

# **TRENDS IN FOOD LEGISLATION IN SOUTHEASTERN EUROPE: LESSONS FROM A REGIONAL TECHNICAL COOPERATION PROJECT**

**SYNTHESIZED BY  
JULIA ROGERS**

*based on the work of  
Carmen Bullón Caro, Ariella D'Andrea,  
Melvin Spreij and Jessica Vapnek*

**FAO  
LEGAL PAPERS  
ONLINE #74  
September 2008**

**FAO Legal Papers Online** is a series of articles and reports on legal issues of contemporary interest in the areas of food policy, agriculture, rural development, biodiversity, environment and natural resource management.

**Legal Papers Online** are available at [www.fao.org/legal/prs-ol](http://www.fao.org/legal/prs-ol)

For those without web access or email, paper copies of Legal Papers Online may be requested from the FAO Legal Office, FAO, Viale delle Terme di Caracalla 00153, Rome, Italy, [devlaw@fao.org](mailto:devlaw@fao.org). Readers are encouraged to send any comments or reactions they may have regarding a Legal Paper Online to the same address.

The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the United Nations or the Food and Agriculture Organization of the United Nations concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

The positions and opinions presented do not necessarily represent the views of the Food and Agriculture Organization of the United Nations.

© FAO 2008

This paper summarizes the work carried out and the regional trends observed under a FAO Technical Cooperation Project, TCP/RER/3002, entitled “Strengthening Food Safety in South East European Transition Countries: A Regional Approach to Food Legislation and Control”.

The Development Law Service would like to thank Mary Kenny, Nutrition Officer (Food Control and Consumer Protection) for her leadership during the life of the project, as well as the many national counterparts and national legal consultants in the participating countries for sharing their expertise.

# CONTENTS

|    |                                                                       |    |
|----|-----------------------------------------------------------------------|----|
| 1. | <b>Introduction</b> .....                                             | 1  |
| 2. | <b>International Context</b> .....                                    | 1  |
|    | <i>World Trade Organization</i> .....                                 | 2  |
|    | <i>Codex Alimentarius</i> .....                                       | 3  |
|    | <i>World Organisation for Animal Health</i> .....                     | 3  |
|    | <i>International Organization for Standardization</i> .....           | 4  |
| 3. | <b>Regional Context</b> .....                                         | 5  |
| 4. | <b>National Legal and Institutional<br/>Frameworks for Food</b> ..... | 7  |
| 5. | <b>Overview of Project Findings</b> .....                             | 8  |
| 6. | <b>Country Reviews</b> .....                                          | 9  |
|    | <i>Albania</i> .....                                                  | 9  |
|    | <i>Bosnia &amp; Herzegovina</i> .....                                 | 10 |
|    | <i>Bulgaria</i> .....                                                 | 12 |
|    | <i>Croatia</i> .....                                                  | 13 |
|    | <i>Kosovo</i> .....                                                   | 14 |
|    | <i>Moldova</i> .....                                                  | 15 |
|    | <i>Romania</i> .....                                                  | 16 |
|    | <i>The Former Yugoslav Republic of Macedonia</i> .....                | 17 |
| 7. | <b>Regional Trends and Recommendations</b> .....                      | 19 |

## 1. Introduction

Over the last decade, there have been significant changes in the national and international regulatory frameworks governing food control, food safety and food trade. The recognition of the Codex Alimentarius as the benchmark of international food standards for food safety by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) in 1995 is one of the most significant recent influences on food regulation worldwide, and can be seen as an acknowledgment of the increasing globalization of food production and food trade. Global outbreaks of food-borne disease, with concomitant media attention and outspoken consumer concerns, have also triggered unprecedented interest in food control and food regulation and in the country-level infrastructures that govern food safety and food quality.

A variety of developments have driven these changes and placed food safety high on the international agenda. International trade in food has grown enormously as countries rely on one another to secure an adequate and varied food supply through the import and export of food products. This has both raised the potential for countries to export products and increased the risks of the spread of food-borne disease due to the ease of moving food products from place to place. At the same time, the lowering of trade barriers has raised fears among some countries that their exports will not be competitive on the market or that other countries may "dump" unsatisfactory products in their markets because of the lack of appropriate legislation and enforceable controls. Furthermore, domestic food producers may face competition from imported foods of lower price and higher quality.

Countries are gaining greater access to export markets, but this has been accompanied by greater competition and the need to ensure confidence in the safety of the food supply. Toward this end, many countries have begun reviewing their institutional and legislative frameworks for food control in order to identify gaps and overlaps in responsibilities, and to assign ultimate authority for carrying out food control and food safety activities.

Responding to requests from FAO member country governments in the Southeastern European region, FAO launched a two-year Technical Cooperation Project entitled "Strengthening Food Safety in South East European Transition Countries – A Regional Approach to Food Legislation and Control" in 2005. The project was implemented in eight countries: Albania, Bosnia & Herzegovina, Bulgaria, Croatia, Kosovo, Moldova, Romania and The Former Yugoslav Republic of Macedonia. The foremost goal of the project was to draft a national food safety strategy for each participating country, aimed at modernizing and strengthening the national food safety system. The process also included a review and analysis of each country's national food safety legislation and the improvement of its institutional framework for food safety and food control.

This paper sets out the results of the project, with an emphasis on the legal component. After first providing an overview of the international context for food regulation and standard setting, the paper reviews the situation in the region and outlines the findings of the FAO international and national legal experts with respect to each participating country. The discussion outlines progress made until now as well as ongoing challenges, and identifies areas where governments should direct future efforts. The paper concludes by drawing out regional themes and recapitulating the project's legal consultants' main recommendations.

## 2. International Context

In most countries worldwide, central governments assign responsibility for human health protection to local authorities on the assumption that they are best able to address local problems through locally tailored solutions. The regulation of safety and quality of foods is generally administered at national and regional levels. Nonetheless, at the outset of the 21<sup>st</sup> century it is impossible to ignore the international context within which national regulation takes place, as international issues have grown in prominence and influence in recent years. This is because of both the extraordinary interdependence of

nations in the trade arena, as well as the growing recognition on the part of national governments of the need or the obligation to base their own national standards on those prepared under the auspices of international or regional organizations.

Numerous governmental, intergovernmental and nongovernmental organizations (NGOs) are active to varying degrees in the formulation of food standards and the search for solutions to global food problems. United Nations (UN) agencies, NGOs, advocacy groups and treaty bodies devote their resources and expertise to one or more of the food-related issues of interest to governments. Accordingly, this section briefly examines some of the most influential international organizations in this area. These bodies serve as fora for governments and other parties to discuss and resolve food-related concerns and to develop international food standards. Such efforts result in the dissemination of guidelines and other forms of advice to national governments and provide a framework for the international trade of food.

### ***World Trade Organization (WTO)***

The World Trade Organization (WTO), located in Geneva, is the international body that deals with rules of the multilateral trade system among states. Its objectives are to help trade flow as freely as possible, to liberalize trade through negotiation and to set up an impartial dispute settlement system. As of July 2008, WTO membership included 153 member states and the European Union (EU), and many other countries are negotiating membership.

At the heart of the WTO are trade agreements, ministerial decisions and declarations that provide the legal ground rules for international commerce. All WTO members have signed and ratified the agreements, and all are bound by the agreements' provisions and requirements. Most prominent is the Marrakesh Agreement (1994) establishing the WTO, which serves as an umbrella agreement, and annexed to it are various agreements on trade in goods and services, trade-related aspects of intellectual property rights, dispute settlement, trade policy reviews, some plurilateral agreements and a number of ministerial declarations and decisions.

Currently, there are about 60 such agreements, declarations and decisions in place.

The SPS Agreement sets out the rights and responsibilities of WTO members wishing to apply measures to protect human and animal life and health (sanitary measures) and plant life and health (phytosanitary measures). For food safety, the SPS Agreement encourages WTO members to base their national measures on the international standards, guidelines and recommendations adopted by the Codex Alimentarius Commission (Codex). Although the SPS Agreement acknowledges the limitations of means, it encourages the participation of member states in Codex and the other international standard-setting organizations (the World Organisation for Animal Health (OIE) for animal health issues and the International Plant Protection Convention (IPPC) for plant health matters), so that they can contribute to the formulation of sanitary and phytosanitary measures and have sufficient information to make decisions regarding the approval of international standards.

The main implication of the SPS Agreement for national legal frameworks is that so long as a WTO member state employs international standards in the formulation of its national measures, these are presumed to be consistent with the provisions of the agreement. However, member states are allowed to adopt measures that establish a higher level of protection than that provided by the relevant international standard if there is a scientific justification, based on risk assessment. Measures may not arbitrarily or unjustifiably discriminate between member states where identical or similar conditions prevail, and importing member states are obliged to accept the measures of other member states as equivalent if the exporting country objectively demonstrates to the importing country that its measures achieve the importing country's appropriate level of protection.

The WTO Agreement on Technical Barriers to Trade (TBT Agreement) seeks to ensure that technical regulations and standards, including packaging, marking and labelling requirements as well as testing and certification procedures, do not create unnecessary obstacles to international trade. The TBT Agreement covers all

technical standards not covered by the SPS Agreement, and applies to all food products, including agricultural ones. Unlike the SPS Agreement, the TBT Agreement does not recommend reliance on a specific international standard-setting body.

### **Codex Alimentarius Commission**

Heightened interest in food safety and quality issues as well as increased concern about the potential for food standards to be applied as trade barriers led to the establishment of the Codex Alimentarius Commission by resolution of the governing bodies of FAO in 1961 and the World Health Organization (WHO) in 1963. Codex was established at a time when food trade was increasing, and harmonization of standards and requirements was considered an important factor in facilitating fair trade. Codex is an international body that brings together scientists, technical experts, government regulators and international consumer and industry organizations to develop food standards. The primary objectives of Codex are to protect consumer health and to ensure fair practices in food trade through the elaboration and harmonization of food standards and other related texts. Its standards, guidelines and recommendations on food safety are specifically mentioned in the SPS Agreement,<sup>1</sup> so any WTO member that adopts them is presumed to be in full compliance with the relevant requirements of the SPS Agreement.<sup>2</sup>

Codex membership is open to all members of FAO or WHO; as of July 2008, it included 174 countries and the European Community. The Codex Secretariat is based at FAO headquarters in Rome. All standards adopted are included in the Codex Alimentarius (Latin for "food code"), which has become the authoritative collection of internationally adopted food standards covering all the principal foods traded internationally, whether processed, semi-processed or raw. The Codex Alimentarius includes standards such as maximum residue limits established for pesticides in foods and animal feeds, residue levels for veterinary drugs in foods of animal origin

and acceptable levels of food additives and maximum limits for contaminants.

The preparation of draft food standards and related texts, whether intended for worldwide use, for a given region or for a select group of countries, takes place in Codex committees. In recent years, there has been a shift in focus to address food safety and human health concerns as well as quality concerns. Thus, within Codex attention has turned to "horizontal" subjects – food hygiene, labelling, additives and contaminants – which, unlike vertical standards, apply across different types and classes of foods.

National inputs into the contents of the many Codex standards and guidelines are solicited, compiled and considered through Codex Contact Points (CCPs), national offices responsible not only for circulating information received from the Codex Secretariat to national stakeholders but also for sending country comments back to the Secretariat. In addition to designating a CCP, a number of countries have established a National Codex Committee to ensure that all relevant national stakeholders can contribute to the work of Codex, including by participation in the elaboration of Codex standards and other instruments. A National Codex Committee can serve as a national forum in which representatives of food industries, consumers and the relevant government authorities discuss the implications of proposed standards and thus contribute to Codex deliberations. Many National Codex Committees are also charged with proposing draft standards, regulations and other instruments to update and improve the country's regulatory framework for food.

### **World Organisation for Animal Health**

The World Organisation for Animal Health, which retains its French acronym "OIE", is an international organization created in 1924 and located in Paris. With 172 member states as of August 2008, its objective is to guarantee the transparency of animal disease status in countries around the world by collecting, analysing and disseminating scientific veterinary information. OIE member countries, usually through their official veterinary services, commit to collecting information on animal diseases in

<sup>1</sup> See Preamble and Article 3.4.

<sup>2</sup> See European Communities – Trade Description of Sardines, WT/DS231/R, 29 May 2002.

their territories. The OIE also provides expertise and technical support to member countries requesting assistance with animal disease control and eradication operations, including for diseases transmissible to humans ("zoonoses"). In addition, the OIE develops standards for international trade in animals and animal products which, as is the case for Codex standards, enjoy the presumption of being in accordance with the SPS Agreement.

OIE's animal health standards are developed and revised by OIE Specialist Commissions, and arise from a consensus of experts from OIE member states. Historically, these standards were not mandatory for OIE member countries. The codes and diagnostic manuals recommend rather than command, and the OIE does not have the remit or the administrative capacity to verify if member countries have implemented its recommendations. However, after the establishment of the WTO and the coming into force of the SPS Agreement, the OIE became the principal reference body for international standards concerning animal health, and accordingly standard-setting rose in importance as a primary task of the OIE alongside its traditional role of reporting disease information and disease control methods. Since all WTO members (i.e. most OIE member states) must comply with the SPS Agreement, the implementation of OIE standards in national legislation has become essential. Different standards may be applied only where the importing country demonstrates scientifically to the exporting country that national animal health conditions require standards over and above those established by the OIE.

### ***International Organization for Standardization***

The International Organization for Standardization (ISO) is a nongovernmental organization established in 1946 to "facilitate the international coordination and unification of industrial standards" for any tradeable goods. Its membership is currently made up of the national standards institutes of 150 countries, and the organization is overseen by a central secretariat in Geneva. In some cases the member institutes are governmental while in others they are entirely private industry initiatives.

Membership in the ISO works on the basis of one member per country, whichever national standards institute or similar organization is the most representative of standardization in the member state.

The ISO formulates technical standards for use by the industrial, technical and business sectors. Although the vast majority of its standards are specific to certain products or services, the ISO has also developed widely accepted generic standards that can be applied to any organization, whatever its size or market. Examples include a standard for establishing quality management systems and a standard to help organizations mitigate environmental damage caused by their activities. In 2005, ISO published *Food safety management systems – Requirements for any organization in the food chain [ISO 22000]*, which sets out the requirements for implementing food safety management systems in organizations at any point along the food chain. ISO 22000 integrates the principles of the Hazard Analysis and Critical Control Point (HACCP) system developed by Codex. It will be complemented shortly by two technical specifications, one providing guidance on its implementation and the other establishing rules for the accreditation of the certification bodies and auditing organizations that will ensure conformity with the standard.

National policymaking and lawmaking on food take place parallel to negotiation and standard-setting carried out under the auspices of a variety of international agreements and organizations, such as those outlined above. Governments as well as experts and observers bring their national experience to the international arena to inform the development of international standards, which are then modified for implementation at national level or simply adopted. In 2008, in the context of ever-increasing internationalization, no national food law or national food policy can be developed in isolation from the international context – neither from the constellation of international organizations and instruments that affect food nor from the empirical changes which those organizations and instruments reflect.

### 3. Regional Context

In addition to the global level, there are organizations that work to establish regional standards and to provide guidance for national governments in a particular region. Of these, the European Union (EU) is the organization that has the most impact on countries in Southeastern Europe. The EU was formed in 1992 through the Treaty of Maastricht, which established a common framework for the three European Communities: the European Coal and Steel Community created in 1950, the European Atomic Energy Community (1957) and the European Economic Community (EEC) (1957). The European Union currently has 27 member states.<sup>3</sup> In Southeastern Europe, Bulgaria and Romania acceded to the EU in 2007 and negotiations are open with Croatia and The Former Yugoslav Republic of Macedonia (candidate countries). Albania, Bosnia & Herzegovina, Kosovo and Serbia (potential candidate countries)<sup>4</sup> are in the Stabilization and Association Process, which should eventually lead to accession negotiations. Moldova is a partner country within the European Neighbourhood Policy (ENP).<sup>5</sup>

The EU is built upon “three pillars”: the European Community (EC), which includes economic, social and environmental policies; a common foreign and security policy; and police and judicial co-operation in criminal matters. Under the second and third pillars, limited powers have been transferred from the EU member states to the EC institutions, whose powers are limited to encouraging and supporting collaboration among the member states. By contrast, in accordance with the provisions of the Treaty Establishing the European Community as modified in Nice in 2002, the transfer of national competences under the first pillar entitles EC institutions to draw up legislation. The EC is active in Codex (member since 2003) and

<sup>3</sup> Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain, Sweden and the United Kingdom.

<sup>4</sup> See [ec.europa.eu/enlargement/potential-candidate-countries/](http://ec.europa.eu/enlargement/potential-candidate-countries/).

<sup>5</sup> The ENP, which was developed in 2004, is designed to prevent divisions between the enlarged EU and its neighbours. See [ec.europa.eu/world/enp/policy\\_en.htm](http://ec.europa.eu/world/enp/policy_en.htm).

the OIE (official observer since 2003), and EC legislation on food safety, food control or food trade takes into consideration the standards and principles of both organizations where appropriate. The EC joined FAO in 1991 and the WTO in 1995.

Whereas EC regulations are directly applicable in all member states, directives allow member states to choose how to implement them in national legislation. The European Court of Justice (ECJ) has imposed an obligation on national administrations and courts to apply EC law in full within their spheres of competence, and to invalidate any national provision which conflicts with EC law. In this way, ECJ case law has harmonized the implementation of EC legislation at state level and created basic principles of interpretation.

Since the earliest days of European integration, agricultural policy and consumer protection from food hazards have formed part of EC legislation. At the heart of the EC is the single market concept with its four basic freedoms and its rules on competition (free movement of goods, free movement of workers, freedom to provide services and free movement of capital and payments). Accordingly, European food legislation was initially developed on the basis of the Common Agricultural Policy and Consumer Protection and was mainly directed at the need to create an internal European market. Then in the 1990s the EU was hit by high-profile food safety scares, including Bovine Spongiform Encephalopathy (BSE, the so-called “mad cow disease”) and cases of animal feed contaminated with dioxin. In 1997, the EU’s executive body, the European Commission, responded to these events by launching a discussion document (the “Green Paper”) to initiate a public debate on the future development of European food legislation. In 2000, the Green Paper was followed by a White Paper on Food Safety, which outlined a comprehensive range of actions needed to expand and modernize EC food legislation. Specifically, it aimed to make EC laws more coherent and understandable, to promote their enforcement and to provide greater transparency vis-à-vis consumers.

The White Paper led to the adoption of a new basic framework for European food legislation, Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety. The regulation applies to all stages of the production, processing and distribution of food and feed, and sets out a number of definitions and principles such as the application of risk analysis, transparency, traceability and precaution. An important attribute of this so-called EC General Food Regulation is that it assigns to farmers, food operators and feed manufacturers the primary responsibility for food safety. It also established EFSA, which works closely with EU member states to provide independent scientific advice and support on food-related risks and keep the general public informed on issues of food safety.

The White Paper also resulted in a number of other European Commission proposals intended to cover the whole spectrum of food-related issues, including animal feed, animal health and welfare, contaminants and residues, food hygiene and food labelling. The main set of regulations is called the "hygiene package", which includes three main texts:

- (1) Regulation (EC) No. 852/2004 on the general hygiene of foodstuffs harmonizes and simplifies the detailed and complex hygiene requirements that all food establishments must follow. All establishments except primary producers must implement HACCP procedures and be able to provide the competent authority with satisfactory evidence that they are complying with the new rules. The regulation also establishes hygiene rules for food products.
- (2) Regulation (EC) No. 853/2004 specifies hygiene rules for food of animal origin.
- (3) Regulation (EC) No. 854/2004 covers official controls on products of animal origin.
- (4) the production, processing, distribution and introduction from third countries of products of animal origin for human consumption.

Another key piece of legislation is Regulation (EC) No. 882/2004 on official controls of food and feed to ensure that they comply with EC food and feed laws and animal health and welfare legislation. According to the regulation, all member states must regularly carry out official risk-based controls on food and feed, applying a scientific approach that takes into account empirical evidence regarding production methods and processes, inspections, sampling, testing and environmental conditions, among other things. This regulation also defines the role of the European Commission's Food and Veterinary Office (FVO) as the auditor of the member states' performance, and establishes a common regime for the control of food and feed imports into the EU. Additionally, it provides a framework for supporting developing countries in meeting EC import requirements regarding food and feed safety in general, and food and feed standards in particular.

Other important regulations regarding the food chain include Regulation No. 2073/2005 on microbiological criteria for food products; Regulation No. 396/2005, updated in 2008, defining maximum residue limits for pesticides in foods of plant and animal origin; and Regulation No. 2377/1990, setting maximum residue limits for veterinary medicinal products in foods of animal origin. Member states must also comply with EC labelling and packaging legislation. All of the regulations mentioned above entered into force on 1 January 2006, with certain exceptions and transitional periods for new member states.

With this international and regional context as background, the next section looks at national legal and institutional frameworks for food control and food safety in general, and then specifically in the countries that participated in the regional FAO Technical Cooperation Project.

## 4. National Legal and Institutional Frameworks for Food

Many areas of law have an impact on food control, food safety and food trade. These include legislation specifically addressing food (such as laws on certain kinds of food, on harmful residues in food or on how food is prepared, treated and sold), as well as many laws and legislative provisions more tangentially related to food (for example related to pesticides, animal feed and veterinary drugs) that nonetheless have an impact on it. All these should be taken into account in the review and revision of a country's legal framework for food.

National legal frameworks governing food vary widely in their complexity and their coverage. In each country the legal framework for food control and food safety reflects a mix of political, societal and economic forces. Laws and regulations may not have been updated or may have been frequently amended, creating a maze of rules which regulators, industry and consumers find difficult to understand and implement. Changes may have been influenced by the need to develop a regulatory framework for the domestic market or to promote exports, in which case the legislative instruments may have addressed only specific products or specific food-related activities. In many cases, the whole system lacks coherence.

A country's institutional framework also has significant implications for the effectiveness of its food control system. One common problem is the failure to identify which ministry, agency or organization has the ultimate power to make certain decisions on food policy and food control, to inspect food products or businesses and to set and enforce food regulations and standards. Alternatively, there may be contradictory provisions within the applicable legislation that appear to give the same or overlapping powers to different entities.

Responsibility for food control is normally been shared among several different ministries. The lead ministry varies from country to country, often based on historical reasons. In the Southeastern European region, food control activities to protect

public health have tended to fall under the purview of the ministry responsible for health, while control over certain categories of food products has remained the responsibility of sectoral ministries and departments. For example, inspection of meat or other animal products has traditionally been assigned to veterinary services, while control over plant products has been the duty of the services in charge of plant health. The veterinary and plant health services are usually located within the ministry responsible for agriculture, whereas the unit responsible for controlling the safety and quality of fish products is often in a separate ministry responsible for fisheries.

The formulation of technical regulations (including food regulations) can be a responsibility of the departments in charge of food, but more frequently, countries have a department that approves technical regulations and standards, including those on food and feed. These standard-setting bodies normally host the Codex Contact Point and include commissions or committees to develop standards for every kind of product.

Local authorities also have powers related to food safety and control, such as licensing of food businesses and monitoring and inspection of street markets, while still other ministries may have powers related to consumer protection, labelling, weights and measures. Businesses wishing to produce, store or sell food may have to apply for a licence from yet another authority, the ministry responsible for commerce or trade and industry. For purposes of inspection, locally produced food may come under one umbrella, whereas border controls of imported food may fall under another, such as the customs authority.

Such a fragmented assignment of responsibilities usually leads to conflicts, overlaps and gaps in coverage and control. Confusion over roles and functions can arise from the failure to properly allocate powers among the different levels of government (central, regional and local administrations), or from the assignment of powers to different ministries or agencies that do not function well together and that seek to preserve their own spheres of influence. Affected systems are bedevilled by duplication of resources (e.g. where one food business is inspected by two or three different agencies) and

burdensome bureaucracies (e.g. where a potential food producer must apply to two or three agencies for a licence or permit). There is also the risk that information is not exchanged freely among officials and professionals from different sectors. This despite the fact that coordination and communication are essential to deal effectively with food contamination incidents.

Another deleterious result of conflicting assignments of responsibility is that key implementing agencies may find that their authority to undertake certain actions is open to legal challenge. Thus the relevant laws and regulations must clearly identify boundaries and delineate mandates, powers and responsibilities as specifically as possible. This can be accomplished through clear assignments of authority in the primary legislation on food, bolstered where necessary by carefully drafted memoranda of understanding which are agreed between and among the various ministries or agencies involved in food control. Strengthening communication and coordination among the different responsible ministries and agencies can lead to higher levels of efficiency and productivity within the existing infrastructure.

To avoid the problem of choosing from among the many ministries with legitimate roles and interests in the food control system and having to iron out the conflicts among them, a number of countries have opted to restructure their institutional framework entirely so as to establish an autonomous national food authority with responsibility for coordinating and overseeing all food control activities in the country. This and other options for structuring the food control system can be seen in the review of the project findings in the next section.

## 5. Overview of Project Findings

The findings and recommendations of this regional project varied according to each country's circumstances, and in large part depended on its relationship with the EU. But in all cases, the objective of the project's activities was to strengthen each country's food safety and food control system and to bring it in line with international and regional requirements, especially with EC provisions.

Countries such as Bulgaria and Romania, which are already EU members, have made the necessary reforms for accession and are now focused on consolidating these changes and improving implementation. By contrast, the candidate countries have a specific time frame and plan for bringing their national food safety legislation in line with that of the EU and reorganizing their institutional structures. Countries that have not yet begun the accession process nonetheless have strong incentives to meet EC requirements, as this will enhance consumer protection and increase export opportunities to the enlarged EU. In addition, these countries will be better positioned for future negotiations to join the EU.

Within each country that participated in this FAO project, national legislative reforms are being undertaken in the context of a larger process of dismantling or modernizing former socialist structures. Legal frameworks are being reformed to enable the transfer from socialist legal systems to modern legal frameworks appropriate for market economies. Laws and regulations aim at disentangling government from the market and the provision of services to create a more favourable environment for private investment and trade. Widespread interest in more effective management is leading to the creation of new legal and administrative structures that favour participation of and cooperation among various actors and stakeholders involved. These developments are taking place in the food sector and indeed, in all sectors of the economy.

The national and international experts engaged under the auspices of this project carried out a detailed review of the institutional and legal frameworks for food control and food safety in the eight participating countries, and regional consultations were held to review the findings. The consultants identified the fragility of institutional frameworks as one of the most prevalent and harmful weaknesses of the food safety and food control systems in the Southeastern European region. In all eight countries, overlapping responsibilities, multiple inspection procedures and burdensome bureaucracies were identified as serious problems negatively affecting the food safety and food control system.

Whereas in most participating countries the ministry responsible for health is generally responsible for the food safety of processed products, control of the primary production process and of foods of animal origin is usually the task of the ministry responsible for agriculture. In addition, other ministries are involved in the food chain in all project countries, including ministries responsible for economy, trade, industry, commerce and standard setting, among others. In some countries, such as Albania, Bosnia & Herzegovina, Croatia and Kosovo, there was a trend toward establishing a new food agency to work alongside other key ministries. Other countries maintained the more traditional model of dividing responsibilities among ministries according to subject matter, while strengthening coordination mechanisms. This approach was observed in The Former Yugoslav Republic of Macedonia and Romania. Both approaches are aimed at a better definition and allocation of powers and mandates as well as improved cooperation and coordination among the various actors involved in the food safety system.

In the legislative arena, the participating countries have been reviewing their national food legislation in line with the EC General Food Regulation (Regulation (EC) No. 178/2002), the hygiene package and other important European instruments. Several of the countries recently enacted new basic food laws (The Former Yugoslav Republic of Macedonia, 2002; Bosnia & Herzegovina, 2004; Moldova, 2004; Romania, 2004; and Croatia, 2007), while others are in the process of updating their existing laws (Albania, Bulgaria) or developing a new basic food law (Kosovo). The degree to which these new framework laws meet the requirements of the EC General Food Regulation and other international norms differs greatly from country to country.

In keeping with the EC General Food Regulation, most of the food laws were kept basic, principally containing definitions and setting out principles of food law. The details and specific requirements of the many subject matters must then be covered in subsidiary laws and regulations, although in several countries these instruments either have not yet been drafted or are inadequate. Often carried out in an ad hoc manner and a complex task under the best of circumstances, the drafting process often

results in a legal framework rife with gaps, inconsistencies, overlaps and ambiguities. An important goal of the legal component of the project was therefore to identify what was needed to convert each country's constellation of food-related legislation into an integrated and effective legal and institutional framework, whether through drafting or amending a food law or enhancing administrative coordination.

The next section outlines the situation in each participating country at the end of the project (October 2007), followed by a review of regional trends observed.

## 6. Country Reviews

### **Albania**

#### Introduction

Albania signed a Stabilization and Association Agreement with the EU in July 2006, and is currently in the process of bringing its food safety legislation in line with EU requirements as well as those of the various international organizations to which it belongs, such as the WTO. The country seeks to establish a modern and effective legislative framework and food control system that will ensure a high level of protection for consumers and encourage agro-food exports to the EU and other international markets.

#### Institutional Framework

The Albanian food control system involves several ministries, namely, the Ministry of Agriculture, Food and Consumer Protection, the Ministry of Health, the Ministry of Economy through its Consumer Protection Department and the Ministry of Environment (responsible for fisheries). Each ministry carries out its sector-specific activities in accordance with its legal powers, while a National Food Board carries out some advisory and coordinating functions. This arrangement has worked poorly, primarily due to ambiguous and vague delegation of powers and responsibilities, and to institutional resistance to collaboration among the line ministries.

During the time this project was being implemented, a draft Law on Food was being prepared, which included a proposal for a new distribution of powers and the creation of a single, executive food authority. Although the agency's precise form and its placement in the system are yet to be determined, it is clearly expected to regulate all elements of the food safety system from policymaking to inspection, and to ensure that relevant legislation is drafted and implemented. It would also subsume the main food safety inspectorates, which are currently spread over different ministries and over central, regional and local levels.

### Legislative Framework

Law No. 7941 on Food (1995) is Albania's main piece of legislation regulating food safety and control. It applies to inspections, food quality and certification, as well as to additives and materials included in the production of food products. Its core objective is the protection of consumer health.

The project's legal consultants found that neither the content nor the enforcement of the Law on Food was in line with EC principles of food legislation and modern requirements for food law frameworks. In particular, the law failed to establish an effective and comprehensive inspection regime. Its fragmented, overlapping and confusing provisions have resulted in the EU rejecting many Albanian products or subjecting them to alerts.

Albania has addressed many of these issues in a new draft Food Law (latest draft 2007). The new law incorporates many key elements of the EC General Food Regulation, but more effort is required to bring it into compliance with the Regulation and with other international instruments. In particular, the draft must better define institutional powers and responsibilities and strengthen collaboration and information-sharing among ministries. The draft should emphasize that food control activities must be based on the principles of risk analysis, and should aim to improve inspections and enforcement mechanisms. Of note is that the Food Law is unique in the region in that it grants food inspectors the right to impose administrative fines.

Other, pre-existing national laws relevant to food are to varying degrees inconsistent with

the draft Food Law, leaving the overall framework marred by gaps, overlaps and inconsistencies. More must be done to create a complete and effective body of national food legislation.

### Conclusion

Albania's food safety system is undergoing significant reform, with the implementation of the EC General Food Regulation as its fundamental objective. The process of translation and approval of the hygiene package and other relevant EC regulations is also under way. The process of harmonizing legislation with EC requirements should include a clear strategy for implementation. Institutionally, the proposed food agency would assist greatly in creating an integrated, effective food safety system.

## ***Bosnia & Herzegovina***

### Introduction

The EU considers Bosnia & Herzegovina a potential future candidate for accession. Negotiations for a Stabilization and Association Agreement were officially launched in November 2005 and the technical rounds of negotiations were successfully completed in 2006. Bosnia & Herzegovina is not a member of the WTO, but participates as an observer. It became a member of Codex in 2007.

### Institutional Framework

The Constitution of Bosnia & Herzegovina provides for a state with two different entities: the Federation of Bosnia & Herzegovina and the Republic of Srpska – each with its own organizational and institutional structure. A third administrative unit – the Brcko District – is under direct state sovereignty, with its administration regulated by statute.

At state level, the Ministry of Foreign Trade and Economic Relations is responsible for foreign trade policy, including trade in agricultural commodities and food products. The ministry has a Veterinary Office and a Plant Health Administration that participate in the management of the food chain. There is no state level ministry of agriculture or

health. Each of the entities and the Brcko District has a ministry in charge of agriculture, a ministry responsible for health and a ministry of trade. A proposal for the reorganization of the state-level administration, including the creation of a ministry for agriculture, was under discussion at the time of this project's implementation.

The institutional structure of Bosnia & Herzegovina relevant to food safety differs significantly from that of its neighbours, in large part due to the complexity of its constitutionally mandated administrative structure. Multi-layered and decentralized, all of its numerous local entities have competencies for food-related policies. As a consequence, there is little coherence in the institutional framework for food. Compounding the problem is a lack of coordination or even communication among the various authorities.

The Food Law of 2004 created a Food Safety Agency (FSA) at state level as an autonomous body empowered to organize, coordinate and regulate the entire system of food safety in the country. Its competencies include carrying out risk assessment, management and communication, drafting implementing regulations and withdrawing substandard food from the market. It should carry out many of its functions in coordination with the Veterinary Office and the Plant Health Administration, and in some instances, such as where foods of plant or animal origin are to be banned or withdrawn from the market, it must get the prior consent of the competent office or administration. In practice, however, the FSA has not yet been fully established, and its powers and responsibilities are still being defined, especially with respect to those of the Veterinary Office. However it has already taken on an important role in the translation and harmonization of EC technical rules and regulations.

### Legislative Framework

The main legal instrument regulating food safety in Bosnia & Herzegovina is the Food Law (2004), which was aimed at creating a single economic space in Bosnia & Herzegovina to remove administrative and technical barriers to trade between and among the entities. Other relevant legislation consists of the Law on Veterinary Medicine

(2002), the Law on Consumer Protection (2002) and the Law on General Safety of Products (2004).

The Food Law is in some respects a comprehensive instrument with a broad scope serving as a basic framework for food safety. It includes most of the principles of the EC General Food Regulation and largely follows the "farm to fork" food safety concept. However, the Food Law contains significant gaps and overlaps with some provisions of other existing legislation related to food, for example the Law on Bottled Drinking Water (2004).<sup>6</sup> The Food Law fails to clearly specify which existing laws or provisions it repeals, in particular with respect to the numerous "rulebooks" (regulations) inherited from the former Yugoslavia which are still in force. These inconsistencies are compounded by problems of interpretation as well as inadequate provisions regarding derogations, transitional clauses and enforcement measures. Another critical shortcoming is the lack of implementing regulations, both vertical (i.e. defining roles and powers at the state, entity, canton and municipal levels) and horizontal (i.e. ensuring harmonization and coordination among the entities). Finally, the Food Law does not address the relationship between the FSA and the inspection services, which remain scattered among the numerous administrations currently involved in food controls.

### Conclusion

The main weaknesses in the food safety system of Bosnia & Herzegovina are the number of administrative levels and public bodies involved and the lack of clarity regarding the distribution of roles and functions. Because some of this complexity is required by the Constitution, these weaknesses must be worked around. The Food Law constituted a significant step toward creating a comprehensive legislative framework in Bosnia & Herzegovina. The next steps will consist of clearly defining the roles and powers of the various institutions

---

<sup>6</sup> For example, the Law on the Surveillance of the Quality of Imported and Exported Products (2003) is also applicable to food products and clearly overlaps with areas covered by the Food Law. Overlaps also exist between the Food Law and the Veterinary Law (2002) with regard to food of animal origin.

and improving coordination and consistency among them. Bosnia & Herzegovina must ensure that its legislative instruments function together to provide a coherent and effective framework for this complex system. Finally, the project consultants believe that the establishment of a state level ministry responsible for agriculture and, eventually, for food safety would further improve Bosnia & Herzegovina's food safety system and would greatly facilitate future negotiations with the EU and harmonization with its standards and requirements.

## **Bulgaria**

### Introduction

Bulgaria entered the EU on 1 January 2007 after undergoing intense reforms that dramatically altered its food safety system in a short period of time. Bulgaria is now in the process of completing and harmonizing its national food legislation with EC requirements.

### Institutional Framework

The competent government authorities implementing Bulgaria's food safety policy are the Ministry of Health through its Public Health Department and the Ministry of Agriculture and Forestry through its Food Control and Safety Department. The Ministry of Economy and Energy has responsibilities in the fields of consumer protection and market inspection.

Coordination among entities is legally established in the Law on Foodstuffs (1999) and other relevant legislation enumerating the powers of each institution. Vertical and horizontal communication is considered satisfactory, with no apparent overlaps or gaps in policy areas. However, problems were identified in the areas of implementation and controls, for example in the programmes for the monitoring of pesticides and certain food colourings and additives.

A National Food Safety Council (NFSC) was created under the Law on Foodstuffs. Composed of representatives from the relevant ministries, the NFSC is responsible for coordinating state policy on food safety and risk management, and has the power, among other things, to propose changes to

legislation and to the organization and structure of the official control activities. A Council on Control Coordination under the NFSC oversees the coordination and planning of control activities at every stage of the food chain. The Council has proven inadequate to face the new challenges of the food safety management system, however, and therefore discussions to establish a new entity in charge of food safety have begun. Bulgaria may consider a centralized executive food authority, especially in light of the ongoing changes to its legal system.

### Legislative Framework

Since its adoption in 1999, Bulgaria's Law on Foodstuffs has undergone a number of modifications (most recently in April 2006) to meet the requirements of European food legislation. As a result, the Law on Foodstuffs now complies with EU principles of food legislation over the entire food chain, from food production to processing and distribution. Of special interest is the degree to which the Law defines the powers of, and the mechanisms of coordination among, the various entities with a role in food safety. The Law is largely complete although amendments continue. According to the project's consultants, future efforts should be directed at elaborating secondary legislation that builds on the principles enunciated in the Law, in particular with respect to monitoring and controls.

Although Bulgaria's national legislation is fully compliant with EC requirements, its implementation has been hampered by a lack of resources and training. The Council of Ministers has approved a plan to improve the food safety skills and knowledge of administrative personnel. Enforcement of penalties and fines has also proved to be problematic; however, no specific measures to strengthen this aspect of the system have been put forward.

### Conclusion

Bulgaria's food safety system experienced important changes as it prepared to join the EU. While the results are quite positive in most respects, the rushed and perhaps overly diligent harmonization with European food legislation produced some problems that will need resolving, most specifically regarding implementation. Attention should

also be paid to ensuring that the constant amendment of national legislation does not weaken the overall legal framework. With a view to strengthening coordination, the project's consultants recommended that Bulgaria review the current institutional framework and consider more centralization and coordination. Meanwhile, ministries should issue instructions on the application of the Law on Foodstuffs and related regulations to improve implementation. Control authorities should also develop and apply an integrated methodology to all food regardless of origin and provide adequate training, resources and laboratories for inspectors.

## **Croatia**

### Introduction

The Republic of Croatia holds accession to the EU as a national and foreign policy priority. The EU opened negotiations with Croatia in October 2005 and the official review of food safety legislation started in March 2006. The main objectives of this process are to adapt Croatia's national legal system to European legislation, to ensure the implementation and enforcement of European regulations and standards and to bring the country's food safety system into compliance with European requirements.

### Institutional Framework

Food safety regulation in Croatia is the shared responsibility of the Ministry of Agriculture, Forestry and Water Management for unprocessed food of plant and animal origin and the Ministry of Health and Social Welfare for processed food. The former deals with food quality issues while the latter is in charge of setting health requirements and ensuring food safety and quality. Both ministries are involved in closing the technical gaps in the country's food legislation and in the systems of inspection and control, to improve and modernize the food safety and control system.

The Food Act (2003, last amended 2006) established the Croatian Food Agency (CFA), empowering it to coordinate the entire food safety administration and deal with risk assessment, risk management and

risk communication. However, in practice the CFA's activities are limited to risk assessment and risk communication, with risk management remaining under the Ministries of Agriculture and Health. Thus each ministry has its own body of inspectors, with competencies divided between unprocessed and processed food. The issue under consideration during the time of implementation of this project was the possibility of creating a national agency for food management, consolidating the powers of the two main ministries.

### Legislative Framework

Croatia's Food Act, which was enacted in July 2003, is the basic law regulating food and feed safety, quality and control. It establishes an integrated approach to food safety regulation throughout the food supply chain, including drinking and bottled water. It incorporates the principles of the EC General Food Regulation.

Revision of Croatia's food legislation was required to harmonize food control with EU systems and to remove overlapping responsibilities in food inspection and management. Problematic aspects of the Food Act are mainly related to overlaps and contradictions with other laws and often concern the inspection regime. Examples include inadequate measures for control and implementation, duplicative functions among bodies of inspectors and inefficiencies resulting from decentralization measures. Implementation of the Food Act is also inadequate. Although a number of regulations have been adopted to improve implementation, other existing regulations are still based on the former Yugoslav legislation and need comprehensive updating.

Several shortcomings were noted with respect to the conformity of the Food Act with EC food safety regulations: (1) food control still focuses mostly on the final product instead of the production process; (2) reference to the precautionary principle is still not in line with European legislation; (3) separation between risk assessment and management is still not clear; and (4) the Act does not follow a "farm to fork" approach. A complete revision of the Food Act, including its harmonization with the entire body of EC food legislation and other EC requirements, was under way at the time of this project's

execution. The new Food Act, approved in May 2007, incorporates the fundamental principles and requirements of EC food legislation and designates the Ministry of Agriculture, Forestry and Water Management as the competent authority responsible for food safety issues in Croatia. The implementation of the Act and its secondary legislation will have to take into account the decentralization of national powers and functions.

The Veterinary Act (May 2004) introduced important food safety principles such as the traceability of animals and veterinary controls in border points. However the provisions regarding slaughterhouses, meat processing plants and dairies are not in line with EC requirements. These provisions must be updated, and secondary legislation must be enacted and implemented.

### Conclusion

Following the recent approval of the new Food Act, efforts must now be directed toward preparing secondary legislation and ensuring the full implementation of the Act. Specific areas requiring attention include responsibilities of food and feed operators and traceability requirements. Finally, Croatia will need to strengthen its administrative capacity to fulfil its European obligations.

## **Kosovo**

### Introduction

Kosovo achieved independence on 17 February 2008. At the time of the FAO missions under this project, Kosovo was an entity under interim international administration by the United Nations, and the observations and analysis in the project consultants' reports, as set out below, are based on Kosovo's status at that time.

### Institutional Framework

Kosovo's food safety administration is a shared responsibility of the Ministry of Agriculture, Forestry and Rural Development (MAFRD), the Ministry of Health (MoH) and, for standardization and consumer protection, the Ministry of Trade and Industry. MAFRD is responsible for inspections of food of

animal origin through its Kosovo Veterinary and Food Service (KVFS). Another department of the MAFRD performs phytosanitary and plant-based food inspections. MoH oversees, among other things, food quality control and agricultural inputs in coordination with the MAFRD.

Kosovo is composed of 30 municipalities that are responsible for local consumer protection, veterinary controls, controls of food sold in markets and public health matters. Each has the power to create local regulations, carry out veterinary and phytosanitary inspections and report its results to the central government. This arrangement has led to uneven reporting and inadequate oversight by the central authorities, resulting in dramatic differences in the level of public health protection among municipalities.

A new Food Law, drafted with the assistance of FAO as a supplemental activity under this project, proposes a centralized executive food control agency under the MAFRD, to be called the Kosovo Food and Veterinary Agency (KFVA). The KFVA would essentially be a stronger version of the existing KVFS, although giving more power to the MAFRD than to the MoH. It would integrate all inspectorates: the KVFS, some or all of the MoH sanitary inspectorate, the phytosanitary inspectorate and the municipal inspection services. It remains to be determined whether the agency would coordinate inspections in the field of fisheries.

### Legislative Framework

Kosovo's legal framework was based on the Constitutional Framework for Provisional Self-Government in Kosovo (UNMIK Regulation No. 2001/9 of 15 May 2001). At the end of this project, a draft Food Law was in the final stages of adoption by Parliament. It largely implements the basic principles of the EC General Food Regulation and includes some provisions of the "hygiene package". However, the law would still benefit from several key revisions, as it is still somewhat incongruent with European legislation and in some places unclear.

## Conclusion

An important step to improve Kosovo's institutional functions in food safety has been taken by proposing the establishment of the KFVA. However, key details are yet to be determined. Although the draft Food Law situates the agency within the structure of the MAFRD, its relationship to the MoH remains unclear (e.g. with respect to sanitary inspections). To accord the agency enough autonomy to perform its duties, the project's consultants recommended placing the proposed KFVA directly under the Prime Minister.

Competence for fisheries inspections is another grey area. Kosovo's new draft Food Law must be improved to more clearly identify and empower each of the entities to carry out its role in the food safety system, and unambiguously set forth decision-making powers and processes. These issues should be considered in collaboration with the relevant ministries in order to create an agency capable of effectively overseeing the food chain.

## **Moldova**

### Introduction

Moldova became independent from the Soviet Union in 1991. At present, it is not included in the group of potential candidate countries for EU accession. Moldova's relations with the EC are based on a Partnership and Cooperation Agreement that entered into force in July 1998. It also benefits from the ENP. Moldova is still in the process of reforming its legislative and administrative systems and, accordingly, many laws and regulations that would facilitate the transition from the old Soviet legal system to a modern legal framework are still under preparation. The situation is further complicated where foods are traded to countries in the region that still require compliance with GOST standards inherited from the former USSR. For the time being, two parallel systems are in place: one moving toward EC requirements and updating laws accordingly and the other maintaining the GOST system for certain food products and trade purposes.

### Institutional Framework

Moldova's institutional framework for food safety and food control is currently dispersed over several ministries and other government institutions. The Ministry of Public Health (MPH) is generally responsible for food safety and food control, while the safety and control of food of animal origin is the responsibility of the Ministry of Agriculture and Food Industry (MAFI). The latter is also responsible for the safety and control of feed. In addition, the State Department of Technical Control, Standardization and Metrology is responsible for setting standards, including those related to food, and for consumer protection. Overlapping veterinary controls are performed by the State Veterinary Department of MAFI and the Sanitary-Epidemiological Service, which is supervised by the MPH, creating confusion for producers and consumers and for the bodies themselves.

There are significant overlaps of functions and lack of coordination among governmental agencies and state control bodies. For example, each of the aforementioned government institutions has its own inspection body, which means that food establishments are frequently confronted with multiple and costly inspection procedures.

To correct these weaknesses, clear mandates, powers and responsibilities must be assigned as specifically as possible. This could be accomplished by clear assignments of authority in the primary food legislation or through carefully drafted memoranda of understanding agreed among the various ministries and other government institutions involved in food control.

### Legislative Framework

Moldova has undertaken some discrete initiatives in furtherance of its goal to harmonize its legal framework with EU requirements and other international standards. A new basic food law entered into force in 2004. Although an English language draft of the law was not made available to the project consultants, according to the report of the national legal consultant it incorporates such basic principles of EC legislation as the "farm to fork" approach, risk assessment and traceability, responsibility of food producers and implementation of HACCP. The production and safety of foods of animal origin are regulated in the Law on Veterinary

Practice (1993), although a newer law is currently under preparation.

The basic food law leaves out some key items while duplicating other issues addressed in specific legislation. For example, the law does not include provisions related to coordination between controls of food and control of animal feed for food-producing animals (as required by the EC General Food Regulation), but it does stipulates issues related to drinking water, although there is a separate law on drinking water. Implementation of the food law has also proved to be unsatisfactory and ineffective.

One reason for the weak legal framework is that legislation is normally drafted by specialists from different ministries (e.g. MAFI or the Ministry of Health) without the participation of lawyers or legal experts. Other factors include frequent changes in government and repeated, piecemeal modifications of the legislative framework.

### Conclusion

After 17 years of transition, Moldova is ready to move on. This period of instability has had a negative impact at all levels of economy, including on the food industry and on the trade of food products. Moldova's food safety system is plagued by fragmentation of efforts and duplication of regulatory activity, with predictable results.

It is unlikely that any one law could ensure the soundness of Moldova's food safety system. Instead, the entire legislative framework of food safety must be reformed. Modern control methods must be introduced in line with international requirements, and duplication of functions must be avoided. This framework must in turn be part of a larger national strategy designed to protect consumer health and to promote trade in safe and high quality food products.

## **Romania**

### Introduction

Romania joined the EU on 1 January 2007. Harmonization of the national legal framework with the requirements of European food legislation is almost

complete. The government's current objective is to further strengthen the food control system, in particular by focusing on implementation and enforcement of existing legislation.

### Institutional Framework

Responsibility for implementing food safety controls rests with four entities: (i) the national Sanitary, Veterinary and Food Safety Authority (SVFSA), in charge of food safety; (ii) the Ministry of Agriculture, responsible for plant health; (iii) the Ministry of Health, responsible for public health; and (iv) the National Consumer Protection Authority.

The SVFSA was created in 2004 to conform the Romanian institutional framework to European models. The SVFSA is the coordinating agency ensuring that food controls are in place at all stages of the food chain "from farm to fork". In this capacity, it monitors the organization and functioning of inter-ministerial working groups and deals with risk assessment, management and communication. It addresses most areas related to food safety, animal health and plant protection, with some exceptions. The project consultants recommended that SVFSA further consolidate its activities and improve its capacity to provide adequate implementation and controls.

The problems in Romania's food system are mainly related to duplication of food control activities among the four state-level authorities listed above. In 2005, these authorities signed a protocol to clarify the distribution of powers and the tasks of each institution, to define the controls to be performed by each body of inspectors and to encourage the creation of instruments for cooperation and collaboration. Though the protocol does not legally modify the existing legal provisions (as this must normally be done through the approval of higher-level legislation), it is being implemented and a number of laws have been amended in accordance with it. The next challenges for Romania are to fully harmonize existing legislation with the new division of powers to ensure legal coherence and to introduce the responsibilities and duties approved by the protocol at the regional and local levels. Additional efforts will be needed to strengthen the capacities of regional and local administrations.

A new process of administrative reform is taking place in the country, reducing the number of administrative divisions and reorganizing the tasks and duties of each level of administration. Implementation of the legal framework should take into consideration this process and strengthen the links among the different levels of administration.

#### Legislative Framework

As a member of the EU, Romania has a legislative framework for food safety that is consistent with European food legislation. The main legal instrument is the Law on Food (2004), which transposes the principles of the EC General Food Regulation and which created the SVFSA. Food of animal origin is regulated in different sectoral laws and regulations.

Romania's revision of its legislation to harmonize with European requirements extended to the main framework laws; most secondary instruments are still based on outdated legislation. Some subsidiary instruments have been amended since the adoption of the Law on Food, but others are still based on earlier framework laws. In order to complete and strengthen the food safety legal system, the entire constellation of food legislation must be updated and revised to form a coherent framework.

#### Conclusion

Romania established the SVFSA and harmonized most of its food safety legislation with strong support of the EU. The institutional framework appears strong and capable of running the food safety system effectively, at least at the central level. Therefore, future efforts should focus on comprehensively updating all food-related legislation and enhancing implementation and enforcement mechanisms, especially at the local level.

### ***The Former Yugoslav Republic of Macedonia***

#### Introduction

In 2004, the Former Yugoslav Republic of Macedonia (FYROM) began the Stabilization and Association Process with the EU and in 2005 obtained the status of candidate country. Within this framework, political and economic relations between FYROM and the EU are advancing rapidly, and an important number of European and internationally funded projects related to food safety are under way.

#### Institutional Framework

In FYROM, the Ministry of Health (MoH) and the Ministry of Agriculture, Forestry and Water Economy (MAFWE) are the main players in the food chain. The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs (2002) assigns most of the competencies related to inspection and supervision of the food chain to the MoH and its Food Directorate. It assigns to the Food Directorate certain activities previously carried out by the Ministry of Economy such as product labelling and quality control. The Food Directorate also participates in the development of regulations relating to food.

Within MAFWE, the Veterinary Directorate is responsible for the safety of food of animal origin (including fish products) and for animal welfare. The Plant Protection Directorate controls foods of plant origin as well as materials used in the agricultural production process, while the State Agricultural Inspectorate controls the entire primary production chain for foods of plant origin and is indirectly involved in monitoring their safety. The latter two bodies have some areas of overlap, a weak point that should be addressed in the future revision of the legislative framework for food.

With so many players in FYROM's food safety system, a high level of organization and coordination would be required for all parts to function effectively as a whole but this is currently lacking. The only coordination mechanism among the various entities is the Macedonian Codex Commission, which is merely an inter-ministerial advisory body empowered to make science-based recommendations on regulations and methods of food analysis. A stronger executive agency with a broader scope and powers would improve coordination, although this concept did not seem to have broad government support at the time of this project's implementation.

### Legislative Framework

The Law on Safety of Foodstuffs and Products and Materials in Contact with Foodstuffs is FYROM's basic food law. Although it was enacted only six years ago, it is still inadequate in several respects. For example, its scope and content are out of line with European legislation, and it neither clearly defines responsibilities of the various ministries and departments nor provides a coordination mechanism among them. Overlaps and inconsistencies therefore continue to create uncertainty and confusion. In addition, the qualifications, powers and responsibilities of inspectors are insufficiently defined.

A new draft food law appears to address some the issues described above, as it would introduce the principles of the EC General Food Regulation and of the hygiene package, and would set out specific rules for the organization of official controls on products of animal origin intended for human consumption. The draft law requires the various ministries to coordinate to achieve an integrated approach to food safety, through the use of non-binding memoranda of understanding.

### Conclusion

The critical weakness of FYROM's legal and administrative system is that it diffuses competencies across several different institutions, and thus the government cannot exert comprehensive control over the food chain. To remedy this failing, the project's consultants recommended that the new food law clearly define each entity's powers and the mechanisms of coordination among the various entities involved in food control and food safety. Moreover, the government will need to take a close look at the wider constellation of provisions relating to or affecting food, to propose amendments to a variety of existing laws and regulations in order to remove gaps, overlaps and inconsistencies.

In addition to revising the legal framework, FYROM should also review its institutional management of food safety, with a view to improving coordination and communication among entities. Establishment of a centralized coordination authority would facilitate more streamlined and effective implementation of legislation, legal certainty and a guarantee of traceability of national products. This could be a strategy for the future when broader support has been garnered in this direction.

## 7. Regional Trends and Recommendations

The preceding brief review reveals that most of the participating countries in the region face problems related to the dispersion or responsibilities and poor coordination in the management of food safety. In addition, their legal frameworks show a number of gaps and overlaps. All eight countries reviewed here suffer from some combination of ill-defined responsibilities among institutions, failed communication and insufficient coordination, resulting in ineffective or redundant efforts. These problems are particularly pronounced in Southeastern Europe because of the rapid and comprehensive reforms the countries are undergoing as they transition away from socialist regimes to legal systems appropriate to market economies. Therefore, future actions should be directed toward reinforcing institutional frameworks by defining and allocating powers and improving the cooperation and coordination among entities.

There are several potential ways to approach achieving these improvements, and the decision in each country depends on the national circumstances at play. Some countries like Croatia and Romania have opted to establish a central and autonomous food authority responsible for coordinating and overseeing all food control activities in the country. This single agency approach ensures the coherent application of the food laws based on the principle “from farm to fork”. Traceability and risk analysis also benefit from this approach. The single agency system is most likely to avoid problems of conflicts and duplication of activities.

On the other hand, the creation of such a centralized system may weigh heavily on governments which will face significant disruption in food control activities, at least at first. Thus some countries such as FYROM have so far preferred to maintain a system in which control is carried out by multiple ministries and agencies. The key to making this multi-agency approach successful is to ensure effective coordination and communication. Examples include protocols with mechanisms for coordination among ministries and detailed legislation or

agreements that clearly and explicitly assign the responsibilities of each ministry and agency.

Increasingly, the traditional focus on regulating food and agriculture sectors individually is shifting to one of ensuring confidence in the overall regulatory framework for agricultural health, including animal health, plant health and food safety measures. A number of countries – including Albania, Kosovo and Moldova – demonstrated interest in taking integration a step further by putting animal health, plant health and food safety into a single authority to cover the whole food chain. In the same way that regulating all foods under one umbrella is desirable for purposes of information collection and transfer and the ease of assigning resources, so the integration of food safety and animal and plant health can improve cost efficiency, foster information exchange and reduce risks across disciplines.

After a government has made its investigations and crystallized its ideal goals for the updated legal framework – the orientation of the law, the institutions it will establish and the policies it should reflect – the next step is to assess the feasibility of implementation. It is important to ask what technical and political steps will be required and what obstacles stand in the way. In some contexts it may be possible to adopt the needed legal reforms; in other circumstances it may be necessary to work within the existing regulatory parameters. In either case, no legislative proposal should be prepared or introduced without a hard look at the likelihood of its being adopted and the problems that may accompany its implementation. A major effort should be made to distribute enforcement powers and coordinate inspections according to actual capacity. Where institutional reform is involved, the change in power distribution often generates “turf wars”. Therefore the legislation must be clear and practical, and must involve all relevant stakeholders, thus avoiding problems that could delay the reform process.

A common feature of all the new and draft basic food laws examined under the project is their focus on European models with an eye to joining the EU or trading with its member states. The objectives, definitions and general principles of these national laws follow those of the EC General Food Regulation, and in many instances are literal transpositions. Using EC legislation as a template has assisted countries with limited resources to develop legislation on their own. But it is not clear that every participating country has truly and seriously taken into account its particular circumstances in developing draft national laws. Instruments developed at the international or regional level should not simply be "imported", as their effectiveness depends on their suitability in specific national contexts. Each country requires policies and legislation tailored to its needs, based on an in-depth analysis of the circumstances in the country, including any existing legislation directly or indirectly applicable to food, the national policy objectives, institutional capacities and social, ecological, political and economic conditions.

Greater difficulties arise after countries have elaborated or adopted a basic food law, when the next step is to complete the legislative framework. Whether by fleshing out the basic legislation through implementing regulations or squaring the basic law with pre-existing food-related legislation to eliminate the gaps, overlaps and inconsistencies, this secondary phase has proven to be much more complex and challenging, both technically and politically, in the project countries. Further efforts should therefore be directed at closer collaboration among relevant entities in the food chain, so as to harmonize the various instruments making up the legal framework for food in order to guarantee a coherent, effective food safety system. It is also essential to involve legal experts alongside food control professionals and experts in the development of priority implementing regulations and subsidiary instruments.

The varied approaches to food systems and food legislation among the project's participating countries have provided useful comparisons as well as an opportunity for the cross-pollination of ideas and methods. This project was only a first step toward sharing experiences and knowledge. Other opportunities for regional collaboration should be explored, including the sharing of resources and expertise for risk assessment, joint training of inspectors and development of regional mechanisms for a rapid alert system. Countries in the region have made great strides in streamlining their food safety and food control systems, improving their legal frameworks for food and complying with international and regional norms. Other countries in the region would benefit from a close look at the experiences gained through participation in this and other regional initiatives.