FOOD LAWS AND REGULATIONS

SECTION IV

FOOD LAWS AND REGULATIONS

Module 1
The U.S. Food Safety System*

Learning Outcome

- ***Participants will be aware of the agencies involved in the U.S. food safety system and their role in the safety of food imports.***

Practical

- ***Discussion Question 7***

Food Safety in the U.S. - A Shared Responsibility

Visual IV.1-1

All foods imported into the U.S. are required to meet the same standards as domestic products. They must be:

- Pure
- Wholesome
- Safe to eat
- Produced under sanitary conditions
- Properly labeled

In the U.S., food safety is a shared responsibility with several departments of the United States government sharing jurisdiction over ensuring the safety of the American food supply (Rawson and Vogt, 1998). These agencies assure that all foods are pure, wholesome, safe to eat and produced under sanitary conditions. They also assure that all imported foods meet the same requirements as those produced domestically.

* Prepared by: Pamela Brady, Ph.D., IFSE, University of Arkansas

Visual IV.1-2

The U.S. Food and Drug Administration

- Regulates both domestic and imported foods, except meat and poultry
- Has primary responsibility for enforcing food safety laws including food import and export regulations

The Food and Drug Administration (FDA) is charged with protecting consumers against food that is impure, unsafe, produced under unsanitary conditions, or fraudulently labeled (FDA, 1998a). Through its Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA), the FDA regulates both domestic and imported foods, except meat and poultry and processed eggs and has primary responsibility for enforcing food safety laws including food import and export regulations.

Some of the activities of the FDA with particular impact on imported produce include:

- Inspecting food production establishments and food warehouses and collecting and analyzing samples for physical, chemical, and microbial contamination.
- Establishing good agricultural practices and good manufacturing practices and other production standards, such as plant sanitation, packaging requirements, and Hazard Analysis and Critical Control Point programs.
- Sampling and inspection of imported foods.
- Working with foreign governments (and with FDA counterparts in these countries, if they exist) to ensure safety of imported foods.
- Taking appropriate enforcement actions.
- Educating industry and consumers on safe food handling practices.

Visual IV.1-3

Other U.S. Federal Agencies with Roles in Safety of Imported Foods

- Centers for Disease Control and Prevention (CDC)
- U.S. Department of Agriculture (USDA)
  - Agricultural Marketing Service (AMS)
  - Foreign Agricultural Service (FAS)
  - Food Safety Inspection Service (FSIS)
  - Economic Research Service (ERS)
  - Animal and Plant Health Inspection Service (APHIS)
- U.S. Environmental Protection Agency (EPA)
- U.S. Customs Service

The Centers for Disease Control and Prevention (CDC) work closely with state and local public health epidemiologists and laboratories to identify illnesses and clusters of illnesses that may be foodborne. CDC surveys and studies various environmental and chronic health problems and administers national programs for prevention and control of vector-borne diseases (diseases transmitted by a host organism) and other preventable conditions.

The **U.S. Department of Agriculture (USDA)** has several agencies that may play a role in assuring food safety by establishing the safety of imported fruits and vegetables.

- The Agricultural Marketing Service (AMS) carries out a wide range of programs aimed at facilitating the marketing of agricultural products, assuring consumers a quality food supply, and ensuring fair trading practices. Certain agricultural commodities (including fresh tomatoes, avocados, mangoes, limes, oranges, grapefruit, green peppers, Irish potatoes, cucumbers, eggplants, dry onions, walnuts and filberts, processed dates, prunes, raisins, and olives in tins) must meet United States import requirements relating to grade, size, quality, and maturity. These commodities are inspected and the AMS must issue an inspection certificate to indicate import compliance.

- The Foreign Agricultural Service (FAS) has primary responsibility for the USDA's overseas programs, including market development, international trade agreements and negotiations, and the collection of statistics and market information.

- The Food Safety and Inspection Service (FSIS) regulates meat, poultry and egg products and maintains a comprehensive system of import inspection and controls.

- The Economic Research Service (ERS) provides estimates of costs of foodborne disease and conducts benefit/cost analyses of alternative regulatory options.

- USDA’s Animal and Plant Health Inspection Service (APHIS) inspects imported agricultural products for disease and pests which might infect plants and animals. Through monitoring activities at airport terminals, seaports, and border stations, it guards U.S. borders against the entry of foreign agricultural pests and diseases.

The duties of the **U.S. Environmental Protection Agency (EPA)** include regulating pesticides and assuring that drinking water meets standards for health. Through the Office of Pesticide Programs (OPP), EPA determines the safety of new pesticide products, sets tolerance levels for pesticide residues in foods,

which FDA then enforces, and publishes directions for the safe use of pesticides. As with other requirements, imported produce must meet the same standards for residues as products produced domestically.

The **U.S. Customs Service** serves as the point of entry for products imported into the U.S. Working with the FDA, the Customs Service participates in the effort to assure produce safety (see section below on Import Regulations and Restrictions).

U.S. Import Regulations and Restrictions

The following description of the FDA's Import Program is adapted from the document, "***U.S. Food and Drug Administration Import Information"*** (FDA, 1999).

Visual IV.1-5

Summary of FDA Import Procedures

1. Importer files entry notice with Customs

2. FDA, notified by Customs of the entry, makes a decision as to admissibility.
   a. The product is allowed to proceed into U.S. commerce, after applicable duties are paid

   OR

   b. FDA decides to examine an entry

3. After examination
   a. If the product is in compliance, it is released by Customs and allowed into U.S. commerce.

   OR

   b. If it appears violative, FDA issues a Notice of Detention and Hearing to the owner or consignee

4. If the product is refused, the importer is required to either re-export or destroy the article

To ensure that FDA is notified of all regulated products imported into the United States, the importer, or his/her representative, must file an entry notice and an entry bond with the U.S. Customs Service (Customs). Specific information on U.S. Customs procedures, requirements, forms, etc., are available from local Customs offices. When FDA is notified by Customs of the entry, a decision is made as to the article's admissibility. If FDA does not wish to examine the entry, the product is allowed to proceed into United States commerce.

Generally, if FDA decides to examine an entry, an FDA representative will collect a sample from the shipment for laboratory evaluation. If the analysis indicates the product is in compliance with U.S. requirements, the shipment may be released into United States commerce. If there is a violation, the product will be refused admission.

When a sample of an article offered for import has been requested by FDA, the owner or consignee shall hold the shipment and not distribute it until further notice is received regarding the results of the examination of the sample. If it appears that the article is violative, FDA issues a Notice of Detention and Hearing to the owner or consignee of the article specifying a place and period of time whereby the individual may introduce testimony either verbally or in writing. The importer is provided an opportunity to submit a petition to recondition the product to bring it into compliance. The owner or consignee may submit an application to FDA to relabel or perform other actions to bring the article into compliance or render the article other than a food, drug, device, or cosmetic. An application for authorization to relabel or perform other actions to bring the article into compliance shall contain a detailed proposal and specify the time and place where such operations will be carried out and the approximate time for completion as specified by regulation. All petitions to recondition a product are subject to FDA review and approval.

If the product is refused, the importer is required to either re-export or destroy the article under U.S. Customs or other approved supervision. If the refused product is not destroyed or re-exported, Customs issues a notice for redelivery to the importer of record. Failure to redeliver the refused product may result in Customs assessing liquidated damages against the importer's bond.

Visual IV.1-6

Detention Without Physical Examination (DWPE)

A product may be detained as soon as it is offered for entry into the United States based on past history and/or other information indicating the product may be violative

In some instances a product may be detained as soon as it is offered for entry into the United States. This procedure is the administrative act of detaining a product without physical examination and is based on past history and/or other information indicating the product may be violative. A product may be subject to a detention without physical examination (DWPE) recommendation until the shipper or importer proves that the product meets FDA guidelines or standards. Occasionally, FDA identifies products from an entire country or geographic region for DWPE when the

violative conditions appear to be geographically widespread. Detention recommendations of this breadth are rare and are initiated only after other avenues for resolving the problem have been exhausted.
It must be emphasized that DWPE matters must be settled well before shipment of fresh produce. All perishable produce must adhere strictly to all import requirements. Delays of questionable items easily result in spoilage, even if the item is subsequently cleared for commerce.

Pesticide Residues on Raw Agricultural Commodities

Tolerances for pesticide residues on many raw agricultural commodities have been established under Section 408 of the Federal Food, Drug, and Cosmetic Act (FDA, 2001). The term "raw agricultural commodity" means any food in its raw or natural state, including all unprocessed fruits, vegetables, nuts, and grains. Foods that have been washed, colored, waxed, or otherwise treated in their unpeeled natural form are considered to be unprocessed. Products of this kind containing pesticide residues are in violation of the Federal Food, Drug, and Cosmetic Act unless: (1) the pesticide chemical has been exempted from the requirement of a residue tolerance; or (2) a tolerance has been established for the particular pesticide on the specific food and the residue does not exceed the tolerance (Sec. 408).

The Environmental Protection Agency establishes, revokes or changes tolerances, as the facts warrant such action. Firms considering offering foods for entry into the United States that may contain pesticide residues should determine if there are tolerances for the pesticides on the product in question. This determination can be made by contacting the EPA (see Additional Resources for contact information).

APHIS Import Authorization System

USDA through the Animal Plant Health and Inspection Service (APHIS) requires permits for certain fresh fruits and vegetables that are imported from any foreign country. Only approved plant parts of the fresh fruits and vegetables are allowed entry. Entry requirements can be obtained from the Import Authorization System available on USDA’s website http://www.aphis.usda.gov/oa/new/at.html.

Summary

1. All foods imported into the U.S. must meet the same requirements as those produced domestically.

2. In the U.S., food safety is a shared responsibility with several departments of the United States government sharing jurisdiction over ensuring the safety of the American food supply. Agencies involved include:

- The Food and Drug Administration - regulates both domestic and imported foods, except meat, poultry and processed eggs, and has primary responsibility for enforcing food safety laws including food import and export regulations.
- The Centers for Disease Control and Prevention - works closely with state and local public health epidemiologists and laboratories to identify Illnesses and clusters of illnesses that may be foodborne.
- The U.S. Department of Agriculture -has several agencies that carry out a wide range of programs that may play a role in assuring food safety by establishing the safety of imported fruits and vegetables.
- The U.S. Environmental Protection Agency - regulates pesticides and assures drinking water meets standards for health.
- The U.S. Customs Service - serves as the point of entry for products imported into the U.S.

3. Firms considering offering foods for entry into the United States that may contain pesticide residues should determine if these residues are within the tolerances for the pesticides on the product in question established by the U.S. Environmental Protection Agency.

Module 2
Investigating Foodborne Disease Outbreaks*

Learning Outcome

- ***Participants should be familiar with the procedures used to investigate foodborne disease outbreaks.***

Practical

- ***Problem Solving: Traceback Investigation***
- ***Discussion Question 5***

Additional Resources

- ***FDA Publications: Farm Investigation Questionnaire***

When foodborne illness occurs, identification of the organisms involved and the food that carried these organisms is important both to assure adequate treatment of infected persons and to protect the public from the risk of continued spread or reoccurrence of the illness.

Possible outbreaks of disease are identified in a variety of ways (Reingold, 1998). Frequently consumers who suspect that a food they ate was associated with illness report the illness to local health departments. Sometimes medical personnel notice unusual numbers of disease cases and report their occurrence to public health officials.

Officials reviewing reports of surveillance data may also detect outbreaks. In the U.S., two surveillance networks, FoodNet and PulseNet, monitor foodborne disease outbreaks on a national level (Guzewich and Salsbury, 2000). The Foodborne Diseases Active Surveillance Network (FoodNet) is a collaborative project of the Centers for Disease Control and Prevention (CDC), nine state sites, the U.S. Department of Agriculture (USDA), and the U.S. Food and Drug Administration (FDA). The project involves active surveillance for foodborne diseases and is designed to help public health officials better understand foodborne disease in the U.S. PulseNet is a national network of public health laboratories that perform DNA "fingerprinting" on bacteria that may be foodborne. The network permits rapid comparison of these "fingerprint" patterns through an electronic database at CDC. The system is used to exchange "fingerprints" when outbreaks of foodborne disease occur (CDC, 1999).

* Prepared by: Pamela Brady, Ph.D., IFSE, University of Arkansas and Juan Silva, Ph.D., Mississippi State University

Once a disease outbreak is recognized, investigation is begun to identify the cause of the outbreak. The main reason to investigate an outbreak is that by identifying and eliminating the source of infection, it may be possible to prevent additional cases of the disease (Reingold, 1998). However, even if the outbreak has reached a point where no further cases are appearing, it may still be important to investigate the outbreak. Such an investigation may provide information which will be useful to (1) prevent similar outbreaks in the future, (2) describe new diseases and learn more about existing ones, (3) evaluate prevention strategies, and (4) address public concern about the outbreak.

Visual IV.2-1

Foodborne Disease Investigations

- Epidemiological investigation
- Laboratory investigation
- Environmental investigation

Foodborne disease investigations have three components: epidemiological, laboratory, and environmental.

Epidemiological investigations verify a diagnosis; identify the range of onset of symptoms; provide case definitions; and determine the association between exposure to a specific food and the occurrence of illness. Epidemiological investigations are usually used to link specific foods and illnesses and can suggest sources of contamination.

The laboratory component of the investigation involves analysis of clinical samples, food samples (if remaining implicated portions or lots are available) and environmental samples. The laboratory analysis of clinical specimens is conducted in order to identify the pathogen causing the disease and may aid in linking cases. Additionally, clinical results are compared with food and environmental results and with epidemiological findings to aid in determining the source of contamination.

Environmental investigations focus on aspects in the environment of the food that may have led to contamination. Areas investigated include food preparation methods, the potential for temperature abuse or cross contamination, and the location of preparation.

Should the epidemiological or environmental investigation determine that the contamination most likely did not occur at the point of food preparation, then a traceback investigation may be initiated.

Rapid Response Programs for Foodborne Disease Outbreaks

With globalization of the food supply and increased transport and trade between states, nations, and continents, foodborne disease outbreaks may involve large populations and spread rapidly. Moreover, many pathogenic organisms have a low infective dose and are sometimes not isolated from the food product.

Visual IV.2-2

Investigating Foodborne Outbreaks

- Early identification of the outbreak
- Rapid and coordinated response to the outbreak
- Confirmation/identification of source(s)/product(s)
- Investigation and confirmation of outbreak
- Determine cause to prevent future outbreaks

Rapid response to a foodborne outbreak will rely heavily on epidemiological data, shared by county, state, national, and international agencies, to insure control and stop the exposure (Majkowski, 1997). Guidelines for improving the coordination and communication on multistate foodborne outbreaks have been developed in the U.S. (FDA, 2001).

International efforts to allow rapid detection of foodborne disease outbreaks require a constant exchange of information and surveillance data. This involves coordination and open channels between various agencies within a country through to the international level, coupled with accurate sampling and rapid laboratory sub-typing. Moreover, industry and others need to have accurate information about the source of the product (i.e. a traceback system).

Fruit and Vegetable Outbreak Traceback

Visual IV.2-3

Traceback

A traceback investigation is a method used to:

- Determine the source(s) and distribution of food(s) implicated in a foodborne disease outbreak
- Identify potential points where contamination could have occurred

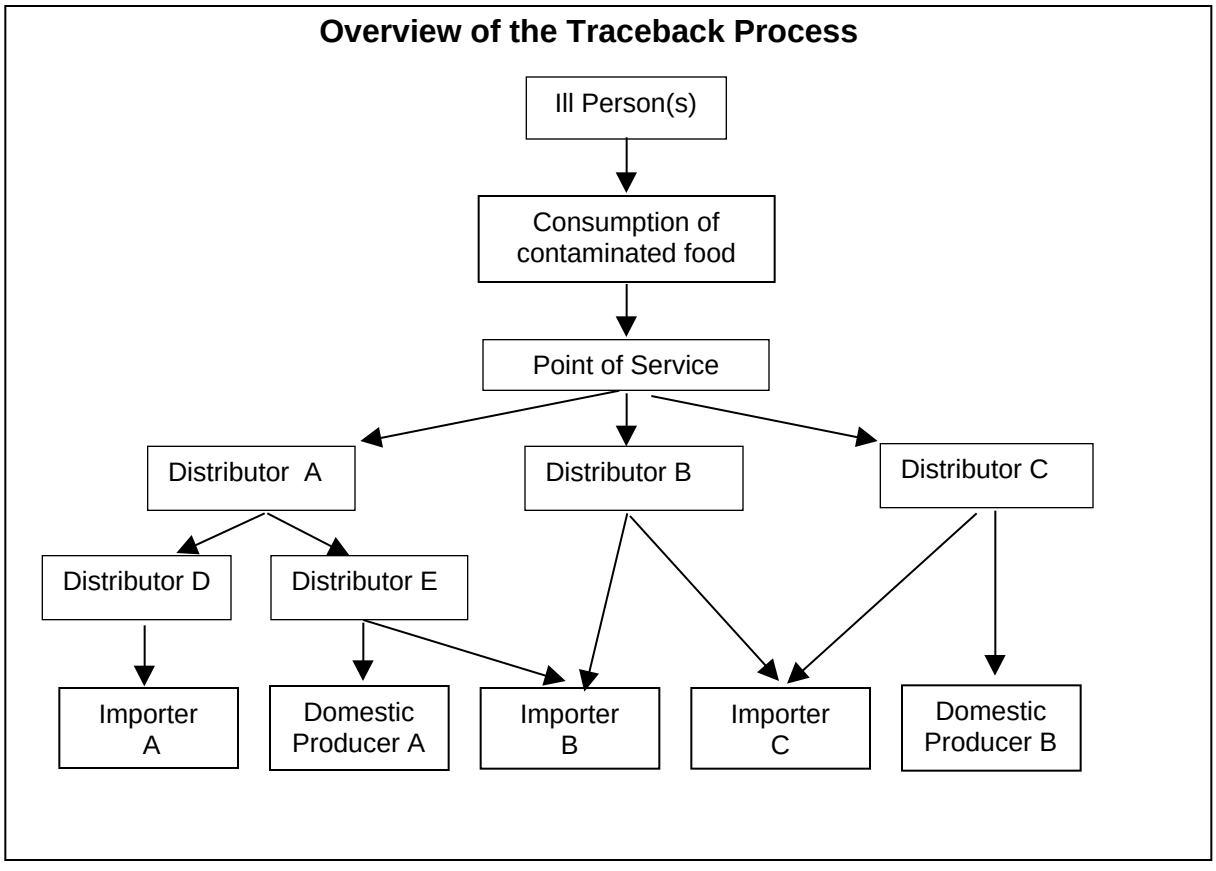
Traceback investigations are conducted to determine the source and distribution of products that were implicated in a foodborne disease outbreak and to identify

potential points where contamination may have occurred (Guzewich and Salsbury, 2000).

Despite the best efforts by produce operators, products may never be completely free of microbial hazards. However, an effective traceback system can give investigators clues that may lead to a specific region, packing facility, even cultivated field, rather than an entire commodity group. Narrowing the potential scope of an outbreak could lessen the economic burden on those industry operators not responsible for the problem. Traceback also can serve as an important complement to good agricultural and manufacturing practices since information gained from a traceback investigation may be useful in identifying and eliminating a hazardous situation.

From a public health perspective, improving the speed and accuracy of tracing implicated food items back to their source may help limit the extent of an outbreak. Tracing implicated food items also may help public health officials determine potential causes of contamination, thereby providing data for growers, shippers, and others for identifying and minimizing microbial hazards.

Visual IV.2-4



The purpose of traceback is to determine and document the distribution and production chain for a product that has been implicated during an epidemiological

investigation of foodborne illness. By tracing the implicated product back to its source, steps can be taken to halt its further distribution. Currently fresh fruits and vegetables are extremely difficult to trace back because, in most instances, lot numbers/grower identifications are not used or recorded on receipt/shipping records so it is difficult for the distributor to identify specific shipments and their source. However efforts are being made to encourage better record keeping that can be used to assist in traceback activities.

Investigators initially visit the Point-of-Service (POS) establishment where the product was sold or prepared to determine when the product was purchased or prepared, and determine receiving, stock rotation, inventory, handling, and shipping procedures (FDA, 1998b). Records are collected covering all suppliers and shipments of implicated product to the POS over the shelf life of the implicated product. Data relating to distribution is charted and analyzed. Following analysis at each distribution level, distributors who supplied suspect shipments of product are visited and interviewed. Distributor interviews and data collection and analysis are repeated for each level of distribution until investigators identify the source of the product.

Produce offers a number of unique challenges to the traceback process. Fresh produce has a relatively short shelf life so is often gone by the time an outbreak is reported. This makes it extremely difficult to identify the item causing the foodborne illness. If fresh produce is linked to an outbreak, current industry practices in the marketing and distribution systems, such as co-mingling during distribution or at retail, make a direct identification of the source of a product very difficult. If an implicated source (for example, a field or packing facility) is identified, the source of contamination may no longer be present when investigators arrive at the site. This variability and lack of a direct determination of cause have resulted in a high degree of uncertainty, and, in some cases, false associations. The economic burden of a false association is especially troublesome for those industry segments that may later be proven not to have been involved in the actual outbreak.

Because of the diversity of handling practices throughout the produce distribution and marketing chain, a traceback system may be easier to implement for some market segments than for others. For example, traceback systems may be more easily implemented by larger operations that have more direct control over a greater number of steps in the growing/packing/distribution chain. However, industry associations, growers, and operators are encouraged to consider ways to provide this capability, where feasible.

Visual IV.2-5

Documentation for effective traceback:
- Date of harvest
- Farm identification
- Who handled the product from grower to consumer
- Identifying codes/lots at each distribution level for retail.

It is important for a company to examine current procedures and, if necessary, to develop new ones to track individual containers from the farm, to the packer, distributor, and retailer. At a minimum, an effective traceback system should have documentation to indicate the source of a product and a mechanism for marking or identifying the product so that it is possible to follow the product from the farm to the consumer. Documentation should include:

a. Date of harvest,
b. Farm identification
c. Who handled the produce from grower to consumer
d. Identifying codes/lots at each distribution level for retail.

Many growers, especially smaller operations, have little control over what happens to produce after it enters the distribution and marketing chain. Therefore, it is critical that growers, packers, and shippers work with their partners in transportation, distribution, and retail to develop technologies that will allow tracking of fresh produce from the grower to the retailer and consumer. Some industry trade groups are developing technologies (such as bar codes, stamps, stickers, tags, etc.) to aid in identifying the source of produce and software to assist retailers in providing more accurate traceback to the grower/packer level.

Farm or Source Investigations

If a traceback identifies the farm(s) as the source(s) of an outbreak, a farm or source investigation may be conducted. Efforts in this investigation are focused on locating possible sources of contamination. Investigators may look at factors such as water management and drainage, flooding or other weather-related contamination, waste management and manure usage, sanitation and handling of tools and equipment, worker health and hygiene, and management of both domestic and wild animals.

The FDA has developed a Farm Investigation Questionnaire that provides an outline of the factors that are studied to determine where product contamination may have occurred on the farm. An abbreviated version of this Questionnaire can be found in the FDA Publications portion of the Resources Section at the end of

this manual. Controls for on the farm factors affecting product contamination are discussed in Sections II and III of this manual.

Regional and Local Considerations

To assist participants in relating to the importance of training to improve the safety and quality of fresh fruits and vegetables, trainers may want to include a discussion of issues related to specific regional and/or local products.

Summary

1. When foodborne illness occurs, identification of the organisms involved and the food that carried these organisms is important both to assure adequate treatment of infected persons and to protect the public from the risk of continued spread or reoccurrence of the illness.

2. In the U.S., two surveillance networks monitor foodborne disease outbreaks:
   - The Foodborne Diseases Active Surveillance Network (FoodNet) involves active surveillance for foodborne diseases and is designed to help public health officials better understand foodborne disease in the U.S.
   - PulseNet uses a national computer network to alert public health officers to possible outbreaks of foodborne disease using bacteria “fingerprinting” that can link cases/clusters occurring in multiple sites.

3. Foodborne disease investigations have three components: epidemiological, laboratory, and environmental.
   - Epidemiological investigations verify a diagnosis; identify the range of onset of symptoms; provide case definitions; and determine the association between exposure to a specific food and the occurrence of illness.
   - Laboratory investigation involves analysis of clinical samples, food samples (if leftovers are available) and environmental samples.
   - Environmental investigations focus on aspects in the environment of the food that may have led to contamination.

4. Should the environmental investigation determine that the contamination most likely did not occur at the point of food preparation, then a traceback investigation may be initiated. Traceback investigations are conducted to determine the source and distribution of products that were implicated in a foodborne disease outbreak and to identify potential points where contamination may have occurred. Produce offers a number of unique challenges to the traceback process.

5. If a traceback identifies the farm(s) as the source(s) of an outbreak, a farm or source investigation may be conducted to locate possible sources of contamination.

Module 3
International Food Laws and Regulations*

Learning Outcomes

- ***Participants will gain insight about the international agreements and regulations affecting trade in food.***

Practical

- ***Discussion Question 3***

Sanitary (human and animal health) and phytosanitary (plant health) standards are necessary to ensure that food is safe for consumers, to prevent the spread of pests and diseases among animals and plants and to ensure fair practices in trade. In recent years, world food trade has been profoundly altered by the adoption of agreements that provide a more precise framework for trade, and define the rights and the obligations of all partners. These agreements served to strengthen the status of institutions like the Codex Alimentarius Commission and the International Plant Protection Convention since these were used as a basis for harmonization.

The Uruguay Round Agreements

The Uruguay Round of Multilateral Trade Negotiations, which concluded in 1994, established the World Trade Organization (WTO) to replace the General Agreement on Tariffs and Trade (GATT). The Uruguay Round negotiations were the first to deal with the liberalization of trade in agricultural products, an area excluded from previous rounds of negotiations. They also included negotiations on reducing non-tariff barriers to international trade in agricultural products and concluded with two binding agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). Members of WTO will apply these agreements and the general terms are also applicable to countries that are not WTO members.

The Agreement on the Application of Sanitary and Phytosanitary Measures confirms the right of WTO member countries to apply measures necessary to protect the life and health of humans, animals and plants (FAO, 2000).

* Prepared by: Catherine Bessy, Consultant, Food Quality and Standards Service, FAO, Rome

Visual IV.3-1

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

- States that measures (laws, regulations, and procedures) adopted by governments to protect animal, plant, or human health should not be maintained without sufficient scientific evidence.
- Requires that WTO members base their national requirements on international standards, guidelines and other recommendations adopted by the FAO/WHO Codex Alimentarius Commission, the IPPC (International Plant Protection Convention (IPPC) and International Office of Epizootics where they exist.

This agreement sets rules in an area previously excluded from GATT disciplines. The purpose of the SPS Agreement is to ensure that measures established by governments to protect human, animal and plant life and health (in the agricultural sector only) are consistent with requirements prohibiting arbitrary or unjustifiable discrimination in trade between countries where the same conditions prevail. It also attempts to establish that these measures are not disguised restrictions on international trade.

The SPS requires that, with regard to food safety measures, WTO members base their national requirements on international standards, guidelines and other recommendations adopted by the FAO/WHO Codex Alimentarius Commission (CAC), where they exist. This does not prevent a member country from adopting stricter measures, if there is scientific justification for doing so or if the level of protection afforded by the Codex standard is inconsistent with the level of protection generally applied and deemed appropriate by the country concerned.

The SPS Agreement covers all food hygiene and food safety measures including control of pesticides and other chemicals. In addition, it covers plant quarantine measures. The SPS Agreement recognizes the IPPC (International Plant Protection Convention) as the relevant international organization responsible for the establishment of international standards for phytosanitary measures and encourages countries to base their phytosanitary measures on IPPC standards, guidelines or recommendations to promote global harmonization of phytosanitary measures in trade. The SPS Agreement recognizes the International Office of Epizootics as the organization to set benchmarks for meeting SPS requirements related to animal health. The WTO Committee on Sanitary and Phytosanitary Measures guides this work.

The SPS Agreement states that any measures taken that conform to international Codex standards, guidelines or other recommendations are deemed to be appropriate, necessary and non-discriminatory. Furthermore, the SPS

Agreement calls for a program of harmonization of national requirements based on international standards.

Visual IV.3-2

Agreement on Technical Barriers to Trade (TBT)

Seeks to ensure that technical regulations and analytical procedures for assessing conformity with technical regulations and standards do not create unnecessary obstacles to trade.

The Agreement on Technical Barriers to Trade was established with the objective of preventing the use of national or regional technical requirements, or standards in general, as unjustified barriers to trade (FAO, 2000). The agreement covers standards relating to all types of products including industrial and agricultural products. Not covered are food standards related to sanitary and phytosanitary measures. It includes numerous measures designed to protect consumers against deception and economic fraud. Examples of food standards covered by the TBT Agreement are those related to quality and labeling.

The TBT Agreement basically provides that all technical standards and regulations must have a legitimate purpose and that the impact or cost of implementing a standard must be proportional to the purpose of the standard. It also says that if there are two or more ways of achieving the same objective, the least trade-restrictive alternative should be followed. The agreement also places emphasis on international standards and WTO members are obliged to use international standards or parts of them except where the international standard would be ineffective or inappropriate in the national situation. The TBT Agreement does not include a program for harmonizing national standards.

Codex Alimentarius

The adoption of the SPS and TBT Agreements resulted in new emphasis and importance being placed on the work of Codex in establishing international food quality and safety standards.

Visual I.3-3

Codex Alimentarius

A code of international food standards. The purpose of Codex is

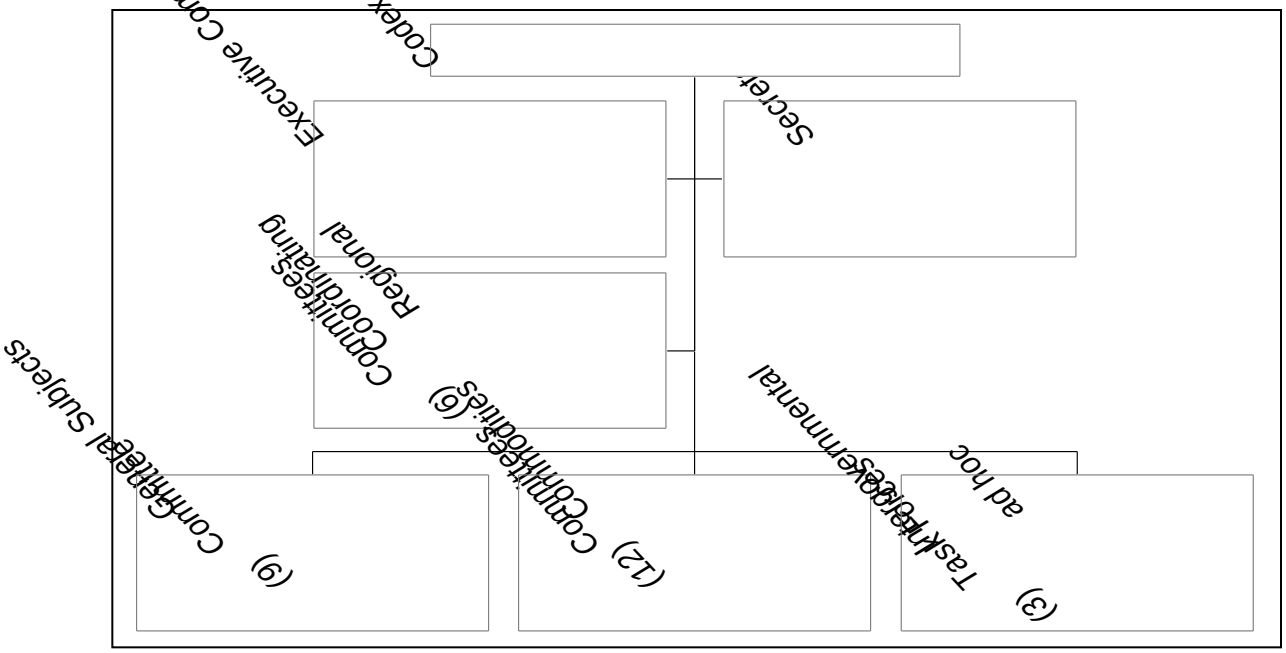
- To guide and promote the elaboration of definitions and requirements for foods and assist in their harmonization
- To facilitate world trade
- To promote consumer protection

The name Codex Alimentarius is taken from Latin and translates literally as “food code” or “food law”. The Codex Alimentarius is a series of food standards, codes and other regulations adopted by the Codex Alimentarius Commission (CAC) that countries can use as models in their domestic food legislation and regulations, and which can be applied to international trade. Codex provides the assurance that any foods produced according to its codes of hygienic practices and complying with its standards are safe and nutritious and offer adequate health protection.

The CAC was created in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Its main purpose is to promote consumer protection and to facilitate world trade in foods through the development of food standards, codes of practice and other guidelines (FAO/WHO, 1999). Since it’s inception, the CAC has been responsible for implementing the Joint FAO/WHO Food Standards Program (FAO, 2000).

The CAC is an intergovernmental body with a current membership of 165 Member governments. Membership is open to all Member Nations and Associate Members of FAO and WHO. In addition, observers from international scientific, food industry, food trade and consumer associations may attend sessions of the Commission and of its subsidiary bodies. While observer organizations can fully participate in the proceedings of the meeting, by statute, only Member governments can participate in any decision process.

Visual I.3



An Executive Committee, six Regional Coordinating Committees and a Secretariat assist the Commission in administering its work and other activities. The work of the CAC is divided between two basic types of committees. The first

type deals with general subject matter(s) that cuts across all food classes or groups. The work of the second type of committee, the Codex Commodity Committees, is specific for foods within a class or group. In addition, three ***ad hoc*** Intergovernmental Codex Task Forces were established by the 23rd Session of the CAC to develop standards, guidelines and recommendations for foods derived from biotechnology, for animal feeding and for fruit juices.

There are nine general subject matter committees, each with different responsibilities. These Committees deal with matters such as hygiene, veterinary drugs, pesticides, food additives, labeling, methods of analysis, nutrition, and import/export inspection and certification systems. For example, one Committee is responsible for developing standards, recommendations and guidelines related to microbiological contamination (Codex Committee on Food Hygiene). This Committee also develops general hygienic (sanitation) practices and conditions for food manufacturing, processing, production, handling, storing and transporting. The subject matter committees interact with the Commodity Committees. For example, the Committee on Food Labeling proposes standards for labeling and for specific labeling requirements of commodities in co-operation with the specific commodity committees.

The second type of Committee is one that deals with a specific type of food class or group, such as dairy and dairy products, fats and oils, or fishes and fish products. There are 12 Commodity Committees. Each works on a specific food or class of food. Since its beginning, the CAC has adopted 204 different standards for food in all of the main groups of food traded at the international level. The Codex Committee on Fresh Fruits and Vegetables has elaborated a number of standards for fresh fruits and vegetables that primarily address quality issues. These are discussed further in Section V.

Codes of Practice provide guidance on acceptable manufacturing, food processing and handling practices during production, transport and storage. The CAC has elaborated 43 Codes. Some of these have a general application across food product classes or groups, while others are specific for certain commodities or foods. These Codes serve as a means of providing recommendations to producers and to government regulatory organizations on specific Good Manufacturing Practices (GMPs) for the commodities they address. These Codes, when used appropriately, can serve to enhance compliance with Codex standards and international trading requirements.

The Codex Committee on Food Hygiene is currently developing a code of hygienic practice for fresh fruits and vegetables entitled ***"Draft Code of Hygienic Practice for Fresh Fruits and Vegetables" (ALINORM 03/13, Appendix II).*** This is available via the Internet at http://www.codexalimentarius.net/Reports.htm***.*** The draft code is due for adoption as final text by the 25th Session of the CAC to be held in 2003. The draft code addresses GAPs and GMPs that will help control microbial, chemical, and physical hazards associated with all stages of the

production of fresh fruits and vegetables from primary production to packaging. Particular attention is given to minimizing microbial hazards.

Related to contaminants, CAC has established guidelines for the maximum tolerable levels for 25 common industrial and environmental contaminants of foods. Food additive evaluations have resulted in establishing acceptable use levels (with no appreciable health risk over a lifetime) for 1300 additives used in food. The review of pesticides for approved use in agricultural pest control resulted in the evaluation of 197 pesticide chemicals, and establishing 2516 maximum residue levels for these pesticides in various foods.

All Codex standards are developed according to the same procedure. The CAC decides that a standard should be developed and determines which subsidiary body should undertake the work. Subsidiary bodies of the Commission also may make the decision to elaborate standards, subject to the approval of the Commission or the Executive Committee. The Secretariat of the Commission then arranges for the preparation of a “proposed draft standard” which is circulated to the Member countries for comments. The subsidiary body reviews and revises the “proposed draft standard” in light of the comments received, then may present the text to the Commission as a “draft standard.” If the Commission adopts the “draft standard,” it is again sent to Member governments for further comments. In the light of the comments received and after further consideration by the subsidiary body concerned, the Commission reconsiders the draft and may adopt it as a “Codex standard”.

Call for Harmonization

Visual IV.3-5

Harmonization
Establishing national measures consistent with international standards, guidelines and recommendations.

To facilitate international trade, it has been necessary for efforts to be made to harmonize food standards. Those involved in harmonization efforts recognized that countries have the right to adopt standards they feel are appropriate to protect human, animal and plant health and the environment. They also have the right to take the steps necessary to assure these standards are met. However, preventing these standards from becoming barriers to trade is important to promote trade between countries (FAO, 1998).

The TBT Agreement does not specifically name the international standard setting bodies whose standards are to be used as benchmarks for judging compliance

with the provisions of the Agreement. However, the SPS Agreement specifically names the CAC as the only recognized international food standard setting body. The fact that the Codex Alimentarius is designated in the SPS Agreement indicates the value given to the Codex Standards in the negotiations of the Agreements and this spills over into the areas covered by the TBT Agreement.

National regulations that are consistent with Codex meet the requirements of SPS and TBT Agreements. When joining the WTO, countries agree to adhere to a number of agreements including the SPS and TBT Agreements. These two agreements set the standards necessary to assure the regulation of food quality and safety in international food trade. WTO Member governments agree to use Codex standards as their reference. As Codex standards have the full support of the SPS Agreement which advocates them as the basis for all national standards, they play a significant role in the harmonization of national food safety standards and may be used as a reference point for resolving trade disputes between WTO Members.

Summary

1. The Uruguay Round negotiations dealt with the liberalization of trade in agricultural products. They also included negotiations on reducing non-tariff barriers to international trade in agricultural products and concluded with two binding agreements: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).

2. The Codex Alimentarius is a series of food standards, codes and other regulations adopted by the Codex Alimentarius Commission (CAC) that countries can use as models in their domestic food legislation and regulations, and which can be applied to international trade. Codex provides the assurance that any foods produced according to its codes of hygienic practices and complying with its standards are safe and nutritious and offer adequate health protection.

3. The Codex Committee on Food Hygiene is currently developing a code of hygienic practice for fresh fruits and vegetables entitled ***"Draft Code of Hygienic Practice for Fresh Fruits and Vegetables (ALINORM 03/13, Appendix II)".*** This draft code addresses GAPs and GMPs that will help control microbial, chemical, and physical hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packaging.

4. To facilitate international trade, harmonization of food standards is necessary to prevent these standards from becoming barriers to trade between countries.

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