

**International Food Safety**

**Sanitary, Phytosanitary and Regulatory Framework<sup>1</sup>**

**Background**

Sanitary and phytosanitary (SPS) measures are applied to plant and animal products, both imported and domestically produced, to protect humans from animal and plant-borne diseases, plants and animals from pests or diseases and countries from the economic cost of pest or disease introduction or spread. SPS measures may address the nature of final products, together with how they are produced, processed, stored and transported. Those measures may include inspections, sampling, compliance testing, quarantine, import bans, etc., which, for WTO members, must be applied in a manner which would not constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail, or a disguised restriction on international trade. SPS measures are defined internationally through the 1994 GATT Agreement on Technical Barriers to Trade and, more recently, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures negotiated during the Uruguay Round.

The importance of SPS measures has been highlighted in recent years through, *inter alia*, the spread of BSE (mad cow disease) and FMD (foot-and-mouth disease) and through the entry of dioxin into food chains. These incidents have raised general awareness of the impact of diseases and contamination on public health and international trade. The increasing use of genetically modified (GM) seeds and food and associated perception that they could affect human, animal and plant health have also amplified community demands that governments remain vigilant in the sanitary and phytosanitary field

The WTO SPS agreement encourages countries to prepare their SPS measures based on international standards or regulations, but also allows countries to modify SPS measures to fit the origin and end use of products. In the case of agriculture, requirements will vary based on pest and disease environments in exporting countries and consumer use patterns in domestic markets. The Agreement requires that members “shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence”. Countries can, however, apply measures on a provisional basis as a precautionary step in cases where there is an immediate risk of the spread of diseases but where the scientific evidence is insufficient. The Agreement also requires that members “do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail” and that measures are “not applied in a manner which would constitute a disguised restriction on international trade”. All WTO member countries must maintain an Enquiry Point, responsible for receiving and responding to information requests regarding their SPS measures, including decisions based on risk assessment. Countries are also required to notify the WTO Secretariat, in advance, of any change to their SPS requirements. Such notifications are circulated to all member countries.

Many transitional economies are not well placed either to protect their communities and economies from introduced contamination, pests and diseases, nor are they always able to effectively protect their interests as defined in international law. They frequently lack information on policies and measures that affect their exports and often do not have

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<sup>1</sup> This paper draws extensively on the work of Dr. Ian Goulding and Dr. Robert Bambauer, who have studied and reported on SPS and food safety issues extensively in most of the countries participating in this workshop. It also uses material from WTO Sanitary and Phytosanitary Agreement: Issues for Developing Countries; Simonetta Zarrilli, South Centre, 1999.

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transparent regulatory frameworks or science-based systems for risk assessment and management, conformity assessment or equivalency. It is also often difficult for these countries to participate effectively in the setting of international standards through such institutions as the FAO/WHO Joint Codex Alimentarius Commission (*Codex Alimentarius*), the Secretariat of the International Plant Protection Convention (IPPC) and the International Office of Epizootics (OIE).

The number and complexity of regulations and standards that countries apply is increasing, in line with the growth in the volume, variety and sophistication of traded products. While most standards reduce risk, respond to consumer concerns and facilitate trade, the concern remains, despite the aforementioned WTO provisions, that, in a world of reduced tariffs and quotas, SPS requirements could be used to constrain trade and protect markets through unjustified specification or costly and time-consuming tests. This is a particular risk with agricultural trade, especially within economies that have traditionally used border taxes to protect support their agricultural economies. Quite often, the line between legitimate requirements and the protection of domestic producers is difficult to define, particularly concerning conformity tests, which assess a product's compliance with a standard or a regulation

Here, the principle of "equivalency" is expected to reduce costs and ensure freer trade. The WTO agreement states that "members shall accept the sanitary or phytosanitary measures of other members as equivalent, even if these measures differ from their own or from those used by other members trading in the same product, if the exporting member objectively demonstrates to the importing member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection". In practice, there has only been limited application of this principal, mainly within trade pacts (EU, NAFTA, etc) with many countries seeking "sameness" instead of equivalency in testing regimes.

### **Effective SPS and Food Safety Services**

Only a few countries represented at this workshop have an overall strategic direction relating to food safety and quality. In most, different organizations frequently work independently in their respective areas, coordinating their efforts only at the margins, where there is a perceived conflict or over-lap of interests. There is little coordination across the whole range of activities. Furthermore, on a national level, there is no overarching mechanism for identifying and quantifying the severity of all food safety risks to the population (risk assessment) or for the allocation of control resources (inspection, sampling, monitoring and laboratory testing) to those hazards which present the greatest risk. Separate approaches may be and frequently are adopted by the different organizations involved.

There is no "right" way to organize a SPS regime or food safety and inspection service. The various structures shown in Table 2 are compliant with EU requirements and some are multi agency based and quite complicated, but work because of long embedded institutional relationships that are not challenged by the constituent agencies. An increasing number of EU Member States, however, have come to the conclusion in the last 5 years that food safety is such an important issue that its management should be dealt with by a single agency with exclusive responsibility for this area. Sweden, Finland, UK, Ireland, Portugal, France and the Netherlands are some of the countries that have, or are in the process of, adopting this approach. Whatever the approach, however, the objective should be to establish SPS and food safety systems that are institutionally efficient, rule based, take into account the concerns of consumers and industry, can act rapidly to address hazards and are consistent with international bodies (EU, WTO, OIE, IPPC and Codex Alimentarius Commission).

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The vision for such a SPS/food safety regime should be to ensure:

- market access worldwide for exports through international negotiations and efficient certification systems;
- protection of the country's agricultural production, consumers and environment through efficient risk analysis and management and inspection systems; and
- protection of human health and the health of the country's flora and fauna through effective quarantine systems.

**WTO and EU Compliance**

The WTO does not require members to operate an end-product standards based food control system per se. The measures applied, however, have to be justifiable and it is likely that many existing standards would not withstand a challenge on the basis of their need in relation to risks to human, plant, or animal health. Risk assessment is a technical procedure in which food safety hazards are identified and characterized, and the exposure of the population to them is quantified. Using this knowledge and information regarding the severity, policy makers are able to assess where best to focus resources for control. The WTO SPS Agreement requires that technical measures be based on risk assessment. The risk assessment therefore provides the defense against challenges from trading partners that technical measures are unduly restrictive. Without such a mechanism for risk assessment, countries are not able to fully benefit from WTO membership and may well be disadvantaged.

EU law gives much clearer guidance on the type of food controls required, both in terms of third country suppliers to the EU market and as an accession partner or full member, which is certainly the long term goal of most countries represented at this workshop. EU Food law is contained in the EU Treaty, case law, a few measures describing the system and a large number of technical measures relating to a diverse range of horizontal and technical requirements, know as the *acquis communautaire*. Whilst all are important, the EU system of control is defined in one principal regulation and two directives. These are:

- regulation (EC)No 178/2002 Of The European Parliament And Of The Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs;
- Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs.

The system defined in these measures comprises four principal activities, described in Table 1 below.

**Table 1 EU Food Safety Requirements**

| Food safety function          | Definition  |
|-------------------------------|---|
| Risk assessment               | scientifically based process consisting of four steps; hazard identification, hazard characterization, exposure assessment and risk characterization; this activity would collate information on food hazards, and applying it to the Croatian situation. |
| Risk communication            | the exchange of information and opinions as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties           |
| Risk management               | the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options      |
| Official control (inspection) | inspection of establishments, processes and products throughout the distribution chain, supported by sampling and checks on Hazard Analysis and Critical Control Point (HACCP) systems  |

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In relation to products of animal origin (meat, fish, dairy products etc) a third country supplier to the EU is required to meet the requirements of specific vertical hygiene directives relating to the control system. This requires the nomination of a “competent authority” and the implementation of a series of controls “at least equivalent” to those defined by the directive including the implementation of the HACCP system. In addition, the third country supplier of products, if of animal origin, should also have in place adequate controls over the use of veterinary medicines as defined in Council Regulation (EEC) No 2377/90 of 26 June 1990, which sets maximum residue limits. In addition there should be residue monitoring, both at farm level, both for banned substances and in final products of foods of animal origin. Concerning the control of non-animal food and feed, a new regulation is being considered by the European Parliament and, when passed, will apply the requirement of “at least equivalency” to control systems for all foods including controls and monitoring of plant protection products.

### **Prevailing Regimes in Transitional Economies**

Typically, in transitional countries, the following organizations are responsible for the implementation of SPS and food safety and quality services:

- ♣ Ministry of Agriculture,
  - Veterinary Department
  - Plant Protection Department, where
  - Food Processing Department
- ♣ Ministry of Health,
  - Sanitary Department
- ♣ Ministry of Industry, Economy or Trade
  - State Department(s) of Standardization, Metrology and Certification
  - State Inspection of Products and Services

This institutional framework encourages competition between institutions for territory and resources, resulting in a substantial amount of overlap between the lawful activities of the different inspection bodies concerned. This is commonly reflected in areas of food safety supervision of food processing establishments and border inspection posts, the monitoring of residues and inspection at markets. In the best of these situations this duplication is resolved by joint inspections or by division of responsibilities within the same establishment, both of which are inefficient. At worst it results in multiple inspections which give conflicting instructions to industry and significantly raises cost, thus reducing competitiveness. Prevailing legislation, which often lacks specificity concerning the distribution of responsibilities and typically empowers people rather than providing rules can exacerbate this situation. The resultant lack of transparency creates the risk that legislation can be used for gain or to protect vested interests. Inspectors can find fault with anything if they look hard enough and potentially suffer a conflict between professional and financial/political interests.

Another common feature of existing structures is the dominance and low capacity of state owned laboratories, which typically suffer from inadequate premises, outdated and broken equipment, limited knowledge of modern technical methodologies and low management capacity, especially in relation to quality assurance. State investment in laboratories is not a pre-requisite for an effective control system. Should the State retains some laboratory capacity, this is likely to require a significant rationalization in their number and scope and the development of a clear policy on the role of the state in providing laboratory services.

Inadequate test accreditation, particularly concerning capacity to accredit tests undertaken by testing laboratories according to international standards, is another common shortcoming. Whilst laboratories are “accredited” to the lower national standards, there is often little

assurance of the quality of the testing services being delivered. For those laboratories with good standards to flourish, the introduction of the EN45001 accreditation benchmark is required, together with advisory services to help laboratories meet these standards.

Food standards are a further constraint as they often involve mandatory vertical product standards containing specifications relating to both food safety and food quality. These cover issues such as fat content of milk, sugar content of jams, meat content of sausages etc. Another aspect of quality relates to foods of special characteristics. This might include the nature of the process giving rise to the food (organic, or environmental labeling schemes) or the controlled designation of origin (where the name of a region is reserved for foods produced in that region according a defined process). While controlled designation of origin may exist for specific products, e.g. wine, generally there is often no scheme that allows agricultural or food producers to define and register a specially designated origin, for any food product. The availability of such a facility is essential to support the development of agricultural markets in agricultural economies that frequently produce high quality specialty foods from regions with special agricultural characteristics.

### **The Way Forward**

A policy debate needs to be started on an informed basis and agreement reached to address the key functional and organizational requirements for the components of a food control system as described in Table 1. Such a policy initiative must be multi agency based otherwise it will not address the issue of an integrated coherent system of food control. That policy debate should address:

- *organizational and structural changes* in SPS management and food safety including the development of a single framework food law, which defines the various components of the food safety system and responsibilities for them. This is likely to lead to the recommendation for a single food safety agency. The law must ensure that all food enterprises, from farm to final sale, are subject to appropriate official food safety inspections and that the food safety condition of each enterprise is inspected and controlled by a single inspection body. The food law should also make provision for a scientific risk-based approach to the management of food safety risks and for the registration and protected designation of foods with special characteristics related to their origin or production process;
- *certification of food*, as the prevailing mandatory standards imposes a financial burden on food businesses for little or no benefit and are generally not sustainable under WTO membership and EU harmonization policies. Modern food control systems now rely substantially on control of the process and production environment to ensure elimination of hazards. This requires well-informed inspectors who use their knowledge of food safety hazards and the conditions that give rise to them, to assess safety of an operation as the condition for approval to operate;
- *laboratory services* for food control, concomitant with the move to process-based rather than end-product controls. Here the role of the laboratory should be to provide testing services to inspectors to assist them in decision making about the safety of processes. The inspector may use the services of any laboratory, subject to that laboratory's testing being of a minimum standard as evidenced by a valid accreditation. While the role of the laboratory is clear, there is also a need for accreditation of laboratories to international standards and for changes to the funding of laboratory services for official control, which should be through a state budgetary provision, managed by the end user of the service, not the laboratory. In addition, laboratories have important food safety functions to fulfil in terms of reference activities and a contribution to risk assessment. Within this framework, a policy choice on the role of public and private testing laboratories is also required.

### **Food Safety Agency**

Considering the existing cross-Ministerial responsibilities for food safety and the limited financial and staff resources and capacity in this field, transitional economies should consider establishing an independent Food Safety Agency with the objective to effectively apply state resources to ensure that food is as safe as possible for human consumption.

The responsibilities of such an Agency would include:

- management of inspection of foods and places where food is produced, processed and distributed (implementation contracted to a responsible government Authority);
- management of inspection and certification of food at borders (implementation would be contracted to a responsible government Authority);
- monitoring of foods on the market to assess compliance and identify and quantify human health hazards (contracted to inspection agencies/accredited laboratories);
- ensuring adequate laboratory provision;
- prosecution of offences against the food law;
- review and development of new food legislation;
- assessment of risks to human health from foods;
- receiving and acting on complaints from consumers;
- providing information to industry and consumers about food safety.

Such an agency is likely to include:

- A Food Safety Council, appointed by a Decision of Government, which would act as the Management Board (the decision making body). The Council would comprise of the Director of the Food Safety Agency and representatives of ministries and agencies responsible for public health, agriculture and animal health, consumers and the food industry. The key functions of the Food Safety Council are to appoint the Director and senior staff, and establish the policies of the Agency in all respects.
- A Scientific Council, appointed jointly by the Ministers of Health and Agriculture, comprising of persons of scientific and technical merit in the domain of food safety. It would include at least the Directors of the Institutes of Public Health and Veterinary Science. It's functions would be to follow scientific and technological progress in food safety, propose and approve the implementation of studies, and information activities directed at improving knowledge on food safety and to disseminate information and knowledge of problems relating to food quality and safety.
- A Consultative Council acting as an advisory body, constituted by members of diverse interests relevant to the area of food safety, namely, by producers, industry, commerce and consumers. The members of the Consultative Council would likely be appointed by the Ministers of Agriculture and Health. The function of the Consultative Council would be to issue opinions on all issues related to food safety.
- Functional departments of the agency are likely to include Inspection and Enforcement, Scientific Affairs, Public Relations and Administration.

Institutional reform is just one step in the establishment of a comprehensive SPS regime and food safety system. Capacity must be built to manage the new functions within the food control system including risk assessment, risk management and communication and the introduction of hazard-based inspections and HACCP. Food inspector would require up-skilling in the areas of food hazards and their controls, the epidemiology of food borne diseases, hygienic design and construction, staff hygiene, water treatment and testing, food processing technology, HACCP and inspection and the food law. An institutional basis and multidisciplinary capacity for risk assessment must established and support provided for the implementation of a series of risk assessment studies. Reference laboratories should be nominated for each test and the national laboratory accreditation service established. And the whole program should be linked to upgrades in production and processing technology.

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### EUREPGAP

Although not part of the SPS regime or official food safety system, I would like to draw your attention to EUREPGAP, a global reference scheme for good agricultural practice.

EUREPGAP sets out a framework for Good Agricultural Practice (GAP) on farms, which defines essential elements for the development of best-practice for whole farm management and specific recommendations for the production of horticultural products – fruit, vegetables and flowers - acceptable to the leading retail groups. EUREPGAP provides a long-term, sustainable framework for agriculture and rural development in Europe and supports the principles of HACCP and encourages its use. EUREPGAP certified farmers must demonstrate their commitment to:

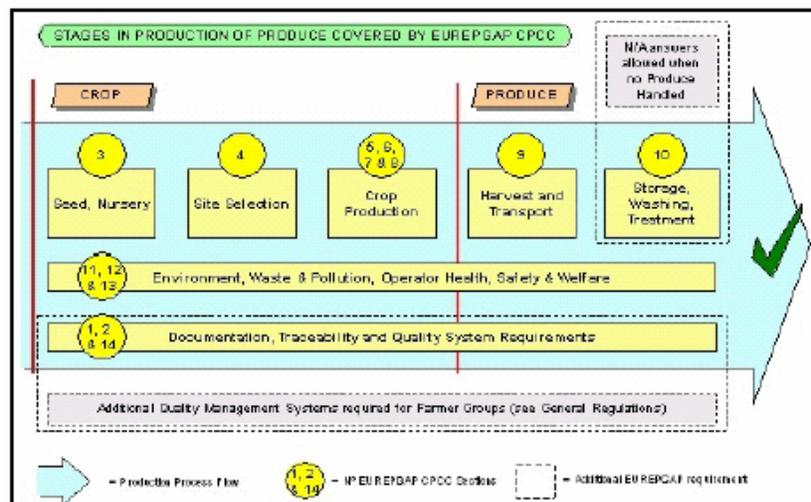
- maintaining consumer confidence in food quality and safety;
- minimizing detrimental impact on the environment, whilst conserving nature and wildlife;
- reducing the use of crop protection products;
- improving the efficiency of natural resource use; and
- ensuring a responsible attitude towards worker health and safety.

Farmers receive their EUREPGAP approval through independent verification from a verification body that is approved by EUREPGAP. The Scheme documents include the:

- **EUREPGAP General Regulations** which sets out the rules by which the standard will be administered;
- **EUREPGAP Control Points and Compliance Criteria Protocol (CPCC)** is the standard with which the farmer must comply, and which gives specific details on how the farmer complies with each of the scheme requirements and
- **EUREPGAP Checklist** which form the basis of the farmer external audit and which the farmer must use to fulfil the annual internal audit requirement.

As described in EUREPGAP General Regulations, this scheme is divided into Major Musts (red background), Minor Musts (yellow background) and Recommendations (green background) activities. All Control Points MUST be audited annually. The verification of compliance demands records that are first linked to the farm (and if applicable also the field, orchard or greenhouse) in which the crop is grown, until the moment when the crop is harvested, after which the recording is linked to batches or lots and the Produce Handling site.

**Figure 1. Stages in the production of product covered by EUREPGAP CPCC**



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**Table 2. Organization of Food Security Services in Some European Union Countries**

| Country     | Agency   | Risk analysis                     |               |            | Official control of food safety   | Food quality                                | Agency responsible to:                                  |
|-------------|--|-----------------------------------|---------------|------------|---|---|---|
|             |  | Assessment                        | Communication | Management |   |   |   |
| 1. Denmark  | Danish Veterinary and Food Administration          | ✓                                 | ✓             | ✓          | 11 Regional Veterinary and Food Control Authorities of the Agency                 | Ministry of Food, Agriculture and Fisheries | Ministry of Food, Agriculture and Fisheries             |
| 2. Ireland  | Food Safety Authority of Ireland                   | ✓                                 | ✓             | ✓          | Other organizations subject to contract   | n/a   | Ministry of Health                                      |
| 3. Finland  | National Food Agency                               | ✓                                 | ✓             | ✓          | Agency does meat inspection. Remainder in municipalities                          | n/a   | Min. of Agriculture, via Food Control Cooperation Group |
| 4. UK       | Food Standards Agency                              | ✓                                 | ✓             | ✓          | Agency does meat inspection. Remainder in municipalities                          | Agency                                      | Parliament, via Ministry of Health                      |
| 5. France   | Food Safety Agency                                 | ✓                                 | ✓             | ✓          | Other organizations/ agencies   | n/a   | Jointly. Ministry of Agriculture/Health/Consumption     |
| 6. Portugal | Food Safety and Quality Agency                     | ✓                                 | ✓             | ✓          | Agency  | Agency                                      | Prime Minister  |
| 7. Sweden   | National Food Administration                       | ✓                                 | ✓             | ✓          | Agency does meat inspection and large establishments. Remainder in municipalities | Agency and Ministry of Agriculture          | Ministry of Agriculture                                 |
| 8. Austria  | Federal Ministry of Social Affairs and Generations | ✓                                 | ✓             | ✓          | 9 Provincial Governorates   | n/a   | Not an independent agency                               |
| 9. Holland  | Netherlands Food Authority                         | Currently in process of formation |               |            |   |   |   |