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# Screening report

## Croatia

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

**Date of screening meetings:**

Explanatory meeting: 9-10 and 13-15 March 2006

Bilateral meeting: 29 May - 2 June 2006

## I. CHAPTER CONTENT

Country alignment and implementation capacity Chapter 12 – Food safety, veterinary and phytosanitary policy - reflects the EU's integrated approach to food safety aiming to assure 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, and implementation by a properly structured and trained administration.

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

In previous accession negotiations, the requirements regarding food of non-animal origin were covered under Chapter 1 – Free movement of goods. Live animals, food of animal origin, feed and plant health issues were covered under chapter 7 – Agriculture. All food safety aspects, veterinary and phytosanitary issues are currently covered in one single negotiation chapter: Chapter 12.

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 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, this part covers packaging, labelling, marketing, additives, extraction solvents, flavouring, food contact materials, food supplements, contaminants, novel food, genetically modified foodstuffs, mineral waters and ionising radiations.

In the areas of veterinary and phytosanitary policy, EU legislation lays down rules for internal trade and introduction from third countries in the veterinary, plant health and animal nutrition sectors while safeguarding public health, plant and animal health and animal welfare. 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 Community *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 Croatia and the discussion at the screening meeting. Croatia indicates that it can accept the *acquis* regarding Food safety, veterinary and phytosanitary policy. Croatia indicates that it does not expect difficulties to implement the *acquis* by accession.

### II.a. General

The main legal acts governing the food safety, veterinary and phytosanitary sector are amongst others the *Veterinary Act* (OG No. 70/97, 105/01 and 172/03), *Animal Welfare Act* (OG No. 19/99), *Livestock Act* (OG No. 70/97, 36/98 and 151/03), *Food Act* (OG No. 117/03, 130/03, 48/04), *Act on Veterinary Medical Products and Veterinary Medical*

*Devices* (OG No. 79/98), *Wine Act* (OG No. 96/03), *Plant health Act* (OG No. 75/05) and the *Plant Protection Act* (OG No. 10/94, 19/94, 117/03).

The overall responsibility for food safety lies with the Croatian Ministry of Agriculture, Forestry and Water Management (MAFWM), which was reorganised early 2006 to better address the EU requirements. However, certain competences are shared with the Ministry of Health and Social Welfare. In addition, the Croatian Food Agency is responsible for risk assessment, risk communication as well as the establishment of networks aiming at implementing efficient risk assessment.

Croatia is in the process of elaborating a Food Safety Strategy with the aim of presenting a detailed plan for achieving full compliance as regards all aspects of EU food safety requirements.

Croatia presented a detailed gap analysis to ensure full compliance of the general food legislation with Community requirements, such as:

- The definition of food, as regards specific definitions of "medicines and medicinal products", "cosmetics", "tobacco and tobacco products" and "natural ingredients injurious to human health".
- The definition of "feed".
- The definition of "competent authorities".
- The function of risk management to be separated from the function of risk assessment.
- Export of non-compliant food and feed.
- Competencies of inspection services regarding import of food and.
- Provisions for the declaration of a whole batch, lot or consignment as unsafe.
- The specific requirements for the use of unsafe feed.
- Responsibility of food and feed business operators to inform the competent authorities.
- The role of the Croatian Food Agency.
- Rules regarding the rapid alert system, emergency measures and crisis management.

Croatia provided a detailed analysis of laboratories in the field of food safety, veterinary and phytosanitary issues including plans for upgrading with a view to full compliance with EU requirements. As regards control of food – including food of animal origin – and feed Croatia has approximately forty-eight laboratories performing analyses Laboratories under the competence of the Croatian Institute for Public Health are classified as laboratories performing: basic activities (17); specialised activities;; (13) and reference laboratories(not yet accredited). The Croatian Accreditation Agency has so far accredited 8 laboratories according to ISO 17025. The Croatian Veterinary Institute operates as reference laboratory for control of food of animal origin as well as for control of animal diseases. In the phytosanitary sector the activities for monitoring pesticide residues will be conducted by the pesticide department of the Croatian Institute for Public Health (reference laboratory). This laboratory will be upgraded in the framework of CARDS programmes. Croatia presented detailed plans for actions and activities to upgrade the laboratory network. These plans address issues such as:

- Avoiding overlap of analytical activities.
- Upgrading of staff resources.
- Upgrading of technical equipment and facilities.
- Further accreditation of laboratories.
- Clearer guidelines and procedures for laboratory methods and technical standards.
- Improved cooperation between laboratories.

The general principles and requirements relating to the hygiene and safety of food and feed are regulated by the Croatian *Food Act*, which determines the obligations of food and feed business operators as well as the general requirements relating to food quality. It further regulates the general requirements for placing of food and feed on the market and the system of official controls of food and feed. It furthermore sets the system for authorised testing and reference laboratories, as well as crisis and emergency management. The *Act* also provides for the establishment of the Croatian Food Agency and determines the competence of the authorities as regards food and feed produced in Croatia (or imported). The scope of the *Act* covers the entire food production, "from field/farm to table". Comprehensive amendments of the *Food Act* were under preparation with a view to achieving compliance with EU requirements. Due to the high number of required amendments, the new Food Act has been prepared and sent to the governmental procedure at the beginning of December 2006.

## **II.b. Veterinary Policy**

The responsibility for veterinary issues lies with the Veterinary Directorate under the MAFWM. The State Veterinary Inspectors (SVIs) and county officers (82) are an integral part of the Veterinary Inspection Department (VID). The local level consists of contracted authorised veterinary organisations (AVOs) employing authorised veterinarians (AVs). The responsibility for establishing and maintaining the animal identification and registration information system is allocated to the Croatian Livestock Centre (CLC).

The main legal framework is the *Veterinary Act* that covers animal health public health for products of animal origin, zootechnics, veterinary protection of the environment, as well as veterinary inspection. Other aspects are covered by the *Animal Protection Act*, the *Livestock Act*, and the *Act on Veterinary Medicinal Products and Veterinary Medicinal Devices*. A number of new acts are under preparation, notably a new *Veterinary Act*. Croatia is also preparing a reorganisation of the veterinary services.

The most important Act in relation to the *control systems in the internal market* is the *Veterinary Act*. With regard to the placing of equidae and cloven-hoofed animals in the market, the *Veterinary Act* requires that they are subject to official veterinary controls and subjected to prescribed diagnostic tests or preventive vaccinations. The animal holder must present a valid certificate of animal health issued by an authorised veterinarian. The use of pharmacological substances making the meat unsuitable for human consumption is forbidden for animals intended for slaughter.

Controls at the place of dispatch as regards live equidae and cloven-hoofed animals are carried out at the place of dispatch by the prescribed veterinary health checks during the loading of the animals. Controls further take place at the place of destination and can also be undertaken during transport by the competent veterinary inspectors or by the police. The *Veterinary Act* further covers the monitoring of the transport of poultry and hatching eggs, live aquaculture organisms as well as of semen, ova and embryos. Croatia plans to achieve full compliance with EU requirements for controls systems by the end of 2007 as regards legislation and by the end of 2008 as regards implementation. Croatia explained that the rules for mutual assistance between the authorities of the member states and the Commission are not applicable before accession. Croatia does not foresee any problems in applying this part of the *acquis*.

The *Veterinary Act* provides for veterinary health checks and a *control systems of imports*. The rules governing veterinary checks at the borders are not in full compliance with those of the EU, which will require upgrading of the physical structures at the veterinary border inspection posts at the future external EU borders. As provided for by the *Veterinary Act*,

consignments of live animals or animal products must be accompanied by appropriate international certificates for animal health and public health, indicating among others origin, destination and means of transport.

The Sector of border veterinary inspection and international trade in the MAFWM is responsible for veterinary - sanitary checks and control at the border inspection posts, whereas the International Trade Department (within Sector of border veterinary inspection and international trade which is under Veterinary Directorate) is responsible for related legislation, health requirements certificates and surveillance. Controls of illegal movements at the land borders are undertaken by the border police.

Croatia currently operates 21 veterinary border inspection posts – at land borders, ports and airports. The MAFWM has drafted a plan for rationalisation of veterinary border inspection posts which foresees 8 border inspection posts at the future external EU borders after accession. The plan includes the categorisation of particular border inspection posts in accordance with EU requirements.

All consignments of animals or animal products entering the territory of Croatia must be checked at one of these inspection posts. The border veterinary inspector is responsible for documentary identity and physical checks

Croatia presented its plan for further activities to improve the efficiency and compliance with EU requirements of its controls of imported animals and animal products. This includes training on specific issues related to control issues, development of manuals for standard checks and control procedures, strengthening of the technical capacity and implementation of TRACES. The new *Veterinary Act* that is under preparation will create the legal basis for the implementation of TRACES.

***Identification and registration of animals*** is regulated by the Veterinary Act, the Livestock Act and the *Ordinance on obligatory identification, entry in the Unique Register of Domestic Animals and record keeping*. Croatia operates a bovine identification and registration system. Bovine animals are tagged with two yellow ear tags with inscriptions according to rules very similar to EU requirements. Bovine animals in movement must have an animal passport, which is issued by the Croatian livestock centre. The animal passport includes arrival and departure forms. Slaughterhouses and border veterinary inspectors (for exported animals) keep records of invalidation of passports. The Unique Register of Domestic Animals is the core database for all bovine animals in Croatia and is managed by the Croatian Livestock Centre (CLC) that became operational in 2003. Data entered at 215 local registration units are transferred via a web server on a daily basis.

All porcine animals older than two months, as well as all porcine animals (regardless of age) placed on the market, must be identified with the prescribed ear tag and registered. Pig holders do not keep registers of pigs at the holding. Registration and movement of pigs is not recorded electronically. Electronic registration exists for breeding purposes and for the system of financial aids but a unique database for all pig holdings does not exist. MAFWM plans to set up such a unique register for all holdings breeding porcine animals. At a later stage the register will be extended to other species. Implementation of the system is foreseen to begin in 2007. It is expected that all pigs will be registered by the end of 2008.

Identification of sheep and goats is performed by authorised veterinarians or technicians of the Croatian Livestock Centre but there is no uniform registration system. 90 % of sheep and goats from holdings of more than 25 sheep or goats are registered in databases with a view

to financial aids or for breeding and selection purposes. Sheep and goats placed on the market are registered by an ear tag but movements are not recorded electronically.

**Control measures for animal diseases** are regulated by the *Veterinary Act*. The sector for animal health protection within the Veterinary Directorate is responsible for the protection of animal health with the aim of ensuring the production of healthy animals, safe animal products and the protection of humans against zoonoses. It undertakes epidemiological surveys and keeps records of occurrences of animal diseases for the recognition of its animal health status.

Measures are taken in accordance with international standards. Croatia claims that no endemic animal diseases are currently present in Croatia/ on their territory. Croatia is in the process of adapting its secondary legislation to the requirements prescribed by the specific rules foreseen by the *acquis*. Croatia assesses that legal compliance is relatively high for some diseases (such as Classical Swine Fever) whereas further adaptation is foreseen with regard to other diseases during 2007 and 2008.

Sporadic cases of Classical Swine Fever (CSF) were found until 2003 (and autumn 2006) in domestic pigs in spite of the prescribed mandatory vaccinations. The cases mostly occurred in small family farms. A new control strategy was introduced from January 2005, which prohibits the use of vaccination. In parallel, a programme of active surveillance of wild boars for CSF is being carried out.

Transmissible Spongiform Encephalopathy (TSE) has not been diagnosed in Croatia. Measures taken against the spread of TSE are similar to EU requirements, including provisions for control measures, monitoring, feed ban, testing and surveillance, disposal of specified risk materials and measures to be taken in case of appearance of the disease. Croatia is preparing amendments for the end of 2006 that would ensure alignment with EU rules for prevention, control and eradication with regard to TSE (Regulation (EC) 999/01).

Provision for ***intra-community trade for live animals, semen, ova and embryos*** are regulated by the Veterinary act, Livestock Act, Ordinance on the production, sale and labelling of genetic material (OG 155/98), Annual Decree on measures to protect animals from infections and parasitic diseases and the financing thereof (for every year the new one), Ordinance on the way of loading, reloading and unloading, and veterinary health check of consignments of animals, products and waste of animal origin and hygienic and on technical conditions with which means of transport and consignments in internal and international transport must comply (OG 13/05) and Ordinance on the manner of conducting veterinary health checks and controls on products of animal origin moving across the borders of the Republic of Croatia (OG 147/04). Croatia runs numerous programmes for control and surveillance of diseases and is applying EU rules as regards production and control of semen, ova and embryos and teams for collection of embryos. Furthermore, preparation for official verification of the centres for artificial insemination according to the EU Directives 88/407/EEC and 89/556/EC already started.

The ***non-commercial movement of pet animals*** in Croatia is regulated by the *Veterinary Medicine Act* (OG No. 70/97, 105/01 and 172/03) stipulating that for dogs and cats accompanied by the owner in inland or international traffic, or in case of temporary change of place of residence, the owner must possess a verified International certificate of vaccination. The International certificate on vaccination for dogs and cats may be issued by veterinary organisations and private practitioners-veterinarians.

The Veterinary Directorate is responsible for ***prohibition of substances and residues control*** in animals and animal products. This area is covered by the *Veterinary Act*, the *Food Act* and related Ordinances. The EU rules for certain  $\beta$ -agonists and substances having a hormonal or thyrostatic action are not fully applied. Controls are carried out in accordance with annual National Residue Monitoring Plan (NRMP) and comprise all live animals and animal products. This plan is approved by the Commission for Croatia as a third Country. Based on the agreements concluded with the Ministry of Agriculture, Forestry and Water Management, the Croatian Veterinary Institute (and its branches in Križevci, Rijeka, Split, and Vinkovci) carries out the analyses of residues foreseen by the National Residue Monitoring Plan for the current year. Some official analyses of residues in imported samples (on pesticides, antibiotics, sulphonamides and heavy metals), and which are not part of the NRMP, are carried out by a separate laboratory. Croatia presented a list of particular measures to address difficulties in implementation until 2008:

- Systematic records of veterinary treatments on farms;
- Systematic production records;
- Avoiding conflicts between responsible officials;
- Professional sampling, packaging and delivery of samples for analysis;
- Prompt analysis of samples by accredited and internationally acknowledged methods;
- Prompt notification of competent authorities, in particular in case of positive samples;
- Generation of databases and networks (records of treatment, production, sampling, analytic results).

For ***import requirements for live animals and animal products***, the *Act on the Amendments to the Veterinary Medicine Act* (OG No. 172/03) regulates the import of products of animal origin intended for human consumption. As it allows imports from third country establishments listed by the EU, it has created a legal precondition for the application of the list of establishments approved by EU in third countries. Other facilities in third countries may be approved by way of derogation, if it is established that these establishments fulfil the same requirements that are laid down for Croatian establishments. Such specific rules exist currently only for heat-treated milk from Bosnia and Herzegovina and from Serbia / Montenegro. Import may also be granted exceptionally from non-EU-listed establishments if rules, standards, processing and supervision performed by the exporting country are identical to Croatian rules.

With regard to ***international veterinary agreements***, Croatia has concluded a number of bilateral veterinary agreements<sup>1</sup>. The agreements mostly contain provisions for import (and transit) of animals, animal products and exchange of information. Croatia will adapt or cancel any of these agreements with effect from the day of accession as required in relation to the *acquis* (all agreements can be terminated with 6 months notice). Croatia foresees no problems with acceding to international veterinary agreements of the Community. Croatia 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, European Commission for the Control of Foot-and-Mouth Disease (EUFMD), Council of Europe. Romania notified on 24<sup>th</sup> November 2006 through diplomatic channels about denouncement of the Agreement between Romania and Croatia on Veterinary-Sanitary Cooperation, signed on 29<sup>th</sup> September 1998. The Croatian side will accept the above mentioned denouncement of the Agreement and its validity.

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<sup>1</sup> Bilateral: Albania, Bulgaria, Czech Republic, Hungary, Slovenia, Turkey, Poland, Romania, Bosnia and Herzegovina, Serbia and Montenegro, Iran, the former Yugoslav Republic of Macedonia, Argentina, Brazil and India; Specific veterinary medicine agreement: Austria, Belgium, Russia, China and Canada.

The *Animal Protection Act* covers the area of animal protection including *animal welfare*, health and animal life. This Act provides the legal basis for a complete transposition of the *Acquis*. By this Act are determined the conditions for keeping, transporting and slaughter production animals, the obligation to register natural and legal persons keeping, transporting and slaughtering production animals, qualifications of persons keeping, transporting and slaughtering animals and the keeping of records. Pursuant to article 68 of the Veterinary Act the MAFWM (Veterinary Directorate) issues decisions for the transit of animal consignments. Each decision specifies veterinary conditions that the consignment of animals has to fulfil.

According to Croatia's assessment, a high level of alignment has already been reached with regard to legal transposition of the rules for laying hens, pigs, calves, transport of animals and conditions at the time of slaughter. Practical and financial problems for the implementation of EU rules can be expected in a number of fields, notably the conditions for laying-hens in non-enriched battery cages (80% of the consumer egg production might not meet EU requirements). Some difficulties are expected for rearing of pigs and calves in small farms, for instance in relation to floor surfaces and the length of pens. Equipping road vehicles with water tanks and suitable navigation systems will also require significant investments.

**Zootechnical issues** and breeding of domestic animals is regulated by the *Livestock Act* and other secondary regulations. The Croatian Livestock Centre, created by the government, organises and coordinates breeding activities and supervises the maintenance of central records. There are 80 registered breeders' organisations keeping herdbooks. In addition to activities related to registration of animals and maintenance of central records, testing of production capabilities, testing of breeding animals, and calculation of breeding values of animals are also carried out. For all domestic animal species, there are special breeding programmes with plans for new and genetically more valuable generations. Croatia cooperates with international organisations involved in genetic improvement of domestic animals, and is a full member of the International Committee for Animal Recording (ICAR), INTERBULL and the European Association for Animal Production (EAAP). As regards the transposition of Directive 90/428/EEC (horses for competition) Croatia plans to ensure the alignment as part of amendments to the Livestock Act.

With regard to *veterinary expenditure*, the *Veterinary Act* provides for compensation for animals that are slaughtered, damaged or destroyed as part of a defined veterinary measure. The funds for these compensations are collected from the fees for veterinary health checks and from the State budget. Croatia mentioned that there is a certain lack of flexibility in the plans for the suppression of infectious diseases due to the procedures of the State budget. In case of particularly dangerous infectious diseases, which require considerable financial resources, special budgetary decisions by the government are possible.

### **II.c. Placing on the market of food and feed**

The Veterinary Directorate of the MAFWM is responsible for: veterinary and sanitary conditions in slaughterhouses; processing establishments and facilities, animal products and animal feed factories. It also keeps the register of these establishments. Furthermore it is responsible for the disposal of animal by-products.

The *Food Act* and several Ordinances provide the legal framework for food business operation, whether processing or distribution. The current legislation only partially complies with the *hygiene rules* set by the *acquis*.

The Veterinary Directorate had registered 1492 establishments by the date of the screening meetings (number is subject to developments). Croatia still applies the "vertical approach" set by the previous EU legal framework for food of animal origin establishments. In the meat sector 30 establishments are approved for export to the EU, 673 are approved only for the domestic market or for export to third countries. In the milk sector 8 establishments are approved for export to the EU, 47 are approved only for the domestic market or for export to third countries. In the fishery sector 34 establishments are approved for export to the EU, 75 are approved only for the domestic market or for export to third countries. In the egg sector 55 establishments are approved only for the domestic market or for export to third countries. Informative meetings are organised throughout the country to give orientations on EU food safety requirements. Systematic inspections are being conducted in a pre-determined number of establishments (slaughterhouses and meat-processing plants) in order to determine the weak points of the existing system and to identify the necessary steps in order to achieve EU requirements. It is planned to categorise all establishments into four categories: A) already fulfil EU standards, B) EU standards achievable over a short period, C) EU standards achievable over a longer period, D) unable to achieve EU standards.

The *Veterinary Act*, the *Food Act* and their secondary regulations lay down the *specific rules for animal products* for all phases of production, processing, storage and distribution of food, of animal origin. Production and storage of foods of animal origin may be carried out only in approved establishments complying with these requirements and monitored by authorised veterinarians. Special requirements apply to vehicles used for the transport of consignments. Croatian legislation has not yet adopted provisions of the 2004 EU hygiene package. Food safety legislation in Croatia was mainly based on the previous *acquis*.

With regard to milk production, 70% of the cows are in small farms (five cows or less). This represents a particular challenge for the microbiological quality of raw milk due to the difficulty of improving the equipment and hygiene standards in small production units. Croatia addressed this problem by introducing a programme of restructuring the milk sector in 2004. The programme offers favourable loan conditions, and farmers are encouraged to improve their production systems by reconstructing or adapting their facilities.

Milk quality is tested by the Central Laboratory for Milk Control. Since the systematic control started in 2003, the quality of milk has gradually improved. In the first 6 months of 2006, 60% of the delivered milk fully met all EU standards regarding the count of micro-organisms and somatic cells. Croatia expects that the present positive trend will continue. An incentive structure is in place where the quality of the milk is directly linked to the price paid to the farmer.

Direct sales of animal products are wide-spread in Croatia, in particular from small farms in the context of local markets or agro-tourism activities. This primarily concerns the sales of milk and milk products (cottage and semi-hard cheese and cream) and, to some extent, traditional meat products and honey. Croatia does not have a complete list of milk and cheese processing farms that sell directly to the consumers, although some of these farms are registered among the farms that also deliver for dairies. The establishment of such a complete register is in an early stage and its completion is expected by the end of 2009.

Croatian legislation for fishing vessels is only partially aligned with EU requirements. The main issues that need to be addressed are: legal definitions, structural requirements, conditions for storage and containers, conditions for chilling, temperature for transporting products. Croatia does not have any registered refrigerator vessels or fish-processing vessels.

**Control rules** are determined by the *Food Act* and the *Ordinance concerning obligatory measures in approved establishments in order to reduce microbiological and other contamination of meat, meat products and other products of animal origin intended for human consumption* (OG 74/97), adopted pursuant to the *Veterinary Act*. The *Food Act* provides introduction of a system of self-control in all food business operators (except at the level of primary production) and feed business operators. The obligatory implementation of HACCP principles is foreseen by the provision of the *Food Act* (OG 85/2006) until the 01 January 2009. Furthermore, implementing conditions for the introduction of the system of self-control in food business operators are foreseen to be determined by MAFWM or the Minister for Health and Social Welfare, in accordance with the competencies provided by the *Food Act*. Thus, according to the above mentioned as well as with accordance to the *Ordinance concerning obligatory measures in approved establishments* (OG 74/97), obligation to introduce HACCP only applies for establishments approved by the MAFWM for export and is voluntary for other operators (until 01 January 2009).

Official controls of sanitary safety and hygiene of food, including controls of the implementation and efficiency of the system of self-control are conducted by sanitary or veterinary inspectors in accordance with the competencies defined by the Act. Croatia assesses that small establishments will have most problems with applying the principles of HACCP. 256 sanitary inspectors are in charge of the food safety control in establishments processing foodstuffs and on the market (60-70% of their work).

**Specific control rules for animal products** do not fully match the recent changes of the *acquis*. The inspection of establishments is performed by authorised (private) veterinarian organisations. These organisations are private and have a contract (authorisation) for 5 years in order to perform official duties (e.g. slaughterhouse inspection). The rules foresee a permanent veterinary attendance during the operation in slaughterhouses. Currently, all establishments are inspected by authorised veterinarians but it is planned to organise official controls aligned with Regulation (EC) 882/2004.

With regard to the **rules for animal by-products** not for human consumption, an Ordinance was issued in May 2006 that, according to Croatia, is almost fully aligned with EU requirements (Regulation (EC) No 1774/2002). Croatia has only one establishment for EU compliant processing material of Category 3, covering the whole country. A second establishment for thermal processing of by-products, a complete new construction is becoming operational on 15 December 2006 and ready for EU compliant processing material of Categories 1 and 2. A second establishment for thermal processing of by-products, a new construction, will become operational by the end of 2006 and ready for EU compliant processing material of Categories 1, 2 and 3. At the moment, Croatia does not have a sufficient number of collection centres for animal by-products as only two collection centres are approved (Rijeka and Pula). Two collection centres were recently approved (Grude and Biljane Gornje).

As regards the *acquis* for **funding of checks**, Croatia stated that its legislation is partially aligned. The *Veterinary Act* determines that fees for veterinary inspections and controls must be paid in favour of the State budget when these are carried out by official veterinarians. If they are carried out by authorised veterinarians, 15% of the fee must be earmarked for the Fund for Animal Health Protection, while 85% goes to the veterinary organisation that carried out the inspection. The level of fees is determined by an Ordinance that only partially uses the approach of the *acquis*. Rates applied for checks in the meat sector are in a number of cases well above the EU minimum rates.

## II.d. Food safety rules

The basic act in the field of food safety is the *Food Act*. Pursuant to this act, the Food Industry Directorate is responsible for foodstuffs, in particular with regard to labelling, natural mineral, natural spring and table waters, vertical regulations on quality, sampling methods and food quality analysis. The Ministry of Health and Social Welfare is in charge of the control of contaminants and pesticides in line with the *Food Act*. The control of these substances is carried out by the Croatian National Institute of Public Health and other regional Institutes of Public Health for the Ministry of Health and Social Welfare.

The field related to **labelling**, presenting and advertising food is the responsibility of the MAFWM with the close involvement of the Ministry of Health and Social Welfare (MHSW). Official control of implementation, presentation and advertising food is the responsibility of the sanitary inspection of the MHSW and the veterinary inspection of the MAFWM. At the level of retail the responsibility for inspection falls with the sanitary inspection, veterinary inspection as well as with the economic inspection of the State Inspectorate. The *Ordinance on general labelling or marking of foodstuffs* is partially aligned with the *acquis*. Further alignment is needed in particular as regards the adaptation of certain lists of food ingredients or substances, the labelling of certain foods, nutrition labelling and labelling of beef products. Full alignment in this field is expected in 2008.

The MHSW is responsible for the **food additives** and **extraction solvents** and the sanitary inspection of the MHSW is responsible for inspection in this regard. The field is regulated by the *Ordinance on food additives*. Croatia assesses that this Ordinance has achieved a very high level of alignment with the *acquis*. Croatia, however, points to a number of issues where further alignment is required, such as the allowed quantities of Na-cyclamate in non-alcoholic drinks, the use of colour E123 and the use of E425, which is prohibited in Croatia. Extraction solvents are provided for by the *Ordinance on Food Additives* but the permitted quantity of residues of extraction substances is in some cases higher than prescribed by the *acquis*. The plan for further alignment in the field of food additives and extraction substances implies the division of the *Ordinance on Food Additives* into three new Ordinances. The completion of the alignment is planned for 2008.

The field of **flavourings** is covered by the *Ordinance on Food Additives*, which is mostly aligned to the *Acquis* regarding food additives and only in basic definitions to the *Acquis* regarding flavourings. Completion of alignment is planned for mid 2007. The *Ordinance on sanitary safety requirements for articles intended to come into direct contact with food* regulates the field of **food contact material**. Croatia assesses that it has a high level of compliance with EU requirements. Croatia pointed out that there is still a need to align the criteria applicable for determination of N-nitrosamines and N-nitrosatable substances. An amended Ordinance will be drafted in 2007 with a view to adoption in 2008.

The field of **food supplements** and **fortified food** is regulated by the *Ordinance on food for particular nutritional uses* under the responsibility of the MHSW. The Ordinance on food for particular nutritional uses comprises the following parts: food for children, gluten free food, salt substitute, dietary foods for special medical purposes, food for weight reduction, food for persons suffering from diabetes, food with low, reduced and/or altered nutrient content, high-nutrient, nutrient-rich and/or nutrient-enriched food, food with a reduced or increased energy value, food supplements, food supplements for athletes. The Ordinance is aligned to the relevant EU requirements with exception only in one part - food for children (processed cereal-based foods) which is not aligned, as it is remarked in screening report. It is planned to amend the Ordinance in 2008. Croatia does not have special legislation in the

field of *quick-frozen foodstuffs*. It is planned to draft the relevant legislation to transpose the *acquis* in this field during 2007.

The field of *contaminants* falls within the responsibility of the MHSW and is regulated by the *Ordinance on toxins, metals, metalloids ad other harmful substances in food*. The maximum permissible levels have been transposed from the relevant *acquis*. Croatia's implementing legislation is, however, only partially aligned. Croatia pointed out that full alignment is still required as regards sampling and analysis methods for controls of levels of certain contaminants. It is planned to achieve this by 2008.

The field of *novel food and GMOs* is regulated the *Food Act* and the *Act on Genetically Modified Organisms* as well as by the Regulation on the level of GMOs in products below which the products shall not have to be labelled as products containing GMOs (0.9 % rule applies). Responsible are the MHSW and the MAFWM. Inspection supervision of the labelling of GMOs and/or products containing and/or consisting of, or originating from GMOs is under the competence of the State Inspector's Office. The Act on Genetically Modified Organisms provides the legal basis referring to the traceability of GMOs. It provides for development of the Unique GMO Register and for assignation of the unique code to each specific type of GMO, which would enable tracing genetically modified organisms in all stages of their placement on the market (defined in the EU by the Regulation 65/2004). Croatia does not yet uses GMO seeds. Full alignment with EU requirements is foreseen for 2008.

The field related to preservation of foodstuffs and general items by *ionising radiation* is regulated by the *Ordinance on requirements for preservation of foodstuffs and general use items by ionising radiation*. Responsible is the MHSW. The Ordinance is not in compliance with the *acquis*. The adoption of a new Ordinance is foreseen for 2007 with a view to achieving compliance with the *acquis*.

The field of *mineral waters* is regulated by the *Ordinance on natural mineral, natural spring and table waters*. Responsible is the MAFWM. A specific Committee provides technical opinions before the MAFWM can deliver the marketing authorisation. Partial compliance with the *acquis* has been achieved. Further alignment is planned for 2007.

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

The Veterinary Medicine Directorate within MAFWM is responsible for the production, control and putting on the market of animal feed. Laboratory tests are performed by the Croatian Veterinary Institute. In line with the *Livestock Act*, the administrative and inspection supervision over animal feed quality is performed by livestock inspectors. Croatia's legislation is in partial compliance with the *acquis*. Further steps are planned in this respect for 2007.

Pursuant to the *Veterinary Act* and the relevant Ordinance, establishments in the field of animal feed must be approved. The approval procedure is based on the procedure prescribed in EU rules. Approval was granted to 66 feed mills and 33 farm mills, as well as 5 establishments for 'pre-mixes' production and 78 quarantine storage premises intended for animal feed import. The rules for the conditions that these establishments must fulfil are currently under revision. Croatia has applied a meat-bone-meal (MBM) feed ban since 2001.

The national list of permitted *feed additives* was aligned with the EU *acquis* end of 2006. The use of antibiotics is not aligned with EU rules. Labelling of *compound feed* is regulated

by the *Ordinance on the quality of animal feed*. Croatia assesses that the rules are aligned with EU requirements.

With regard to **undesirable substances**, the *Ordinance on the quality of animal feed* lays down detailed rules as regards prohibited and harmful substances, i.e. maximum permitted amounts of undesirable substances in the feedingstuffs and in the mixtures of feedingstuffs. The list of substances covered is not fully compliant with EU rules. A fully aligned Ordinance is planned for 2007. Croatia has not aligned its legislation related to **feedingstuffs intended for particular nutritional purposes** and **certain products use in animal nutrition (bioproteins)**. Current planning foresees the alignment by mid 2007. Regulations with regard to undesirable substances, feedingstuffs intended for particular nutritional purposes and certain products used in animal nutrition (bioproteins labelling of compound feed) are on the list for transposition according to NPIEU (National Programme for the Integration of the Republic of Croatia into the European Union) for 2007.

**Medicated feedingstuffs** may only be manufactured in the establishments to which the Ministry of Agriculture, Forestry and Water Management granted approval to manufacture medicated feedingstuffs. The use of antibiotics as veterinary drugs via medicated feed is regulated by the *Ordinance on the conditions governing the preparation, placing on the market and use of medicated feedingstuffs* (OG No. 105/2005), which is aligned with the regulation of the EU. Control of the use of antibiotics, anticoccidiostatic substances and growth promoters in the animal feed is carried out by means of systematic monitoring.

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

The Ministry of Health and Social Welfare is in charge of the control of contaminants and pesticides in line with the Food Act. The control of these substances is carried out by the Croatian National Institute of Public Health and other regional Institutes of Public Health for the Ministry of Health and Social Welfare.

The basic act with regard to the rules for **plant health (harmful organisms)** is the Plant Protection Act. This Act provides for regular mandatory plant health checks during the vegetation period of all domestic production of seeds and propagating material, crops and facilities at the production site as well as growing media on which such plants are cultivated. These provisions of the Plant Protection Act will be replaced in January 2008 by the provisions of the Plant Health Act that will introduce the use of plant passports.

The mandatory plant health checks are conducted by experts from the Plant Protection Institute in cooperation with the Institute for Seeds and Seedlings. The Plant Health provides the phytosanitary inspection service with the competence to carry out phytosanitary inspections of plants, plant products and other regulated objects at any time and at any place where they are produced, moved, processed, stored, sold or used in some other way. The forestry inspection is in charge of inspecting forestry plants.

Consignments of plants, plant products and other regulated objects being imported, which may carry organisms harmful to plants, have to undergo a phytosanitary inspection at the point of entry into the Croatia. There are 41 points of entry – 15 at road border crossings, 8 at rail border crossings, 7 at seaports, 2 at river ports, 4 at airports and 5 at post offices for customs clearance. Croatia made clear its intention to substantially reduce the number of crossing points before accession. Cooperation with customs is based on the Plant Health Act and secondary legislation.

Croatia assesses that its legislation with regard to phytosanitary controls at import is very close to full compliance. Substantial efforts are, however still necessary to ensure the effective enforcement of EU rules for performing phytosanitary inspections, improving the capacity of phytosanitary inspectors, and developing the necessary laboratories.

Croatia's list of quarantine pests was last amended in 2001. It is closely based on the European and Mediterranean Plant Protection Organisation (EPPO) list of quarantine pests. The Croatian lists do not include pest specific for crops that are not grown in Croatia. Croatia's list of quarantine pests follow the same structure as the EU list but is not identical to the EU list. According to a detailed analysis undertaken in 2005, there are approximately 100 differences between the two lists. The main reason for the differences is that the presence of crops and pests in Croatia is different from that in the EU. Croatia plans to gradually adapt its list in order to achieve full compliance by accession.

Since 2001, Croatia conducts systematic surveys on the basis of annual plans in order to establish the presence or absence of harmful organisms. The annual programme determines the number and species of harmful organisms to be surveyed as well as the mode of conducting the survey. Croatia provided an overview of the results of these surveys. The Plant Health Act provides for the possibility of protected zones. It is foreseen that more detailed rules will be issued in implementing regulations. The provisions will only enter into force upon accession to the EU.

The Plant Health Act lays down the obligation of official registration of any operator engaging in the production, processing, introduction from third countries or distribution of specific plants, plant products or other registered object, including collective warehouses and dispatching centres. The provisions are in line with EU requirements but will only be applicable in Croatia from 1 January 2008. All producers and importers of seeds and propagating material who meet certain conditions must be entered into official registers

With regard to **plant protection products** the procedure for granting authorisation for active substances and plant protection products are determined by the Plant Protection Act (until the commencement of the new Act on Plant Protection Products). The procedure involves the MHSW as well as the MAFWM. According to the latest processed data, the number of approved active substances in Croatia is 283. Croatia provided detailed information about differences between EU lists and the Croatian list. As regards prohibited active substances the Croatian list is in full compliance, while there are certain differences with regard to the status of active substances for which the EU has adopted a decision of non-inclusion in Annex I to Directive 91/414/EEC.

As regards pesticide residues, a special Commission set up under the MHSW pursuant to the Food Act establishes Maximum Residue Levels. The definition of these levels is based on international recommendations (FAO/WHO – Codex Alimentarius) and EU legislation. New implementing legislation is under preparation in order to setting out more clearly the roles and responsibilities of the definition of maximum residue levels.

Controls with residues are the responsibility of the MHSW, with the consent of the MAFWM. Annual programmes for such controls must be established. Croatia assesses that the basic principles for these inspections are in line with EU requirements.

**Quality of seeds and propagating material** is the responsibility of the Institute for Seed and Seedlings, which is an authorised institution for seed certification. The Act on Seeds, Planting Material and Registration of Plant Varieties, which will apply from 1 January 2008, will ensure certification fully in line with EU requirements. The Institute for Seed and

Seedlings is responsible for conducting field inspection to control agricultural propagating material. Such field inspection is based on performing compulsory examinations of seed crops of fodder plants, cereals, oil and fibre plants, beets, vegetables and potatoes in order to determine the origin of seeds, species purity, varietal identity and purity, seed categories, sanitary status for the purpose of seed certification. The Institute maintains official lists of varieties that can be placed on the market in Croatia.

**Plant variety rights** are regulated by the Plant Variety Protection Act which is aligned with the International Union for the Protection of New Varieties of Plants (UPOV) convention. Croatia became a member of UPOV in 2001. Croatia recognises and confirms the UPOV 1991 Convention and has adopted the Regulation on the accession to the International Convention for the Protection of New varieties of Plants. Breeders' rights can be obtained through an administrative procedure under the responsibility of Department for the registration and the protection of new plant varieties within the Institute for Seed and Seedlings. Rights are granted on the basis of "novelty, distinctness, uniformity, stability and denomination".

With regard to **international phytosanitary agreement**, Croatia has concluded a number of bilateral agreements on cooperation in the field of plant protection, mainly with other countries in the region<sup>2</sup>. The agreements aim at facilitating the exchange of plants and plant products. Croatia foresees to adapt or cancel any of these agreements with effect from the day of accession as required in relation to the *acquis*. All agreements can be terminated with a notice of 6 months.

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

Overall, Croatia has reached a reasonable level of alignment in the preparation for accession.

Croatia has worked over the past years intensively on transposition and implementation of the EU *acquis* in the fields covered by this chapter. In most fields concrete steps have been taken to transpose the *acquis* and a detailed analysis of remaining gaps has been made. A good understanding of the *acquis* on the Croatian side was demonstrated during the screening and efforts to prepare for EU requirements have been made in all major areas. A substantial amount of work remains, however, as regards transposition of requirements of the EU *acquis* in particular as regards the adoption of a new legislative framework which complies with the EU *acquis*. It is essential that a comprehensive food safety strategy covering all aspects of food safety, veterinary and phytosanitary legislation is elaborated in order to serve as a basis for a global transposition in the food sector. Specific attention will be required as regards the control and eradication of Classical Swine Fever.

The necessary institutions for implementing and enforcing the *acquis* for food safety and veterinary and phytosanitary legislation are in general in place but adequate capacity needs to be ensured. The pending revision of the legislative framework should clarify the competences as regards the food chain. Disputes between veterinary and food inspectors are affecting the efficiency of controls. It is crucial to solve the issue of overlapping of competences by a coherent repartition of responsibilities. Provisions for the functioning of a bovine animal identification and registration system needs to be secured and extended to pigs, caprine and ovine animals.

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<sup>2</sup> Albania, Bulgaria, Czech Republic, Hungary, the former Yugoslav Republic of Macedonia, Montenegro, Poland, Slovak Republic, Romania, Serbia and Turkey.

The *acquis* in the field of food safety and veterinary and phytosanitary legislation requires substantial administrative capacity. 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 is in particular the case for the competent authorities provided for by the *acquis* as well as laboratories and border inspection posts (BIPs). The provided overview of relevant laboratories is a useful basis for the work to ensure that Croatia will have the necessary laboratory capacity before accession. Before elaborating a national plan for the upgrading of food establishments, Croatia needs to classify its current establishments based on the EU *acquis*.

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

Croatia's general legislation on food safety covers all main areas of EU food law and makes out a good basis for the further work to achieve full compliance with EU requirements. The detailed gap analysis provided by Croatia points to a good understanding by the authorities as regards legislative and administrative requirements as well as the need to upgrade inspection and laboratory capacity. Substantial efforts are, however, still needed in order to ensure full compliance. 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. The elaboration of a comprehensive strategy covering all aspects related to food safety should be strongly encouraged as the main priority at the present stage. Such a plan should emphasise the thorough preparation of framework laws that can serve as the basis for a comprehensive transposition of all parts of the *acquis* in this chapter.

As evident from the provided gap analysis, Croatia's Food Act already takes into account many aspects of the *acquis* but will need to be amended in a number of fields, in particular as regards the precise competencies of various authorities, the responsibilities of operators, basic functions such as risk assessment and risk management, as well as the definition of various terminology applied by Community food safety legislation. It is of particular importance that the new Food Act is drafted in a way that ensures full compliance and facilitates the transposition of secondary legislation.

EU requirements regarding the role of the European Food Safety Authority and the rules regarding the rapid alert system, emergency measures and crisis management can only be taken fully into account from the day of Croatia's accession. Croatia's legislation and administrative control system in these fields should however be prepared well in advance of accession.

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

As evident from the detailed gap analysis presented by Croatia, its legislation in the veterinary field covers all main areas of the *acquis*. The degree of compliance of its present legislation is, however, uneven. Croatia is in the process of preparing comprehensive amendments of the Veterinary Act, which will serve as the basis for bringing a substantial amount of secondary legislation into full compliance. It is of substantial importance that the preparation of such framework laws is done thoroughly and in a way that facilitates the introduction of the secondary legislation.

Croatia's veterinary services are in general professional and effective but a careful assessment of staff, resources and organisation will need to be made to ensure the necessary administrative capacity at the of accession.

In respect of the ***control systems in the internal market***, the basic challenge for Croatia 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. Croatia will be faced with the task of maintaining the efficiency of the national control system until the day of accession and at the same 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, preserving the safety of other member states by all necessary means including the competence to block specific regions of Croatia.

Croatia has already taken steps to ensure some degree of compliance with EU principles of the internal market control system in its legislation. As evident from the information provided by Croatia, amendments of the legislation are, however, still required, in particular with regard to the introduction of the system of disease free regions, the models of certificates, establishing electronic information exchange (TRACES) and registering markets, animal traders and transporters.

As regards the ***control system of imports***, some efforts have already been made to take EU requirements into account in the existing import rules of Croatia. As evident from the analysis provided by Croatia, a coherent effort will be necessary to ensure full compliance of legislation, including the detailed procedures for the inspection at the borders. Inspection services will need to be upgraded in terms of infrastructure, equipments and staff resources. Whereas the controls at the future internal EU borders will be abolished, controls at the future external EU borders must be 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, Croatia will need to fully clarify its plans for the locations of the posts that will remain after accession.

Croatia has achieved some results in the area of ***identification and registration of animals***. As regards bovine animals, Croatia needs to increase the speed of notification and review the system of numbering (identification and holding codes). Croatia should be encouraged to maintain the good progress to ensure that remaining gaps are addressed in an orderly and well-planned way in good time before accession, in particular setting up a central computerised database for porcine, ovine and caprine animals. The system needs some improvement and its continuity must be guaranteed. Some controls of holdings have been carried out but insufficient cooperation between the various officials involved has to be corrected. The system for bovines should also be extended to other species. It is vital for Croatia to have a fully operational identification and registration system for bovines, ovine, caprine and porcine animals in order to control animal diseases. The system will also ensure the traceability of animals and their products required by the *acquis*.

The veterinary services of Croatia in general deal with ***control measures of animal diseases*** in a professional and effective way. Resources and qualifications are adequate for undertaking the necessary control measures for animal diseases in accordance with international standards. Croatia applies international veterinary standards and has made efforts to take into account specific EU requirements. It therefore has a relatively high level of legal compliance with regard to some diseases whereas substantial work is still outstanding for other diseases. The prohibition of vaccination against Classical Swine Fever constitutes an important step towards meeting EU requirements but the development must be followed closely. Swill feeding should be gradually phased out. Sustained efforts and detailed monitoring of the continued progress will be necessary before it can be decided to

allow pigmeat from Croatia to circulate in the internal market. Due to the presence of the disease an efficient plan for control and eradication of classical swine fever in domestic pigs and wild boars is necessary. Provision for *intra-community trade for live animals, semen, ova and embryos* are largely aligned with the *acquis*. Croatia will need to set rules for accepting EU certificates. As regards the *non-commercial movements of pet animals*, animal health certificates for pets are partially aligned with the model passport for intra-Community movements of dogs, cats and ferrets. Croatia expects to align its legislation by end of 2006.

As regards *prohibition of substances and residues control*, Croatian legislation is partially aligned with the *acquis*. Further efforts must be made to ensure full compliance, in particular as regards issues such as: definitions of classifications of prohibited substances and improvement of forms, lists and procedures. Attention must be given to the control and inspection bodies, including in particular the testing and laboratory capacity. In addition the performance of the residue control system is affected by deficiencies related to analytical capability of laboratories and the absence of mandatory substance groups in the national residue control plan. The list presented by Croatia of measures planned to address particular difficulties with regard to the implementation of the annual National Residue Monitoring Plan is a good basis for sustained improvement. Rules on *import requirements for live animals and animal products* will only be legally fully applicable upon accession. However, it is up to Croatia to ensure the necessary preparation for implementation of the EU *acquis* by accession.

Croatia signalled that it will review its *international veterinary agreements* by accession. Croatia will need to prepare new framework legislation in the field of *animal welfare* in order to ensure the necessary basis for compliance with the *acquis*. According to the detailed overview given by Croatia, a high level of formal compliance has already been achieved with regard to legal transposition although the rules are not yet applicable. As announced by Croatia, particular problems can be expected with regard to laying-hens in battery cages, the rearing of pigs and calves in small farms and the equipment of road vehicles used for animal transport. 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 step to effectively comply with EU requirements upon accession at the latest.

With regard to *zootechnical issues*, Croatia will need to take the necessary steps to ensure that all EU requirements are fulfilled. As regards *veterinary expenditure*, Croatian legislation is only compliant with the *acquis* to a limited degree. Further efforts must be made to ensure full transposition of the *acquis*.

### **III.c. Placing on the market of food and feed**

Croatian legislation with regard to *hygiene rules* and *specific rules for animal products* has been only brought partially into compliance with the *acquis* and will need to take into account the "food safety package" of 2004 and its relatively recent implementing rules. This is understandable and acceptable at this stage. As pointed out by Croatia substantial amendments or replacements of current rules if necessary will be required to achieve full compliance, in particular as regards the implementation and enforcement of legislation, the obligations of food business operators, classification of establishments, data exchange on the food chain and a number of sector-specific requirements. Croatia has made little progress in building up registers of establishments and classifying them according to the degree of compliance with EU standards. An important number of establishments have been approved for exports to the EU. However, a substantial proportion of the establishments currently do not meet all EU requirements. Croatia has to prepare a plan for modernisation of its

establishments. IPARD funding will be available to support these restructuring of establishments. As part of this plan, efforts should be made to inform the operators and encouraged the upgrading process. Particular efforts must be taken to support small establishments in meeting EU requirements. Drafting of individual plans for each establishment indicating their particular short-comings and plans to remedy will have to be prepared at a later stage. No information was provided on establishments in the sector of food of non animal origin.

The official administrative bodies and inspectorates will need to be upgraded to ensure an efficient implementation of EU **control rules** but it is essential that also 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. Particular attention must be given to the obligation to apply HACCP principles in all establishments. Efforts must also be made to develop the inspection system and, in particular, to ensure that the inspectors have a thorough knowledge about the relevant EU requirements related to **specific control rules for animal products**.

Croatia has made good progress in recent years with regard to the quality of raw milk, although full compliance with EU rules will still require efforts focusing on both the conditions in the farms and the collection system. The system of payment for milk deliveries that gives an incentive to improve milk quality can be an important instrument in this respect.

With regard to the direct sales from farms, and in particular cheese products, Croatia should improve the registration of the producers and to make efforts to improve the hygiene conditions in this respect. The traditional production, processing and distribution of fresh cheese, in particular, is important for many small farms and for agro-tourism and Croatia should be encouraged to be in compliance with the *acquis*.

Croatia needs to make some further efforts to ensure full legal compliance with EU requirements as regards **animal by-products**. The creation of adequate collection and treatment capacities of animal by-products, including the proper handling of Specified Risk Material (SRM), should be a priority during the pre-accession phase. The evolution of the situation must be closely monitored on the spot. The Croatian rules for **funding of checks** differ to a large degree from the *acquis*. Further efforts must be made to ensure full transposition and implementation of the *acquis*.

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

The Croatian Food Act and its pursuant secondary legislation take into account the main areas regarding food safety rules. Progress has been made in taking over EU requirements. The responsibility in this field is shared between the Ministry of Health and Social Welfare and the Ministry of Agriculture, Forestry and Water Management. Attention must therefore be given to ensure that the responsibility for the various initiatives is clearly placed. The authorities should maintain the good pace of harmonisation.

According to the detailed analysis provided by Croatia, a reasonable level of legal compliance has been reached in the fields of **food additives, extraction solvents, flavourings** and **food contact material** (determination of vinyl chloride monomer released is, however, still missing), whereas partial alignment has been achieved in the field of **labelling**, presenting and advertising food. Croatia has to review the legalisation regarding **food supplements** (including **fortified food** and **food for particular nutritional uses**), where provision for cereal based food and baby foods for infants needs revision. Maximum

permissible levels (MPL) of *contaminants* need to be brought in line with EU standards. Progress has been limited in the fields of *quick-frozen foodstuffs* (where a basic legal is missing), *novel food and GMOs* (where the Act on GMOs needs to be enforced), preservation of foodstuffs and general items by *ionising radiation* (radiation doses need revision). Partial alignment was also reached in the area of *mineral waters*. Croatia plans to achieve a high level of compliance in most of these fields by mid 2007, and to be fully compliant by the end of 2008. The further process of transposition and implementation will need to be closely monitored.

### III.e. Specific rules for feed

As evident from the analysis provided by Croatia, legislation as regards the specific rules for feed is still some way from full compliance. Further work with transposition is required in particular as regards the conditions for feed establishments, the list of permitted *feed additives* (use of antibiotics) and the list of *undesirable substances*. Legislation as regards *medicated feedingstuffs* needs to be further aligned with the *acquis*. Labelling of *compound feed* can be considered as well advanced. The further process of transposition and implementation will need to be closely monitored. Croatia has to align its legislation related to *feedingstuffs intended for particular nutritional purposes* and *certain products use in animal nutrition (bioproteins)*. Particular attention must also be given to the planning, coordination and organisation of official feed controls and ensuring that the feed business operators are informed about EU requirements and make the necessary preparations before accession.

### III.f. Phytosanitary policy

Croatia has made substantial progress in the phytosanitary field. As regards the *acquis* for *plant health (harmful organisms)* a good level of compliance has already been achieved in many fields. Further work is however required to achieve full compliance. Croatia must move from a national control system protecting the own territory to a system without controls at the internal EU borders but based on the implementation of the same rules by the authorities in the Member States, emphasis on controls at the place of origin and non-discriminatory controls during transport and at the place of destination . Croatia will be faced with the challenge of maintaining the efficiency of the national control system until the day of accession and at the same time preparing well in advance of accession for the entry into force of the internal market control system. Considering its application of international standards and its efforts to take over the *acquis*, Croatia has already ensured a good level of compliance with measures related to harmful organisms. Croatia maintains a system of mandatory health checks. There is, however, a need to ensure that these checks follow EU requirements and that both inspectors and operators are made aware of the detailed EU rules. There is also a need to monitor to what extent procedures for import controls and surveys comply with EU standards. Croatia will need to adopt the EU list of quarantine pests adopted to the phytosanitary status of the enlarged EU. Croatia has to ensure that the lists of officially registered operators are kept in accordance with the *acquis*.

In the field of *plant protection products*, further transposition of the *acquis* is still required. According to the detailed information provided by Croatia, it is in full compliance as regards the list of prohibited active substances but will need to address certain differences for the status of authorised active substances. As regards pesticide residues, Croatia's legislation and administrative practices are based on international standards and on the EU *acquis* but there is a need to closely monitor further preparations to ensure effective implementation.

As regards *quality of seeds and propagating material* new legislation is required. Croatia plans to achieve full compliance as regards registration by the beginning of 2008. Particular attention must be given to ensuring implementation of this new legislation. There is a need to ensure that inspectors are fully aware of EU requirements and that operators are also informed.

As regards *plant variety rights*, Croatia is a member of the International Union for the Protection of New Varieties of Plants (UPOV) and good progress has been made in aligning with EU requirements. Croatia signalled that it will review its *international phytosanitary agreements* by accession.