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# ENTERPRISE DEVELOPMENT AND MARKET COMPETITIVENESS (EDMC)

**LEGAL FRAMEWORK, INSTITUTIONAL SETUP AND QUALITY  
INFRASTRUCTURE APPLICABLE TO THE AGRICULTURAL  
AND AGRO-PROCESSING SPHERE**

October 5, 2012

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# ENTERPRISE DEVELOPMENT AND MARKET COMPETITIVENESS PROJECT

LEGAL FRAMEWORK, INSTITUTIONAL SETUP AND QUALITY  
INFRASTRUCTURE APPLICABLE TO THE AGRICULTURAL AND AGRO-  
PROCESSING SPHERE

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## 1. Food Safety and Agricultural Health Management in Armenia

Quality infrastructure applicable to the agricultural and agro-processing sphere covers Food Safety<sup>1</sup> and Agricultural Health<sup>2</sup> control systems, which are two different but related categories, namely risks to consumers from potential illnesses from consuming contaminated goods and risks to producers in the form of potential damage or destruction of production capacity, respectively (for specifics, see footnote).

Three main principles that currently guide Food safety and Agricultural health management activities in many parts of the world will also be applied in Armenia (see also Annex 1).

- The farm-to-table concept for food safety focuses on the prevention of quality and food safety risks at all stages of production, marketing, processing, retailing, and consumption. This concept emphasizes the vital importance of including all players in the food chain, from the agricultural input providers and farmers to consumers.
- The integrated agricultural health safeguarding system concept provides integral, seamless systems for protection of food from alien pests and diseases through exclusion, surveillance, control and eradication, and certification activities.
- Finally, because of the sector's great diversity and dynamic changes, a broad-based institutional approach for improving Food safety and Agricultural health control systems that seeks to improve the overall institutional and regulatory framework rather than a focus on a particular commodity or group of commodities is followed. The framework will provide stakeholders in a particular food chain with a solid foundation for coordination and development of commodity-specific efforts based on market demand, risks imposed, and the stakeholders' needs.
- Internationally Food safety and Agricultural health management is done also through utilization of risk analysis concept and The Hazard Analysis Critical Control Point (HACCP) concept.

This report will discuss in detail the application of these initial best practice concepts by Armenian Government. In this regard, we recommend a prioritizing/focus in the following areas:

- Accelerated movement towards better inter-institutional coordination at the national level and between the field and national levels and the eventual establishment of an independent agency (a role which could in principle be played by the Armenian Food Safety Agency)

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<sup>1</sup> *Food Safety* deals mainly with maximum residue levels chemical substances (for example, pesticides, heavy metals, antibiotics, hormones, and other drug or animal feed additives), natural toxins (aflatoxins and so on), zoonotic diseases (bacterial and parasitic), food additives, decomposition of the food product, and other microbial or chemical contaminants. Food safety concerns affect both domestic and global market access. Internationally, food safety standards are defined by *Codex Alimentarius*, although increasingly private sector buyers or consortia of private buyers, such as GlobalGAP, are defining protocols concerning issues other than food safety standards and sometimes have stricter standards than those of the international bodies; and

<sup>2</sup> *Agricultural Health* deals mainly with the protection of the importing country from the introduction of pests and animal diseases. Agricultural health standards include lists of pests, defined under the aegis of the International Plant Protection Convention (IPPC), and lists of diseases, defined by the World Animal Health Organization (OIE), and including contagious diseases with significant effects on international trade (the so-called the list A diseases), including Foot and Mouth Disease, Classical Swine Fever, Newcastle Disease and Avian Influenza etc.

- Accelerated movement towards harmonization of national and international standards and technical regulations
- Assessment of the prospects for/advisability of developing a comprehensive risk analysis capacity versus core reliance on outside capacity through international technical assistance or private consultancy services.
- Determining the optimal balance between national and regional oversight of pest and disease surveillance and response institutional structures and initiatives; including the establishment of effective coordination and cooperation mechanism between national and provincial authorities

## 2. Farm-to-table Approach for Food Safety Management

Food safety programmes increasingly focus on a farm-to-table approach as an effective means of reducing food-borne hazards. The Armenian Government has recently followed a holistic strategy to control food-related risks through reviewing every step in the chain, from the use of raw materials to food consumption. This farm-to-table approach emphasizes preventive interventions at critical control points. Hazards can enter the food chain at the farm level, and persist or grow at any point in the chain until the food reaches the consumer. The farm-to-table system focuses on the domestic food supply, attempting to reduce or eliminate food-borne organisms and residues in the domestic food chain, as well as in exports.

Effective food safety management aims to increase the supply of safe and healthy food, and minimize food-borne diseases. The immediate objectives of farm-to-table approach in food safety management are as follows:

- Improve access to safe food and minimize injuries and losses caused by food-borne diseases;
- Increase access to international and domestic food markets;
- Reduce the incidence of emerging plant pests and animal diseases; and
- Strengthen Armenia's capacity to effectively implement of its WTO SPS commitments.

Implementing the farm-to-table approach requires five steps as described below.

I. Strengthen surveillance systems of food borne diseases in Armenia Surveillance of food-borne diseases is an increasingly high-priority public health measure in countries around the world. Surveillance is essential to estimate the impact of such diseases on health and economics, and evaluate disease prevention and control programs. Surveillance is also important for rapid detection and response to outbreaks.

Activities:

- Strengthen the government's commitment to surveillance of food borne disease.
- Strengthen surveillance systems epidemiologically and in the laboratory and in food monitoring programs.
- Identify, adapt and coordinate with global approaches for food-borne disease surveillance.

## II. Develop methods to assess the safety of foods produced by new technologies

The application of biotechnology to food production raises new questions.

Activities:

- Development of improved, internationally agreed methods and guidelines for evaluating the safety of new technologies.
- Formulation of policy and guidance on the use of foods and food ingredients derived from genetic engineering.
- Development of an evaluation framework that accounts for safety, health benefits, environmental effects and socioeconomic consequences.

## III. Promoting communication of risks and benefits.

Good information and communication about the farm-to-table program will stimulate useful dialogue between the stakeholders (consumers, industry, producers) on risks and benefits, and will deepen their participation in the process. It will also increase promote the improvement of food safety practices at home.

Activities:

- Advocacy to ensure that food safety is considered a public health priority.
- Advocacy to ensure that the results of risk assessments and analyses are communicated in a readily understandable form to permit dialogue between stakeholders, including consumers.
- Development and delivery of food safety products and publications.
- Foster public participation in discussion of risks and benefits.

## IV. Improving international cooperation

Use international best practices to formulate a sustainable, integrated food safety system to reduce health risks along the entire food chain, from primary production to the consumer.

Activities:

- Apply food safety considerations in food imports and exports, particularly in cooperation with EU.
- Coordinate and harmonize with food safety measures and standards adopted in Europe, and by international bodies at the country level.
- Develop effective links and coordination among agencies involved in food safety control in main exporting markets of Armenia

## V. Strengthening cooperation with stakeholders within the country.

Build the national food safety apparatus involving the health, agriculture, trade and commerce sectors, as well as provincial and municipal governments, and NGOs.

Activities:

- Make common cause with international donor agencies for food safety as a priority in public health

- Develop food safety management capacities at the regional (marz) level based on regional needs.
- Provide technical assistance, education and training for food safety initiatives implemented by NGOs and industry associations.

### 3. Integrated Safeguarding System for Agricultural Health Management

An integrated agricultural health safety system such as the farm-to-table approach emphasizes preventive interventions at critical control points. The agricultural health safety system focuses on protecting Armenia agriculture from the introduction and establishment of alien pests and diseases, and reducing the impact of pests and diseases already found in the country. Risk analysis and HACCP in agricultural health and safety require that information be analyzed on a scientific basis. Risk analysis tends to work at the strategic and planning level, though, whereas HACCP works at the operational level.

Protection from alien agricultural pests and diseases should be a seamless integrated safeguarding system and utilize a series of interventions at critical control points: international activities, ports of entry, detection/surveillance, and response (eradication/control).

Both international efforts and measures taken at the port of entry provide protection from pests and diseases from entering the country. Detection and surveillance measures focus on rapid detection and diagnosis of alien pests and diseases, and on mitigating the impact of established alien pests and diseases through eradication or control programs. A strong agricultural health safety system assures the safety of fresh agricultural products by excluding alien pests and diseases or, when they do breach the borders, by detecting and responding to these invasions in a timely and effective manner. The importing country has the authority within the food safety and agricultural health management framework and implementing guidelines to defend against alien pests and diseases.

### 4. Broad-based Institutional Approach

#### a. Institutional Framework

The national food safety and agricultural health management and control infrastructure consists of three main components: Policy, inspection, and laboratory testing. Strong public and private institutions and effective coordination among them will be a critical element of the integrated agricultural health safety system and farm-to-table approach for food safety. In 2010, the Armenian government initiated reforms to bring public management of food safety and agricultural health area in conformity with general EU general approaches. Following the EU approach, the Armenian government appointed the following ministries and agencies, to implement, control and enforce food safety and agricultural health control legislation<sup>3</sup>:

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<sup>3</sup> Current trends in many of the industrialized countries (Australia, New Zealand, Canada, and the EU) are to create independent agencies, in particular for policymaking and food inspection. Recent food scandals have highlighted the weakness and conflict of interest in situations where policy preparation, enforcement, and evaluation are left to one department, often closely linked with the farm and processing sector, rather than to consumers. The new tendency is, therefore, to separate policymaking and evaluation from actual implementation, putting these tasks in the hands of an

- The Ministry of Agriculture is responsible for policy drafting and implementation in broader Food safety and Agricultural health strategy;
- The Ministry of Healthcare is responsible for policy drafting and implementation in food safety, especially toward the retail and consumption end of the value chain;
- The Food Safety State Service of the Ministry of Agriculture is responsible for food safety and agricultural health control and enforcement. For years food safety and agricultural health control responsibilities have been concentrated within the Quality Inspectorate, currently reorganized into Market and Consumer Protection State Inspection within the Ministry of Economy. Recently, however, following donor agency and particularly the EU lead, strengthened again the responsibilities of the Ministries of Agriculture, through Food Safety State Service, in the food safety control area.
- The Ministry of Healthcare is responsible for the inspection of hygienic conditions of products manufacturing, transportation, storage, marketing, catering, and rendering.
- The Market and Consumer Protection State Inspectorate of the Ministry of Economy is the authorized body for the control of labelling, weights and measures, and inspection of compliance of all kind of products (except pharmaceuticals) with normative requirements at all stages of handling with products – processing, storage, transportation, utilization, placing at the market

There are convincing reasons for increasing involvement by the Ministry of Agriculture. The most important is the trend toward addressing food safety and agricultural health control issues along the entire production chain, as recommended by the farm-to-table approach. The Ministry of Healthcare, in addition to its food safety responsibility, is responsible for a large variety of other health-related issues including health care, pharmaceuticals, tobacco control, and diseases, as well as for special purposes food. Following the EU approach, the Armenian government set out to create a unified agency with food safety and agricultural health control and enforcement functions. Accordingly, in 2010, the Food Safety State Service (FSSS) of the Ministry of Agriculture<sup>4</sup> was formed through the merger of Food Safety and Veterinary State Inspectorate and the Plant Quarantine and Farming State Inspectorate<sup>5</sup>.

With a much stronger focus on the total food chain worldwide, the coordination between different institutions has assumed major importance. In Armenia, several ministries share responsibility to assure a safe food supply. However, lines of demarcation are not clearly defined, and there is danger of overlap as well as of neglect of important issues. Clarification of respective roles, communication among ministries, and coordination of effective use of laboratory capacity are challenges to a comprehensive food safety action plan. Experience shows, however, that clear lines of command in the Armenian public sector are difficult to achieve, and so. Institutional change should be gradual, utilizing the existing administrative structure.

The agencies concerned with food safety and agricultural health set the standards as well as implement and monitor them, thus creating a vested interest in underreporting or delayed reporting of infringements, to avoid exposing failures in implementing and enforcing the standards. Increasingly in the OECD countries, standards setting, implementation, and monitoring are therefore allocated to separate institutions. Another important function is technical assistance on procedures to be followed by inspectorates, which include publication of work plans, periodic reporting, and the conduct and publication of performance audits.

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independent agency, at “arm’s length” from the sector ministries. The technical implementation of policies (for example, vaccination campaigns and pest control) can be left to the responsibility of the technical agencies.

<sup>4</sup> With regard to human and animal health and plant protection issues, including pre-market authorization procedures and market surveillance

<sup>5</sup> The President Decree N-292, dated December 11, 2010

Inspectors often require companies to adhere to norms approved at the minister level, and sometimes even to GosStandards (GOST standards), inherited from the Soviet Union. This is because public authorities have not yet formulated and enacted modern regulations in the health protection area that would replace Soviet-era standards.

A case in point: Armenia lacks an adequate legislative and organizational infrastructure to regulate pesticides, and at the field level, little coordination takes place between producers and the regulator. But to have a clear understanding of agricultural practices and of the main “entry points” for contaminants, and the regulator needs to be informed on the use of new pesticides, feed additives, and antibiotics.

Strengthening food safety and agricultural health control services requires considerable investment in testing laboratories and a monitoring infrastructure, which are an essential component of a food control, surveillance and monitoring. The capacity of the system needs to be built up incrementally, and it needs resources.

In 2006, the government segregated control and enforcement functions of state inspectorates from monitoring and laboratory testing functions to increase the independence of the supervision function. As a result, public laboratories and monitoring facilities are currently managed by ministers rather than by the inspectorates. Inspectorates retained the control and enforcement functions, including determination of sanctions in the food safety and agricultural health control area, whereas monitoring, research, testing, diagnostics, vaccine distribution, animal registration, and other activities in human, animal, or plant health protection have been passed to entities that are independent from laboratories.

In May 2011, the government separated administrative responsibilities for the following functions: Laboratory testing and examination<sup>6</sup>, general monitoring and implementation of the programs for food safety and agricultural health and quarantine, implementation of national food control programs, developing emergency responses in food safety and agricultural health management<sup>7</sup>, and research and risk assessment in human, animal and plant health protection<sup>8</sup>.

To increase agricultural exports, Armenian producers need access to accredited laboratories capable of providing internationally recognized certifications for foods and beverages. However, none of Armenia’s accredited laboratories meet ISO 17025 requirements. Armenian laboratories comply with some international standards (best practices), in such areas as facility construction, utility services, laboratory equipment, laboratory management practices, laboratory staff number and training level, reagents, samples collection, labelling and handling, reporting procedures, quality control procedures and program, equipment maintenance and repair, but none of the laboratories showed full compliance with all criteria set forward by ISO standards<sup>9</sup>.

Public laboratories and testing centers are under-funded and so testing equipment, monitoring and control capacities and technical skills of personnel fall short of modern food safety requirements. In particular the laboratories in marzes (regions) and in border posts need upgrading if not replacement. In addition, because of low testing demand from the private companies, operation of the public laboratories and testing centers depends primarily on requests for their services by inspectorates. Therefore, public laboratories and testing centers are strongly linked with inspectorates, which calls into question their independence

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<sup>6</sup> Decree N 631-N of the Government of Armenia, dated May 5, 2011

<sup>7</sup> Decree N 637-N of the Government of Armenia, dated May 5, 2011

<sup>8</sup> Decree N 630-N of the Government of Armenia, dated May 5, 2011

<sup>9</sup> USAID Armenia Enterprise Development and Market Competitiveness Project; *Laboratory Assessment Report*; AUGUST 10, 2012

The establishment, operation and maintenance of laboratories requires considerable capital investment so the government should identify public laboratory upgrade opportunities through consolidation of public laboratories, staff reduction and operational cost downsizing. For example, the infrastructure, equipment and personnel for quarantine, laboratory, and surveillance operations are often similar.

Because EU markets are a natural outlet for Armenia's agricultural exports, most laboratories and testing centers need substantial improvements towards Good Laboratory Practice (GLP) levels, to be recognized as a reference laboratory in EU. To achieve this, the government needs to update laboratory certification practices to meet international best practice standards including regular monitoring of the laboratories and revocation of certificates of laboratories that do not meet standards. The government can also create liberal regime encouraging local exporters to use laboratory capacities in neighboring countries or the EU as an alternative to capacity in Armenia.

Provincial, district, and local entities carry out important functions in food safety and agricultural health. Provincial bodies play a crucial role in implementing and supporting pest and disease surveillance and response initiatives. They are responsible for the declaration of pest and disease outbreaks, and for the payment of compensation for destroyed animals. Effective implementation of national programs in a decentralized structure, however, requires effective coordination and collaboration between the national and provincial authorities, but unfortunately this is often lacking in Armenia.

## **b. Legislation**

Armenia is a member of major international treaties and organizations in the food safety and agricultural health control area,<sup>10</sup> and critical framework laws were adopted in conformity with Armenia's commitment under WTO agreements (See Annex 2). However, EU funded analysis has uncovered a number of discrepancies between the core legal/regulatory framework in Armenia and EU standards<sup>11</sup>. Accordingly, the EU Advisory Group is advising the government on development of a new food safety law, to facilitate a higher level of compliance with EU standards.

Currently in the domestic food safety sector, there are national (ANS), international (ISO), European (EN), and interstate (GOST) standards, which define the quality and safety requirements, testing methods of plant and animal origin food production, and requirements for storage, packaging, transportation, labelling and other stages of the product chain, as well as consumer information standards.

In terms of the core regulatory framework being applied, until 2005 Armenia heavily relied on 18 000 GosStandards (GOSTs) in Food safety and Agricultural health areas. GOSTs were not harmonized with the norms of the International Standards Organization (ISO) and the European standards (EN). They contained both mandatory safety requirements and voluntary product specifications in one document. In 2005, following Armenia's WTO accession, GOSTs, once applicable as mandatory technical regulations, became voluntary and a huge regulatory gap emerged, as very few mandatory technical regulations had been approved at that time. So far the government has developed several of its own technical regulations in food safety control, and few

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<sup>11</sup> A.R.S. Progetti s.r.l. of Dialogue Consortium; *Support to the Government of Armenia for implementation of administrative capacities evaluation: Report on the assessment of institutional structure and administrative capacities in the field of food safety, veterinary and phytosanitary policy*; prepared Karine Azatyan, Iren Melkonyan, Colm Halloran; page 36

in animal and plant health control (see Annex 3)<sup>12</sup> to replace GOSTs. These regulations deal with product standards, processing standards and production methods. However, the compliance of the newly-enacted technical regulations with EU and other international standards may be uncertain, because many of the new technical regulations cases were based on technical regulations of the Russian Federation rather than the EU. While the shared regulatory history allows Armenia to export its agricultural goods to countries of the former Soviet Union, especially Russia, EU markets have higher food safety standards, effectively barring Armenian agricultural products from their borders. It will take considerable time for Armenia to assimilate International and EU practice and implement the necessary domestic legislation (see Annex 2).

Armenian public authorities (ministries, inspectorates, and the National Institute of Standards) lack sufficient staff trained on EU, WTO and other international approaches on technical regulation and standardization<sup>13</sup>. Inadequate command of English on the part of civil servants, contributes to Armenia's isolation from mainstream policy and practices. There is also a lack of coordination among different government agencies and private sector stakeholders in regulatory development. Regulations are mainly developed in isolation by the appointed government agencies, which rarely call on the expertise of other public and private sector stakeholders.

Adoption of EU and international food safety technical regulations is a precondition for access to international markets, but it is a complex, time and resource consuming process. It must be done gradually, as rapid introduction of such standards would likely have a significant negative impact on current market players, as well as on market entrants. Ideally the government would craft the policies, regulatory framework and procedures associated introducing EU food safety standards after a performing a detailed economic analysis of public and private sector costs associated introducing such requirements via regulatory impact assessment.

## 5. Risk Analysis

Risk analysis employs risk management, risk assessment, and risk communication techniques to help decision makers (risk managers) compare strategies and priorities using well-accepted principles. It allows managers in the food safety and agricultural health field to consider the core needs and requirements of the supply chain, monitor and evaluate their implementation, and communicate with stakeholders to ensure that the analysis and decisions taken address the appropriate priorities<sup>14</sup>. Importing countries are responsible for conducting the risk analysis and establishing their own import requirements. Exporting countries are responsible for providing up-to-date information on the pests and diseases found at home. The integrated safeguarding action plan, when fully implemented, will then produce the critical risk information. Until that time, though, the continued use of ad hoc targeted surveys of commodities with export potential will provide the needed data.

The risk analysis approach is adopted because the regulation of risk is one of the most important

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<sup>12</sup> For a long time, the Ministry of Health was more advanced than other government agencies in developing food and agricultural health control regulations. However, for past few years the Ministry of Agriculture has participated in regulatory drafting activities, and now it has developed a government-approved set of technical regulations in SPS area, resulting in less reliance on non-binding administrative notices (orders of the Minister) in this area.

<sup>13</sup> CASE; Economic feasibility, general economic impact and implications of a free trade agreement between the European Union and Armenia; CASE Network Report, No 80/2008; Warsaw; ISBN 978-83-7178-458-3; EAN 9788371784583, page 75

<sup>14</sup> The risk analysis process identifies the pests and diseases of concern, the risk of introduction, and the measures needed to reduce the risk to an appropriate level based on the best scientific information available.

emerging roles of government (see Annex 4). Food can never be 100 percent free of pathogens and other contaminants; and quarantine, pest and disease surveillance systems can never provide full protection. Minimizing those risks, by evaluating probabilities of pest and disease threats and trade-offs between the different options for risk reduction is, therefore, the basic purpose of any food safety/agricultural health management system. The SPS agreement very specifically mentions the risk analysis paradigm as one of the main decision tools for evaluating market access in international trade. Finally, regulatory agencies in the main OECD markets use the risk analysis approach to intervene in the global marketplace to protect the public from undue risks such as the entry and establishment of alien disease and pests. To implement the risk analysis requirements, Armenia needs to develop its staff capacity to collect and analyze the needed data.

Codex Alimentarius (further referred to as Codex) developed an internationally agreed framework for risk analysis that serves as a basis for setting food standards at national and international levels, and has focused attention on the adequacy of risk assessments in Armenia. In light of the framework, we think the government should implement the following activities;

- Development of internationally agreed tools for national standard setting and setting national priorities and food safety initiatives.
- Development of timely, appropriate risk assessments to serve as a basis for international standards and guidelines and national food regulations.
- Development of accurate, comprehensive information on the status of food-borne disease and on chemicals and microorganisms in food.
- Development of timely, readily available risk assessments from JECFA<sup>15</sup>, JMPR<sup>16</sup> and JEMRA<sup>17</sup>
- Effective transfer of technologies and data for microbiological risk assessments between countries.

The danger of unfocused data collection, which is costly and counterproductive, should be recognized, however, and choices should be made on the most likely export commodities and markets to tailor data collection only to those commodities and markets. The ministries of Agriculture or Healthcare, or interested exporters could hire international consultants to conduct analyses and submit them to the trading partner, while collecting the needed data for other commodities

Simultaneously, Armenia needs to build up its own capacity by increasing standards awareness at the policy level, and by developing basic skills in this area. This could be done either by sending analysts overseas for training or by hiring consultants to come to Armenia to teach selected analysts.

Prospective analysts should have a strong background in statistics, economics and probability theory, or be scientists familiar with pests, diseases, or microbial pathogens. As there are very few staff now familiar with statistics and economics, it will be necessary to train professionals in the ministries of health and agriculture in the analysis of probabilities and costs/benefits. The National Enquiry Point and Notification Authority could play an important coordinating role in this area, although the focus would need to be on capacity building in the respective technical departments

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<sup>15</sup>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international expert scientific committee that is administered jointly by FAO and WHO

<sup>16</sup> FAO/WHO Joint Meeting on Pesticide Residues (JMPR) is composed of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and in the Environment and the WHO Core Assessment Group

<sup>17</sup> Joint expert consultations to assess risk associated with microbiological contamination of foods (JEMRA) was initiated by the Codex Alimentarius Commission, FAO and WHO

from which, in the medium-term future, the risk analysis would be carried out. In addition, a needs assessment should determine the current status of human resources and laboratory infrastructure in the different areas of food safety and agricultural health, and of the requirements for integrating local, regional, and national laboratory systems and the various national systems.

The medium-term emphasis should be on setting up programs in the technical departments to conduct analysis and participate in domestic decision making regarding the control of disease, pests, and food safety, and to identify optimal control measures for export-oriented firms. A more in-depth training program, probably at a small number of universities, on how to conduct risk assessments and economic analysis would be needed. At the field level, the existing, passive surveillance systems should be expanded and intensified to become more active systems targeting pests and diseases of economic and quarantine importance, as well as covering larger areas. In addition, the gaps identified in the diagnostic capacity (human skills, laboratory equipment and infrastructure) need to be addressed. Improvements in the current fragmented and incomplete databases and documentation systems would be required, with emphasis on the priority areas of pesticide use, plant pests, and animal diseases. Finally, it is critical to raise awareness in the general public, particularly smallholder producers and traders and their customers, about agricultural health and food safety issues.

With increased capacity in the technical departments, the strategy could be either to continue analysis at the ministries or increasingly to contract out to qualified national institutions (universities, research think tanks, or consultants). As in the area of food safety controls, so too in the area of risk analysis, the danger exists of conflict of interest in giving the responsibility for the analysis to a technical sector agency. Asking the Ministry of Agriculture, for example, to assess the risk of using certain pesticides or feed additives could bias the recommendations towards the producers. Analyses would need to be linked to economic analysis so decision makers (risk managers) understand the impact of the decisions on all size producers, and the initial risk analysis could be expanded to include different size producers and domestic consumption. The capacity should be established to alter and update analyses under emergency circumstances, such as a disease outbreak, to identify optimal control measures and emergency responses. Finally, emergency response systems should be developed.

## 6. HACCP Concept

The Hazard Analysis Critical Control Point (HACCP) concept focuses on verifiable controls of food handling processes to help decision makers take appropriate corrective actions.<sup>18</sup> The use of this approach in the food industry became mandatory in the EU for all supply chains, and in the United States for some products, including juice, fish, and meat. It is increasingly required for developing countries that export food products into the former, leading to the incorporation of HACCP principles into Codex's food hygiene codes starting in 1995. HACCP transfers the primary burden for certifying quality and food safety to the producers and processors. Not only is that approach more cost effective compared with testing a product and then destroying or reworking it, but it also provides firms with flexibility in approach. It identifies the hazard and its place of occurrence in the process; defines critical control points, critical limits, and monitoring procedures for each of the

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<sup>18</sup> The HACCP) concept was developed as a private-sector management tool for specific food processing processes, but it is increasingly applied as a public/private partnership policy tool that combines elements of process and performance standards. HACCP has been proven to be an effective way to establish good production, sanitation, and manufacturing practices that produce safe food.

critical control points; establishes corrective actions to be taken when a deviation from the limits occurs; and establishes a recordkeeping and system verification.

There are no legal impediments to the voluntary introduction of Hazard Analysis and Critical Control Points (HACCP) in Armenia. The law stipulates that the government shall support companies in introducing HACCP.<sup>19</sup> In an effort to harmonize its compliance with EU statutory provisions, Armenian legislation establishes mandatory requirements for Armenian producers to introduce HACCP for the purposes of securing food safety.<sup>20</sup> The timeline for introducing HACCP for food processing sectors is prescribed by government decision,<sup>21</sup> although businesses may introduce HACCP even before the established mandatory timelines on a voluntary basis. Firms should follow seven critical steps in the HACCP introduction process:

- Prepare a list of steps in the process where significant hazards can occur and describe the preventive measures;
- Identify the Critical Control Points (CCPs) in the process;
- Establish critical limits for preventive measures associated with each identified CCP;
- Establish CCP monitoring requirements, and procedures for using the results of monitoring to adjust the process and maintain control;
- Establish corrective actions to be taken when monitoring indicates that there is a deviation from an established critical limit;
- Establish effective record-keeping procedures that document the HACCP system; and
- Establish procedures for verification that the HACCP system is working correctly.

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<sup>19</sup> Article 6, Law on Food Safety

<sup>20</sup> Article 6 (7), Law on Food Safety

<sup>21</sup> Government Decision N 531-N of May 3, 2007. According to the established timeline, a number of sectors, including meat and meat processing, fish and fish processing, baby food and diet food production are required to introduce HACCP as of January 1, 2011. The timeline for HACCP introduction in other sectors varies from 2012 to 2014.

## **Annex 1: Information Requirements - National Food Safety and Agricultural Health Management**

Planned implementation of a national food safety and agricultural health management activities calls for the collection, collation and evaluation of the following type of information:<sup>22</sup>

### Status of food and agriculture sector

- Data and information on: primary food and agriculture production; food processing industry (i.e. types and number of establishments, processing capacity, value of production etc); food distribution and marketing.
- Information on formal (organized) and informal (cottage or household units, street-foods) industry.
- Potential for industry development.
- Food chain and identification of key intermediaries who may influence quality and safety of foods.
- Market infrastructure including assets and deficiencies.
- Safety and quality management programmers including level of HACCP implementation in the industry.
- Food consumption data. Information on consumers will include data on energy/protein intake, percentage of the population dependent upon subsistence economy, and per capita income.
- Cultural, anthropological, and sociological data including information on food habits and food preferences.

### Food security, food imports and nutritional objectives

- Food demand for nutritional requirements; post-harvest food losses; type and quantities of food imports.

### Consumer concerns or demand

- Consumer demand on safety, quality and information (labeling) issues.

### Food exports

- Quantity and value of food exports and potential for growth in export trade
- Data on detentions or rejections of food exported
- Information on number and types of complaints from buyers and remedial action
- Identification of foods with potential for export and target countries for export

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<sup>22</sup> Food and Agriculture Organization of the United Nations, World Health Organization; *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*; ISBN 92-5-104918-1

## Epidemiological information

- Information on prevalence and incidence of food borne disease; procedures used for investigating and notifying forborne diseases; information on food incriminated; suitability of collected data for risk assessment purpose.

## Food contaminant s data

- Information on prevalence and level of contamination of food; monitoring programmers for biological and chemical contamination of food; suitability of collected data for risk assessment purpose.

## Human resources and training requirements

- Information on the number and qualification of personnel involved in food control, i.e. staff engaged in inspection, analysis and epidemiological services; information regarding ongoing training, and educational activities; projections on future staffing and training needs.

## Extension and advisory services

- Information on the existing extension and advisory services for the food sector as provided by the government, industry, trade associations, non-governmental organizations, and educational institutions; train-the-trainer type of activities; training needs analysis.

## Public education and participation

- Consumer education initiatives in food hygiene; potential for increased involvement and interaction between government, consumer associations, non-governmental organizations, and educational institutions in risk communication activities; risk communication to prevent food borne diseases and possible improvements.

## Government organization of food control systems

- Listing of government departments and authorities concerned with food safety and food control activities
- Description of the food control system and an overview of the resources, responsibilities, functions, and coordination between the entities; methods of determining priorities for action; options for raising resources.

## Food Legislation

- Current food legislative arrangements, including regulations, standards, and codes of practice
- Information on authorities empowered to prepare regulations and standards, and how they coordinate their activities and consult with industry and consumer organizations
- Capacity to carry out risk assessment.

## Food control infrastructure and resources

- Organization of inspection, surveillance, and enforcement activities (national, provincial, and local levels)
- Number and qualifications of inspection personnel
- Resources within inspection agency, and assessment of strengths and weaknesses
- Analytical support facilities (number of laboratories, facilities and equipment, monitoring programmes)
- Codes of hygienic practice
- Licensing arrangements for food premises.

## **Annex 2: Key Armenian Laws and Regulations on Food Safety and Agricultural Health**

The key Armenian laws and regulations on food safety and agricultural health include:<sup>23</sup>

- Law on Food Safety, HO-193-N, adopted on November 27, 2006, governs the relations with respect to food safety at the stages of import, export, manufacturing, processing, packing, labelling, transporting, storage and placing on the market, as well as at stages of trading and mass catering, and addresses materials in contact with food and food additives.
- Law on Phytosanitary (formerly the "Law on Plant Quarantine and Plant Protection), HO-209-N, adopted on November 27, 2006, regulates relationships in the field of plant quarantine and plant protection between the state authorized body and entities acting in Armenian territory.
- Law on Trade and Services, HO-134-N, adopted on November 24, 2004, regulates state management of trade, catering, and personal services in Armenia. The law regulates the implementation of the activities in trade and services, as well as ensures the protection of consumer rights.
- Law on Ensuring Sanitary and Epidemiological Safety of the Population, HO-43, accepted on December 12, 1992, defines the legal, economic, and organizational basis for ensuring sanitary and epidemiological safety of the population. It describes general requirements for production, transportation, storage, and marketing for foodstuffs and primary production.
- Law on Protection of Consumers Rights, HO-197, adopted on June 26, 2001, regulates the relationship between consumers and producers in the sale of products. It determines consumer rights to safe products of acceptable quality and for receiving correct information on products and. The law defines state and public protection of consumer' rights, as well as mechanisms for enforcement of those rights.
- Law on Standardization, HO-21-N, adopted on February 8, 2012, defines the legal basis for standardization in Armenia and the competencies of its participants, and also regulates the development and application of the principles of standardization normative documents. The law describes the objectives and objects of standardization, principles of standardization, legal regulation, whole process of standardization, and financing of standardization.
- Government Decree N 744-N, adopted on June 26, 2009 on approval of technical regulation on juices and juice products.
- Technical Regulation on Fresh Fruits and Vegetables (Government decree No1913-N) adopted on December 21, 2006, regulates the trade of fresh fruits and vegetables. In particular, it contains a list of fruits and vegetables with codes, safety norms (acceptable level of poisonous elements, pesticides, nitrates, radionuclide contamination), packing, transportation, and storage requirements.
- Government Decree No1904-N on the maximum allowed limits of residues of pesticides and nitrates in the food of animal and plant origin, adopted on December 14, 2006, regulates maximum allowed limits of residues of pesticides in animal origin products, plant origin

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<sup>23</sup> USAID Armenia Enterprise Development and Market Competitiveness Project; *Defining domestic legal framework, technical standards, practices, and institutional set-up governing SPS and TBT applicable to the food processing (fruit/vegetable/herbs) value chain and highlighting corresponding EU and other internationally accepted requirements*; June 26, 2012

products, plant oils and animal fats, as well as the maximum allowed limits of nitrates in animal and plant origin food.

- Order of the Minister of Healthcare No 790-N “Sanitary rules and norms (SanPins) on storage, transportation, application and sale of pesticides,” adopted on August 30, 2005, provides norms and rules for storage, transportation, application, and sale of pesticides. It provides control over the implementation of sanitary norms and rules for storage, transportation, application, and sale of pesticides by the heads of regional bodies of hygienic and anti-epidemiology services.
- Order of the Minister of Healthcare No 256-N “Sanitary rules and norms (SanPins) for production, storage, transportation and realization of mineral fertilizers” adopted on March 24, 2005, provides norms and rules for production, storage, transportation, and sale of mineral fertilizers.<sup>24</sup>
- Government decree 514-N on Sampling Procedure for Phytosanitary Examination adopted on April 8, 2004, regulates the procedure of sampling for phytosanitary examination purposes. This decree describes a detailed procedure of sampling from seed material, planting material, food and technical foodstuffs, developing average samples, and storage of samples.
- Government Decree No1632-N on Licensing Procedures of Production and/or Sale of Chemical and Biological Substances for Plant Protection and Approval of the Form of License was adopted on November 3, 2011. It approves licensing procedure for production and sale of chemical and biological substances for plant protection in Armenia.
- Government Decree “On Approving Procedures on Providing Phytosanitary Certificates for Import, Export, and Re-export of Plant, Plant Products and Regulated Articles” 1093-N, accepted on August 30, 2007, regulates issuing a phytosanitary certificate for import, export, and re-export of plant, plant products and regulated articles.

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<sup>24</sup> Until now a number of “de facto” technical regulations have been developed and approved by the line ministries. The mandatory rules approved by the ministers are referred as “norms”, whereas those approved by the decree of the Government are referred as “technical regulations.” Particularly, the Minister of Healthcare approved a number of such norms related to SPS area – Sanitary-hygienic norms. In practice, though norms are approved at the ministry level, they are still enforced on a compulsory basis. But in view of local and international legal frameworks, the compulsory enforcement of these norms is not immune from challenge.

### **Annex 3: Approaches for Harmonization of Armenia’s Regulations to EU and International Standards**

The Armenian government has considered the following approaches for harmonization of Armenia’s technical regulations with international and EU standards.<sup>25</sup>

- Until 2006-2007 the Government was favoring intensive approximation of local regulations with EU statutory provision (package approach). The EU-funded AEPLAC<sup>26</sup> project for few years coordinated the implementation of the national program for harmonization of EU and Armenia legislations. Up to 50 national and international experts were involved. As a result, a comprehensive research facility was developed, which enables on-line screening, comparison, and final development of a searchable detailed Armenian legal database including comparison with the EU Acquis.<sup>27</sup> However, only in a few areas did the Government proceed with actual harmonization of local regulations with EU legal framework.
- In 2008, to facilitate EU-Armenia legal and regulatory harmonization, the Government of Armenia created the Translation Center in the Ministry of Justice.<sup>28</sup> The mission of the Translation Center is to provide high-quality translation of the legal acts of Armenia and those of the EU in English and Armenian respectively. It was expected that government agencies relying on the EU-Armenia regulatory approximation database developed by AEPLAC and the capacities of Translation Center would precede regulatory harmonization activities. Although progress was made, EU Acquis consists of several thousand statutory provisions, and the “package” approach for implementation of EU-Armenia regulatory harmonization became an unrealistic target. The “Agriculture” chapter alone of EU Acquis consists of more than one thousand regulations, directives, decisions and other legal acts adopted by different EU institutions.
- The government has pursued a gradual approach for implementation of regulatory harmonization program. In particular, it is planning to harmonize regulations based on priorities in agricultural sector development in the food safety action plan. It is anticipated that assistance in drafting of the list of legal acts for regulatory approximation program will be rendered by the EU Advisory Group.
- For last several years, the government has also addressed the possibility of initiating legal amendments that would enable it to incorporate into Armenia’s legal framework the full text of standards and technical regulations in English. With it, the government seeks to establish a simpler procedure for incorporation of international regulations into Armenia’s legal framework. Accordingly, in 2008 the National Assembly introduced new amendments to the legislation, which enable the Government to approve regulations on foreign languages.<sup>29</sup>

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<sup>25</sup> USAID Armenia Enterprise Development and Market Competitiveness Project; *Business Enabling Environment Reform in Armenia, Status Report/Support Recommendations*; November 18, 2011

<sup>26</sup> Armenian-European Policy and Legal Advice Center

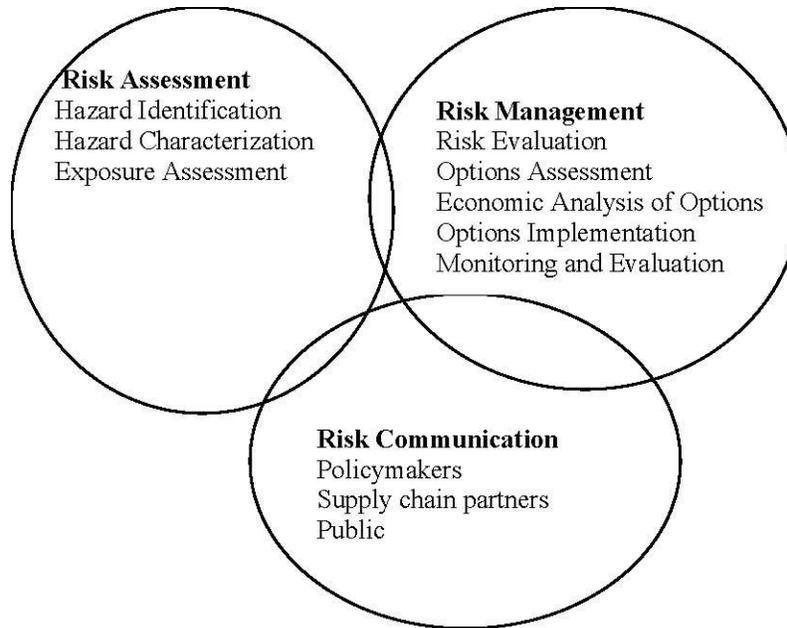
<sup>27</sup> Community acquis, *acquis communautaire* or EU acquis is the accumulated legislation, regulations, court decisions which constitute the body of European Union law.

<sup>28</sup> <http://www.translation-centre.am/eng/>

<sup>29</sup> Article 36, Part 1, Part 1.1, Part 1.2 of the Law on Legal Acts

## Annex 4: Risk Analysis Framework<sup>30</sup>

The *Risk Analysis framework* has three major interrelated components: risk management, risk assessment, and risk communication.



**Risk management** is at the core of the risk analysis paradigm. The risk manager is concerned with the evaluation of the risks and the identification and implementation of strategies to control those risks, based on the scientific tools provided by the risk assessors. The risk management process identifies the options for eliminating or reducing the hazard, their effectiveness, feasibility, and impact on various stakeholders, and the certainty of achieving expected results. In decision making, policymakers need to evaluate the risks, match the identified risks with risk reduction options, and develop a realistic operational approach that balances protection and resources. The risk manager also needs to monitor and improve the implementation of the selected risk reduction option.

**Risk assessment** is a systematic approach for organizing and analyzing scientific information for potentially hazardous activities or substances that may pose a risk to humans, animals, or plants. It identifies a hazard, gauges its potency, estimates the likelihood of occurrence, characterizes the risk, and determines the magnitude of its consequences. The output of the assessment aids policymakers (risk managers) in their decision making about alternative control options.

**Risk communication** ensures that what has been done is continuously communicated between analysts and risk managers and to the public (national and international). Stakeholder collaboration early in the process can deflect polarization, build up broad consensus and thus make the whole process much more effective.

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<sup>30</sup> [Spencer Henson, Julie Caswell](#); *Food safety regulation: an overview of contemporary issues* and the World Bank; *Food Safety and Agricultural Health Action Plan*, Report No. 35231 VN, February 2006