all potentially contaminated substances or waste, such as animal feed, manure, slurry, straw and other matter;
- destruction of poultry and bird eggs from the contaminated holdings, laid in the period from the import of the causative agent to the holding until the proscribed measures were in place;
- laboratory diagnostic testing and placing under surveillance the poultry and the birds from fertile eggs and originating from the contaminated holding, laid in the period from the import of the causative agent to the holding until the proscribed measures were in place;
- cleaning and disinfection of the facilities at the holding of vehicles, equipment and places that were used for transfer and movement of the animals;
- ban of re-stocking poultry and birds to the holding at least 21 days after the final disinfection has been performed;

Veterinary inspector may proscribe measures for other holdings if possible contamination may be suspected based on their position, distribution or contacts with a holding at which the disease has been confirmed.

The Protection and Surveillance zone

When laboratory results confirm the presence of highly pathogenic AI, the minister competent for veterinary matter sets the borders of the protection zone in a 3 km radius and of the surveillance zone in a 10 km radius around the centre of contamination.

In cases when there is epizootiological justification, the Ministry may define an additional protection zone around the protection and surveillance zone.

The following Measures will be Taken in the Protection and Surveillance zone:

- determine of the transport routes for the movement of poultry and birds, poultry meat products, animal feed, manure, slurry, used straw, staff and objects that have, or may have been, in contact with the infected poultry and birds, as well as vehicles used in poultry production;
- collection of information from the owners and keepers of the poultry and the birds, about the import and the export of poultry, birds and eggs to and from the holding, as part of an epizootiological investigation

Measures Taken in the Protection zone:

- list of all holdings that breed poultry and birds, as soon as possible, starting with the borders of the protection zone and moving to the centre of the outbreak;
- biosafety measures at holdings, including disinfection barriers at entries and exits to the holding containment of poultry and birds in closed facilities and prevention of contact with wild bird and other poultry and birds;
- clinical testing of all poultry and birds, collection of samples if necessary and sending them for laboratory testing, according to the Contingency Plan;
- clinical testing of poultry and birds at the holdings with intensive poultry production, while the veterinarian who hasn't been in contact with poultry or birds from the holdings in the protection and surveillance zone takes precaution measures;
- ban of populating the hunting land with upland birds and trade in upland birds while proscribed measures are in force;
- ban of trade in poultry and birds, one-day chicks, eggs, fertilised eggs and transferring carcasses from the holding;
- transfer of consignments with poultry, birds, one-day chicks, eggs and fertilised eggs only by main roads and rail, as well as ban of stopping for vehicles and ban of uploading and downloading consignments;
- ban of trade in poultry meat and products from the slaughterhouse, processing and stocking within the protection zone, except for the meat of poultry from outside the protection zone, or slaughtered at least 21 day before the first occurrence of infection at the holding.. Such meat and products may not come in contact with the meat and products originating from the protection zone

The following measures will be taken at the holdings in the protection zone:

- containment of poultry and birds in holding facilities. If this is practically impossible for the reason of animal welfare, they may be contained in some other facility at the farm, in order not to come into contact with poultry and birds from the neighbouring holding.s.
- safe disposal of bodies of poultry and birds;
- disinfection of the vehicles and equipment used for transporting poultry, birds, products, waste, manure, slurry and other materials that could transmit the causative agent;
- ban of trade in poultry, birds and domestic mammals without a permit from the Ministry, except in case of domestic mammals who were not in contact with poultry and birds;
- ban of importing new poultry and birds to the holdings;
- urgent reporting on every case of increased morbidity and mortality at the farm, as well as of every drop of productivity and of laying of eggs to veterinary inspector In all cases of mortality higher than three times and cases of a drop in laying eggs or food and water consumption higher than 5% at the protection zone holdings, sampling and laboratory testing of poultry is proscribed;
- preventive protection measures for preventing the risk of transmitting the causative agent by people entering or leaving a holding for breeding and keeping poultry and birds;
- mandatory register of people who were in contact with poultry and birds at the holding, kept by the owner or the keeper of poultry and birds.

Measures for prevention of spreading, suppression, and eradication of highly pathogenic AI shall be in force at least 21 days after the contaminated holdings were cleaned, washed and finally disinfected, or 21 days after the epizootiological and laboratory testing of poultry and birds in the protection zone showed negative results.

After the expiry of this period, the protection zone becomes a part of the surveillance zone. Measures proscribed for the surveillance zones shall be taken in this area as well, for a 9 day period. 30 days after the cleaning, washing and final disinfection at the contaminated holdings and facilities, the proscribed measures are not in force and all bans related to the trade in poultry, birds and poultry products are abolished.

The following measures are taken in the surveillance zone:

- list of all holdings that breed poultry and birds, as soon as possible, starting with the borders of the surveillance zone and moving to the protection zone;
- biosafety measures at holdings, including disinfection barriers at entries and exits to the holding, containment of poultry and birds in closed facilities and prevention of contact with wild bird and other poultry;
- ban of trade in poultry, birds and eggs within and from the surveillance zone, as well as in domestic mammals, except for those that move in space free of contact with poultry and birds;

- transfer of consignments with poultry, birds, one-day chicks, eggs and fertilised eggs only by main roads and rail, as well as ban of stopping for vehicles and ban of uploading and downloading consignments;
- urgent mandatory reporting on every case of increased morbidity and mortality at the holding, as well as of every drop of productivity and of laying of eggs to veterinary inspector In all cases of mortality at holdings in the protection zone that are higher more than three times and cases of a drop in laying eggs or food and water consumption higher than 5%, sampling and laboratory testing of poultry is required;
- cleaning and disinfection of all parts of equipment and of vehicles used by people entering and exiting the holding and may have been contaminated by the causative agent;
- preventive protection measures for preventing the risk of transmitting the causative agent by people entering or leaving a farm for breeding and keeping poultry and birds;
- mandatory register of people who were in contact with poultry and birds at the holding, kept by the owner or the keeper of poultry and birds;
- ban of organising fairs, exhibition competitions and markets, or any other, similar gathering for poultry and birds;
- ban of populating the hunting land with game birds while proscribed measures are in force.

Measures for prevention of spreading, suppression, and eradication of highly pathogenic AI shall be in force in the surveillance zone at least 30 days after the cleaning, washing and final disinfection at the contaminated holdings, facilities and equipment, or until the animals have been diagnostically tested.

Depending on the epizootiological evaluation, intensity and the level of spreading of the disease, the Ministry proscribes all or individual measures for prevention of spreading, suppression, and eradication of highly pathogenic AI that are in force in the protection and surveillance zone.

The Ministry may, if there is epizootiological justification, and based on risk analysis approve of prevention measures in the protective area, such as preventive slaughter and humane stamping out of poultry and birds at holdings.

Measures in Case of a Suspected or Confirmed Highly Pathogenic AI in a Slaughterhouse or a Vehicle:

In case of a suspected or a confirmed highly pathogenic AI disease in a slaughterhouse or a vehicle, the veterinary inspector immediately conducts and epizootiological investigation at the holding which the confined poultry or birds originate from, with the aim of confirming the presence or absence of the disease.

In case of a suspected or a confirmed highly pathogenic AI disease of the poultry in a slaughterhouse, after risk assessment criteria for the risk of spreading of AI have been considered, the emergency stamping out of all poultry found in the slaughterhouse is

performed and the slaughterhouse is placed under official surveillance with the following measures put in place:

- clinical and laboratory testing of all poultry in the slaughterhouse. Representative sample for slaughterhouse poultry is at least 5 dead or slaughtered out animals with characteristic pathoanatomic changes;
- in cases when the animals have already been slaughtered out, their meat, animal by-products, the meat and waste of other poultry must be kept separately under the surveillance of an inspector.
- ban of trade in meat and animal by-products;
- safe disposal of meat and animal by-products in case of a confirmed highly pathogenic AI disease;
- the slaughterhouse and the equipment must be cleaned, washed and disinfected as soon as possible

In case of a suspected or a confirmed highly pathogenic AI disease of the poultry and birds at a border crossing, after risk assessment criteria for the risk of spreading of AI have been considered, the emergency stamping out of all poultry and birds found at the border crossing or a vehicle, and their storing in isolated facilities, if it is possible, in a way to prevent contact with other birds and poultry, until the presence or absence of the highly pathogenic AI disease has been confirmed.

The Following Measures are Taken in Case of Highly Pathogenic AI Caused by H5N1 Virus

In case of a suspected highly pathogenic AI disease, caused by H5N1, indicated by the clinical picture and the epizootiological investigation, or confirmed by laboratory results, the Ministry defines Zones A and B.

Zone A covers the protection and surveillance zone, and is considered a high risk area for the spreading of the disease, according to epizootiological and geographic factors.

Zone B covers parts of the protection area, or its entire territory, and is considered a low risk area for the spreading of the disease, according to administrative, epizootiological and geographic factors.

In cases when Zones A and B have been established based only on suspicion of infection of poultry and birds with H5N1, while the laboratory tests do not confirm that the causative agent does not belong to neuraminidases type N1, the Ministry shall nullify the Zones.

Measures that are in force in the protection and surveillance zone are applied in Zone A, as well as measures applied at holdings in the protection and surveillance zone for the highly pathogenic AI disease.

In addition to the ban of trade in poultry, birds, fertilised eggs, eggs and egg products that is in force in case of the occurrence of the highly pathogenic AI disease, the following measures are applied:

- ban of export and trade in poultry, birds, game birds and fertilised eggs from Zone B to other parts of the country. This ban does not apply to pets and to birds that are intended for populating special holdings. Transport shall be permitted under the condition that it does not endanger the disease control and animal health;
- ban of export and trade in wild game products for human consumption, from Zones A and B to other parts of the country;
- ban of trade in animal by-products, deriving from poultry and birds, from Zone A to Zone B and vice versa, and ban of trade in animal by-products, deriving from poultry and birds from these Zones to other parts of the country;
- ban of organising fairs, exhibition competitions and markets, or any other similar gathering for poultry and birds in Zone B;

The Following Measures are Taken in Case of a Confirmed AI Disease - Low Pathogenic AI at a Holding

When AI disease - low pathogenic AI has been confirmed at a holding, the following measures are taken:

- emergency stamping out in a humane way of poultry and birds that have been confirmed to be infected with the - low pathogenic AI virus;
- stamping out in a humane way of and safe disposal of poultry and birds that are not a hazard for further spreading of the low pathogenic AI disease;
- depopulation of poultry and birds at contact holdings, after risk assessment criteria for the risk of spreading of AI and the epizootiological investigation, and after setting a justified epizootiological indication. Depopulation is stamping out and slaughtering of poultry and birds in slaughterhouses that have been approved by the Ministry;
- destroying rodents and insects at holdings and in the facilities;
- ban of trade in holding poultry and birds until depopulation and safe disposal have been undertaken. Ban of trade may also apply to domestic mammals, unless they are transferred to space in which they have no contact with poultry and birds;
- after the humane stamping out of poultry and birds and safe disposal of carcasses, the facilities, equipment and vehicles used for transport of poultry, carcasses, animal feed, manure, slurry, straw and other contaminated substances, must be cleaned, washed and disinfected.

In case when low pathogenic AI has been confirmed, the following measures are also taken:

- fertilised eggs from the holding that has been confirmed low pathogenic AI disease, collected in a period from the probable time of import of the causative agent to the holding until the proscribed measures were in place, must be, when possible, found and incubated under permanent surveillance of a veterinary inspector;
- chicks that have hatched from the eggs, must be, when possible, found and placed under the surveillance of a veterinary inspector, along diagnostic procedures, including mandatory laboratory tests of the samples taken from these;
- eggs that were found at a holding, and those produced at the holding until the moment of the humane stamping out and safe disposal, may be sent to an egg processing facility and used for egg product.

- equipment and materials found at the holding that may have been contaminated by the causative agent, must be cleaned, washed and disinfected, or destroyed in a way that ensures a complete destruction of the AI virus;
- manure, slurry and straw must be treated in a way that ensures a complete destruction of the AI virus.

When the laboratory test results confirm the low pathogenic AI disease, the minister sets the borders of the protection and surveillance zone (restricted area) in a radius of at least 1 km around the outbreak..

Measures are Taken in the Restricted Area:

- listing of commercial holdings, at the shortest notice;
- laboratory testing of poultry and birds at the commercial holdings
- movement and trade control for poultry, birds and eggs from the restrictive area;
- ban of movement and trade in poultry, birds and eggs from the restrictive area;
- biosafety measures at the entries and exits to the holding, for preventing the spreading of the disease;
- cleaning and disinfection of all parts of equipment and of vehicles used by people entering and exiting the holding and may have been contaminated by the causative agent;
- ban of exporting manure, used straw and slurry, except in case strict biosafety measures have been taken for the destruction or further treatment in a way that ensures a complete destruction of the causative agent.
- ban of organising fairs, exhibition competitions and markets, without a permit from the veterinary inspector;

Additional measures may be taken in the restricted area, if there is epizootiological justification, and based on risk analysis for the spreading of the low pathogenic AI disease.

The proscribed measures in the restricted area shall be in force:

- at least 21 days after the mechanical cleaning, washing and final disinfection have been performed in the contaminated facilities and at the holdings, or until epizootiological and laboratory tests of poultry have been performed at all holdings in the restricted area and the laboratory tests came back negative. Epizootiological test results must unequivocally confirm that the possibility of transmission of the low pathogenic AI disease is insignificant.
- at least 42 days from the moment results have confirmed the presence of low pathogenic AI at the holdings, or until epizootiological and laboratory tests of poultry have been performed in the restricted area and the epizootiological test results confirm that the possibility of transmission of the low pathogenic AI disease is insignificant.

Measures for Prevention of Spreading and Suppressing AI in Porcine animals

Once AI has been confirmed in poultry and birds, the following measures are taken:

- laboratory testing of porcine animals found at a contaminated holding. If the total number of porcine animals is higher than 60 animals, by production unit 60 will be tested from each production unit. Tracheal/oropharyngeal swabs and blood samples are taken for the laboratory tests, 2-4 weeks after the safe disposal of the poultry. The samples are taken in a way which ensures that each sample is from a porcine animal that is in direct contact with other porcine animals and together they make one group;
- ban of trade in porcine animals from contaminated holdings, until the final results have returned, confirming the presence, or absence, of the porcine infection with AI;
- emergency humane stamp out and safe disposal of porcine carcasses from the holding, in case the tests are positive to AI infection;
- ban of trade in porcine animals from the contaminated holding. The Ministry may approve of the trade, if the laboratory test -showed negative results for the porcine. Transport will be approved 14 days after the safe stamp out of the poultry, at the earliest.

With the aim of preventing the transmission of AI virus to other species, additional protection measures may be introduced to the contaminated contact holdings. Scope of application for these measures will be defined based on the epizootiological assessment of the risk analysis of spreading of AI to other animal species.

In case of a suspected infection of other animal species with AI virus H5 and H7, sampling and laboratory testing are undertaken.

Measures for Prevention of Spreading, Suppressing and Eradicating High Pathogenic AI disease in Wild Birds

When laboratory test results confirm the highly pathogenic AI disease caused by A type virus subtype H5, regardless whether H1 has been confirmed or it is suspected, the minister determines the borders of the protection zone at a 3 km radius and of the surveillance zone in a 10 km radius around the outbreak.

The following measures are taken in the protection zone:

- list of all holdings and clinical testing of poultry and birds, as soon as possible, starting with the borders of the protection zone and moving to the outbreak
- periodic clinical examination of poultry and birds, after examination from point 1 of this paragraph, and sampling and laboratory examination if necessary;
- clinical examination of poultry and birds at the holdings with intensive poultry production, by persons who haven't been in contact with poultry from holdings in the protection and surveillance zone takes precaution measures;
- biosafety measures at holdings, including disinfection barriers at entries and exits to the holding, containment of poultry and birds in closed facilities and prevention of contact with wild bird and other poultry;

- ban of organising fairs, exhibition competitions and markets, or any other, similar gathering for poultry and birds;
- ban of populating the hunting land with game birds and trade in game birds while proscribed measures are in force;
- ban of hunting game, according to a special regulation;
- ban of trade and export of poultry, one-day chicks, birds and carcasses from the holdings within the area;
- ban of trade in fertilized eggs from the protection zone;
- transfer of consignments with poultry, birds, one-day chicks and eggs only by main roads and rail through the protection zone; with a permission from the veterinary inspector, as well as ban of stopping for vehicles and ban of uploading and downloading consignments;
- ban of trade in poultry meat and products and meat of game birds from the protection zone, except for the meat of poultry from outside the protection zone, or slaughtered at least 21 day before the first occurrence of infection at the holding. Such meat and products may not come in contact with the meat and products originating from the protection zone;
- ban of exporting the manure, used straw and slurry from the holding in the protection zone and their dissemination on arable land before the biothermal process has been completed.

The following measures are taken in the surveillance zone:

- list of all holdings in the surveillance zone
- biosafety measures at holdings, including disinfection barriers at entries and exits to the holding, containment of poultry and birds in closed facilities and prevention of contact with wild bird and other poultry;
- official control of trade in poultry and birds, one-day chicks and fertilised eggs;
- ban of trade in poultry and birds in a period of 15 days after the surveillance zone has been established;
- ban of organising fairs, exhibition competitions and markets, or any other, similar gathering for poultry and birds;
- ban of populating the hunting territory with bird game bird and ban of trade in game bird as long as the measures for the prevention of spreading, suppression and eradication of the highly pathogenic AI disease in the protection zone;
- ban of hunting birds, according to a special regulation;

Additional protection measures may be taken in addition to the above listed, based on the epizootiological risk assessment of the disease spreading.

Vaccination of poultry and birds for AI is not permitted in the republic of Serbia. In exceptional cases, the Ministry may define the territory and the time frame for a fast and systematic vaccination (emergency vaccination), in case of a suspected occurrence of AI on the territory of the republic of Serbia and in its surroundings (neighbouring countries). In exceptional cases, the Ministry may define the territory and the time frame for a preventive vaccination, as a long term measure of suppressing and eradicating AI, when

the epizootiological risk assessment shows that certain geographic areas in the Republic of Serbia are exposed to a permanent risk of AI occurrence.

NEWCASTLE DISEASE

Measures for suppressing and eradicating the Newcastle disease are proscribed in the Rulebook on Measures for Early Identification, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Contagious Newcastle Disease (Official Gazette of RS No. 95/2009).

The Ministry must be reported without any delay about every suspected occurrence and every occurrence of Newcastle disease.

In case of a suspected infection or contamination of poultry with the Newcastle disease causative agent, the veterinary inspector immediately conducts an epizootiological investigation and orders sampling for laboratory testing.

Measures Taken in Case of a Suspected Newcastle Disease

In case of a suspected Newcastle disease, the following measures are taken:

- placing the holding under surveillance;
- identifying the numbers for poultry, by category, by number of dead animals in each category, category with obvious clinical signs and without any clinical signs of the Newcastle disease. This data should be updated daily, taking into consideration the number of hatched chicks and of deaths in the period of the suspected occurrence of the disease;
- all holding poultry must remain in its place, or it must be quarantined in some other place;
- ban of importing poultry to the holding and ban of trade;
- ban of movement or transfer, without an approval of the veterinary inspector, for all people, other animals or vehicles, to or from the holding;
- ban of exporting poultry meat or carcasses, animal feed, equipment, waste, manure, used straw, or anything that may transmit the Newcastle disease, without an approval of the veterinary inspector;
- ban of trade in holding eggs, except for eggs that have been directly dispatched to the facility for manufacturing egg products and were transported with the consent of a veterinary inspector.

The veterinary inspector may proscribe any of the given measures at other holdings as well, if their position or contact with the holding that has been suspected for the occurrence of the Newcastle disease indicates a possible contamination.

All the above measures are taken until the suspicion of Newcastle disease has been officially ruled out.

Measures in Case of a Confirmed Occurrence of the Newcastle Disease

Once the Newcastle disease has been officially confirmed in holding poultry, the following measures are taken in addition to the above measures:

- immediate stamping out of all holding poultry and safe disposal of all poultry carcasses and all eggs in a way to minimise the hazard of spreading the disease;
- destroying or appropriate treatment of all objects, waste, animal feed, straw or faeces that may have been contaminated, in a way to ensure the destruction of the Newcastle disease virus;
- safe disposal of poultry meat from the time of the presumed incubation period of the disease;
- destruction of fertilised eggs produced during the presumed incubation period of the disease at the holding and at other holdings, when confirmed that they originate from the contaminated holding. Poultry that has hatched in the period of the presumed incubation period must be placed under official surveillance. Eggs for consumption produced during the presumed incubation period that originate from the contaminated holding must be safely destroyed, unless they have previously been appropriately disinfected;
- cleaning and disinfection of the facilities for keeping the poultry, of their surrounding environment, of vehicles and equipment that may have been contaminated after the control measures took place;
- ban of re-stocking the poultry to the holding at least 21 days after cleaning and disinfection have been performed;
- epizootiological investigation;

Veterinary inspector may order the above control measures for other holdings if possible contamination may be suspected based on their position, distribution or contacts with a holding at which the disease has been confirmed.

The Protection and Surveillance zone

When laboratory tests confirm the occurrence of the Newcastle disease, the minister competent for veterinary matter defines the Protection and surveillance zone.

The following measures are taken in the protection zone:

- list of all poultry holdings and listing of the number of animals at each holding;
- regular control of all poultry holdings, clinical examination of the poultry, including, if necessary, sampling for laboratory testing, which should be registered;
- confinement of poultry in a facility, or a space where it could be isolated;
- use of appropriate disinfectants at the entries and the exits of the holding;
- movement control for people who work with poultry, poultry carcasses and eggs, control of vehicles used for transport of poultry, carcasses and eggs in the protection zone,, with the ban of transport of poultry through the protection zone,, except for transit on main roads and railway;

- ban of trade in poultry and fertilized eggs from the holding at which they are kept, unless otherwise permitted by the veterinary inspector;
- ban of exporting or distributing of the used straw and manure without an approval;
- ban of organising fairs, exhibition competitions and markets, or any other, similar gathering for poultry and birds;

Measures for the protection zone remain in force at least 21 days after the disinfection has been performed at the contaminated holding. After the measures have been implemented, the protection zone becomes a part of the endangered area.

The following measures are taken in the surveillance zone:

- list of all holdings with poultry within the surveillance zone;
- control of poultry and fertilised eggs trade in the surveillance zone
- ban of trade in poultry meat outside the endangered area in the first 15 days, except for direct transport to the slaughterhouse outside the surveillance zone that has been approved of by the Ministry. This poultry meat must have a certificate of health according to the special regulation that define the terms of animal health in the aspect of the control of fresh poultry meat intended for the market;
- ban of trade in fertilised eggs outside the surveillance zone, except to the incubation station approved of by the Ministry. Before the dispatching, the eggs and their packaging must be disinfected;
- ban of exporting or distributing of the used straw and manure outside the surveillance zone;
- ban of organising fairs, exhibition competitions and markets, or any other, similar gathering for poultry and birds;
- ban of poultry transport, except for transit on main roads or railway.

Measures for the surveillance zone remain in force at least 30 days after the disinfection has been performed at the contaminated holding.

FISH AND MOLLUSC DISEASE

Measures for suppressing and eradicating fish diseases are proscribed by the Rulebook on Suppressing and Eradicating of Trout Coenurosis (Official journal of SFRY, No. 72/91) and the Rulebook on Suppressing and Eradicating of Trout Furunculosis (Official journal of SFRY, No. 72/91).

The following measures will be taken at the trout breeding farm that has been confirmed for coenurosis:

- ban of catching the trout and transferring them from one rearing farm to another, or to other waters;
- ban of releasing the trout from the rearing farm facilities into open water;
- ban of issuing the health certificate for the animals;
- safe disposal of gravely ill and dead trout;
- ban of entry or restriction of entry to third parties and visitors;

- diagnostic testing of the trout in the water upstream and downstream from the rearing farm;
- mechanical cleaning of the trout rearing farm, of the gates, canals and of the equipment, and a disinfection with an appropriate disinfectant.

If all the proscribed measures of cleaning and disinfection have been undertaken and if the clinical picture and laboratory test results of the newly populated trout are negative, the contaminated trout rearing farm is considered to be free of coenurosis.

The following measures are proscribed at the trout breeding farm that has been confirmed or is suspected for furunculosis:

- ban of catching the trout and transferring them from that rearing farm to another, or to other waters;
- ban of releasing the trout from the rearing farm facilities into open water;
- ban of issuing the health certificate for the animals;
- safe disposal of gravely ill and dead trout;
- ban of entry or restriction of entry to third parties and visitors;
- applying appropriate medical drugs;
- disinfection of roe after spawning with an appropriate disinfectant;
- mechanical cleaning of the trout rearing farm, of the gates, canals and of the equipment, and their disinfection.

The contaminated trout rearing farm is considered free of furunculosis if all the proscribed measures have been taken and if at least 3 weeks have passed since.

The Veterinary Directorate is in the process of preparing a regulation that shall be in alignment with the provisions of the Directive 2006/88/EC that refers to the terms of animal health in aquaculture and their products, as well as to the prevention and control of some aquatic animal diseases. Related to this, at the premises of the Veterinary Directorate an expert mission was organised by TAIEX in October 2010, as assistance in drafting this regulation.

BLUE TONGUE DISEASE

Measures for suppressing and eradicating the blue tongue disease are proscribed in the Rulebook on Early Detection, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Contagious Blue Tongue Disease and their Implementation (Official Gazette of RS No. 18/2009).

The Following Measures are Taken in Case of a Suspected Case of Blue Tongue:

- list of all holdings keeping or breeding susceptible animal species, list of all susceptible animal at the holding, as well as the list of dead and infected animals and those suspected of having been contaminated;
- list of locations at and around the holding at which a suspicion has been established, and which may be potential habitat of vectors;

- epizootiological investigation;
- inspection of the holding, with clinical examination of the animals and the pathoanatomical examination of the dead animals, and laboratory tests to confirm the presence of the disease;
- ban of transfer of susceptible animal species from the holding;
- confining of susceptible animals in the facilities when possible, in the period of vector activity;
- treating the animals, facilities and the environment where they are kept, as well as treating the vehicles for animal transport with an insecticide approved for that purpose, taking into consideration the stability of the insecticide and the weather conditions;
- safe disposal of animal carcasses.

The Following Measures are Taken in Case of a Confirmed Case of Blue Tongue:

- immediate stamping out of all susceptible animals at the holding, in a way that prevents the spreading of the blue tongue disease;
- safe disposal of dead and stamped out animals;
- measures taken in case of suspected occurrence of the disease are taken at other holdings in a 20 km radius around the contaminated holding;
- vaccination according with the special vaccination programme;
- epizootiological holding;

Ways of Establishing the Borders of the Protection and Surveillance zone

Once the diagnostic testing results confirm the presence of the blue tongue disease, borders of the protection and surveillance zone are set, based on geographic, administrative, environmental and epizootiological factors.

The protection zone is part of the territory of the Republic of Serbia, with a radius of at least 100 km from the holding that has been confirmed to the blue tongue disease.

The surveillance zone is part of the territory of the Republic of Serbia, with a radius of at least 50 km from the protection zone border, in which there has been no vaccination campaigns in the previous 12 months.

If the protection and surveillance zone is on the border with a neighbouring country, the minister determine the borders of the protection and surveillance zone in cooperation with the competent authority of that neighbouring country.

Measures in the Restricted Area:

- urgent listing registering of all holdings keeping susceptible animal species;
- epizootiological investigation based on monitoring:
 - sentinel animal groups, consisting of cattle or, if they are unavailable, of other ruminants;
 - vector population;

- ban of trade and movement for susceptible animals outside the restricted zone.

Defining the Zone that is Seasonally Free of the Blue Tongue Disease

With the goal of defining of a geographic area of epizootiological significance, which is seasonally free of the blue tongue disease and seasonally free of vectors, the Ministry applies general, special and additional criteria.

The general criteria are:

- establishing the monitoring program and the program of monitoring the blue tongue disease;
- identifying the annual periods when the vectors are inactive, taking into consideration species of *Culicoides* vectors that have been proven, or are suspected of being, main vectors in the geographic area of epizootiological significance;
- existing data for the current and the previous year and a possibility of standardising the monitoring data.

The special criteria are:

- absence of circulation of the virus, causative agent of the blue tongue disease, within the geographic area of epizootiological significance, according to the blue tongue disease monitoring program, or other proof indicating that the circulation of the virus, causative agent of the blue tongue disease has been stopped.
- cessation of vector activity and potential vector activity, as concluded by the epizootiological surveillance, as part of the blue tongue disease monitoring program
- captured species of *Culicoides* that have been proven or are suspected of being vectors of the serotype present in the geographic area of epizootiological significance, in a quantity below the permitted minimum for vectors that have been collected, which is defined for the given geographic area of epizootiological significance. In absence of solid evidence that would support the set permitted maximum, the absolute absence of *Culicoides imicola* and less than 5 pairs of *Culicoides* per trap must be used.

Additional criteria are temperature conditions that affect the vector behaviour in the geographic area of epizootiological significance. Temperature limit values are defined on account of the behaviour of those species of *Culicoides* that have been proven or are suspected of being vectors of the serotype present in the geographic area of epizootiological significance.

TSE (TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES)

Decree on Taking Measures to Prevent the Import of Contagious Animal Disease Transmissible Spongiform Encephalopathy to the Republic of Serbia (Official Gazette of RS, No. 8/2009).

Considering the fact that not a single case of TSE has been registered in the Republic of Serbia, import of the following is banned with the aim of preventing the import of this contagious disease to the country:

- 1) cattle, except in cases when their country, or region of origin is:
 - a) with an insignificant level of BSE risk, for cattle:
 - born and continuously bred in a country, or a region with an insignificant level of BSE risk,
 - that have been marked by applying a permanent identification system that enables the identification of their movement and origin to the mother and the herd of origin,
 - that are not clinically suspect of BSE,
 - that were not raised in their first year with BSE positive animals, and those that have been confirmed after a control not to have been fed with the same, potentially contaminated animal feed in this period,
 - that were not born in the same herd as the BSE positive animals in a period from one year before and one year after a BSE positive animal has been born – in case a conclusion cannot be made based on the control mentioned,
 - that were born after the introduction and implementation of a temporary ban on feeding the ruminants with meat-and-bone meal and greaves originating from ruminants, and after the birth of the last autochthonous case of a BSE positive animal after this feeding ban has been implemented – in case the consignment originates from a country that had an autochthonous case of a BSE positive animal;
 - b) with a controlled BSE risk, for cattle:
 - that have been marked by applying a permanent identification system that enables the identification of their movement and origin to the mother and the herd of origin,
 - that are not clinically BSE suspected animals,
 - that were not raised in their first year with BSE positive animals, and those that have been confirmed after a control not to have been fed with the same, potentially contaminated animal feed in this period,
 - that were not born in the same herd as the BSE positive animals in a period from one year before and one year after a BSE positive animal has been born – in case a conclusion cannot be made based on the control mentioned
 - that were born after the introduction and implementation of a temporary ban on feeding the ruminants with meat-and-bone meal and greaves originating from ruminants, and after the birth of the last autochthonous case of a BSE positive animal after this feeding ban has been implemented;
 - c) with an undefined BSE risk, for cattle:

- that have been marked by applying a permanent identification system that enables the identification of their movement and origin to the mother and the herd of origin,
- that are not clinically BSE suspected animals,
- that were not raised in their first year with BSE positive animals, and those that have been confirmed after a control not to have been fed with the same, potentially contaminated animal feed in this period,
- that were not born in the same herd as the BSE positive animals in a period from one year before and one year after a BSE positive animal has been born – in case a conclusion cannot be made based on the control mentioned,
- that were born after the introduction and implementation of a temporary ban on feeding the ruminants with meat-and-bone meal and greaves originating from ruminants, and after the birth of the last autochthonous case of a BSE positive animal after this feeding ban has been implemented;

If these animals are imported exclusively for slaughter, they may be slaughtered only in a facility that has been registered for the slaughter of imported animals.

2) sheep and goats, except in the following cases:

- a) sheep and goats that were born and continuously bred at a farm that never had a single case of sheep scrapie diagnosed, and with breeding sheep and goats – those that have been continuously from birth, or in the last three years bred at a farm that fulfils the following conditions for the last three years:
 - that is under continuous veterinary control,
 - that has not been diagnosed with a single case of sheep scrapie,
 - at which all dead and killed animals older than 18 months have been tested for sheep scrapie according to the World Organisation for Animal Health Code (OIE),
 - at which the animals are marked by applying a permanent identification system that enables the identification of their movement and origin to the mother and the herd of origin,
 - which imports sheep and goats from the farms that meet requirements from this subclause, except for the sheep with APP/APP prion protein genotype;
- b) sheep and goats from a farm that didn't have a single case of sheep scrapie diagnosed in the previous 6 months - in case of the sheep with APP/APP prion protein genotype.

If these animals are imported exclusively for slaughter, they may be slaughtered only in a facility that has been registered for the slaughter of imported animals.

3) semen and fertilised ova of sheep, goats and cattle, except in case of:

- a) semen and fertilised ova of sheep and goats originating from animals that have been continuously from birth, or in the last three years bred at a farm that fulfils the following conditions in the last three years:
 - that is under continuous veterinary control,
 - that has not been diagnosed with a single case of sheep scrapie,
 - at which all dead and killed animals older than 18 months have been tested for sheep scrapie according to the proscribed OIE Code,
 - at which the animals are marked by applying a permanent identification system that enables the identification of their movement and origin to the mother and the herd of origin,
 - which only imports sheep and goats from the farms that meet requirements from this subclause, except for the sheep with APP/APP prion protein genotype;
 - b) ram semen collected from males that are with APP/APP prion protein genotype and fertilised ova of sheep that originate from an ewe with APP/APP prion protein genotype;
 - c) cattle semen and fertilised ova, in case the semen and the fertilised ova collected in vivo and accordance with the recommendations of the International Embryo Transfer Society and OIE.
- 4) food of the ruminant origin from the countries, or regions with an insignificant and controlled BSE risk (meat, hatched meat – minced, diced, prepared for shaping, minced and shaped), meat products, offal – including blood, melted fat, solid residue with protein content from the melted fatty tissue (greaves), gelatine, processed (salted, dried, bleached) stomachs, intestines and bladder, except if they originate from countries, or regions:
- a) with an insignificant BSE risk
 - if the food from the consignment originates from the cattle, sheep and goats that were born, continuously bred and slaughtered at the slaughtering facility in a country, or a region with an insignificant BSE risk and whose meat and all accompanying parts have been pronounced fit for human consumption after inspection,
 - in case the country, or region, have been diagnosed with an autochthonous case of BSE, if the food from the consignment:
 - originates from cattle, sheep or goats that were born after the introduction and implementation of a ban on feeding the ruminants with meat-and-bone meal and greaves originating from ruminants,
 - does not contain and does not originate from SRM and MDM of cattle, sheep or goat bones.
 - b) with a controlled BSE risk
 - if the food from the consignment:
- originates from cattle, sheep or goats slaughtered in an animal slaughtering facility that were not narcotised by the introduction of gas into the cranial cavity or killed by that same method, nor were they

shocked by the destruction of the CNS tissue with a long rod shaped instrument that was introduced into the cranial cavity and whose meat and all accompanying parts have been pronounced fit for human consumption after inspection.

- does not contain and does not originate from SRM and MDM deriving from cattle, sheep or goat bones.
- c) if the food in the consignment from has been made from stomachs, intestines and bladders deriving from a country, or a region with an insignificant BSE risk level, and:
 - if the stomachs, intestines and bladders originate from the cattle, sheep and goats that were born, continuously bred and slaughtered at the slaughtering facility in a country, or a region with an insignificant BSE risk and whose meat and all accompanying parts have been inspected before and after slaughtering and pronounced fit for human consumption after inspection,
 - in case that in the country, or a region with a low or insignificant BSE risk stomachs an autochthonous case of BSE has been diagnosed – if stomachs, intestines and bladders originate from animals that have been born after the introduction and implementation of ban on feeding the ruminants with meat-and-bone meal and greaves originating from ruminants.
- 5) food originating from ruminants from countries, or regions with undefined BSE risk level, except in cases of consignment of:
 - meat, hatched meat (minced, diced, prepared for shaping, minced and shaped) and meat products, if the food from the consignment derives from cattle, sheep and goats that were not fed with meat-and-bone meal and greaves originating from ruminants,
 - were slaughtered in an animal slaughtering facility, and whose meat and all accompanying parts have been pronounced fit for human consumption after inspection
 - were not narcotised by the introduction of gas into the cranial cavity, nor were they shocked by the destruction of the CNS tissue with a long rod shaped instrument that was introduced into the cranial cavity, or killed by that same method;
 - does not contain and does not originate from SRM and MDM deriving from cattle, sheep or goat bones, or nerve tissue, lymph node tissue which is visible during the deboning process;
 - processed stomachs, intestines and bladders, if they have been produced from stomachs, intestines and bladders originating from a country, or a region with an insignificant BSE risk:
 - if the stomachs, intestines and bladders originate from the cattle, sheep and goats that were born, continuously bred and slaughtered at the slaughtering facility in a country, or a region with an insignificant BSE risk and whose meat and all accompanying parts have been inspected before and after slaughtering and pronounced fit for human consumption after inspection,

- in case that in the country, or a region with a low or insignificant BSE risk stomachs an autochthonous case of BSE has been diagnosed – if stomachs, intestines and bladders originate from animals that have been born after the introduction and implementation of ban on feeding the ruminants with meat-and-bone meal and greaves originating from ruminants.
- 6) food of animal origin with content of ruminant origin, except in cases of consignments that have content of ruminant origin that meets the requirements of this Decree, if the material is from the cattle coming from countries, or regions with undefined BSE risk level,; in additions to the terms of this Decree, the material must meet the following conditions:
 - a) to originate from animals that have been born 8 years after the introduction of a temporary ban of feeding ruminants with proteins of mammal origin;
 - b) to originate from animals that were born, bred and kept in a herd that didn't have a single case of a BSE positive animal diagnosed, for which there is a certificate.
 - 7) animals belonging to the Cervidae family, as well as food originating from these animals, except in case of consignments from countries, or regions with insignificant controlled, or undefined BSE risk, in case the consignment fulfils the following conditions:
 - a) the animals from the consignment must be from:
 - a herd that had no suspected or confirmed presence of Chronic wasting disease (in further text: CWD) - in case of farm-bred animals;
 - from a zone where there was no suspected or confirmed presence of CWD – in case of wild animals;
 - b) the food of animal origin may not derive, or contain offal and spinal cord, and in case of:
 - farm-bred Cervidae – it must originate exclusively from the meat of animals that have been confirmed to have CWD by pathohistological, immunohistochemical or some other OIE Code recommended method,
 - wild Cervidae - it must originate exclusively from the meat of animals that have been confirmed to have CWD by pathohistological, immunohistochemical or some other OIE Code recommended method, and it may not originate from animals that are from zones that were suspected or diagnosed with CWD in the previous 3 years
 - 8) mechanically deboned meat (MDM);
 - 9) waste of animal origin, including bones, that are not intended for human consumption and categorised into Category 1, 2 and 3, in accordance with the special regulation, except in case when the consignment originates from a country, or a region with an insignificant and controlled BSE risk level for consignments of Category 3 waste of animal origin, if the consignment does not contain waste of ruminant origin.
 - 10) products made of waste of animal origin (beef lard and its derivatives, blood products, bone products, including bone meal, calcium diphosphate and calcium triphosphate, gelatine, processed animal protein including meat meal, meat-and-

- bone meal, skin, blood and liver meal, fish meal and greaves, except in case when the consignment is from a country, or a region with an insignificant and controlled BSE risk level for consignments of Category 3 waste of animal origin, if the consignment does not contain waste of ruminant origin, and in case:
- a) beef lard – and if containing insoluble impurities less than 0.15% of its weight, or in case of beef lard derivatives – and if they were made of lard with identical characteristics;
 - b) bone products, including bone meal, calcium diphosphate and calcium triphosphate – in case there are no traces of proteins and fats.
- 11) animal feed, except for pet food, that contains products listed in the previous clause, except in case the consignment is from a country, or a region with an insignificant and controlled BSE risk level for consignments of animal feed, except for pet food, in case it contains products made of Category 3 waste of animal origin, and does not contain ruminant origin proteins.
 - 12) pet food, except in case the consignment is from a country, or a region with an insignificant and controlled, or unidentified BSE risk level for consignments of pet food in original packaging, which contains products made of Category 3 waste of animal origin, if the waste originates from animals that were not narcotised by the introduction of gas into the cranial cavity or killed by that same method, nor were they shocked by the destruction of the CNS tissue with a long rod shaped instrument that was introduced into the cranial cavity, and that do not contain or derive from SRM and MDM from beef, sheep or goat bones.
 - 13) Specific Risk Material (SRM), as well as food of cattle, sheep and goat origin that contains SRM, except in cases of a consignment of SRM for laboratory diagnostic, education and scientific research needs, from a country, or a region with an insignificant and controlled BSE risk level.
 - 14) cattle born and bred on the territory of UK until August 1, 1996;
 - 15) last offspring of female cattle infected with TCE, and sheep and goats that had a confirmed presence of BSE, that was born in the course of the previous 2 years, or during the period following the first clinical symptoms of the disease.

All the listed consignments, as well as consignments of milk, milk, skin gelatine and collagen products, deriving from the skins must originate from healthy animals. The import of consignments may be from countries, or regions with an insignificant and controlled BSE risk level that have signed an agreement on recognition of the International Veterinary Certificate with the Ministry.

Pursuant to the Decree on taking measures for prevention of occurrence, detection, prevention of spreading, elimination and eradication of transmissible spongiform encephalopathy (the “RS Official Gazette” no. 17/06, 110/06, 52/07 and 41/10), is prescribed that in the animal keeping and breeding facilities, as well as in facilities for animal slaughtering, meat cutting and production of food of animal origin, the animal carcasses and animal waste are categorised in 3 categories as following:

- a) first category:
 - trunk and all animal body parts, including the skin with sub dermal tissue; suspected animals, or those that have been

confirmed for TSE, animal killed according to the TSE eradication programme, pets, zoo and circus animals, animals used for experiments, as well as wild animals in case of a suspected or a confirmed transmissible disease that can be transmitted from animals to humans;

- SRM and ruminant carcasses,
- food and products of animal origin deriving from animals that had substances and medical drugs applied to them which are not permitted in veterinary medicine, or if they contain harmful matter from the environment in a quantity bigger than proscribed,
- material of animal origin collected during pre-treatment and treatment of waste water in facilities for slaughter of cattle, sheep and goats, in facilities for collecting, processing and destroying of first category material, and other facilities where SRM is eliminated, including the material collected from waste water grid, mix of grease and oil, sludge, as well as material from the drains,
- ruminant blood,
- mixture of animal origin materials from the first category with the material from the second and the third category,
- waste from the food in international transit;

b) second category:

- manure and the content of the digestive tract,
- material of animal origin collected during pre-treatment and treatment of waste water in facilities for animals slaughter, except for those used for slaughter of cattle, sheep and goats, in facilities for meat cutting and processing, facilities where SRM is eliminated, in facilities for collecting, processing and storing of second and third category material including the material collected from waste water grid, mix of grease and oil, sludge, as well as material from the drains,
- food and products of animal origin that contain residues of veterinary drugs in a quantity that is bigger than permitted,
- food and products of animal origin that are intended for, or are already placed on the market, which do not belong to the first category material as they do not meet the requirement set by regulations for the placement on the market of food and the products of animal origin,
- animal carcasses, that died or were killed for the reasons of suppressing and eradicating transmissible diseases,
- animal parts or animals that do not belong to the first category material and are from the facilities for animal slaughter that are suspected, or confirmed to a transmissible animal and human disease,

- a mixture of second category material with the third category material,
 - other material of animal origin, except for the material of the first category and material of the third category;
- c) third category:
- parts of slaughtered animals that may be used for human consumptions, but are not intended from human consumption for commercial reasons,
 - parts of the animal trunk that have been discarded as useless for human consumption and that have not been found positive to a transmissible animal or human disease, that derive from animals that are fit for human consumption;
 - blood of animals, except for ruminant blood, that have been slaughtered in an animal slaughtering facility and that have been approved after the veterinary-sanitary control,
 - skin, hoofs, hooves, horns, swine bristles and feathers of animals that have been slaughtered in an animal slaughtering facility and that have been approved after the veterinary-sanitary control,
 - material of animal origin that was a by product in the production of food of animal origin – food that is entirely, or partially of animal origin and has not been placed on the market for commercial reasons, because of production flaws or faulty packaging, and is not a human and animal health hazard,
 - raw milk from animals that are not showing clinical signs of a transmissible human or animal disease,
 - material of animal origin from a hatchery, if it originates from animals that are not showing clinical signs of a transmissible human or animal disease,
 - material of animal origin from facilities for processing fish meat and for producing food from fish meat.
 - broken eggs, egg shells, unhatched eggs and animal waste from incubators, if they originate from poultry that is not showing clinical signs of a transmissible human or animal disease, as well as broken eggs and egg shells from the processing facilities,
 - skin, hoofs, hooves, horns, swine bristles, feathers wool and fur of animals that have not shown clinical signs of a transmissible human or animal disease.

In the facilities for slaughtering cattle, sheep and goats, as well as in the facilities for cutting and processing the meat of cattle, sheep and goats, SRM is collected in vessels marked with "SRM" in red letters, or in red vessels marked with "SRM" in black letters.

Separate containers should be used for collecting and storing of animal carcasses and animal waste, depending on their category.

Containers for collecting the first category material must be marked with a 10-15 cm wide red ring and with the text: “Category 1” in red letters.

Containers for collecting the second category material must be marked with a 10-15 cm wide yellow ring and with the text: “Category 2” in yellow letters.

Containers for collecting the third category material must be marked with a 10-15 cm wide green ring and with the text: “Category 3” in green letters.

During the processing of the first, second and third category material in animal pound facilities:

- a) brim length of individual pieces of material of animal origin that has been diced in a grinder may not be more than 50m,

- b) after dicing, the material of animal origin is heated in a destructor to a temperature that achieves the heating of the inside parts of the pieces to a minimum temperature of 133°C that is maintained continuously for at least 20 minutes, at pressure of 3 bars,

- c) the processing is performed in a continuous or a discontinuous system.

Instruments for monitoring and registering the temperature, pressure and duration of thermal treatment must be installed on the processing line from clause a) and the logs for these instruments must be kept for 3 years.

Safe destruction of the first category material and the meat-and-bone meal and bone meal derived from the processing of the first category material is performed by incineration in furnaces, at a temperature of 850°C, and the temperature logs must be kept for 3 years.

Second and third category material and the meat-and-bone meal and bone meal derived from the processing of the second and third category material may be used as pet food.

Facilities for keeping and breeding of animals, slaughtering of animals, dicing of meat and production of food of animal origin keep logs on quantities of material of the first, second and third category.

Facilities for collecting and processing of material of the first, second and third category keep logs on quantities of the received material by category, as well as logs on quantities of meat-and-bone meal and bone meal in the production process and in the turnover.

Facilities for producing pet food keep logs on quantities of meat-and-bone meal and bone meal in the pet food production process, as well as on pet food volume in the turnover.

Facilities for the destruction of the first category material, and of meat-and-bone meal and bone meal, keep logs on quantities and categories of the destroyed material.

The rules on establishing measures for early detection and diagnosis of infectious disease transmissible spongiform encephalopathy, the manner of implementation of such measures, as well as measures for the prevention of spreading, elimination and eradication of this infectious disease (the “RS Official Gazette” no. 96/10) prescribe measures for early mere detection and diagnosis of infectious disease transmissible spongiform encephalopathy, the manner of implementation of such measures, as well as measures for the prevention of spreading, elimination and eradication of this infectious disease.

Measures for early detection and diagnosis TSE

For the purpose of measures for early detection and diagnosis of TSE, it is necessary to conduct monitoring of TSE on cattle, sheep and goats and, as needed, other categories and species of animals.

The monitoring involves active control and is based on diagnostic testing of a sampled part of the brain.

Monitoring of cattle is based on diagnostic testing of autochthon cattle, imported cattle and offspring of imported mother, i.e. cattle that were slaughtered for human consumption and cattle that are not intended for human consumption. Cattle slaughtered for human consumption include cattle:

- 1) older than 24 months, as follows: (1) that were subject to special emergency slaughtering, (2) in which infectious disease was confirmed and which were slaughtered in order to eliminate and uproot this disease, except for animals that do not show clinical symptoms, (3) in which infectious disease was not confirmed, but which show clinical symptoms or their general condition is such that there is a suspicion of infectious disease;
- 2) older than 30 months, as follows: (1) in which infectious disease was confirmed and which were slaughtered in order to eliminate and uproot this disease, but which do not show clinical symptoms, (2) which are healthy, whereby the number of cattle on which the testing is conducted is determined pursuant to the program of measures for animal health protection.

Diagnostic testing of cattle that are not used for human consumption concerns all animals older than 24 months that died or were killed, except for animals that died or were killed within the measures for the prevention of spreading infectious diseases that have a character of epidemics (e.g. foot and mouth disease).

In the procedure of diagnostic testing of cattle slaughtered for human consumption, carcass of the animal from which a sample was taken for diagnostic testing on BSE is marked, in accordance with a special regulation that regulates labeling of food of animal origin, upon receiving negative result of diagnostic testing which is conducted based on rapid test method. Other parts of the animal, including skin, are kept under monitoring pending the negative result of the rapid test, unless if, in accordance with the regulation that regulates byproducts of animal origin, these are destroyed as material of Category 1.

Carcass and other parts of the animal for which the result of rapid test is positive or inconclusive, as well as at least one carcass immediately before and two carcasses immediately after the carcass of that animal in the same slaughtering line shall be destroyed as material of Category 1, in accordance with the regulation that regulates byproducts of animal origin, except for materials which are, with respect to diagnostic processes, kept in laboratories.

Monitoring of sheep and goats is based on diagnostic testing:

- 1) of autochthon animals and imported animals which:
 - (1) were slaughtered for human consumption, whereby the number of sheep and goats on which the testing is conducted is determined pursuant to the program of measures,
 - (2) are not intended for human consumption, and died or were killed, except for animals that died or were killed within the measures for the prevention of spreading infectious diseases and animals from sub-clause (1) of this clause;
- 2) sheep and goats in herds in which TSE was diagnosed;
- 3) which are conducted for the purpose of genotyping.

Diagnostic testing of sheep and goats that were slaughtered for human consumption, as well as of sheep and goats not intended for human consumption, is related to animals older than 18 months or animals that have more than two permanent fangs that protruded through gums.

In the procedure of diagnostic testing of sheep and goats that were slaughtered for human consumption, carcass animals from which sample was taken for diagnostic testing on TSE shall be marked in accordance with regulation that regulates labeling of food of animal origin, upon receiving negative result of diagnostic testing based on rapid test method. Other parts of animal bodies, including skin, are kept under monitoring pending the negative result of the rapid test, unless if, in accordance with the regulation that regulates byproducts of animal origin, these are destroyed as material of Category 1. Carcass and other parts of the animal for which the result of rapid test is positive or inconclusive, shall be destroyed as material of Category 1, in accordance with regulation that regulates byproducts of animal origin, except for materials which are, with respect to diagnostic processes, kept in laboratories.

In case of occurrence of TSE in sheep, prion protein genotype shall be determined for codons 136, 154 and 171. Confirmed cases of TSE in sheep with genotype that code alanine on both alleles on codon 136, arginine on both alleles on codon 154 and arginine on both alleles on codon 171 shall be immediately reported to the European Commission, and in case of occurrence of TSE which is atypical scrapie, prion protein genotype shall be determined for codon 141. In addition to genotyping from paragraph 1 of this Article, prion protein genotype shall be determined for codons 136, 141, 154 and 171 shall also be determined on sampled sheep, whereby the sample should represent the entire sheep population.

Monitoring of other animals is based on diagnostic testing:

- 1) of cattle, regardless of their age:
 - (1) which were born or originate from herds in which a BSE case was confirmed,
 - (2) in which diet the animal food was used contrary to the provisions of these Rules;
- 2) sheep and goats:
 - (1) that are used in milk production,
 - (2) regardless of age:
 - which were born or originate from herds in which a TSE case was confirmed,
 - in which diet the animal food was used contrary to the provisions of these Rules;
- 3) other animal species.

Measures for the prevention of occurrence, spreading, elimination and eradication of TSE

For the purpose of preventing occurrence and spreading, as well as for the purpose of elimination and eradication of TSE:

- 1) animals shall be fed with animal food that does not pose risk;
- 2) during production, transport and storing animal food, as well as during feeding of individual species and categories of animals with animal food that can pose a risk, measures for minimizing such risk must be taken.

Proteins of animal origin and food that contains such proteins must not be used in animal food for bred animals. In addition to proteins of animal origin, animal food for bred animals, except for carnivores that are bred for the production of fur, the following must especially not be used:

- 1) Processed protein of animal origin;
- 2) Gelatin originated from ruminants;
- 3) blood products;
- 4) hydrolyzed protein;
- 5) dicalcium phosphate and tricalcium phosphate of animal origin.

For feeding bred animals, under certain conditions, it is possible to use the following proteins of animal origin, animal food that contains such proteins, as follows:

- (1) Milk, dairy products and colostrums,
- (2) Eggs and egg products,
- (3) Gelatin originated from non-ruminants,
- (4) Hydrolyzed protein produced from parts of the body of non-ruminants and skin of ruminants;
- 2) In the diet of bred non-ruminants, the following proteins of animal origin can be used, as well as products produced from such proteins, as follows:
 - (1) Fish flour,
 - (2) Dicalcium phosphate and tricalcium phosphate of animal origin,
 - (3) Blood products produced from non-ruminants;
- 3) In the diet of fish, blood flour produced from non-ruminants is used;

- 4) The diet of bred animals should include animal food of plant origin which contains insignificant quantity of parts of bones and animal food which contains such animal food;
- 5) In the diet of suckling ruminants fish flour should be used.
Control of animal food in terms of using proteins of animal origin and fish flour in animal diet is conducted by applying the method of standard microscopy, and the number of samples for diagnostic testing is determined in the program of measures.

Measures taken for specific risk material (SRM)

For the purpose of preventing occurrence and spreading, as well as for the purpose of elimination and eradication of TSE, the following fibers are categorized as SRM:

- 1) in cattle:
 - (1) regardless of age: tonsils and bowels of duodenum up to rectum with mesenterium,
 - (2) older than 12 months: tonsils, bowels of duodenum up to rectum with mesenterium, skull, except for lower jaw bone, including brain, eyes and spinal cord with membrane;
 - (3) older than 30 months: tonsils and bowels of duodenum up to rectum with mesenterium, skull, except for lower jaw bone, including brain, eyes and spinal cord with membrane, backbone, except for transversal and spinal stems of cervical, toracal and lumbar region, tail bone and bone of median ridge and the sacral wing, including dorsal root of ganglion;
- 2) in sheep and goats:
 - (1) regardless of age: spleen and ileum,
 - (2) older than 12 months, i.e. which developed permanent fangs: spleen, ileum, skull bones, brain, eyes, tonsils and spinal cord with membrane. Immediately upon removal, SRM shall be color marked and destroyed in accordance with regulation that regulates byproducts of animal origin.

Mechanically separated meat (MSM)

Bones or pieces with bones of cattle, sheep and goats are not used in the production of MSM

Stunning

Stunning of cattle, sheep or goats the meat of which is intended for human consumption or for production of animal food, cannot be conducted by destroying the tissue of central nervous system by using elongated rod-shaped instrument which is inserted into cranial cavity.

Separation and collection of cattle tongues

Tongues of cattle that are intended for human consumption or for production of animal food, regardless of age of cattle, shall be separated in the slaughterhouse by means of perpendicular cut rostrally from the tongue elongation of the basihyoid bone.

Separation and collection of meat from head of cattle

Meat from heads of cattle older than 12 months shall be separated and collected in the slaughterhouse, in accordance with the control system that is approved by the competent authority, for the purpose of preventing possible contamination of head meat with the tissue of central nervous system. If brain is sampled for the purpose of diagnostic testing on TSE, *foramen magnum* shall be closed immediately after the testing.

Measures applied in case of suspicion of occurrence of TSE

In case of suspicion of occurrence of TSE, it is necessary to conduct epizootiological inquiry and it is prohibited to allow movement of animals suspected of TSE until the results of clinical testing are obtained, and the suspected household shall be placed under official control. If TSE cannot be excluded as the result of clinical testing, the animal shall be slaughtered and its brain, if it is determined by the competent authority, in accordance with the law that regulates veterinary medicine, as well as other tissues shall be removed and sent for diagnostic testing. Movement of other cattle, sheep and goats from the same household shall be prohibited until test results are obtained, unless if, on the basis of epizootiological inquiry, it is determined that the animal suspected of TSE was not exposed to the infection of TSE on that household. In addition to the household on which the animal suspected of TSE is located, it is possible to place under official control other households, on the basis of epizootiological inquiry.

Milk and dairy products of sheep and goats on the household that is under official control and on which sheep and goats were present from the date when suspicion on TSE arise, until positive test results are obtained, can be used only on that household.

Carcass and other parts of body of animal suspected of TSE shall be placed under official control until positive results of diagnostic testing are obtained, or shall be destroyed in accordance with regulation that regulates byproducts of animal origin.

Measures after official confirmation of TSE

When TSE is officially confirmed, the following measures must be implemented as soon as possible:

- 1) Carcass and other parts of animal body shall be destroyed in accordance with regulation that regulates byproducts of animal origin, except for materials which, in accordance with these Rules, are kept for the record;
- 2) Epizootiological inquiry;

- 3) All animals and products that pose risk, and which are determined by means of epizootiological inquiry, shall be slaughtered, and destroyed in accordance with regulation that regulates byproducts of animal origin.

In addition to these measures, the TSE infected household shall be placed under official control, and movement of animals susceptible to TSE and products of animal origin produced from such animals to or from the household can be conducted only with the approval of veterinary inspector, and in such a manner as to ensure traceability and identification of such animals and products of animal origin. If on the basis of epizootiological inquiry it is determined that the household where the sick animal was located at the time of official confirmation of TSE is not the household where that animal was exposed to infection from TSE, both households or only the household where the infection occurred can be placed under official control. In order to prevent occurrence and spreading, as well as for the purpose of eliminating and eradication of TSE, the last offspring of female cattle infected with TSE, i.e. sheep and goats with confirmed BSE, and which were born during the period of two years before the occurrence of the first clinical symptoms of the disease, as well as during period after the occurrence of clinical symptoms of the disease, cannot be marketed.

The following is to be identified by means of epizootiological inquiry:

1) in case of cattle:

- (1) presence of other ruminants on the household on which the animal with officially confirmed disease is located,
- (2) offspring born in the period of two years before or after clinical occurrence of the disease, when the disease is officially confirmed in female,
- (3) presence of animals from cohort where disease was confirmed,
- (4) possible sources of infection,
- (5) other susceptible animals on infected household, i.e. animals on other households which could have been infected with the TSE agent, or which were fed with the same animal food or were exposed to the source of infection,
- (6) movement of potentially contaminated animal food, as well as materials, or methods through which the TSE agent could be transferred to or from the infected household;

2) in case of sheep and goats:

- (1) presence of other ruminants on the infected household,
- (2) if possible, who are the parents, and for females, all embryos, ova and the last offspring of the female in which the disease was officially confirmed,
- (3) presence of other sheep and goats on the infected household,
- (4) possible sources of infection and other households where embryos, ova or animals:
 - could have been infected with TSE,
 - were exposed to the source of infection,
 - were fed with the same animal food;

- (5) Movement of potentially contaminated animal food, as well as materials, or methods through which the TSE agent could be transferred to or from the infected household.

When BSE in cattle is officially confirmed, exceptionally, it can be decided to:

- 1) not slaughter and not destroy all animals from the cohort, if it is proved that such animal was not fed with the same food as the infected animal;
- 2) postpone the slaughtering or destroying of animals from the cohort until the end of their productive life with respect to bulls that are continuously kept in the centre for animal reproduction and artificial insemination and the carcass of which shall be destroyed in accordance with regulation that regulates byproducts of animal origin.

When, after the testing, TSE in sheep and goats is officially confirmed, and BSE cannot be excluded, the measures include at least destroying embryos, ova and animals, i.e. products that were identified by means of epizootiological inquiry, as well as milk and dairy products produced from such animals that were on the household in the period from the date of official confirmation that BSE cannot be excluded until the day of their slaughter.

After implemented measures, the household shall be subject to the following measures:

- 1) Only the following animals can be introduced into the household:
 - (1) rams of genotype ARR/ARR,
 - (2) sheep – females that carry at least one allele ARR and none allele VRQ,
 - (3) goats, provided:
 - on the household there is no a single sheep for breeding, except those with genotype ARR/ARR or ARR and none with allele VRQ,
 - after depopulation in all facilities for animals on the household were cleaned and disinfected;
- 2) in breeding, only sperm of rams with genotypes ARR/ARR can be used and embryos that carry at least one allele ARR and none allele VRQ;
- 3) the following animals from the household can be marketed:
 - (1) ARR/ARR sheep without limitation;
 - (2) sheep that carry only one allele ARR, and that only directly for slaughtering for human consumption or destruction, except:
 - sheep – females that carry one allele ARR and none allele VRQ, which can be transferred to other households that are under restrictions because of the implemented measures,
 - lambs and kids, which can be transferred to other households for the purpose of fattening for slaughter, provided on that other household there are no other sheep or goats, except those that are fattened for slaughter, and that that other household such live sheep or goats are transferred only for the purpose of slaughter in the territory of the Republic of Serbia,
 - (3) goats, provided more intensive monitoring of TSE is conducted on the household, including testing of all goats older than 18 months, as follows:
 - slaughtered for human consumption at the end of their productive life, or

- died or slaughtered on the household, from those that are not intended for human consumption, (4) lambs and kids younger than three months, which can be sent directly from the household for slaughter for human consumption.

The said measures shall be implemented on the household continuously, as well as in the following period of two years from:

- 1) the day of gaining ARR/ARR status for all sheep on the household, or
- 2) the last day of holding a sheep or goat on the household, or
- 3) day when more intensive monitoring of TSE started, or
- 4) day when all breeding rams on the household are of ARR/ARR genotype and all breeding sheep carry at least one allele ARR and none allele VRQ and if the result of diagnostic testing on TSE in animals older than 18 months, during that two year period is negative, as follows:

- (1) for sheep slaughtered for human consumption at the end of their productive life,
- (2) all sheep not intended for human consumption, and which died or were slaughtered on the household.

When, after the testing, scrapie is officially confirmed in sheep and goats, measures shall be implemented in one of the following ways:

- 1) slaughtering and destroying of all embryos, ova and animals, which were identified by means of epizootiological inquiry, and when the case of typical scrapie is officially confirmed, milk and dairy products produced from animals that were on the household in the period from the day of official confirmation of the case of typical scrapie until the day of their destruction shall not be used for the food of ruminants, except for food of ruminants on that household, and can be marketed as animal food intended for the feeding of non-ruminants in the territory of the Republic of Serbia, provided:

- (1) the document attached to the shipment of milk and dairy products, as well as their packaging, is clearly marked with words: „CANNOT BE USED FOR THE FEEDING OF RUMINANTS”,
- (2) THE animal food that contains such products is not used or stored on the household where ruminants are bred,
- (3) bulk animal food that contains such products is not transported in vehicles used for the transport of food for ruminants at the same time, and if such vehicles are subsequently used for the transport of food for ruminants, such vehicles shall be cleaned in accordance with the approved procedure, in order to prevent cross-contamination, or

- 2) slaughtering and destroying of all embryos, ova and animals, which were identified by means of epizootiological inquiry, except:

- (1) breeding rams of genotype ARR/ARR,
- (2) breeding sheep that carry at least one allele ARR and none allele VRQ and, if breeding sheep are gravid in the period of testing, lambs born after that, if their genotype meets such conditions,
- (3) sheep that carry at least one allele ARR which are intended solely for slaughtering,

- (4) sheep and goats younger than months which are intended solely for slaughtering.

When the officially confirmed case on the household is atypical scrapie, during two breeding years after identifying the last case of TSE, in addition to the specified measures, the following measures can also be implemented:

- 1) identification of all sheep and goats on the household;
- 2) more intensive monitoring of the household on TSE, including testing of all sheep and goats that were slaughtered for human consumption that died or were slaughtered on the household, older than 18 months;
- 3) embryos, ova and live sheep and goats from the household can be marketed in the territory of the Republic of Serbia.

Diagnostic procedures

Collection of samples for diagnostic testing is conducted by applying methods and protocols in accordance with Rules on standards for diagnostic testing and vaccines for land animals of the World Organization for Animal Health. If the Rules of OIE does not contain appropriate methods and protocols, methods and protocols of the Reference Laboratory of the European Union for TSE shall be applied.

Diagnostic procedures for cattle

Samples taken from cattle, in which TSE cannot be excluded, shall be tested immediately in order to confirm the disease, by applying at least one of the following confirmation methods in accordance with the protocol of the Rules of OIE, as follows:

- 1) immunohistochemical method (IHH);
- 2) SAF-immunoblotting or alternative method, in accordance with the Rules of OIE;
- 3) proving characteristic fibrils by means of electronic microscopy;
- 4) pathohistological testing;
- 5) combination of rapid tests.

Samples taken from cattle during the implementation of monitoring, shall be tested by means of rapid test.

Diagnostic procedures for sheep and goats

Samples taken from sheep and goats in which TSE cannot be excluded, shall be tested immediately in order to confirm the disease, by applying at least one of the following confirmation methods in accordance with the protocol of the Rules of OIE, as follows:

- 1) immunohistochemical method (IHH);
- 2) SAF-immunoblotting or alternative method, in accordance with the Rules of OIE;
- 3) proving characteristic fibrils by means of electronic microscopy;
- 4) pathohistological testing.

Samples taken from sheep and goats during the implementation of monitoring, shall be tested by means of rapid test, by using appropriate methods and protocols, in accordance with the instructions of the Reference Laboratory of the EU, in order to identify all known strains of TSE.

Pursuant to the Decree on taking measures for prevention of occurrence, detection, prevention of spreading, elimination and eradication of transmissible spongiform encephalopathy (the “RS Official Gazette” no. 17/06, 110/06, 52/07 and 41/10), in facilities for breeding and keeping of animals, cutting meat and production of foodstuffs of animal origin it is necessary to classify animal carcasses and waste of animal origin into three categories, as follows:

The rules on establishing measures for early detection and diagnosis of infectious disease transmissible spongiform encephalopathy, the manner of implementation of such measures, as well as measures for the prevention of spreading, elimination and eradication of this infectious disease (the “RS Official Gazette” no. 96/10) prescribe measures for early mere detection and diagnosis of infectious disease transmissible spongiform encephalopathy, the manner of implementation of such measures, as well as measures for the prevention of spreading, elimination and eradication of this infectious disease.

SALMONELLA

Measures for suppressing and eradicating the Salmonellosis in poultry are prescribed in the Rulebook on establishing of Measures for Early Detection, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Poultry Infection caused by specific Salmonella Serotypes((Official Gazette of RS, No. 7/2010).

According to the regulation that is in force, salmonellas are:

- salmonellas of the category 1: Salmonella enteritidis and Salmonella typhimurium, except for the cultures of vaccinatied stains;
- salmonellas of the category 2: Salmonella hadar, Salmonella virchow and Salmonella infantis;
- Salmonella gallinarium pullorum.

Suspected infection of Salmonella category 1 or 2 is present when the holding owner performs self control at the holding upon which an authorized laboratory isolated salmonella at the holding.

Infection with Salmonella category 1 or 2 is present if the infection has been confirmed by an authorized laboratory after an official control.

Breeding holdings

The farm is quarantined when an official control confirmed category 1 salmonella infection. The following may be removed from the holdings, or from the contaminated production unit at holdings with more production units:

poultry:

- for diagnostic purposes;
- for slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated;
- laying hens for stamping out and safe disposal.

non-incubated eggs:

- for processing in the egg processing facility, under the condition that they are treated in a way that guarantees that Salmonella category 1 is destroyed according to the special regulation;
- for safe disposal.

The holding is placed under quarantine when based on an official control infection by Salmonella category 2 has been confirmed. The following may be removed from the holdings, or from the contaminated production unit at holdings with more production units:

hens:

- for diagnostic purposes;
- subsequent to treatment, vaccination or other types of treatment, the purpose of movement to another, cleaned and disinfected production unit within the same holding;
- for slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated;
- for safe disposal.

non-incubated eggs:

- for processing in the egg processing facility, under the condition that they are treated in a way that guarantees that Salmonella category 2 salmonella is destroyed according to the special regulation,
- for safe disposal.

Hatching eggs in the hatchery and which derive from the breeding holding, or a production unit at the farm holding where infection by Salmonella category 1 or category 2 has been confirmed to be infected by category 1 and 2 salmonella, are safely disposed. Hatched chicks are killed and safely disposed. As an exception, hatched chicks may be moved to another, cleaned and disinfected production unit at the same holding, where they will be vaccinated or treated in another way, while the breeding holding is quarantined.

Salmonella infection is ended if:

- all hens, non-incubated eggs and chicks were removed from the facility, or the contaminated production unit affected by the infection and if infected hatching eggs have been removed from the hatcheries;
- the facilities, production units or hatcheries have been cleaned and disinfected, if deratisation was undertaken, and if the authorized laboratory has confirmed the negative results for salmonella tests (control swabs);
- a double laboratory investigation has been performed within period of two weeks in facility or in the production unit where hens were medically treated or vaccinated against Salmonella category 2. The first control is carried out after withdrawal period

Breeding holding:

If there is a suspected infection with salmonella after a self control, the hens from the breeding holding or from suspected production units are quarantined and may be removed only:

- for diagnostic purposes;
- for slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated
- for killing and safe disposal.

The holding is placed under quarantine when based on an official control infection by Salmonella category 1 has been confirmed.. The following may be removed from the removed, or from the infected production unit at holdings with more production units:

- pullets::

- for diagnostic purposes;
- for slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated;;
- for killing out and safe disposal.

- eggs:

- for processing in the egg processing facility, under the condition that they are treated in a way that guarantees that Salmonella category 1 is destroyed according to the special regulation;
- for safe disposal.

The holding is placed under quarantine when, based on an official control, infection by Salmonella 2 has been confirmed. The following may be removed from the farms, or from the holding, production unit:

- pullets:

- for diagnostic purposes;

- subsequent to medical treatment, vaccination, for the purpose of movement to the another, cleaned and disinfected production unit at the same farm.
 - for slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated;
 - for killingout and safe disposal.
- eggs:
- for processing in the egg processing facility, under the condition that they are treated in a way that guarantees that Salmonella category 2 is destroyed according to the special regulation.
 - for safe disposal.

Salmonella infection is considered to be ended if:

- all animals have been removed from the holding or the infected production unit;
- the facilities and production units have been cleaned and disinfected, if deratisation was undertaken, and when the authorized laboratory has confirmed the negative results for salmonella tests (control swab)
- a double laboratory investigation has been performed within period of two weeks in facility or production unit where animals were treated or vaccinated against Salmonella category 1 or 2.. The first control shall be carried out after the period during which, according to the instruction of the producer, adequately high immune protective response to the vaccine will be genied.

Laying hen holdings:

A *holdings* or a suspected production unit are placed under quarantined in case of a positive result of a performed self control or some other indicator shows there is a suspected category Salmonella 1 infection; hens and eggs may be removed only for diagnostic purposes until an official control of the farm has been performed.

Veterinary inspector performs an official salmonella control at the laying hen holdings during the period of exploitation.

In case of a suspected salmonella infection, the veterinary inspector performs an official control of the suspected flock and prescribes:

- that the eggs from the holding suspicious of hosting a Salmonella can not be placed on the market as table eggs but have to undergo heat tretment;
- that the eggs from the holding where infecion with *S. enteritidis* or *S. typhimurium*, has been confirmed or eggs from the holding that have not been tested for salmonella must undergo heat treatment
- that the laying hens from the holdings that have been tested for *S. enteritidis* or *S. typhimurium* and the results were positive, must be killed and disposed safely;
- the slaughtering is to be performed according to special regulations and all measures to reduce the risk of spreading of the disease must be taken.

The facility is placed under quarantine when based on an official control of the laying hens holding, Salmonella category 1 infection has been confirmed .

The following may be removed from the infected holding or production unit:
hens:

- for diagnostic purposes;
- for slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated; ;
- for safe disposal of carcasses.

- eggs:

- for processing in the egg processing facility, under the condition that they are treated in a way that guarantees that Salmonella category 1 is destroyed according to the special regulation;
- for safe disposal.
- the prescribed quarantine is repealed after the salmonella infection has been ended.
- Salmonella category 1 infection is ended if:
- the infected hens and eggs have been removed from the holding or the infected production unit;
- if cleaning and disinfection of the poultry farm or production units, premises, access, facilities, equipment and other objects which can be carriers of Salmonella has been carried out and when negative results of the presence of Salmonella (control swab) has been confirmed by the authorized laboratory. On the poultry holding and in the immediate vicinity deratisation is compulsory.

Hatchery:

The incubator or a suspected hatchery are placed under quarantine in case of a suspicion that hatching eggs placed in the incubator originate from poultry holding infected with Salmonella category 1 or 2, or that there are chickens hatched from such eggs.

Hatching eggs or one day old chickens can be removed from suspicious hatchery or incubator only for diagnostic purposes

Eggs from the hatchery marked as hatching eggs are handled identically as hatching eggs in the hatchery originated from the breeding holding or a production unit within a holding that was confirmed to be infected with Salmonella category 1 or 2, and they are safely disposed. Hatched chicks are killed and safely disposed. As an exception, hatched chicks may be moved to another, cleaned and disinfected production unit within the same holding, where they will be vaccinated or treated in another way, while the breeding holding is placed under quarantine.

The owner of the hatchery must perform the disinfection and the deratisation.

One-day chickens or hatching eggs from the hatchery or an hatchery unit that tested positive for Salmonella category 1 or 2 can not be placed on the market, except in case when hatching eggs in the hatchery are originated from the breeding holding or a production within a holding that was confirmed to be infected with Salmonella category 1 or 2, when they are safely disposed. Hatched chickens are killed and safely disposed. As an exception, hatched chickens may be moved to another, cleaned and disinfected production unit within the same holding, where they will be vaccinated or treated in another way, while the breeding farm is placed under quarantined.

Salmonella infection is ended and quarantine is repealed if:

- all infected one-day chickens and hatching eggs have been removed from the hatchery or the infected hatchery unit;
- the hatchery or the hatchery unit have been cleaned and disinfected, if deratisation was undertaken, and when the authorized laboratory has confirmed the negative results for salmonella tests (control swab)

Poultry fattening holdings:

Holding or production unit is placed under quarantine if following the examination for the presence of Salmonella on the fattening poultry holding carried out by the owner there is suspicion of the infection by Salmonella of category 1

The following may be exported from the infected holding or production unit:

- broiler chicks, for diagnostic purposes;
- broiler chicks, for slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated;
- broiler chicks, for killing and safe disposal.

In case of a suspected Salmonella category 1 infection, the authorized laboratory and the poultry owner are obliged to notify the veterinary inspector, who will perform an official control.

Once the official control of the poultry fattening holding has confirmed a Salmonella category 1 infection, all members of the flock must be killed and safely disposed, in order to reduce the risk of spreading of Salmonella with an exemption in following cases:

- broiler chicks that are sent to an authorized laboratory for diagnostic purposes;
- broiler chicks, slaughtering based on risk analysis and subsequent to approval by the Ministry that all measures had been taken to prevent spreading of the infection during transportation to the slaughtering facility and provided that slaughtered poultry is heat treated;

Salmonella infection is ended when all poultry has been removed from the holding or the production units, when cleaning and disinfection, were performed and when an authorized laboratory confirms a negative result of the salmonella test (control swabs).

After the removal of poultry and eggs from the infected holdings or production units, it is necessary to:

- perform mechanical cleaning, washing and disinfection of the production units, of the access, equipment and other objects which can be contaminated with Salmonella category 1 and/or 2 and also perform deratisation;
- incinerate the animal feed and litter that could be carriers of Salmonella 1 and/or 2 or to pack it up together with poultry manure. Animal feed may undergo a treatment that ensures the destruction of Salmonella category 1 and/or 2, provided that there is no danger of spreading of the infective agent;
- pack the manure in a location inaccessible to the poultry, disinfect it and store it for at least 3 weeks. Liquid excrements from poultry facilities or from other facilities for keeping poultry should be disinfected;
- incinerate and safely dispose infected material from the hatchery/incubator (cardboard boxes, egg trays containers and other waste) and to clean and disinfect all soiled surfaces in order to prevent the spreading of salmonella.

Protection Measures for Salmonella Gallinarum Pullorum:

The authorized laboratory and the owner of holding for all types of poultry production are obliged to immediately notify the veterinary inspector about a positive test result for salmonella gallinarum pullorum once it has been isolated and confirmed after self auto control and the official control.

The veterinary inspector must prescribe the stamping out and safe disposal of the poultry from the farm if the salmonella gallinarum pullorum infection has been confirmed.

Vaccination for salmonella gallinarum pullorum is not permitted, nor are vaccines containing a salmonella gallinarum pullorum antigen permitted for any purpose (scientific tests, test farms).

RABIES

Suppression and eradication measures for the transmissible disease rabies are proscribed by the Rulebook on Establishing the Measures for Early Detection, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Rabies infectious Disease Rabies and the manner of their Implementation (Official Gazette of RS No. 78/2009, of September 2009)

The identification of dogs, keeping records of dogs and cats, and vaccination of dogs and cats are carried out for the purpose of prevention of emerging and spreading of rabies in animals. Dogs and cats are vaccinated for rabies with an inactivated vaccine. All dogs and cats older than 3 months must be vaccinated for rabies once per year.

Animals infected with rabies, as well as animals suspected of rabies infection, must not be vaccinated and treated, except for the purposes of scientific research.

For the purpose of suppression and spreading prevention of rabies the Ministry of Agriculture, Forestry and Water Management, Veterinary Directorate may order the vaccination of susceptible animals against rabies in the protection and surveillance zone including wild animals.

In case of a suspected case of rabies, an epizootiological inspection and clinical testing of the animal is performed, in order to confirm the suspicion. If the suspicion of rabies has been confirmed, the head or the carcass of the animal is sent to an accredited laboratory for testing.

When a rabies case is confirmed, the Minister issues a Decree establishing the protection and surveillance zone. Based on this, the competent veterinary inspector defines the borders of the protection and surveillance zones directly in the field, according to the epizootiological data and geographic parameters.

The following measures are taken in the protection zone:

- separation, enclosure and isolation of animals under suspicion of rabies infection.
- ban on movements outside of enclosed areas for dogs younger than 3 months;
- keeping dogs and cats under control, by keeping cats in enclosed areas and by taking dogs for a walk on a leash and with a muzzle;
- ban or limitation on organising exhibitions, shows and other forms of public exhibiting of dogs and cats;
- vaccination of unvaccinated dogs and cats and if necessary, vaccinating other animals susceptible to rabies;
- killing out of stray dogs and cats;
- organised reduction of the fox population, and if necessary, of other wild animals in the hunting area;
- killing of rabid animals infected with rabies, of unvaccinated that have been in contact with an infected animal or are suspected to have been in contact with an infected animal;
- isolation of animals vaccinated against rabies that are suspected of having been in contact with an animal infected with rabies or an animal suspected to be infected with rabies, and their keeping in quarantine under the supervision of their owner, throughout the duration of mentioned measures
- ban of carrying out products of animal origin and objects that may spread the rabies from the outbreak;
- ban of trade and slaughter of animals suspected of rabies, sale and consumption of individual parts of these animals, milk or other products deriving from these animals, as well as their skinning;
- ban of skinning foxes.

In case of emerging of rabies in game or in hunting grounds, hunting game may be banned for a specified period of time.

During the vaccination campaign the choice of species to be vaccinated, the timeframe of the vaccination with the deadlines and the type of the vaccine to be used shall be determined .

If the period required for acquiring immunity has passed after a performed vaccination, the following animals may move freely: shepherd dogs with a grazing herd, official police and army dogs, rescue team dogs, and guide dogs for the blind.

All the mentioned measures are in place in an surveillance zone, except for the ban or limitation of exhibitions, shows and other forms of public exhibiting of dogs and cats and the killing out of stray dogs and cats.

In case of emerging of rabies , or an unfavourable epizootiological situation with foxes and other wild animals, the Ministry for Agriculture, Forestry and Water Management, Veterinary Directorate may prescribe intensified culling and an oral vaccination campaign, as well as the monitoring of foxes and other wild animals. The Ministry sets the oral vaccination program that identifies the time frame and the area in which the oral vaccination shall be undertaken, the way of distributing rabies baits, vaccination strategy, number of rabies baits and the finalisation of the vaccination, in accordance with the disease epizootiology and the geographic parameters. Hunting ground users must intensify the fox hunt and participate in the distribution of the rabies baits in accordance of the oral vaccination program.

The area or space, in which the infected animal was living, as well as the equipment that was in touch with the infected animal, must be disinfected up to the culling of the animal, and the final disinfection must be performed thereafter. Disinfection may be performed also in case of a justified suspected occurrence of rabies, before the disease has been confirmed or the suspicion is over.

Rabies is considered to be eliminated if all the prescribed measures have been taken and the final disinfection was performed and if 3 months have passed from the last confirmed case of rabies, in which period not a single case of rabies was confirmed.

Only dogs and cats with a certificate of vaccination against rabies in cats and dogs may participate in exhibitions, shows and other forms of public exhibiting of dogs and cats.

Only dogs that had their last rabies vaccine at least 15 day earlier, this being the period sufficient for building up immunity, may be used for hunting. Hunting ground users are obliged to keep records logs on dogs used for hunting in the hunting grounds.

The first general oral vaccination of wild animals in the entire country was undertaken in November and December of 2010, as a part of the IPA 2008 project, Support for the control/eradication of classical swine fever and rabies in Serbia. 1.4 million doses of the vaccine were distributed during this aerial rabies vaccine campaign.

BOVINE TUBERCULOSIS

Suppression and eradication measures for the infectious disease bovine tuberculosis are prescribed by the Rulebook on Establishing the Measures for Early Detection, Diagnostics, Prevention of Spreading, Suppression and Eradication of the Infectious Disease Bovine Tuberculosis and the manner of their Implementation, and the Way of Confirming an officially tuberculosis-free Status for holdings (Official Gazette of RS, No. 51/2009, from 14 July 2009).

Measures taken in case of a suspicion of bovine tuberculosis on holding

The following measures are taken in case of a suspicion of bovine tuberculosis:

- placing the herd under surveillance;
- separation and isolation of cattle from a herd suspected for tuberculosis;
- undertaking adequate diagnostic tests;
- ban of insemination and mating of cattle suspected of tuberculosis;
- ban of use and consignment of milk from cows originating from an infected herd, except for corresponding heat treatment, according to the special regulation ;
- ban of exporting animal feed from the holding that was, or could have been in contact with cattle suspected of tuberculosis;
- ban of common water space use;
- ban of removing manure and slurry from the holding;
- ban of introducing into a herd, or placing on the market of the animals from the herd, except for the purpose of slaughter without delay;
- ban of introducing to the holding and or placing on the market of the animals from the holding.

These measures are applied as long as the suspicion of bovine tuberculosis is ruled out.

Measures taken in case of an suspected occurrence of bovine tuberculosis on holding

When the bovine tuberculosis has been confirmed, except the above listed measures, the following measures are taken:

- separation and isolation of cattle with confirmed tuberculosis from other cattle in the herd, until they are sent to forced slaughter;
- ban of use of milk of infected cows, except as feed for animals on that holding and after it has been heat treated ;
- storing manure from the stables or other facilities used by the animals in a place that is unreachable to the farm animals from that holding;
- treatment of manure and slurry with an appropriate disinfectant, according to manufacturer's instructions and ban of use it for at least 3 weeks, except in case the manure is covered with a layer of uncontaminated manure or with earth, in which case the use of disinfectant is not necessary.

Once the tuberculosis has been confirmed in a herd, the veterinary inspector inspects the processing plant for animal by products, in order to establish that there is no hazard of

spreading of bovine TB through them.

Cattle that have been confirmed for tuberculosis are not therapeutically treated. Cattle are not vaccinated for against tuberculosis

After a bacteriological, pathological, tuberculin or molecular testing, the cattle that have been confirmed positive to tuberculosis must be slaughtered under the surveillance of a veterinary inspector, at the latest 30 days after their owner, or keeper has been informed about the test results.

This due date may be extended to a period not longer than 3 months for the cattle with a positive result to tuberculosis, but no clinical signs of the illness, if:

- it is a pregnant animal due in the following 3 months;
- slaughtering of all cattle in the herd has been ordered, for a herd that has more than 20 animals and is located in an area where slaughterhouses of appropriate capacity do not exist and when slaughter cannot be performed in 30 days.

Cattle that have been confirmed to have a positive or a suspected reaction to tuberculosis and are sent to slaughter, have the entry in their animal health certificate: “Bovine TB”.

After the slaughter of the diseased animals and before the introduction of new animals to a herd, animal keeping facilities and the equipment used with the cattle are cleaned, washed and disinfected under the surveillance of a veterinary inspector.

All vehicles and locations of animal loading are washed and disinfected after use, loading and transport of the cattle from the infected herd, as well as other objects that were in contact with infected cattle.

The disinfectants that are used and their solution concentration must be approved for use and in accordance with the special regulation.

In the infected herd from which the diseased cattle originate, the following measures are taken:

- ban of removing the cattle from the herd, except for the purpose of slaughter without delay with the approval of the veterinary inspector;
- diagnostic testing of all remaining animals from the herd;
- ban of introducing newly acquired animals into the herd until all cattle from the herd that are older than 6 weeks undergo one or more diagnostic tuberculosis

After the removal of the cattle diseased with tuberculosis, a disinfection and simultaneous intradermal tuberculin testing, and after the expiry of at least 6 weeks from the previous intradermal tuberculin testing with the bovine tuberculin that gave a positive result, it is considered that bovine tuberculosis has been eliminated from the holding.

BOVINE BRUCELLOSIS

Measures of Early Detection and Diagnosing of the Bovine Brucellosis and the manner of their Implementation

Owner or keeper of the animal immediately notifies a veterinarian or a veterinary inspector about every change in the animal health status at the holding and reports on every abortion. A cattle suspected of brucellosis is an animal that shows the brucellosis symptoms and for which the presence of brucellosis has been neither confirmed nor ruled out.

In case of establishing a suspicion to the presence of brucellosis, the veterinary inspector must immediately prescribe blood sampling and diagnostic testing, with the goal of confirming the presence or absence of brucellosis in the herd. The following measures are taken in case of a suspected case of bovine brucellosis:

- placing the herd under surveillance;
- ban of introducing into a herd, or placing on the market of the animals from the herd, except for the purpose of slaughter without delay;
- separation and isolation of cattle from a herd suspected for brucellosis;
- ban of insemination and mating of cattle suspected for brucellosis;
- ban of use of milk of cows suspected for brucellosis.

Exceptionally the veterinary inspector can approve, trade of previously castrated cattle; if suspected animals have been separated from the herd and under the condition that the castrated animals are moved to fattening herds and then sent to the slaughterhouse.

These measures are in force until the official confirmation of the bovine brucellosis has been ruled out.

Measures for the Prevention of the Spreading, for Suppression and for Eradication of Bovine brucellosis

The case of occurrence of bovine brucellosis is an occurrence of the disease in one or more animals in the herd, which has been officially confirmed. Cattle are considered to be infected with brucellosis if it had a positive reaction on at least two serological tests and whose microbiological test results of appropriate samples confirmed brucellosis. Serologic and microbiologic tests are performed in accordance with the last edition of the OIE Manual of Standards for Diagnostic Test and Vaccines.

Once the brucellosis in a herd has been officially confirmed, the veterinary inspector prescribes measures for the prevention of spreading and for suppressing of the disease at the infected holding farm as following:

- separation and isolation of the cattle that have been officially confirmed to have brucellosis and that were in contact with infected cattle;
- killing of the infected cattle and safe disposal of carcasses under the surveillance of a veterinary inspector in seven days time, at the latest;
- immediate diagnostic testing on brucellosis of all susceptible animals at the holding ;

- ban of use of milk from all infected cows from an infected herd;
- immediate safe disposal and destruction of aborted fetuses, stillborn calves, calves which have died from brucellosis after birth, as well as of placentas, except in case they need to be diagnostically tested;
- disinfection and safe removal of straw, manure and top layers of dirt, and other objects that were in contact with an infected animal, placenta or other contaminated material;
- packing or disinfection and storing of the manure from the infected facilities to a place that is inaccessible to animals, disinfection of liquid waste from the infected animals and ban of use of manure for fertilising arable land for at least 3 weeks.

The veterinary inspector may approve the slaughtering of previously castrated cattle from the holding, if the animals with bovine brucellosis were separated from the herd.

After removing the infected cattle from the holding, and before introducing new animals to the herd, the equipment and objects used with animals are cleaned, washed and disinfected under the supervision of a veterinary inspector. Re-use of pastures which have contained infected animals is permitted 60 days after their removal from such pastures. The use of pasture is exceptionally permitted for castrated animals 30 days after the infected animals have stopped using it, under the condition that these animals are sent from the pasture directly to a slaughterhouse or are moved to a fattening facility from which they will be sent directly to a slaughterhouse. Place where the infected animals were uploaded, vehicles and equipment that were in contact with the infected animals or material from the infected animals are all cleaned, washed and disinfected after use, upload and transport of the infected animals. The type and concentration of the solution of the disinfectants that are used must be in accordance with the special regulations.

Following the removal of the infected animals and the implemented measures, the cattle is tested to brucellosis in the herd, with prescribed tests, in order to confirm that the disease has been eradicated. The herd is not restocked with animals for breeding until the animals over 12 months old remaining in it for this purpose have passed one or more official serological examinations for brucellosis.

It is considered that brucellosis has been eliminated from the holding after the successful implementation of all measures and after all official diagnostic tests have been performed.

The veterinary inspector takes control measures in herds in which brucellosis has been eliminated in order to prevent re-infection of cattle from other sources of infection, and supervise every introduction of cattle into the herd and the moving of cattle within the herd that is in the program of eradicating brucellosis.

Cattle that have been confirmed for brucellosis are not therapeutically treated. Cattle are not vaccinated against brucellosis.

SHEEP AND GOAT BRUCELLOSIS

Diagnostic testing of sheep, goats and swine is mandatory in the following cases:

- 1) abortions (on samples of secretion, excretion and abortions fetuses) and after 15 days from an abortion on blood serum samples;
- 2) animals with clinical signs of brucellosis;
- 3) if changes characteristic for brucellosis have been identified during the slaughter, or the pathologic-anatomic inspection ;
- 4) if the people who are in direct contact with the animals were confirmed to have brucellosis.

In the yard or a facility that has been confirmed to sheep, goat or swine brucellosis, depending of the level of spreading, the following measures will be prescribed:

- humane killing of the infected animals and safe disposal of carcasses;
- slaughter or humane killing of animals that didn't have antibodies for the brucella species;
- diagnostic testing on brucellosis of all susceptible animals;
- diagnostic testing on brucellosis of all susceptible animals in back yards and the facilities that are epizootiological-epidemiologically connected to the outbreak;
- castration of porcine animals;
- disinfection of the infected facility and the infected back yard, and of the objects that were in contact with the infected animal
- disinfection and safe disposal (burial) of straw, hay and upper layers of dirt in the place where the infected animal was kept;
- packing or disinfection and storing of the manure from the infected facilities to a place that is inaccessible for animals, disinfection of liquid faeces (slurry) from the infected animals and ban of use of manure for fertilising arable land.
- ban on the use of pastures

ENZOOTIC BOVINE LEUKOSIS

Cattle with suspected presence of enzootic leucosis are:

- when they show clinically manifested changes (swelling of lymph nodes and similar) characteristic for the bovine enzootic bovine leucosis;
- that do not have tumour like changes on their skin, lymph nodes and organs, while the serological test shows a suspicious reaction;
- that originate from the herd officially infected with enzootic bovine leucosis or suspected on it;
- that had characteristic tumour like changes identified during slaughter or after dying, while pathohistological test was not performed;
- whose haematological test showed leucocytosis with extreme lymphocytosis (65%).

Suspected occurrence of enzootic bovine leucosis

The following measures are taken in case of a suspected case of bovine enzootic bovine

leucosis:

- placing the herd under surveillance;
- separation and isolation of cattle suspected to be infected with enzootic bovine leucosis;
- ban of insemination and mating of cattle suspected to be infected with enzootic bovine leucosis;
- ban of use and of consignment of milk of cows from a herd suspected to be infected with enzootic bovine leucosis to the dairies, except for the appropriate heat treatment, without prejudice to the special regulations;
- ban of removing animal feed that was, or could have been in contact with the cattle suspected to be infected with enzootic bovine leucosis;
- ban of common water space use;
- ban of restocking manure and slurry from the holding;
- ban of restocking into a herd, or placing on the market of the animals from the herd, for the purpose of slaughter without delay;

These measures are in force until the suspicion on enzootic bovine leucosis in the herd is officially ruled out.

Confirmation of the bovine enzootic bovine leucosis

A holding is considered infected if one or more animals are confirmed to be infected with bovine enzootic leucosis.

A cattle is considered to be infected with bovine enzootic leucosis if:

- 1) serologic testing, agar-gel immunodiffusion or ELISA method confirms positive reaction;
- 2) morphologic and pathohistological changes characteristic for enzootic bovine leucosis are found in organs and tissues during the slaughter.

A Cattle with enzootic leucosis is not therapeutically treated. There is no vaccination against enzootic bovine leucosis.

The Following Measures are Taken in Case of a Confirmed Case of Enzootic Bovine Leucosis:

- feeding of animals with the milk of the infected cows is permitted only after an appropriate heat treatment or after the milk has been sent to a dairy for heat thermal treatment, while feeding the cattle with the milk that hasn't been heat treated can be done only in herds in which all the cattle is intended for slaughter;
- processing of entire carcasses, half-carcasses, quarters,, pieces of and offal from infected cattle that are intended for feeding of animals, in a way that prevents the spreading of the bovine enzootic bovine leucosis.

Once the bovine enzootic leucosis has been confirmed in a herd, the veterinary inspector must inspect the processing plants for animal by products in order to confirm that there is

no risk of spreading of the enzootic bovine leucosis with animal products from those facilities.

The owner is obliged to notify a veterinarian or a veterinary inspector about every case of dying or forced slaughter without delay at the holding;

The health certificate of the cattle sent for slaughter that have been confirmed to have enzootic leucosis have an entry: "Enzootic Bovine Leucosis".

In order to eradicate the enzootic bovine leucosis, all cattle from the herd that was confirmed to be infected with enzootic bovine leucosis will be slaughtered, at the latest in 30 days after the owner or the keeper of the animals has been informed about the test results.

In case the cattle are sent for slaughtering, not a single bovine animal may leave the herd without the permission of the veterinary inspector.

All cattle from with confirmed cases of enzootic bovine leucosis must be diagnostically tested for that disease.

Cattle from herds that are not infected with enzootic bovine leucosis may be used for the restocking of the herd.

After the slaughtering of the cattle and prior to restocking cleaning, washing and disinfection of the sheds and other herd quarters as well as of the containers and the equipment is performed, under the surveillance of the veterinary inspector.

Vehicles, containers and equipment are washed, cleaned and disinfected after the transport of the cattle or the material from infected cattle, as well as of the equipment and materials that were in contact with these animals. Locations are cleaned and disinfected after use.

The owner or the keeper of animals prevents contact of their animals with cattle from the herds that do not have the same health status.

ANIMAL ANTHRAX

The anthrax area is an area in which anthrax has been diagnosed in previous 20 years.

If an individual case of anthrax has been confirmed, releasing of animals from the infected back yard will be banned in the duration of the infection, or in the duration of the danger from infection.

If anthrax has been identified in more than 3 cases and with a greater number of outbreaks, depending on the epizootiological situation, the veterinary inspector will prohibit the issuance of health certificates for susceptible animals and limit their

movement to the territory of their village until 14 days after the last animal died, or the recovery of the infected animal and of the performed final disinfection.

Animals infected with anthrax and animals suspected to be infected with anthrax may not be slaughtered.

The use, exploitation and trade with infected and suspected to be infected animals, and the sale of milk and dairy products of these animals is prohibited.

Carcasses of animals that have died of anthrax, and meat and parts of slaughtered animals that were diagnosed with anthrax after killing, must be kept from coming in contact with people and animals and must be safely disposed, together with the skin, offal and waste.

Carcasses of animals suspected to have anthrax are transported solely in vehicles and containers that do not allow the falling out of waste and part in solid or liquid state.

Only a veterinarian may therapeutically and give the serum to the infected animals and vaccinate the suspected animals.

The following measures are taken in an infected area and a suspected area:

- active protection of oxen, buffaloes, sheep, goats and equidae, according to the instructions of the anthrax vaccine manufacturer;
- ban of dissecting the carcasses of the animals that have died from anthrax, and of carcasses of animals suspected to have died of anthrax, unless conditions for preventing the spreading of the disease have been ensured;
- thorough disinfection of the place where an animal had died of anthrax or was suspected to have died of anthrax. If the animal died on the ground, the surface 30 cm layer of dirt must be scraped and buried for safe disposal;
- dissecting the carcasses and collecting materials from carcasses of animals that have died from anthrax, and of carcasses of animals suspected to have died of anthrax may be done only in the presence of a veterinarian. People with injuries on their hand may not perform the dissection nor collect samples for laboratory tests.

When anthrax has been confirmed by a laboratory, and the source of disease cannot be identified and made harmless for further spreading of the disease, the local veterinary inspector will identify the areas and proscribe vaccination of cattle, sheep and horses for anthrax.

Cattle, buffaloes, sheep, goats and equidae that use feed from the anthrax area are subject to mandatory vaccination.

Ministry defines the scope and the time of the vaccination and the species of animals that will be vaccinated against anthrax.

After the last animal has recovered and after the safe disposal of carcasses, by products and waste of infected or of suspected to be infected animals, a mandatory cleaning and intensive final disinfection is performed in the facilities, slaughterhouses and back yards in which the animals were kept, with an appropriate disinfectant.

Manure and waste found in the area must be safely disposed.

In the facilities, slaughterhouses and back yards infected with anthrax, tools and equipment that were in contact with infected or suspected animals or their carcasses, or their parts, must be appropriately disinfected.

ANIMAL TRICHINELOSIS

The following measures are taken in the infected area:

- listing of porcine animals;
- ban of sale and trade of porcine animals from the holding;
- diagnostic testing with ELISA test of other animals, if necessary,
- systematic deratisation in a prescribed way;
- mandatory inspection of porcine animals slaughtered for household needs, by one of the prescribed methods;
- stamping out of stray dogs and cats.

The following measures are prescribed in the infected holding:

- ban of trade of porcine animals, and products, by-products and waste from the slaughtered porcine animals;
- ban of use of uncooked swill without previous heat treatment;
- reporting of every slaughter of porcine animals in household to the veterinary inspector;
- destroying of the trichinella larvae in all parts of the carcasses of dead and slaughtered animals;

The destruction of the trichinella larvae is done by:

- melting of the fatty tissue;
- cooking of meat pieces not thicker than 10 cm, in water, or in steam, for at least 2.5 hours in order to achieve the temperature of 80°C for at least 30 minutes in the centre of the pieces;
- incineration.

Slaughter of all porcine animals and the destruction of trichinella larvae at the infected backyard are performed under the supervision of a veterinary inspector, who writes record on the event.

The citizens, animal keepers and hunters will be regularly informed on the course and the significance of the implementation of the mentioned measures.

Trichinellosis is considered to be eliminated if all the measures have been implemented and deratisation was undertaken after the death and slaughter of all animals infected with Trichinellosis.

SWINE VESICULAR DISEASE

Measures for suppressing and eradicating the swine vesicular disease are defined in the Rulebook on Establishing the Measures for Early Detection, Diagnostics, Prevention of Spreading, Suppression and Eradication of the infectious Swine Vesicular Disease and the manner of their Implementation (Official Gazette of RS No. 10/2010);

Suspected occurrence of the swine vesicular disease

The ministry must be notified, without any delay about every suspected occurrence and every occurrence of the swine vesicular disease.

Measures Taken in Case of Suspected Swine Vesicular Disease at a Holding

In case of suspicion that the porcine animals have been infected by the causative agent of the vesicular disease, the veterinary inspector performs an immediate epizootiological; investigation, in order to confirm the presence, or absence of the swine vesicular disease and places the holding under surveillance. Immediately after the reported suspicion on swine vesicular disease at the holding, the following measures are taken:

- listing of porcine animals by categories, with the number of dead animals in each category, categories of animals with clinical signs and categories of animals without the clinical signs of the disease. The list must be daily regularly updated in order to include the newborn and dead animals in the period during the suspect presence of the swine vesicular disease at the holding; the data from the list must be made available on the request of the veterinary inspector and checked during every official control and surveillance;
- containment of all susceptible animals at the holding or their isolation in some other way at the holding,, taking into consideration the role of the vector;
- ban of movement of susceptible animal species to and from the holding;
- setting disinfectant barriers at the entries and the exits of the facility with susceptible animal species and at the entries and the exits of the holding;
- collecting samples for laboratory testing.

All movement of people and animals that are not susceptible to this disease, of vehicles to and from the holding, transport of meat or carcasses, animal feed, of equipment, manure or anything else that may transmit the swine vesicular disease, must be approved of by the veterinary inspector and conducted according to his instructions.

Measures in case of a suspicion on swine vesicular disease at a holding may be implemented at other holdings, if their position or distribution related to the holding suspected for the swine vesicular disease indicates possible contamination with the causative agent, as well as at the cattle market, fair, exhibition or any other public event and in transport, in case of a suspicion on swine vesicular disease.

These measures are applied until the suspicion on swine vesicular disease has been officially ruled out.

Measures Taken in Case of Confirmed Swine Vesicular Disease at a Holding

When swine vesicular disease has been confirmed at a holding, in addition to the given measures, epizootiological investigation is performed and the following measures are taken:

- immediate killing in humane manner stamping out of all porcine animals and safe disposal of carcasses of animals that have died or were slaughtered, by incineration or burial on the spot, if there are conditions to do so, or their safe disposal at the processing plant for animal by-products, in order to minimise the risk of spreading the causative agent of the swine vesicular disease, according to the special regulation. If the carcasses are buried on the spot, the hole for carcasses and waste should be deep enough to prevent the carnivores from digging out its content and its position must be such to prevent the contamination of water or the environment;
- destroying or appropriate treatment of all objects, waste, animal feed, straw or excrements that may have been contaminated, in a way to ensure the destruction of the swine vesicular disease causative agent;
- cleaning and disinfection of the facilities for keeping the susceptible species, of their surrounding environment, of vehicles and equipment that may have been contaminated;
- identification and safe disposal of the meat of porcine animals that have been slaughtered from the time of likely entry of the swine vesicular disease virus to the holding to the time of the beginning of the prescribed measures.

These measures in may be implemented at other holdings, if their position or distribution related to the holding where swine vesicular disease has been confirmed indicates possible contamination with the causative agent, as well as in case of a confirmed swine vesicular disease at the livestock market, fair, exhibition or any other public event and in transport.

It is considered that the spreading of the swine vesicular disease at the holding is stopped if all necessary measure have been taken and if final cleaning and disinfection have been performed.

Measures at Contact Holdings

When the veterinary inspector has justified doubt, or establishes after an epizootiological investigation that the swine vesicular disease virus was imported from other holdings to the holdings suspected for swine vesicular disease, or a holdings with a confirmed case of the swine vesicular disease, or from these holdings to other holdings or the slaughterhouse, as a result of the movement of people, of animals or of transport vehicles, or in some other way, those holdings will be placed under supervision and the above

listed measures will be taken at them as well.

The measures at contact holdings are in force for at least 28 days.

The implementation of the measures at contact holdings may be limited to a part of the holdings and the animals in that part, if those animals are kept, bred and fed separately and if different staff is in charge for them.

Measures at holdings with two or more production units

If the swine vesicular disease has been confirmed at a holding with two or more production units, the Ministry may allow exceptions to the measures for the holding in the production unit with healthy porcine animals, under the condition that the structure and the size of these production units and the activities taking place in them enable complete separation regarding the keeping, staff, equipment and feeding, in order to prevent the spreading of the causative agent from one production unit to the other.

Measures Taken in Case of Suspicion and Confirmation of Swine Vesicular Disease in a Slaughterhouse

When there is a suspicion of the swine vesicular disease in a slaughterhouse, the veterinary inspector performs an epizootiological investigation without delay places the slaughterhouse under supervision and prescribes the isolation of animals suspected to have swine vesicular disease, as well as clinical and laboratory testing of all porcine animals in the slaughterhouse, in order to eliminate any suspicion of the disease.

Once the swine vesicular disease has been confirmed in a slaughterhouse, the following measures are taken without delay:

- killing in humane manner of the infected porcine animals;
- slaughter of healthy porcine animals in a slaughterhouse;
- separate keeping under inspector's supervision of the meat and animal by-products from slaughterhouse waste of previously slaughtered porcine animals from the meat and animal by-products of other porcine animals;
- destruction of carcasses and offal of infected and dead porcine animals in a way to avoid any risk of spreading the swine vesicular disease virus, and to enable its destruction;
- cleaning and disinfection of the facilities, equipment and the vehicles, under the supervision of the veterinary inspector;
- ban of delivering of porcine animals for slaughter, or trade, until 24 hours have expired after the cleaning and the disinfection.

The manner of Establishing the Borders of the Protection and the Surveillance Zones

When the diagnostic test results confirm the presence of the swine vesicular disease, the Ministry defines the borders of the protected and the surveillance zones based on epizootiological, geographic, administrative and environmental factors.

The protection zone is part of the territory of the Republic of Serbia with a radius of at least 3 km from the holding where the swine vesicular disease has been confirmed.

The surveillance zone is part of the territory of the Republic of Serbia with a radius of at least 10 km from the holding where the swine vesicular disease has been confirmed.

The borders of the protected and the surveillance zone may change, depending on:

- geographic position, especially natural and man made borders;
- environmental factors;
- meteorological conditions;
- the presence, the distribution and the type of vectors;
- epizootiological investigation results;
- laboratory testing results.

The measures taken in the protected zone:

The following measures are taken in the protected zone:

- listing of all holdings that keep susceptible animal species;
- regular control of all holdings that keep susceptible animal species, clinical testing of those animals including the collection of the statistical number of samples for the laboratory testing, keeping a record of tests and the results, where the control frequency should be proportional with the severity of the epizootiological situation at the highest risk holdings;
 - ban of transport of susceptible animal species, by public or other roads, except for the utility roads at the holdings. The veterinary inspector may allow the transit of animals on the roads or the railway, without unloading or stopping;
 - ban of movement of susceptible animal species from the holding at which they are kept and to that holding;

These measures are implemented at list for the period equal to the maximum incubation period from the time of eliminating the animals from the infected holding and the final cleaning and disinfection.

When the disease is transmitted by vectors and insects, the duration of the measures and the conditions for potential testing on sentinel animals may be estimated, based on the risk analysis.

In the protection zone after the maximum incubation period has expired, measures for the surveillance zone will be in place.

Transport of susceptible species of animals may be exceptionally permitted in case of the transport of animals for urgent slaughter without delay, directly to the slaughterhouse in the protection and surveillance zone, approved by the Ministry, under the following conditions:

- that they spent at the holding of origin at least 21 days after the elimination of the

- porcine animals from the infected holding and after the cleaning and disinfection;
- that all porcine animals were clinically inspected at the holding of origin;
- that the porcine animals were identified in a prescribed way;
- that the transport is performed under official surveillance and in a sealed vehicle;
- that all porcine animals that are sent for slaughter have been clinically examined and diagnostically tested;
- that the veterinary inspector at the slaughterhouse has been informed about the sending of animals for slaughtering.

Porcine animals from the protection zone must be kept in the slaughterhouse separated from other animals. Vehicles and the equipment used for the transport of porcine animals must be cleaned and disinfected before leaving the slaughterhouse.

Statistically representative blood sample is taken during the inspection, before the slaughter and post mortem. If the laboratory test result of the statistically representative blood sample is negative, the meat may be used for human consumption, and if it is positive, if the swine vesicular disease has been confirmed, the above listed measures are in place.

If the fresh meat is dispatched to a facility approved of by the Ministry, each consignment must be sealed by a veterinary inspector and it must remain sealed during its transport to the approved facility.

The measures taken in the surveillance zone:

The following measures are taken in the surveillance zone:

- listing of all holdings with susceptible animal species;
- ban of transport of susceptible animal species by public roads, except on pastures or to the facilities in the surveillance zone where they are kept enclosed and under the supervision of the veterinary inspector;
- ban of transit of susceptible animal species, except the transit of animals on the roads or the railway without unloading or stopping approved by the veterinary inspector.;
- ban of trade of susceptible animal species from the surveillance zone;
- ban of leaving the surveillance zone for trucks and other vehicles and the equipment used for the transport of porcine animals or other animals or materials that might be contaminated, before they have cleaned and disinfected,.

The Ministry may allow the transport of the porcine animals directly to the approved slaughterhouse for slaughter without delay, under the above mentioned conditions.

The given measures that are taken in the surveillance zone are in force at least during the period that is equal to the maximum incubation period, after the animals from the infected holding have been removed and after the cleaning and the disinfection.

When the disease is transmitted by vectors and insects, the duration of the measures and the conditions for potential testing on sentinel animals may be estimated, based on the

risk analysis.

Exceptionally, transfer of susceptible species animals may be permitted from the surveillance zone, under the following conditions:

- that they have spent at least 21 day before the transport at the holding of origin;
- that the porcine animals were examined at the holding at least 48 hours before the transport;
- that the porcine animals that should be moved were clinically examined 48 hours before the transport, under the condition that the test results were negative;
- that serologic testing of the statistical sample taken from the porcine animals that need to be moved was performed, and that anti bodies to the swine vesicular disease were not found in a period of 14 days before the transport;
- that the porcine animals were identified in a prescribed way;
- that the vehicles and the equipment used for the transport of porcine animals was cleaned and disinfected before and after every transport.

If the measures are implemented over 30 days due to the occurrence of new cases of swine vesicular disease, and as a consequence of these measures problems occur with keeping the animals, based on the justified request of the owner, the transport of animals from the holding,, within the borders of the protection or the surveillance zone may be allowed, if:

- all animals farm the holding are clinically examined;;
- animals that should be transported are clinically examinedand and the results are negative;
- every animal is identified in a prescribed way;
- the holding to which the animals are sent is within the borders of the protection or the surveillance zone;
- the vehicles and the equipment used for the transport of porcine animals or other live animals are cleaned and disinfected, in order to prevent the risk of spreading the causative agent during the transport.

Termination of the disease in the protection and the surveillance zone

It is considered that the swine vesicular disease is eliminated if all the prescribed measures were taken in the protection and the surveillance zone, and the final cleaning and disinfection have taken place, and if the maximum period of incubation has passed from the last case of the disease, without an occurrence of a new case during that time.

Measures for detection, diagnosing, preventing the spreading and suppressing the disease of wild animals

For the early detection,, diagnostics, prevention of spreading, suppression and eradication of the swine vesicular disease the with animals, appropriate methods will be applied in

accordance with the above listed measures.

Vaccination for the against swine vesicular disease

Vaccination against for the swine vesicular disease is not organised, and the animals infected, or suspected to be infected with the swine vesicular disease are not therapeutically treated.

The Ministry may allow exceptions, for scientific research, and if the epizootiological situation requires vaccination.

In case the epizootiological situation requires vaccination, the Ministry prepares and presents the vaccination plan which is an integral part of the Contingency plan.

The Vaccination Plan must include the data on:

- porcine animals population density in the protection zone;
- characteristics and content of each vaccine used;
- model and procedure of controlling the vaccine distribution, storage and use;
- animal categories that can or must be vaccinated;
- areas in which vaccination may or must be performed;
- time frame for the vaccination.

Vaccination and re-vaccination and the use of hyperimmune serum for susceptible animal species suspected to be infected is not performed.

The following measures are taken during the vaccination:

- special identification of vaccinated animals with a clear and visible mark;
- ban of movement of vaccinated animals outside the area of vaccination, unless they are sent to a slaughterhouse approved by the Ministry, for an slaughter without delay after all suspected animals at the holding have been tested and the results have confirmed that not a single animal is infected.

Transport of susceptible animal species from the vaccination area may be permitted by the Ministry after the vaccination has been finished.

As a part of the First Component of the Instrument for Pre Accession Assistance of EU – transition support and capacity building, IPA 2008 project - Support for the control/eradication of classical swine fever and rabies in Serbia, oral vaccination of foxes and other wild animals for rabies started, and the monitoring of classical sine fever is in place as well as the vaccination for the classical swine fever.

See Annex III, Animal Health – comparison to the EU legislation

- Trade in live animals, semen, ova and embryos;

See the answer to question 10, chapter 2, in the part control system in the internal market and control system for imports.

- Non-commercial movements of pet animals;

Until the adoption of the Rulebook that will regulate the non-commercial movement of pet animals according to the EU Regulation 998/2003, the Instruction on the Procedure for Non-commercial Import of Dogs and Cats to the Republic of Serbia, from 24 March 2010 is in force. Some basic provisions from the EU Regulation were transposed in the Instructions, including the List of countries with a favourable situation with regard to rabies.

If the country of origin is on this list, the Ministry issues a permit for non – commercial import into the Republic of Serbia, with an indication that no quarantine is necessary after the import. The animals must have an international veterinary certificate or a passport during the process of being imported. This document confirms that:

a) they are permanently marked with a microchip by the ISO standards 11784 and 11785 or a clearly visible tattooed number;

b) they have been vaccinated against rabies with a registered inactive vaccine that contains at least one antigen dose per unit (WHO standard), if it is an animal older than 3 months; In case of the first rabies vaccination against rabies, 21 days must expire from the vaccination for the animals to be imported. Vaccination and re-vaccination of the animals must be performed according to the manufacturer's instructions.

Animals imported from the country of origin that is on the list and are younger than 3 months and are not vaccinated for rabies may be imported:

- a) if the accompanying documentation shows that they have not changed the place of residence from birth and that they were not in contact with wild animals that may be infected with rabies, or
- b) if they are imported with their mother that they still depend on,

If the country of origin is not on this list, the Ministry issues a permit for non – commercial import into the Republic of Serbia, with an indication that no quarantine is necessary after the import. The animals must have an international veterinary certificate or a passport during the process of being imported. In addition to the above listed data, this document confirms that:

- a) they did not show clinical signs of rabies in the 48 hours previous to the transport,
- b) they were subjected to the blood serum test for the titre values of specific neutralising antibodies against the rabies virus, at a laboratory authorized by the European Union with the minimum titer at least 0.5 IU/ml. The testing must be performed at least 30 days after the vaccination and 3 months before the import. The testing does not have to be repeated if the animals have been re-vaccinated according to this Instruction.

Non-commercial import of animals is registered in a competent department of the Ministry (Department for Border Veterinary inspection) and informs on a monthly level the Department for International Transport and Certification, at latest by the 15th of day in the month for the previous month.

The updated EU List contained in the Regulation EC/998/2003 is regularly monitored and updated by the Ministry (Department for Animal Health, Welfare and Control Traceability of animals) and it is an integral part of the Instruction.

- Prohibition of substances and residue monitoring;

Monitoring of prohibited substances

The Ministry of Agriculture, Forestry and Water Management makes the list of prohibited substances and medicines intended for use in veterinary medicine for the treatment of animals intended for human consumption in accordance with the Law on Medical Drugs and Medicines (Official Gazette of RS, No. 30/2010). According to the recommendation of the Agency for Medical Drugs and Medicines, this list is harmonised with the current prohibitions and terms of use of drugs issued by EMEA and proscribed by the EU as a condition for the use or the prohibition of use.

According to this, the Ministry of Agriculture, Forestry and Water Management issued the Decision on the Prohibition of Trade and Use of Substances and Drugs Intended for the Use in Veterinary Medicine in Treating Animals Used for Human Consumption (Official Gazette of RS, No. 96/2009).

The Rulebook on Establishing the Program of Systematic Residue Monitoring of Pharmacological, Hormonal and Other Harmful Materials in Animals, Animal Products, Food of Animal Origin and Animal Feed (Official Gazette No. 91/2009), defined the list of prohibited substances in accordance with the A list of the Directive 96/23/EC.

Monitoring of residue

Residue Monitoring Program/Plan for living animals, primary products or animal origin and animal feed is implemented in accordance with:

1. Law on Veterinarian (Official Gazette No. 91/05, 30/2010),
2. Law on Food Safety (Official Gazette No. 41/09),
3. The Rulebook on Establishing the Program of Systematic Residue Monitoring of Pharmacological, Hormonal and Other Harmful Materials in Animals, Animal Products, Food of Animal Origin and Animal Feed (Official Gazette No. 91/2009),
4. Instruction for Rules of Official Sampling for the Monitoring of Substances and Residues in Live Animals and Animal Products No. 323-07-01577/2010-05,
5. Decision on the Prohibition of Trade and Use of Substances and Drugs Intended for the Use in Veterinary Medicine in Treating Animals Used for Human Consumption (Official Gazette of RS, No. 96/2009),

6. Rulebook on Maximum Quantities of Residue of 25/10)

7.

The Department for Veterinary Public Health in the Veterinary Directorate is the central competent organ for the planning, monitoring and surveillance of the residue control system.

The Goal of the Residue Monitoring Program is to ensure with a systematic control of an appropriate number of distributed samples an efficient monitoring of prohibited treatment of animals or the levels of residue in the excretions and body fluids of live animals and in the tissues of killed animals, in primary animal products and animal feed;

The Agency for Medical Drugs and Medicines is in charge of the registration and approval for placing veterinary drugs on the market, including the approval for importing veterinary drugs.

The Agency for Medical Drugs and Medicines is responsible for preparing and updating of lists of all medicines containing active substances and are on the market of the Republic of Serbia.

The Department for Veterinary Public Health prepares an annual residue monitoring program, issues the orders to veterinary inspectors for sampling and monitors the realisation of the programme.

The Instruction for implementing the residue monitoring program defines the basic principles of sampling, the criteria for the collection of samples, quantities and types of collected samples, method of collecting, packing and marking of the samples, required documentation, reporting model and the procedure in case of a positive result.

The veterinary inspectors collect samples on a weekly level, according to the order issued by the Veterinary Directorate/ Department for Veterinary Public Health, in an unexpected and unannounced way for the subject in the food trading business, throughout the year.

In case of a positive result, the veterinary inspection starts an inquiry and takes measures according to its competences.

The national referent laboratory for residue control is the Institute for Meat Hygiene and Technology in Belgrade. The Institute is the only laboratory authorised by the Ministry of Agriculture, Forestry and Water Management that has signed an agreement with the Veterinary Directorate that defines mutual obligations in the sphere of sample testing according to the National Plan for Residue Monitoring.

The Institute has been accredited for ISO standard IEC 17025 by the Accreditation Body of Serbia (ATC).

The funds for implementing the Plan for Residue Monitoring come from the budget of the Veterinary Directorate.

The Veterinary Directorate submits the Annual Plan for the current year and the Report of the Monitoring Results for the previous year to the EU Commission DG SANCO by 31 March of the current year.

The EU has approved the plan of the Republic of Serbia for systematic residue monitoring in live animals, primary animal products and animal feed, for cattle, horses, sheep, goats, swine, hares, wild game, aquaculture, eggs, honey, milk (Commission Decision 327/2010/EC on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC).

- Import requirements for live animals and animal products;

International trade is prescribed in Chapter XI of the Law on Veterinary Matters (Official Gazette of RS, No. 91/2005 and 30/2010), and general principles of international obligations are prescribed in Article 7 of that Law.

Live animals may be imported if requirements related to animal health and welfare were met and if the animals have been marked in accordance with the regulations of the country of export, or the country of origin of the consignment.

Import of live animals may be permitted in case different standards have been applied, for which the competent authority in the country of export can provide scientifically based evidence of achieving the same level of health protection to the level that would be achieved with procedures prescribed in the Republic of Serbia.

The import of products of animal origin, food of animal origin, animal feed, animal by products and related items is approved from the establishments that meet the prescribed conditions, which are registered in the EU and under control of the Competent authority. The Ministry may approve import from other establishments when it has been established that the regulations, standards, production and surveillance performed by the country of export are identical with those in the Republic of Serbia and that an equal level of consumer protection is ensured.

The Ministry may carry out control of the establishment for the purpose of inspection. Inspection costs are covered by the importer.

Procedures that have been officially adopted by the relevant international organisations for defining health protection standards are accepted for procedures that provide an identical level of health protection as procedures prescribed in the Republic of Serbia.

General obligations for import and export of food and animal feed are prescribed in the Article 14 and Chapter VII, of the Law on Food Safety (Official Gazette of RS, No. 41/2009).

The international obligations in the field of food safety shall be executed in accordance with the recommendations of relevant international organizations, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), international conventions and other relevant international agreements, and information shall be exchanged with other national organizations responsible for food safety.

Measures based on scientific principles, international standards, guidelines and recommendations shall be applied for food and feed safety purposes, to the extent necessary to protect life and health.

Food and feed safety measures shall be applied in such a way as to avoid arbitrary and unjustified discrimination between the countries in which the same or similar conditions prevail, in a way which does not represent a disguised restriction of foreign trade.

For the purpose of achieving a higher level of protection of the life and health than the one achieved through the measures based on international standards, guidelines and recommendations, other food and feed safety measures may also be applied when scientific justification exists or if such international measures would result in a protection level which is different from the one considered necessary by the Republic of Serbia.

The food and feed safety measures applied by other countries shall be deemed identical to the measures prescribed in the Republic of Serbia, if the exporting country objectively demonstrates that they are scientifically based and that their application ensures the appropriate level of human life and health protection required in the Republic of Serbia.

The prescribed food and feed safety measures must be adjusted to the characteristics of the region that could affect the food and feed safety, either in the country as a whole or a part of the country, several countries or parts of several countries from which the product originates or to which the product is destined, taking particularly into account the level of prevalence of certain diseases or pests, existence of eradication or control programs and relevant criteria and recommendations of relevant international bodies.

The procedures for checking and insuring the application of food and feed safety measures shall be conducted efficiently and in a manner no less favorable for imported products than for similar products of domestic origin.

Identical measures for import and export

The food and feed imported in the Republic of Serbia for the purpose of placing on the market must meet the requirements in accordance with regulations on food or the requirements recognized by the Republic of Serbia as identical thereto, or if an international agreement exists with the requirements contained therein.

Notwithstanding the provision of paragraph 2 of this Article, with the exception of food which is harmful to health or unsafe feed, food and feed may be exported or imported for

the purpose of being exported if the responsible authorities of the country of destination have expressly agreed to that having been fully informed of the reasons and circumstances preventing that food or feed from being placed on the market in the Republic of Serbia.

If the provisions of an international agreement between the Republic of Serbia and the importing country are applicable, the food and feed exported from the Republic of Serbia to that country must meet the requirements contained in that international agreement.

In case of a threat of the entry of a notifiable infectious disease into the territory of the Republic of Serbia or it can be transmitted through consignment, the Minister of Agriculture, Forestry and Water Management may:

- 1) ban or limit import, export or transit of animals, products of animal origin, food of animal origin, animal feed, animal by-products and related items;
- 2) order control of movement of animals, products of animal origin, food of animal origin, animal feed, animal by-products and related items, in surveillance border areas, including roads, bridges and ferries, and
- 3) order in the surveillance areas the disinfection of people and vehicles that are crossing the border of the Republic of Serbia;

In addition to the mentioned above, in accordance with the risk analysis and depending on the type of the contagious disease and other threats, specific additional veterinary – sanitary import conditions may be prescribed (additional tests, limitations and other precaution measures) that can be applied to all types and categories of consignments that are a risk for a certain threats.

Special veterinary-sanitary conditions for imports regarding TSE/BSE are also prescribed by the Order on implementation of measures to prevent entry of the contagious disease of transmissible spongiform encephalopathies in Republic of Serbia (Official Gazette of RS, No. 8/2009) with the purpose to prevent the import of the transmissible spongiform encephalopathies (in further text: TSE), the Republic of Serbia ban the import of. Measures for preventing the introduction of TSE are shown in II. Veterinary policy, answer to question 10. - animal disease control measures,

Consignments of animals, products of animal origin and animal feed in import or transit, must:

- 1) be free from notifiable contagious diseases and properly marked;
- 2) have an original international veterinary certificate, issued and signed by the competent veterinary inspector or the authorized veterinarian of the exporting country or country of transit;
- 3) be identified and accompanied by an appropriate identification document, when they are live animals;
- 4) have a licence of veterinary-sanitary conditions for import/transit, and

- 5) depending on the nature of the contagious disease and the possible risk, they shall not originate from a holding, region or the exporting country, nor be in transit through a region or a country where there is an notifiable contagious disease.

Consignments of food of animal origin that are imported or in transit, must:

- 1) be safe for human health
- 2) have an original international veterinary certificate, issued and signed by the competent veterinary inspector or the authorized veterinarian of the exporting country or the country of transit;
- 3) have a licence of veterinary-sanitary conditions for import/transit, and
- 4) be identified in a way that enables the origin of the consignment, and of the establishment in which product and food were manufactured.

The international veterinary certificate must be original, issued on the day of dispatch, for a one animal species or products, and for one recipient, properly certified, identified with a serial number, compulsorily written in the Serbian language and in the language of the country of origin, while the consignments in transit may have a certificate in English and in other languages officially recognised in international trade.

The Veterinary Directorate prepares the forms of veterinary certificates in accordance with the regulations of the Republic of Serbia and conditions prescribed by the country of import or export. After the harmonisation procedure is completed, they are appropriately marked, the original copy of the certificate is controlled before the printing, printing is granted, and the distribution, registration and issuance are controlled.

Rulebook on conditions for issuing International veterinary certificates for consignments of live animals, products of animal origin, food of animal origin, animal feed and other consignments that are consist of products of animal origin. (O.G. of the Republic of Serbia No. 76/10) closely prescribes the manner and the procedure if issuing of International Veterinary Certificates for consignment of animals, products of animal origin, food of animal origin, animal feed, animal by-products and related items and record keeping of issued certificates. This Rulebook was prepared in accordance with Council Directive 96/93/EC on the certification of animals and animal products.

For the export consignments of live animals and products of animal origin, original International Veterinary Certificate is issued, confirming that the consignment fulfils all the conditions of the importing country, and for the food of animal origin, that it is safe for human consumption.

The competent veterinary inspector issues the original International Veterinary Certificate during the loading, in the place of origin of the consignment and the establishment that has been approved or registered in the Veterinary Directorate. The International Veterinary Certificate is issued on the printed form according to international standards or in accordance to the form prescribed by the country of import.

Every consignment of live animals, products of animal origin, animal feed and veterinary medicines is subjected to a veterinary-sanitary inspection at the place of entry into the country.

Live animals are inspected and in case of a positive decision, transport to the quarantine is permitted. The quarantine is specified in the Quarantine decree issued by the Veterinary Directorate. After unload at the place for the quarantine, the animals shall be inspected.

At the border crossing at which the consignment is entering the country, the border veterinary inspector identifies the consignment, controls the accompanying documents and performs a physical checks of the consignment, which includes collecting samples for a laboratory analysis. If sampling is necessary and the collection of samples is for some reason impossible at the border crossing, the consignment may be directed to the place of storage where the local competent veterinary inspector will check the consignment and collect samples for a laboratory analysis.

- Bilateral veterinary international agreements with EU Member States, candidate countries and other third countries (if any).

Table Agreements or Contracts shows bilateral veterinary agreements that are in force.

STATE	Name of the Agreement or the document
ALBANIA	Veterinary Convention between Yugoslavia and Albania signed on 3 October, 1968.
ARGENTINA	Agreement on Veterinary Cooperation between the governments of the Republic of Serbia and Argentina, signed on 10 May, 2010.
ARAB REPUBLIC OF EGYPT	Memorandum of understanding between the MAFWM of Republic of Serbia and the Ministry of Agriculture and Melioration of the Arab Republic of Egypt on veterinary cooperation, signed on 28 May, 2010.
BELARUS	Agreement on Veterinary Cooperation between the Federal government of Federal Republic of Yugoslavia and the Republic of Belarus, signed on 30 January, 1998.
Bosnia and Hercegovina	Agreement on Veterinary Cooperation between the government of the Republic of Serbia and the Ministry Council of Bosnia and Hercegovina, signed on 01 November, 2010.
BULGARIA	New Agreement on the border crossing procedure in railway transport, signed on 15 April, 2005.

MONTENEGRO	Protocol on the harmonisation of procedures in the foreign trade with goods that are subject to veterinary – sanitary control and to phytosanitary control at border crossings, signed on 29 April, 2003.
FINLAND	Veterinary – Sanitary Agreement between the governments of SFRY and the Republic of Finland was signed on 08 June, 1979
CROATIA	Agreement on Veterinary Cooperation between the governments of the Republic of Serbia and Croatia, signed on 23 November, 2005.
INDIA	Agreement on Cooperation in Agriculture and familiar sectors signed between the government of Republic of Serbia and India, on 03 March, 2009.
IRAN	Agreement on Veterinary Cooperation and Animal Health Protection between the governments of the Republic of Serbia and the Islamic Republic Iran was signed on 8 May, 2009.
CHINA	Memorandum of understanding between the Ministry of Agriculture, forestry and Water Management of RS and the General Administration for Quality Monitoring, Inspection and Quarantine of PRC on cooperation in the field of animal health, plant health and food safety, signed on 17 April, 2007.
MACEDONIA	Agreement on Veterinary Cooperation between the governments of the Republic of Serbia and Macedonia, signed on 23 April, 1997.
MONGOLIA	Veterinary Convention between governments of SFRY and PR of Mongolia, signed on 09 March, 1977
RUSSIAN FEDERATION	Agreement on Veterinary Cooperation between MAFWM of the Republic of Serbia and the Federal Office for Veterinary and Phyto-Sanitary Control of the Russian Federation, regarding terms of delivery of fish and fish and sea products from RS to RF, signed on 28 August, 2010.
SLOVAKIA	Memorandum of understanding in veterinary practice and food safety, signed in March 2006 in Belgrade
URUGUAY	Sanitary-Veterinary Convention between the Federal Executive Council of the SFRY Assembly and the government of the East Republic of Uruguay, signed on 14 May, 1985.
BRAZIL	Additional agreement to the Basic agreement on Technical Cooperation between the governments of the Republic of Serbia and Federal Republic of Brazil on cooperation in veterinary practice, signed on 5 January, 2010.
CUBA	Memorandum of Understanding on Capacity Building and Technical Cooperation between the Ministry and the Ministry of Agriculture of the Republic of Cuba, signed on 2 October, 2008 in

Animal welfare:

- **Farm animals, laying hens including information on conditions of production, chickens kept for meat production, calves, pigs;**
- **Animals during transport;**
- **Animals at the time of slaughter or killing.**

The Law on Animal Welfare ("Official Gazette of RS", No. 41/09) prepared in accordance with the Directives Decisions and Regulations of the European Union and the European Commission, the recommendations of the World Organization for Animal Health (OIE), and the European Conventions for the Protection of Animals of different species was adopted in the Republic of Serbia in 2009. The Law specifies the welfare requirements for different categories of animals kept in different conditions.

The Law governs the general animal welfare protection strongly emphasizing the rights and obligations of animal owners and keepers, and special animal welfare protection, in particular the welfare of animals on farms, during transport, at the time of slaughter and killing, the welfare of animals used for experimental and other scientific purposes, the welfare of pets, abandoned and stray animals and the welfare of wild animals in captivity. The Law is general and tentative while the detailed provisions of the EU legislation have been included in the by-laws.

Inspection supervision over the enforcement of the Law on Animal Welfare and the regulations enacted on the basis of the Law is conducted by the Ministry of Agriculture through veterinary inspectors. The inspection supervision is conducted on the basis of risk analysis, by random sampling and on the information about actions contrary to the provisions of this Law.

In performing inspection supervision over the enforcement of this Law, a veterinary inspector shall have powers and duties to check:

- 1) manner of handling the animals;
- 2) the animal keeping and breeding conditions;
- 3) the facilities, space and premises in which the activities of keeping, breeding, reproduction, sales, slaughter, experiments, training accommodation and care of animals are conducted;
- 4) fulfilment of the requirements concerning training for animal welfare;
- 5) possession of the necessary documentation and records keeping in compliance with this Law;
- 6) the animal trade, transport, killing and slaughtering, animal training and public displaying;
- 7) means of transport;

- 8) animal resting places and control posts; and
- 9) implementation of the measures in accordance with this Law.

In performing the inspection supervision, a veterinary inspector is obliged and authorized to:

- 1) order removal of irregularities in keeping, breeding, reproduction, slaughter, killing, loading, reloading, unloading, transport, training and use of animals;
- 2) temporarily or permanently seize the animals to protect their lives and welfare, if the owner acts contrary to the provisions of this Law;
- 3) order killing of animals at the expense of their owner i.e. keeper cost, in the case when the animals are incurably sick, injured or physically deformed so that their recovery is not possible;
- 4) prohibit killing of animals by an incompetent person and in the manner that is not in compliance with the provisions of this Law;
- 5) temporarily or permanently prohibit keeping and reproduction of animals if the owner i.e. keeper acts contrary to the provisions of this Law;
- 6) prohibit loading, reloading, transport and unloading of animals if the requirements prescribed by this Law have not been satisfied;
- 7) temporarily prohibit slaughter of animals, that is performed contrary to in compliance with the provisions of this Law;
- 8) temporarily seize documentation and objects which can serve as evidence in offence or criminal proceedings, issuing a receipt for such an action;
- 9) order seizing of the animals in case of non-compliance with the decree by the inspector who has prohibited or ordered the measure for removal of irregularities;

Moreover, the Law prescribes that, for the purposes of veterinary inspection, some professional activities specified by this Law may be performed by veterinary station post and an authorized veterinarian who conducts the activities in accordance with the Law governing the veterinary matters, thereby checking the following:

- 1) manner of handling of animals;
- 2) animal keeping and breeding conditions;
- 3) fulfillment of animal welfare requirements concerning establishments, area and premisses for animal keeping, breeding, reproduction, sales, training, housing and care have been satisfied;
- 4) fulfillment of the requirements concerning training for animal welfare in accordance with this Law have been satisfied;
- 5) possession of the required documentation and keeping of records in compliance with this Law;
- 6) performance of animal trade, transport, animal training and public presentation;
- 7) means of transport;
- 8) animal resting places and control posts;

- Farm animals, laying hens including information on conditions of production, chickens kept for meat production, calves, pigs;

The table shows the current situation in the Republic of Serbia, i.e. number of farms depending on animal species and production:

FARMS		
ANIMAL SPECIES	NUMBER OF FARMS	TOTAL NUMBER
Bovine animals	1328	1915
Diary cows	587	
Laying hens	784	1780
Chickens kept for meat production	996	
Pigs	824	

The general requirements for keeping and handling of animals are prescribed by the Law on Animal Welfare, and one of the basic principles of this Law is the principle of responsibility referring to all owners and keepers of animals, regardless of business operations they perform in connection with animals and different animal species. The Law prescribes that all legal and natural persons are entitled to keep and breed animals if they meet the requirements for keeping and breeding the animals. Any person shall be obliged to take taking care of animals, in particular of the animals whose survival directly depends on him/her and to give giving aid and provide the professional help to any animal he/she has injured.

In addition, owner i.e. keeper of an animal is obliged to:

- 1) handle the animal with due diligence and provide keeping and caring conditions in line with the animal species breed, sex, age as well as physical, biological and productive specificities and properties with respect to animal behavior and health conditions;
- 2) provide prompt veterinary aid if the animal is ill, during parturition as well as shall take care of a diseased, injured and exhausted animal.

The owner i.e. keeper of an animal is responsible for its life, health and welfare and has to undertake all necessary measures to ensure that unnecessary pain, suffering, fear, stress and injury has not been inflicted on the animal.

The Law governs animal keeping, breeding and trade, whereby the animals can be kept, bred and placed on the market, for production purposes, in the establishments fulfilling the animal welfare requirements with respect to the space for animals premises and equipment and that are entered in the Register of establishments kept by the Ministry in compliance with the Law governing the veterinary matters.

Persons engaged in keeping, breeding and trade of animals for production purposes shall be obliged to keep the records, in particular with regard to movement, feeding and medical treatment of animals.

The Law on Animal Welfare clearly specifies the animal owner's i.e. keeper's responsibilities so that he/she is obliged to provide the following:

- 1) appropriate and safe accommodation of animals, and micro-climatic and hygienic conditions, sufficient space, freedom of movement, feed and water in line with the animal species, breed, sex age and physical, biological, production and behaviour needs;
- 2) protection of animals from harmful effects of weather conditions and natural enemies;
- 3) separate keeping of animals disturbing each other or presenting the danger to other animals or humans;
- 4) separate housing of diseased, injured and exhausted animals;
- 5) care of animals by sufficient number of trained persons

The Law on Animal Welfare prescribes that owner i.e. keeper of animal that has been deprived of their free movement, must provide such a accommodation space in which animal can lie down and stand up, extend its anterior and hind legs without difficulties, as well as in the same area and space freely turn around in standing and lying position, without bending its trunk and head.

More detailed requirements for farm animal welfare are laid down by the Rulebook on animal welfare requirements with respect to space for animals, premises and equipment in which animals are kept, bred and placed on the market for production purposes, the manner of keeping, breeding and trade of individual species and categories of animals, as well as the content and manner of keeping the animal records (Official Gazette of RS, No. 6/10).

This Rulebook lays down general requirements for animal welfare i.e. laying hens, pigs, calves and chickens kept for meat production (broilers) in terms of space, premises and equipment, temperature, humidity, ventilation, automatic and mechanical equipment, etc. and it also prescribes in detail the manner of keeping, breeding and trade of different animal categories, in particular:

Laying hens – The general requirements for all laying hen maturity periods are prescribed, in particular with respect to area, lighting, noise, which can be performed disinfection, control and specific conditions for individual breeding systems, such as alternative breeding system, breeding in unenriched cages and enriched cages.

Broilers – Specific requirements are prescribed in terms of stocking density, feeding, bedding, lighting, noise level, ventilation, examination and check and any interventions that might be carried out.

Calves – The requirements are prescribed in terms of manner of keeping (housing in group or individual boxes or by tethering or without tethering), floor space to be provided dependent on animal weight, equipment, floor, bedding, lighting, noise level, humidity, temperature, feeding and watering examination and check on calves.

Pigs – The general keeping requirements for all pig categories are laid down (in terms of space, floor, slatted floors and grating gaps, lighting, unobstructed floor space, noise level, group housing, individual housing of aggressive pigs, floor, bedding, feeding and

watering, reduction of the teeth and tail cutting). The specific requirements for different categories of pigs are specified i.e. specific requirements for boars, specific requirements for sows and gilts and specific requirements for piglets before weaning and for weaners and rearing pigs.

- Animals during transport;

The Law on Animal Welfare governs the general requirements for animal transport, i.e. animal transport may be carried out by legal and natural persons i.e. entrepreneurs registered in the Register on transporters of animals kept by the Ministry of Agriculture and authorized for that activity by the same Ministry.

Upon entry into the Register of transporters of animals, the Ministry issues to a legal and natural person i.e. entrepreneur a authorization for longer or shorter transport of animals. The entry into the Register of transporters of animals and authorization to transport animals is not required:

- 1) if animals are transported by a natural person for his/her personal needs up to the distance of 65 km, from the place of loading to the place of unloading;
- 2) in the case of pet transport for personal needs, apart from the transport for commercial purposes,
- 3) in the case of seasonal displacement of animals for pasture.

Any legal and natural person i.e. entrepreneur shall be entered into the Register of animal transporters if he fulfils the requirements for transport of animals in terms of means of transport and training for animal welfare during transport.

In addition, a transporter is obliged to carry out the transport of animals in such a way as to provide the animal life and welfare protection, and prior to the commencement of transport, to complete a journey log which must be in the vehicle during transport and in particular must contain the following: business name, name and surname of the transporter, registration number from the Register of animal transporters,, place of loading, reloading, resting and unloading of animals; route plan; duration of transport.

The animals during transport must be accompanied by person, assigned by the transporter (hereinafter referred as: Attendant) to take care of animals and who is trained for animal welfare during transport.

The Law on Animal Welfare prescribes that animals may be transported only if they are fit for travel, and driving, loading, reloading, unloading, and transport of animals must be carried out in a manner which will not inflict pain, suffering, injures and animals must neither be deprived of their basic physiological needs nor be caused their death during transport.

The unloading of animals must be carried out without any delay upon arrival at the place of destination.

The place of loading, reloading and unloading of animals, place of rest and control posts must fulfil the requirements for animal welfare with respect to the area, premises and equipment for animals. These requirements shall be laid down by a separate Rulebook.

In compliance with the Law on Animal Welfare it is prohibited to transport:

- 1) heavily pregnant female animals being in the last 10% of gestation, female animals if seven days have not elapsed since the parturition, newly born animals in which the navel have not healed up completely, ill or injured animals, unless the transport of animals is necessary for their medical treatment, emergency slaughter and/or emergency killing;
- 2) animals transported in uncovered means of transport boxes, containers and other equipment in which they are not protected from adverse effects of weather conditions and differences in climat conditions;
- 3) animals transported in closed means of transport, boxes, containers and other equipment during hot season if a appropriate v ventilation system is not provided;
- 4) animals sensitive to temperature changes if stable temperature is not provided;
- 5) animals if the transport vehicle does not meet the prescribed requirements;
- 6) animals if accommodation is such that injuries to animals or their falling out of the transport vehicle will be possible;
- 7) animals if during transport no water, food, first aid and veterinary treatment of diseased and injured animals cannot be provided;
- 8) aquatic animals if sufficient quantities of water of the appropriate temperature and oxygen concentration is not provided;
- 9) animals if any materials detrimental to their health are transported with them or they are transported with animal carcasses;
- 10) animals by post;
- 11) animals if a transporter is does not in possession of accompanying documentation in accordance with this Law.

The Law prescribes the duties of police or customs authorities to retain the consignment of animals, transporter and transport vehicle no more than two hours, if transport of animals is carried out contrary to the provisions of the law and to inform the official veterinary inspector thereon.

Detailed requirements to be fulfilled by means of transport in road transport,, railway, river transport (livestock vessel and roll-on roll-off-vessel) and air transport in terms of space, ventilation, lighting, loading and unloading equipment are prescribed by the Rulebook on requirements for means of animal transport used in in which animals are transported (Official Gazette RS, No. 14/10).

Detailed requirements concerning the content and manner of keeping the Register and on transporters of animals and performance of training are laid down by the Rulebook on animal welfare training programme during transport as well as content and manner of keeping the Register of transporters (Official Gazette RS, No. 73/10).

As for detailed provisions concerning the manner of treatment of handling the animals during transporters authorization, content, of journey log, a separate more detailed regulation governing this field has been planned.

- Animals at the time of slaughter or killing.

General requirements for animal welfare at the time of slaughter are governed by the Law on Animal Welfare, while more detailed provisions on the manner of animal treatment prior to the slaughter, method of stunning and bleeding the animals are laid down by a separate by-law.

The Law prescribes that an animal must be treated in a humane manner before it is slaughtered, i.e. prior to the slaughter, the animal must be stunned in such a way as to cause immediate loss of consciousness and the slaughter must be carried out as close to the place of keeping.

When stunning, the animals must not be restrained by the methods which will inflict pain and suffering, and the animal's hind legs must not be tied; the animal must not be suspended prior to stunning and bleeding. Only poultry and rabbits may be suspended before stunning for slaughter purposes, provided that they are stunned immediately after suspension.

The Law on Animal Welfare prescribes the requirements for stunning of animals before slaughter, so that animals must not be slaughtered before they are stunned in a professional and prescribed manner. Therefore, for the purpose of stunning an animal before slaughter, it is prohibited to use dagger, hammer, axe or other tools not specified for such activities in compliance with this Law.

The processing of slaughtered animals must not be continued unless bleeding the animal has not been completely finished.

Animals may be slaughtered without previous stunning in the case of:

- 1) poultry and rabbit slaughter in a household for personal consumption, in a manner and by tools leading to immediate death;
- 2) emergency slaughter for the purpose of ending the animal's pathological state which may lead to its death due to severe injuries caused by accident or for other health reasons, if no stunning is possible;
- 3) religious slaughter that is carried out in accordance with regulations of a religious community registered in the Republic of Serbia.

In the case of slaughter without prior stunning of animals, they must be restrained in a suitable manner, bled in a rapid and professional manner to minimize pain and suffering as much as possible.

The Law prescribes that restraining, stunning and slaughtering of animals, other than poultry and rabbits being slaughtered in a household for personal consumption, may only be carried out by a person trained for animal welfare at the time of slaughter.

A veterinary inspector in a slaughterhouse is responsible for animal welfare at the time of restraining, stunning and slaughtering.

Detailed requirements for slaughtering and killing of animals are governed by the Rulebook on requirements and methods for killing of animals, the manner of animal treatment immediately prior to slaughter, the method of stunning and bleeding the animals, requirements and methods for slaughtering the animals without prior stunning, as well as training programme on animal welfare during slaughter (Official Gazette of RS, No. 14/10).

This Rulebook prescribes: animal treatment prior to slaughter (general treatment requirements, treatment of animals brought in containers and animals not brought in containers), a method for restraining and stunning of animals (requirements for mechanical stunning by penetrating captive bolt pistol and percussion stunner, stunning by electronarcosis,, stunning of poultry in water bath stunners, stunning of pigs by exposing them to carbon dioxide, stunning of poultry by exposing them to gas mixture), method for animal bleeding, requirements and methods for slaughter without prior stunning, methods and means of killing the animals which are not bred for fur production, methods and means of killing fur animals, methods and means of killing animals for the purpose of disease control purposes, methods and means of killing day-old chicks and embryos from hatchery waste and welfare training programme on animal welfare at the time of slaughter and killing.

Zootechnical legislation

The Law on Veterinary Matters Article 46, lays down that local self-government shall, in its own territory, establish a zoohygiene service to perform the following duties:

- 1) catch abandoned animals and accommodate them in animal shelters;
- 2) safely dispose animal bodies from public sites and facilities for breeding, keeping, training, displaying, competition, or circulation of animals;
- 3) to transport or organize the transport of animal carcasses from public sites and facilities referred to in paragraph 2) to the collection centres or facilities for the processing or destruction of waste of animal origin in such a way as to pose no risk to other animals, humans or the environment.

The local government shall be in possession of a facility for collection of animal carcasses. From the facilities mentioned in paragraph 2), other animal by-products may be collected too.

The local government which has not established zoohygiene service shall finance disposal of carcasses until such a service is established.

When an animal dies in the circumstances not considered normal, the animal carcass may be disposed only by order of a veterinary inspector.

The Law on Veterinary Matters Chapter XII. - The Law environmental protection (Articles 135-137) prescribes that:

- all persons shall apply the measures for protection of the environment from adverse effects associated with animal breeding, keeping and trade, with production of and trade in products of animal origin, food of animal origin, animal feed and by-products of animal origin, and during prevention of occurrence and spread, during containment and eradication of infectious animal diseases;
- all persons shall handle by-products of animal origin, and animal secretion, waste and waste water in compliance with the conditions and regulations enacted on the basis of this Law and the regulations enacted on the basis of the law governing the environmental protection;
- persons dealing with collection of by-products of animal origin shall provide their transfer to the nearest waste collection facility or to the facility in which these by-products are processed or destroyed in a safe manner.

It is prohibited to throw animal carcasses into rivers, other water streams or draining systems or to abandon them on roads, in open area, forests or in other places.

Animal owners and keepers have to notify the death of an animal to the Zoohygiene Service and to observe all the instructions issued by this Service in connection with carcass disposal and to inform the Central Base on animal death, except for pets.

When an animal is suspected of having died from infectious disease which has to be reported, a veterinarian or veterinary inspector will collect pathological material and send it for testing to establish the cause of death.

The Zoohygiene Service is obliged, when necessary, to provide transport of the carcasses from the place of death to post-mortem examination or collection facilities for processing or destruction, and to ensure the disinfection of the place of death, vehicles and equipment. As an exception, animal carcasses shall be buried or incinerated at animal burial place or in a burial pit fulfilling the prescribed requirements.

When an animal is suspected of having died from infectious disease it is necessary to find the cause of its death.

The domain of zootechnics in the Republic of Serbia is governed by the Law on Livestock and relevant rulebooks specifying individual specific zootechnical fields.

The Law on Livestock governs the objectives in livestock production and entities in livestock production, their organizational structures, registration of breeding establishments and establishments with special powers, breeding objectives and

implementation of breeding programmes, productivity control and preservation of domestic animal characteristics, breeding of domestic animals, keeping of bees, breeding of wild game, aquaculture animals, preservation of domestic animal genetic values and biological diversity in livestock breeding, production of and trade in feed of plant origin for domestic animals and animal products, trade in breeding stock and other issues significant for livestock breeding.

The Law on Livestock governs breeding and production of breeding stock and good quality breeding domestic animals, artificial insemination of domestic animals, trade in breeding stock, zootechnical requirements for breeding of domestic animals, environmental protection during breeding and use of domestic animals, quality of plant origin feed for domestic animals and animal product quality, breeding objectives and implementation of breeding programmes, testing of productive capability of domestic animals and control method of the activities prescribed by the law.

In addition to the Law on Livestock, the requirements for breeding and production of breeding and good quality breeding domestic animals are prescribed by the following Rulebooks:

- 1) The Rulebook on model and content of an application for entry in the Register of breeding establishments and establishments with special powers as well as the content and the manner of keeping such Register (Official Gazette of the Republic of Serbia, No. 67/09).

- 2) The Rulebook on requirements to be met for acceptance for breeding purposes of domestic breeding animals and good quality domestic animals (Official Gazette of the Republic of Serbia, No. 94/09), which specifies in more details the requirements to be met by domestic animals to be accepted for breeding purposes, the manner of giving a licence to male breeding heads, and the quality of male breeding heads used in the reproduction and insemination centres;

- 3) The Rulebook on requirements to be met by quality domestic breeding animals of complete and incomplete origin for entry in the Register, and the content and the manner of keeping the Records and/or Register (Official Gazette of the Republic of Serbia, No. 94/09), specifies in more details the requirements for domestic animals to be entered in the Register of domestic animals;

- 4) The Rulebook on requirements for the facilities and equipment to be fulfilled by breeding establishments and establishments with special powers and requirements for professional staff to be provided by the latter (Official Gazette of the Republic of Serbia, No. 103/09), that specifies in more details the requirements to be met by breeding establishments when performing the selection of domestic animals, as well as detail requirements for establishments with special powers to deal with livestock activities;

- 5) The Rulebook on the List of genetic reserves of domestic animals, the manner of preserving genetic reserves of domestic animals, and also on the List of indigenous breeds of domestic animals and endangered indigenous breeds of domestic animals (Official Gazette of the Republic of Serbia, No. 38/10), specifies the manner of preserving the genetic reserves of domestic animals, their minimum number, and the name of indigenous breeds and endangered indigenous breeds of domestic animals;

- 6) The Rulebook on demand in terms of breeding of and trade in the indigenous breeds of domestic animals, and also about content and governing of the register of

indigenous breeds of domestic animals (Official Gazette of the Republic of Serbia, No. 56/10), specifies in more details the manner in which the breeding of indigenous breeds of domestic animals can be performed, the manner of trade in and registration of indigenous breeds of domestic animals.

7) The Rulebook on protective band size and specific requirements for trade in and movement of bees and bee breeding stock, and specific requirements for bee breeding in the protective band around the queen bee selection centre (Official Gazette of the Republic of Serbia, No. 67/10), specifies the minimum size of the protective band around the Queen Bee Selection Centre, and the requirements for trade in bees and bee breeding stock in the protective band, as well as the manner of placing the bee farm in the band.

8) The Rulebook on content and manner of keeping the bee pasture register (Official Gazette of the Republic of Serbia, No. 67/10) prescribes the content of register, entity responsible for keeping such register and the manner of its updating;

9) The Rulebook on requirements and a manner of bee keeping and movement, transport permit content and requirements for issuance of approvals to bee keepers from other countries to enable them to use bee pastures in the territory of the Republic of Serbia (Official Gazette of the Republic of Serbia, No. 73/10) lays down the types of apiaries, the manner of placing them in relation to the buildings and other apiaries, the manner of pasture order management, bee movement and the requirements for beekeepers from other countries to use the bee pasture in the territory of the Republic of Serbia.

The major part of the Law on Livestock governs the breeding of good quality domestic breeding animals and prescribes the necessary procedures for domestic animal breeding. The breeding of good quality domestic breeding animals is performed under the control of breeding establishments and establishments with special powers to conduct the operations provided for by this Law within the scope of their competences.

By the Law on Livestock and accompanying rulebooks, the Republic of Serbia endeavours to introduce the EU regulations governing the zootechnical field into the Serbian legislation.

Expenditure in the Veterinary Field

The answer to this question is given in Chapter II item 10 – Payment and Checking, Internal Trade System Control and Import System Control that specifies veterinary-sanitary fee and according to the zootechnics legislation, the costs are borne by local government.

III PLACING ON THE MARKET OF FOOD, FEED AND ANIMAL BY-PRODUCTS

Please provide information on the following areas:

General:

11. General architecture of the legal basis; organisation and powers of different institutions involved.

Placing on the market of food, feed and animal by-products is regulated by the following legal acts:

- The Food Safety Law (Official Gazette RS, No. 41/2009) lays down the general food safety rules, requirements for placing on the market of food and feed, obligations and responsibilities of food and feed business operators rapid alert system, emergency measures and crises management plan, food and feed hygiene and quality.
- The Law on Veterinary Matters (Official Gazette RS, No. 91/2009 and 30/2010), in addition to health protection, improvement and welfare of animals, lays down requirements for official control and requirements for production of and trade in animals, animal by-products, food of animal origin and feed for animals.
- The Law on Genetically Modified Organisms (O. Gazette RS, No. 41/2009) lays down the issuance of approvals for use in closed systems and for intentional application to the environment of genetically modified organisms and products made from genetically modified organisms.
- The Rulebook on the List of composite food (Official Gazette of RS, No. 33/10) specifies the List of composite food, and the competences in official control on the composite food placed on the market.

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.

The Ministry of Agriculture, Forestry and Water Management adopts regulations for implementation of laws under its competence – rulebooks, orders, instructions, monitoring plans, crisis management plan, etc.

The Veterinary Directorate prepares technical bases for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan concerning the safety of food of animal origin and feed for animals.

The Phytosanitary Administration

The Phytosanitary Directorate prepares technical bases for laws, rulebooks, orders, instructions, monitoring plans, crisis management plan, concerning the food safety of plant origin food at the level of primary production.

General Inspectorate

Phytosanitary inspection (internal, border and food safety inspection) carries out the inspection supervision through phytosanitary inspectors, and the agricultural inspectorate (food safety of plant origin and composite food, inspectorate for wine, brandy, alcoholic and non-alcoholic drinks) through agricultural inspectors, implements the Food Safety Law and bye-laws on the basis of this Law concerning the food of plant origin in all stages of production, processing and wholesale and retail trade, and composite food of plant origin and non-alcoholic drinks.

12. Respective fields of responsibilities of competent authorities concerned.

See the answer in Chapter I, question number 1, page 1

The Ministry of Agriculture, Forestry and Water Management implements the Food Safety Law and bye-laws adopted on its basis in the field of plant origin food, composite food, food of animal origin and feed in production, processing, wholesale and retail trade. The Ministry of Agriculture, Forestry and Water Management carries out inspection supervision through phytosanitary and agricultural inspectors from the General Inspectorate and veterinary inspectors from the Veterinary Directorate.

The Ministry of Health carries out inspection supervision through sanitary inspectors.

The Veterinary Directorate implements the Food Safety Law, the Law on Veterinary Matters and bye-laws adopted on the basis of these laws in the field of the food of animal origin, in all stages of production, processing and wholesale and retail trade, composite food, feed and animal by-products of animal origin.

The Veterinary Directorate carries out inspection supervision through veterinary inspectors.

The Ministry of Health implements the Food Safety Law and bye-laws in the field of dietetic food, food intended for infants – substitute for mother's milk, novel food, dietetic supplements and salts for human consumption, production of additives, flavourings, non-animal enzyme preparations, ancillary non-animal auxiliary agents and drinking water.

As regards the importation of food, **the Ministry of Health** shall carry out the following:

- documentary check,
- determining conditions of food transport hygiene,
- physical check on food at customs clearance posts,
- organoleptic check on food,
- sampling for laboratory analyses for health safety.

According to point (b) Article 12 (1) of the Law on Food Safety, the importer shall submit to the Ministry of Health:

- a request, directly or through representative (forwarding agent), upon receipt of the consignment being imported, to the sanitary inspector in the department/section for supervision of border for checking consignments being imported; -as regards this obligation, the importer shall submit the request in writing for each consignment to be assessed for safety of food being imported, with the following consignment data:

- name and address of the sender, importer and user,
- accurate data for identification of each type of food in the consignment (type of food, purpose, series, lot, batch, quantity, weight...),
- packaging condition and type and packaging unit number,
- means of transport sign (ship, wagon, automobile, etc.),
- declaration and purpose of the consignment,
- possible damage during transport,
- time when the consignment will be prepared for check, and the place of checking,
- number and date of customs declaration (or other similar document for identification of consignment).

The request for checking consignment of food being imported is subject to paying fees. Fees shall be paid to the appropriate giro account of the Budget of the Republic of Serbia in accordance with the Law on Republic Administrative Taxes. Along with the request for checking the consignment and depending on the type of food, importers have to submit documents required for food safety assessment.

Documents to be submitted together with the request for import of food:

1. Document certifying that food is safe, issued by the competent authority of the country of export (HEALTH CERTIFICATE);
2. The manufacturer's statement with data on the type, content and purity of raw materials, chemicals, additives, aroma and other substances used in food production (manufacturer's specification);
3. Evidence of origin of gelatine and other materials in contact with food, if food is packed in such type of material (such as products in capsules);
4. Report on laboratory analyses with regard to food safety;
5. Translation of the product declaration by an approved court translator;
6. Certificate issued by the Medicines and Medical Devices Agency of Serbia, certifying that according to the Law on Medicines and Medicinal Devices the products concerned are not subject to controls (dietary products);
7. Written evidence issued by the competent authority of the manufacturer country regarding the type of the product registration (curative, drug, dietary product, other type of food);
8. Written evidence of the manufacturer related to the self-control system application (HACCP, BRC, IFS, ISO 22000:2005), in case the food manufacturer operates in accordance with these standards.

At the request of the sanitary inspector, importers shall also submit other required documents in accordance with the Law on General Administrative Procedure.

For all these documents, certified copies of the originals and their translation in the Serbian language done by an approved court translator have to be submitted.

If a party does not submit required evidences, the sanitary inspector shall act in accordance with Article 127 (2) and (3) of the Law on General Administrative Procedure, i.e. the sanitary inspector shall inform the party to submit required evidences within a subsequently specified period of time. In case the party does not submit the required evidences within the subsequently specified period of time, the sanitary inspector shall, by conclusion, reject the request as if it had not been submitted (Article 58 (2) of this Law).

The importer or manufacturer of a dietary product, prior to import and/or placing the dietary product on the market in the territory of the Republic of Serbia shall submit the application for entering the dietary product in the database that is maintained by the Ministry (hereinafter referred to as: the database). The person applying for the entry of a dietary product in the database of the Ministry shall submit the following documents:

- 1) qualitative and quantitative content of the dietary product;
- 2) specification of raw materials, origin and analytical method, certificates for raw materials with a risk of bovine spongiform encephalopathies and other transmissible spongiform encephalopathies and genetically modified micro-organisms and appropriate statements of the raw materials manufacturer;
- 3) description of production process;
- 4) results obtained from the accredited laboratory from the country of the manufacturer, with regard to checking the content and safety of ready products (laboratory accreditation in accordance with the following standards): EN ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories, EN 45002 - General criteria for the assessment of testing laboratories, EN 45003 - Calibration and testing laboratory accreditation system - general requirements for operating and recognition;
- 5) instruction on intended use and manner of taking the dietary product;
- 6) restrictions regarding the use and specific warning, if any;
- 7) dietary product declaration;
- 8) analytical report on its health safety, prepared by the Institute of Public Health (of Serbia, Vojvodina, Nis, Kragujevac), Institute of Public Health of Belgrade, Institute of Hygiene of the Military Medical Academy;
- 9) expert opinion and categorization prepared by the Faculty of Pharmacy - University of Belgrade;
- 10) decision on compliance with sanitary-hygienic and health requirements for using facilities, with a short description of facilities for production and storage, and evidence that principles of good manufacturing and hygiene practices and HACCP have been established (in case the dietary product is produced in the Republic of Serbia, documentation on the producer shall be submitted);

11) evidence that a product is manufactured in compliance with the principles of good manufacturing and hygiene practices and HACCP (Hazard Analysis and Critical Control Point), if the dietary product is imported in the Republic of Serbia;

12) if a dietary product is imported in the Republic of Serbia, the evidence that the product is registered and/or is in circulation in the country of manufacturer shall be submitted, and the evidence of its marketing in at least one EU country;

13) photocopy of payment slip for covering the costs of the dietary product entry procedure into the Ministry database;

14) data on the importer and/or manufacturer (full name of the business entity, name and family name of the responsible person and address: place, street and number, telephone number, fax number and e-mail).

Persons applying for the dietary product entry in the database shall submit the documents referred to in paragraph (1) points 1), 2), 3), 4), 5), 6), 7), 11) and 12) of this Article (original or their copies), and Serbian translations of these evidences done by an approved court translator.

13. 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.

See Annex IV, List of regulations in the field of food, feed, and animal by-products safety in the Republic of Serbia.

14. Please provide information for each item listed below.

Hygiene rules

The Food Safety Law (O. Gazette 41/2009) prescribes the general and specific requirements for food hygiene in any stage of production, processing, distribution and trade, and the requirements concerning veterinary public health, as well as the conditions and methods of treating animal by-products obtained during food handling.

The Rulebook on requirements for establishments for animal slaughter, processing, treatment and storage of food of animal origin (O. Gazette of SFRY, No. 0.53/1989) and the Rulebook on the veterinary-sanitary requirements for establishments production of and trade of food of animal origin (Of. Gazette of RS, No. 11/08) prescribe more detailed requirements for the following:

- Infrastructure of establishment and technical/technological requirements for production of food of animal origin – establishment area, arrangement of premises, technological permanent flow of raw materials, products and people,

- pests control, adequate lighting, ventilation, dressing rooms and resting place for employees.
- necessary number of rooms and equipment for performance of the envisaged technological operations, (for acceptance of animals, stream line description, sanitary premises, premises for sanitation of equipment, hand washing and disinfection facilities, water supply points, waste water system, cooling and freezing rooms, heat treatment facilities, storage for packaging and wrapping materials, product storage, premises and conditions for specific risk material and categorization of animal by-products),
 - requirements for specific production (room temperature, sanitation equipment, hygienic conditions)

The valid Rulebook on microbiological safety of foodstuffs in trade (O. Gazette of FRY No. 26/93 and 53/95), lays down the microbiological criteria for the food placed on the market. The count of micro-organisms in 1g and/or 1ml of foodstuff in terms of this Rulebook are the count of microorganisms cultivated on a nutritive agar medium in accordance with the methods prescribed for microbiological analysis and super analysis of foodstuffs.

According to this Rulebook, foodstuffs on the market must not contain: Bacteria of *Salmonella* spp. in 25g/ml, coagulase-positive staphylococci in 0.01g/ml, sulphite-reducing clostridia in 0.01 g/ml, proteus spp. in 0.01 g/ml. This Rulebook (O. Gazette of FRY, No. 26/93 and 53/95) shall be valid until 1 June 2011, when the Rulebook on general and specific requirements for food hygiene in any stage of production, processing and trade shall be effective – the Rulebook on Microbiological Criteria (O. Gazette of RS, No. 72/2010) that is harmonized with Regulation EC 2073/2005 on Microbiological Criteria, including all amendments adopted by the end of 2010.

The establishments in the Republic of Serbia which are approved for export to the market of the European Union perform the microbiological tests of food carried out in compliance with the European provisions in approved and accredited laboratories according to the Rulebook, (O. Gazette of RS, No. 72/2010) as Regulation EC 2073/2005.

For the purposes of prevention purposes and eradication of certain zoonotic diseases, the Veterinary Directorate has adopted the Rulebook on measures for early detection, diagnosis, spreading, prevention, suppression and eradication of poultry infection by certain types of *Salmonella* (O. Gazette of RS, No. 7/10) that is harmonized with Regulation EC 2160/03, including the Regulation for implementation of Regulation EC 2160/03.

The diagnostic salmonella analysis shall be conducted for: poultry feed, equipment and premises for poultry egg incubation, inseminated eggs from which no chicks have hatched out during incubation, dead or stunted chicks, one day-old chicks that died during transport and chicks that died during the three-day period after transport, poultry meat and eggs production establishments and holdings for poultry breeding – during

production, by swabs; pooled sample of young chicks and laying hens feces, cadavers of dead poultry from parents' flocks and laying hen flocks used for production of table eggs.

The regulations that have been harmonized with the EU "hygiene package" shall be in force from 1 June 2011. The preparation of instructions and guides concerning this field have been planned for food business operators and competent authorities.

The Rulebook on general sanitary requirements to be satisfied by establishments subject to sanitary surveillance (Official Gazette of RS, No. 47/2006).

This Rulebook prescribes general sanitary requirements to be satisfied by each establishment subject to sanitary surveillance, starting from its area to the conditions in the establishment itself:

- 1) that it is supplied with healthy drinking water;
- 2) that waste water discharge and disposal of solid and other waste materials from the facility is carried out in hygienic manner;
- 3) that artificial light has been provided and if possible, natural light too, and natural and/or artificial ventilation and prescribed and/or necessary temperature;
- 4) that it is tidy and clean and that the hygiene on interior space and premises, plant, unit, furniture, equipment, accessories, vehicles and their equipment is maintained by hygiene measures (putting in order, cleaning, washing, maintenance, ventilation, disinfection, disinsection, rodent control, and the like) and good standard of hygiene in the establishment and its close area is achieved;
- 5) that, according to the type of business performed in the establishment, suitable space, plants, units, furniture, equipment, accessories and vehicles have been provided.

The Rulebook on sanitary-hygiene requirements for the establishments for production of and trade of foodstuffs and general use items are performed (Official Gazette of RS, No. 6/97, 52/97).

This Rulebook lays down in more details the sanitary-hygiene requirements for the establishments for production of and trade in foodstuffs (food) and general use items are performed, in terms of establishment location, its area, construction, water supply, waste water discharge, disposal of solid wastes, premises and equipment, with the exception of the waterworks facilities and industrial and handicrafts facilities for slaughter of animals production, treatment, processing and storage of products of animal origin products.

15. Specific rules for animal products, including information on the situation concerning agrifood establishments and the microbiological quality of raw milk

The Food Safety Law prescribes that food business operators shall, in addition to general requirements, fulfil the specific hygiene requirements for products of animal origin in all stages of production, processing and trade.

In compliance with the Law on Veterinary Matters and the Food Safety Law, the system based on HACCP principals must be implemented in all establishments for producing food of animal

The Rulebook on requirements to be satisfied by establishments for animal slaughter, processing, treatment and storage of food of animal origin (O. Gazette of SFRY, No. 0:53/1989) and the Rulebook on veterinary-sanitary requirements for food of animal origin production and trade establishments (Of. Gazette of RS, No. 11/08) and the Rulebook on shape and content of the stamp and/or health certificate of safety of wild game meat intended for human consumption and on the method and procedure for labelling of food of animal origin (Of. Gazette of RS, No. 44/2007) shall, in addition to general requirements, lay down specific requirements for the food of animal origin, including structural conditions, temperature requirements in certain stages of production, processing and trade; maintenance of cold chain, as well as the procedure for identification of food of animal origin

Food of animal origin food can be only produced and stored in approved establishments that fulfil the defined requirements and which are under veterinary inspection supervision.

The Veterinary Directorate shall approve the following establishments:

- Establishments for slaughter of ungulates, poultry, lagomorpha,
- Establishments for cutting and processing of meat of ungulates, poultry, lagomorphas, wild game
- Combined establishments for slaughter, cutting, processing, treatment of meat of ungulates, poultry, lagomorpha and wild game meat,
- Establishments for slaughter and processing of fish,
- Establishments for milk processing – dairies,
- Milk collection stations
- Establishments for milk treatment/processing in households,
- Establishments for processing of snails/frogs' legs,
- Establishments for egg processing,
- Establishments for honey treatment and processing,
- Establishments for egg grading and packaging,
- Establishments for processing of natural casings,,
- Establishments for production of artificial casings,
- Storage with a temperature regime (cold stores)
- Establishments for feed production
- Establishments for processing animal by products

Number of approved establishments for production and storage of animal origin food:

Type of establishment	Establishment(1) (Inter. mark.)	Establishment Export (EU)	Establishment(2) Export (TC)
Slaughterhouses (red meat)	183	1	11
Slaughterhouses (poultry)	31	-	-
Combined establishments (slaughter, cutting, processing – red meat)	327	4	31
Combined establishments (slaughter, cutting, processing – poultry)	45	-	12
Red meat– cutting/deboning/processing	472	-	36
Poultry meat – cutting/deboning, processing	3	-	-
Ests for processing wild game meat	10	-	1
Milk processing – dairy factories	253	2	45
Milk collection stations	1421	-	-
Milk processing households,	1313	-	-
Slaughter processing establishments of Fish	40	1	9
Snails/frogs’ legs processing establishments,	7	-	4
Egg processing establishments	1	-	1
Honey processing establishments	38		
Honey collecting and packaging – households facilities	263	-	-
Egg grading and packing	8	-	8
Processing of natural casings	9	-	4
Production of artificial casings	1	1	1
Storages (cold stores)	731	-	16
(1) Total number of establishments, including export establishments			
(2) Total number of export establishments, including establishments approved for export to the EU			

Larger establishments for retail trade (“supermarkets”) are subject to approvals if their activities include: cutting and processing of meat, cutting and packaging of fish meat, slicing and packaging of dairy products (cheese, cream).

The Veterinary Directorate keeps the records of all approved establishments for production, processing and trade food of animal origin.

The Rulebook on quality of raw milk (O. Gazette of RS, No. 21/2009) lays down the quality and methods of raw milk control during delivering. In addition to the quality parameters, the raw milk hygiene parameters for raw milk have also been established: total plate count and somatic cell count.

Within the meaning of this Rulebook, raw milk means a product of mammary gland, obtained by permanent milking of healthy, properly fed and regularly milked animals, at least 30 days before or 8 days after parturition, and that has not been heated to the temperature above 40°C; milk with nothing added or removed. Within the meaning of this Rulebook, raw milk is, according to animal species, cow's milk, sheep's milk and goat's milk.

On the basis of raw milk analysis results provided by an authorized laboratory, cow's raw milk is classified according to the microorganism count, as:

- 1) E class milk – contains up to 100.000 cfu/ml
- 2) I class milk – contains from 100.001 to 400.000 cfu/ml
- 3) II class milk - contains above 400.000 cfu/ml

On the basis of raw milk analysis results provided by an authorized laboratory, sheep's and goat's raw milk is classified according to the microorganism count, as:

- 1) I class milk – contains up to 1.500.000 cfu/ml
- 2) II class milk - contains more than 1.500.000 cfu/ml

16. Control rules including implementation of HACCP (Hazard Analysis and Critical Control Points) by food operators. Also please provide statistics on the number of establishments (according to the activity) applying HACCP.

- The implementation of self-control systems based on HACCP principles in the establishments dealing with for production and processing of and trade food of animal origin, is mandatory for all food business operators in compliance with the Law on Veterinary Matters e and the Food Safety Law as from 1 January 2009.
- The implementation of self-control systems based on HACCP principles by the establishments for production, processing and trade food of plant origin food is mandatory for all all food business operators in compliance with the Food Safety Law as from June 2011.
- Food business operator on the level of primary production level shall establish and implement principles of good hygiene, practice, good manufacture practice and good breeding practice.
- The National Guide for development and implementation of prerequisite programmes and principles of HACCP for certain fields of food production fields, is available at the website of the Ministry of Agriculture, Forestry and Water Management. The Guide is intended for food business operators and competent authorities. The food operators can use it as a guide for to development and implementation of prerequisite programmes and procedures based on HACCP principles, including the principle of flexibility principle for small food business operators.

During the period of 2005 to 2008, the Ministry of Agriculture granted the subsidiaries funds to the establishments from different food production sectors (meat, milk, cold

stores) for implementation of HACCP system (the amount of 500.000 EUR was granted to 615 operators).

The number of establishments in Serbia that have implemented HACCP system

	Type of production	Number of establishments with implemented HACCP system
1.	Slaughterhouses, cutting and processing – red meat	281
2.	Slaughterhouses, cutting and processing – poultry meat	33
3.	Fish slaughter and processing	20
4.	Wild game processing	1
5.	Snails/frogs' legs processing,	4
6.	Processing of natural casings	7
7.	Milk processing	90
8.	Egg processing	1
9.	Honey processing establishments	16
10.	Egg grading and packaging	8
11.	Storages (cold stores)	126

17. Specific control rules for animal products

Specific requirements for control of products of animal origin are laid down by the following regulations:

- 1) The Law on Veterinary Matters (O. Gazette of RS, No. 91/05 and 30/2010),
- 2) The Food Safety Law (O. Gazette of RS, No. 41/09),
- 3) The Rulebook on requirements for the satisfied by establishments for animal slaughter, processing, treatment and storage of food of animal origin food (O. Gazette of SFRY, No. 53/1989).

This Rulebook lays down requirements (architecture, technical-technological, site and other requirements) to be satisfied by establishments engaged in slaughter of animals and products of animal origin.

- 4) The Rulebook on veterinary-sanitary requirements to be satisfied by establishments for production of animal food (O. Gazette of RS, No. 11/2008).

This Regulation lays down in detail the veterinary-sanitary requirements in terms of construction, that must be fulfilled by establishments for production of food of animal origin: facilities for cutting and processing of meat, removal of animal by-products, cold stores, storages, repackaging and wholesale facilities and facilities for processing and cutting of wild game meat.

This Rulebook is partly harmonized with Regulation 853/2004/EC.

- 5) The Rulebook on veterinary-sanitary inspection and animal control prior to the slaughter and animal product control (O. Gazette of RS, No. 68/1989),

In compliance with this regulation, the veterinary inspectors carry out the control on the premises and equipment in the establishments engaged in production, processing and storage products of of animal origin products, animal slaughter control and supervision, control on meat of slaughtered animals, milk and dairy products, eggs and aquaculture products that have been produced for human consumption. This regulation is partially in compliance with Regulation 854/2004/EC.

- 6) Instruction No. 323-07-03143/2010-05 laying down general and specific hygiene requirements and organisation of official control of products and establishments being approved for export of milk and dairy products to the market of the European Union.

It is harmonized with the requirements prescribed for the establishments dealing with milk production and processing, and with raw milk requirements as laid down by Regulation 853/2004/EC.

The Instruction gives guidelines for food operators who collect raw milk or produce milk or dairy products destined for export to the market of the European Union, and for veterinary inspectors who perform the official control of such establishments. In addition to the valid provisions of the Republic of Serbia, the mentioned food operators have to fulfil the requirements prescribed by this Instruction.

18. Rules for animal by-products including information on the system of collection of cadavers and materials and situation of establishments

The system in the field of animal by-products is governed by the Law on Veterinary Matters ("Official Gazette of RS", No. 91/2005, 30/2010, hereinafter referred to as: the Law).

The local government shall organise the zoohygiene service in its territory to perform the following activities: safe disposal of animal carcasses from public sites and animal keeping, breeding, training, exhibition, competition or trade facilities; transport or arranging the transport of carcasses from public sites and animal breeding, keeping, training, exhibition, competition or trade facilities to the facilities used for collection, processing or destruction of animal by-products in such a way as to pose no risk to other animals, humans or the environment. When an animal dies in the circumstances not considered normal, the animal carcass may be disposed only by order of veterinary inspector. The local government shall provide a facility for collection of carcasses in which other animal by-products collection is possible. The local government that has not established zoohygiene service shall finance disposal of animal carcasses until such a service has been established. (Article 46 of the Law).

The collection, processing and destruction of animal by-products may only be carried out in the facilities meeting the prescribed requirements (Article 72 of the Law) in relation to the construction, equipment, veterinary-sanitary and other requirements, depending on the activities being performed therein.

Upon a request to the Ministry and the decision of the Minister on compliance with the veterinary-sanitary requirements, the facilities for collection, processing and destruction of animal by-products shall be entered in the Registry of facilities and granted a veterinary approval number (Article 73 of the Law).

The animal by-products must be collected, processed or destroyed in the facilities intended for processing, treatment or destruction of animal by-products. The facilities for the collection, processing and destruction of animal by-products shall maintain the prescribed records which are kept for three years. (Article 117 of the Law).

The Government shall establish a public service to deal with the collection, processing and destruction of animal by-products. The Act on founding the public service for collection, processing and destruction of animal by-products shall particularly define the following: headquarters, business activities, management, internal organisation, founding budget, sources of funding the business activities, participation of founder in management and decision making process, requirements and selection criteria relating to management, supervising activities, acting directors, deadline for adoption of the statute, and appointment of the director (Article 118 of the Law).

Legal entities may be contracted by the Ministry to perform the collection, processing and destruction of animal by-products upon fulfilment of the prescribed conditions (Article 119 of the Law).

All persons shall apply measures to protect the environment from the adverse effects associated with animal breeding, keeping and trade, and production of and trade in products of animal origin, food of animal origin, animal feed and by-products, and during prevention of occurrence and spread, during suppression and eradication of infectious animal diseases. Animal by-products, secretion, waste and waste water shall be treated by all persons in accordance with the conditions and regulations enacted on the basis of the

Law and the regulations enacted on the basis of the law governing the environmental protection. Persons dealing with business operations that result in the production of animal by-products must provide transfer of such by-products to the nearest collection facility or to the facility in which these by-products are processed or destructed in a safe manner.

It is prohibited to throw animal carcasses into rivers, other water streams or draining systems or to abandon them on roads, in open area, forests or in other places. Animal owners and keepers shall report the death of an animal to the Zoohygiene Service and follow any instructions they may provide regarding disposal of the carcasses. When an animal is suspected of having died from infectious disease which has to be reported, a veterinarian or veterinary inspector will collect pathological material and send it for testing to establish the cause of death. The Zoohygiene Service shall provide, when necessary, transport of the carcasses from the place of death to a facility for post-mortem examination or collection facility for processing or destruction, and must also ensure the hygienic disinfection of the place of death, vehicles and equipment (Article 136 of the Law).

As an exception animal by-products are buried or incinerated at animal burial place or buried in burial pit complying with the prescribed conditions. When an animal is suspected of having died from infectious disease it is necessary to find the cause of its death. (Article 137 of the Law).

The following facilities have been approved in the territory of the Republic of Serbia on the basis of the business operations carried out therein:

TYPE OF ESTABLISHMENT	TOTAL NUMBER OF ESTABLISHMEN TS
Establishment for collection	3
Establishment for processing	8
Compost production establishment	3
Burial pit for burying of pets	6
Animal burial place for burying of animal carcasses	1
Establishments for producing maggots for fishing bait	2
Establishment for production of trophies (bones, horns, hoofs, claws, teeth)	21
Establishment for manufacture of technical products	86

Out of total number of the establishments for collection, processing and destruction of animal by-products, 3 establishments are state-owned of which 2 are operational. For the purpose of risk management, it has been planned that these establishments are to process

the materials of category 1 and 2. The other establishments are private and they process the materials of category 3 on the commercial basis.

The manner of treatment and requirements in the domain of animal by-products are governed by:

- 1) 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 of animal carcasses and animal waste (Official Gazette of SFRY, No. 53/89). The requirements laid down for the establishments dealing with collection, establishing the cause of death, processing, incineration and burial are general and specific requirements;
- 2) The Order for taking the measures for prevention of occurrence, for detection and prevention of spread, for suppression and eradication of transmissible spongiform encephalopathia (Official Gazette of RS, No. 17/2006, 110/06, 52/07 and 41/2010). 3) This Order classifies the animal waste into three categories (category 1, category 2 and category 3) and prescribes the following:
 - technological processing by which the edges of individual pieces of the material of animal origin, cut up in small pieces in a crusher must not be longer than 50 mm;
 - after cutting up in small pieces, the animal materials shall be heated up in a destructor in order to obtain the minimum inner material temperature of 133°C that is to be constantly maintained at least 20 minutes under the pressure of 3 bar; the Order specifies the installed equipment for monitoring and control of the achieved temperature, pressure and the period of thermal treatment to be entered in the records that shall be kept for three years along with the documentation;
 - the materials of category 2 and 3, and meat meal, meat and bone meal and bone meal obtained by processing of materials, categories 2 and 3, may be used as pet food and exceptional meat, meat-bone and bone flour obtained by their processing, may be used as pig and poultry feed on prior approval of the Ministry competent for veterinary issues;
 - safe destruction of materials, category 1, and meat meal, meat and bone meal and bone meal obtained by processing of that material, category 1, is performed by incineration in the incinerator at the temperature of 850°C, and documentation on registered temperature is kept for three years.

- Funding of checks

In Chapter II, paragraph 10 – Payment and Checking, Internal Trade System Control and Import System Control - the veterinary-sanitary fees have been described.

When taking the food or feed samples, any food or feed operator shall make available the required quantity of free samples to the official inspector at his/her disposal for laboratory tests.

The charges for analysis and super analysis of all samples shall be borne by a party from whom the sample has been taken, if the final procedure shows that food or feed is not in compliance with the prescribed properties.

If the sample is complied with the prescribed properties, the charges of laboratory analysis and super analysis shall be paid from the funds envisaged in the Budget of the Republic of Serbia.

Food and feed operators pay fees for laboratory testing of the samples taken during official checks, as well as for the performed official checks in the case when the test result is unsatisfactory.

The National Programme/Plan for monitoring of residues in live animals, primary products of animal origin and feed for animals is completely financed from the Budget of the Republic of Serbia.

19. Specific rules for feed hygiene, including information on the applicable legislation and procedures for approval/registration of feed establishments

Feed is governed by the following legal acts:

- The Food Safety Law (O. Gazette of RS, No. 41/09) lays down the general feed safety rules, responsibilities of feed business operators and contains the basis for adoption of bye-laws in this field;
- The Law on Veterinary Matters (Official Gazette 41/2009, 30/2010) lays down veterinary-sanitary control and the requirements for feed production and trade.
- The Law on Genetically Modified Organisms (O. Gazette of RS, No. 41/2009) lays down the issuance of approvals for use in closed systems and for intentional application to the environment of genetically modified organisms and products made from genetically modified organisms.

The Ministry of Agriculture, Forestry and Water Management is a policy maker in the field of food and feed safety, and it prepares the proposals of laws, which after the appropriate procedure, have to be established. by the Parliament

The Ministry of Agriculture, Forestry and Water Management adopts regulations for implementation of laws, - rulebooks, orders, instructions, monitoring plans, crisis management plan in the field of animal feed .

The Veterinary Directorate implements the Food Safety Law , the Law on Veterinary Matters and bye-laws adopted on the basis of these laws in the field of animal feed, and carries out inspection supervision through its inspectors.

In compliance with the provisions of the Food Safety Law and the Law on Veterinary Matters , the establishments for feed production must be approved by the Veterinary Directorate.

The procedure for approval of establishments for feed production is as follows:

1. Review of technical-technological documentation for feed establishment,
2. Issuance of decisions for technical-technological documentation,
3. A team of inspectors performs on-spot inspection and checks compliance with the structural and general hygiene requirements in an establishment,
4. Issuing of a temporary/conditional approval for a feed establishment for the period of 3 to 6 months at most and allocation of veterinary control number,
5. Follow-up inspection and verification that the food business operator has introduced self-control system (GMP, GHP, self-checks, HACCP)
6. Issuing of a decision on approval for the establishment and verification of veterinary control number.

In the case of an export approval the inspection team controls compliance with the regulations of an importing country and a special decision and export control number is given to the establishment.

Number of approved establishments for feed production and storage:

TYPE OF ESTABLISHMENT	APPROVED ESTABLISHMENTS
Commercial feed mills	371
Own holding feed mills	35
Pet food production	16
Feed storage	212

The Rulebook on requirements for labelling, marking and advertising of animal feed for animals (O. Gazette of RS, No. 4/10) lays down that before starting feed production the producer issues the producer's specification that contains the following elements to be put into the declaration:

1. trade mark and name of feed;
2. raw materials used in production, in descending order of quantities, and additives are marked by the international mark ("E number");
3. guaranteed analyses;
4. other information of significance to production of the feed that has impact on its characteristics;

5. storage conditions;
6. name and place of a producer with establishment veterinary control number;
7. date of production and shelf life – marked as “use-by date” or “produced on”;
8. net weight

The feed intended to be marketed in closed original packaging must be labelled. The labelling must be sewn in, glued or printed on individual items, and besides, the labelling must be glued or sewn in common packages (package with more individual items) and transport package (package of more common packages on a pallet).

If the feed is placed on the market in bulk, the labelling must be on the container and attached to the documentation accompanying the consignment during transport.

The labelling must be in the Serbian language, easily visible, clear, legible and indelible and must not be covered with other words or marks.

The original feed package must be made from the materials that are not harmful or toxic but preserve keep the product quality to the time of its opening within the durability date.

The Rulebook on feed quality (O. Gazette of RS, No. 4/10) lays down feed requirements that must be satisfied during production and trade: feedingstuff categories, physical, chemical and nutritive properties of raw materials and products; type and quantity of raw materials and processing procedures applied in production.

Within the meaning of this Rulebook, feed means any substance or product, whether processed, partially processed or unprocessed, intended to be used for feeding the animals, and used for production of feed in the form of:

1. feedingstuffs
2. vitamin-mineral pre-mixtures-premixes
3. mixtures

This Rulebook lays down approved feed additives: vitamins and provitamins; micro-elements and minerals; non-protein nitrogen compounds; amino acids; growth stimulators; coccidiostats; other permitted additives (antioxidants, cohesive agents, emulgators, stabilizers and coagulators, dying substances including pigments, flavourings, preserving agents, enzymes, agents for utilization rate of feed).

Feed must not contain hormones, sedatives and tyreostatics.

Mixtures must not contain antibiotics and sulphonamides.

Feedingstuffs and mixtures must not contain bacteria toxins in 1 g (*Clostridium botulinum*, *Clostridium perfringens* and *Staphylococcus pyogenes*).

The Rulebook (O. Gazette of RS, No. 4/10) lays down the maximum quantities of: residues of pesticides or metabolites thereof in feed, non-organic substances, sodium

chlorides in mixtures according to the animal type and category, albumen originated ammonium in feedingstuffs and parasitic fungi.

Feed may contain saprophytic microorganisms not exceeding the maximum of:

Feedingstuffs and mixtures	Count of bacteria in 1 g	Count of yeast and mould in 1 g	Permitted deviation defined by microbiologic analysis
Feedingstuffs of plant origin	6.000.000	200.000	15%
Feedingstuffs of animal origin	12.000.000	10.000	10%
Mixtures for young animals	3.000.000	50.000	10%
Mixtures for adult animals	5.000.000	200.000	15%

Feed may contain pathogenic microorganisms not exceeding the maximum of:

Type of microorganisms	Product	Count of microorganisms
Salmonellae	feedingstuffs and mixtures	0 in 25 g
Sulphite reducing clostridia	feedingstuffs and mixtures	1000 in 1 g
Staphylococcus coagulase positive	feedingstuffs and mixtures	0 in 1 g
Other pathogenic microorganisms	feedingstuffs and mixtures	0 in 50 g

The Rulebook on requirements for feed producing establishments, as well as on the model and content of records kept in feed producing and trading establishments (O. Gazette of RS, No. 103/09) lays down general and specific structural, hygienic and technological-technical conditions for construction, arrangement and equipping of feed producing establishments.

The Rulebook on requirements for self-control assessment procedures in feed business operations (O. Gazette of RS, No. 94/09) lays down the responsibilities of feed business operators that include the implementation of principles of good manufacture practice and good hygiene practice and implementation of self-control system based on HACCP principles.

The Rulebook (O. Gazette of RS, No. 103/09) and the Rulebook (O. Gazette of RS, No. 94/09) shall be valid until 1 June 2011, when the Rulebook on general and specific requirements for feed hygiene (O. Gazette of RS, No. 78/10), laying down the general

and specific feed hygiene requirements in compliance with Regulation EC 1831/2003 shall apply.

The Rulebook on feed hygiene for animals with special nutritive needs (O. Gazette of RS, No. 53/10) lays down the requirements to be satisfied in the case of feed for disabled animals as well as a manner of labelling such a feed.

The feed for animals with on feed hygiene for animals with special nutritive needs may be placed on the market if it fulfils the requirements in terms of special nutritive effects and labelling.

Label for feed for animals with special nutritive needs shall include the mark “dietetic” and indicate the species or category of animal for which the feed is intended, and special nutritive effects of the feed; label shall contain accurate instructions for proper use, nutritive properties significant to the animal category and feed analytical values that provide appropriate nutritive effects.

IV FOOD SAFETY RULES

General:

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

See the answer to question 11 in Chapter III, section XII, page XX.

21. Please provide information on respective fields of responsibilities of competent authorities concerned.

See the answer to question 12 in Chapter III, Section XII, page XX.

22. 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.

See the answer to question 13 in Chapter III, Section XII, page XX.

For the purpose of improving the legal basis for comprehensive transposition of the EU regulations into the national legislation in the food safety domain, the following list of regulations have been envisaged:

National text	EU text	Date (expected) of transposition / implementation
Rulebook on veterinary-sanitary conditions, as well as general and specific hygiene rules for food of animal origin	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin,	Feb 15,2011/ June 1, 2011
Rulebook on conditions for enforcement of official control	Regulation EC 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules	Feb 15, 2011 / June 1, 2011
Rulebook on the official controls on food of animal origin Rulebook on the mode and procedure of official controls on food of animal origin and on the mode of official controls on animals before and after slaughter (OG RS 99/2010).	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption	PUBLISHED - OFFICIAL GAZZETTE No.99/2010Feb 15,2011/ June 1, 2011
Rulebook on specific rules on official controls for Trichinella in meat	Regulation (EC) No 2075/2005 laying down specific rules on official controls for Trichinella in meat	Jan 1,2012 / Jan 1,2012

23. Please provide information for each item listed below.

- **Labelling, presentation and advertising of foodstuffs including nutrition and health claims and nutritional labelling;**

In compliance with Articles 30 and 32 of the Food Safety Law (“Official Gazette of RS” No. 41/2009, food business operators are responsible for:

- establishing the systems and procedures that ensure available data on traceability of food;
- marking, labelling, advertising and exposing of the food;
- placing on the market (domestic and international), and
- ensuring that the indicated food information must not mislead the consumer

More detailed rules on labelling and marking of food are as follows:

1) The Rulebook on labelling and marking of packaged foodstuffs (O. Gazette of SM, No. 4/2005), Articles 3 and 8 lay down the labelling procedure when the packages are in packaging materials whose visible scope of field is 10 cm or single package is 100 g and/or ml of weight, and the declaration shall include:

- name under which the product is sold and trade name of foodstuff;
- net quantity, and
- durability date

provided that other information is indicated on the collective package from which a product is sold. Imported foodstuffs must have an original declaration written in the language of manufacturing country, and translated into Serbian. In accordance with Article 7 of the above Rulebook, in addition to the name, headquarters, and address of manufacturer or operator packing a product, it is necessary to indicate the origin of product (country of origin-produce of), name of the exporting country (imported from);

2) Rulebook on the form and content of the seal and health certificate on safety of wild game meat intended for human consumption and on the method and procedure for labelling of food of animal origin (Official Gazette of RS No. 44/2007) relating to the manner and procedure of labelling of all products of animal origin in one of the manners regulated in Article 27:

- by directly impressing the identification mark on product packaging material
- by impressing the identification mark on labelling;
- by printing the identification mark on label, declaration or direct packaging material (packing bag, foil, etc.), and
- by lithographing or on a non-removable pendant.

The size of identification marks must be adapted to a package size (Article 3 of the Rulebook on labelling and identification of packaged foodstuffs), clearly visible and indelible, and letters and numbers must be legible, of oval shape; the marks must contain the producing country code in the top row (RS according to ISO Standard 3166), whereas an export control number must be in the bottom row.

The Rulebook on marking of packaged foodstuffs intended for infants and small children (O. Gazette of SM, No. 4/2005), and the Rulebook on health safety of dietetic products (O. Gazette of RS, No. 45/2010).

The Rulebook on marking of packaged foodstuffs intended for infants and small children (O. Gazette of SM, No. 4/05) lays down the marking procedure of the packaged foodstuffs intended for infants and small children, that are intended, without further processing, to consumers and public feeding facilities, and of general use items that are used for packaging, transporting, serving and consuming this food.

- Additives authorized and purity criteria

Under Article 12, paragraph 1, item 5) of the Food Safety Law, the Ministry of Health is responsible for additive health safety control over the production, processing, trade, import and export. The regulation governing this issue in more details is the Rulebook on quality and conditions for use of additives in foodstuffs and on other requirements for additives and mixtures thereof (O. Gazette of SM, No. 56/03, 4/04 and 5/04) that shall be applicable until the rulebook on health safety on the basis of the above Law has been adopted.

This Rulebook 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.

Food enzymes;

Under Article 12, paragraph 1, item 5) of the Food Safety Law, the Ministry of Health is responsible for health safety control of enzyme preparations of non-animal origin during production, processing, trade, import and export. The regulation governing this issue in more details is the Rulebook on quality and other requirements for enzyme preparations for food products (O. Gazette of SM, No. 56/03, 4/04 and 5/04) that shall be applicable until a rulebook on health safety on the basis of the above Law has been adopted (Official Gazette of FRY, No. 12/2002, O.G. of SM, No. 56/2003, 4/2004).

Requirements for food enzymes are laid down by the Rulebook on quality and other requirements for enzyme preparations used in food products. The rulebook provides the definitions of enzymes and enzyme preparations, the positive list of enzyme preparations which includes: ordinal number, trivial name, classification name, systematic name, EC number and origin, special quality conditions for enzyme preparations such as: sources, active principles, systematic name and number, catalyzed reactions, characteristics, use and testing.

- Extraction solvents;

Under Article 12, paragraph 1, item 5) of the Food Safety Law, the Ministry of Health is responsible for health safety control of non-animal auxiliary means in production, processing, trade, import and export. The regulation governing this issue in more details is the Rulebook on quality and other requirements for auxiliary means in production of food products ("O. Gazette of FRY", No. 62/02, 4/04 and "O. Gazette of SM", 56/03 and 4/04) that shall be applicable until the rulebook on health safety based on the above Law has been adopted.

The Rulebook on quality and other requirements for auxiliary means in production of food products provides the main definitions and prescribes the quality and other requirements for auxiliary means in food production. The Rulebook classifies the auxiliary means into categories and includes a positive list of auxiliary means in production.

- Flavourings;

Under Article 12, paragraph 1, item 5) of the Food Safety Law, the Ministry of Health is responsible for health safety control of flavourings in production, processing, trade, import and export. The regulation governing this issue in more details is the Rulebook on quality and other requirements for foodstuff flavourings (O. Gazette of SM, No. 21/2006) that shall be applicable until the rulebook on health safety based on the above Law has been adopted.

The Rulebook provides the definitions for flavourings, flavouring substances, flavouring preparations, heat treatment flavourings, smoke flavourings and mixtures thereof, maximum permitted quantities of substances originating from flavourings or other ingredients with flavouring characteristics in foodstuffs (Annex 1), and flavouring substances are classified according to increasing FL number (EU Flavis Database) (Annex 2).

- Food contact materials

The Ministry of Health is responsible for control on safety of general use items including packaging material for foodstuffs. In addition to the Law on Safety of Foodstuffs and General Use Items ("O. Gazette of SFRY", No. 53/91, FRY, No. 24/94, 28/96, 37/02, O. J. No. 79/05, 101/05), the Rulebook on conditions of health safety of general use items that may be placed on the market (O. journal of SFRY, No. 26/83, 61/84, 56/86, 50/89 and 18/91) is also applicable.

Adoption of a new regulation is planned in 2010, for the purpose of harmonisation with the EU requirements.

The Law on Food Safety prescribes the competence in control on materials, packaging materials and items coming into contact with food, in compliance with the division of competences under Article 12 thereof.

- Food supplements;

The answer to both above-stated questions is the same.

Under Article 12, paragraph 1, item 5) of the Food Safety Law, the Ministry of Health is responsible for health safety control on dietetic products in production, processing, trade, import and export. The regulation governing this issues in more details is the Rulebook on health safety of dietetic products (“O. Journal of RS”, No. 45/2010).

Dietetic products are destined to satisfy specific nutritive requirements of: 1) healthy infants and small children; 2) some persons having problems with digestion and metabolism; 3) some persons who are in special physiological state requiring a controlled intake of some food ingredients to achieve special effects.

Dietetic products, depending on their composition and purpose, are placed on the market as: 1) formula for infants; 2) food for infants and small children; 3) food for persons on loose weight diet; 4) food for specific medical purposes; 5) food for persons intolerant of gluten; 6) salt supplement for human consumption, and 7) food supplements (dietetic supplements).

Dietetic products are only placed on the market as packaged products.

Each package of dietetic product shall be marked “dietetic product”, and supplements shall be marked “food supplement”.

Nutritive statements used in commercial communication, either in declaration, presentation or in advertising the dietetic products must be in compliance with the regulations governing labelling and marking of packaged foodstuffs, unless otherwise laid down by this rulebook.

Health statements may be used in declaration, presentation or advertisements of dietetic products that are placed on the market in the Republic of Serbia, only if they are in compliance with this rulebook.

The Rulebook is accompanied by the following annexes: Vitamins and minerals that may be labelled and their recommended daily intake (RDI); Basic composition of initial formulas for infants; Basic composition of transitional formulas for infants; Nutritious substances; Nutritive and health statements for initial formulas for infants and conditions for their utilisation; Necessary and conditionally necessary amino acids in mother’s milk; Special conditions for content, source and method of processing proteins used in production of initial formulas for infants on the basis of hydrolysate of whey protein originated from cow’s milk protein with protein content less than 0,56 g/100 kJ (2,25

g/100 kcal); Reference values (RV) for nutritive labelling of formulas for infants; Pesticides that must not be used in agricultural production of ingredients intended for production of infant formulas and food for infants and small children; Maximum permitted concentrations of certain pesticide residues or pesticide metabolites in infant formulas and food for infants and small children; Maximum permitted concentrations of certain chemical contaminants in infant formulas; Basic composition of cereal-based processed foodstuffs intended for infants and small children; Basic composition of processed foodstuffs for infants and small children; Amino acidic composition of caseins (g/100 g of proteins); Nutritious substances; Reference values for nutritive labelling of food for infants and small children; Maximum permitted concentrations of certain chemical contaminants in food for infants and small children; Basic composition of food intended for the loose weight diet; Content of essential amino acids in reference protein; Basic composition of the food for special medical purposes; Substances that may be added for special nutritive purposes to the food intended for the loose weight diet and to the food for special medical purposes; List of permitted salt supplements for human consumption; Vitamins and minerals that may be used in production of food supplements/dietetic supplements/and units to be used for labelling; Substances that may be used as vitamin and mineral sources in food supplement production (dietetic supplements); Maximum permitted vitamin and mineral quantities for a daily dose of food supplements for adults; Maximum permitted concentrations of certain chemical contaminants in food supplements (dietetic supplements); Ingredients of foodstuffs to be stated in accordance with Articles 90 and 91 of this Rulebook/marketing of allergens/ and Microbiological criteria.

- Food for particular nutritional uses;

See the answer to question 23 in Chapter III, Section XII, page XX, “Food supplements”.

-Quick-frozen Foodstuffs

There is no a specially united regulation but only individual rulebooks on quality specifying this field for each foodstuff.

- Contaminants

More detailed requirements for maximum residue limits on contaminants are set out by:

- The Rulebook on quantities of pesticides, metals and metalloids and other toxic substances, chemotherapeutics, anabolics and other substances that may be found in foodstuffs (“O. Gazette of FRY”, No. 5/92 and 32/02) lays down the limits on maximum residue of heavy metals and non-metals, anabolics, mycotoxins, PBS, PHB and other contaminants in food.
- The Rulebook concerning the maximum residue limits on plant protection agents in food and feed and also concerning the food and feed to be checked for

maximum residue limits on plant protection agents (“O. Gazette of RS”, No. 25/2010) lays down maximum residue limits on pesticides.

The Food Safety Law (O. Gazette of RS, No. 41/09) defines the following:

The food is considered unsafe for human consumption if:

- it contains microorganisms, parasites, bacteria toxins and histamines above the values prescribed;
- it contains natural toxins or other natural toxic substances above the values prescribed;
- it contains heavy metals, residues of pesticides, veterinary medicinal products, mycotoxins and other substances above the values prescribed;
- it contains substances that have not been toxicologically evaluated, checked and safe for human consumption;
- it contains mechanical impurities;

More detailed requirements are set out by:

The Rulebook on quantities of pesticides, metals and metalloids and other toxic substances, chemotherapeutics, anabolics and other substances that may be found in foodstuffs (“O. Gazette of FRY”, No. 5/92 and 32/02) lays down the limits on maximum residue of heavy metals and non-metals, anabolics, mycotoxins, PBS, PHB and other contaminants in food.

The Rulebook concerning the maximum residue limits of plant protection agents in food and feed and on food and feed to be checked for maximum residue limits, that was published in “O. Journal” of RS, No. 25/2010 on 21 April 2010, lays down in Article 10 that on its effective date, the Rulebook on quantities of pesticides, metals and metalloids and chemotherapeutics and anabolics and other substances that might be found in foodstuffs shall be repealed.

For the purpose of protecting food and feed safety pursuant to Article 69 of the Law on Food Safety, the Minister of Agriculture and the minister responsible for public health shall prescribe in more details the measures of systemic control on microbiological, chemical and biological contaminants in food and feed in all stages of production, processing and trade, conditions and manner of monitoring, control methods, conditions and manner of sampling and keeping samples, keeping records of samples and methods of laboratory analyses for certain microbiological, chemical and biological contaminants, in accordance with the division of competences referred to in Article 12 of the Law on Food Safety.

- Novel foods;

Novel food is defined by the Food Safety Law, Article 59, (“O. Gazette of RS”, No. 41/2009), and the Minister responsible for public health shall prescribe, in more details, the conditions for placing novel food on the market.

- Ionizing radiation;

The field relating to food conservation by way of ionizing radiation is governed by the Rulebook on conditions under which foodstuffs and general use items conserved by ionizing radiation may be placed on the market.

According to the Law on Protection from Ionizing Radiation and Nuclear Security (O. Gazette, No. 36/09), the Agency for Protection from Ionizing Radiation and Nuclear Security of Serbia is authorized to monitor the scope and change in radioactivity level and to assess its effects on the population and the environment, and to order the implementation of necessary measures and monitor their enforcement.

Radionuclide content in food is controlled in accordance with the Decision on systematic inspection of radionuclide content in the environment (O. Journal of FRY, 45/97) and the Rulebook on radioactive contamination limits of the environment and method of decontamination (O. Gazette of FRY 9/99).

According to Article 3 of this Rulebook, the food radioactive contamination limits are determined by limits of radionuclide annual intake by ingestion and derived radionuclide concentrations in the environment. According to Article 20 of the same Rulebook, radioactive contamination levels of food and other imported goods may not be higher than radioactive contamination level prescribed for equivalent domestic products. Annex 1 to the Rulebook shows Table 1 with derived concentrations in potable water of some most frequent radionuclides and Table 2 with expected dose values per each intake that are used for calculation of ingestion-intake radionuclide annual limits.

The drafts of Rulebook on determination of programme for systematic radioactivity measuring in the environment, the Rulebook on content in radionuclides in potable water, foodstuffs, feed, drugs, general use items, construction materials and other goods placed on the market and the Rulebook on goods radioactivity control during import, export and transit, that shall be harmonized with the EU legislation, are being prepared.

The Agency for protection from ionizing radiation and nuclear security of Serbia, is authorized to give approvals to legal persons for performance of the activities in the domain of protection from radiation, that include systematic radioactivity measuring or single measuring within monitoring, determination of radionuclide content in potable water, foodstuffs, feed, drugs, general use items, construction materials and other goods placed on the market and determination of radionuclide content in goods during import, export and transit.

- Mineral waters.

Under Article 12, paragraph 1, item 5) of the Food Safety Law, the Ministry of Health is responsible for health safety control of potable water in original packaging (table water, mineral water and spring water) in all stages of production, processing, trade, import and export, until the Rulebook on health safety based on the above Law has been adopted, the regulation governing the mentioned issue in more details is the Rulebook on quality and other requirements for natural mineral water, natural spring water and table water (O. Gazette of SM, No. 53/2005). The stated Rulebook lays down the requirements on mineral composition and safety of mineral water.

- Bilateral international agreements with EU Member States, candidate countries and other third countries (if any).

See the answer to question 10 under “Bilateral veterinary international agreements with EU Member States, candidate countries and other third countries (if any)” in Chapter II, Section II, page XX.

V SPECIFIC RULES FOR FEED

General:

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

The field of Animal Feed is regulated by the following legal acts:

- The Food Safety Law (O. Gazette of RS, No. 41/09) lays down the general feed safety rules, responsibilities of feed business and contains the basis for adoption of bye-laws in this field;
- The Law on Veterinary Matters (Official Gazette 91/2005, 30/2010) lays down the requirements for official control and requirements for feed production and trade.
- The Law on Genetically Modified Organisms (Official Gazette 41/2009) lays down general rules for placing on the market and marking of GMO products.

The Ministry of Agriculture, Forestry and Water Management is a policy maker in the field of food and feed safety, and it prepares the proposals of laws to be passed by the Parliament, following the appropriate procedure.

The Ministry of Agriculture, Forestry and Water Management adopts regulations for implementation of laws, - rulebooks, orders, instructions, monitoring plans, crisis management plan in the field of feed.

25. Please provide information on respective fields of responsibilities of competent authorities concerned.

Production, trade and use of feed of animal origin and composite feed are under veterinary inspection supervision, and feed of plant origin is under supervision of the General Inspectorate.

The control in the domain of feed safety is performed by:

- Veterinary inspection - feed of animal origin,
- Phyto-sanitary inspection - feed of plant origin,

Veterinary Inspection in the stage of production, processing and trade;

During import, transit and export, the control is conducted by:

- Veterinary Inspection - feed of animal origin and composite feed,
- Phyto-sanitary inspection - feed of plant origin.

The border veterinary inspection is composite to control:

- 1) feed raw materials, pre-mixes and other supplements during import,
- 2) raw materials of animal origin as feed ingredients,
- 3) feed during production on presence of residues.

Veterinary Inspection shall send the samples taken, marked and sealed to the reference laboratory (Veterinary Institute in Belgrade, Veterinary Institute in Novi Sad) for veterinary-sanitary testing – microbiological, chemical and physical analysis as well as the analysis for presence of antibiotics. The results of analyses conducted by the labs shall be sent to importers and producers and inform the inspection. The special attention is taken in case of production of feed for ruminants, where special requirements are requested – everyone who uses feedingstuffs of animal origin must have a separate line for production of ruminant feed.

Care is especially taken in case of feed for ruminants where special production requirements are requested – everyone who uses feedingstuffs of animal origin must have a separate line for production of ruminant feed.

The reference laboratories performing the feed control for presence of animal protein in accordance with item 9 of the Order on taking the measures for prevention of occurrence, for detection, prevention of spread and for eradication of transmissible spongiform encephalopathia (Official Gazette of RS, No. 17/2006) are approved by the Ministry of Agriculture, Forestry and Water Management.

26. 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.

List of regulations in the feed domain in the Republic of Serbia is stated in the answer to question 13 in this Chapter.

List of planned regulations in the feed domain in the Republic of Serbia

National text	EU text	Date (expected) of transposition / implementation
Rulebook on additives for use in animal nutrition.	Regulation (EC) No 1831/2003 on additives for use in animal nutrition	Feb 1, 2011 / Feb 1, 2011
Rulebook on conditions for preparation, placing on the market and use of medicated feedingstuffs	Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community	Feb 1, 2011 / Feb 1, 2011
Rulebook on the marketing of compound feedingstuffs	Council Directive 2002/32 /EEC on the marketing of compound feedingstuffs	July 1, 2011 / July 1, 2011
Rulebook on placing on the market and use of feed	Council Directive on placing on the market and use of feed 2009/767/EC	2012

27. Please provide information for each item listed below:

- Placing on the market and use of feed;

The Rulebook on quality of feed quality (O. Gazette of RS, No. 4/10) lays down requirements for quality of feed that must be fulfilling during production and trade: feedingstuff categories, physical, chemical and nutritive properties of raw materials and products; type and quantity of raw materials and technological procedures applied in production.

Note: See more details in Point 19, Chapter III – Placing on the market of food, feed and animal by-products.

Within the meaning of this Rulebook, feed means any substance or product, whether processed, partially processed or unprocessed, intended to be used for feeding the animals, and used for production of feed in the form of:

1. feedingstuffs
2. vitamin-mineral pre-mixtures-pre-mixes
3. mixtures

This Rulebook lays down approved feed additives: vitamins and provitamins; micro-elements and minerals; non-protein nitrogen compounds; amino acids; growth stimulators; coccidiostats; other permitted additives (antioxidants, cohesive agents, emulgators, stabilizers and coagulants, dying substances including pigments, flavourings, preserving agents, enzymes, agents for utilization rate of feed).

Feed must not contain hormones, sedatives and thyrostatics.

Mixtures must not contain antibiotics and sulphonamides.

Feedingstuffs and mixtures must not contain bacteria toxins in 1 g (*Clostridium botulinum*, *Clostridium perfringens* and *Staphylococcus pyogenes*).

The Rulebook (O. Gazette of RS, No. 4/10) lays down the maximum quantities of: residues of pesticides or metabolites thereof in feed, inorganic substances, sodium chlorides in mixtures according to the animal type and category, albumen originated ammonium in feedingstuffs and parasitic fungi.

Feed may contain saprophytic microorganisms not exceeding the maximum of:

Feedingstuffs and mixtures	Count of bacteria in 1 g	Count of yeast and mould in 1 g	Permitted deviation defined by microbiologic analysis
Feedingstuffs of plant origin	6.000.000	200.000	15%
Feedingstuffs of animal origin	12.000.000	10.000	10%
Mixtures for young animals	3.000.000	50.000	10%
Mixtures for adult animals	5.000.000	200.000	15%”

Feed may contain pathogenic microorganisms not exceeding the maximum of:

Type of microorganisms	Product	Count of microorganisms
Salmonellae	feedingstuffs and mixtures	0 in 25 g

Sulphite reducing clostridia	feedingstuffs and mixtures	1000 in 1 g
Staphylococcus coagulase positive	feedingstuffs and mixtures	0 in 1 g
Other pathogenic microorganisms	feedingstuffs and mixtures	0 in 50 g''

The Rulebook on general and specific requirements for feed hygiene (O. Gazette of RS, No. 78/10) laying down the general and specific feed hygiene requirements in compliance with Regulation EC 1831/2003 shall be effective from 1 June 2011.

- Authorized additives in feedingstuffs;

The Rulebook on feed quality (O. Gazette of RS, No. 4/2010) lays down the use of feed additives and includes the list of feed authorized feed additives: vitamins and provitamins, microelements and minerals; non-protein nitrogen compounds; amino acids; growth simulators; coccidiostats; other permitted additives (antioxidants, cohesive agents, emulgators, stabilizers and coagulants, dying substances including pigments, flavourings, conserving agents, enzymes, agents for improvement of usability rate of feed.

The preparation of Rulebook on additives to be used in feed is under way and it will be harmonized with Regulation EC 1831(2003).

- Undesirable substances in animal feed.

The Law on Food Safety (O. Gazette of RS, No. 41/2009) defines that the feed shall be considered as unsafe, if:

- it has harmful effect on animal or human health;
- the products obtained from food-producing animals are not unsafe for human consumption.

Feed shall be considered unsafe if:

- it contains microorganisms, parasites, bacteria toxins and histamines above the maximum permitted quantities,
- it contains natural toxins or other natural toxic substances above the maximum permitted quantities,
- it contains heavy metals, metalloids, residues of pesticides, veterinary medicinal products, mycotoxins and other substances above the maximum residue limits
- it contains additives that must not be used in certain types of feed for animals or the content in permitted additives is above the maximum permitted quantities;
- it contains radionuclides above the prescribed prescribed.

The domain of undesirable substances in the Republic of Serbia is regulated by the following legal acts:

- The Rulebook on establishing the programme for systematic monitoring of residues of pharmacological, hormonal and other harmful substances in live animals, products of animal origin and animal feed (O. Gazette of RS, No. 91/2009) that contains a list of unauthorized substances, including some undesirable substances (e.g. cadmium, mycotoxins), and a list of authorised substances unless they exceed the maximal residue limits quantities in animal feed.
- The Rulebook on maximum permitted residues of plant protection agents in food and feed (O. Gazette of RS, No. 25/10) lays down the maximum permitted residue limits of certain pesticides in animal feed.
- The Rulebook on feed quality (O. Gazette of RS, No. 4/10) lays down the maximum permitted quantity of mould, yeast and their toxins.

The preparation of Rulebook on undesirable substances in animal feed is under way and it will be harmonized with Instruction 2002/32/EC.

- **Conditions governing the preparation, placing on the market and use of medicated feedingstuffs.**

In the Republic of Serbia, there are no approved establishments for production of medicated feedingstuffs.

In compliance with the Rulebook on the manner of prescribing and issuing the medicines used in veterinary medicine (Official Gazette of FRY, No.20/94), animal feed producers may add the coccidiostats to the feed but the on declaration of product must be clearly indicate the type of coccidiostats, type of animal for which they are intended, and their withdrawal periods.

The use of antibiotics and other veterinary medicinal products is allowed only on prescription from and under supervision of an authorized veterinarian.

The domain of medicated feedingstuffs shall be governed by the Rulebook on requirements for preparation, placing on the market and use of medicated feedingstuffs that will be harmonized with the Council Instruction 90/167/EEC.

- **Bilateral international agreements with EU Member States, candidate countries and other third countries (if any).**

See the answer to question 10 under “Bilateral veterinary international agreements with EU Member States, candidate countries and other third countries (if any)” in Chapter II, Section II, page XX.

VI PHYTOSANITARY POLICY

General

28. Please provide information on general architecture of the legal basis; organization and powers of involved institutions.

The Ministry of Agriculture, Forestry and Water Management (MAFWM) is a public administration body in charge of policy making in the phytosanitary field and of supervision over the legality and appropriateness of the work of the authority within the MAFWM.

The MAFWM is the authority in charge on the field of plant health, seed and planting material, plant protection products, plant nutrition products and soil enhancers, registration of plant varieties, protection of plant varieties (plant variety rights), pursuant to the following laws:

- The Law on Plant Health (“Official Gazette of RS”, No. 41/09),
- The Law on Plant Protection Products (“Official Gazette of RS”, No. 41/09),
- The Law on Plant Nutrition Products and Soil Enhancers (“Official Gazette of RS”, No. 41/09),
- The Law on Seed (“Official Gazette of RS”, No. 45/05),
- The Law on Planting Material of Fruit Trees, Vine and Hops (“Official Gazette of RS”, No. 18/05),
- The Law on Seed and Planting Material (“Official Gazette of RS”, No. 54/93),
- The Law on Protection of Plant Breeders Rights (“Official Gazette of RS”, No. 41/09),
- The Law on Plant Varieties Registration (“Official Gazette of RS”, No. 30/10),
- The Law on Genetically Modified Organisms (“Official Gazette of RS”, No. 41/09),
- The Law on Forest Reproductive Material (“Official Gazette of RS”), No. 135/04, 8/05 and 41/09)
- The Law on Forestry (“Official Gazette of RS”, No. 30/10),.

As the bodies within the MAFWM, established by the Law on Ministries (“Official Gazette of RS”, No. 19/2004, No. 65/2008) that governs the establishment of the ministries and other public administration bodies and other issues relevant for the public administration work, the activities within the phytosanitary field are conducted by:

- Plant Protection Directorate,
- Forestry Directorate,
- General Inspectorate (phytosanitary, forest and hunting inspection services),

Apart from the above stated bodies, **the Directorate for National Reference Laboratories**, established by the Law on Food Safety (“Official Gazette RS”, No. 41/09), as a body within the MAFWM, in charge of laboratory research activities and related professional activities in food chain, inter alia, conducts the activities of laboratory research in phytosanitary field.

The Plant Protection Directorate (PPD) as a public administration body within the MAFWM is in charge of a direct enforcement of regulations and administration and administration-related activities, as well as for the coordination and contacts in relation to the issues relating to phytosanitary field.

The General Inspectorate (GI), as a public administration body within the MAFWM conducts the inspection activities relating to: Phytosanitary supervision and inspection in local and cross-border trade in the field of plants, seed and seed material, plant protection products and plant nutrition products, as well as for other inspection activities in the field of agriculture, forestry and water management, in accordance with the law.

Forestry Directorate (FD), as a public administration body within the MAFWM conducts the activities of public administration and professional activities relating to: forestry policy; forest preservation; forest improvement and use; implementation of forest preservation measures; control of seed and seed material in forestry, as well as other activities in this field.

The Rulebook on internal organization and job systematization (with description) governs the scope of work of all bodies within the MAFWM that participate in the implementation of phytosanitary policy, as well as the maximum number and description of the systematized job posts in accordance with the Decision on a maximum number of employees within the public administration bodies, public agencies and mandatory social security organizations.

The answers with respect to human and material resources, as well as the financial resources allocated pursuant to the 2010 Budget Law have been provided in the answer to question no. 2, in Section I General Information, Chapter 12 , as follows:

- for PPD, in item *1.2. Plant Protection Directorate*,
- for GI, in item *1.3. General Inspectorate*.

The descriptions of the existing structures and organizational charts have been provided in the answer to the question no. 3, in Section I - General Information, Chapter 12, as follows:

- for PPD, in item *1.2. Plant Protection Directorate*,
- For GI in item *1.3. General Inspectorate – Phytosanitary Border Inspection Department, Phytosanitary Inspection Department and Department for Forestry and Hunting Inspection*.

29. Please provide information on respective fields of responsibilities of competent authorities concerned.

Plant Protection Directorate (PPD)

At the central level, the administrative, legislative and international activities, as well as the relevant professional activities in phytosanitary field have been under the competence of the Plant Protection Directorate of the Ministry of Agriculture, Forestry and Water Management.

The PPD consists of five organizational units:

- Section for Plant Health and Plant Quarantine,
- Department for Plant Protection Products and Plant Nutrition Products,
- Section for Plant Variety Registration,
- Group for Seed and Planting Material , and
- Group for Plant Variety Protection and Biological Safety.

The activities of the PPD include:

- Regulatory activities
- Organizational and coordination activities
- Information activities
- Administrative activities

Regulatory activities:

- preparation of experts basis for drafting laws and proposals of implementing provisions in the phytosanitary field;
- preparation of plans and instructions that synchronize the work of all subjects in the phytosanitary field;
- preparation of plan documents;
- preparation of plan proposals and programs for the allocation of financial resources;
- monitoring the EU regulations and EPPO standards.

Organizational and coordination activities:

- Coordination and liaison of all subjects in phytosanitary field;
- organizing local and international expert groups in view of providing assistance in resolving problems in the phytosanitary field;
- organization of trainings in cooperation with local and international experts;
- cooperation with other public administration bodies;

- direction of researches and organizing public invitations for projects in the phytosanitary field;
- preparation of the platform for the participation in international negotiations in the phytosanitary field.

Information activities:

- providing information to international organizations and relevant bodies of other states in the phytosanitary field;
- providing information and notifications to all subjects in the phytosanitary field;
- preparation of text documents for the Internet page of the MAFWM;
- maintenance of Serbia web page at www.ippc.org;
- cooperation with the media in view of presenting the information of public relevance.

Administrative activities:

- issuing approvals for importing harmful organisms and particular plants and plant protection products for the purposes of a scientific research;
- issuing approvals for importing plants that have not been registered within the Variety Register;
- issuing certificates on recognition of seed crops and certificates of planting material production;
- registration in the Register of phytosanitary field;
- establishment and maintenance of registers and records in the phytosanitary field;
- registration of plant protection products and plant nutrition products;
- establishment and maintenance of records of legal persons authorized for heat treatments and labelling of wood packaging material for packaging;
- keeping records of issued phyto-certificates and notifications;
- passing decisions, conclusions and other administrative acts in accordance with the laws in the phytosanitary field and the Law on General Administrative Procedure;
- entrusting activities and issuing decisions on granting authorizations;
- preparation of professional grounds for drafting agreements with holders of public authorizations;
- collection of data, regular and irregular reports by all subjects in the phytosanitary system;
- conducting competitions for the activities of public interest in the phytosanitary field and drafting agreements;
- registration of plant varieties;;
- protection of plant varieties (plant variety rights);
- activities in the field of biological safety (genetically modified organisms)..

Based on the authorization of the PPD, professional agricultural services in the territory of the Republic of Serbia perform the following activities:

- monitoring and examination of plant health status during its growth and development in fields, plantations, premisses and other surfaces and keeping related records, including wild plants;
- conducting health examinations of crops and premisses for the production of seed and planting material other than seed and issuing the Certificate of health condition;
- conducting health examinations of premisses for the production of planting material for fruit trees, vine and hops for the presence of harmful organisms and issuing the Certificate of health condition;
- conducting health examinations of premisses for the production of roses and ornamental plants and issuing the Certificate of health condition;
- conducting plant health examinations of consignments of plants, plant products and regulated objects¹ and issuing phyto-certificates;
- conducting and implementation of the Program of plant health protection measures;
- collection of biological, meteorological and other data for making forecasts of harmful organisms occurrence;
- reporting on the presence, occurrence and spreading of harmful organisms and forecasts of harmful organisms occurrence, development and movement of their population and determining optimal timeframes for their suppression and keeping records on the prescribed forms;
- Professional examinations of crops and premisses for the production of seeds and planting material of agricultural plants and roses
- Education of the plant holders, service providers and others about the harmful organisms and prescribed phytosanitary measures

The network of professional extension services (PES) with the regional scope of activity.

NAME OF AGRICULTURAL EXTENSION SERVICE	REGIONAL SCOPE OF ACTIVITY	
	ADMINISTRATION DISTRICT	MUNICIPALITY
PSS "SUBOTICA" DOO, Subotica	Severnobački	Subotica
PSS "BAČKA TOPOLA" DOO, Bačka Topola	Severnobački	Bačka Topola i Mali Idoš
PSS "ZRENJANIN" DOO, Zrenjanin	Srednjobanatski	Zrenjanin, Nova Crnja, Novi Bečej, Sečanj i Žitište
PSS "SENTA" DOO, Senta	Severnobanatski	Senta, Ada, Kanjiža i Čoka
PSS "KIKINDA" DOO, Kikinda	Severnobanatski	Kikinda i Novi Knežavac
INSTITUT "TAMIŠ", Pančevo	Južnobanatski	Pančevo, Alibunar, Kovačica i Opovo
PSS "VRŠAC" DOO, Vršac	Južnobanatski	Vršac, Bela Crkva i Plandište i Kovin
PSS "SOMBOR" DOO, Sombor	Zapadnobački	Sombor, Apatin i Odžaci,
PSS "VRBAS" DOO, Vrbas	Zapadnobački	Kula
	Južnobački	Vrbas, Srbobran i Bečej

¹ *regulated objects* shall mean plots of agricultural and forest land, facilities intended for storing, treating, finishing and processing plants and plant products, product and transportation packagings, containers, earth and other substrata in or on which are cultivated plants or other organisms, objects and materials which may contain and transmit harmful organisms (The Law on Plant Health).

NAME OF AGRICULTURAL EXTENSION SERVICE	REGIONAL SCOPE OF ACTIVITY	
	ADMINISTRATION DISTRICT	MUNICIPALITY
PSS "NOVI SAD" DOO Novi Sad	Južnobački	Novi Sad, Žabalj, Bački Petrovac, Beočin, Sremski Karlovci, Temerin, Titel, Bač i Bačka Palanka
PSS "RUMA" DOO, Ruma	Sremski	Ruma, Irig i Indija,
PSS "SREMSKA MITROVICA", DOO Sremska Mitrovica	Sremski	Sremska Mitrovica Stara Pazova, Pećinci i Šid
PSS "ŠABAC" DOO, Šabac	Mačvanski	Šabac, Bogatić, Vladimirci i Koceljeva
ZAVOD ZA POLJOPRIVREDU "Loznica"	Mačvanski	Loznica, Krupanj, Ljubovija i Mali Zvornik
PSS "VALJEVO" DOO, Valjevo	Kolubarski	Valjevo, Lajkovac, Ljig, Mionica, Osečina i Ub
PSS "SMEDEREVO" DOO, Smederevo	Podunavski	Smederevo, Velika Plana i Smederevska Palanka
PSS "POŽAREVAC" DOO, Požarevac	Braničevski	Veliko Gradište, Golubac, Žabari, Žagubica, Kučevo, Malo Crniće, Petrovac i Požarevac
PSS "KRAGUJEVAC" DOO, Kragujevac	Šumadijski	Arandelovac, Batočina, Knić, Lapovo, Rača, Topola i Kragujevac
PSS "JAGODINA" DOO, Jagodina	Pomoravski	Despotovac, Jagodina, Paraćin, Rekovac, Svilajnac i Čuprija
PSS "NEGOTIN" DOO, Negotin	Borski	Bor, Kladovo, Majdanpek i Negotin
CENTAR ZA ISTRAŽIVANJA Zaječar	Zaječarski	Zaječar, Boljevac, Knjaževac i Soko Banja
PSS "UŽICE" DOO, Užice	Zlatiborski	Užice, Arilje, Bajina Bašta, Kosjerić, Nova Varoš, Požega, Priboj, Prijepolje, Sjenica i Čajetina
PSS "ČAČAK" DOO, Čačak	Moravički	Čačak, Gornji Milanovac, Ivanjica i Lučani
PSS "KRALJEVO" DOO, Kraljevo	Raški	Kraljevo, Vrnjačka Banja, Novi Pazar, Raška i Tutin
PSS "KRUŠEVAC" DOO, Kruševac	Rasinski	Kruševac, Aleksandrovac, Brus, Varvarin, Trstenik i Čičevac
PSS " NIŠ" DOO, Niš	Nišavski	Grad Niš, Aleksinac, Gadžin Han, Doljevac, Merošina, Ražanj i Svrljig
VPPŠ-ZAVOD ZA POLJOPRIVREDU Prokuplje	Toplički	Prokuplje, Blace, Žitorađa i Kuršumljica
PSS "PIROT" DOO Pirot	Pirotski	Pirot, Babušnica, Bela Palanka i Dimitrovgrad
PSS "LESKOVAC" DOO, Leskovac	Jablanički	Leskovac, Vlasotince, Bojnik, Lebane, Medveđa i Crna Trava
PSS "VRANJE" DOO, Vranje	Pčinjski	Vranje, Bosilegrad, Bujanovac, Vladičin Han, Preševo, Surdulica i Trgovište

NAME OF AGRICULTURAL EXTENSION SERVICE	REGIONAL SCOPE OF ACTIVITY	
	ADMINISTRATION DISTRICT	MUNICIPALITY
INSTITUT PKB "AGROEKONOMIK" Beograd	Grad Beograd	Palilula, Savski Venac, Zvezdara, Stari Grad i Vračar
PSS "KOSMAJ" DOO, Mladenovac	Grad Beograd	Mladenovac, Sopot, Lazarevac, Barajevo, Voždovac, Grocka, Obrenovac, Rakovica, Zemun, Surčin, Čukarica i Novi Beograd
PSS "KOSOVSKA MITROVICA"	Kosovsko Mitrovački	Kosovska Mitrovica, Vitina, Gnjilane, Vučitrn, Zvečan, Zubin Potok, Leposavić i Srbica

The activities of professional and technical support (laboratory testing of samples of plants and plant product, plant protection products and plant nutrition products; applied researches, variety examinations, researches of plant protection products and plant nutrition products undergoing the registration procedure) are conducted by faculties, scientific institutes and professional agricultural services, based on the authorization by the Plant Protection Directorate and Forestry Directorate.

Network of authorized laboratories of the scientific institutes and faculties
<ol style="list-style-type: none"> 1. Institute for plant protection and environment, Belgrade: ISO 9001 2. Institute for Pesticides and Environmental Protection: ISO 9001, ISO 17025 3. Institute of pomiculture and viticulture, Čačak: ISO 9001 4. Institute for Field and Vegetable Crops, Novi Sad: ISO 9001, ISO 17025 5. Faculty of Agriculture, Zemun 6. Faculty of Agriculture, Novi Sad 7. Faculty of Forestry, Belgrade 8. Institute of Forestry, Belgrade 9. Institute of Lowland Forestry and Environment, Novi Sad

Authorised laboratories of agricultural extension services
1. AES Sombor, Sombor
2. AES Sremska Mitrovica, Sremska Mitrovica
3. AES Smederevo, Kolari
4. AES Čačak, Čačak
5. AES Niš, Niš

The list of authorized phytosanitary laboratories and methods that they apply has been provided in the answer to question number 6, point 5, Section I – General Information, Chapter 12.

Directorate for National Reference Laboratories

A newly-established Directorate for National Reference Laboratories (DNRL) of the MAFWM is not currently operable in terms of conducting laboratory researches. After it has become fully operable, the DNRL shall coordinate the work of authorized laboratories and ensure the establishment of a functional network of authorized laboratories for exercising control in food chain, and its organizational units - National Reference Phytosanitary Laboratory (plant health) and the National Reference Laboratory for Residues (sub-registration control of plant protection and plant nutrition products and monitoring plant protection products residues) shall perform laboratory researches in the phytosanitary field.

General Inspectorate (GI)

Inspectional supervision in the phytosanitary field is exercised by the MAFWM General Inspectorate inspectors, as follows:

- Border Phytosanitary Inspection Department is in charge of conducting phytosanitary inspection of import consignments of plants, plant protection products and plant nutrition products issuing of phyto-certificates and taking prescribed phyto-sanitary measures;
- Phytosanitary Inspection Department is in charge of: phytosanitary supervision of plants, plant products and regulated objects in the production, trade, finishing process, storage; official sampling for laboratory testing for the presence of harmful organisms; control of plant protection products and plant nutrition products on the market and use; control of production, finishing process, circulation and use of seed and seed material of agricultural plants; supervision over the work of authorized institutions and taking prescribed phytosanitary measures;
- Department for forestry and hunting inspection is in charge of supervision over the implementation and application of laws and other regulations in the field of forestry, forest seed and seed material and forest protection; of issuing certificates of origin of consignments of seed and cuttings made by dividing the original consignment; of issuing certificates of origin of forest seed material; of supervision over the exercise of public authorizations by enterprises and other organization entrusted with the exercise of public authorizations.

Forestry Administration (FD)

At the central level, the administrative, legislative and international activities, as well as the relevant professional activities in the field of forest protection, as well as monitoring

the activities of production, finishing, certification and circulation of forest reproductive material are under the competence of the Forest Administration.

The FD entrusts a part of the activities under its competence to the authorized institutions, as follows:

- Institute of Forestry, Belgrade,
- Institute of Lowland Forestry and Environment, Novi Sad,
- Faculty of Forestry, Belgrade.

The authorizations and tasks of the FD in the field of production of forest reproductive material are as follows:

- establishing regional provenience of forest reproductive material,
- keeping Register of provenience regions and the recognized basic material for the production of forest reproductive material,
- keeping the Register of lemon balm, forest plantations and suppliers of forest reproductive material,
- entrusting the activities of recognition of the basic material for the production of forest reproductive material and control of production of the reproductive material to the authorized institutions,
- issuing certificates on the recognized basic material and certificates of origin of forest seed and cuttings;

The authorizations and tasks of the authorized institutions entrusted with the activities:

- professional – field activities of recognizing the basic material for the production of forest reproductive material,
- regular annual controls of production and health examinations of forest reproductive material,
- issuing certificates of health condition of the facilities for the production of forest reproductive material,
- testing the quality of forest seed and issuing certificates of forest seed quality.

30. 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.

The Law on Plant Health (“Official Gazette of RS”, No. 41/09)

The Law on Plant Health has established a legal framework for the system of plant health protection, harmonized with the EU *acquis* (in accordance with the Council Directive 2000/29, celex No. 32000L0029).

The Law governs the plant health protection, measures for prevention of introduction and spreading of harmful organisms, as well as measures for their suppression, health

supervision of plants and consignments of plants in production and trade, prescribing the obligation of registration of producers, processors, finishers, importers, storage operators and distributors of plants, plant products and regulated objects; establishment of the system of issuance of a plant passport; prescribing the conditions for identification of protected areas; establishment of the information system at the national and international level.

The Law defines the general provisions for transposing the EU regulations and the implementing provisions by which this area will be fully harmonized with the EU legislation.

This Law and the implementing provisions to which other EU regulations have been or will be transposed has created the basis for:

- establishment of the plant protection system as in other EU member states in terms of harmonization of phytosanitary measures applied at the common market;
- application of internationally recognized principles, standards, risk assessment and other scientifically based measures in the field of plant protection;
- mutual cooperation and exchange of data and information from databases relating to the field of plant health;
- establishment of the Register of producers, processors, importers and distributors of plants, plant products and other regulated objects, as well as the plant passport system;
- conducting phytosanitary examinations and issuance of plant passports for certain plants subject to the movement within the single market;
- conducting special survey over particular harmful organisms on plants;
- establishment of protected zones;
- establishment and development of the information system and obligation of notification and keeping the required records;

Pursuant to the Law on Plant Health, the plan for the adoption of the implementing provisions within the National Program for Integration of the Republic of Serbia in the EU (NIP) for the period between 2009-2012 has been drafted in detail.

Pursuant to the Law on Plant Health, 14 new rulebooks have been adopted. The effective national regulations previously adopted shall be applied until the remaining implementing provisions have been adopted.

The preliminary TOC – Table (Table of Correspondence – TOC) with respect to Council Directive 2000/29/EC has been prepared within the Twinning Project CARDS 2005 “Building Institutional Capacities of the Plant Protection Administration”. The Law shall be amended upon the preparation of the TOC Table in case discrepancies have been identified in certain segments.

Please refer to Annex V, Priority and Framework Plan of Harmonization with the EU Acquis - clear table in the field of plant health.

The Law on Seed (“Official Gazette of RS”, No. 45/05) and the Law on Planting Material of Fruit Trees, Vine and Hops (“Official Gazette of RS”, No. 18/05)

The Law on Seed (“Official Gazette of RS”, No. 45/05) and the Law on Planting Material of Fruit Trees, Vine and Hops (“Official Gazette of RS”, No. 18/05) have been partially harmonized with the “marketing directives” (Marketing Directives EU).

The new Law on seed and planting material of agricultural and ornamental plants has been subject to the adoption procedure and it provides for general provisions for transposing the EU regulations and implementing provisions by which this field will be fully harmonized with the EU legislation. The plan for the adoption of implementing provisions for the period until 2012 has been prepared.

The effective national regulations previously adopted shall be applied until the remaining implementing provisions have been adopted.

**PRIORITY AND FRAMEWORK PLAN OF HARMONIZATION
WITH EU ACQUIS- CLEAR TABLE IN THE FIELD OF SEED AND PLANTING
MATERIAL**

Regulation (working title)	Planned for	EU Acquis with which it shall be harmonized
2011. YEAR		
The Law on Seed and Planting Material of Agricultural and Ornamental Plants	I Quarter	Council Directive 66/401/EEC, Council Directive 66/402/EEC, Council Directive 2002/54/EC, Council Directive 2002/55/EC, Council Directive 2002/56/EC, Council Directive 2002/57/EC, Council Directive 68/193/EEC, Council Directive 98/56/EC, Council Directive 2008/90/EC, Council Directive 2008/72/EC
The Rulebook on Registering Seed and Planting Material of Agricultural and Ornamental plants into the Register	IV Quarter	
The Rulebook on Production and Market of Planting Material of Ornamental Plants	IV Quarter	Council Directive 98/56/EC, Commission Directive 99/66/EC, Commission Directive 93/49/EEC
The Rulebook on Production, Circulation and Quality of Seed material of Fruit Trees	IV Quarter	Council Directive 2008/90/EC, Commission Directive 93/48/EEC
The Rulebook on Production, Circulation and Quality of Cereals' Seed	IV Quarter	Council Directive 66/402/EEC
The Rulebook on Production, Circulation and Quality of Potatoe Seed	IV Quarter	Council Directive 2002/56/EC
The Rulebook on Production,	IV Quarter	Council Directive 2002/57/EC

Circulation and Quality of Industrial Plants Seed		
2012. YEAR		
Rulebook on beetroot seed		Council Directive 2002/54/EC
The Rulebook on vine planting material		Council Directive 68/193/EEC
Rulebook on fodder crops seed		Council Directive 66/401/EEC
Rulebook on vegetables seed		Council Directive 2002/55/EC
Rulebook on agricultural plants nurseries		Council Directive 2008/72/EC, Commission Directive 93/61/EEC

The production, finishing and circulation of forest reproductive material has been prescribed by the Law on Forest Reproductive Material (“Official Gazette of RS”, No. 135/04, 8/05 and 41/09), and implementing provisions adopted based on it, as follows:

- The Rulebook on recognition of basic material and control of production of forest trees reproductive material (“Official Gazette of RS”, No. 76/05, 105/05 and 83/09).
- The Rulebook on identifying small quantities of forest seedlings and forest seed (“Official Gazette of RS”, No. 76/09),
- The Rulebook on quality of poplar and willow-trees reproductive material (“Official Gazette of RS”, No. 76/09),

The Law on Forest Reproductive Material (“Official Gazette of RS”, No. 135/04, 8/05 and 41/09), and implementing provisions adopted based on it have been harmonized with the EU Acquis, as follows:

- Council Directive 1999/105/EC of 22 December 1999 on the circulation of forest reproductive material,
- 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 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.

The Law on Registration of Agricultural Plants Varieties (“Official Gazette of RS”, No. 30/10): see the answer to question no. 31, Registration of varieties, catalogues, in this Title.

The Law on Protection of Plant Breeders Rights (“Official Gazette of RS”, No. 41/09): see the answer to the question no. 31, Plant Variety Rights (Plant Variety Protection,), in this Title.

The Law on Plant Protection Products (“Official Gazette of RS”, No. 41/09)

The Law on Plant Protection Products has been partially harmonized with the Council Directive 91/414/EEC regarding the marketing of plant protection products.

This Law contains basic provisions of a new EU legislation framework in the field of plant protection products (PPP) from 2011, as follows:

- Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC: provisions related to basic substances and adjuvants have been transposed;
- Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides: provisions related to integrated pest management, training of all professional users of PPP, distributors and advisors, inspection of machinery for the application of PPP have been transposed;
- Regulation (EC) No. 1185/2009 of the European Parliament and of the Council concerning statistics on pesticides: certain provisions relating to the collection of data on the market and PPP;
- Directive 2009/127/EC of the European Parliament and of the Council amending Directive 2006/42/EC with regard to machinery for pesticide application): certain provisions relating to the establishment of the system for the control of equipment and devices for the application of PPP have been transposed.

Pursuant to the Law on Plant Protection Products, the plan for the adoption of the implementing provisions within the National Program for Integration of the Republic of Serbia in the EU (NPI) for the period between 2009-2012 has been drafted in detail.

The preliminary TOC – Table (Table of Correspondence – TOC) with respect to Council Directive 91/414/EEC and the Regulation (EC) 1107/2009 of the European Parliament and of the Council No. 1107/2009 has been prepared within the Twinning Project CARDS 2005 “Building Institutional Capacities of the Plant Protection Directorate”.

Under the NPI, the amendments of the Law on Plant Protection Products have been envisaged for adoption in the fourth quarter of 2011. The amendments shall refer to:

- Directive 2009/128/EC of the European Parliament and of the Council in terms of prohibition of aerial spraying of PPP, other than in exceptional cases (Article 9); reduction of pesticide use or pesticide risks in specific fields (Article 13); handling and storage of pesticides and treatment of their packaging and residues (Article 12);
- Regulation (EC) No. 1107/2009 in terms of requirements for co-formulants synergists and safeners, and the list of unacceptable co-formulants, while the other provisions of the Regulation (EC) No. 1107/2009 shall be added according to the recommendations of the Twinning Project IPA 2008 (SR 08 IB AG 01) “Harmonization of national legislation in the area of registration and control of

- plant protection products with the EU legislation and the application of new legal provisions”, applied as of 1 October 2010;
- detailed rules about registration procedures for PPP until 31 December 2013.

Harmonized risk indicators in accordance with Article 15 of Directive 2009/128/EC of the European Parliament and of the Council shall be added after their implementation in the EU.

Please refer to Annex VI. PLACIN ON THE OF PLANT PROTECTION PRODUCTS

31. Please provide information for each item listed below.

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 Law on Plant Health (“Official Gazette of RS 41/09) has established a legal framework for the system of plant health protection in the Republic of Serbia.

The plant health protection in the territory of the Republic of Serbia has been ensured, within their authorizations, by:

- The Ministry of Agriculture, Forestry and Water Management of the Republic of Serbia (MAFWM);
- Plant Protection Directorate (PPD);
- Forest Directorate (FD);
- National Reference Phytosanitary Laboratory (NRPL);
- Phytosanitary Inspection (inland and border) (FI);
- legal persons conducting the affairs of public interest pursuant to this law;
- legal persons and entrepreneurs providing services in the field of plant health;
- Holders of plants.

Measures and procedures for plant health protection in terms of this law are as follows:

- permanent supervision over plants that includes cultivated plants (fields, perennial plantations, plantations, nurseries, central plantations, greenhouses, netting structures, laboratories, etc.), spontaneous flora, as well as plants and plant products in storages, finishing process, processing and during transport;
- monitoring and the risk assessment of harmful organisms and their suppression;
- the phytosanitary control at import in view of preventing the introduction and spreading of harmful organisms;

- conducting phytosanitary control at exports of consignment of plants and plant products with respect to which other countries pose specific phytosanitary requirements;
- special phytosanitary inspections for the presence of particular harmful organisms by checking the health status, monitoring and special survey;
- conducting phytosanitary examinations for the purpose of issuance of plant passports, phytosanitary certificates and other official documents and acts;
- conducting inspectorial supervision for the purposes of plant health protection;
- implementation of phytosanitary measures;
- conducting laboratory analyses and testing of plants, plant products and regulated objects for the purposes of detecting the presence of harmful organisms and intensity of their presence;
- Forecasting the occurrence of harmful organisms, development and movement of their populations and determining optimal timeframes for their suppression;
- applied and other research in the area of harmful organisms diagnostics and plant health protection;
- education and providing advice and recommendations on harmful organisms;
- suppression of harmful organisms by implementation of disinfection, disinsection, deratization, decontamination and application of other treatment procedures.

For the purpose of reviewing professional issues, rendering professional opinions and participating in the implementation of project assignments related to the protection of plant health, the Minister pursuant to the legislation governing the state administration shall by decision establish a specialized working group - the Expert Council for Protection of Plant Health.

The Expert Council shall review professional issues, render professional opinions and participate in the implementation of project assignments in relation to the following:

- risk analyses of the introduction and spread of harmful organisms and estimates of possible negative consequences for the plant health;
- long-term plant health protection strategies;
- harmful organisms, for which the Program of Measures for the Protection of Plant Health is adopted;
- proposed lists of harmful organisms and lists of plants, plant products and regulated objects;
- plant health protection plans and special programs;
- phytosanitary measures which need to be adopted or amended for the purpose of promoting plant health protection;
- issuing recommendations for professional training;
- performing other necessary tasks in connection with the protection and promotion of plant health;

The Council's work is coordinated by the Plant Health and Plant Quarantine Department – Plant Protection Directorate.

The Plant Health and Plant Quarantine Department of the PPD performs the activities in relation to monitoring official and international standards, other documents in view of promoting the activities in the field of plant health and plant quarantine; issuing approvals for imports of harmful organisms and plants; establishment of phyto-register and the plant passport system; cooperation with international organisations and national services of other countries in the field of plant health and plant quarantine; monitoring and harmonization of legal and implementing provisions, regulations and recommendations with decisions, standards and recommendations of international organizations in the field of plant health and plant quarantine; outlining professional bases for drafting regulations in the field of plant health and plant quarantine; conducting competitions for the activities of public interest in the field of plant health; the preparation of elements necessary for drafting the financial plan of the Administration in relation to the costs in the field of plant health and plant quarantine; keeping records on issued phyto-certificates and notifications, harmful organisms, post-quarantine survey, etc., and performs other activities in this field.

The organizational chart of the Plant Protection Directorate and the levels of competence in the field of plant health have been provided in the answer to question no. 3, in Item 1.2. - Plant Protection Directorate, in Section I –General Information, Chapter 12.

For the purpose of preventing the introduction, spread of harmful organisms and their suppression in the territory of the Republic of Serbia, the Lists of harmful organisms and the Lists of plants, plant products and regulated objects that may be the carriers of harmful organisms are prepared.

For the purpose of preventing the occurrence, introduction and spread of harmful organisms and their suppression, the annual Program of Measures for Plant Health Protection has been adopted (hereinafter referred to as: “the Program of Measures”). The Program of Measures define the actual measures, time limits, manner of implementing those measures, the entities that will implement them, sources of funds and manner of provision and use of the funds, as well as the manner of controlling the implementation of the measures.

Within the Program of Measures for Plant Health Protection, for the purposes of preventing the occurrence, early detection, monitoring, suppression and eradication of harmful organisms and their suppression on the plants, the following activities are conducted:

- permanent supervision over plants by the official process of recording, collecting and processing the data on the presence and absence of harmful organism on the basis of phytosanitary inspections, monitoring, forecasts, check of health status or other procedures and on the basis of all other available resources. The permanent supervision shall be conducted for all cultures whose cultivation is relevant for the Republic of Serbia or for particular regions on the basis of preparation and submission of reports on the presence of harmful organisms;
- specific survey over harmful organisms prescribed by this program, conducted within a determined period of time for the purpose of detecting harmful organisms

or determining the characteristics of their population or determining the border of the field in which they are present or absent.

The activities under the Program of Measures for Plant Health Protection apart from phytosanitary inspectors are conducted by all authorized agricultural services and authorized laboratories and institutions that have been entrusted with the performance of the said activities referred in the Program of Measures under the Agreement concluded with the Ministry – Directorate.

The Plant Protection Directorate prepares the Instructions for the implementation of the Program of Measures for the current year. The final reports on the conducted activities and implemented measures under the program of measures are submitted to the Plant Protection Directorate on prescribed forms.

The Program of Measures for Plant Health Protection and the Instructions for the implementation of the Program of Measures prescribe that in case of suspicion of the occurrence of a quarantine harmful organism, a phytosanitary inspector must be immediately informed and take a sample, send it under the label “URGENT” for a laboratory analysis and prescribes an appropriate phyto-sanitary measure.

The attachment of the Instructions to all holders of public authorizations includes the contact details of all phytosanitary inspectors in the territory of the Republic of Serbia, head of Phytosanitary Inspection Department, Head of Plant Protection and Plant Quarantine Department and the telephone numbers of the authorized laboratories.

In case of the occurrence of harmful organism referred to in List IA part I, List IA part II, List IIA part I and the List IIA part II on plants, plant products and prescribe objects, the holder of plants shall be obliged to immediately report it to the Plant Protection Directorate through a competent phytosanitary inspector.

When on the basis of the results of examination the infection by a harmful organism referred to in the List IA part I, List IA part II, List IIA part I and List IIA part II or harmful organism referred to in the List IB and List IIB in a protected zone has been determined, the phytosanitary inspector shall be obliged to, depending on the circumstances, order one or more phytosanitary measures, as follows: treatment, destruction or other form of removal of the harmful organism, infected plants, plant products and regulated objects, for the purpose of preventing the spread of the harmful organism, its suppression or eradication.

The phytosanitary measures applied for the purpose of plant health protection have been based on the principles of risk assessment and risk management. The Plant Health and Plant Protection Section in cooperation with the expert working group prepares the proposal of the Order on prescribed phytosanitary measures, passed by the Ministry of Agriculture, Forestry and Water Management.

While conducting the risk assessment, the following is taken into account:

- available scientific data;
- processes and production processes;
- methods of inspection supervision, sampling and testing;
- distribution of particular harmful organisms;
- existence of the field without harmful organisms;
- environmental conditions;
- quarantine or other procedure.

The risk management includes the consideration of the economic justification in terms of loss of production or sales in case of introduction and spreading of harmful organisms, costs of their suppression and eradication, as well as their cost-effectiveness.

For the purpose of preventing infections or infestations with harmful organisms, the Administration shall inform other entities and holders of plants about the occurrence and intensity of the infection, phytosanitary measures and the threat posed by the harmful organism, and the measures recommended by international plant protection organizations.

In case of the occurrence of harmful organism referred to in List IA part I, List IA part II, List IIA part I and the List IIA part II, the holder of plants shall be obliged:

- to protect plants, plant products and regulated objects by applying phytosanitary measures ordered by the phytosanitary inspector;
- prevent contacts between infected plants and other plants, plant products and regulated objects to which the infection could spread.

The Phytosanitary Inspection Service of GI orders the prescribed phytosanitary measures and supervises the implementation of phytosanitary measures.

In the performance of the activities prescribed by the Law on Plant Health, a phytosanitary inspector may order the enforcement of the following measures:

- prohibit the introduction of harmful organisms from the lists prescribed by this Law and regulated harmful organisms;
- prohibit the imports and trade of plants, plant products and regulated objects which do not fulfill requirements prescribed by this Law;
- temporarily prohibit cultivation of plant species at the place of production which are potential hosts of harmful organisms;
- order phytosanitary measures in conformity with international guidelines and recommendations on plants, plant product and regulated objects, in production, finishing, trade, processing, storage, import and export, in case of suspected infection with harmful organisms;
- order changes of the purpose of plants, plant products and regulated objects if they determine that such a procedure will not result in spreading of harmful organisms;
- order the destruction of plants, plant products and regulated objects in production, finishing, processing, storage and trade and when there exists a risk of spreading of

harmful organisms or where requirements prescribed by this law have not been fulfilled;

- order the destruction of consignments of plants, plant products and regulated objects at imports when there is a risk of spreading of harmful organisms or where requirements prescribed by this law have not been fulfilled;
- prohibit the movement, division or sampling of consignments of plants, plant products and regulated objects until the completion of phytosanitary examinations;
- temporarily prohibit production, processing or trade in whole or in part, until it is determined that there no longer exists a threat of spreading of harmful organisms;
- prohibit the issuance of plant passports in cases where the conditions required for its issuance have not been fulfilled;
- order measures to eliminate irregularities which have been established when the supervision procedure has determined that plant health regulations have not been applied or have been applied improperly;
- file a request for initiating a misdemeanor proceeding, or a complaint for an economic offence or file a criminal complaint with the respect to violation of any the provisions of this Law and regulations adopted under this Law;
- order other measures and undertake other actions, in conformity with this Law.

The Plant Protection Directorate (PPD) as a *single authority* shall improve the institutional capacities through the operation of the Plant Health and Plant Quarantine Section with a clear defining of administrative activities, allocation of clear competences and authorizations with the process of promoting cooperation, knowledge and exchange of information within the system itself (administration, inspection, laboratory) and exchange of information with other institutions.

An adequate system of training of complete administration, phytosanitary inspectors and laboratory staff should be established in view of implementation of the EU acquis communautaire and improve the system of fast communication and data exchange and perform the additional purchase of equipment and appropriate software.

Specific Control Measures

The Program of Measures for Plant Health Protection prescribes a survey of over harmful organisms: *Ralstonia solanacearum*; *Clavibacter michiganensis* ssp. *sepedonicus*; *Globodera pallida*, *Globodera rostochiensis*, *Synchytrium endobioticum*, *Phytophthora ramorum*, *Pepino* mosaic virus (PepMV).

The phytosanitary measures are implemented by phytosanitary inspectors in accordance with the prescribed national regulations harmonized with the EU regulations, as well as with the international guidelines and recommendations.

The following documents have been adopted:

- the Contingency Plan for prevention of spreading and suppression with the aim of eradication of potato ring rot disease;

- the Contingency Plan for prevention of spreading and suppression with the aim of eradication of potato brown rot disease and bacterial wilt of potato and tomato;

These documents provide the instructions on:

- the history of disease;
- legislative competence and responsibilities of competent structures;
- The elements taken into account during the implementation of phytosanitary measures for the purpose of prevention of spreading and suppression with the aim of eradication of potato ring rot and brown rot disease;
- Emergency procedures and measures implemented for the purpose of prevention of spreading and suppression with the aim of eradication of potato ring rot and potato brown rot.

Protected zones:

The Law on Plant Health prescribes a legal basis for the adoption of the implementing provisions (rulebook) related to the establishment of protected zones.

Registration of entities with business operations in this field (plant passports):

The Plant Protection Directorate establishes and develops the phyto-register that is kept in the electronic form. The registration of entities with business operations in the field of plant health has been initiated and it will be conducted in phases. The Plant Protection Directorate has established the registers of producers, entrepreneurs, importers and finishers of seed and plant material of agricultural plants.

The information brochure has been prepared for producers and plant holders subject to the obligation of registration, as well as application forms in accordance with the Commission Directive 92/90EEC and 93/50 EEC. The adequate software for keeping the register is necessary to be established.

Imports, Inspections and Notifications of Non-Adjusted Consignments:

Plants, plant products and regulated objects are subject to phytosanitary examination by the border phytosanitary inspection service at border crossing points;

Importation, transit and exportation of plants, plant products and regulated objects may be performed through the border crossings with the organized phytosanitary inspection service and which fulfill hygienic, technical and working requirements.

Consignments which are not subject to phytosanitary examination which are packed in wooden packaging material – WPM may be imported through border crossings at which customs service has been organized.

Consignments of plants, plant products and regulated objects on the List VB part I. which are being imported, their packaging and their means of transportation shall be subject to

customs supervision and compulsory phytosanitary examination performed in whole or on the basis of a representative sample;

Plants, plant products and regulated objects referred to in the List VB part I must be accompanied by a phytocertificate, or phytocertificate for re-export;

Phytocertificate and phytocertificate for re-export must be issued in conformity with the International Plant Protection Convention;

The phytosanitary examination is conducted in accordance with ISPM 12 and it consists of:

1. Inspection of documentation the consignment should be accompanied by the following documents at imports:

- application for the inspection of a consignment subject to phytosanitary examination;
- international certificate of the health status of plant consignments – a phytocertificate and phytocertificate for re-export (this applies to the consignments referred to in the List VB part I of the Rulebook on the lists of harmful organisms and the lists of plants and plant products and regulated objects (“Official Gazette of RS“ 7/10);
- a copy of the Decision on the registration within the register of importers (phyto-register);
- OECD and ISTA certificates for seed consignments – if they accompany a consignment and a certificate of production for planting material consignments;
- other documents accompanying a consignment – CMR, invoice, bill of lading.

A border phytosanitary inspector also checks whether a variety has been registered within the Variety Register – for seed consignments, consignments of seedlings and planting material (www.minpolj.gov.rs).

By Documentary check is determined whether:

- The importer is registered in the Register of producers, processors, importers, distributors and storage operators of certain plants, plant products and regulated objects under supervision, in accordance with the Law;
- Consignment is accompanied by a valid phytosanitary certificate or other equivalent document;
- Consignment is marked with the indication in accordance with phytosanitary standards adopted under the Convention IPPC;
- Consignment does not contain plants, plant products or other regulated objects listed in List III A,
- Consignment which is intended for scientific research meets the requirements prescribed by Law.
- Phytosanitary certificate contains in the heading "Additional Declaration": reference to the appropriate point of the List IVA part I, which phytosanitary certificate confirms.

2. Identification of a consignment (identity check) – is performed by comparing the data from the accompanying documentation with the consignment identifiers (consignments of seed, seedlings and planting material must be labeled by the prescribed declarations).

3. Examination

- examination of a means of transport – includes first the identification of a means of transport – freight space in which a consignment with the data from the accompanying documentation has been placed and then the examination of the means of transport and all the parts for the presence of harmful organisms.
- examination of the packaging – includes the examination for the presence of harmful organisms on and within the packaging;
- examination of plants (plant health check)– includes the examination of the whole consignment and sampling of the consignments when this is necessary and possible, in accordance with the prescribed procedures.

The examination of samples is conducted in a border crossing laboratory.

If there is a suspicion of the presence of a harmful organism whose presence is not possible to determine at a border crossing (hidden infections) or it is necessary to determine a harmful organism, the samples shall be packed, sealed and sent to an authorized laboratory in a prescribed manner.

4. Decisions upon the completed control: If the above indicated requirements in terms of accurate documentation, identification and examination on a border crossing point have been met, and the results of a laboratory analysis have been obtained, import and customs clearing of the consignment shall be allowed by issuing the Decision on the approval of import and customs clearing. At the same time phytosanitary certificate and re-export phytosanitary certificate to accompany the consignment shall be verified by the seal “Consignment examined – Import approved”.

If a consignment does not possess a necessary documentation, if it cannot be identified or it has not been appropriately labeled/declared, a border phytosanitary inspector shall issue the decision on the prohibition of import and order the return (reject) or destruction of the consignment.

When during the examination of a means of transport, packaging and/or the plants, and based on the obtained results of a laboratory analysis it has been determined that the consignment does not meet the requirements prescribed by the law, and that it has been infected by a harmful organism (organisms), a border phytosanitary inspector shall issue a Decision on the prohibition of imports and order taking of measures prescribed by the law – reject, destruction of the consignment or disinfection measure, depending on the type of the detected harmful organism, as well as on the type of plants.

The ordered measure for destruction or disinfection shall be conducted at the border crossing point if the conditions for enforcing such measure exist, otherwise the inspector

shall send the consignment based on a temporary decision and with the enforcement of preventive measures to the closest place where the ordered measure may be enforced under the customs supervision.

In case when a consignment is rejected, the phytosanitary certificate, and/or re-export phytosanitary certificate shall be verified by a red triangular stamp with the inscription “certificate rejected”.

In case when appropriate phytosanitary measures are taken, upon the issuance of the final decision the Form 2 – Notification of Interception shall be filled in, as an integral part of the Rulebook on a phytosanitary control of plants, plant products and regulated objects in the international trade (“Official Gazette of RS“ 32/10), and sent to the Plant Health and Plant Quarantine Section of the Plant Protection Directorate.

The Plant Protection Directorate shall notify the country of export about the interception on a prescribed form.

In the performance of inspection supervision activities, phytosanitary inspectors shall have a right and a duty to:

- check whether producers, processors, finishers, keepers, importers and traders of prescribed types of plants and plant products and regulated objects have been registered in the Register;
- control fulfillment of contractual obligations assigned by public bid;
- control the implementation of the Program of Measures and specific programs for protection of plant health;
- take official samples of plants, plant products and regulated objects without giving compensation for their value, in conformity with the provisions of this Law;
- control the implementation of measures which have been ordered in the event of the occurrence of harmful organisms, as well as prevention of contacts between the infected plants, plant products and regulated objects to which the infection may be transmitted;
- perform a survey of harmful organisms, in accordance with the Program of Measures;
- control the fulfillment of conditions for introduction of harmful organisms, or the importation of plants, plant products and regulated objects, for the purpose of experiments, research work or cloning selection work;
- control the production, finishing, processing, storage and trade of plants, plant products and regulated objects;
- control whether plants, plant products and regulated objects on List VA part I and List VA part II are accompanied in trade by plant passports, or seed on List IVA part I and List IVA part II by the label;
- perform phytosanitary, as well as occasional phytosanitary examinations of plants, plant products and regulated objects at the sites where they are produced, moved, processed, finished, stored, sold, as well as at the buyers of plants, plant products and regulated objects;
- control the fulfillment of requirements for the issuance of plant passports;

- calculate the fees for the performed phytosanitary examinations of consignments in production and circulation;
- control the implementation of the measures in accordance with this law.

Border phytosanitary inspectors engage in the activities of phytosanitary control during full working hours.

The phytosanitary inspectors working within the internal units conduct the activities of the implementation of phytosanitary policy apart from the activities of control.

Costs in the phytosanitary field;

The reimbursement of the costs for a conducted phytosanitary examination of consignments in trade over the state border has been prescribed by the Decision on the amount of reimbursement for the conducted phytosanitary examination of plants and the control of pesticides and fertilizers in trade over the state border (“Official Gazette of RS”, No. 57/08).

The border phytosanitary inspection service collects the administrative fees in accordance with the Law on the administrative fees of the Republic of Serbia with respect to filing the application, issuance of the appropriate decision, as well as the issuance of phytocertificates and phytocertificates for re-export.

The border phytosanitary inspection of the General Inspectorate of the MAFWM collects the fees and administrative duties in accordance with the indicated regulations.

Pursuant to the Law on Plant Health, the Rulebook on the Program of Measures for Plant Health Protection is adopted for the current year.

The funds for the implementation of the Program of Measures for Plant Health Protection (phytosanitary examinations, sampling, laboratory analyses) have been provided by the budget of the Plant Protection Directorate in the amount of 37.100.000 RSD.

Apart from phytosanitary inspectors, the activities under the Program of Measures are conducted by all authorized agricultural services and authorized laboratories and institutions entrusted with the said activities referred to in the Program of Measures in accordance with the Agreement concluded with the Ministry – Plant Protection Directorate.

The Plant Protection Directorate prepares the Instructions on the implementation of the Program of Measures for 2010. The final reports on the conducted activities and measures taken under the program of measures shall be submitted to the Plant Protection Directorate on prescribed forms.

The Plant Protection Directorate has no accounting item and allocated funds for the compensation of damage to holders of plants in case of eradication.

The following activities are conducted under the Program of Measures for 2010:

1) Survey in potato:

- bacteria: *Ralstonia solanacearum*; *Clavibacter michiganensis* ssp. *sepedonicus*;
- nematodes: *Globodera pallida*, *Globodera rostochiensis*, *Meloidogyne chitwoodi*, *Meloidogyne falax*;
- viruses: *Tomato Spotted Wilt Virus*, Potato spindle tuber viroid;
- phytoplasmas: *Potato stolbur*;
- funghi: *Synchytrium endobioticum*.

2) Survey in Pomefruit

- bacteria: *Erwinia amylovora*;
- phytoplasmas: *Apple proliferation phytoplasma* (apple),
Pear Decline phytoplasma (pear)

3) Survey in Stone fruits

- bacteria: *Pseudomonas syringae* pv. *persicae*
Xanthomonas arboricola pv. *pruni*
- viruses: *Plum pox virus*
- phytoplasmas: *European stone fruit yellows*

4) Survey in grape (Vitis)

- phytoplasmas: *Flavescence doree*;
- insects: *Scaphoideus titanus* as vector

5) Survey in strawberry

- bacteria: *Xanthomonas fragariae*;
- funghi: *Phytophthora fragariae* var. *fragariae*;

6) Survey in beans

- bacteria: *Xanthomonas axonopodis* pv. *phaseoli*

7) Survey in tomatoe

- bacteria: *Xanthomonas axonopodis* pv. *vesicatoria*
Clavibacter michiganensis ssp. *michiganensis*

8) Survey in pepper

- bacteria: *Xanthomonas axonopodis* pv. *vesicatoria*
- pepper viruses

9) Survey in protected crop production

(1) *Phytophthora ramorum*

Survey on *Phytophthora ramorum* is conducted in decorative plants within the genera: *Rhododendron*, *Viburnum*, *Pieris*, *Syringa*, *Pseudotsuga menziesii*, *Kalmia*, *Camellia*, *Leucothoe*, *Taxus baccata*.

(2) *Phytophthora kernoviae*

Survey on *Phytophthora kernoviae* is conducted in decorative plants within the genera: *Fagus*, *Rhododendron*, as well as *Drimys winteri* (Winteraceae), *Fagus sylvatica*

(Fagaceae), *Gevuina avellana* (Proteaceae), *Hedera helix* (Araliaceae), *Ilex aquifolium* (Aquifoliaceae), *Liriodendron tulipifera* (Magnoliaceae), *Magnolia* spp. (Magnoliaceae), *Michelia doltsopa* (Magnoliaceae), *Pieris formosa* (Ericaceae), *Quercus ilex* (Fagaceae), *Quercus robur* (Fagaceae), *Vaccinium myrtillus* (Ericaceae).

(3) *Iris yellow spot virus (IYSV)* - Alert lista

Survey on *Iris yellow spot virus* (vector *Thrips tabaci*) is conducted in decorative plants, including other plant species grown in a closed space: *Allium cepa*, *A. porrum*, *Eustoma russellianum*, *Iris hollandica*, *Amaryllis* sp.

(4) *Impatiens necrotic spot virus*

Survey on *Impatiens necrotic spot virus* is conducted in decorative plants, including other plant species grown in a closed space: *Impatiens New Guinea*, *Aconitum*, *Alstroemeria*, *Anemone*, *Antirrhinum*, *Begonia*, *Bouvardia*, *Callistephus*, *Columnnea*, *Cyclamen persicum*, *Dahlia*, *Dendranthema x grandiflorum*, *Eustoma grandiflorum*, *Exacum affine*, *Fatsia japonica*, *Gerbera*, *Gladiolus*, *Limonium*, *Lobelia*, *Pittosporum*, *Primula*, *Ranunculus*, *Senecio cruentus*, *Sinningia speciosa*, *Zantedeschia aethiopica*, *Capsicum annum*, *Cichorium endivia*, *Cucumis sativus*, *Lactuca sativa*, *Ocimum basilicum*, *Valerianella olitoria*.

(5) *Pepino mosaic virus (PepMV)* - Alert lista

Survey on *Pepino mosaic virus* is conducted in tomato crops in a closed space (greenhouses, polythene greenhouses)

10) Survey over insects

Ceratitis capitata

Tuta absoluta

Lyriomyza spp., *Bemisia* spp., *Thrips* spp.

11) Post-quarantine control

The funds for the conduct of post-quarantine supervision by authorized agricultural services and laboratory testing of plants (up to 50 samples) in case of a suspicion of the presence of quarantine harmful organisms have been provided in the budget of the Republic of Serbia.

Status of harmful organisms stated on the EU Acquis.

See the answer in the annex VII.

Plant health, plant protection products:

- Placing on the market of plant protection products;

1. Legal framework (present/planned)

The Law on Plant Protection Products governs the field of authorization of plant protection products (PPP) for the purposes of their placing on the market, conditions for import, placing on the market and use of plant protection products in accordance with human health protection, environmental protection and procedures relating to harmful organisms suppression, activities of public interest in the field of PPP, provision of services, record keeping, collection and exchange of data in the field of PPP. This Law governs the establishment of maximum residue levels of plant protection products and their control in food and feed.

This law is a legal basis for drafting implementing provisions that will be harmonized with the EU legislation. The term for the adoption of the implementing provisions pursuant to the law is 10 June 2012, and the regulations adopted pursuant to the old Law on Plant Protection will be applied until the adoption of new implementing provisions, such as the Rulebook on the methods for testing of pesticides (“Official Gazette of FRY”, no. 63/01 and 65/01, “Official Gazette RS”, no. 93/05) and pursuant to the Law on production and placing on the market of poison matters, such as the List of poison substances classified in groups (“Official Gazette of RS”, no. 91/08).

The adoption of new framework acts in the field of PPP with the explanation to what extent they cover phytosanitary *EU Acquis* (their harmonization with the EU Acquis) have been provided in Annex VI.

2. Competent authorities/competences, authorized institutions, professional services

The competence within the field of plant protection products in the Republic of Serbia was allocated to three ministries until the adoption of the Law on Plant Protection Products (until 10 June 2009): The Ministry of Agriculture, Forestry and Water Management – MAFWM (a part of the registration procedure – physical and chemical properties and efficacy, control of production, import, circulation and application), the Ministry of Environment and Spatial Planning (control of PPP production, classification and labelling) and the Ministry of Health (establishment of maximum residue levels of PPPs in food products and the control of PPP residues in food).

After the Law on Plant Protection Products had come into force, the MAFWM became a central authority for policy making, legislative and inspection activities and international cooperation, as well as the appropriate administrative procedures in relation to PPPs (the authorization procedure, placing on the market and use of PPPs, entering into the Register of distributors and importers of PPPs).

The MAFWM is the authority in charge of registration and control of PPP, and within the MAFWM:

- Plant Protection Directorate (PPD);

- Directorate for National Reference Laboratory (DNRL) is in charge of laboratory activities in the food chain. Within the DNRL, the National Reference Laboratory for residues performs the activities of laboratory testing of PPPs and PPP residues in the food of plant origin in the procedure of the post-registration control. Due to non-operability of the National Reference Laboratory for residues (employs only one officer who is engaged in the performance of the administrative activities of the laboratory in accordance with the job systematization of the MAFWM), the testing of PPPs in the process of post-registration control (PPP formulations and residues in the food of plant origin) is still performed by the institutions authorized by the MAFWM;
- General Inspectorate (GI).

Human, material and financial resources of the competent authorities in the field of PPPs have been provided in the answer to the question number 2, Section I –General Information of this chapter.

The Plant Protection Directorate (PPD) is in charge of the authorization procedure of PPPs, establishment of maximum residue levels of PPPs residues in food and feed and the establishment of monitoring of residues in food of plant origin. These activities are conducted within the Department for Plant Protection Products and Plant Nutrition Products. Out of 8 employees in this Department, 5 officers perform the following activities:

- PPP registration (PPP assessment in terms of efficacy and partially physical and chemical properties);
- establishment of the monitoring program for the post-registration control of PPP including the monitoring program of PPP residues in food, apart from the PPP formulations;
- preparation of expert bases for drafting regulations in the sphere of PPP;
- monitoring of the condition in the field of placing PPP on the market;
- implementation of good agricultural practice principles and the establishment of the system for the integrated pest management;
- issuance of approvals for testing non-registered PPP for the purposes of scientific research;
- entering into registers, keeping records and registers (Register of distributors and importers of PPP for wholesale and retail sale, Register of service providers in the field of PPP, records of production, placing on the market and application of PPP);
- implementation of international conventions, agreements and information exchange;
- participation in the work of international authorities and organizations;
- establishment of the information system, collection, processing and storage of data;
- preparation of reports, analyses, information and other materials, in accordance with the regulations and international contracts and agreements and other entrusted activities.

General Inspectorate (GI)

The phytosanitary inspection of the GI is in charge for control in the field of the PPP. The powers of the phytosanitary inspection service have been based on the application of: The Law on General Administrative Procedure, the Law on State Administration, the Law on Food Safety, the Law on Plant Protection Products, rulebooks, orders, programs, instructions, etc.

Import control of plant protection products

The Department of Border Phytosanitary Inspection Service of the MAFWM General Inspectorate is in charge of the control of PPP imports, as well as of the control of PPP residues in imported consignments of food of plant origin (primary production, simple processing, composite food).

The import of plant protection products may be conducted through border crossings with the established phytosanitary inspection service. The customs service may not start the customs clearance procedure until a phytosanitary inspector has completed the examination. Importers, carriers and their authorized agents are obliged to announce a consignment and file the application for the examination to a border phytosanitary inspector. The application is filed in the written form, with the indication of all documents accompanying the consignment.

The procedure of the inspection control of consignments of plant protection products at border crossings includes as follows:

- examination of documentation (documents) accompanying consignments in view of identification with the designations on the packaging material, packaging and identified contents of a consignment and verification of the conditions prescribed by the law:
 - quality certificate,
 - bill of lading/ship's bill of lading,
 - invoices, delivery notes and other documents accompanying a consignment,
 - decision on the registration within the Register of distributors and importers,
 - decision on the registration of plant protection products, and the evidence that the active substance is included in the list of approved substances;
- a physical inspection of a consignment:
 - a visual inspection,
 - inspection of a means of transport,
 - inspection of packaging and all designations (labels, seals, etc.);
- sampling.

For the purposes of analyzing physical and chemical properties, the samples are sent to the institutions authorized by the MAFWM.

The procedure for sampling PPP consignments, the list of authorized institutions conducting analyses and testing methods have been provided in the answer to the

question No. 6, point 2. Plant Protection Products and Residues thereof, Section I – General Information, Chapter 12.

The consignments that have been sampled by a phytosanitary inspector are placed under customs surveillance and must not be placing on the market prior to obtaining the results of the examination.

If it is established that PPP:

- do not conform to declared quality, as confirmed by laboratory tests, phytosanitary inspectors issue a decision to prohibit their import and order the return of the consignment to the sender;
- conform to declared quality, as confirmed by laboratory tests, phytosanitary inspectors issue a decision allowing the import.

With regard to the consignments imported in containers through the border crossing not designated for container inspection, phytosanitary inspectors only check the accompanying documentation. If the consignment is accompanied by appropriate documentation, phytosanitary inspectors allow transport of containers under customs supervision to the approved place of inspection where the containers can be opened.

Consignments transported by rail are inspected at railway stations designated by the MAFWM. Air and mail consignments and goods in lots are inspected at the customs warehouse in specified examination field that meets inspection requirements.

Consignments in transit through the territory of the Republic of Serbia, which are reloaded or split, are subject to compulsory examination at border crossings.

Control of plant protection product on internal market

The Phytosanitary Inspection Department performs the control in the field of PPP on internal market.

While performing the control, a phytosanitary inspector:

- checks whether PPPs are authorised, and whether a decision on registration has been issued, and whether it has been accompanied by label and directions for use, as well as the shelf life of plant protection products has been displayed;;
- checks the fulfillment of the requirements for placing on the market (wholesale, retail) of PPP, packaging, labeling, sale and use of PPP; checks the documentation accompanying PPP on the market;
- checks whether registers and records have been kept;
- checks the performance of professional activities and tasks of authorized legal persons and the activities conducted by service providers;

- takes samples for the post-registration control of PPP;
- takes samples of plants, plant products and regulated objects, water and soil to check whether PPP have been applied as prescribed (e.g., damage incurred by crops, non-compliance with the preharvest period, etc);
- temporarily prohibits, until irregularities have been removed, market of PPPs if a legal person and entrepreneur have not been registered within the Register of importers and distributors of PPP or if they do not fulfil the prescribed requirements;
- checks whether plant protection products have been applied in accordance with the approval, and instructions for use and label with the compliance of good agricultural practice for plant protection products, integrated pest management and environmental protection;
- checks whether plant protection products have been applied in such a manner so as not to cause harm to human and animal health (pollution of residential, industrial and other facilities in which humans and animals stay, as well as the pollution of water and soil);
- checks whether PPP residues exceed the prescribed level, and when it has been established that the residues exceed the maximum residue level, a phytosanitary inspector in charge of such plants, plant products and food shall order appropriate measures (destruction or in any other way prevent their use for human or animal consumption);
- checks the conditions for marketing and use of machinery for the application of PPP, and whether the owner of a machinery has performed control testing.

A phytosanitary inspector checks the fulfillment of the conditions for wholesale and retail sale and imports of PPPs, for the purpose of registration of legal persons and entrepreneurs in the Register of distributors and importers of PPPs. The conditions subject to the checks performed by a phytosanitary inspector have been prescribed by the Rulebook on the requirements with respect to facilities, equipment and professional qualifications of staff that must be met by a distributor and importer to be registered within the register of distributors and importers, as well as on the requirements with respect to facilities, equipment and professional qualifications of staff that a distributor to be met by distributors for placing on the market particularly dangerous PPPs ("Official Gazette of RS, No. 80/10).

In accordance with this Rulebook, a distributor may be registered within the Register of distributors and importers:

1) for wholesale and importer, if:

- if it owns a warehouse or leases a warehouse of the appropriate capacity for storage and sale of PPP;
- if it employs at least one person for an indefinite period of time for full working hours, who has graduated from the second degree studies (academic studies - master, specialist academic studies, specialist vocational studies), and who has graduated from basic academic studies in duration of at least four years in the field of plant protection;

- if it employs at least one person performing the activities of storage and sell of plant protection products in a warehouse, for an indefinite period of time and for full working hours holding at least a high school degree in agriculture or chemistry and the evidence of professional qualifications for circulation of plant protection products.
- 2) for retail sale, if:
- it owns a warehouse or leases a warehouse of the appropriate capacity for storage and sell of plant protection products;
 - if it employs at least one person performing the activities of storage and sell of plant protection products in an agricultural pharmacy, for an indefinite period of time and for full working hours holding at least a high school degree in agriculture or chemistry and the evidence of professional qualifications for circulation of plant protection products.

Exceptionally, in case of retail sale of plant protection products for general use, a retail sale distributor may be registered within the Register of distributors and importers if it employs at least one person for an indefinite period of time and for full working hours, holding at least a high school degree in trading activities.

Authorized institutions

The authorization for the performance of particular professional and technical activities, particularly related to the assessment of active substances and PPP, performance of physical-chemical analyses and biological efficacy of PPP in the procedure of authorization and control, as well as the post-registrational control (PPP formulations and PPP residues in the food of plant origin) has been granted by the MAFWM to particular professional and scientific institutions, in accordance with the old Law on Plant Protection, including the institutions that conducted a part of the assessment activities of active substances and PPP until 10 June 2009 in accordance with the authorizations of the Ministry of Environment and Spatial Planning.

Due to non-operability of the National Reference Laboratory for residues (employs only one officer who is engaged in the performance of the administrative activities of the laboratory in accordance with the job systematization of the MAFWM), the testing of PPP in the process of post-registration control (PPP formulations and PPP residues in the food of plant origin) is still performed by the institutions authorized by the MAFWM.

The list of authorized institutions, the accreditation status, methods of testing and sampling have been provided in the answer to the question No. 6, point 2. Plant Protection Products and Residues thereof, Section I – General Information, Chapter 12.

Agricultural Extension Services

The collection of data on PPP placing on the market (only from retail sale outlets for the time being) has been performed by agricultural extension services (34) deployed in 25 districts. These institutions perform the said activities in accordance with the agreement

with the Plant Protection Directorate concluded at the annual level and including not only the said activities but also the activities in accordance with the Law on Plant Health related to the implementation of the program of measures in the field of plant health.

The list of the agricultural extension services has been provided in the answer to the question no. 29, Section VI – Phytosanitary policy, Chapter 12.

Since the Law on plant protection products envisages the professional trainings delivered to distributors and end users of PPP, these services will deliver the trainings according to the training program prepared by the MAFWM until the announcement of the competition for the performance of the activities of public interest (professional trainings of persons in charge of storage, placing on the market and use of PPPs). The second phase of the training program delivered to end users of PPPs (Safe application of pesticides and environmental protection) is currently implemented with the assistance of the USAID Agro-business project.

The training program was prepared in 2007 with the assistance of USDA and the experts of the Iowa State University . During 2009, the first 500 agricultural producers were trained and the plan for 2011 envisages the training of new 2.500 agricultural producers and advanced trainings for the first 500 agricultural producers that attended the training sessions during 2009. The plan envisages that 25% of totally registered agricultural producers should be trained by June 2012 through these programs.

The training program for PPPs distributors has been planned for the first half of 2011 when the Rulebook on the requirements with respect to facilities, equipment and professional qualifications of staff that must be met by a distributor and importer to be registered within the register of distributors and importers, as well as on the requirements with respect to facilities, equipment and professional qualifications of staff that a distributor to be met by distributors for placing on the market particularly dangerous PPPs (“Official Gazette of RS, No. 80/1 will come into effect.

2. Procedure of registration of plant protection products

The Law on plant protection products has implemented certain provisions from the EU legislation, but with derogations:

- with respect to the registration of new PPPs which have not been registered in the Republic of Serbia, the old procedure from previous Law on plant protection is applied (“Official Gazette FRY” No. 24/98 and 26/98 and “Official Gazette RS“, no. 101/05) (Article 86),
- with respect to re-registration procedure of PPP in line with the EU requirements the provisions of the new law (Article 11-25. of the Law) shall be applied as of 31 December 2013 (Article 90).

This period (till 31 December 2013) shall ensure to the Republic of Serbia enough time for:

- a competent authority to build its capacities for a full implementation of this law in line with EU requirements (capacity building for evaluation), as well as the availability of documentation subject to the assessment (in the process of assessing the equivalence of active substances), as well as
- stakeholders to harmonize their operations with the new law (the compilation of dossier for the registration in accordance with EU requirements).

The first capacity building of the competent authority in the field of PPP was carried out through the Twinning Project CARDS 2005 "Capacity building of the Plant Protection Directorate". Employees of the Department for Plant Protection Products and Plant Nutrition Products, the phytosanitary inspection and the authorised institutions participating in the registration procedure were provided with the basic knowledge on approval procedures for active substances at the EU level, evaluation of the PPP at member state level and postregistration control (sampling and testing of PPPs and food of plant origin for the presence of PPPs).

The basis for further capacity building of the competent authority is the Twinning Project approved within the IPA 2008 - "Harmonization of national legislation in the field of registration, circulation and control of PPP with the EU legislation and their application. The implementation of the Project (SR/08/IB/AG/01) started in October 2010. The project refers to the assistance in harmonization and implementation of new regulations of the Republic of Serbia in line with the *Acquis communautaire*, building of the administrative capacities of the Department for Plant Protection Products and Plant Nutrition Products as internal evaluators, experts in selected national institutions as external evaluators and the Phytosanitary Inspection Department for the implementation of the EU procedures in the field of registration and placing on the market of plant protection products.

In August 2010, the Plant Protection Directorate (PPD) adopted the Directive on the registration procedure of plant protection products, which defines the different registration procedures based on the status of active substances in the EU, required documentation and administrative steps in processing of applications for registration. This Directive is an internal document, adopted in accordance with Article 44 of the Law on State Administration, pursuant to which there is no obligation of publishing in the "Official Gazette of RS", but it obliges the PPD staff to comply with its provisions. However, based on this directive, eight guidelines for different types of the registration procedure have been drafted and made available to the applicants on the official website of the MAFWM.

The registration procedure of new PPPs that have not been registered in the Republic of Serbia to-date depends on status of active substances in the EU. In case:

- PPP contain the active substances for which there exists a decision on inclusion in the Annex I of the Council Directive 91/414/EEC, the authorization shall be issued for the period of maximum 10 years;
- PPP contain the active substances for which there exists no decision on inclusion in the Annex I of the Council Directive 91/414/EEC, the authorization shall be issued for the period of maximum 3 years;
- PPP contain the active substances with respect to which there exists a decision on non-inclusion in the Annex I, the registration of new plant protection products shall not be possible in the Republic of Serbia, other than in case these plant protection products contain the active substances voluntarily withdrawn and with respect to which the application for re-inclusion in the Annex I has been submitted, and their authorizations shall be valid until 31 December 2013, and until the final decision has been made on the EU level.

With respect to already registered plant protection products that contain the active substances that have not been included in the Annex I and whose authorizations expire:

- during the period as of 10 June 2009 (the date of coming into force of the Law) until 31 December 2013, the current registrations shall be valid by 31 December 2013 at most, taking into account the final decision on the status of these active substances at the EU level, in the following cases:
 - when they contain the active substances that have been withdrawn voluntarily withdrawn and with respect to which the application for re-inclusion in the Annex I has been submitted,
 - when they include the active substances with respect to which there exists a decision on non-inclusion in the Annex I, but with respect to which the application for re-inclusion has been filed;
- during the period as of 10 June 2009 (the date of coming into force of the Law) until 31 December 2013, when they contain the active substances that have not been listed in the previous case (contain the active substances with respect to which there exists a decision on non-inclusion and with respect to which the application for re-inclusion has not been submitted), the authorizations shall expire on the date of expiry of the term for which they have been granted;
- after 31 December 2013, the final decision on their status in the Republic of Serbia shall be passed in the fourth quarter of 2011 for which the adoption of the amendments to the Law on Plant Protection products has been envisaged (Article 20 which shall be applied as of 31 December 2013) and after which the list of approved substances will be adopted in accordance with the Annex I of Council Directive 91/414/EEC.

The registration of new PPP based on the active substances that are new to the market of the Republic of Serbia shall be conducted on the basis of the assessment:

- of toxicological and ecotoxicological profile of the active substance and PPP, as well as their fate and behavior in the environment, exposure of operators and consumers,
- of chemical and physical characteristics of PPP,
- of PPP's efficiency.

The following documentation should be submitted for the assessment of toxicological and ecotoxicological profile of an active substance and PPP, as well as their fate and behaviour in the environment:

- the analytical profile of five typical batches of the active substance (testing conducted in other countries shall be accepted),
- chemical and physical properties of the active substance based on testing conducted in other countries, and all available data on chemical and physical properties of the active substance,
- data on the toxicological profile of the active substance, as follows: acute and sub-acute toxicity, sub-chronic toxicity, chronic toxicity and carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, as well as other toxicological tests if necessary such as the effects on the endocrine system and neurotoxicity, case studies (testing conducted in other countries shall be accepted),
- data on the toxicological profile of a plant protection product, the acute toxicity in particular (testing conducted in other countries shall be accepted),
- data on the eco-toxicological profile of the active substance, as follows: toxicity for birds, bees, aquatic organisms, earthworms, soil microorganisms, beneficial arthropods, bioaccumulation (testing conducted in other countries shall be accepted),
- data on the fate and behaviour in the environment, as follows: mobility and discharge into groundwater, adsorption, degradation in soil, degradation in water at different pH, degradation in the water/sediment system (testing conducted in other countries shall be accepted),
- analytical methods for determining the purity of the active substance and significant toxicological and ecotoxicological relevant impurities in the technical active substance,
- analytical methods for determining the residue in/on plants and plant products, in the food of plant and animal origin and feed,
- certificate by a base producer on the purity of active substance,
- the composition of a plant protection product,
- the letter of access in case a producer of an active substance is not a producer of a plant protection product at the same time,
- Material Safety Data/Safety Data Sheet (MSDS/SDS) for a PPP and coformulants.

Based on the submitted data, a document under the title “Toxicological Assessment” is drafted and it includes the risk assessment of the active substance and the plant protection product with respect to human and animal health and the environment. The documentation is submitted through the Plant Protection Directorate which keeps records of the submitted documentation and forwards it to the authorized organization for the purpose of conducting a toxicological assessment.

The following documents should be submitted for the assessment of chemical and physical properties of a plant protection product:

- the report of the authorized organization on testing chemical and physical properties of a plant protection product conducted in the Republic of Serbia,

performed in accordance with the FAO specifications for a certain form of formulation,

- testing of chemical and physical properties made by a producer of a plant protection product,
- the composition of a plant protection product,
- safety instructions for a plant protection product and co-formulants.

The following documents should be submitted for the assessment of the efficiency of a plant protection product:

- the report of the authorized organization on testing of the efficacy of a plant protection product conducted in the Republic of Serbia, in two vegetation seasons for obtaining the authorization for the period of up to 10 years, and in one vegetation season for obtaining the authorization for the period of up to 3 years,
- the authorization issued in the country of a producer of a plant protection product or in one of the European Union countries (only for plant protection products produced by foreign producers).

The documentation submitted shall be considered at the Expert Council for plant protection products, which meets once a month. The Expert Council takes into consideration the professional issues, provides expert opinions and participates in the implementation of project tasks related to: the PPP registration procedure; testing of PPP; application of PPP; plans and special programs in the field of PPP; providing recommendations for professional trainings delivered to staff; providing recommendations for drafting regulations in the field of PPP; performance of other required tasks concerning PPP.

The members of the Expert Council belong to prominent public scientific and professional circles for plant protection, environmental protection, chemistry, biochemistry, technology, toxicology and other professional circles relevant for the sphere of PPPs.

The Expert Council counts 20 members and it is divided into six groups: a group for the assessment of physical and chemical properties and maximum residue levels (4 members), a group for the assessment of toxicological properties (2 members), a group for the assessment of eco-toxicological properties (2 members), a group for the assessment of fate and environmental behaviour (2 members), a group for the assessment of efficacy (7 members) and a group for the assessment of an operator exposure (2 members). The groups may have separate meetings. Conclusions and recommendations of the groups are adopted on the monthly meetings of the Council. The most members of the Expert Council come from organisations authorised for testing and assessment of PPPs.

On the basis of opinion of the Expert Council, the PPD issues an authorisation for placing on the market of plant protection product.

The Republic of Serbia is not an EU Member State. Thus the whole documentation on the inclusion of an active substance is not available in terms of an analytical profile of five typical batches, producer and place of production and FAO specifications are used as a reference source when assessing the equivalency of the active substance. As a reference source for the active substances with no available FAO specification, the requirements from the Annex I of the Council Directive no. 91/414/EEC are used in terms of the minimum purity of the active substance and maximum impurity of toxicological and ecotoxicological relevance. The Guidance document on the assessment of the equivalence of technical materials of substances regulated under Council Directive no. 91/414/EEC Sanco/10597/2003 – rev. 8.1, June 2008 is used for the assessment of the equivalence of an active substance.

The registration of new PPP based on generic active substances shall be conducted on the basis of the assessment:

1. of the analytical profile of five typical batches of the active substance (testing conducted in other countries shall be accepted) in terms of the assessment of the equivalence (see the previous paragraph), with the submission of the following documentation:
 - analytical methods for determining the purity of the active substance and significant toxicological and ecotoxicological and relevant impurities in the technical active substance,
 - analytical methods for determining the residue in/on plants and plant products, in the food of plant and animal origin and feed,
 - certificate by a base producer on the purity of an active substance,
 - the composition statement of a plant protection product,
 - the letter of access in case a producer of an active substance is not a producer of a plant protection product at the same time,
 - Material Safety Data/Safety Data Sheet (MSDS/SDS) for a plant protection product and co-formulants;
2. chemical and physical properties of a plant protection product, and the same procedure applies as previously indicated in relation to the registration of a new PPP based on new active substances,
3. efficacy of a plant protection product, and the same procedure applies as previously indicated in relation to the registration of a new PPP based on new active substances, but the efficacy tests are performed during one agricultural season (one year).

If the equivalence has been confirmed, conducted by the authorized organization for the issuance of the Toxicological assessment, that assessment is made on the basis of the available documentation (it is not necessary that a producer should conduct toxicological and eco-toxicological testing, as well as the testing of fate and environmental behaviour), while the assessment in relation to a plant protection product is made on the data available for the active substance and coformulants contained in the plant protection product..

Processing of the application for a PPP registration and decision making:

- an applicant files the application for testing the efficacy and physical and chemical properties to an authorised organization, and submits the copy of this application to the Plant Protection Directorate;
- Toxicological assessment: the submission of the documentation for conducting a toxicological assessment of an active substance and a PPP to the Plant Protection Directorate that keeps records of the submitted documentation and forwards it to the authorised organization for the purpose of conducting a toxicological assessment, which sends a report to the applicant upon the completion of the assessment;
- the authorised organisation sets up field trials for testing the efficiency of PPPs (in one or two vegetation seasons), notifies the PPD thereof, and sends a report to the applicant upon the completion of the said tests;
- the authorised organization conducts the testing of physical and chemical properties of PPPs, including the testing of technical purity of the active substance and impurities of toxicological and ecotoxicological relevance, and submits a report to the applicant upon the completion of the said tests;
- Once the all above mentioned documentation has been collected, the applicant shall file the application for registration, including other relevant documentation. The application shall be considered at the session of the Expert Council for plant protection products. The Council meets once a month to consider the applications.
- On the basis of opinion of the Expert Council for plant protection products, the PPD issues the decision on the authorization.

- Setting up and controls of maximum residue levels.

1. Regulatory framework (current / planned)

Adoption of The Law on Food Safety created the general horizontal legal framework for further harmonization in this field, and adopted Law on Plant Protection Products regulated the issue of residues PPP in food and feed of plant origin, by the adoption of by-laws under this Law and in accordance with special vertical EU regulations.

In addition to registration, placing on the market and application of the pesticides, Law on Plant Protection Products regulates the establishment of their maximum residue levels and their control in food and feed of plant origin.

Based on this Law, with the approval of the Ministry of Health, the Rules on the maximum residue levels of PPP in food and feed and on food and feed for which is determined the maximum residue levels, is adopted (Official Gazette of RS, No. 25/2010), that complies with Regulation 396/2005.

Law on Plant Protection Products regulates also and post-control of PPP that, pursuant to Article 28, includes:

- plant protection products, i.e. testing of chemical and physical properties of samples of registered plant protection products taken from the wholesale and retail distributors of plant protection products;
- residues of plant protection products, i.e. testing of the samples of food of plant origin for the presence and level of residues of plant protection products, collected from primary producers, distributors and importers.

Law on Plant Protection Products regulates also the Annual Program of post-registration-control (Article 29), that is being implemented with the aim of:

- monitoring in the field of residues of PPPs in food in terms of presence and levels of residues of PPPs in foods of plant origin in the Republic of Serbia for the assessment of population health vulnerability;
- informing of producers, distributors, importers and consumers about the irregularities;
- exclusion from the market in the Republic of Serbia of foods of plant origin, which does not meet the prescribed residue levels of pesticides.

Annual Programme for 2010, due to lack of funding, laboratory capacity and the applied methods (multi-residue methods-MRMs) has not been passed.

Residue Monitoring Program of PPP in food of plant origin will observe the levels of residues with the aim of health risk assessment of the population in the Republic of Serbia. This program is under preparation to be adapted in 2011, in accordance with the Law on Plant Protection Products. In order to ensure compliance with maximum residue levels and assessment of consumer exposure to residues of PPP through food of plant origin, the coordinated control program of the EU in 2011, 2012 and 2013 will be taken into account, while conceptualizing of future program (Commission Regulation No. 915/2010 from 12.10.2010 in connection with continuing coordinated program of Union for 2011, 2012 and 2013) and the approved budget for the Plant Protection Directorate for 2011 by the Ministry of Finance.

By the Residue monitoring program of PPPs in foods of plant origin, executives of monitoring will be determined (phytosanitary inspection and laboratories until the setting-up of operations of the National Reference Laboratory for Residues), the priority of taking samples of food of plant origin, the number of samples, the active substances in the food of plant origin that will be studied for monitoring of residue levels in accordance with the levels of residues prescribed by the Rules on the maximum residue levels of PPPs in food and feed and on food and feed for which is determined the maximum residue levels (Official Gazette of RS, No. 25/2010), which is harmonized with the EU maximum residue levels of pesticides in/on food and feed.

The procedure for adopting the Rules on food sampling methods for detection of pesticides in food of plant or animal origin, that is fully compliant with the 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.

Until the adoption of this regulation, phytosanitary inspectors sample foods of plant origin in order to examine the residue of pesticides in accordance with instructions issued under the project "The remains of pesticides in foods of plant origin", that was funded by the Plant Protection Directorate in 2005 and 2006, and fully compliant with the Directive 2002

2. Competent authorities / jurisdiction and the authorized institution

Until 10.06.2009, the competence in the field of establishing maximum residue levels and control of PPP residues in food was the responsibility of the Ministry of Health.

Upon entry into force of the Law on Plant Protection and The Law on Food Safety from 10.06.2009, the MoAFWM is the central body for policy, regulatory and inspection activities and international cooperation in the field of PPPs, including the field of establishing maximum residue levels and control of PPP residues in food and feed.

Plant Protection Directorate

In accordance with the organisational structure of the MoAFWM, activities relating to the establishment of maximum residue levels PPP in food and feed and adoption of the Annual Post-control program is performed by the Plant Protection Directorate (DPP), and within DPP, Department for Plant Protection Products and Plant Nutrition Products, responsible for direct enforcement of regulations and activities in the field of PPP related to:

- monitoring program of post-registration control of PPPs and PPP monitoring program of residues in food and feed of plant origin;
- monitoring the situation in the field of PPP residues in food of plant origin;
- establishment of information systems, data collection, processing and storage;
- preparing of reports, analysis, information and other materials, in accordance with regulations and international agreements and treaties, and other activities that are its competence.

General Inspectorate (GI)

Phytosanitary inspection GI is responsible for controlling the field of PPP residues in food and feed of plant origin in terms of sampling of food of plant origin and to take measures in case of divergence from the established level of PPP residues in food of plant origin.

National Reference Laboratory for Residues

National Reference Laboratory for residues as part of the Directorate of National Reference Laboratories of the newly established organizational units of the MAFWM, shall carry out laboratory tests within the post-registration control of products for plant protection and plant nutrition and food samples for the presence of residue of pesticides, as well as testing of formulations of products for plant protection and nutrition.

For now, National Reference Laboratory for residues employs only one executive who, according to the systematization of jobs MAFWM, is engaged in laboratory administration. Therefore, testing of residues of PPP in food continues to be performed by the institutions accredited and authorized by the MAFWM, or with ones that the contract is made with to perform the tasks of public interest, in accordance with The Law on Food Safety (Official Gazette, No. 41/09).

Program of monitoring and control of PPP residues in animals, food of animal origin and animal feed shall be conducted by the Veterinary Directorate of MAFWM

3. Future state

Future annual program will take into account:

- the number of inhabitants per municipality;
- statistical data on the consumption of foods of plant origin;
- data on domestic production and imports of foods of plant origin;
- data on the level of residues from previous years;
- the capacity of laboratories, applied methods (Multi-Residue Methods - MRMs);
- risk assessment of PPPs;
- registered PPPs for certain types of goods;
- the number of warehouses, wholesalers, importers and retailers of food of plant origin.

Programmes will include both food of domestic origin and imported food with the priorities:

- check that the residues of PPP do not exceed allowable limits of MRL (Maximum Residue Levels);
- check if some unexpected residues of PPP in certain kinds of foods of plant origin are present;
- check if the input of PPP residues by the food of plant origin is at an acceptable level.

Priorities will be based on risk analysis, prior evidence of health impact to the population in Serbia and abroad, and in accordance with European and other international obligations and harmonized recommendations.

Priority ranking system	
Monitoring	Type of monitoring
Low priority level <ul style="list-style-type: none"> • there is no evidence of exceeded MRL or 	Check objective: legal compliance and providing of necessary

<p>non-approved PPP in / on food of plant origin (source: previous monitoring reports, Rapid Alert System, or other monitoring data of other countries)</p> <ul style="list-style-type: none"> • low number of expected residues of PPP on/ in foods of plant origin • foods of plant origin are insignificantly present in the diet of any population group 	<p>information.</p> <p>Foods of plant origin are monitored at least every four years.</p>
<p>Mid-level priorities</p> <ul style="list-style-type: none"> • there is evidence of exceeded MRL or non-approved PPP on/in food of plant origin (source: previous monitoring reports, Rapid Alert System, or other monitoring data of other countries) • expected incident of remains of the PPP on/in foods of plant origin is largely represented in the diet of any population group 	<p>Test objective: Fresh food of plant origin. Monitoring of previous results.</p> <p>Foods of plant origin are monitored every second or third year.</p>
<p>The high level of priority</p> <ul style="list-style-type: none"> • recent evidence of exceeded MRL or non-approved PPP on/in foods of plant origin (source: previous monitoring reports, Rapid Alert System, or other monitoring data of other countries) • evidence that an entry can exceed the acute reference dose / Acute Reference Dose • Expected PPP residues on/in food of plant origin that is of great importance for a category of consumers 	<p>Annual monitoring of food of plant origin that is important in the diet and/or targeted monitoring of identified problems.</p>

Planned annual reports will contain:

- 1) analysis of inspection results;
- 2) possible reasons for exceeding the established MRL with appropriate remarks concerning the possibility of risk management,
- 3) analysis of chronic and acute health risks for consumers from residues of pesticides;
- 4) assessment of consumer exposure to residue of pesticides,
- 5) LOD that were applied,
- 6) information on laboratories that are performing tests of the samples, details about the accreditation of laboratories, as well as data on laboratory proficiency regarding the participation in tests relevant to the combination of active substance/product, that are sampled and tested within the Annual Programme,
- 7) details on the implementation of the measures taken.

These reports shall be submitted to the Expert Council for risk assessment in food safety, for review, scientific opinion and recommendations.

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:

- Registration of varieties, catalogues;

The field of registration of varieties of agricultural plants, as well as keeping the Register of varieties of agricultural plants is regulated by the Law on Registration of Varieties of Agricultural Plants (Official Gazette No. 30/10).

Compliance of Law on Registration of Varieties of Agricultural Plants with *Acquis communautaire*:

- Council Directive 2002/53/EC of 13 June 2002 on the Common Catalogue of varieties of agricultural plant species - Directive on the joint catalogue of varieties of agricultural plants (harmonized in the part of the obligation to form a National Register of Plant Varieties of agricultural plants and in the part of registration of Agricultural Plant Varieties);
- Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed - Directive on the marketing of vegetable seed species (aligned in part of registration of vegetable crops varieties);
- 2003/90/EC Commission Directive 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 - Directive on the minimum conditions necessary for testing in registration of varieties of agricultural plants (full compliance will be achieved by making by-laws adopted pursuant to this law by the end of 2012.)
- 2003/91/EC Commission Directive 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 agricultural plant species - Directive on the minimum conditions necessary for testing in registration of varieties of agricultural plants (full compliance will be achieved by making by-laws adopted pursuant to this Act by the end of 2012.)
- Commission Directive 2007/49/EC of 26 July 2007 amending Directive 2003/91/EC 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 – Amending basic directive regarding the protocol for examining of certain plant varieties (full compliance will be achieved by making by-laws adopted pursuant to this Act by the end of 2012);
- Commission Regulation (EC) No 637/2009 of 22 July 2009 establishing implementing rules as to the suitability of the denominations of varieties of agricultural plant species and vegetable species – Regulates denominations of

varieties of agricultural plant species and vegetable species (full compliance is achieved by the adoption of Rules on denominations of varieties of agricultural plant species (Official Gazette of RS, No. 76/10);

- Council directive 92/34/EEC of 28. April 1992B on the marketing of fruit plant propagating material and fruit plants intended for fruit production – Regulates the marketing of fruit plant propagating material and fruit plants intended for fruit production (harmonized in part related to marketing permission only for varieties entered in the Register of Agricultural Plant);
- 2009/74/EC Commission Directive of 26 June 2009 amending Council Directives 66/401/EEC, 66/402/EEC, 2002/55/EC and 2002/57/EC as regards the botanical names of plants, the scientific names of other organisms and certain Annexes to Directives 66/401/EEC, 66/402/EEC and 2002/57/EC in the light of developments of scientific and technical knowledge - Regulating taxonomic names of crop species (full compliance will be achieved by making of by-laws adopted pursuant to this law by the end of 2012.).

Rulebooks enacted under the Law on Registration of Varieties of Agricultural Plants:

- Rulebook on the content and form of application for the registration of varieties of agricultural plants, as well as documentation to be submitted with the request (Official Gazette of RS, No. 53/10);
- Rulebook on the contents and form of application for the registration of foreign varieties of fruit trees and vines in the Register of Agricultural Plant Varieties (Official Gazette of RS, No. 72/10);
- Rulebook on the contents and manner of keeping the Register of Agricultural Plant Varieties (Official Gazette of RS, No. 73/10);
- Rulebook on denomination of varieties of agricultural plants (Official Gazette of RS, No. 76/10).

All by-laws stipulated in this law shall be issued within the period of two years from the date of adoption of the law or no later than the end of 2012.

Seed certification;

1. Institutions responsible for the procedures of certification and quality of seeds of agricultural plants

Ministry of Agriculture, Forestry and Water Management (MoAFWM) is a state body that organizes and controls the process of certification and seed quality. Two bodies within the MoAFWM are included in the seed certification activities, i.e.:

- Plant Protection Directorate, and
- Phytosanitary Inspection of the General Inspectorate.

Plant Protection Directorate performs administrative and professional activities in the field of seeds, preparation of legislation and delegation of tasks of professional control of seed production and health checks.

Inspectorate General, through phytosanitary inspectors performs control of production registration applications, control of documents and inspects the work of agricultural services, seed quality control and control over seed market.

Agricultural expert services carry out field inspections - technical and health control of seed crops.

2. The procedure of certification of seeds of agricultural plants

Certification of seeds of agricultural plants include:

- 1) professional control which determines the origin of the used seeds, species, varieties and categories and
- 2) health control of seeds of agricultural plants.

Expert control

Seed production of agricultural plants is carried out in accordance with the following regulations:

- Law on Seed (Official Gazette of RS, No. 45/05);
- Rulebook on the control of seed production, content and manner of documenting the production of propagating material of agricultural plants (Official Gazette of RS, No. 60/06);
- Rulebook on the quality of seeds of agricultural plants (Official journal of SFRY, No. 47/87, 60/87, 55/88, 81/89, Official Journal of FRY, No. 16/92, 8/93, 21/93, 30/94, 43/96, 10/89, 15/01, 58/02 and Official Gazette of RS, No. 23/09, 64/2010 and 72/2010)
- Rulebook on the content and manner of keeping the register of seed processors (Official Gazette of RS, No. 59/06);
- Rulebook on the content and manner of keeping the register of seeds producers.. (Official Gazette of RS, No. 51/06)
- Rulebook on conditions to be met by expert organization issuing the label, the size of individual packages of seeds and the records of issued labels (Official Gazette of RS, No. 66/06 and 73/06)

In accordance with Article 4 of the Law on Seed, categories of seeds of agricultural plants are:

- pre-basic seed (upper elite) - is produced under the control of the maintainer of a variety;
- basic seed (elite) - produced under the control of the MAFWM;
- certified seed of the first generation (original) - produced under the control of the MAFWM;
- certified seed of second generation (certified) - produced under the control of the MAFWM.

The production of agricultural plant seeds can be carried out by a company or enterprise, other legal entity or entrepreneur registered in the Register of producers of seed, propagating material, mycelium of edible and medicinal mushrooms as well as an individual on the basis of the concluded agreement on cooperation with the seed producer. Seed produced from this cooperation is considered to be the production of the producer.

Registration in the Register of seeds, propagating material, mycelium of edible and medicinal mushrooms is done on the bases of application that producer shall submit to MAFWM.

The application for registration shall include:

- data on producer (name, seat, address, registration number and tax number);
- code of activity of the producer;
- information about the location of seed production (cadastral parcel, treatment, care, protection and conservation of biological and chemical properties of soil for seed production);
- information about the seed type and category and production volume;
- information regarding the responsible person (name, address, ID number and proof that it has completed University studies at the Faculty of Agriculture, Department of Field and Vegetable Crops, or from other course with relevant exam on seed science with at least three years of experience).

If the producer carries on business in several different places, the application shall include the information for each producing site.

Seed production is subject to mandatory professional control, that is to determine: the origin of the used seeds, species, varieties and categories.

Technical control of seed production of pre-basic seed is carried out by the variety maintainer, and of other categories of seed is MAFWM.

Professional activities of control of the seed production of agricultural plants, may be delegated by MAFWM to the professional organization (agricultural expert services).

Control of seed production is based on applications submitted by the producer to MAFWM for each parcel on which the seed crop is started, filed on a prescribed form.

Together with the application, producer submits:

- proof of origin of used seed (document of varietal, declaration of seeds);
- agreement with the holder of the variety protection right on compensation for the temporary use of the protected variety, that is reported for control;
- a sketch of the plot location where the seed crop is established.

Control of seed production includes a review of documentation on the origin of used seed and professional examinations in the growing season. Examination of the records is to determine the origin of the used seeds, species, varieties and categories. Expert

examination during the growing season is to determine the characteristics of varieties and other elements as stipulated by this Act when they are the most prominent, or when they can be observed and measured.

Application is rejected if:

- the applicant is not registered in the Register of seeds, propagating material and mycelium of edible and medicinal mushrooms;
- have not been filed within the statutory time limit;
- the application is not accompanied with the necessary documents;
- seed category declared for the production is contrary to regulations;
- variety for the seed production is not registered in the Register of varieties of agricultural plants.

Control of seed production includes a review of documentation on the origin of used seed and professional examinations in the growing season. Examination of the records is to determine the origin of the used seeds, species, varieties and categories. Expert examination during the growing season is to determine the characteristics of varieties and other elements as stipulated by this Act when they are the most prominent, or when they can be observed and measured.

Records on check-ups are kept on the prescribed forms, namely: minute on seed production control and minute on control of hybrid pollination.

Data, performance review and evaluation are entered into the record of inspection. Minutes shall be taken for each plot of seed crop that is reported for the control of production. Concluding of the record is done immediately after harvest of seed crops. The records shall include data on the yield of natural seeds and assessment of the yield of processed seed. Record on inspection of seed production and the control of pollination of seed shall be made in three copies, one copy to be left to the producer of seed. Responsible person that manages the process of seed production have to be present during the examinations and formulating of record.

Based on conducted inspection, record on seed production control and health certificate on seed crop, the Minister of Agriculture issues Certificate of Seed Crop Recognition for each reported plot.

If the review determines that the seed crop does not meet the requirements for recognition, or for the issuance of certificates, the record containing data on these conditions and the minute of survey performed are concluded.

The certificate is not issued if:

- it has been determined that seed crop does not meet the requirements of this Act;
- breeder of the variety proposes the adoption of solutions of non-recognition of seed crops;

- the health examination determines the presence of pests and diseases that cause the prohibition of use of seed for production and marketing according to the regulations on protection of plant health.

3. Certification of forest seeds

According to the Law on Reproductive Material of Forest Trees, there are four categories of forest reproductive material, depending on the type of recognized source material from which the production starts:

- known origin,
- selected,
- qualified,
- tested.

Certification of forest seeds begins by recognizing the basic material for production of forest reproductive material. When the reproductive material is recognized, production - harvesting or collection of seeds, or extraction from natural regeneration, as well as production of propagating material from parental material is done under the supervision of the National Forestry Inspection.

Producer of seed, or cuttings is obliged to notify the forestry inspector seven days before the collection of seeds or making cuttings (Article 27, paragraph 3 of the Law on Reproductive Material).

Upon completion of measuring of the amount of collected seeds or cuttings produced, the producer shall submit to the Ministry - the Forestry Directorate application for issuing of certificates of origin ("Master certificate"), with a copy of minute made by inspector on the amount that is produced. At the same time the sample of seed shall be submitted to the authorized laboratory for quality testing and obtaining of declaration of quality.

Notice of collection - Collection - The certificate of origin

(Producer sends to the Inspector)... (report made by Inspector)... (Forest Administration)

There are three types of the form of certificates of origin, depending on the place where the reproductive material is produced.

If previous seed processing is necessary, forestry inspector formulates a new record on the amount obtained by processing, with issuing of the certificate of origin.

For planting material that is generated in the registered forest nurseries, the producer issues its own document - the label (supplier's document) for the amount of up to 1000 pieces. Exceeding that amount, shipment of nursery stock is accompanied in distribution, apart from label of supplier, with certificate of origin issued by the inspector.

Reproductive material of known origin can be used only within the region of provenance where it is produced. In Serbia, the regions of origin are established for the following species of forest trees: oak, field ash, beech, pine, white pine, fir and spruce. For other types of forest trees, the entire territory of Serbia is the one region of provenance.

Recognition of the starting material

Recognized as a basic following material can be used:

- Seed source
- seed stands
- seed plantation
- parent trees
- clone and clone mixtures.

Category of the reproductive material depends from which recognized starting material it has been obtained.

Recognition of the starting material is carried out by MAFWM, that may delegate the recognition of the starting material for the production of reproductive material that has been selected and of known origin to the institutions that meet prescribed conditions, but the recognition of the starting material for the production of qualified and tested reproductive material shall be carried out by the commission appointed by the Minister.

All terms are fully compliant with the Annexes to Instructions of the Council 1999/105/EC. Basic general characteristics of a recognized source material are that it is in good health, of good morphological properties, adapted to site conditions, isolated from the influence of unwanted pollination, adapted to prevailing ecological conditions and the like. Special conditions are prescribed for each category in the Rulebook on recognition of source material and production control of reproductive material of forest trees, and for the tested reproductive materials special procedures of recognition in the field trials.

Producer of forest reproductive material, makes application for the recognition to MAFWM – Forestry Directorate, which forwards the request to the authorized institution. Representatives of accredited institutions ascertain in the field if the prescribed conditions for recognition are fulfilled, make up record and submit to the Forestry Directorate proposal for recognition, or if the requirements are not met for the denial. MAFWM issues a certificate of the starting material as of accredited and registers object in the Register of the provenance regions and the acknowledged source material for the production of forest reproductive material.

Summary results from the Registry are published in the National list of recognized source material, whose form and content was done according to the 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.

4. Health check of seeds of agricultural and forest plants

Health checks of seeds of agricultural plants are carried out in accordance with the following Acts:

- Law on Plant Health (Official Gazette of RS, No. 41/09);
- Rulebook on health testing of crops and facilities for the production of seeds and propagating materials and health testing of seeds and propagating materials (Official Journal of FRY, No. 66/99 and 13/2002, Official Journal of SMN, No. 10/2003 and 13/2003 and Official Gazette of RS, No. 39/2006, 59/2006, 115/2006, 119/2007 and 107/2008).

Control of seed health is currently prescribed in the Rulebook on the health testing of crops and facilities for the production of seeds and propagating materials and health testing of seeds and propagating materials, namely:

- time and manner of carrying out of health testing of crops and facilities for the production of seeds and propagating materials, and health testing of production of seeds and propagating materials that are virus-free and tested on certain viruses, and health testing of soil on nematode;
- criteria for determining the health of crops and facilities, seeds, propagating materials and other products in domestic trade and trade across state borders;
- form of certificate on health status of crops and facilities for the production of planting material of perennial plants;
- the form of certificates on health status and testing for viruses and the like organisms on plant material of perennial plants and seeds;
- conditions that must be fulfilled by legal persons engaged in health testing of crops and facilities, as well as health testing of seeds that are virus-free and tested on certain viruses, propagating materials and land on the nematodes.

Subject to health testing are:

- crops and facilities;
- land and substrate;
- herbs that may be a potential host and carrier of harmful organisms and plants which are located in the vicinity of crops and facilities, that is determined by the Criteria for determining the health of crops and facilities, seeds and propagating materials, as integral part of this Act, and plants located in fields where the crops are established, and facilities.

Crops and facilities are clearly marked with information about the producer, type of plant varieties and reproduction, the land field or number of plants and trees.

The first review of potatoes – up to 21 days after planting, if conditions are favourable for the manifestation of disease or when the potato plants reach a height of 10 to 25 cm, the second - when the plants are in full bloom, if the conditions are favourable for viewing or

after flowering and before desiccation has taken place, the third (post control) - of making the mandatory desiccation, and the fourth - before placing on the market.

Health testing of soil and substrate, on the presence of nematodes is done once a year, 30 days before the start of production - establishing the crop, 30 days before entering into facilities and every four years in the nursery, before beginning of vegetation.

Health testing of crops and facilities under this Article shall be conducted in the presence of producer of seed and propagating materials.

Producer of seeds and of seeds and propagating material of agricultural and forest plants, is obliged to make application to the competent authority for the health testing:

- soil and substrate - at least 30 days before establishing the crop, or facility;
- crop - at least 30 days from the finished planting, except for potatoes that is no later than 15 October of current year for the next year.

Application for the health testing shall be filed on prescribed forms. Forms are kept in triplicate.

With the application for health testing of crops and facilities, the producer encloses an agreement concluded with the legal entity authorized to perform the health testing of facilities and crops during the growing season for the presence of harmful organisms.

In addition to harmful organisms, Criteria for small grains, millet like grain, vegetables, also determines manner of finding out harmful organisms in the crop, allowed percentage for plant and reproduction material and notes.

During the first health test of crops and facilities, legal entity authorized to perform the health testing reviews documentation and determines:

- If there is a certificate on production of seed crops and the declaration of quality of seeds for the seed used for crop establishment, and whether for raising of stem planting of fruit trees there is proof of its founding of the base material, i.e., whether for reproductive plant material used on a facility there is a Health Certificate and declaration of quality;
- if there is a report on the completed testing on the presence of certain nematodes in the soil or substrate.

After each performed health testing, record shall be made on the completed health testing and health status of crop seeds and seedlings. Data on completed test shall be recorded on the site of inspection.

Minutes shall be made in three copies, one of which shall keep a legal entity authorized to perform the health testing, the other copy shall keep the producer of seed, or plant material, and the third copy shall be submitted to the competent federal authority by the legal entity authorized to perform the health testing

Report on the results of completed testing on the presence of nematodes, as well as tests for viruses, is an integral part of the record of health testing.

If the health testing proved that the crop or the facility are healthy, a legal entity authorized to perform the health testing, issues upon examination a certificate of health of agricultural crops for seed production during the growing season, seed health and proper conditions of facilities for the production of planting material, perennial plants during the growing season in the prescribed form, within ten days from the date of the completed health testing and for the virus free material the certification of the health condition and testing for the presence of harmful organisms on the seeds and propagating materials of perennial plants, ten days after the end of indexing .

If the health test determines that there are plant quarantine harmful organisms in any percentage, or that there are economically harmful organisms in the percentage greater than the percentage of specified criteria, it shall be considered that the entire crop is infected, or an entire facility - if on that crop, or in that facility is carried out production of seeds or seedlings plant species in which these organisms cause disease or pest attack plants and can be transferred by.

Only the quantities of seeds and planting materials that are not infected with certain viruses or with all known viruses and similar organisms on those types of plants and that are produced from the tested material that has been subject of health testing and over which the health testing has been conducted and tests showed that they were not infected by viruses, or certain viruses, and like organisms, can be used for distribution.

5. Quality of seeds of agricultural plants

The quality seed of agricultural plants is prescribed by the Law on Seed (The Official Gazette RS, No. 45/05).

Regarding the quality, seeds must meet the prescribed standards of quality.

Quality of seeds that are placed on the market is the responsibility of seed processor, or of the importer.

Testing and determination of seed quality is done prior to marketing and use, for each lot of seed.

Testing and determination of seed quality is carried out by the accredited laboratory. List of accredited laboratories is given in answer to question No. 6, first subparagraph (a part on investigations of the quality of the seeds of agricultural plants), Section I – General Information, Chapter 12.

Processor files the application for the testing and quality assessment and sampling of seeds to an accredited laboratory.

With the application for testing, processor shall submit a certificate of recognition of seed crop.

Accredited laboratory issues a report on seed quality following the testing procedure. Accredited laboratory is required to keep seed tested samples one year from the date of issuance of reports on seed testing, and documentation of testing of seed for at least six years from the date of this report.

Accredited laboratory is required to keep the samples of tested tubers, bulbs and cloves for a month from the date of issuance of report on testing of their quality, and documentation of testing for six years from the date of this report.

Seed processor, or importer is responsible for damage to the end user if the seed does not meet the requirements in respect of the declared type, variety and quality of seeds.

Rulebook on the quality of seeds of agricultural plants (Official journal of SFRY, No. 47/87, 60/87, 55/88, 81/89 and Official Journal of FRY, No. 16/92, 8 / 93, 21/93, 30 / 94, 43/96, 10/89, 15/01, 58/02 and Official Gazette of RS, No. 23/09, 64/2010 and 72/2010), prescribes the method and procedure for testing the quality of seeds of agricultural plants and method of packaging and labelling of seeds, whereas the requirements from this Act apply to the seed that is imported.

Research of seed quality in the Republic of Serbia carry out 18 laboratories accredited by the Accreditation Board of Serbia and 2 laboratories that have the accreditation issued by Institute of Field and Vegetable Crops and Maize Research Institute, Zemun Polje.

6. Packaging labelling and notification of seed

Seed in the market must be packaged in original packaging in a manner that ensures the preservation of its quality and must meet the quality specified in the declaration and on the label.

Depending on the type and category of seed declarations and labels must be unique to the content, size, and colour and must have a serial number.

The label is issued by professional organizations authorized by the MoAFWM.

Label for small packs of seed issues the processor, or importer.

Professional organizations must meet the requirements for professional staff, equipment, facilities and space. Professional organizations keep records of issued labels.

- Approval of propagating material.

Plant Protection Directorate, as an entity within the MAFWM, is in charge at the central level for the administrative, legislative and international activities of approving planting material.

Inspection supervision and supervision of authorized institutions are conducted by phytosanitary inspectors of the General Inspectorate of MAFWM.

The newly established Directorate of National Reference Laboratories of MAFWM will perform duties of laboratory tests in this field and the organization of certification of planting material.

Control operations (health and technical examinations and laboratory tests) of planting material are carried out by the agricultural expert services and performed under the authority of the Plant Protection Directorate.

Law on Fruit Trees, Vines and Hops Propagating Material is a framework for the field of plant material and issuing of approval of the planting material. This law, together with the accompanying subordinate legislation is partially aligned with EU regulations. The legislation defines the production, marketing and import of planting material, planting material categories, controlling of the production and notification of nursery stock.

The existing legal framework in the field of fruit trees, vines and hops:

- Law on Fruit Trees, Vines and Hops Propagating Material(Official. Gazette of RS, No. 18/05)
- Regulation on the recognition of parent trees, vines and shrubs of fruit trees, vines and hops Official Gazette of RS, No. 51/06)
- Rulebook on standards of quality, packaging, sealing and marking of propagating material of agricultural plants (Official Journal of SFRY, No. 45/75 and 26/79),
- Rulebook on conditions to be met by the dealer that distributes planting materials of fruit trees, vines and hops (Official. Gazette of RS, No. 29/06),
- Rulebook on the contents and manner of keeping a registry of producers of fruit trees, vines and hops propagating material (Official. Gazette of RS, No. 29/06),
- Rulebook on the manner and production procedure of fruit trees, vines and hops propagating material (Official. Gazette of RS, No. 40/06 and 58/06)
- Rulebook on health testing of crops and facilities for the production of seeds, propagating materials and seeds and propagating materials (Official Journal of FRY, No. 66/99 and 13/2002, Official Journal of SMN, No. 10/2003 and 13/2003 and Official Gazette of RS, No. 39/2006, 59/2006, 115/2006, 119/2007 and 107/2008).

Registered producers of plant material can only produce planting material of varieties that are registered in the Register of varieties and rootstocks, and shall provide the permission

of the variety certificate holder for the reproduction of varieties of planting material if the variety is protected.

Under special circumstances approved by PPD, domestic producers may also, for a foreign customer, produce from the imported reproductive material the varieties of plant material or substrate that are not registered in the Register of varieties and rootstocks, based on the agreement with the procuring foreign entity stipulating that the procuring entity takes over the entire amount of produced seedlings. This planting material is not allowed to be marketed in the territory of the Republic of Serbia.

Registered producer of plant material in the process of approval must file a application for the production and application for health testing on the prescribed forms and within the prescribed deadlines.

Producer of planting material is required to annually submit an application for control over the production of seedlings by 30 April each year for both planting materials and products for reproductive material to be used for seedling production. Application for establishing of stem plantations has to be done in vegetation period prior to establishing of stem nursery and no later than 30 days upon planting.

Application should be submitted for each location in which production is carried out separately. Application contains a detailed production plan. Along with the application, evidence on the origin of the used plant material is to be submitted .

Control of planting material consists of:

- Document review
- Review of the production site (spatial isolation) and review of plant material (appearance, consistency, growth, variety and type authenticity and health conditions).
- Mandatory parent plant sampling and sampling in case of doubt.

At least two tests are mandatory, first when the plants characteristics of species and cultivars are the most pronounced and when symptoms of plant diseases and pests can best be seen, and the other at time when plants express a uniform development and the general appearance of plant material, and a yield estimate is possible to be made.

On each such control minute is made, signed by the responsible person from the producer side and authorized persons exercising testing.

If the control determines that the plant material does not meet the conditions specified in the law and its implementing regulations, plant material must be destroyed in the presence of phytosanitary inspectors.

If the control determines that the planting material meets all the requirements prescribed, authorized Agricultural Expert Service issues certificate of health, and Plant Protection Directorate, certificate on planting material production.

After obtaining the certificate on production, the producer is filing application to phytosanitary inspection for printing and publishing labels for all categories of plant material. Label has a unique serial number and it marks the planting material in the marketing. Printing labels is carried out by the authorized organization. Colour of label is prescribed for each category of plant material. Authorized organization shall keep record of issued labels.

Planting stock on the market must match the declared type and variety, the prescribed standards of quality, must be of correct health, originally packaged and labelled, marked individually or in a group (collectively).

Packaging and labelling of plant material is carried out by the producer.

Prior to marketing, the producer of planting material, applies for the health testing of plant material and for the obtaining of certificates on the health status of consignments of plants in domestic distribution.

Categories of plant material are:

- Pre-basic
- Basic
- Certified
- Standard
- Standard marked with the label S-A in distribution

Pre-basic propagating material is reproductive material produced under the responsibility of the breeder or his agents, is used for the production of basic plant material, has been tested according to the latest international standards for the presence of diseases and pests. It is held in strict conditions with no possibility for infection.

The basic planting material is reproductive material derived from pre-basic propagating material used for production of certified planting material, produced in home plantings (facilities) under the control of an authorized organization. It is marked with a white label in the distribution.

Certified planting material is propagating material created from the basic planting materials intended for the production of certified plants or production of standard plant material. It is marked with a blue label in the distribution.

Standard planting material is reproductive planting material created by copying material from certified plants and is intended for the production of standard seedlings. It is marked with orange certificate in the distribution.

Standard planting material that is created by copying of materials from standard plants, or from parent plants approved in accordance with the Law on Seeds and Propagating Material (Official Gazette of RS No. 54/93), or for species that do not have a certification scheme, it is marked in distribution with certificate of orange colour and with special label S-A.

Plant variety rights

1. Organization and structure

On the basis of Article 8 of the Law on Ministries (Official Gazette of RS 65/08 and 36/09) Plant Protection Directorate of the Ministry of Agriculture, Forestry and Water Management is responsible for activities in the field of plant variety protection (plant breeders rights/plant variety rights).

The Plant Protection Directorate, Group for plant variety protection and biosafety exercises administrative procedures related to the provisions of the Law on protection of plant breeders rights and to the granting of plant breeders rights.

Group for plant variety protection and biosafety performs tasks related to: protection of the plant breeders rights and biological safety, monitoring and preparation of laws and regulations in accordance with the resolutions, standards and recommendations of the European Union, UPOV and other international organizations from the field of protection of plant breeders rights and biological safety, cooperation with international organizations (UPOV, CPVO) and national agencies of other countries in protecting the plant breeders rights and biological safety, planning, preparation and implementation of national and international projects for the establishment and improvement of the protection plant breeders rights and biological safety, keeping of registers required in the field of protection of the plant breeders rights and biological safety, coordinating the work of the Expert Council for Protection of the Plant Breeders Rights and the Expert Council for Biological Safety, preparing data for the preparation and updating of national databases to protect plant breeders rights and biological safety, establishment and implementation of measures for biological safety, a mechanism for making and implementing decisions concerning the safe transfer, handling and use of genetically modified organisms (GMOs) in order to prevent and reduce the potential of possible adverse effects of GMOs on the environment and health of humans and animals, and carries out other activities in this area.

2. Resources (human, material, financial)

Human resources

The Group for the Plant Variety Protection and Biosafety currently has four full-time employees (Head of the Group and three other employees). Currently the two employees

carry out the activities of plant variety protection (plant breeders rights), besides the head of the group. In addition to work on the protection of plant varieties, Group for the Plant Variety Protection and Biosafety, carries out operations related to the biological safety (genetically modified organisms - GMOs).

As the Republic of Serbia, for the first time, establishes a system for plant variety protection (plant breeders rights) and taking into account the implementation of specific legal provisions in the field of plant varieties protection (plant breeders rights), as a kind of intellectual property protection in practice, it is necessary to hire new human resources. Also, to adequately perform the activities in the field of bio safety (GMOs) it is necessary to increase the number of employees.

However, according to the decision on the maximum number of employees in public administration, public agencies and organizations for social security, and the Law on Determining the Maximum Number of Employees in the Republican Administration, the total number of employees in the Plant Protection Directorate can not be greater than 32 (plus the position of Director). In order to fully meet the demands that are placed in the field of harmonization of phytosanitary issues, it should be necessary to further engage the executives, for certain jobs, based on the contract.

Material resources of the Plant Protection Directorate are given in answer to question number 2, Item 1.2. Material resources, Section I – General Information, Chapter 12.

Financial Resources

All sources of funding for performing the jobs of plant variety protection (plant breeders rights) come from the budget funds allocated for the Plant Protection Directorate (answer to question No. 2, Item 1.2. Financial Resources, Section I – General Information, Chapter 12).

3. Current and planned structure

Since 2009. Plant Protection Directorate has been included in the program of cooperation with the Community Plant Variety Office-CPVO on the establishment and development of systems for protection of plant varieties (plant breeders rights) in the Republic of Serbia (Multi-beneficiary Program on Participation of Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Kosovo under UNSC Resolution 1244/99 and Turkey in CPVO). In 2010, employees of the Plant Protection Directorate, working on the protection of plant varieties, participated in seminars and trainings organized by CPVO. Training includes also experts from the experimental stations where the testing of varieties in field trials to determine the distinctness, uniformity and stability of varieties is carried out (DUS tests). The experimental stations should be equipped with necessary devices to perform technical testing of varieties.

In the framework of Technical Assistance and Information Exchange Instrument (TAIEX) programme, managed by the Directorate-General for Enlargement of the European Commission, training and knowledge improvement of employees in the field of protection of plant varieties and GMOs are taking place.

In accordance with the Law on Protection of Plant Breeders Rights, the Expert Council for Protection of Plant Breeders' Rights will be established, as a special expert body for the purpose of monitoring of situation in the field of protection of plant breeders' rights, consideration of professional issues, providing expert opinion and suggestions, as well as participation in the implementation of project tasks in the field of protection of plant breeders' rights. Minister of Agriculture, Forestry and Water Management shall issue a decision on granting of the plant breeders rights, based on the results of the variety examination and proposal of the Expert Council.

4. Legislation

Plant Variety Protection (plant breeders rights) in the Republic of Serbia is regulated by the Law on Protection of Plant Breeders' Rights (Official Gazette of RS, No. 41/09) adopted by the Assembly of the Republic of Serbia on 29th May, 2009, on force from 10th June, 2009. Ministry of Agriculture, Forestry and Water Management – Plant Protection Directorate, Group for Plant Variety Protection and Biosafety, is responsible for the Law enforcement. The Law applies to all plant genera and species.

After the accession of Serbia to the European Union, two articles of the Law on Protection of Plant Breeders' Rights will be changed, in order to become harmonized with EU legislation, namely:

- Article 5 Paragraph 2 of the Law that does not comply with Article 49 of the Treaty establishing the European Community and Article 4 of the Directive 77/249/EC on instructions to facilitate the effective use of the free provision of services by a lawyer. At the moment of the accession of Serbia to the EU, the said provision of the Law will be changed to make it apply to EU citizens by force of *acquis communautaire*.
- Article 27 of the Law provides for a national system called the exhaustion of the breeders' right that does not cover the situation where the material of the protected variety is placed on the market for the first time by the holder or with his consent outside the territory of the Republic of Serbia. This approach, which does not exhaust the right to breeder in marketing material of the protected variety, either directly or with his consent in the territory of a Member State or the European economic area and gives to holder the right to prevent the import of such materials in the Republic of Serbia from the Community, will be effective only until the accession of the Republic of Serbia to the EU. From the moment of accession of Serbia to the EU, article of the Law will be amended and the principle of community exhaustion of the breeder of the protected plant variety will apply, in terms of interpretation of the principle of superiority of *acquis communautaire*.

In March 2010. the Parliament of Serbia adopted the Law on Ratification of the International Convention for the Protection of New Varieties of Plants (Official Gazette of RS-International Treaties, No.19/10 of 26th March, 2010, entered into force on 3rd April, 2010), thus the Republic of Serbia ratified the International Convention for the Protection of New Varieties of Plants (1991 Act of UPOV Convention).

So far three regulations has been adopted based on the Law on Protection of Plant Breeders' Rights:

- Rulebook on content and manner of keeping the Register of applications for granting plant breeders' rights, Register of granted breeders' rights, Register of transferred rights and Register of license agreement (Official Gazette of RS, No. 70/09, of 27.08.2009, entered into force on 4.9 .2009).
- Rulebook on form and content of the application for granting plant breeders' right, the required documentation, the amount and manner of delivery of reproductive material samples (Official Gazette of RS, No. 82/2009 of 6.10.2009, entered into force on 14.10.2009).
- Rulebook on the list of species of agricultural plants to which are related exceptions to the breeder's right and the elements for establishing small farmers (Official Gazette of RS, No. 38/10 of 4.6.2010, entered into force on 12.06.2010)

Also the Rulebook on test methods for distinctness, uniformity and stability of plant varieties (DUS) for the purpose of granting of the plant breeders rights was prepared and sent for the adoption in November 2010.

Harmonization of laws and regulations was carried out with:

- International Convention for Protection of New Varieties of Plants, March 19, 1991, and
- Council Regulation (EC) No. 2100/94 on Community Plant Variety Rights of 27 July 1994.

At the 25th extraordinary session of the Council of UPOV, held in April 2008, the conformity of the Law on Protection of Plant Breeders' Rights with the UPOV Convention of 1991 was discussed, and a positive decision about the conformity of the draft Law with the UPOV Convention was obtained. In preparing the draft of the law for adoption by the National Assembly of the Republic of Serbia in 2009, the Law has undergone certain structural changes in term of aligning of the draft law with the legislation of the Republic of Serbia and the EU regulation in this field, to the extent it was possible to implement. Law on Protection of Plant Breeders' Rights, which is effective from 10th June, 2009, has to be submitted to the Office of UPOV for the review of conformity with the UPOV Convention of 1991. If the Council of UPOV awards a positive opinion about the law, the Republic of Serbia will initiate the procedure for membership in The International Union for the Protection of New Varieties of Plants (UPOV).

5. Control activities and implementation of policies

Supervision of enforcement of the Law on Protection of Plant Breeders' Rights and regulations made under this Law shall be carried out by MAFWM. The Law stipulates that the inspection is limited to the control of persons responsible for variety testing carried out for MAFWM. In performing inspection supervision, the inspector has the right and duty to check whether the variety is tested in accordance with the requirements of this Law, or whether the contractor is eligible for testing of varieties in accordance with the Law. Inspector may impose measures as to:

- order the contractor to correct the deficiencies reflected, if it is obvious that the variety is not examined in compliance with conditions stipulated in this Law;
- order the contractor to correct the deficiencies reflected, if it is determined that contractor does not fulfil the requirements for variety examination in accordance with the terms of this Law;

6. Implementation

The procedure for granting of the plant breeders' rights is launched upon request for granting of plant variety rights that the breeder or his authorized representative submitted to the Ministry. The breeder or his authorized representative shall submit the information on breeding history and a proposal for the variety denomination and, at the request of the Ministry is obliged to submit the appropriate samples of propagating material of varieties for testing to determine whether the conditions for granting breeders' rights are met.

Right to the breeder is granted if the variety is new, distinct, uniform and stable (determined by the DUS test) and meets the requirements for denomination of the variety, in accordance with the provisions of this Law.

The Ministry shall inform the competent authorities of all member states of UPOV on issues relating to the denomination of the variety, and in particular on the proposal, registration and cancellation of the variety denomination. The competent authorities of members of UPOV can submit their objections regarding the registered denomination of the variety to the Ministry.

The breeder who has duly applied for a grant of the breeder rights to the competent authority of another member of UPOV (hereinafter referred to as: the first application) is entitled to enjoy the right of priority for granting the breeders' rights in the Republic of Serbia for the period of 12 months from the date of the first application, provided that the day of filing is not included in this period.

The Ministry may use the results of variety technical examination (DUS) performed in another member state of UPOV.

Based on examination results and proposals of the Expert Council, the Minister adopts a decision on granting of plant breeders' rights, or refuse the grant to the breeder.

Exclusive rights to breeder of the protected variety are granted for a period of 25 years, and for potato, trees and vine for a period of 30 years from the date of grant.

For a variety of plant species that is included in the list of species of agricultural plants involving exceptions to the plant breeders' rights, it is considered that breeder's right shall not be infringed by a farmer who, within reasonable limits and subject to the safeguarding of the legitimate interests of breeders, uses for propagating purposes, on his own holding, the product of harvest which he has obtained by planting, on his own holding, the protected variety ("farm saved seed"). Varieties of fruit trees, ornamental plants, vegetable plants and forest trees can not be included in a list of crop species. Agricultural producers, except for small farmers, are obliged to pay to the holder of the plant breeders' rights a reasonable fee, in accordance with market conditions, for the use of "farm saved seed", which is significantly lower than the fee for purchased seed.

Bilateral phytosanitary international agreements with EU Member States, candidate countries and other third countries (if any).

Bilateral phytosanitary international agreements

Country:	Name of the Agreement or Contract
Russian Federation	Memorandum between the Ministry of Agriculture, Forestry and Water Management of Republic of Serbia and the Federal Service for Veterinary and Phytosanitary Control (Russian Federation) on the safety of products of plant origin that come from Serbia to Russia (in part related to the content of pesticides, nitrate and nitrite), signed on 23 July 2009.
People's Republic of China	Memorandum of Understanding Between the Ministry of Agriculture , Forestry and Water Management of the Republic of Serbia and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China on Cooperation for animal and plant health and food safety,
People's Republic of China	Protocol of Phytosanitary Requirements for the export of wheat from Serbia to China between the Ministry of Agriculture, Forestry and Water Management of the Republic of Serbia and the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China,
Republic of Hungary,	Letter on Intend on the cooperation in plant protection between the Ministry of Agriculture and Rural Development of the Republic of Hungary and the Ministry of Agriculture, Forestry and Water Management of the Republic of Serbia signed on 24.11.2009.

VII. Genetically modified organisms

33. Please provide information on general architecture of the legal basis; organisation and powers of different institutions involved.²

In Serbia, the legal basis for the regulation of genetically modified organisms (hereinafter referred to as: GMOs) is contained in Article 97, Paragraph 1, item 9 of the Constitution of the Republic of Serbia, stipulating that the Republic of Serbia provides a system of protection and improvement of environment protection and improvement of flora and fauna.

The matter of GM crops in the Republic of Serbia is regulated by:

- Law on Genetically Modified Organisms (Official Gazette of RS, No. 41/09), and
- The Law on Food Safety (Official Gazette of RS, No. 41/09).

The Law on Genetically Modified Organisms (in force since 10.06.2009) shall govern the procedure for issuing approvals for use in closed systems, for deliberate release into the environment of genetically modified organisms (hereinafter referred to as: GMO) and products containing GMO, conditions for use in closed systems and for deliberate release into the environment GMO, handling, packaging and transport of GMOs and products containing GMO, as well as other issues of importance for GMO and products containing GMO.

Republic of Serbia adopted the Law on Ratification of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, with annexes (Official Journal of State Union of SMN - International Treaties No. 16/05), and became a member of the Cartagena Protocol on Biosafety. (The Cartagena Protocol on Bio safety)

In addition to general food safety rules, conditions for placing on the market food and feed, duties and responsibilities of food and feed business operators and food for animals, the rapid alert system, emergency measures and crisis management, hygiene and quality of food and feed, The Law on Food Safety stipulates the first marketing of genetically modified food (GMO foods) and genetically modified feed (GMO animal feed), the method of issuing permits for the first placement on the market of GMO food and GMO feed records of licenses issued, traceability and labelling of GMOs in particular GMO food and feed, and inspections in these fields.

34. Please provide information on respective fields of responsibilities of competent authorities concerned.

² Please note, that in Questionnaire received No. 32 is omitted in order of questions, probably due to technical mistake. We have kept original numbering, thus question 31. is followed by question 33.

Ministry of Agriculture, Forestry and Water Management of Republic of Serbia (MAFWM) is national designated authority for creating and implementing policies on genetically modified organisms or for monitoring and controlling the implementation of the Law on Genetically Modified Organisms and The Law on Food Safety, in part related to GMO food and GMO feed.

In the MAFWM activities related to GMOs are carried out by:

- Plant Protection Directorate
- General Inspectorate (GI), and
- Veterinary Directorate.

Flowchart - levels of competences - management lines of services responsible for food safety, veterinary and phytosanitary policy, including GMOs, are given in answer to question No. 1, in Section I – General Information, Chapter 12.

Besides the MAFWM, in the activities in the field of GMOs participate:

- Expert Council for Biosafety, and
- accredited laboratories.

Plant Protection Directorate

Plant Protection Directorate, as an authority within the MAFWM, in the field of genetically modified organisms is in charge of receiving and reviewing applications for approval to work with GMOs in closed systems and the deliberate release of GMOs into the environment (field trials with GMOs) or for all expert and technical tasks related to biological protection in the use of GMOs.

In accordance with Article 61, of The Law on Food Safety, MAFWM is responsible for issuing permits for first placing of GMO foods and GMO feeds on the market, and on the basis of a prior opinion of the Expert Council for risk assessment in the field of Security of food, and in accordance with the regulation concerning the conditions of placing of GMOs on the market.

Within the Plant Protection Directorate, activities in the field of biosafety perform Group for Plant Variety Protection and Biosafety, with only one position for work on matters concerning the GMOs.

Human, material and financial resources of the Plant Protection Directorate (including activities related to GMOs) are given in answer to question No. 2, in point *1.2. Plant Protection Directorate* in Section I –General Information, Chapter 12, while the descriptions of the existing structure and organization charts (including activities related to GMOs) are given in the answer to a question No. 3, in point *1.2. Department for Plant Protection* in Section I, Chapter 12.

Expert Council for Biosafety

In accordance with Article 6 of the Law on Genetically Modified Organisms, for the considerations of expert issues and providing expert opinion related to GMOs, Expert Council for Biosafety has been established, consisting of 18 members chosen among outstanding scientists and experts in the fields that are relevant for biosafety (biologists, geneticists, entomologists, ecologists, veterinarians, agronomists, nutritionists, toxicologists, allergists and other professions).

Activities of the Expert Council for Biosafety are stipulated in Article 7, and are related to:

- evaluating of the reliability of data from the application submitted for approval of use in closed systems and the deliberate release into the environment, on the basis of submitted documentation, and using the data from the international practice;
- risk assessment for the deliberate release into the environment;
- providing of expert opinion for the MAFWM on meeting the requirements for a license for use in closed systems;
- providing expert opinion for the MAFWM on meeting the requirements for the approval for deliberate release into the environment;
- reviewing the results of the deliberate release into the environment;
- considering proposals for amending of regulations on GMOs;
- consideration of other expert opinions relating to GMOs and GMO products.

Expert Council for Biosafety operates on the principle "case by case", and is guided in its work by data that are based on scientific knowledge, respecting the precautionary principle.

Member of the Expert Council for Biosafety, that is related or in a business or having financial connection with applicant can not participate in making decisions in the procedure of giving opinion; and considering the fact that representatives of state administration are not members of Expert Council, opinions given by Expert Council for Biosafety the MAFWM, as the competent authority in the field of GMOs, are autonomous.

General Inspectorate and Veterinary Directorate

General Inspectorate and the Veterinary Directorate, as organizations within the MAFWM, are liable for the supervision and control of experimental work with GMOs, as follows:

- in a closed system (work with GMOs or GMO products that are used, bred, propagated, stored, transported, disposed, destroyed, or otherwise used in the facility or installation, or a separate physical space, or a combination of physical barriers to chemical and / or biological barriers, which prevent the contact of GMOs with the environment and their impact on it),
- for the deliberate release into the environment (experimental/limited release of GMOs for the purpose of experiments in the field, demonstration experiments in the field and the development of new varieties).

In accordance with the division of responsibilities for food safety (Article 12 of The Law on Food Safety) and Article 38-41 of the Law on Genetically Modified Organisms is enforced by:

- General Inspectorate, control GMO food through all stages of food production, processing and transport of GMOs, namely: Department of Phytosanitary Border Inspection, Phytosanitary Inspection Department and the Department of Phytosanitary Inspection for safety of food and feed of plant and mixed origin.
- Veterinary Directorate controls GMO feed all stages of production, processing and placing on the market through: Department of Border Veterinary Inspection and the Department of Veterinary Inspection.

In accordance with the Law on Genetically Modified Organisms and the The Law on Food Safety, rights and duties:

- Of phytosanitary inspectors are: monitoring of the use of GMOs in closed systems, as well as of the deliberate release of GMOs into the environment by such approval; checking whether authorized laboratory meets the requirements for testing of GMOs and GMO products, check the security measures on deliberate release of GMOs into the environment, checking the plan's implementation measures and monitoring plan on deliberate release into the environment, checking of registration and documentation accompanying GMOs and GMO products, take samples for testing of GMOs and GMO products; sampling to determine the presence of unauthorized GMOs or products GMO; checking of treatment of waste that is containing, consisting of, is derived from, or resulting from the use of GMOs. Measures that, in accordance with this Law may Phytosanitary Inspector undertake: prohibition of the use of GMOs in closed systems and the prohibition of the deliberate release of GMOs into the environment, order emergency measures to protect human health and the environment; order the destruction of GMO and GMO products; order destruction of wastes containing, consisting of, is derived from, or resulting from the use of GMOs;
- Of veterinary inspectors are: taking samples for testing of GMOs and GMO products that are planned to be used as animal nutrition; sampling to determine the presence of unauthorized GMOs and GMO products; verification of registration and the documentation accompanying GMOs and GMO products; checking of waste management containing, consisting of, is derived from or resulting from the use of GMOs. Measures that can be ordered by a Veterinary Inspector are: order the destruction of GMO and GMO products, order the destruction of wastes containing, consisting of, are derived from, or resulting from the use of GMOs; controls whether a feed business operator that is placing on the market genetically modified food for animals delivers to an entity that receives such food, data in writing; controls whether genetically modified feed, that was put on the market contains on label additional information on these properties, in addition to the general requirements for the labelling.

Department of Border Phytosanitary Inspection checks the presence of GMOs in shipments of plants and plant products subject to phytosanitary control placed on the market across the national border.

Department of phytosanitary inspection checks the use in closed systems and the deliberate release of GMOs into the environment for which the approval was granted; check safety measures on deliberate release of GMOs into the environment, controls the manner and record keeping and documentation accompanying GMOs and GMO products, take samples for determining the presence of unauthorized GMOs or GMO products, check the disposal of waste containing, consisting of, derived from or resulting from the use of GMOs.

Department of Border Phytosanitary Inspection for safety of food and feed of plant and mixed origin controls presence of GMOs in food that is placed on the market across national borders.

Phytosanitary inspectors take samples for testing of GMOs and GMO products, and take samples to detect the presence of unauthorized GMOs or GMO products that are used for the food production of plant and mixed origin, in accordance with legal regulations for the purpose of analyses and super analyses of food of plant and mixed origin in order to investigate the safety and quality of the food.

Accredited laboratories

Testing of GMOs and GMO products for the purpose of identification and quantification of genetic modification is carried out by laboratory accredited by the MoAFWM. The authorization is issued by the Minister.

Conditions to be met by an authorized laboratory in terms of facility, technical equipment and staff training, and analytical methods used for testing of GMOs and GMO products will be regulated by special regulations.

At this point, the three laboratories are accredited to carry out identification and quantification of genetic modifications in GMOs and GMO products, for the needs of the Ministry of Agriculture, namely: "SP Laboratory", Novi Becej, "AbioTech Lab, Sremska Kamenica and laboratories of the Institute of Field and Vegetable Crops, Novi Sad. All three authorized laboratories base their analytical methods for identification and quantification of GMOs on polymerase chain reaction (PCR) and all are accredited in accordance with the SRPS/ISO/IEC 17025:2006. Accredited laboratories are included in the Proficiency Testing for GM food and GM feed organized by the Joint Research Centre of the European Commission. Republic of Serbia has no national reference laboratory for GM food and feed.

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

Until the adoption of the by-laws in accordance with the new Law on Genetically Modified Organisms, by-laws that are passed under the old Law on Genetically Modified Organisms shall be applicable (Official Journal of FRY, No. 21/01 and Official Gazette of RS, 101/05-ref. dr. zakon), if not inconsistent with the new Law on Genetically Modified Organisms, i.e.:

- Rulebook on the contained use of genetically modified organisms (Official Journal of FRY, No. 62/02) - harmonized with the Directive 90/219/EC,
- Rulebook on deliberate release of the genetically modified organisms and products derived from genetically modified organisms into the environment (Official Journal of FRY, No. 62/02) - harmonized with the Directive 2001/18/EC,
- Rulebook on the contents and data of the Register of genetically modified organisms and products derived from genetically modified organisms (O. Journal of FRY, No. 66/02).

Article 2 of the Law on Genetically Modified Organisms stipulates the prohibition of marketing of GMOs and GMO products, as well as the ban on commercial cultivation of GMO: "None of modified living organism or a product containing genetically modified organisms can not be put on the market, or grown for commercial purposes on the territory of Republic of Serbia ".

Taking into account that the prohibition of placing on the market of GMOs and GMO products, as well as the ban on commercial cultivation of GMOs is not conformed with EU legislation in this field, a Draft Law on Amending and Chages to the Law on Genetically Modified Organisms, is made, towards to its harmonisation with Directive 2001/18/EC on the deliberate release of GMOs into the environment, Regulation 1829/2003/EC on genetically modified food and feed, Regulation 1830/2003/EC on the labeling and traceability of GMOs, Regulation 1831/2003/EC on additives for feed, the Regulation 1946/2003/EC on transboundary movement of GMOs and Regulation 65/2004/EC on unique identifiers..

After passing of Draft Law on amending and Changes to the Law on Genetically Modified Organisms, it is planned to develop and adopt a set of regulations, by-laws that are necessary to implement legislation in the field of biological safety when working with GMOs. These are:

- Rulebook on the use of GMOs in closed systems,
- Rulebook on deliberate release of GMOs into the environment,
- Rulebook on the placing on the market of GMO and GMO products,
- Rulebook on labeling and traceability of GMOs and GMO products,
- Rulebook on the Register of GMOs,
- Rulebook on the authorized laboratories,
- Rulebook on confidential information,
- Rulebook on handling, packaging and transport of GMOs and GMO products.

Rules will be harmonized with relevant EU legislation in the field of work with GMOs.

36. Please provide information for each item listed below:

- Release into the environment;

According to the Law on Genetically Modified Organisms, deliberate release of GMOs in the environment means experimental (limited) introduction of GMOs into the environment for experiments, demonstration experiments and the development of new varieties.

The procedure for approval of deliberate release of GMOs into the environment is launched upon filed application of creators, users, or their authorized representative in the Republic of Serbia.

Application is to be filed also in the case when the GMO was obtained by crossing of two or more GMOs by the use of conventional methods, and submitted to the Group for the Plant Variety Protection and Biosafety of the Plant Protection Directorate, MAFWM.

The procedure for considering a request and an application for obtaining of approval

The data required in the application dossier are laid down in Article 10 Law on Genetically Modified Organisms, by the Rulebook on contained use of GMOs and by Rulebook on deliberate release of GMOs and GMO products

During the period of application consideration (30 days) the authority, first of all, check whether the application is complete in terms of required documents and communicate with the applicant to the submission of supplementary information if needed.

Application dossier contains: 1) a description of the GMO, 2) business name, location and address of legal entity or entrepreneur, the name, address and identification number of an individual, or personal name and address of their authorized representative, 3) the location where the GMO is to be released in environment, 4) plan and methods of

monitoring of GMOs and GMO products, as well as a plan of measures in case of incident, 5) risk assessment to human health and to the environment.

If the application does not contain the above data, the Plant Protection Directorate will notify the applicant within 30 days to eliminate the identified deficiencies.

The applicant may designate certain information in the report as confidential. Confidential information shall be kept by all persons to whom confidential data are available, 10 years from the date of filing. Data marked as confidential will remain confidential even if the applicant withdraws the application.

Risk assessment procedures

Risk assessment is carried out by the Expert Council for Biosafety as an expert, advisory body. The task of the Expert Council is to offer scientific risk assessment of the proposed work with GMOs.. Expert Council defines opinion on the submitted application and communicates it to the Plant Protection Directorate.

Decision-making procedure

Based on the opinion of the Expert Council for Biosafety, taking into account the relevant comments of the public and accredited laboratory report, if report is asked, the Director of the Plant Protection Directorate, and under the authorization of the Minister, issues a decision approving the use of GMOs or deliberate release of GMOs into the environment, determines the safety measures and the duration of the approval, or issues a resolution rejecting the proposed work with the GMO with an explanation.

GMOs and GMO products for which the approval was granted for work in closed systems or for deliberate release into the environment, are being recorded in the Register of GMOs and GMO products by the competent authority.

The duration of the consideration of the application for the proposed work with GMOs and the process of making decision is 90 days, not including the time when the applicant was requested to provide supplementary information. Each application is considered by applying "case-by-case" principle.

During and after the deliberate release of GMOs into the environment, within the periods specified in the permit, the applicant shall submit to the MAFWM the reports on the deliberate release into the environment in written or electronic form. In handling, packaging and transportation, including transportation throughout the territory of the Republic of Serbia, GMOs and GMO products should be accompanied by the documentation which must contain data clearly indicating that it is a GMO and GMO products. For deliberate release of GMOs into the environment, the documentation must contain the identity and relevant characteristics of the GMO and GMO products, the

requirements for safe handling, storage, transport and use, as well as a place to gather information about it.

Mechanism of Information and Public Participation

Upon receiving the request and application for work with GMOs MAFWM makes available to the public content of the application. Public hearings on the application lasts for 30 days from the date of the public disclosure of the application contents. The opinion of the Expert Council for Biological Safety and the final decision with explanations by, MAFWM, also makes available to the public.

The procedure for approval for use in a closed system, i.e. for work with GMOs or GMO products that are used, bred, propagated, stored, transported, disposed of, destroyed, or otherwise used in the facility or installation, or in a separate space with physical barriers or a combination of physical with chemical and/or biological barriers, that prevent the contact of GMOs with the environment and their impact on it is the same as for approval of deliberate release of GMOs into the environment.

- Genetically modified food and feed

According to the Law on Genetically Modified Organisms, no modified living organism or a product containing genetically modified organisms can not be placed on the market, or be grown commercially in the Republic of Serbia (Article 2 of the Act).

In accordance with Article 3 of this Law, an agricultural product of plant origin that contains a quantity up to 0.9% GMO ingredients and ingredients derived from GMOs is not considered as a genetically modified organism. Seed and reproductive material are not considered as a genetically modified organisms if the volume content of genetically modified organisms and ingredients derived from genetically modified organisms is up to 0.1%.

In accordance with this provision, in the Republic of Serbia, it is possible to import and place on the market all GMOs and GMO products (a product consisting or containing or derived from GMOs, GMO food and feed), whether they are approved in the EU or not, if the volume content of the genetic modification is less than 0.9%, because these are not considered as a genetically modified organisms. Also, it is possible to import and place on the market the genetically modified seed and reproductive material, whether GMOs approved in the EU or not, if the volume content of the genetic modification is less than 0.1%, because these are not considered as a genetically modified organisms.

Field of genetically modified food and genetically modified feed is also regulated by The Law on Food Safety. According to this Law, genetically modified food and genetically modified feed is:

- genetically modified organisms used as food and feed;
- food and feed containing or consisting of genetically modified organisms;
- food and feed produced or containing ingredients produced from genetically modified organisms.

Food and feed must not:

- has a harmful impact on human health, animal health or on the environment;
- mislead the consumer;
- differs from food and feed, i.e. ingredients of food and feed for which it is intended to be used as a substitution, to the extent that calls for questioning of its nutritive value.

For the first placement on the market of genetically modified food and genetically modified feed in the Republic of Serbia, business operator that is distributing food or feed must be licensed in accordance with the provisions of this Law and special regulations. Permit is issued by the Minister, based on the prior opinion of the expert scientific advice, in accordance with the regulation concerning the conditions for the marketing of genetically modified food and genetically modified feed.

From the above-mentioned legal provisions, it is evident that an issue of the use of genetically modified food and genetically modified feed needs to be further regulated so that the existing discrepancy could be resolved: on the one hand the Law on Genetically Modified Organisms prohibits commercial growing and marketing of GMOs and GMO products, including GM food and GM feed, and on the other hand The Law on Food Safety, prescribes procedures for issuing permits for trade in GM food and GM feed.