

# Screening report

## Serbia

### Chapter 12 – Food safety, veterinary and phytosanitary policy

**Date of screening meetings:**

Explanatory meeting: 3-7 February 2014

Bilateral meeting: 20 - 24 October 2014

## **I. CHAPTER CONTENT**

The *acquis* on food safety, veterinary and phytosanitary policy reflects the EU's integrated approach to food safety aiming at ensuring a high level of food safety, 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. The principal pre-requisites for a candidate country in this domain are the transposition of the EU legislation, as well as its implementation by a properly structured and trained administration.

The *acquis* in this chapter consists of a very large number of Regulations, Directives and Decisions.

For the implementation of food safety legislation, each Member State must have appropriate administrative structures to be able to carry out inspection and control of food products including an appropriate laboratory capacity. The basic rules are defined by the general food and feed law Regulation EC (n°) 178/2002 providing the general principles and requirements of food production, processing, packaging, labelling, marketing and distribution. In particular, it lays down definitions, principles and obligations covering all stages of food/feed production and distribution. Fulfilment of traceability requirements for all food and feed, as well as related business operators, are compulsory. Furthermore, food safety legislation covers packaging, labelling, marketing, additives, extraction solvents, flavouring, food contact materials, food supplements, mineral waters and ionising radiations, contaminants, novel food, quick frozen food, quality of seeds and propagating material, plant protection products, harmful organisms, plant variety rights, as well as genetically modified organisms.

In the areas of veterinary and phytosanitary policy, EU legislation lays down rules for internal trade and introduction of live animals and products from third countries in the veterinary, plant health and animal nutrition sectors while safeguarding public health, plant and animal health and animal welfare, as well as the safety of food of animal origin in the internal market. The EU regime is based on the implementation of the same rules by the authorities in the Member States. Veterinary and plant health checks at internal borders are abolished. A common regime of checks at the external borders is applied. A substantial part of the *acquis* in this field covers hygiene aspects related to processing and placing on the market of food of animal origin, the control of animal diseases and the protection of plants.

## **II. COUNTRY ALIGNMENT AND IMPLEMENTATION CAPACITY**

This part summarises the information provided by Serbia and the discussion at the screening meeting. Serbia indicated that it accepts the *acquis* regarding Food safety, veterinary and phytosanitary policy and that it does not expect difficulties to transpose and implement the *acquis* by the date of accession.

### **II.a. General**

The main Serbian legal acts governing the food safety, veterinary and phytosanitary sector are the Law on Food Safety (OG RS No. 41/2009), the Law on Veterinary Matters (OG RS No. 91/05, 30/10, 93/12), the Animal Welfare Law (OG RS No. 41/09), the Law on medicines and medical devices (OG RS No. 30/10, 107/12), the Law on Plant Health (OG RS No. 41/09), the Law on Plant Protection Products (OG RS No. 41/09), the Law on Genetically Modified Organisms (OG RS No. 41/09), the Law on Seed (OG RS No. 45/05), the Law on Plant Varieties Registration (OG RS No. 30/10), the Law on Protection of Plant Breeders' Rights (OG RS No.

41/09 and 88/11), the Law on Planting Material of Fruit Trees, Vine and Hops (OG RS No. 18/05), the Law on Forest Reproductive Material (OG RS No. 135/04, 8/05 and 41/09), the Law on Forestry (OG RS No. 30/10), the Law on Sanitary Surveillance (OG RS No. 125/04) and the Law on Health Surveillance of Food and Items of General Use (OG RS No. 48/94). There is no specific law on animal feed, but the issue is covered by the Law on Veterinary Matters and the Law on Food Safety. The Law on Food Safety includes general principles of risk assessment, communication and management, precaution, protection of consumers' interests and transparency.

Serbia indicated that the Ministry of Agriculture and Environmental Protection (MAEP) is the central competent authority for food and feed safety. Within the Ministry, the Veterinary Directorate, the Plant Protection Directorate and the Sector for Agricultural Inspection have responsibility for food and feed safety and quality. The Veterinary Directorate is in charge of regulations in the areas of food of animal origin, feed, animal health and welfare, the use of Veterinary Medicinal Products (VMPs) and composite food products. The Plant Protection Directorate is in charge of regulations in the areas of plant, plant production, seed and planting material, plant primary products, plant protection products, plant breeders' rights, GMOs, as well as of imports of composite food and of feed of plant origin. The Ministry of Health is in charge of regulations in the areas of novel foods, infant formulas, dietary products and supplements, salt for human consumption, additives, flavourings, enzyme preparations of non-animal origin, drinking water, and food contact materials.

Article 12 of the Law on Food Safety sets out the division of responsibility for inspections between MAEP's agricultural inspection, veterinary and phytosanitary inspection (including border inspection) and the Sector for Inspection Affairs in the Ministry of Health. Within the MAEP the phytosanitary inspection is in charge of food of plant origin in primary production, primary products of plant origin, food of plant origin, and composite food on import and GMOs at all stages of production, processing and distribution (except for GMO feed), while the agricultural inspection is in charge of food of plant origin, as well as wines and spirits and non-alcoholic beverages. The Ministry of Health is responsible for sanitary inspection of novel foods, infant formulas, dietary products and supplements, salt for human consumption, production of additives, flavourings, enzyme preparations of non-animal origin, drinking water and food contact materials.

One of the main areas of intervention of the Strategy for Agriculture and Rural Development 2014-2024 is the permanent improvement and promotion of food safety and food quality. Serbia presented a list of future steps in its strategy for full harmonisation with the *acquis*, including legal alignment, implementation and enforcement:

- Overcoming the main challenges: process of upgrading food establishments, Animal By-Product (ABP) management, improvement of raw milk quality
- Increasing awareness and providing assistance for stakeholders
- Capacity building within MAEP and the Ministry of Health
- Elaboration of multiannual control plans for the whole of the food chain
- Ensuring the full functioning of the National Reference Laboratories
- Development of integrated IT systems

The legal basis of the establishment of laboratories lays in the Law on Food Safety, Art. 18-22, and the rules on veterinary, sanitary and health and phytosanitary matters. A Directorate for National Reference Laboratories is in place in MAEP, but it is not yet fully operational. Official laboratories are selected through a public competition procedure and authorised by the competent Ministries, the MAEP or the Ministry of Health. Reference and official laboratories

must be accredited by the Accreditation Board of Serbia. By 2009, the year of the adoption of the Law on Food Safety, 45 official laboratories for food safety and quality and for plant health had been designated, all under ISO/IEC 17025 standard. A National Reference Laboratory for milk testing has yet to be established. The Law on Food Safety also foresees the establishment of an Expert council for risk assessment in the field of food safety, which will ensure independent risk assessment, scientific advice and risk communication.

Serbia stated that the Law on Food Safety incorporates the general principles of the EU *acquis* as regards risk analysis (in particular risk assessment, communication and management) and its scientific basis, the precautionary principle, the protection of consumers' interests, and the principle of transparency and public consultation. The Law also sets general principles and international standards for trade in food and feed, food and feed safety requirements, labelling advertising and presentation, responsibilities of food and feed business operators and inspection authorities, and traceability requirements.

Its scope is applicable through the whole food chain. It foresees the registration and approval of all food businesses, including legal or natural persons, and of each establishment and stage of production processing and distribution of food and feed. Only following their registration and approval can these establishments start production and distribution of food and feed. A secondary legislative act (Rulebook) on the manner and organisation of the Rapid Alert System for food and feed (RASFF) sets out the organisation of the RASFF, the exchange of information between Serbia and the EU RASFF, the establishment of a national contact point and specific contact points on the basis of responsibilities, the type of notifications and of actions and measures to be taken.

The Law on Food Safety also introduces food hygiene requirements by means of hazard analysis and critical control points (HACCP) controls.

## **II.b. Veterinary policy**

The Veterinary Directorate in the MAEP is the competent administration for implementing veterinary legislation. Its Department for veterinary inspection supervises inspection at central, regional and local level. At the moment of screening, there were 13 members of staff working at central level and 25 on the regional level of veterinary inspection. In addition, at the time of the bilateral screening, there were 740 authorised veterinarians employed in 242 veterinary stations, which have obtained the authority to perform administrative tasks following public tenders.

The main legal framework consists of the Law on Veterinary Matters, the Animal Welfare Law and the Law on medicines and medical devices.

The **control system in the internal market** is regulated by the Law on Veterinary Matters, the Law on Food Safety and the Law on Animal Welfare. Controls are obligatory for live animals, animal products, and fallen stock and animal by-products. Controls on the national market are carried out through official veterinary checks during loading, unloading and transportation, as well as through the supervision of the control system of live animals and animal products and by-products by central, regional and local veterinary inspectors. Thus, veterinary and zootechnical checks on the national market concern animal welfare and breeding controls, animal health controls, controls at the place of origin and dispatch before placing on the market, controls at the stage of transport and at the place of destination.

The control system ensures the control of the production and trade of bovine, porcine, ovine, caprine and equine species, of poultry, of semen and embryos of bovines and semen of porcines

and of products of animal origin. The conditions for putting the equidae and cloven-hoofed animals on the market prescribe that animals are subject to regular official veterinary controls (diagnostic tests or preventive vaccinations), properly identified and registered in the central database, and accompanied by a valid animal certificate issued by an authorised veterinarian. There is a guarantee that animals intended for slaughter have not been treated with unauthorised medication. The means of transport need to comply with prescribed requirements and to have been properly cleaned and disinfected. Controls at the place of dispatch include visual examination, identity check of each consignment, control of the means of transport and its registration, and control of the loading as regards animal welfare standards. Bovines, in particular, are accompanied by a cattle passport with the animal and owner's data. Control at the place of destination is mandatory for equidae and cloven-hoofed animals. The carrier or the owner are obliged to report the consignment to the authorised veterinary station within seven days of its arrival to the destination. There are regular controls of the transport of animals by the regional or local veterinary inspectors with the cooperation of the police. Similar controls are in place for poultry and hatching eggs.

Serbia stated that it is largely aligned with the acquis as regards animal health requirements for the trade of ovine and caprine animals, and that it does not foresee any particular difficulties regarding its implementation. Serbia also stated, however, that it will be necessary to provide training to veterinarians and veterinary inspectors, and to complete the guidelines on veterinary controls and animal welfare.

The **control system for imports** is governed by the Law on veterinary matters, the Law on food safety, the Law on animal welfare, the Law on genetically modified organisms and the Law on nature protection. Serbia stated that it is a member and applies the recommendations of the World Organisation for Animal Health (OIE), of FAO and of the World Health Organisation related to public and animal health and food safety. It also stated that, being in process of accession to the WTO, it applies the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT).

Serbia's import preconditions require that the exporting country is an OIE member, that a cooperation agreement with the competent authority is in place, that it has at least an equivalent level of animal health protection, and that there is an agreed veterinary certificate and additional safeguard measures. The Serbian Law on veterinary matters foresees that consignments of animals, products of animal origin and related items destined to free zones and customs warehouses are subject to the same procedures for veterinary control as those applied to import consignments.

According to Serbia, import controls are supervised by the Department of Border Veterinary Inspection, which comprises seven Chiefs of Border Veterinary Stations, 23 Border Veterinary Inspectors and 17 Border Inspection Posts (BIPs). 10 BIPs are situated at the external EU borders (2 with Hungary, 3 with Croatia, 3 with Romania, and 2 with Bulgaria), another 6 are situated at the borders with CEFTA countries (Bosnia and Herzegovina, Montenegro, former Yugoslav Republic of Macedonia) and one at the Belgrade international airport. In addition, two Common Control Points are performing controls for consignments coming from Kosovo\*.

Serbia clarified that, for imports of live animals, prenotification must be given 24 hours before their arrival at the border, whereupon a documentary check of the Veterinary Import Condition Decision, the veterinary certificate and related documents and a physical check of the animals

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\* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

are carried out. The equivalent procedure for the import of products foresees, in addition and after the physical sensor checks, laboratory sampling and holding the products for results. As regards controls of live animals and products in transit, the border veterinary inspectors control the documentation and check the identity and transport conditions for live animals and products of animal origin.

The import control system is based on a risk analysis. The requirements for importation or transit are regulated under the Law on veterinary matters. Importation and custom clearance can be allowed without laboratory examination of the shipment, if previous controls established that the exporting country and a particular production facility are safe to use and followed by appropriate international veterinary documents.

Serbian authorities issue electronic veterinary certificates for products intended for the EU market in the Trade Control and Expert System (TRACES) for approved veterinary authorities, food establishments and FBOs.

Serbia indicated that the **identification and registration of animals** and their movements are regulated by the Law on veterinary matters and the Rulebooks on the identification and registration of bovine animals and on the identification and registration of ovine and caprine animals. The competent authority is the Veterinary Directorate in the MAEP, and notably the Department on animal health, welfare and traceability. The Animal identification and traceability group consists of the Head of the Group, two coordinators, the database administrator and one computer operator. There are also 25 district offices which provide the first level of support after the data entry in the database by the authorised veterinarian.

Every animal holding (farm, pasture, livestock market, fair, slaughterhouse, animal trader, quarantine, etc.) must be registered in the holding registry of the central database. The registration is carried out through prescribed holding registration forms by the authorised veterinarians.

The establishment of the central database and district offices for *bovine animals* started in 2005. Every bovine animal older than 20 days must be identified with two identical ear tags, which are supplied directly to veterinarians by the authorised suppliers. Birth must be notified by the keeper within 7 days through the prescribed notification form. The application of ear tags must take place by the 20<sup>th</sup> day. Bovine animals imported from EU countries retain their original ear tags, while those imported from third countries are retagged, and after the quarantine period they are entered into the central database and receive their cattle passports with all necessary identification data and where also animal movements are recorded. There is no need to register bovine animals intended for slaughter within three days from import. Every animal movement must be notified by its keeper and the animal has to be accompanied by the cattle passport, the movement document and its health certificate. Departures must be notified 24 hours in advance and arrivals within 7 days.

Identification and registration of *sheep and goats* started in 2006 with the establishment of a central database. Every animal older than six months must be identified, and in any case prior to its departure from its holding. The notification must be done by the farmer when the animals turn five months or 15 days prior to their departure. Serbia informed that currently there is no movement control for sheep and goats. Movements are recorded only by means of health certificates that accompany animals during trade and transport. The database for movement control is being prepared and the adoption of the new Rulebook regulating movement control is pending. Serbian authorities explained that it is not compulsory to identify lambs younger than 6 months if slaughtered for own consumption.

The legal basis for identification of *pigs*, which started in 2006, is provided by the Law on veterinary matters and the Rulebook for the identification and registration of pigs. More than 25 million pigs have been entered into the central database. Identification of pigs is carried out for animals older than 45 days simultaneously with their vaccination against classical swine fever. It is compulsory even for younger animals prior to departure from the holding. Farmers must provide notification within seven days from birth. Serbia informed that currently there is no movement control for pigs. Movements are recorded only by means of health certificates that accompany animals during trade and transport. A database for movement control is being prepared and the adoption of the new Rulebook regulating movement control is pending. Serbian authorities explained that it is not compulsory to identify pigs younger than 45 days if slaughtered for own consumption.

The legal framework for identification of *horses*, which started in 2008, is provided by the Law on veterinary matters and the Rulebook for the identification and registration of equidae. Every animal older than six months must be permanently identified, and in any case prior to its departure from the holding. In certain remote regions or natural parks, wild or semi-wild horses do not have to be identified. There are no passports for equidae at the moment.

Serbia indicated as challenges in this area convincing keepers that animal identification and traceability improves consumer confidence and supports exports of bovine animals. As regards sheep and goats, it is not easy to keep up-to-date registers for small holdings. The principle of traceability needs to be introduced into the cross compliance system for subsidies by the Directorate for Agrarian Payments of the MAEP. In order for this to happen, the animal registration database will need to be further developed and redesigned in order to connect it with other national information systems.

As regards **control measures for animal diseases**, the Veterinary Directorate includes an Animal Health Unit within the Department for Animal Health, Welfare and Traceability. There are 12 Veterinary Institutes, veterinary epidemiology centres, 12 rapid response teams and four advanced emergency veterinary teams. There are 298 authorised veterinary stations and 904 veterinary stations, clinics and ambulances. There are 12 accredited veterinary institutes responsible for laboratory investigation and epidemiological support. The Pathology Department within the Faculty of Veterinary Medicine of Belgrade is responsible for TSE/BSE<sup>†</sup> tests, while the Institute for Meat Hygiene and Technology tests residues of VMPs and other contaminants in food of animal origin.

Notification of animal diseases is compulsory on the basis of the Law on veterinary matters, the Criminal Code and the Rulebook on the list of particularly contagious animal diseases, the list of notifiable animal diseases and the notification procedure. It is mandatory for the Veterinary Directorate to issue an immediate notification of the primary outbreak of any notifiable disease without delay, and within 24 hours, to the OIE and competent veterinary authorities of Serbia's neighbours. Six-monthly reports are sent to the relevant OIE information system.

A Rulebook on establishing a programme of measures for animal health protection is established on an annual basis. It includes animal identification and registration, zoosanitary, biosecurity and animal welfare measures, general and active surveillance, education and awareness, vaccinations, diagnostic investigations, surveillance of high impact animal diseases, monitoring of endemic diseases, monitoring of artificial insemination centres and an abortus programme.

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<sup>†</sup> Transmissible Spongiform Encephalopathy (TSEs); Bovine Spongiform Encephalopathy (BSE).

The testing scheme includes measures for bovine and ovine brucellosis, bovine tuberculosis, enzootic bovine leucosis and other animal diseases.

Serbia has been certified by OIE as free from foot and mouth disease without vaccination since 2006. There is a national reference laboratory and, due to epidemiological risks, preparedness activities and control measures are in place. At the date of the screening, the last case of Classical Swine Fever was reported in 2010. Due to epidemiological risks, a vaccination policy and preparedness activities are in place. A new strategy and a National Veterinary Compensation Fund are being developed. Serbia plans an evaluation of the epidemiological situation, preparedness and capacities for non-vaccination policy, through the implementation of biosecurity measures, animal identification and movement control, surveillance and monitoring activities, and improvement of the early warning system and rapid response to outbreaks.

Serbia pointed out that African swine fever has never been confirmed or suspected in the country, but, due to the epidemiological risk, there is ongoing surveillance and monitoring of wild boar and preparedness activities. There is active surveillance for avian influenza, of which the last confirmed case was in 2006. The epidemiological situation for Newcastle disease is stable due to compulsory vaccination and implementation of registration of poultry holdings. In 2014 there were 644 cases of bluetongue disease, in parallel with a regional outbreak. No cases have been confirmed in 2015. Vaccination has been carried out at the end of 2015 in emerging zones at the border with affected regions, with plans to extend vaccination in 2016. There is a monitoring programme for bovine tuberculosis. Vaccination for brucellosis is prohibited. Rabies is still present in wild animal population, with sporadic cases in domestic and pet population. A campaign of oral vaccination is being carried out on a yearly basis, yielding satisfactory results as regards the reduction of reported cases. Serbia has introduced an integrated food safety system to address the risk of salmonella. In June 2016 Serbia notified occurrence of lumpy skin disease of cattle in the south and south-east regions and subsequently started vaccination of the national cattle herd.

Serbia explained that general provisions for intra-community **trade for live animal, semen, ova and embryos** are laid down in the Law on veterinary matters. Only those animals can be placed on the market which have undergone regular veterinary controls, are properly identified and registered, have been clinically examined prior to movement, have been tested or vaccinated and are accompanied by a valid animal certificate. The Rulebook on establishing a programme of measures for animal health protection foresees testing schemes for bovine brucellosis and tuberculosis, and for enzootic bovine leucosis. Following authorisation of the Veterinary Directorate, centres for artificial insemination and stations for transport of embryos may place the genetic material on the market with the obligation of keeping prescribed records.

The **non-commercial movement of pet animals** is regulated by the Law on veterinary matters and the Law on animal welfare. Domestic animals (dogs and cats) are vaccinated for rabies preventively. There is a system of identification for dogs, while both dogs and cats are registered in a central database and receive a passport for internal and international movement. Serbia has one laboratory on the list of EU approved laboratories for rabies' testing. Documentary and identity checks are carried out by the customs authorities at BCPs. Serbia informed of its intention to prepare a new Rulebook on non-commercial movement of pet animals in accordance with Commission Regulations 576/2013 and 577/2013.

Serbia indicated that general provisions for **prohibition of substances and control of residues** are laid down in the Law on veterinary matters, the Law on food safety, the Law on medicines and medical devices and the Law on plant protection products. The basic regulations are included in the Rulebook on establishing systematic monitoring of residues of pharmacological,

hormonal and other harmful substances in animals, animal products and animal feed. The Law on medicines and medical devices lays down rules for the authorisation, production, distribution, dosage and use of veterinary medical products. Official checks focus on illegal treatment, use of substances that exceed maximum residue limits, contamination, and undertaking preventive measures for the protection of public health.

The national residue monitoring programme aims at monitoring and detecting the presence of unauthorised substances and the residue level of veterinary drugs and contaminants in live animals, primary animal products, animal feed and drinking water for animals. The Department of Veterinary Public Health within the Veterinary Directorate is responsible for drawing up the annual monitoring programme and for the coordination and monitoring of the relevant activities. The national reference laboratory for residue testing is the Institute of Meat Hygiene and Technology of Belgrade. Serbia explained that the data needed for the preparation of the national residue monitoring programme are in line with those foreseen under Directive 96/23 and include information from EFSA, EMEA and RASFF. The Serbian authorities send the current year's monitoring programme and the previous year results to the Commission. Serbia underlined that further development of analytical and testing methods in line with the *acquis*, building specialised investigative teams and improving the sampling methodology are included in the future plans in this area.

**Import requirements for live animals and animal products** are regulated by the Law on veterinary matters, the Law on food safety and the Law on animal welfare. Such requirements are in compliance with OIE and EU requirements for import from third countries. The Law foresees that consignments of food of animal origin, in import or transit, shall be safe for human health, be accompanied by an original international veterinary certificate, an import or transit permit and include a mark of origin and of the production facility. In case of a threat of the entry of a notifiable infectious disease, the MAEP may order a ban or limitation on the import or transit.

Imported animals are subject, upon decision of the Veterinary Directorate, to quarantine with a view to checking their health condition. Serbia highlighted that it approves imports of products of animal origin from EU establishments that meet the prescribed conditions and under the control of an EU Member State competent authority. The MAEP may carry out controls on consignments from establishments not included in the EU list. The cost of such controls is covered by the importers.

The legal framework for **animal welfare** is provided by the Law on animal welfare. It is complemented by a series of Rulebooks, laying down detailed rules as regards animal welfare on the farm, during transportation, at the time of slaughtering or killing, at zoos, as regards dangerous dogs, stray animals and animals in breeding establishments. The implementation of animal welfare controls is carried out by veterinary inspectors on the basis of risk analysis and by random sampling. Serbia stated that the control of animal welfare on the farm and during slaughtering is already applied in practice. Serbia has ratified a number of European Conventions for the protection of animals kept for farming purposes, for slaughter, used for experimental and other scientific purposes and for the protection of pet animals.

The Serbian authorities acknowledged the need for improving animal welfare conditions on the farm for pigs, cattle and hen production, requiring important financing investments and increased public awareness. The Law on animal welfare and secondary legislation will be amended to fully align with the *acquis*.

The Law on animal husbandry provides the legal basis in the area of **zootechnics**, complemented by provisions of the Law on subsidies in agriculture and rural development, the Law on veterinary matters and the Law on animal welfare. The organisation of zootechnical activities includes the central, regional and primary breeders' organisations, and the artificial insemination centres. Pure-bred breeding animals can be imported following a quarantine decision by the Veterinary Directorate and the opinion of the scientific expert council for animal husbandry. Most imports of pure-bred breeding animals come from the EU with pedigree certificates.

The measures under the breeding programme for cattle include productivity and fertility controls, grading of the exterior and selection. The main goal of the pig breeding programme is the increase of meat production. The goal of the breeding programme for sheep and goats is increased productivity in meat, milk and wool. Establishing a unified software for maintaining of the registers and increasing the number of animals under control are common challenges for the above programmes. As regards equidae, the number of animals is significantly reduced. Stopping this decline in numbers, unifying the database which is split among different breeder's associations and implementing DNA testing were mentioned as main challenges. As regards poultry, the main challenge is the increased utilisation of the genetic potential of imported flocks. The beekeeping sector has significant development potential and can be a source of income for a large number of producers.

With regard to **veterinary expenditures**, Serbia indicated that the Law on veterinary matters, the Law on the budget, and the Government decision on veterinary expenditures provide the legal basis. Veterinary expenditures are financed from the State Budget. The Law on veterinary matters foresees emergency measures to combat certain animal diseases, an annual programme of measures to protect animals from infectious and parasitic diseases, the right of animal holders to compensation and the rules and financial sources for damage compensations. There is an annual surveillance of animal diseases and implementation of measures to control disease outbreaks, such as culling of animals, slaughter for diagnostic purposes, and disinfection. The availability of diagnostic tests and vaccines, the establishment of rapid response teams and of crisis management centres for animal health, risk assessment and reporting are ensured through contracts with veterinary institutes. The owners, whose duty is to protect animals and their welfare and to report immediately and take measures against any case of infectious disease, have a right for compensation of damages for the euthanasia or slaughtering of animals and damaged or destroyed food and equipment on market prices. Serbia estimated that increasing the funds for implementation of animal control programmes, for compensation in support of animal disease control programmes, and ensuring the sustainability of the system and of disease eradication programmes remain challenges in this area.

### **II.c. Placing on the market of food, feed and animal by-products**

Serbia outlined that the Law on food safety is the main piece of legislation regulating **general and specific hygiene rules for animal products**. It is complemented by the Rulebook on food hygiene requirements and other secondary legislation. The hygiene requirements cover all food and foodstuffs, present an integrated approach ("from stable to table"), and concern all stages of production, processing, distribution and export, under the primary responsibility of food business operators. As regards primary production, hygiene requirements concern protection against contamination, animal health and welfare, facilities, the cleanliness of animals, cleaning and disinfection, water supply, pest control, handling of waste, feedstuffs and record keeping. Further requirements include compliance with microbiological criteria and temperature control requirements, maintenance of the cold chain, sampling and analysis, good practice guides and traceability.

In addition, the Rulebook on food hygiene requirements requires that all food business operators shall put in place, implement and maintain a permanent procedure based on HACCP principles (except for primary production), provide the competent authority with evidence of compliance, update procedure documents and keep records for official controls.

The Law on food safety prescribes that all animal establishments and food businesses involved in any stage of production, processing and distribution of food and feed shall be notified to the competent authority and registered. Business operators are not permitted to start the production and distribution of food and feed before entering in the central registry or a registry of approved establishments.

Serbia also explained that, as regards slaughterhouses, slaughter cannot take place before the food chain information is received 24 hours in advance, checked by the operator and transmitted to the official veterinarian who must check and analyse it before slaughter. Information can be provided on an individual animal or a batch of animals. If it is not delivered, animals are killed separately and the meat is characterised as not fit for human consumption.

The approval procedure for establishments is provided by the Law on veterinary matters and is carried out by an inspection team which assesses the general and specific hygiene conditions, creates an official record and issues a decision of approval for the domestic market and/or for export. Derogations are foreseen for food with traditional characteristics. Serbia clarified that there is a Directive on official control for *trichinella spiralis* in meat.

At the date of the bilateral screening the Veterinary Directorate had approved 159 (2)<sup>‡</sup> red meat and 28 poultry slaughterhouses, 302 (7) slaughterhouses for cutting and processing red meat, 58 (1) slaughterhouses for cutting and processing poultry, 371 (2) establishments for processing red meat products, 2 establishments for processing poultry meat products, 12 establishments for wild game meat, 242 (7) establishments for milk processing and dairy products, 45 (4) establishments for fishery products, 9 (1) for frogs' legs and snails, and 2 (1) for eggs and egg products. In addition, 697 cold stores, 5 cheese wrapping establishments, 1 rendering establishment for animal fats and greaves, 12 (1) for treated stomachs, bladders and intestines, and 1 (1) for collagen have also received approval authorisation.

Serbia indicated that it is developing a national strategy and a national programme for upgrading of establishments producing food of animal origin based on EU *acquis*. This will include assessment criteria and checklists. Based on the assessment results, food establishments will be categorised.

With regard to raw milk, the permitted aflatoxin level is currently not aligned with the *acquis*. Serbia is working to develop a national strategy for the progressive achievement of raw milk quality standards and establishing two laboratories for the control of raw milk quality on the whole national territory.

**Control rules** are laid out in the Law on food safety. The law allocates competences to the veterinary inspection services for primary production, processing, wholesale and export stage for food of animal origin. Phytosanitary inspection is responsible for primary production, processing and import of food of plant origin. Imports are controlled by the border veterinary inspection and the phytosanitary inspection, while exports are controlled by the veterinary, phytosanitary and agricultural inspection. At the date of screening, the sanitary inspection under the Ministry of

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<sup>‡</sup> In brackets the number of establishments authorised to export to the EU.

Health was responsible for control of novel food, infant formulas, dietary products and supplements, salt for human consumption, additives, flavourings, enzyme preparations of non-animal origin, drinking water and food contact materials. Controls of wine and alcoholic beverages are carried out by the agricultural inspection.

Serbia pointed out that veterinary inspectors undergo a state examination and need to have minimum three years' service in the veterinary field, while the same requirement for border veterinary inspectors is five years. Control activities of the inspection services include documentary check, inspection of the establishment conditions and control of food hygiene conditions, control of the HACCP system and traceability, labelling, implementation of previous measures and measures for enforcement and infringements. Serbia is aware of the importance of inspectors being independent in carrying out their duties. Controls are based on risk analysis, which derives from the results of previous controls, production capacity and volume, the type of production, the cooperation with the food business operator and corrective measures. An inspection plan is developed on an annual basis. Checklists have been developed for the inspection of slaughterhouse and food production, for controlling the implementation of HACCP, traceability and hygiene conditions and for inspection of mass caterers.

Sanitary surveillance is conducted by the Ministry of Health under the Law on sanitary surveillance, which regulates sanitary inspections, methods and procedures, the areas and objects of inspection and the powers, rights and duties of inspectors. Areas under sanitary surveillance include protection of the population from infectious diseases, food and health safety of products of general use coming in contact with food, and the public supply of drinking water. The sanitary inspection is also carrying out health surveillance at the border. As regards human resources, there are 309 veterinary inspectors, 113 phytosanitary inspectors, 55 agricultural inspectors and 215 sanitary inspectors at local level.

Serbia explained that the Law on veterinary matters, the Law on food safety and the Law on animal welfare regulate the **specific control rules for animal products**. Mandatory checks of animals are performed by authorized veterinarians before and after slaughter. Approval for an establishment is provided only when the food business operator has demonstrated that it meets all relevant requirements. If the competent authority identifies serious deficiencies and the operator cannot provide adequate guarantees, it can impose corrective measures and impose a withdrawal period or ban the use of premises and equipment. Establishments no longer in compliance are removed from the registry. Official controls are carried out with regard to food chain information, the design and maintenance of premises and equipment, hygiene conditions, personal hygiene and training, pest control, water quality, temperature control, compliance with microbiological criteria, residues, contaminants and prohibited substances. Animals are examined *ante* and *post mortem*. The authorized veterinarians check identification marks of animals and accompanying documents as well as conditions for protection of animal welfare during transport and before slaughter.

The Law on veterinary matters provides the legal framework for **animal by-products**. It is complemented by the Rulebook on the way of classification and handling animal by-products (OG RS No. 31/11, 97/13). As regards ABP/TSE, it is covered by a specific Rulebook establishing measures for its early detection and diagnosis. Under the Law, the local self-government is obliged to establish a zoohygiene service and build a plant and collect cadavers or pay for their safe disposal. The central government provides a public service by means of two processing plants, and in addition to the public facilities, private legal entities meeting the requirements may be contracted to carry away and dispose the cadavers. At the time of the screening, two intermediate plants for animal by-products are authorised to handle category 1

material, two are authorised to handle both category 1 and 2, and 17 treat category 3 material. In addition, there are 64 category 3 technical plants for hides and skins.

As regards **funding of checks**, the Law on veterinary matters foresees that authorised veterinarians are employed and paid by the authorised veterinary organisations. Fees are collected for a number of operations, such as the issuance of animal health certificates, inspection of loading consignments of animals, veterinary and sanitary inspection, identification, registration and monitoring of the movement of animals and veterinary and sanitary inspection of international trade consignments. The costs of administrative procedures are borne by the applicant. The Law also foresees that the testing fees are borne by the party from which samples have been taken if the final testing has shown that the sample does not have adequate properties. In the opposite case, it is paid from the public funds allocated for animal health protection.

#### **II.d. Food safety rules**

Serbia indicated that the basic act in the field of food safety is the Law on food safety. MAEP and the Ministry of Health are the competent authorities in this field. Pursuant to this act, the Ministry of Health is responsible for food safety of novel foods, infant formulas, dietary products and supplements, salt for human consumption, additives, flavourings, enzyme preparations of non-animal origin, drinking water and food contact materials. Its food safety department carries annual control, monitoring and contingency plans, it registers and approves establishments in these areas and drafts reports. The Veterinary and Phytosanitary Directorates of MAEP are in charge of safety of food and safety of traded food of animal origin and food of plant origin at primary production, primary products of plant origin, food of plant origin and composite food on import.

The area of **labelling** is regulated by the Law on food safety and relevant Rulebooks. Article 30 of the Law on food safety lays the standards for labelling, marking and advertising of food and feed. The Rulebook on labelling, marking and advertising of foodstuffs applies to food intended to the final consumer and for supply of catering establishments. For labelling of prepacked foods the food business operator listed on the product is responsible, while for non-prepacked foods it is the food business operator who sells to the final consumer. Labelling must not be misleading or attributing a medicinal function to the foodstuff. Controls are carried out by veterinary, phytosanitary, agricultural and sanitary inspectors within their respective areas of competence.

According to the Law on food safety, the Ministry of Health is the competent authority for **food supplements, food of particular nutrition uses, food fortification and mineral waters** and for the surveillance in all phases of production, processing and trade. Inspection in all phases of production, processing and trade is carried out by the Department for sanitary inspection, which disposes 128 sanitary inspectors for territorial surveillance and 30 sanitary inspectors for the border area dealing with imports. The Law on food safety and the Rulebook on health safety of dietetic products lays down the legislative framework for this area. The Rulebook provides the basic definition and lists the categories of dietetic products. It foresees a three-step notification procedure, first receiving the opinion and approval of the labelling from the Faculty of Pharmacy of the University of Belgrade, then obtaining a laboratory report on health safety, in order finally to be included in the dietetic product database. Serbia has 26 producers of natural mineral water, nine producers of spring water and one for table water. The monitoring of bottled water quality is done by the institutes of public health. The adoption of a Rulebook on bottled water harmonised with EU rules is pending.

Serbia pointed out that the same administrative bodies as mentioned above are in charge of **food additives, enzymes, extraction solvents and flavourings**. The general principles, which are laid down in the Law on food safety, are described in detail in a series of Rulebooks.

The Rulebook on *food additives* lays down rules for food additives including a list of approved food additives and conditions for their use in food, a list of additives including carriers approved for use in additives, enzymes, flavourings and nutrients and the conditions for their use, the functional classes for food additives, the carry-over principle and labelling requirements. The general requirements for the use of food additives are that they do not pose a safety concern to the health of the consumer at the level of proposed use, there is a reasonable technological need for their use which cannot be achieved by other means, they are not misleading for the consumer and there are advantages and benefits from their use. The Rulebook prescribes specific labelling requirements for foods containing food additives. The Serbian authorities indicated that this Rulebook is regularly amended in order to harmonise with the updates in EU *acquis*.

The Rulebook on quality and other requirements for enzyme preparations for food lays down requirements for *food enzymes*, inter alia the maximum permitted levels of chemical and microbiological contamination, the conditions for their use in food, labelling requirements, and a positive list of enzyme preparations.

Specific secondary legislation provides definition, labelling of extraction *solvents*, as well as a positive list of processing aids.

The Rulebook on quality and other requirements for food *flavourings* lays down rules as regards maximum permitted levels of contaminants, conditions for their use in food, requirements for smoke flavourings, labelling, and maximum limits, as well as a positive list of flavouring substances.

Requirements on **novel food** are laid down in the Law on food safety. The administrative set up and responsible body is the Ministry of Health. Requirements for novel food are that it does not present a threat to consumer health, does not mislead the consumer and does not differ from foods or food ingredients which it is intended to replace to an extent that would bring into question its nutritive value and safety. The Ministry of Health has not yet adopted secondary legislation in this field. A novel food that has been authorised in the EU market may be placed on the Serbian market. Supervision of establishments approved by the Ministry of Health is carried out by the sanitary inspectors.

The field of **contaminants** falls within the responsibility of the MAEP and the Ministry of Health and is regulated by the Law on food safety and the Rulebook on maximum residue levels of plant protection products in food and feed. A regulatory programme for the control of residues checks levels of chemical elements and other contaminants. Monitoring is performed by the phytosanitary, veterinary and sanitary inspectors in accordance with the repartition of competences.

The field of **quick frozen food** falls within the responsibility of the MAEP and is regulated by the Law of food safety and relevant secondary legislation.

Serbia indicated that the preservation of foodstuffs and general items by **ionising radiation** are regulated by the Rulebook on conditions for obtaining licence to perform radiation practice and the Rulebook on registration and notification of sources of ionising radiation. The former contains the list of foodstuffs that may be treated with ionising radiation and maximum permitted radiation doses.

**Food contact materials** are defined by the Law on food safety and the Law on health safety of products of general use. The relevant Rulebook lays down the requirements that should be complied by dishes, utensils and packaging for foodstuff. Authorized laboratories and sanitary inspection of the Ministry of Health are in charge of its implementation.

### **II.e. Specific rules for feed**

Serbia indicated that the Veterinary Directorate within the MAEP is responsible for preparing legislation and transposing EU *acquis*, registration and approval of establishments and maintaining the Register of approved establishments for the production, storage and distribution of feed, the control and supervision of production, placing on the market and use of feed, feed additives, undesirable substances, medicated feed and specific rules for feed hygiene. The area is regulated by the Law on food safety and the Law on veterinary matters, as well as by a number of Rulebooks. Serbia stated that methods of sampling and analysis are partly in line with Regulation 152/2009. Rules for feed hygiene are laid down in the Rulebook on general and special conditions on hygiene of feed. The general conditions for feed hygiene foresee that HACCP should be used at all stages of the production, and that measures and procedures need to be put in place to prevent contamination of the feed.

The law prohibits producing, **placing on the market** of unsafe feed (e.g. feed with an adverse effect on animal or human health) and feeding food-producing animals with such feed.

Establishments in the field of animal feed must be registered and approved. At the time of the bilateral screening, there were 295 establishments producing feed meals (and 11 with temporary approval), 348 storages for feed materials, 59 feed meals approved for export and 2 feed additives.

A register of **feed additives** does not include a list of all EU approved additives.

With regard to **undesirable substances**, including inorganic contaminants and nitrogenous compounds, Serbia declared that the levels approved by the Serbian legislation are already in line with EU standards, with the exception of the level of aflatoxin B1.

Rules on **feed intended for particular nutritional purposes** are laid down in the Rulebook on feed for animals.

Rules for **medicated feedingstuffs** are laid down in the Rulebook on conditions for production, methods and procedures for labelling, placing on the market and use of medicated feedingstuffs and their use subject to a prescription of a medicated premix.

### **II.f. Phytosanitary policy**

MAEP is the authority responsible for policy making in the phytosanitary field. The Plant Protection Directorate within MAEP is responsible for the coordination and exchange of information between official bodies and, as national contact point, for reporting at national and international level. It consists of the Plant Health and Plant Quarantine Department, the Plant Protection Products and Plant Nutrition Products Department, the Seed and Planting Material Department, the Department for Varieties Registration, the Department for Plant Variety Protection and Biosafety, the Phytosanitary Inspection Department and the Border Phytosanitary Department.

The Plant Protection Directorate carries out phytosanitary controls at BCPs and in the domestic production and internal market, verifies the activities of Agricultural Services, guarantees, in cooperation with the Forestry Directorate, the forestry inspections, has an organising and coordinating role, collects phytosanitary data and receives scientific support for the sector. The Expert Council for Plant Health and Expert Council for Plant Protection Products provide expert opinions and are coordinated by the Department for Plant Health and Plant Quarantine and the Plant Protection Products and Plant Nutrition Products Department.

The Department for Plant Health and Plant Quarantine (eight employees) is responsible for the organisation and implementation of surveillance of harmful organisms, providing information to international organisations, and implementation of international standards. The Border Phytosanitary Department (36 employees) examines consignments of plants, issues phytosanitary certificates and takes prescribed phytosanitary measures at BCPs. The Phytosanitary Inspection Department (59 employees) supervises the implementation and application of plant health legislation and the work of authorised institutions. The Forestry Inspection Department (44 employees) supervises over the implementation and application of laws and other regulations in the area of forestry.

In addition, there are 29 authorised Agricultural Services (96 employees) monitoring plant health, examining crops and premises for the production of seed, seedling and plant propagation material, issuing phytosanitary certificates and reporting on the presence and spreading of harmful organisms.

The Plant Protection Department authorises regional phytosanitary laboratories for routine tests and laboratories of Faculties and Institutes for full identification and confirmation of harmful organisms. It also carries out inspection supervision with regard to ensuring implementation of legislation.

Serbia stated that a comprehensive phytosanitary legislation as regards general control measures, based on the following main acts, is in place: the Law on Plant Health (OG RS No. 41/09), the Rulebook on lists of harmful organisms and lists of plants, plant products and other regulated objects (OG RS No. 07/10, 22/12), the Rulebook on phytosanitary control of plants, plant products and regulated objects in international trade (OG RS No. 32/10), the Decision on minimum conditions for carrying out plant health checks at border crossings (OG RS No. 37/10) and the Rulebook on the conditions and the criteria for conducting risk assessment for the reduction of plant health checks of certain plants, plant products or regulated objects (OG RS No. 67/11).

There are mandatory plant health checks during the production of seeds, plant propagation material and other plants for planting at least twice yearly. Phytosanitary examinations of plants, plant products and regulated objects for issuing plant passports are carried out at least once a year. Specific control of harmful organisms and phytosanitary export certification is also taking place in a regular manner.

The Plant Protection Directorate deals with **plant health protection** and **harmful organisms**. The Law on plant health introduces measures for the prevention of introduction and spreading of harmful organisms, and measures for their suppression, measures for plant health control of plants, plant products and regulated objects in import, production and trade, the implementation of internationally recognisable principles, standards, risk assessment and other scientifically based measures in the field of plant protection, the establishment of a Register of plant producers, processors, importers and distributors, phytosanitary controls, plant passports,

establishment of protected zones, obligations of notifications and record keeping, and of an information system.

Serbia stated that the methods used for diagnosing harmful organisms are in line with EU requirements and European and Mediterranean Plant Protection Organisation (EPPO) methods. Serbia has ratified the International Plant Protection Convention and is therefore member of the International Plant Protection Organization.

Plant consignments may only be imported through specified points of entry following customs and phytosanitary inspection on the basis of the Integrated Border Management agreement.

All regulated imported commodities of plants, plant products and regulated objects are subject to phytosanitary checks performed by 36 phytosanitary inspectors at 24 Border Inspection Posts: 10 at road border crossings, eight at rail border crossings, three at post office for border clearance, one at the airport and two at river ports. Importers of consignments should be registered and these consignments should be accompanied by a phytosanitary certificate. The phytosanitary inspector performs documentary, identity and plant health checks. Wood packaging material is controlled according to international standards. If legal requirements are met, the import is allowed; in the opposite case, the phytosanitary inspector intercepts the consignment and orders measures, informing also the customs.

Serbia pointed out that phytosanitary inspectors also perform internal controls on plants, plant products and regulated objects, as well as on control and eradication of harmful organisms, take samples and check the registration process of operators. In case of irregularity, the inspector may start a procedure before a court for minor offences, impose fines and order protective measures, if plant holders are found guilty.

The Law lays down the obligation of official registration for any operator engaging in the production, processing, introduction and distribution of plant products. Operators are entered in the Register if they have a person responsible for plant health and submit an application in the prescribed form, confirming their readiness to assume the obligations prescribed by the law. Registered operators are obliged to make available a production plan, keeping a record of plant transactions, be personally available for contact, make regular plant health checks, inform of any unusual occurrence of harmful organisms and provide access to the place of production for inspectors. A Plant Passport System is in place for propagating material of fruit and vines.

Serbia stated that its framework Law on **Plant Protection Products (PPPs)** is partially in line with the *acquis*. Serbia also stated that it is using the list of EU – approved active substances and that only products containing the approved substances can be placed on the market. Currently, only plant protection products containing active substances approved in the EU are accepted. The MAEP is responsible for the policy on plant protection products and residues, whereas the Plant Protection Products and Plant Nutrition Products Department, the Phytosanitary Inspection Department and the Border Phytosanitary Department are responsible for its implementation. Official controls of imports of PPPs are carried out in 24 Border Inspection Posts. Every consignment is under control. Market controls and controls of the use of PPPs include documentary check, identification and inspection, and optional sampling and laboratory tests. Based on the results, infringement procedures may be initiated.

Serbia pointed out that the Plant Protection Directorate is responsible for the implementation and certification of **quality of seeds and propagating material**. The Law on acceptance of varieties of agricultural plant species and concomitant secondary legislation regulates acceptance of new agricultural, vegetable, fruit and grape varieties. It defines conditions for acceptance of varieties

of agricultural and vegetable species, and the procedure of acceptance for domestic or inscription of foreign fruit or grape varieties into the Register of Agricultural Plant varieties. A variety must be distinct, uniform and stable, have better value for cultivation and use and be in conformity with given legislation in order to be included in the Register of Agricultural Plant Varieties for a period of 10 years. Registration of fruit and grape varieties is not subject to time limitations.

Production of seed and vegetable propagating material is regulated by the Law on seed and relevant secondary legislation. Seed producers have to be registered and the variety of seed material produced has to be registered in the Register of agricultural plant varieties. Seed producers may produce seed of varieties not entered in the aforementioned register only with the approval of MAEP and under the obligation to export the entire amount of production. Official field inspection of the production of seed material is under responsibility of the authorised agricultural services and the Phytosanitary Inspection Department. Controls of seed production are performed through documentary checks, expert controls and plant health checks. If the crop meets the prescribed requirements, the authorities issue certificates of recognition and on the plant health condition.

Propagating material can only be produced, marketed and imported by a registered legal person from varieties entered in the Register of agricultural plant varieties. Production, import and trade of propagating material of fruit, vine and hops is regulated by the Law on Planting Material of Fruit Trees, Vine and Hops. Vegetable propagating material other than seed can only be produced from varieties entered in the Register of Varieties of Agricultural Plants.

The law on the Protection of Plant Breeders' Rights regulates the conditions, manner and procedure for setting up the **plant variety rights** system. It is in line with the International Union for the Protection of New Varieties of Plants (UPOV) Convention. Serbia is a UPOV member since 2013. The Plant Protection Directorate is the designated authority for the protection of plant breeders' rights. Breeders' rights can be obtained through an application addressed to the Plant Protection Directorate of MAEP. Rights are granted for 25 years as a rule and 30 years for potato, trees and grapevine. Rights are granted on the basis of novelty, distinctness, uniformity, stability and denomination.

## **II.g. Genetically Modified Organisms**

The Law on **genetically modified organisms (GMOs)**, which entered into force in 2009, is complemented by a number of Rulebooks. The current law covers GMOs to be used in closed systems and also contains provisions for the deliberate release of GMOs in the environment for the purpose of carrying out experiments, demonstration experiments and development of new varieties. The Law prohibits the placing on the market of GMOs and GMO products, as well as the commercial growing of GMOs on the territory of the Republic of Serbia. The Law on food safety foresees that the first placing of GM food and feed on the market has to be approved, records of the approval kept and requirements of traceability and obligatory labelling fulfilled. MAEP is responsible for drafting legislation in this field, for the authorisation process and for supervision and inspection control.

## **III. ASSESSMENT OF THE DEGREE OF ALIGNMENT AND IMPLEMENTING CAPACITY**

Overall, Serbia has achieved good progress in alignment with the *acquis* in the Food safety, veterinary and phytosanitary chapter. It has demonstrated a clear and good understanding of the legislative gaps and the related administrative requirements to be addressed by the date of accession.

A substantial amount of work remains to be done as regards the establishment of the necessary administrative and control capacities required by the *acquis*. In particular, Serbia needs to adopt a comprehensive food strategy to align with the *acquis*. Specific attention will be required as regards closing the gaps on animal by-products, upgrading of establishments, eradicating rabies and Classical Swine Fever as well as on and strengthening the capacity of all Directorates within MAEP.

Serbia continues to work on upgrading its national legislation to meet *acquis* requirements. In most fields, concrete steps have already been taken to align with the *acquis* and Serbia is committed to achieving alignment by the date of accession.

Systematic efforts remain to be undertaken as regards the legislative alignment and implementation of the *acquis*, in particular the adoption of the above mentioned legislative framework.

Serbia's administrative and control capacity forms a good basis for the development of the capacity necessary to allow the country to discharge properly its future responsibilities with regard to the implementation and enforcement of the *acquis* in this area. Administrative, inspection and control bodies will need to be upgraded as regards procedures, technical equipment and facilities as well as staff training and staff numbers. This applies in particular to the competent authorities required by the *acquis* as well as laboratories and border inspection posts (BIPs).

The ongoing revision of the legislative framework needs to clarify the responsibilities of all the bodies involved in control of the food chain to further ensure efficiency of controls. The lack of administrative capacity needs to be addressed notably through a coherent distribution of responsibilities, adequate training and, where necessary, recruitment of additional staff.

The gaps identified in this report will need to be analysed in detail during negotiations.

### **III.a. General**

Serbia's general legislation on food safety covers all main areas of EU food law and is partially aligned with EU requirements. Serbia has implemented the main principles of the EU food law.

The detailed gap analysis provided by Serbia points to a good understanding by the authorities of legislative and administrative requirements, as well as of the need to upgrade inspection and laboratory capacity. Due to the complexity of the food safety field, it is of particular importance that the preparation of framework laws and more specific legislative provisions is thorough and well planned throughout the period until accession. It is also important to reflect on the designation of a single competent coordination body in charge of food safety. The establishment of a comprehensive strategy covering all aspects relating to food safety needs to be completed. Such a strategy will lay down responsibilities for a comprehensive alignment with all parts of the *acquis* in this chapter.

Serbia's current capacity as regards administration, control and laboratories forms a good basis for the implementation of the *acquis*, but the development of additional administrative capacity is necessary. It therefore requires overall strengthening of the concerned services, and particularly in the areas of veterinary inspection, phytosanitary and national reference laboratories. There is a need for enhancing the capacity and preserving the institutional memory in central services and notably in the Veterinary and Phytosanitary Directorates of MAEP.

### III.b. Veterinary policy

As regards the **control system in the internal market**, the Law on veterinary matters is partially aligned with EU legislation. The main focus should be placed in moving from a national control system to a system without controls at the internal EU borders but with an emphasis on controls at the place of origin and non-discriminatory controls during transport and at the place of destination. Serbia will be faced with the task of maintaining the efficiency of the national control system until the day of accession and at the same time, preparing well in advance for the entry into force of the internal market control system. The transition from a control system protecting the own territory to the internal market control system requires in particular: abolishing controls at the internal EU borders, abolishing import licenses, strengthening the controls at the place of origin, strengthening the controls at the external EU borders and preserving the safety of other Member States by all necessary means.

Serbia has already taken certain steps to bring its legislation in line with EU principles on the internal market control system. However, further amendments of the legislation are still required, in particular with regard to establishing electronic information exchange (TRACES) and aligning with EU requirements on control of products of animal origin.

As regards the **control system for import**, efforts have already been made to take EU requirements into account in the existing import rules. However, not all facilities and premises are in line with EU requirements. Serbia has an adequate understanding of the challenges ahead. Further efforts will be necessary to ensure full compliance of legislation with the *acquis* as well as an adequate and well trained administrative capacity. Inspection services will need to be upgraded in terms of infrastructure, equipment and staff resources. Whereas the controls at the future internal EU borders will be abolished, controls at the future external EU borders need to be further developed to take into account all EU requirements. This will, among other things, require upgrading of the physical infrastructures at the Border Inspection Posts. In order to ensure the most efficient use of investments, Serbia will need to clarify its plans for the locations of the posts which will remain after accession.

Serbia's current system on **identification and registration of animals** provides for a good basis to meet EU requirements by accession, as the Veterinary Law and the rules on animal identification and registration are largely in line. Serbia needs to address the remaining gaps in an orderly and well planned way, in good time before accession, in particular as regards the upgrading of its IT system and improved cooperation and awareness between all actors involved. Like for all Member States, it is vital for Serbia to develop a fully operational identification and registration system in order to control animal diseases. This system also needs to ensure the traceability of animals required by the *acquis*.

Serbian legislation in the area of **control measures for animal diseases** is partially aligned with the *acquis*, but harmonization needs to be completed. In addition, further efforts are needed to ensure adequate financial and human resources as well as capacity to undertake the necessary control measures and surveillance activities in accordance with international standards. In particular, Serbia needs to complete its network of reference laboratories and ensure better coordination and communication between all actors involved in the control of animal diseases. Serbia already applies international veterinary standards and has taken into account specific requirements. It therefore has a relatively high level of compliance with the *acquis* with regard to most diseases. The prohibition of vaccination against Classical Swine Fever would constitute an important step towards meeting EU requirements. Sustained efforts are also needed to ensure durable eradication of rabies. Further efforts are also needed to align with Regulation 2160/2003 on the control of Salmonella and other specified food-borne zoonotic agents.

Serbia's legislation on **intra-community trade for live animal, semen, ova and embryos** is partly in line with the *acquis*. Serbia needs to complete alignment in this area and prepare for full compliance with EU certificates. This will require earmarking sufficient financial and staff resources as well as upgrading laboratory capacities and/or network.

Serbia needs to further align its legislation and complete alignment in the area of **non-commercial movement of pet animals**.

National legislation on **prohibition of substances and control of residues** is partly in line with the *acquis*. Serbia needs to complete alignment in this area, in particular as regards EU rules and requirements for pesticide residues monitoring. Attention must be given to strengthening the capacities of laboratories, training activities, as well as cooperation between competent institutions. This would contribute to further improving the implementation of residue monitoring programs.

Rules on **import requirements for live animals and animal products** will only be legally fully applicable upon accession. Notwithstanding this, Serbia has a clear understanding of the gaps and needs for reinforcing implementing and training capacities. It has already started updating its legislation.

As regards **animal welfare**, national legislation is partly in line with the *acquis*, in particular as regards slaughterhouses and transport of animals. Sustained efforts are required throughout the entire pre-accession period to ensure that the national legislation is aligned to the existing EU animal welfare rules and that farms and other operators are informed about EU requirements and take the necessary steps to effectively comply with them upon accession at the latest. This includes investments, training and awareness raising measures.

Serbia's legislation on **zootechnics** is has a reasonable level of alignment with the *acquis*, but needs to be fine-tuned to fully meet EU requirements and ensure appropriate implementation. Further efforts are also needed to strengthen breeders' associations and develop related programmes. This would also imply a number of training and awareness raising activities on the importance of zootechnics at all levels.

As regards **veterinary expenditures**, Serbia should ensure full legislative alignment and implementation of the *acquis* by the date of accession. This would imply improving administrative capacity and ensuring the sustainability of financing.

### **III.c. Placing on the market of food, feed and animal by-products**

Serbia's legislation in the area of **general and specific hygiene rules for animal products** shows a reasonable level of alignment with the *acquis*. The Rulebook on general and specific hygiene conditions of food of animal origin is in line with Regulation EC (No) 853/2004 laying down specific hygiene rules on the hygiene of foodstuffs. However, further efforts are needed to ensure full harmonization with the EU food hygiene package. As regards implementation, Serbia needs to adopt a strategy on upgrading and classifying establishments according to the degree of compliance with EU standards. A small number of establishments have already been approved for exports to the EU but a very significant part of the establishments do still not meet EU requirements. As part of this strategy, efforts need to be made to inform and reinforce training of food business operators by developing adequate manuals. Drafting of individual plans for each establishment indicating their shortcomings and plans to remedy will have to be prepared at a

later stage. Development of laboratory capacity for the control of raw milk quality is also an important requirement.

The official administration and inspection bodies in charge of **control rules** will need to be reorganised, streamlined and merged under a single central authority. In addition, control guidelines and procedures should be improved and training capacity enhanced. It is also necessary that the operators in the food chain are informed by the competent authorities and make the necessary preparations to be in compliance by the day of accession. In addition, national legislation needs to be brought fully in line with the *acquis*.

While existing legislation provides a good basis for efficient implementation of controls, Serbia will need to amend its legislation on **specific control rules for animal products** to fully align with Regulation EC (No) 854/2004.

As regards **animal by-products** Serbia's legislation is partially aligned with the *acquis*. Serbia needs to develop and implement a strategy on the management of animal by-products. It should implement relevant FVO recommendations, ensuring that official controls at slaughterhouses provide reliable guarantees. The creation of adequate collection and treatment capacities of animal by-products, including proper handling of Specified Risk Material (SRM), should be a priority during the pre-accession phase. Achieving this in time of accession will be a challenge as it requires heavy investment and training activities. The evolution of the situation must be closely monitored.

Serbia's legislation is only partially aligned with the *acquis* as regards the **funding of checks**. Efforts are needed to ensure adequate legislative alignment and implementation by the date of accession.

### **III.d. Food safety rules**

Serbia's legislation in the field of **labelling** has a reasonable level of alignment with the *acquis*. Further harmonisation will be necessary on nutritional declarations and health claims, rules for distant selling, origin labelling of unprocessed meat and information on gluten.

Serbia's legislation on **food supplements, food of particular nutrition uses, food fortification and mineral waters** needs to be further aligned with recent developments in the EU *acquis*, in particular as regards dietary food. Serbia also needs to align its legislation with Regulation 1925/06 on the addition of vitamins, minerals and certain other substances to foods. Serbian legislation is partially aligned with Directive 2009/54.

As regards the area of **food additives, enzymes, flavourings and extraction solvents**, legislation on *additives* is partially in line with the *acquis*. Serbia has to review its legislation regarding definition of *enzymes*; the same applies to *solvents and flavourings*. Legislation on *flavourings* is partially in line with the *acquis*. Particular attention is needed to ensure regular updates of positive lists in force in the EU.

Legislation on **novel food** shows a good level of alignment with the *acquis* with small discrepancies to be addressed by accession.

Legislation on **contaminants** shows a good level of alignment with the *acquis*, but needs to be complemented as regards designating a competent body for preparing legislation and for laboratories, and establishing maximum levels of contaminants.

Legislation in the field of **quick frozen foods** and **ionising radiation** is partially in line with the *acquis*.

Legislation on **food contact materials** shows a reasonable level of alignment with the *acquis*. Secondary legislation still needs to be adopted.

In all these food safety areas, gaps with the *acquis* are clearly identified and corrective alignment plans already foreseen. Proper implementation of the newly adopted legislation will have to be ensured.

### **III.e. Specific rules for feed**

Serbia's legislation on **specific rules for feed** is partially in line with the *acquis*. However, further efforts are needed to complete alignment as regards the conditions for feed establishments, the list of permitted **feed additives** and the list of **undesirable substances** as well as feed intended for particular nutritional purposes and certain products used to feed animals (bio-proteins) and medicated feeding stuffs. Particular attention should also be given to the planning, coordination and organisation of official feed controls and ensuring that feed business operators are informed about EU requirements and make the necessary preparations before accession.

### **III.f. Phytosanitary policy**

Serbia's legislation is partially aligned with the *acquis* on phytosanitary policy.

Legislation on **harmful organisms** is partially in line with the *acquis*. Further efforts are needed to ensure a smooth transition from a national control system: such a system would protect not only Serbia's territory, but also the region and the EU. Upon accession, in line with the *acquis*, systematic internal border controls will be abolished and replaced by stringent controls at the place of origin and non-discriminatory controls during transport and at the place of destination.

Serbia's legislation on **plant protection products** has reached a good level of alignment with the *acquis* and the on-going revision of legislation should contribute to further bringing the legislation in line. The rules on control of residues of pesticides including sampling requirements are partially in line with the *acquis*. The country lacks a reference laboratory for the monitoring of pesticide residues. There is no system for the evaluation of active substances and no statistics on the use of pesticides. Due to a lack of IT resources, it is difficult to establish independence of functions for carrying out sampling and analysing of results. The Law on PPPs should be amended, in order to bring it in line with Regulation 1107/2009. Harmonisation with Regulation 752/2014 is pending.

Serbia has partially implemented the *acquis* for **quality of seed and propagating material**, but further efforts are needed to ensure full compliance by the date of accession. Particular attention should be paid to ensuring implementation of the legislation and that inspectors are fully aware of EU requirements and operators well informed.

Serbia's legislation on **plant variety rights** is in line with the rules of the International Union for the Protection of New Varieties of Plants (UPOV) and with EU rules. Serbia should request assistance from CPVO for the use of denominations.

### **III.g. Genetically modified organisms**

The Law on **genetically modified organisms (GMOs)** is not aligned with EU *acquis*. Serbia needs to modify its national legislation in order to become member of the WTO.

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