10) FOOD SAFETY AND HYGIENE REGULATIONS AT INTERNATIONAL AND NATIONAL LEVELS

INTRODUCTION

A safe food supply of adequate quality is essential for sustaining humanity and quality of human life. The food supply must not endanger consumer health through physical, biological, and chemical contaminants and it must be presented in the markets honestly. Controls for food safety and quality ensure that the desirable characteristics of food are retained throughout the production, handling, processing, packaging, distribution, and preparation stages. This promotes healthy diets, reduces economic losses and encourages domestic and international trade of food. Consumers have the right to a good quality and safe food supply, and government and food industry actions are constantly needed to ensure this. For this aim, effective food safety and quality control programs are essential, but in order to establish them and keep them running we need both well-prepared food legislation and an effective state authority for applying the respective legislation. Taking into consideration the ever increasing and globalisation trends of food trade, international controls for food safety are becoming another requirement of modernity.

Universal food safety requirements:

1. Only food that is safe under normal and reasonably foreseeable conditions of use should be placed on the market.
2. Food is considered as "unsafe" if it is:
   a. Potentially injurious to health;
   b. Unfit for human consumption or contaminated.
3. In determining whether any food is potentially injurious to health, the following should be considered:
   a. The normal conditions of use of the food should not present a risk which is unacceptable for the health of a person consuming the food;
   b. It is not only the possible immediate or short term effect of that food on the health of a person consuming it, but also the potential cumulative toxic effects of a food on the health of a person, or on subsequent generations of a person consuming that food in ordinary quantities that should be considered;
   c. The particular sensitivities of specific sensitive categories of consumers (i.e. pregnant women, diabetics, infants etc.) should be specifically considered where the food is intended for that category of consumers.
4. In determining whether the food is safe, consideration should be given for the information provided to the consumer, like information on the label, concerning the avoidance of specific adverse health effects from a particular food or category of foods.
5. Where any food, which is unsafe, is part of a batch, lot or consignment of food of the same class or description, it should be presumed that all of the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
6. Where there are no specific provisions, food should be deemed to be safe when it conforms to the specific provisions of national food law of the State in whose territory the food is in circulation.
7. The safety of food should be considered at all stages of production and distribution, taking into account its normal and reasonably foreseeable conditions of use.

Regulating Food Safety at National Level

National food legislations have evolved spontaneously and independently over the last forty years reflecting a blend of scientific, societal, political and economic forces, and the inevitable effect of creating quite different sets of standards. Overall objectives for developing national food laws:

1. Food law must provide a high level of health protection for consumers.
2. States have an obligation to ensure that only safe food and feed are placed on the market; and have both national and international obligations particularly in relation to trade of foods. Therefore, the effective functioning of both the local and the internal market in safe food and feed should be assured.
3. Where appropriate, the protection of the environment, the protection of animal health, life and welfare and the protection of plant health and life should be taken care of.

Further Points to be taken into consideration:

1. States are responsible for the enforcement of food law; but primary responsibility for safe food and feed rests with businesses. Food business operators should ensure that all stages of production and distribution are under their control are carried out in such a manner that food complies with the relevant provisions of food law, and in particular, of food safety. Traceability (identification of the source) of food, feed, ingredients and food-producing animals have to be attained by producers and monitored by state. Recent food scares (BSE and dioxin crises) have demonstrated that traceability, or being able to identify the origin of feed, food and the respective ingredients as to their sources, is of prime importance for the protection of consumers. In particular traceability facilitates the withdrawal of foods and enables consumers to be provided with targeted and accurate information concerning implicated products. Therefore, all feed and food businesses should have "systems" so that they can identify the supplier of foods, feeds and food-producing animals to their businesses and also to whom they have supplied such products. This information should be made available to the authorities if requested. Importers are similarly affected, as they will be required to identify from whom the product was exported in the third country.
2. Consumers have rights: right to know, not to be misled and to have access to accurate information. Therefore transparency of the development of food law and the access to information in this regard should be secured.
3. The "precautionary principle" foresees to develop provisional measures where an unacceptable level of risk to health has been identified but further scientific data is required to arrive at a comprehensive assessment of risk to health.
4. Food law should be based on high quality, transparent independent scientific advice following the three interconnected components of risk analysis: risk assessment, risk management and risk communication.

Here:

"RISK" means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard. "Risk analysis' means a process consisting of three interconnected components: risk assessment, risk management and risk communication.
- "Risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

- 'Risk management' means 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;
- "Risk communication' means the interactive exchange of information and opinions throughout the risk analysis process 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, including the explanation of risk-assessment findings and the basis of risk-management decisions.

Today, general safety concerns regarding foods focuses on four areas:

1. The microbiological safety of food where problems such as Salmonella, *E.coli*, Listeria suggest to the public that modern systems of farming, processing, distribution and retailing have inadequate safeguards. The "modern food chain" means that infection on a single farm can soon become very widely distributed.
2. The chemical safety of food with long-standing concerns about pesticides and heavy metal contamination.
3. Genetically modified organisms, novel foods and processes.
4. The nutritional quality of the diet: the public perceives correctly that nutrition is of major importance for their health.

But there have been and always are expected to be some "rapidly emerging risks" like the "dioxin" and "BSE" and GMO" crisis. These recent events have demonstrated the importance of establishing clearly defined operational procedures, which allow the authorities to manage food crises efficiently especially where there are specific needs for coordination and/or close interaction with scientists.

Food Safety at International Level

Since the quite different sets of food safety standards developed by individual nations are having the effect of becoming "technical barriers to trade" for both importing and exporting countries, some international modalities have been sought, which are also required to ensure optimum global coordination and to strengthen the national authority's overall capacity to identify the most effective measures to prevent, reduce or eliminate a risk for human health. These also permit an optimised approach for the safety of the global food chain, encompassing all products for both human consumption and for animal feed.

Unfortunately, "national" food laws sometimes have either no provisions for the unexpected food "crisis" issues that have emerged in the last decade or they have provisions which might be "trade barriers" to global trade.

Fortunately, there are a multitude of international for a like those of UN (FAO/WHO-Codex Alimentarius standards) and WTO (trade agreements) showing serious efforts to harmonize national legislations. Especially effective are the following three key organisations involved in developing international regulations for controls on food: FAO (the Food and Agriculture Organisation), WHO (the World Health Organisation), and WTO (the World Trade Organisation

International harmonisation can be achieved if all countries harmonize their regulations by using international standards as a basis for their sanitary measures. National standards stricter than Codex Standards should always be scientifically justified.

FAO
FAO The Food and Agriculture Organization was founded in October 1945 with a mandate to raise levels of nutrition and standards of living, to improve agricultural productivity, and to better the condition of rural populations. Today, FAO is the largest autonomous agency within the United Nations system with 180 Member Nations plus the EC (Member Organization). FAO's staff includes almost 2 300 people at Headquarters and more than 2 000 working at decentralized offices and field projects.

The main food control activities of the FAO are within the 'Economic and Social Department' (ES), which has a Division known as the 'Food and Nutrition Division' - within that Division is the Food Quality and Standards Service (given the abbreviation 'ESNS' for reference purposes).

WHO
The WHO Food Safety Programme operates to ensure that information on food safety is properly collected and circulated to provide the basis for policy and monitoring; health-oriented guidelines are constantly updated; an international independent body plays a public health advocacy role vis-à-vis the strong economic forces acting within the areas of food production, retailing and global marketing. The main activities within the WHO Food Safety programme are:

- Assistance to countries for support to policy development
- Surveillance of food-borne disease
- Microbiological and chemical contamination of food
- Promotion of objective information on current hot topics like biotechnologies and GM foods, food irradiation
- Transmittable Spongiform Encephalopathy (TSE)
- Monitoring system for multi-drug resistance
- Dissemination of relevant scientific information.

"CODEX ALIMENTARIUS" -FOOD LAW

The Codex Alimentarius Commission (CAC) is the main UN international body concerned with the setting of international food standards. The body was established in 1962 and is jointly funded by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). The Secretariat of the CAC is based at the headquarters of the FAO in Rome. Membership is open to any country, which is a member of the FAO or WHO and currently numbers 162. Also other nations and bodies can have "observer" status. The full Commission meets every two years in either Rome or Geneva. There are three main groups of subsidiary bodies: World Wide General Subject Committees, World Wide Commodity Committees, and Regional Coordinating Committees. The Committees are hosted by various nominated countries and invitations to attend are extended to all Codex member countries (i.e. the committees are not restricted to selected countries). The Committees can meet once each year although many only meet once every two years and some have completed their current work and have been adjourned sine die.

<u>Codex Alimentarius Elaboration Procedure</u> (8 steps in normal Procedure)
 There is a specified 'stepwise' approach to the adoption of C.A. standards.

STEP 1 Codex Alimentarius Commission or Codex Executive Committee takes decision to elaborate a new standard and decision as to which subsidiary body is to undertake the work
STEP 2 Volunteer country (ies)/ observers, preparation of a Proposed Draft Standard
STEP 3
Circulation of the Proposed Draft Standard for comments by governments
STEP 4 Relevant Codex Committee takes into consideration of comments and makes amendment of the Proposed Draft Standard
STEP 5 Codex Alimentarius Commission or Codex Executive Committee's Adoption as a Draft Standard
STEP 6 Circulation of the Draft Standard for comments by governments
STEP 7 Relevant Codex Committee takes into consideration of comments and makes amendment of the Draft Standard
STEP 8 Codex Alimentarius Commission's Adoption as a Codex Standard and publication in the "Codex Alimentarius". This procedure can take some considerable time (typically 5-8 years). However, when a matter is regarded as "urgent" as a result of new scientific information or of new technology (ies) or of urgent problems related to trade or public health or the revision or up-dating of existing standards, an accelerated procedure can be followed which allows for the omission some steps. Following the adoption of a standard, it is offered to the member countries for acceptance. The Commission has three specified forms of acceptance:

1. Full acceptance - the country will apply with the standard to all products and will not restrict distribution of products complying with the standard.
2. Acceptance with specified deviations - the standard is accepted (as in 'full acceptance') except that there are certain aspects, which are not accepted.
3. Free distribution - products complying with the standard will be allowed free distribution. This allows a country to retain a separate national standard but permitting imports of products complying with the Codex standard.

Codex Alimentarius Standard Categories:

I. Codex Alimentarius General Standards: Food labelling, Food additives, Contaminants, Methods of analysis and sampling, Food hygiene, Nutrition and foods for special dietary uses, Food import and export inspection and certification systems, Residues of veterinary drugs in foods, and Pesticide residues in foods. These form the basis of EU horizontal regulations.
II. Codex Alimentarius Commodity Standards: For individual food commodity groups
   - Format for every commodity includes provisions for:
   - Scope, including the name of the standard
   - Description, essential composition and quality factors
   - Food additives for commodity
   - Contaminants for commodity
   - Hygiene and weights and measures
   - Labelling
   - Methods of analysis and sampling for commodity

Codex Alimentarius Structure:
- Volume 1A -General requirements
- Volume 1B -General requirements (food hygiene)
- Volume 2A -Pesticide residues in foods (general texts)
- Volume 2B -Pesticide residues in foods (limits)
- Volume 3 -Residues of veterinary drugs in foods
- Volume 4 -Foods for special dietary uses
- Volume 5A -Processed and quick-frozen fruits and vegetables
- Volume 5B -Fresh fruits and vegetables
- Volume 6 -Fruit juices
- Volume 7 -Cereals, pulses (legumes) and derived products and vegetable proteins
- Volume 8 -Fats and oils and related products
- Volume 9 -Fish and fishery products
- Volume 10 -Meat and meat products; soups and broths
- Volume 11 -Sugars, cocoa products and chocolate and miscellaneous products
- Volume 12 -Milk and milk products
- Volume 13 -Methods of analysis and sampling

Food Safety within the Codex Alimentarius: Food Hygiene Standard and HACCP

 In 1993 the Joint FAO/WHO Codex Alimentarius Commission endorsed "The Hazard Analysis and Critical Control Point (HACCP) system" which is a scientific, rational and systematic approach to identification, assessment and control of hazards during production, processing, manufacturing, preparation and use of food to ensure that food does not present an unacceptable risk to health.   It is the most cost-effective approach devised to date to ensure food safety. Since 1993, its application has been evolving and expanding to form a basis for official food control and for establishing food safety standards for the international food trade as well. A great deal of national and international activity that relates to the utilisation of HACCP based systems in food safety assurance are currently under way. It is increasingly being promoted throughout many countries, where the national food control agencies are mandating the food industry, including importers/exporters, to use HACCP based systems to assure food safety.

HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end product testing. The main responsibility for the implementation of a HACCP-based approach to food safety lies with:

- Industries involved in all stages of food chain
- Policy makers and planners who have the mandate to facilitate the adoption of HACCP systems
- Government authorities, including legislators, regulatory food control officials, and health education bodies.

As countries become more and more committed to a move from prescriptive food hygiene rules to an HACCP based approach, harmonization is needed on strategies for its implementation. The role of governments and industries is not always understood and needs to be clearly defined. In fact, in ensuring food safety, governments and industry (as well as consumers) must play their specific role in the food supply and consumption. At regulatory

level, a number of government departments or agencies are concerned with application of HACCP for food safety. It is the principal role of government to define and establish nationally acceptable levels of food safety risk. Food safety objectives, as defined by governmental authorities, represent the maximum level of hazard in a food considered acceptable for human consumption and, therefore, the minimum target on which food operators base their own approach. Another role of governments is to establish HACCP implementation priorities relating to food types, facilities and processes; and, to integrate HACCP implementation throughout the food chain. The link between food legislation and primary production is not always in place and harmonisation of these two sectors is still required in some countries. Governments should further provide an infrastructure which is conducive to the development of HACCP plans by industry, (including primary producers, e.g., farmers - by providing advice and guidance to undertake voluntary measures to promote safety) and which includes regulations, training, inspection for compliance and guidelines. Large-scale producers of foods as well as the entire food industry, irrespective of their size or origin, have a fundamental responsibility to produce food that is safe. This may be achieved in part by following accepted codes of practice and complying with relevant laws and regulations set by the governments.

The industry is expected to produce under Good Manufacturing Practices (GMP) and voluntarily establish a system for safety assurance of the products by adopting appropriate procedures and technologies. The HACCP system has now become a tool, which can serve as a common platform for international safety issues. Of course, the ISO9000 series approach can be combined with the HACCP system in order to constantly assure the high quality of food products. Recently there has been increasing interest on the part of governments to integrate an HACCP based system into their legislation and food inspection service programmes. The European Union's Council Directive (DIR/93/43/EEC) requires that food business operators shall identify any step in their activities, which is critical to ensuring food safety, and ensure that adequate safety procedure are implemented, maintained and reviewed on the basis of HACCP. The hygiene directive 93/43/EEC has been in the meantime fully implemented into European Member States' national legislations. Outside the EU and USA, implementation of the HACCP system has also had some success in many countries as in Turkey too, where legislative provisions have facilitated implementation of HACCP.

WTO

The World Trade Organization came into being in 1995 and is the successor to the General Agreement on Tariffs and Trade (GATT) established after the Second World War. So while the WTO is still young, the multilateral trading system that was originally set up under GATT is already 50 years old. The past 50 years have seen an exceptional growth in world trade. Merchandise exports grew on average by 6% annually. Total trade in 1997 was 14-times the level of 1950. GATT and the WTO have helped to create a strong and prosperous trading system contributing to unprecedented growth. The system was developed through a series of trade negotiations, or rounds, held under GATT. The first rounds dealt mainly with tariff reductions but later negotiations included other areas such as anti-dumping and non-tariff measures. The latest round (the 1986–94 Uruguay Round) has led to the WTO's creation. The Uruguay Round of Multilateral Trade Negotiations (concluded in April 1994) has also thrown a light on food safety.

WTO Agreements since 1995

<u>Uruguay Round of Multilateral Trade Negotiations Marrakech Agreement</u> - (April 1994): Countries agreed to reduce " Tariff Barriers," Non-Tariff Barriers became a real concern.

<u>SPS Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)</u> - Recognizes the Codex Alimentarius as International Standards for Food Safety. Signed and committed by all Members of the World Trade Organisation (WTO)], governments are encouraged to establish national sanitary and phytosanitary measures consistent with internationally agreed standards, guidelines and recommendations. Also under the SPS, compliance with these standards is considered as conforming to the obligations of the Agreement. Members may require a higher level of health protection, and apply measures only if based on a risk assessment.

Its major contents:

1. <u>International Harmonization</u> (Article 3): Can be achieved if all countries harmonize their regulations by using international standards as a basis for their sanitary measures; National standards stricter than Codex Standards should be scientifically justified
2. <u>Risk Assessment</u> (Article 5 & 6): All sanitary measures should be based on "Risk Assessment". Expert Bodies: Joint FAO/WHO Expert Committee on Food Additives (JECFA). Joint FAO/WHO Expert Meetings on Pesticide Residues (JMPR)
3. Microbiological Risk Assessment body
4. <u>Transparency</u> (Article 7): Notification before enforcement of regulation Establishment of Inquiry Point
5. <u>Technical Assistance</u> (Article 9): Necessity of strengthening national food control system, which requires both manpower and financial investment. Also requires assistance from other countries and international organizations (e.g., WHO, FAO, WTO)

<u>"The Technical Barriers to Trade Agreement"</u> of WTO similarly acknowledges the need for member countries to use international standards on which to base their regulatory measures unless using such a standard would be an ineffective or inappropriate means for the fulfilment of its legitimate objectives.

 FOOD SAFETY SYSTEMS IN EUROPE

The Community is the world's largest importer/exporter of food products. Therefore their legislation and respective actions (especially those expressed in the White Paper) need to be effectively presented and explained to all trading partners. After the BSE crisis, the "consumer focus" has much increased, and EU Commission became consumer-confidence driven.

<u>PRE-SINGLE MARKET</u>
Range of national legislation
Harmonised legislation for Intra-community trade
Differing standards for export/national trade: "Cassis de Dijon" agreement

SINGLE MARKET:
Definition from Treaty of Rome: " An area without internal frontiers in which the free movement of goods, services and capital is assured."
Resulted in raft of harmonised EU legislation
Member Countries took "copy out" approach, as is currently being done also in Turkey.

HARMONISATION OF EU FOOD HYGIENE LAW
Single market legislation:
Range of EU product specific (Vertical) Legislation:
Products of animal origin
Prescriptive standards
Approval/licensing systems
Health mark/traceability of product
General/Horizontal legislation:
Non-animal origin products and Retail/Catering systems are less prescriptive

HARMONISATION OF ENFORCEMENT OF HYGIENE LEGISLATION:
OFFICIAL CONTROL OF FOODSTUFFS DIRECTIVE (89/397/EEC)
Member States are obliged to put effective controls in place.
This requires:
- "Regular" inspections by competent officials
- Annual returns on enforcement by Member States to EU Commission
- Co-ordinated sampling and surveillance programmes
- Commission inspections to assess Member State and Member State performance
- Microbiological criteria:
- EU approach still under discussion
- Microbiological criteria specified in some "vertical" EU Hygiene Legislation
- Hazard management
- Comprehensive Integrated Approach
- Primary responsibility lies in the Industry
- Consumers have a role to protect themselves
- Full Traceability
- Feed to Food Consumption
- Surveillance and monitoring of food safety systems at EU level
- Crisis Management
- Rapid alert systems in cases of crisis

KEY ISSUE - HACCP

- HACCP-based requirements in EU Hygiene legislation
- Documented "own checks" are required in vertical regulations   e.g. meat/milk products
- "Hazard analysis" (non-documented HACCP) in Hygiene of Foodstuffs Directive 93/43
- Good HACCP implementation in manufacturing premises is requisite but it is more random in retail and or catering establishments.
- Training:
- Made mandatory through EU Hygiene Legislation

- Flexible requirements reflecting EU dimension
- Approximately 300,000 food hygiene training certificates awarded annually.

FUTURE ISSUES for EU:
Horizontal/vertical reviews
Single simplified hygiene text under discussion
Efficient "Farm to fork" controls

EU WHITE PAPER ON FOOD SAFETY and EU FOOD AGENCY:
1. EU white paper: new 'general food law': Published in January 2000, it is a proactive new food policy: modernising legislation into a coherent and transparent set of rules, reinforcing controls from the farm to the table and increasing the capability of the scientific advice system, so as to guarantee a high level of human health and consumer protection.

The White Paper also foresees a European Food Authority starting operations 2002 and contains 80 actions to close loopholes in legislation.
- 'Farm to Table' action programme
- 'Most radical and far reaching proposals'
- Absence of regulations for production of food of plant origin at level of farm
- Will introduce procedure for laying down microbiological criteria
- Transparency
- Science based approach to risk analysis
- Science networks between member states
- Ad-hoc research on problem issues
- Increase capacity of the risk assessment system
- Legislation overhaul
- A General Food Law
- Legal framework for animal feed
- Implementing regulation for novel foods
- Food control
- Framework for national food safety systems
- Focus on strengthening controls on food of non-animal origin.
- Increase power of EC to punish infringement and strengthen the European Food and Veterinary Office
- Risk Communication
- Focus on food labelling
- Ensure public participation in controversial debates

EUROPEAN FOOD AUTHORITY

This new establishment is also expected to become a World Authority n food safety
Issues in the near future. The scope of its responsibility include objective "risk assessment and risk communication, keeping it separate from the " risk management" processes for which national governments will be held responsible but who also should base their policies on the scientific risk assessments made by the EU authority. Primary assets and objectives of European Food Authority:

- Guided by best science, and independent of industrial and political interests
- Open to rigorous public scrutiny, scientifically authoritative

- Work closely with other national scientific bodies
- Principles, obligations well defined
- Different hygiene regimes for food of animal/plant origin can only be justified for historical reasons.

GENERAL OBLIGATIONS IN FOOD TRADE

"Fair trade" requires that the following obligations set forth in Articles 11 and 12 of EU White Paper should also be valid for all other food trading countries:

Article 11: Food and feed imported into the Community for being placed on the market therein should comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

Article 12: Food and feed exported or re-exported from the Community for being placed on the market of a third country should comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country. In other circumstances, except in the case where foods are injurious to health or feeds unsafe, food and feed can only be exported or re-exported provided that the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances under which the concerned food or feed could not be placed on the market in the Community. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country should comply with the said provisions.

Major Reference: "International Standards for Food Safety", by Naomi Rees and David Watson, Aspen Publishers, Inc., USA ISBN-0-8342-1768-6, 2000.