

# Screening report

## Montenegro

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

**Date of screening meetings:**

Explanatory meeting: 15-19 October 2012

Bilateral meeting: 28 January- 1 February 2013

## **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 Montenegro and the discussion at the screening meeting. Montenegro 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. Montenegro stated that it has a very good knowledge of the *acquis* covered by this chapter, that it is fully aware of the challenges ahead to ensure full implementation of the *acquis* by the date of accession and that it has a clear overview of the steps needed to achieve this goal.

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

The main legal acts governing the food safety, veterinary and phytosanitary sector are, among others, the Food Safety Law (OG n°14/07), the Veterinary Law (OG n° 30/12), the Law on Animal Identification and Registration (OG n°48/07 and 73/10), the Law on Animal Welfare Protection (OG n°14/08), Law on Livestock Farming (OG n°72/10), the Law on Plant Health

Protection (OG n°28/06, 28/11), the Law on Plant Protection Products (OG n°51/08), the Law on Agricultural Plant Seeds Materials (OG n°28/06, 61/11), the Law on Planting Material (OG n° 28/06, 61/11), the Law on Plant Varieties Protection (OG n° 48/07, 48/08, 73/10 and 40/11) and the Law on Reproductive Material of Forest Trees (n°37/47,40/11) as well as the Law on Genetically Modified Organisms (OG n°22/2008). The Food Safety Law contains general principles on risk analysis, transparency, precaution, traceability and consumer's interests.

Several ministries and central administrations share responsibilities in the field of food safety, veterinary and phytosanitary policy. Competencies in the field of food safety are laid down in articles 8 and 9 of the Food Safety Law: the Ministry of Agriculture and Rural Development is responsible for the policy and legislation relating to food safety of animal origin, food of plant origin at the primary production level and feed, whereas the Ministry of Health is the reference body when it comes to adopt and implement regulations on safety of food of animal and plant origin *following primary production* level, food safety of composite products and other food. Furthermore, the Ministry of Agriculture is responsible for the policy and legislation related to veterinary and phytosanitary issues and has veterinary<sup>1</sup> and phytosanitary<sup>2</sup> departments, implementing the related legislation in their respective fields of competences.

The Directorate for Inspection Affairs established by the Food Law performs monitoring and surveillance activities following the provisions of the Food Safety Law. It, among others, checks control systems established by the food business operators, inspects establishments, takes samples and controls the respect of specific hygiene requirements. The Directorate for Inspection Affairs started operating in June 2012 as the single inspection and enforcement body for the inspections including veterinary, phytosanitary and sanitary inspections. Previously, inspections services were disseminated in the Ministry of Health and the veterinary and phytosanitary departments. Inspectors are allowed to take administrative measures and actions - such as withdrawal/destruction of unsafe food or restriction of trade in food - which can be enforced by penal sanctions if required.

In addition to these institutions, Montenegro established in September 2009 a new advisory government body, the National Council for Food Safety Assessment, which monitors and performs risk assessment.

Montenegro presented a detailed gap analysis to ensure full compliance with all aspects of the *acquis* on food safety, veterinary and phytosanitary policy. Montenegro is therefore in the process of elaborating an Integrated National Food Safety Strategy that will focus on revising its Food Safety Law and adopting relevant Action Plans with a view to:

- achieving full compliance with the *acquis*
- appointing a single authority responsible for food safety
- ensuring better coordination and communication among the different control bodies acting in the field of food safety through the adoption of a revised Food Safety law by the end of 2013.

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<sup>1</sup> The Veterinary Directorate is in charge of regulations in the areas of food safety and veterinary: animal health, animal welfare, animal identification and registration, animal by products, food of animal origin, composite food and feed in production, international trade, wholesale trade, and of retail trade in meat, fish and other products of aquaculture.

<sup>2</sup> The Phytosanitary Directorate is in charge of regulations in the areas of: safety of food of plant origin at the primary production level, plant health protection, seeds and propagating material, harmful organisms, plant variety rights, fertilizers plant protection products (pesticides), pesticides residues in food of plant origin at the primary production level, GMO.

- developing procedures and guidelines for official controls
- securing adequate funds
- developing emergency response procedures and contingency plans
- conducting risk analysis.

Montenegro has three public state-owned laboratories: the Institute of Public Health, the Centre for EcoToxicological Researches and the Veterinary Diagnostic Laboratory. There is also the Biotechnical Faculty of the University of Montenegro within which the following laboratories operate: Phytosanitary Laboratory (Centre for plant protection in Podgorica) (diagnostic analysis of harmful plant organisms and plant products and analyses of biological efficiency of pesticides); Laboratory for Seeds (Centre for Field Crops, Vegetables and Forage Crops) (analysis and quality assessment of planting material and agricultural plants material); Laboratory for seeds propagating material (Centre for Fruit and Vine Growing, Podgorica and Centre for Subtropical cultures in Bar) (analysis and quality assessment of planting material).

The Accreditation Body of Montenegro was established in 2007 and is, since 2011, a full member of the European Cooperation for Accreditation (EA).

The general principles and requirements relating to the hygiene and safety of food and feed are regulated by the Montenegrin Food Safety Law which i) aims at ensuring a high level of protection of human life and consumer health and ii) determines the general requirements relating to food safety as well as the obligations of food and feed business operators including Hazard analysis and critical control points (HACCP) controls. It also lays down general principles for trade in food and feed.

Montenegro stated that it is, as a small country, facing a shortage of administrative capacity and lacks of adequate staff to fill the current vacancies. Montenegro is in the process of redefining the job curricula and competences of the required staff to ensure a better efficiency of its administration, taking into account its limited resources.

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

The *Veterinary Administration*, under the Ministry of Agriculture and Rural Development, is the competent administration for implementing legislation in the areas of food of animal origin, composite food, feed, animal health, animal welfare as well as animal identification and registration. It also prepares technical ground for the adoption of legislation. It consists of two departments: the department for animal welfare and animal health (with 4 advisers) and the department of veterinary public service (2 advisers). There are 20 official veterinarian inspectors (administratively based in the Directorate for Inspection Affairs) and private veterinarians authorised by the Veterinary Directorate to carry out inspection at slaughter line. Montenegro stated that it is currently preparing a reorganisation of its veterinary administration.

The main legal framework consists of the Veterinary Law (OG n°30/2012), the Law on Animal Identification and Registration (OG n°48/07) and the Law on Animal Welfare Protection (OG n°14/08).

The Veterinary Law is the main legislation on **control system in the internal market**. It stipulates that trade in live animals may only occur if animals have been identified and registered. The animal holder must present a valid certificate of animal health, issued by an authorised veterinarian, for the following species: solipeds, cloven-hoofed animals, poultry, lagomorphs, fishery and aquaculture products, consignments of snails, bees, wild game, dogs and

cats. In addition, animal traders have to be registered and approved for trade. The legislation also covers semen, ova and embryo although there is no such production in Montenegro.

Montenegro indicated that controls at the place of dispatch are carried out by the prescribed veterinary health checks. The veterinary inspector supervises the safety of products of animal origin in production, international trade, wholesale trade and retail trade. Veterinary inspectors are also responsible for checking wild and aquaculture fish and their products, as well as snails. Official controls are carried out at all stages of production and trade, including transport. In case an animal or a product of animal origin, put on the market, is not in compliance with national requirements, the official veterinarian can order quarantine or temporarily storage at the expense of the person responsible for the animal or the product of animal origin. If there is a suspicion of disease or if a product originates from an infected area, the official veterinarian can order the culling of the animal or the destruction of the product. There are regional cooperation agreements with Croatia, Serbia, and Bosnia and Herzegovina on the obligation to notify, report and take measures in case of disease.

Montenegro acknowledged a shortfall of veterinarians (there is no veterinary faculty in the country) and indicated that it is working on a new job classification to improve the efficiency and the attractiveness of the Veterinary Administration. Montenegro informed that it intends to adopt in 2014 new legislation to align with EU requirements on control of products of animal origin and to achieve full compliance with control systems by the date of accession. In addition, Montenegro indicated that it does not foresee any problems in applying the *acquis* in this area.

Several pieces of Montenegrin legislations govern **control system for imports**, namely, the Veterinary Law, the Law on Food Safety, the Law on Animal Welfare Protection and the Law on Animal Identification and Registration. The rules governing veterinary checks at the borders are not in full compliance with the EU *acquis*, which will require structural upgrading of the veterinary facilities at the future external EU borders.

The Veterinary Administration (under the Ministry of Agriculture and Rural Development) is responsible for related legislation whereas the Directorate for Inspection Affairs is responsible for veterinary checks and surveillance. By law, animals and products of animal origin can only be imported through border inspection posts where veterinary checks are performed. There are currently 10 official border veterinary inspectors. In addition, Montenegro indicated that plant health checks are performed at the same locations as veterinary checks.

The Veterinary Law of 2012 includes a section on official controls at borders. Consignments of live animals or animal products must be accompanied by appropriate international certificates for animal health and public health. Montenegro stated that the certificates are in line with the *acquis*. Veterinary inspectors check and control such consignments, deliver certificates and take samples. Veterinary inspectors have the power to reject consignments. They also monitor the situation of infectious diseases in the neighbouring countries. In cases of risk of introduction of infectious diseases, protective measures aiming at restricting or prohibiting trade in animals, semen, ova and embryos are set by order of the Ministry of Agriculture and Rural Development

Montenegro currently operates 9 veterinary Border Inspection Posts (7 BIPs at land borders, one BIP at Bar port and one at the Podgorica airport). Sanitary checks are not performed at BIPs, only at the final destination of consignments. Phytosanitary checks on import of regulated consignments is performed by 13 phytosanitary inspectors, at 13 Border Inspection Places designated as official points of entry (road, railway, port, airport, post). All consignments of animals or animal products entering the territory of Montenegro must be checked at one of these inspection posts. The border veterinary inspector is responsible for documentary identity and

physical checks. Montenegro stated that secondary legislation on pre-notification of arrival of veterinary consignments entering Montenegro is under preparation and should be adopted by the end of 2013.

Montenegro indicated that the busiest BIPs were the ones located at the borders with Croatia and Serbia. Montenegro stated that current facilities and premises are not in line with EU requirements. The fees for border veterinary controls are regulated in the Decision on the Amount of Fees for Veterinary-Sanitary Checks performed in Trade across the Republic of Montenegro (OG RMNE 50/05 and 37/10). In line with its 2005 Strategy for Integrated Border Management and 2010 secondary legislation on border inspection posts, Montenegro is working on a plan to rationalise its BIPs and ensure better IT connection between them, the Veterinary Administration and the Phytosanitary Administration. The upgrading of the BIP located at Bar is a priority and has already started as the port is expected to be an external border point at the time of accession. New facilities should be completed by the end of 2014 and Montenegro was invited to send a blueprint of the facilities to the Food and Veterinary Office (FVO)..

Trade Control and Expert System (TRACES) is not yet in place in Montenegro but, as described above, priority is given to provide all the BIPs with adequate equipment and training.

In addition, Montenegro plans to adopt legislation to improve the efficiency of controls of imported animals and animal products at its borders and to align with EU requirements in this field by the date of accession. Montenegro indicated that the legislation should provide for a comprehensive framework for control system, adapted to the geographic and economic constraints of the country.

**Identification and registration of animals** is regulated by the Veterinary Law and the Law on Animal Identification and Registration. The Veterinary Administration under the Ministry of Agriculture and Rural Development is responsible for the central register of holdings, the operation of the IT database, procurement and distribution of eartags, issuance of movement documents as well as control plans. Identification of animals at holdings is compulsory and ISO-compliant eartags are subject to international procurement.

The IT database (e.g. the veterinary information system) consists of the central register of holdings, the holding register for bovine animals and the holding register for sheep and goats.

*Bovine animals* are identified individually through two yellow eartags with inscriptions. The animal keeper has to cover 50% of identification costs in 2013. The keeper has the obligation, within 7 days, to report to the IT database all movements to and from the holding. According to Montenegrin legislation, double notification of movements is compulsory this is not yet fully implemented. Calves to be slaughtered of less than 4 months old do not need to be eartagged. Montenegro plans to improve the efficiency of its IT database in order to ensure better cooperation between the actors involved and to reinforce control of identification and registration.

First tagging campaign of *sheep and goats* was completed in March 2011. Small ruminants are tagged individually and registered in the holding register for sheep and goats. The same rules as for bovine animals apply. Montenegro informed that national legislation contains a specific movement form for animals on transhumance (summer grazing period from 1 May to 15 October). As the total number of ovine and caprine animals in Montenegro is less than 600 000, electronic identification could be made optional for animals not involved in intra-EU trade. Annual census of sheep and goats is performed. Montenegro plans to adopt in 2013 secondary

legislation on methods of ovine and caprine identification and registration and the related IT database.

Identification and registration of animals is currently limited to bovine, sheep and goats. Montenegro plans to extend it to other species. Identification of *pigs* is considered a priority.

Official veterinary inspectors supervise the implementation of identification and registration requirements whereas authorised veterinarians carry out animal identification and registration of holdings on the ground. The Veterinary Administration also produces yearly reports on the state of identification, registration and controls in Montenegro.

Montenegro indicated that it faces challenges related to very small holdings of one to two animals (almost half of the registered holdings), lack of IT experts and limited veterinary staff which impact on the quality of controls. Home slaughtering is also still widely practised.

The Veterinary Law regulates **control measures for animal diseases**. The animal health department (4 senior advisors) within the Veterinary Administration is responsible for the protection of animal health, including the elaboration of contingency plans. Official veterinarians undertake epidemiological surveys and examinations, keep records of occurrences of animal diseases and can order measures for control, including killing or emergency slaughter, as prescribed by the veterinary law (article 59). Outbreaks of infectious notifiable diseases are notified to the European Commission and the World Organisation for Animal Health (OIE). The national Diagnostic Veterinary Laboratory in Podgorica is the only accredited body for animal diseases. The legislation allows for the possibility to appoint foreign reference laboratories to perform tests on specific disease.

The national legislation includes preventive measures (implemented by the animal keepers and the veterinary services, and related penalties and sanctions), classification of infectious animal diseases as well as preventive protective measures against infectious animal diseases. This classification is based on the former lists of the World Organisation for Animal Health (OIE). Montenegro stated that reporting and notification of infectious animal diseases (OG n°5/2008) are to a large extent in line with Directive 82/984/EEC.

Montenegro states that it is currently free of bovine, ovine and caprine brucellosis, and that it is partly aligned with related EU legislation. Since 2006, Montenegro has the OIE status of a country free from foot and mouth disease without vaccination and since 2009, free from rinderpest. Montenegro plans to adopt contingency plans in line with Directive 2003/85/EC. There are limited cases of enzootic bovine leucosis, bovine tuberculosis and bee diseases.

In spite of mandatory vaccination of dogs and oral vaccination of foxes, rabies is still present in Montenegro and measures to prevent occurrence, diagnosis, control and eradication of rabies were adopted (OG n° 53/2011). The next vaccination campaign is expected to start in spring 2013. In total, vaccination will last for a minimum period of five years (five vaccination programmes with spring and autumn campaigns each).

Since 2008, Montenegro is free of classical swine fever in domestic pigs and wild boars but applies mandatory vaccinations. The coverage is close to 100% and Montenegro intends to stop vaccination of swine. In addition, Montenegro informed that secondary legislation is under preparation to align with Directive 2002/106/EC. The Veterinary Law requires the adoption of a contingency plan and the draft contingency plan has been prepared.

As regards other diseases, Montenegro plans to align its legislation with the *acquis* on African swine fever, African horse sickness, avian influenza, Newcastle disease, fish diseases, molluscs disease and bluetongue disease.

Transmissible Spongiform Encephalopathy (TSE) has not been diagnosed in Montenegro. Currently Montenegro does not have in place an active monitoring system for animal TSEs and plans to align with Regulation EC (No) 999/2001 as regards monitoring requirements, sampling and training activities. Montenegro implements a feed ban.

Monitoring of zoonoses as well as detection and control of salmonella are prescribed by law.

Montenegro already participates in the Animal Diseases Notification System (ADNS) on a voluntary basis.

General provisions for **intra-community trade for live animal, semen, ova and embryos** are laid down in the Veterinary Law and Directives 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine and 78/52/EEC establishing the Community criteria for national plans for the accelerated eradication of enzootic leukosis in cattle are partially aligned. Montenegro intends to fully align with EU requirements by the date of accession. The Law provides for preventive and contingency measures in case of infectious animal diseases, provisions on animal gatherings and trade in animals for breeding and production as well as obligations on transporters and traders in animals. Semen is imported in Montenegro and there is no storage facility in the country. Montenegro runs regular controls through its epizootiological surveillance network and annual programs of mandatory animal health protection measures.

The **non-commercial movement of pet animals** is regulated by the Veterinary Law, the Law on Animal Identification and Registration and the Law on Animal Welfare Protection (OG n°14/08). Keepers of dogs and cats need to present a veterinary health certificate established three days before the trip and to hold an international certificate or passport specifying that the animal is permanently marked with a microchip or clearly readable tattoo and is vaccinated against rabies. Montenegro stated that it aligned with Commission decision 2005/91/EC, establishing the period after which the anti-rabies vaccination is considered as valid. The system of dogs' identification has not yet been established. The Veterinary Law prescribes that control of non-commercial movement of pet animals across the borders of Montenegro is carried out by the customs administration.

General provisions for **prohibition of substances and control of residues** are laid down in the Veterinary Law, the Law on Food Safety and the Law on Medicines (OG n°56/11). Montenegro stated that it applies EU legislation on maximum residues levels. Since 2009, Montenegro is on the EU list of third countries with approved residue monitoring plans, in accordance with Directive 96/23/EC. A residue monitoring plan for milk has not been approved yet as the number of milk samples is not in compliance with Commission Decision 97/747/EC.

The Ministry of Agriculture and Rural Development is in charge of policy activities; the Agency for Medicines and Medical Devices issues approvals for placing on the market veterinary medicinal products and the importation of products. The Veterinary Administration carries out yearly monitoring of unauthorized substances and residues as well as controls on the ground whereas the Department of veterinary public health issues orders to veterinary inspectors for samplings. The Centre for EcoToxicological Researches is the only accredited body for residues analysis, which has performed residue analysis since 2007.

The Veterinary Law regulates **import requirements for live animals and animal products**. It defines requirements for imports of animals, products of animal origin, feed and by products. Montenegrin legislation allows imports from third country establishments if they are already listed by the EU. Montenegro stated that additional facilities in third countries may be approved by the Veterinary Administration if they fulfil the same requirements as the ones prescribed by Montenegro in terms of consumer protection. However, Montenegro indicated that specific rules exist for establishments from the former Yugoslav republics (Croatia, Serbia, Bosnia and Herzegovina) that are not listed in the EU. The law also lays down criteria for the issuance of international certificates as well as safeguard measures such as temporary ban of imports.

Imported animal and animal reproductive material are subject, upon decision of the Veterinary Administration, to quarantine with a view to checking their health condition. Animals imported for participation in sport competitions, exhibitions and fairs, cats and dogs are exempted from this measure if there is no risk of infectious animal disease in the country of origin.

As regards **EU international agreements** on veterinary and phytosanitary matters, Montenegro informed that it would align with EU requirements by the date of accession. Montenegro is member of the following international organisations or commissions in the field of veterinary issues (among others): Food and Agriculture Organisation (FAO), World Organisation on Animal Health (OIE), Codex Alimentarius.

The Law on Animal Welfare Protection (OG n°14/08) is the framework legislation for **animal welfare**. It lays down basic provisions for keeping, transporting, and killing animals. It applies to all vertebrates animals, with the exception of aquaculture production and hunting. Montenegro indicated that the country's landscape is characterized by small farms, where the level of animal welfare is traditionally good and that there are only a few holdings with intensive production. There is no annual monitoring or training for keepers.

According to Montenegro, a high level of alignment has already been reached with regard to legal transposition of the rules for animals kept for farming purposes, pigs, calves, laying hens and chickens.

Montenegro informed that it intends to revise its legislation to fully meet EU requirements as regards transport of animals and conditions at the time of slaughter.

The 2010 Law on livestock farming (OG n°72/10) is the main piece of legislation regulating **zootechnics**. It contains basic provisions on farming, breeding and trading of domestic animals as well as on the preservation of animal genetic resources, education and research activities. Montenegro's livestock is characterized by rearing ruminants (cattle, sheep and goats), poultry production, beehives, and a small number of horses whereas pig production is not well developed, primarily due to the lack of national production of cereals. Domestic production of meat and milk only covers respectively 36% and 80% of the needs of the country.

For all domestic species, special 5-year- breeding programs are to be adopted by the Government that stipulate, among others, methods for breeding of domestic animals. Montenegro indicated that there is no breeding program for pig, poultry, horses and sheep. Registered breeders' organisations do not comply with the EU standards but are fully involved in the implementation of the breeding programs. There is no breeders' association for horses. As far as administrative capacity is concerned, the Livestock Selection Service under the biotechnical faculty of the University of Montenegro is responsible for the implementation of breeding activities. It consists of 6 regional centres covering all municipalities. It notably performs milking controls of cows

using the rules of the International Committee for Animal Recording (ICAR), and implements support schemes in the livestock sector.

With regard to **veterinary expenditures**, the Veterinary Law provides for compensation for animals that are slaughtered, damaged or destroyed as part of a defined veterinary measure. Compensation has to be prompt, proportionate and based on market value. Veterinary expenditures are financed from the State Budget. A programme of mandatory animal health protection is adopted on a yearly basis to monitor, prevent occurrence, control and eradicate infectious and parasitic diseases. The Veterinary Administration, field veterinary service and the Veterinary Diagnostic Laboratory are in charge of its implementation. Veterinary inspection from the Directorate for Inspection Affairs performs monitoring and surveillance of implementation of activities. The programme is co-financed by Montenegro, international donors and animal keepers.

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

The Food Safety Law is the main piece of legislation regulating **general and specific hygiene rules for animal products**. It defines general obligations for food business operators who must ensure safety of food and feed at all stages of production and circulation; ensure traceability of food and feed as well as of raw materials and substances that are incorporated into them; withdraw unsafe food. In addition the law introduces the obligation to perform HACCP control procedures (except at primary production). The definition of primary product is in line with the *acquis*.

All food business operators engaged in primary production of food and feed of animal origin and non-animal origin must be registered by the Veterinary Administration, Phytosanitary Administration and the Ministry of Health in line with the Food Safety Law and the rulebook on general hygiene requirements (OG n°14/09). The rulebook on specific hygiene requirements for food of animal origin lays down specific rules for animal products for all phases of production, transport and distribution.

The register of registered establishments, under the control of the Veterinary Administration, collects data on establishments performing: primary production of food of animal origin, and the associated activities except for the establishments that are subject to approval. The Veterinary Administration has registered 341 establishments. The Register of Establishments that is kept with the Ministry of Health encompasses 2,065 establishments (for production, catering, wholesale and retail trade of food of non-animal origin and other food). Montenegro stated that the Food Safety Law therefore provides for flexibility provisions for small establishments.

The Veterinary Administration has approved 25 establishments for meat of ungulates, 5 for poultry meat, 40 for meat products (31 only for meat cutting and processing and 9 for slaughtering, meat cutting and production of meat products), 3 for minced meat, meat preparations and mechanically separated meat, 14 for fishery products (2 fish processing establishments, 4 land-located establishments for fresh marine fish - approved to export to the EU- and 8 freezing vessels), 2 establishments for live molluscs, 28 for dairy products (10 for producing milk and fermented products; 18 for cheese only). There is no establishment registered for neither farmed wild game slaughtering and cutting nor wild game meat processing and cutting. In the egg sector, 5 establishments are approved within larger farms to collect, pack, store and label eggs whereas there is no stand-alone establishment for egg packing or liquid egg production and delivery. In addition, there are 133 registered establishments for repacking and storing products of animal origin.

As regards controls, the majority of large capacity establishments apply HACCP principles. Montenegro stated that small establishments will have most problems with applying these principles. Hence, training is ongoing to raise awareness on implementation of HACCP principles within small-scale establishments.

With regard to raw milk, the majority of the production emanates from small farms (five cows or less). The central database of holdings of animals is part of the register of establishments. Milk samples are regularly performed by dairy laboratories and secondary legislation was adopted in 2012 to implement microbiological quality controls in line with the *acquis*.

**Control rules** are determined by the Law on Inspection Supervision (OG n°39/03, 76/09 and 57/11), the Law on Civil Servants and State Employees (OG n°50/08), the Food Safety law, the Veterinary law, the Law on Animal Welfare Protection and the Law on Animal Identification and Registration. The Law on Inspection Supervision defines the competencies and obligations of inspectors who must undertake administrative measures in case of violation of the law or non-compliance. The Food Safety law designates competent authorities to perform official controls relevant to food and feed safety: the Ministry of Health performs controls of food of plant origin *after* primary production whereas the Veterinary Administration and Phytosanitary Administration under the Ministry of Agriculture and Rural Development perform controls for food of animal origin and food of plant origin at primary production level.

The Ministry of Health adopts annual control plans as well as monitoring and contingency plans and approves establishments producing and trading food of plant origin after primary production. The Veterinary Administration drafts controls, monitoring and contingency plans relating to the safety of food and feed of animal origin; it develops certificates, registers, approves establishments and provides training activities. The same applies to the Phytosanitary Administration in its areas of competence. There are 3 authorised laboratories plus 3 laboratories in the Biotechnical faculty of Montenegro that examine all kinds of sample. The Food Safety Law may authorise a foreign laboratory to serve as reference laboratory for Montenegro.

The scope of official controls is wide as they cover animals, products of animal origin and by-products; establishments and equipment, means of transport and conditions as well as animals and products of animal origin from import or intended for export. The Food Safety Law clearly defines the duties and powers of the official veterinarians. These can include a ban on trade in animals or on performing activities in establishments for production and trade in animals, the closing of establishments, the withdrawal of circulation or a ban on releasing certificates. Penal sanctions ranging from EUR 500 to 20,000 are foreseen by law. All inspection activities are carried out by the Administration of Inspection Affairs. Veterinary, sanitary and phytosanitary inspectors perform official controls of sanitary safety and hygiene of food at all stages, in accordance with the competencies and prerogatives defined by law, including penal provisions. As regards human resources, there are 20 veterinary inspectors, 17 phytosanitary inspectors and 34 sanitary inspectors at local level.

According to Montenegro, the above legislative framework regulates the **specific control rules for animal products**. Mandatory checks of animals are performed by authorized veterinarians before and after slaughter. The authorized veterinarians check identification marks of animals and accompanying documents as well as conditions for protection of animal welfare during transport and slaughter. Authorized (private) veterinarians may perform checks on behalf of the Veterinary Administration but are not entitled to undertake administrative measures or actions. Production of animal origin intended for human consumption produced outside registered/approved establishments is prohibited.

The Veterinary Law is the framework legislation for **animal by-products**. There are 9 registered establishments (also for exports to the neighbouring countries; 3 of them are on the EU list.). There are no rules in place in Montenegro for Specified Risk Material (SRM) which is disposed of and destroyed as any other animal by-products. In view of the setting up of an EU compliant system in Montenegro, a pre-feasibility study was carried out. It estimated the cost of an EU-compliant rendering plant at EUR 11 million and therefore Montenegro considers operating a regional rendering plant to limit the investment costs.

As regards **funding of checks**, the Veterinary Law identifies checks for which fees have to be paid. Fees are paid directly to the State budget. Montenegro stated that inspection fees partially follow the principles laid down in Regulation EC (No) 882/2004. Rates applied for checks in the meat sector (with the exception of poultry) are in a number of cases well above the EU minimum rates whereas Montenegrin rates for checks at the borders are lower due to the country's dependence on imports of products of animal origin and live animals.

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

The basic act in the field of food safety is the Food Safety Law. Pursuant to this act, the Ministry of Health is responsible for food safety of plant origin after primary production, safety of composite food and safety of traded food. 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 Administration of the Ministry of Agriculture and Rural Development are in charge of safety of food and safety of traded food of animal/plant origin at primary production.

The area of **labelling** is regulated by the Food Safety Law and relevant rulebooks. Article 29 of the Food Safety Law provides for mandatory labelling and marking to ensure traceability of food and feed, raw materials, matters and substances which are incorporated in food and feed. It also provides for mandatory labelling and marking of food for animal consumption and final products at all stages of production and trade. According to Montenegro, the available information should not mislead the consumer or the animal keeper nor mention medical characteristics. Controls are carried out by sanitary, veterinary and phytosanitary inspectors within their respective areas of competences.

Montenegro indicated that the administrative bodies in charge of labelling are also responsible for **food supplements, food of particular nutrition uses, food fortification and mineral waters**. The Law includes comprehensive provisions on dietary foodstuffs and defines natural mineral water. Further detailed provisions on quality requirements and control as well as conditions for placing on the market and labelling are included in specific implementing legislation from 2005. Implementation, supervision and control activities are carried out by sanitary inspectors and authorized laboratories. Montenegro informed that it expects full alignment of national legislation on drinking and natural mineral waters in the short term future.

The same administrative bodies as mentioned above are in charge of **food additives, enzymes, extraction solvents and flavourings**. Additives, flavourings and enzymes are placed on the Montenegrin market based on positive lists dating back to federal laws which are still in force.

The Food Safety Legislation provides for a thorough definition of *additives* and lists (22 additive categories as of 2005). Specific requirements on quality and conditions for use of additive are included in secondary legislation. Montenegro indicated that additives not intended for the final consumer shall be placed on the market only if the packaging or container includes legible and

clear information on the name of the additive and its E number; on the indication and instruction of use and storage; on the batch or lot number and the name and address of the manufacturer; on the percentage of each ingredient with quantitative limitation, net quantity and any other information of interest for the consumer. Additives intended for sale to the final consumer are placed on the market only if their wrapping or container includes clear, legible and indelible information on the name of the additive and its E number according to the positive list of additives; on the indication and instructions for use and storage; on the batch or the lot number, name and address of the manufacturer, net quantity and expiry date. It is compulsory to indicate whether an additive is genetically modified or contains genetically modified organisms. There is no national production of food additives in Montenegro.

Specific secondary legislation lays down requirements for *food enzymes*, their placing on the market as well as a positive list on enzyme preparations. Genetically modified enzyme preparations have to be marked visibly.

Specific secondary legislation provides definition, categories and placing on the market of extraction *solvents* as well as a positive list.

Secondary legislation from 2006 regulates quality and other requirements for *flavourings* in production and trade. The legislation includes maximum quantities of certain substances as well as a positive list.

Controls in these areas are performed by authorised laboratories in cooperation with sanitary and veterinary inspectors. Montenegro stated that due to the small size of the country and its limited human resources, it is not in a position to develop further its capacity with regard to evaluation of food additives, flavourings and food fortification. Montenegro has therefore opted for a system of recognition of authorisations already used in EU Member States.

Requirements on **novel food** are laid down in the Food Safety Law. The administrative set up and responsible bodies are the same as already described in this section. Novel food authorised as such in the EU market may be placed on the Montenegrin market upon having been granted approval on EU market. Import, distribution and retail sale of novel food is carried out by food business operators. Supervision of establishments approved by the Ministry of Health is incumbent to sanitary inspectors.

The field of **contaminants** falls within the responsibility of the Ministries of Agriculture and Health and is regulated by the Food Safety Law and the Law on Plant Nutrition Products (OG n°48/07 and 76/08). Secondary legislation stipulates maximum levels of heavy metals, metalloids, mycotoxins and other substances in food as well as quantities of pesticides and other substances that may be contained in foodstuffs. 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 Ministries of Agriculture and Health and is regulated by the Food Safety Law and relevant secondary legislation.

Montenegro indicated that the preservation of foodstuffs and general items by **ionising radiation** are regulated by a rulebook from 1998. It contains the list of foodstuffs that may be treated with ionising radiation and maximum permitted radiation doses.

**Food contact materials** are defined by the Food Safety Law and secondary legislation from the former Federal State. Authorized laboratories and veterinary, phytosanitary and sanitary inspectors are in charge of its implementation.

## II.e. Specific rules for feed

The Veterinary Administration within the Ministry of Agriculture and Rural Development is responsible for policy, production and implementation of the safety of feed whereas the Inspection Administration performs, through veterinary inspectors, official controls of feed at all stages of production and trade. Laboratory tests are carried out by the Centre for EcoToxicological Research (which performs testing of chemical and radiological contamination of feed) and the Diagnostic Veterinary Laboratory (which performs microbiological analyses of feed and tests for ruminant protein feed).

Montenegro indicated that further steps are planned in this respect through the adoption of secondary legislation and revision of the Food Safety Law in line with the National Strategy for harmonisation with the *acquis*. Montenegro does not produce feed additives or compound feedstuffs.

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. Feed in production and trade must be labelled and marked to ensure its traceability at all stages of production and trade. Feed business operators must obey to these rules, produce feed in respect of HACCP principles and withdraw unsafe feed from the market. Pursuant to the Veterinary Law, establishments in the field of animal feed must be approved: there is only one approved feed producing establishment for breeding of pigs and laying hens as Montenegro imports all finished feed mixtures and feed additives from Serbia and EU.

Legislation on **feed additives**, as laid down in the rulebook on quality and other requirements for feed (OG of SRY n° 20/00 and 38/01) and will be subject to thorough revision.

With regard to **undesirable substances**, the rulebook on maximum quantities of harmful matters and ingredients in feed (OG of SRY, n° 2/90 and 27/90) lays down detailed rules as regards prohibited and harmful substances, i.e. maximum permitted amounts of undesirable substances in feedingstuffs and mixtures of feedingstuffs.

Montenegro has been applying a meat-bone-meal feed ban since 2001 as well as a ban of trade in consignments of feed containing ingredients of animal proteins.

Montenegro has no legislation on **feed intended for particular nutritional purposes and certain products used to feed animals (bioproteins)**.

Montenegro stated that **medicated feedingstuffs** may only be manufactured in establishments that have been granted approval by the Veterinary Administration. Rules for prescribing and selling veterinary medicinal products are set out in the Law on medicines.

## II.f. Phytosanitary policy

The Phytosanitary Administration, within the Ministry of Agriculture and Rural Department, is in charge of implementing the legislation in the fields of plant health protection, safety of food of plant origin at primary production level, plant protection products, pesticides residues, seeds material, planting material, plant varieties, and GMOs. It consists of the Department for plant

health protection (3 staff), the Department for plant protection product (1 staff) and the Department for plant variety production, GMOs, seeds and planting production (1 staff).

Montenegro stated that a comprehensive phytosanitary legislation, based on the following main acts, is in place: the Law on Plant Health Protection (OG n°28/06 and 28/11), the Law on Plant Protection Products (OG n°51/08 and 40/11), the Law on Agricultural Plants Seeds Materials (OG n° 28/06 and 61/11), the Law on Planting Material (OG n° 28/06 and 61/11) and the Law on Plant Varieties Protection (OG n°48/07,48/08,73/10 and 40/11).

The Biotechnical Faculty of the University of Montenegro is in charge of laboratory analyses in its different centres.

There are three specialised laboratories (the phytosanitary laboratory, the laboratory for seeds and the one for seeds material) that operate under the biotechnical faculty of the University of Montenegro.

The Department for Health Protection within the Phytosanitary Administration deals with **plant health protection** and **harmful organisms**. The Law on Plant Health Protection regulates the protection of plants, measures on i) the prevention of introduction and spread and control of harmful organisms and ii) checks of plant health and plant health consignments. Secondary legislation is updated on a regular basis to ensure further compliance with the *acquis*. Harmful organisms are classified according to the level of risk to health of plants and plant products, existence of individual species of plants and in relation to the risk of extensive economic damage they may cause. The Law provides for a list of quarantine harmful organisms relevant for the whole territory of Montenegro and a list of harmful organisms to be monitored. Montenegro informed that it does not intend to request protected zones; however, it has already aligned with the relevant EU legislation.

Montenegro states that the methods used for diagnosing harmful organisms are in line with EU requirements and European and Mediterranean Plant Protection Organisation (EPPO) methods. Montenegro has ratified the International Plant Protection Convention and is therefore member of the International Plant Protection Organization since 2009. It plans to join EPPO in 2013.

All regulated imported commodities of plants and plant parts are subject to phytosanitary checks performed by 13 phytosanitary inspectors at the 13 official points of entry: 8 at road border crossings, 2 at rail border crossings, one at post office for border clearance, one at the airport and one at bar seaport. 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. The customs administration is in charge of checking luggage of travellers that may contain small quantities of plants and plant products.

Inspection controls are also carried out at export for consignments of plants originating from Montenegro and for which a phytocertificate is issued. Consignments in transit or temporarily stored in Montenegro are also controlled. Phytocertificates follow the model of the International Plant Protection Convention.

Phytosanitary inspectors also perform internal controls on plants, plant products and regulated articles 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 for withdrawing the authorisation and apply penal provisions.

The Law lays down the obligation of official registration for any operator engaging in the production, processing, introduction and distribution of plant products. This provision does not apply to non-professional small scale producers if production is intended for own use or local market. Montenegro plans to establish a comprehensive phytoregister that will gather the current registers of importers of seeds and planting materials, producers of seeds and planting materials and the register for the treatment and/or marking of wood packaging material (currently 6 registered operators). The Plant Passport System is not yet in place but Montenegro plans to establish it once the phytoregister is operational. First plant passports will be issued for seed potato consignments. For the time being, only a health certificate is issued.

Montenegro indicated that as part of the 2012 programme of phytosanitary measures, systematic surveys of harmful organisms are carried out in line with the *acquis*, with a particular emphasis on potatoes and palm trees. Montenegro applies a ban on import of seeds of potato from non-EU countries. Montenegro stated that when a harmful organism is detected, the phytosanitary inspector should notify the plant holder and order contingency measures.

Montenegro stated that its framework law on **Plant Protection Products** is in line with the *acquis*. Montenegro has been using since 2009 the list of EU – approved active substances and 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. Currently, all plant protection products are imported. The Ministry of Agriculture, the Ministry of Health and the Ministry of Sustainable Development and Tourism are responsible for the policy on plant protection products whereas the phytosanitary inspectorate under the Directorate for Inspection Affairs is responsible for its implementation. It also performs checks of consignments of plant protection products at border inspection posts. Only operators listed in the register for distribution of plant protection products for retail and wholesale at the Phytosanitary Administration can import plant protection products in Montenegro.

The Centre for EcoToxicological Research and the Biotechnical Faculty of the University of Montenegro are the main laboratories.

Yearly monitoring of pesticide residues is performed since 2009, in line with EU recommendations. Montenegro is in the process of amending its legislation on plant health protection to align with EU requirements (Directive 2009/128/EC and Regulation EC (No) 396/2005) on pesticides residues and maximum residue levels. Montenegro also informed that it has carried out a number of training activities on the use of pesticides.

As a small country with limited human resources, Montenegro indicated that it does not intend to develop further its capacity for evaluating plant protection products but that it would continue to rely on the system of recognition of authorization of other EU Member States. The same applies to pesticide residues where Montenegro intends to take the maximum allowed levels set at EU level. Montenegro stated that revised legislation on plant health protection is expected to be adopted by the end of 2013.

The Phytosanitary Administration and the Directorate for Forestry are responsible for the implementation and certification of **quality of seeds and propagating material**. The Law on Seed Material and Agricultural Plants regulates certification, production and approval of seed materials of fodder plants, cereals, vegetable seeds and material other than seeds, beet, potatoes, ornamental plants from seeds, oil and fibre plants. Montenegro plans to adopt and implement, by the date of accession at the latest, secondary legislation in line with EU requirements.

There is no breeding company in the sector of seeds in Montenegro and potato and cereals seeds are the only seed materials produced in the country. Seed producers have to be registered and the variety of seed material produced has to be registered in the register of varieties. In addition, the producer has to obtain approval of the variety owner for reproduction of seed material of a protected variety. Approvals for seed material production are granted on a yearly basis by the Phytosanitary Administration. Official field inspection of the production of seed material is under responsibility of the Phytosanitary Administration whereas the Biotechnological faculty of Podgorica (centre for crop, vegetable and fodder production) is authorised for official field inspections, quality control and issuing health certificates for seeds. On this basis, the Phytosanitary Administration issues a certificate for seed crops which is required for placing on the market. Only processed seed material can be placed on the market. In case the seed material is from organic production or genetically modified, it has to be labelled. Montenegro indicated that its secondary legislation on marketing of cereals, potatoes and fruits is under revision to meet EU requirements.

The Law on Propagating Material contains provisions on propagating materials and certification for wine, fruit and ornamentals other than seeds. 34 producers are registered so far in the register of producers of propagating materials. The conditions for the application procedure, the field inspection controls and the placing on the market are the same as described above.

Montenegro stated that it does not yet have a national catalogue of plant varieties and does not intend to establish one in the near future due to the small size of the country and its limited administrative capacity. However, Montenegro plans to recognize EU catalogues while ensuring appropriate control system.

Imports of consignments of seeds and propagating materials are also regulated in details by law.

The law on the Protection of Plant Varieties is the legal framework for **the plant variety rights** system. It is in line with the International Union for the Protection of New Varieties of Plants (UPOV) Convention. Montenegro plans to become an UPOV member in 2013. Rights are granted for 25 years as a rule and 35 years for trees and wines. They are granted on the basis of novelty, distinctness, uniformity, stability and denomination. Montenegro already performs Value for Cultivation and Use (VCU) testing. Breeders' rights can be obtained through an administrative procedure under the Phytosanitary Administration.

Montenegro indicated that it has no tradition in breeding and selecting new varieties and therefore plans to postpone the implementation of the system for the protection of new plant variety rights and find a solution tailored to Montenegro's needs and specificities.

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

The Law on **genetically modified organisms (GMOs)** entered into force in April 2008. Several institutional bodies are involved in GMOs which renders the situation quite complex: The Ministry of Agriculture and Rural Development and the Ministry of Sustainable Development and Tourism are responsible for legislation; the Ministry of Agriculture authorises testing laboratories and approves use of GMOs for experimental purposes whereas the Ministry of Health receives applications for authorising GMOs in food. The Environmental Protection Agency approves the intentional introduction into the environment of GMOs. Montenegro indicated that no single application has been received so far and that the National Council for Biological Safety has not yet granted authorisations nor monitored GMO cultivation in Montenegro. Currently, no local GMO food is authorised for placing on the market. According to Montenegro, the national legislation provides for an adequate control framework. However,

there is no accredited laboratory to test GMOs and tests are performed in accredited laboratories in Serbia.

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

Overall, Montenegro has achieved a good level of alignment with the *acquis* in the Food safety, veterinary and phytosanitary chapter. Montenegro 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, Montenegro needs to adopt a comprehensive food strategy to align with the *acquis*. Specific attention needs to be paid to close the remaining gaps as regards animal by-products and upgrading of establishments.

Montenegro continuously works on upgrading its national legislation to meet *acquis* requirements and plans to adopt in the third quarter of 2013 a revised Food Safety Law fully in line with the *acquis*. In most fields, concrete steps have already been taken to align with the *acquis* and Montenegro is committed to achieving alignment by the date of accession.

Substantial 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. The comprehensive national Food Safety strategy covering all aspects of food safety, veterinary and phytosanitary legislation, which is currently under preparation, could serve as a basis for a full alignment with the *acquis* in the food sector. Specific attention will be required as regards closing the gaps on animal by-products, upgrading of establishments, eradicating rabies and Classical Swine Fever.

Given the small size and limited resources of the country, Montenegro's administrative and control capacity forms a good but insufficient basis for the development of the capacity necessary to allow Montenegro 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 competences 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 repartition of responsibilities and adequate training.

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

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

Montenegro's general legislation on food safety covers all main areas of EU food law and is partly in line with EU requirements. Montenegro has implemented the main principles of the EU food law.

The detailed gap analysis provided by Montenegro 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 law and more specific legislative provisions is thorough and well planned throughout the period until accession. Montenegro needs to align with the EU provisions on Rapid Alert System for Food and Feed (RASSF). It is also important to reflect on the designation of a single competent coordination body in charge of food safety. The elaboration of a comprehensive strategy covering all aspects relating to food safety, which Montenegro considers as a priority, needs to be completed. Such a strategy will laid down competencies for a comprehensive alignment with all parts of the *acquis* in this chapter.

Montenegro's current capacity as regards administration, control and laboratories forms a good but insufficient basis for the implementation of the *acquis*. It therefore requires overall strengthening.

### **III.b. Veterinary policy**

As regards the **control system in the internal market**, the Veterinary Law is partly in line with EU legislation. However, the basic challenge for Montenegro is to move 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. Montenegro 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.

Montenegro 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**, some efforts have already been made to take EU requirements into account in the existing import rules of Montenegro. However, current facilities and premises are not in line with EU requirements. Montenegro has an adequate comprehension 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, Montenegro will need to clarify its plans for the locations of the posts which will remain after accession.

Montenegro's current system on **identification and registration of animals** provides for a good basis to meet EU requirements by the date of accession as the Veterinary Law and the Law on Animal Identification and Registration are largely in line. In addition, the system is in place for

bovine and is broadly in line with the *acquis*. Montenegro needs to address the remaining gaps in an orderly and well planned way, in good time before accession, in particular as regards the identification and registration of all species (with a special attention on pigs), the upgrading of its IT system and improved cooperation and awareness between all actors involved. Like for all Member States, it is vital for Montenegro 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*.

Montenegrin legislation in the area of **control measures for animal diseases** is partially in line with the *acquis* but harmonization needs to be completed. In addition, significant 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, Montenegro needs to reinforce its network of reference laboratories and ensure better coordination and communication between all actors involved in the control of animal diseases. Montenegro 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 some diseases whereas substantial work is still outstanding for other 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.

Montenegro's legislation on **intra-community trade for live animal, semen, ova and embryos** is partly in line with the *acquis*. Montenegro needs to complete alignment in the area of **intra-community trade for live animal, semen, ova and embryos** 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.

Montenegro needs to fine tune its legislation and complete alignment in the area of **non-commercial movement of pet animals**. In particular, a pet passport systems needs to be established.

National legislation on **prohibition of substances and control of residues** is partly in line with the *acquis*. Montenegro needs to complete alignment in this area, in particular as regards EU rules for certain beta-agonists and substances having hormonal or thyrostatic action, the performance of analytical methods as well as the classification of pharmacologically active substances. Sampling and monitoring activities are performed in accordance with EU requirements and the Centre for EcoToxicological Research operates according to EU requirements. However, attention must be given to strengthen the capacities of laboratories, training activities as well as cooperation between competent institutions. This would contribute to further improve the implementation of residue monitoring programs.

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

Montenegro indicated that it will review all its **international veterinary and phytosanitary agreements** by accession to bring them in line with the *acquis*.

As regards **animal welfare**, national legislation is partly in line with the *acquis*. As regards chickens kept for meat production, legislation is not fully harmonised with Directive 2007/43/EC

and Montenegro still produces laying hens in non-enriched battery cages which is not in line with Directive 2002/4/EC on the registration of establishments keeping laying hens. Montenegro intends to adopt a strategy to fully harmonize its legislation with the *acquis* and establish annual plans for control requirements in farms with intensive production as well as training programs. Substantial efforts need to be undertaken to meet EU requirements on laying hens and ensure their appropriate implementation as well as proper consumer information on eggs. Sustained efforts are required throughout the entire pre-accession period to ensure 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 addition staff resources within the Veterinary Administration as the current number of veterinarians is insufficient to perform adequate controls.

Montenegro's legislation on **zootecnics** is broadly in line with the *acquis* but needs to be fine-tuned to fully meet EU requirements and ensure appropriate implementation. Further efforts are also needed to establish breeders' associations for all species and develop related programs. This would also imply a number of training and awareness raising activities on the importance of zootecnics at all levels.

As regards **veterinary expenditures**, Montenegro plans to ensure full legislative alignment and implementation of the *acquis* by the date of accession. This would imply upgrading the human resources and laboratory system, in particular through the setting up of a combined system of registers, records and IT system, namely the so called Veterinary Information System.

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

Montenegro's legislation in the area of **general and specific hygiene rules for animal products** is broadly in line with the *acquis*. The rulebook on specific hygiene requirements for 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, Montenegro 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 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. Particular efforts must be taken to support small establishments in meeting EU requirements. Drafting of individual plans for each establishment indicating their shortcomings and plans to remedy will have to be prepared at a later stage.

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 plans, techniques and procedures should be improved and training capacity thoroughly enhanced. It is also necessary that the operators in the food chain inform themselves about *acquis* requirements and are informed by the competent authorities and make the necessary preparations to be in compliance by the day of accession. Montenegro needs to increase labour capacity and to designate reference laboratories for each of the EU reference laboratories. 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, Montenegro will need to amend its legislation on **specific control rules for animal products** to fully align with Regulation EC (No) 854/2004. Given the limited resources of the Veterinary

Administration and the continuous need of training, amendments of the national legislation to allow, in line with the *acquis*, the transfer of certain tasks to private bodies is a possibility.

As regards **animal by-products** Montenegro's legislation is partially aligned with the *acquis*. Montenegro needs to develop and implement a strategy on the management of animal by-products. 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 on the spot.

Montenegrin legislation is not fully in line 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

Montenegro's legislation in the field of **labelling** is broadly in line with the *acquis* and the current small discrepancies, in particular as regards nutrition and health claims, need to be addressed. Montenegro informed that the revised Food Safety Law to be adopted by the end of 2013 will be fully in line with the *acquis*.

Montenegrin legislation on **food supplements, food of particular nutrition uses, food fortification and mineral waters** needs to be fine-tuned to fully meet EU requirements and reflects the recent developments in the *acquis*, in particular as regards dietary food. Indeed, the Food Safety Law provides for a definition of **food supplements** which is not fully in line with the *acquis* as it only includes nutriment.

Particular attention should be paid to ensuring adequate administrative capacity to implement legislation on **food additives, enzymes, flavourings and extraction solvents** while taking into account Montenegro's limited human resources and needs. Legislation on *additives* is partly in line with the *acquis* and the revised Food Safety Law to be adopted by the end of 2013 will allow for taking over EU authorisation methods. Montenegro has to review its legislation regarding definition of *enzymes*; the same applies to *solvents and flavourings*. Legislation on *flavourings* is partly in line with the *acquis*. Particular attention is needed to ensure regular updates of positive lists in force in the EU.

Montenegro's legislation on **novel food** is mostly in line with the *acquis* with small discrepancies to be addressed by the time of accession. Secondary legislation on novel food is expected to be adopted in 2014.

Legislation on **contaminants** is mostly in line with the *acquis* but needs to be complemented as regards placing on the market of food with contaminants. Further efforts are also needed to meet EU requirements on controls and samplings.

Legislation in the field of **quick frozen foods** and **ionising radiation** is partly in line with the *acquis*. Montenegro informed that the revised Food Safety Law to be adopted by the end of 2013 will address these gaps.

Legislation on **food contact materials** is not fully in line with the *acquis* as it does not cover chemicals and hygiene rules; there are also some discrepancies as regard the definition of food contact materials. Montenegro foresees no difficulty in aligning with the *acquis*.

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**

Montenegro's legislation on **specific rules for feed** is partly 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 (bioproteins) and medicated feedingstuffs. 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**

Montenegro's legislation is broadly in line 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 Montenegro's own territory but the whole EU territory. 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. Montenegro is working on upgrading its administrative and IT capacity to ensure better information exchange and communication between all involved actors. Montenegro foresees no difficulty in implementing the *acquis* by the date of accession.

Montenegro's legislation on **plant protection products** is broadly in line with the *acquis* and the on-going revision of legislation should contribute to further bring the legislation in line. The rules on control of residues of pesticides including sampling requirements are in line with the *acquis*.

Montenegro 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 to ensure that inspectors are fully aware of EU requirements and operators well informed.

Montenegro's legislation on **plant variety rights** is in line with UPOV and the EU rules. The Commission takes note of Montenegro's intention to postpone the implementation of the system for the protection of new plant variety rights and to decide by law to ask another country to perform tests on its behalf.

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

The Law on **genetically modified organisms (GMOs)** is only partly in line with EU requirements. Montenegro foresees no difficulty in aligning its legislation by the date of

accession and is undertaking the necessary steps to streamline its institutional set up with a view to ensuring its effectiveness.

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