

## **1. Where does Kosovo have to get tomorrow?**

### **1.1 Summary**

The food safety policy objective for an EU membership candidate country is to develop and implement an effective food safety control system based on strong science and EU legislation, enforced by an integrated official control service under the umbrella of a single food safety agency that ensures a high level of public health and consumer confidence in food.

### **1.2 Policy**

The objective of food safety policy in the European Union is to protect consumer health and interests while guaranteeing the smooth operation of the single market. In order to achieve this objective, the EU ensures that control standards are established and adhered to as regards food and feed hygiene, animal health and welfare, plant health, and preventing the risk of contamination from external substances. It also lays down rules on appropriate labelling for food and food products.

This policy was developed in the early 2000s, in line with the "Farm to Fork" approach, thereby guaranteeing a high level of safety for food and feed marketed within the EU, at all stages of production and distribution. This approach covers food and feed that is produced within the European Union and food and feed that is imported from third countries.

Further reform in 2004 made business operators primarily responsible for ensuring the safety of food and feed they produce and sell through the mandatory implementation of management systems based on HACCP principles.

Food chain safety policy in EU Member States is formulated on the basis of scientific evidence and the three elements of risk analysis namely risk assessment, risk management and risk communication.

The aim is to ensure a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment. This integrated approach is an underlying principle of all EU food chain safety policy.

Risk management, i.e. the process of weighing policy alternatives in the light of results of risk assessment, must be an integral part of the policy development process. This is necessary in order to enable appropriate actions to be taken to prevent, reduce or eliminate risks and to ensure the high level of health protection determined as appropriate in the EU.

In the risk management phase, decision makers consider a range of information in addition to the scientific risk assessment. This includes, for example, the feasibility of controlling a risk, the most effective risk reduction actions depending on the part of the food chain where the problem occurs, the practical arrangements needed, the socio-economic effects and the environmental impact.

EC Regulation 178/2002 establishes the principle that risk management actions are not just based on a scientific assessment of risk but also take into consideration a wide range of other factors legitimate to the matter under consideration.

### **1.3 Implementation**

#### **1.3.1 Legislation**

A country seeking EU membership must conform to the conditions set out in Article 49 and the principles laid down in Article 6(1) of the Treaty on European Union. Relevant criteria were established by the Copenhagen European Council in 1993 and

strengthened by the Madrid European Council in 1995. These include adopting the common rules and standards that make up the “acquis communautaire”.

When new member states join the EU and therefore enter the EU single market, transitional measures are put in place to allow time to adapt to the EU's food chain safety standards. However, food and feed that does not meet EU standards cannot be traded with other EU countries on the internal market.

The Commission has not generally compromised on food chain safety standards, and recent accession negotiations have closed without "transitional periods" or derogations from transposition and implementation of food chain safety legislation.

Depending on the nature of the measure, food and feed law, and in particular measures relating to food chain safety must be underpinned by strong science.

In addition to the umbrella legislation that applies to all food and feed, the EU has adopted targeted legislation on specific food chain safety issues and specific foods. These include the use of pesticides, food supplements, colourings, antibiotics and hormones in food production, addition of vitamins, minerals and similar substances to foods, products in contact with food, meat, gelatine and dairy products.

There are also stringent rules governing release, marketing, labelling and traceability of crops and foodstuffs containing genetically modified organisms (GMOs).

All of this needs to be transposed into the food chain safety legislation of Kosovo.

### **1.3.2 Organisation**

The organisation of the food chain safety control system needs to ensure that scientific assessment of risk can be undertaken in an independent, objective and transparent manner based on the best available science.

Food chain safety and the protection of consumer interests are of increasing concern to consumers, non-governmental organisations, professional associations, international trading partners and trade organisations. EC Regulation 178/2002 therefore establishes a framework which enables stakeholders at all stages to be involved in the development of food chain safety policy and legislation, and establishes the mechanisms necessary to increase consumer confidence in the safety of food on the internal market. This needs to be built into Kosovo's national food chain safety control system.

Consumer confidence is an essential outcome of successful food chain safety policy and is therefore a primary goal of all EU actions related to food chain safety.

Transparency of legislation and effective public consultation are also essential elements in building this greater confidence. Better communication about food chain safety and the evaluation and explanation of potential risks, including full transparency of scientific opinions, are of key importance.

Organisation of the official control services is based on three key EC legal acts. The first is Regulation 882/2004 on official controls to verify compliance with feed, food, animal health, and animal welfare rules. The second and third are Directive 89/662/EEC concerning veterinary checks on intra-Community trade, and Directive 97/78/EC on the principles governing the organisation of veterinary checks on products entering the EU from third countries.

The system also requires access to official laboratories that are accredited to ISO 17025 standards, and which have the resources to carry out monitoring and surveillance activities to provide scientific evidence for the risk assessment and food chain safety policy development processes. Hazards that are identified through the monitoring and surveillance process and which have a potential effect beyond

Kosovo's borders have to be communicated to the European Commission through the Rapid Alert system.

### **1.3.3 Management Control Systems**

The European Commission monitors the implementation and enforcement of EU feed and food law by checking that EU legislation has been properly incorporated into Member States' law, by double-checking compliance through reports from Member States and other countries, and through on-the-spot inspections in the EU and outside.

The Commission's Food & Veterinary Office (FVO), which is based in Ireland, carries out these inspections. The FVO has power to check individual food and feed production plants, although its main task is to check that governments of EU Member States and of third countries have the necessary machinery for checking that their own producers are implementing the EU's food chain safety standards. The FVO focuses on making checks where risks are highest.

Kosovo therefore needs to ensure that it has developed and implemented its own systems for checking that its food chain safety policy and implementation are in line with EU priorities and objectives. It must also ensure that the EU laws it has transposed into national legislation are accurate and kept up to date, and that those laws are being implemented and enforced effectively.

### **1.3.4 Staffing**

Article 4 of Regulation EC 882/2004 requires EU Member States to have a sufficient number of suitably qualified and experienced staff to carry out official controls. These staff must meet the minimum training requirements set out in Annex II of Regulation 882/2004. Official Veterinarians and Veterinary Auxiliaries must also meet the professional training requirements set out in Annex I of Regulation EC 854/2004.

Official Veterinarians, sanitary inspectors and phytosanitary inspectors must work within the framework of an integrated system of official controls in which functions and duties are clearly allocated and overlaps and gaps are eliminated.

The official control service should operate on the principle of "one enterprise, one inspector" so as to avoid the sometimes competing demands which arise when a variety of different inspectors are responsible for inspecting the same businesses.

In addition to inspectors, staff will also be required for management and administrative duties, for laboratories, for the compilation and analysis of statistics and other data, and for media and stakeholder communications.

### **1.3.5 Budget**

Budget headings include:

- Staff – inspectors, chemists, microbiologists, managers, administrators;
- Accommodation – offices, laboratories, border inspection facilities, warehouses, garages;
- Utilities and services – electricity, water, telephone, internet;
- Equipment – furniture, computers, laboratory equipment, mobile phones, sampling equipment, fridges, freezers, digital thermometers,
- Transport and travel – cars, vans;
- Sampling, monitoring, and surveillance – payment for testing, payment for samples, data analysis; and
- Laboratories – consumables, calibration, maintenance, renewal.

## **2. Where is Kosovo today?**

### **2.1 Summary**

Kosovo has made good progress in establishing a legal basis for its food chain safety control system. Some key EU Regulations and Directives have already been transposed, including the “hygiene package”, legislation on food additives and food contact materials, and the official controls Regulation.

The new food law will create an integrated food chain safety agency, although it is being delayed by ongoing disagreement over the remit and scope of the proposed new Agency and its “host” Ministry. This has the “knock-on” effect of delaying the implementation of other transposed legislation.

### **2.2 Policy**

Food safety policy development since the end of the war in 1999 has largely been focused on rebuilding the food chain safety control system along the lines of the general policy priorities and objectives of the European Union.

Responsibility for food chain safety policy development is shared between the Ministry of Agriculture, Forestry and Rural Development and the Ministry of Health, creating the possibility of development of divergent and inconsistent policy between the two Ministries, particularly in the absence of a co-ordinating mechanism.

Crude data that is available, such as the statistics published by the Statistical Office of Kosovo, which show almost 40,000 reported cases of acute diarrhoea, 369 parasitic intestinal infections, and 41 human cases of Brucellosis in Kosovo in 2006, provide pointers to national policy priorities.

However, there has been little real opportunity so far to begin development of national food chain safety policy, due to a lack of robust scientific data and the absence of national monitoring and surveillance programmes to provide the data for risk analysis.

The development of national policy to address Kosovo’s particular food chain safety hazards and risks requires a more systematic approach to data collection and analysis (see below).

### **2.3 Implementation**

#### **2.3.1 Legislation**

Kosovo’s food chain safety legislation is currently a mix of new laws and sub-legal enactments that have been made and promulgated since the end of the war in 1999 and the laws of former Yugoslavia which still apply where new laws and sub-legal enactments have not been made.

The Veterinary Law 2004/21, promulgated by UNMIK Regulation 2004/28, gives responsibility for official controls on products of animal origin, including food of animal origin, to the Kosovo Veterinary and Food Agency, which is an Executive Agency of the Ministry of Agriculture, Forestry and Rural Development.

The Law on the Sanitary Inspectorate of Kosovo 2003/22, promulgated by UNMIK Regulation 2003/39, gives responsibility for official controls on food of all types to the Sanitary Inspectorate of Kosovo, which comprises sanitary inspectors at central, border, regional and municipality level.

Other laws that relate directly or indirectly to the food chain have been passed since the end of the war. These include laws on seeds (2003/5); fertilisers (2003/10); pesticides (2003/20), planting material (2004/13), consumer protection (2004/17), water (2004/24), livestock production (2004/33), wine (L2/L-8), market inspection (L2/L-1), animal welfare (L2/L-10), fishery and aquaculture (L2/L-85), plant protection

(L2/L-95), protection of plant varieties (L2/L-98), public health (L2/L-78), prevention and control of infectious diseases (L2/L-109), apiculture (L2/L-111), and organic farming (L2/L-122).

A new food safety law, based on EC Regulation 178/2002, was drafted in summer 2005 and sent to the Kosovo Assembly for adoption in November 2005. However, an ongoing disagreement over the “host” Ministry for the new Agency, and a new dispute over the scope and remit of the proposed new Agency are delaying the passing of the new law. It was re-introduced into the Assembly following the formation of the new Government in February 2008, but is still only making slow progress.

### **2.3.2 Organisation**

The organisation of the food chain safety control system in Kosovo is currently shared between three Ministries, five inspection services, and two levels of Government, resulting in a service that is somewhat fragmented and uncoordinated.

The Ministry of Agriculture, Forestry and Rural Development has a significant range of responsibilities for ensuring the safety of the food chain, including responsibilities for the safety and use of pesticides and fertilisers, plant health, primary production including crops and livestock, organic production, and the production of food and feed of animal origin.

The Kosovo Veterinary and Food Agency is an Executive Agency of the Ministry, established by the Veterinary Law in 2004. It has responsibility for official controls on animal health, animal welfare, the use of veterinary drugs and medicines, and for the inspection of slaughterhouses, meat cutting and processing plants, dairies and other establishments that produce food of animal origin.

The Agency is also responsible for border controls on live animals, products of animal origin, and plants and planting materials, controls on the disposal of animal waste and by-products, and for contingency planning for the control of contagious disease in livestock and other animals.

The Veterinary Law also gives the Minister of Agriculture, Forestry and Rural Development the power to prescribe the veterinary inspection duties to be undertaken by the municipalities in relation to live animals, animal waste, pathogens, and products of animal origin.

The Sanitary Inspectorate of the Ministry of Health has responsibility under the 2003 Law on the Sanitary Inspectorate of Kosovo for controlling the safety of food of all types, including food of animal origin. The Sanitary Inspectorate of Kosovo as established under the 2003 law includes the sanitary inspectors at central, regional, border and municipality levels, and is in effect an integrated inspection service, although its responsibilities overlap with the responsibilities of the Kosovo Veterinary and Food Agency.

The Ministry of Economy and Trade has responsibility under the 2004 Law on Consumer Protection for ensuring the hygienic and sanitary conditions of retail sellers of consumer products, and for the labelling of food.

The Kosovo Institute of Public Health has responsibility under the 2007 Law on Public Health for analysing and evaluating the quality of drinking water and all types of food, researching food-borne infections, supervising and inspecting drinking water, bottled water and natural springs and mineral water.

### **2.3.3 Management Control Systems**

Monitoring and evaluation of the effectiveness of implementation and enforcement of controls that are designed to ensure the safety of the food chain is an area in which

Kosovo has made some limited progress so far. The only significant activity is the veterinary medicine residues monitoring programme that is undertaken by the Kosovo Veterinary and Food Agency.

The legal basis of food chain safety control is being established, albeit in a rather fragmented manner, and the phytosanitary, sanitary and veterinary inspection services at central, regional and border level are relatively well staffed and well trained.

However, there are currently no performance standards, and no monitoring of how effectively the law is being applied in practice. It is therefore impossible to determine objectively how effective the inspection services are at implementing and enforcing the law and ensuring the safety of the food chain.

There is also little official monitoring and surveillance to determine the incidence and prevalence of zoonoses in livestock, food-borne infection in the population, or the presence of contaminants and residues in food and feed. This results in a fragmented picture of food chain safety in Kosovo, which will be of concern to the European Commission's Food and Veterinary Office if the situation has not been addressed by the time the Commission comes to assess Kosovo's readiness to join the European Union.

There is also insufficient monitoring of changes in the underlying EU legal framework of food chain safety control, and therefore little consequential revision and updating of Kosovo's food chain safety legislation. This will result in the legislation gradually becoming out of date and no longer aligned with the EC's *acquis communautaire*.

#### **2.3.4 Staffing**

The Kosovo Veterinary and Food Agency and the Plant Production and Protection sectors within the Ministry of Agriculture, Forestry and Rural Development, and the Sanitary Inspectorate of Kosovo in the Ministry of Health are all well staffed, qualified and trained, and very capable of carrying out their functions and duties.

The Kosovo Institute of Public Health and the Kosovo Institute of Agriculture also have well qualified and trained staff to test and analyse food and feed.

However, most food chain safety fieldwork is carried out at municipality level, and although all the municipalities in Kosovo each have at least one sanitary inspector and one phytosanitary (agricultural) inspector, with the larger municipalities having more than one, some municipalities do not have a single veterinary inspector.

Municipality inspectors also have other duties and responsibilities in addition to food chain safety control, and some of these municipality inspectors do not have official cars, computers, or access to e-mail or the internet.

The staffing level and the lack of basic equipment are therefore likely to have an adverse impact on implementation and enforcement at municipality level, although the absence of performance standards and central monitoring of performance at municipality level makes this very much a subjective assessment.

#### **2.3.5 Budget**

The Kosovo Veterinary and Food Agency is well resourced, accounting for between 50% and 60% of the Ministry of Agriculture, Forestry and Rural Development's budget. This budget derives mainly from retention of a proportion of fees that are charged to food business operators, importers and exporters for official controls. The Agency is in effect self-financing, and is even a net contributor to the Kosovo consolidated budget.

The Ministry of Agriculture has also part-funded the capital cost of reconstructing the Kosovo Veterinary Laboratory in conjunction with the World Bank, with new

equipment being provided by the EU through a supplies contract that was delivered in July 2005.

However, the Sanitary Inspectorate of the Ministry of Health does not generate much income, compared to the Kosovo Veterinary and Food Agency, and its budget derives mainly from the Ministry of Health's allocation from the Kosovo consolidated budget. The Ministry of Health does not have the resources to carry out any monitoring or surveillance of the safety of the food chain, or to provide equipment for taking and transporting samples by municipality inspectors.

Budgets for food chain safety control at municipality level are variable. Some services are relatively well resourced, with inspectors provided with vehicles, equipment for sampling, computers, and access to e-mail and the internet. Inspectors in other municipalities lack even basic essentials such as mobile telephones, and vehicles to travel around their areas.

Official laboratories at the Kosovo Institute for Public Health and the Kosovo Institute of Agriculture charge inspectors the samples they submit for testing or analysis. However, most municipalities have little or no budget for carrying out this type of sampling, which in turn contributes to the lack of scientific data for food chain safety risk assessment.

### **3. Kosovo's road map for change**

#### **3.1 Summary**

Kosovo's advantage over neighbouring countries is being in the position to be able to rebuild its food chain safety control system from scratch. Kosovo is the first country in the region to propose a single food safety agency according to the EU model. However, the food safety law needs to be passed before the new Agency can develop and implement its monitoring and surveillance programmes, performance standards for municipalities, guidance for inspectors, and a strategy for upgrading food manufacturers and processors.

#### **3.2 Policy adjustments**

Kosovo has to make a very important food chain safety policy decision without further delay, namely the food safety agency's scope and remit, and its position as an Executive Agency within the structure of Government. This must be resolved at the earliest opportunity so that the food safety law can be passed and the new Agency can be established.

Once the new Agency is "up and running" it must quickly focus on identifying the food chain safety policy issues that must be addressed and prioritised, which needs robust national scientific data from monitoring and surveillance to be available for input into risk assessment (see below).

It is possible at this stage to guess what the national priorities might be, since human epidemiological evidence suggests that zoonoses such as Brucellosis and parasitic infections in livestock may be causing serious human infection, and microbiological quality of food and water may be causing widespread gastro-intestinal infection.

This indicates that controlling zoonotic and parasitic infections in livestock and the development of a national strategy for phased implementation of HACCP-based food safety management systems are likely to be amongst Kosovo's highest national food chain safety policy priorities.

#### **3.3 Implementation adjustments**

##### **3.3.1 Legislation**

The Administrative Instructions that were identified as priorities and drafted within the frame of the FSCK Project, and the Administrative Instruction on Official Controls, and the Guidance for Municipalities that has been drafted within the frame of the ISMAFRD Project, should be implemented as soon as the food safety law has been passed, as should the Administrative Instructions that have been drafted directly by the KVFA and MoH. The passing of the food safety law is therefore an urgent priority.

The transposition process also needs to be managed, and a rolling programme developed in which new priorities are identified and progressed, and existing EU-based legislation is reviewed and updated as necessary to keep pace with the constant changes in the *acquis communautaire*.

Other laws that deal with the safety of the food chain, including the Law on the Sanitary Inspectorate of Kosovo, the Law on Public Health, and the Veterinary Law need to be reviewed and amended where necessary to eliminate any conflicts and overlaps with the new food safety law.

The FSCK Project's final report recommended that the Project's Legislation Working Group should continue to function as well as coordinate and prioritise the transposition of the food safety *acquis communautaire*.

Kosovo should also establish a National Codex Alimentarius Committee, with membership drawn from the broad range of stakeholders in food chain safety. This could be based around the Legal Working Group.

### **3.3.2 Organisation**

Reorganisation of the inspection services into a unified inspectorate under the umbrella of the new food safety agency is a key priority.

Roles and responsibilities of the agricultural, phytosanitary, sanitary and veterinary services at central, regional, border and municipality levels need to be clearly defined so as to eliminate overlaps and gaps, and implement the "one enterprise, one inspector" principle wherever possible.

Roles and responsibilities of the Kosovo Institute of Public Health, Kosovo Institute of Agriculture and Kosovo Veterinary Laboratory should be clearly defined. A framework also needs to be established that enables data from the laboratories and other scientific institutions in Kosovo to be collated and inputted into the risk analysis process.

The organisation of the municipality inspectors on a regional basis to cover gaps in service, for example by providing municipalities that do not require a full-time veterinary inspector but need a veterinary inspection service from time to time, should be considered.

### **3.3.3 Management control systems**

A management control system to ensure that policy is implemented, legislation is up to date and being enforced, and hazards and risks are identified needs to be developed and implemented to ensure that Kosovo is meeting the food chain safety standards required for EU membership.

The basis of the control system should include codes of practice and guidance for inspectors, performance standards for municipalities, an EU legislation tracking mechanism, and comprehensive food chain safety monitoring and surveillance programmes.

### **3.3.4 Staffing**

A key task for the new food safety agency will be to conduct an organisational review and restructuring, in order to reform the existing inspection services into a new

integrated staffing structure that reflects the principle of “one enterprise, one inspector”.

### **3.3.5 Budget**

Budget priorities should address the allocation of resources to the development and implementation of monitoring and surveillance programmes, the collation of scientific evidence to input into the risk analysis process, and the purchase of land for construction of an animal waste rendering and incineration facility.

### **3.3.6 Projects**

Technical assistance is required under an EU global framework contract project to carry out pre-design studies for a new rendering facility. Such assistance should cover the design of the new rendering facility, the drafting of the tender documents, and the supervision of its construction under a works contract.

The phytosanitary sector has received some technical assistance within the frame of the FSCK, IBM and ISMAFRD projects, but has not had a targeted project since 2003.

### **3.3.7 Twinning**

The veterinary and food safety twinning project that is scheduled to start in late 2008 or early 2009 has been designed in part to assist the new food safety agency to implement and enforce the new EU-based legislation, and develop monitoring and surveillance systems.

During the course of the twinning project, opportunities for “twinning light” projects and complementary assistance from TAIEX to address specific issues should be identified.

### **3.3.8 Training and skill transfer**

Training and skill transfer is incorporated within the frame of the new veterinary and food safety twinning project, particularly in the form of mentoring and “on the job training”.