Improving the Safety and Quality of Fresh Fruits and Vegetables: A Training Manual for Trainers

Section VII

Food Laws and Regulations

Module 1 The U.S. Food Safety System for Fresh Produce

Module 2 Investigating Outbreaks of Foodborne Disease

Module 3 International Laws and Regulations

Introduction

In the U.S. there are a number of federal, state and local agencies that regulate and have oversight for the safety of various food groups. Meat, poultry, seafood, milk, eggs, processed fruit and vegetables, etc., all are subject to specific rules and regulations. This Module focuses primarily on the entities that are involved with the fresh produce industry. It is not intended to provide a comprehensive review of all laws and regulations regarding food safety, but to provide an informative overview.

Basic Requirements for Food

All foods consumed in the U.S., whether produced domestically or internationally, must conform to a simple set of principles. Food must be pure, wholesome and safe to eat, produced under sanitary conditions and properly labeled. The globalization of our food supply during the past few decades has dramatically complicated the work of the regulatory environment by creating the challenge of ensuring that imported foods meet the same standard of quality and safety that is demanded of domestic products.

Although the above requirements appear to be straightforward, they all are subject to interpretation. In order to achieve uniformity in food quality and safety, the regulatory system in the U.S. has evolved into a complex set of laws enforced by numerous agencies. The complexity of the system is evident in the following list of agencies that are involved.

Federal Agencies Involved in Food Safety

The U.S. Department of Health and Human Services (HHS) has within its organizational structure two units that have food safety responsibilities. These are only two of the units housed in HHS, an agency with many other responsibilities not discussed here.

The Food and Drug Administration (FDA) regulates all foods other than meat, poultry and processed eggs. FDA plays many vital roles in support of the fresh produce industry and these are discussed in more detail throughout this Module.

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 illness that may be foodborne. They study environmental and chronic health problems, administer national programs for prevention and control of vector-borne diseases, and fulfill other important roles in service to the domestic and international communities.

The U.S. Department of Agriculture (USDA) has broad oversight for issues in practically all segments of the agricultural industry. Several units within USDA have roles in food safety assurance.

The Food Safety and Inspection Service (FSIS) is responsible for regulation of meat, poultry and processed eggs. Because of the potential for commingling and cross-contamination between different food groups, the FSIS is increasingly involved in discussions and issues surrounding fresh produce food safety.

The Animal and Plant Health Inspection Service (APHIS) addresses animal diseases that could affect food safety and maintains a comprehensive system of import inspection and controls. Through monitoring activities at airports, seaports and border stations it guards against the entry of foreign agricultural pests and diseases that affect both plants and animals.

The Foreign Agricultural Service (FAS) is primarily responsible for the USDA's overseas programs, including market development, international trade agreements and negotiations, and the collection of statistics and market information. The FAS is well positioned to assist other agencies with evaluating food safety capabilities and identifying training opportunities in foreign countries.

The Agricultural Marketing Service (AMS) carries out programs aimed at facilitating the marketing of

agricultural products, assuring consistency in quality, and establishing fair trading practices. This entails a broad program of inspections for domestic and imported foods.

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

The Environmental Protection Agency (EPA) regulates pesticides, determines the safety of new pesticides, establishes tolerances or maximum levels for pesticide residues, and regulates water safety and quality. Chemical hazards presenting food safety risks in fresh produce would be of particular concern to the EPA.

The Department of Homeland Security (DHS), through Customs and Border Protection (CBP), enforces customs regulations and assists other agencies, particularly FDA and USDA, when food safety and protection is of concern with imported products. The various roles and responsibilities of DHS to the fresh produce industry are addressed later in this Module.

State and Local Agencies

Each state has its own set of agencies that address food safety issues within the state. They may also regulate interstate movement of some agricultural products. Counties, municipalities or other localities often have agencies that assume a food safety role that typically is restricted to oversight of food service facilities, restaurants, local markets, etc. These state and local agencies and their various powers are beyond the scope of this manual, although state and local rules may influence exporters of food to the U.S.

The Food and Drug Administration (FDA)

The FDA is charged with protecting consumers from food that is impure, unsafe, produced in unsanitary conditions or fraudulently labeled. The responsibilities that FDA has are enormous. A few of FDA's activities include inspecting production facilities and food warehouses; collecting and analyzing samples for all types of hazards; establishing GAP, GMP and HACCP in appropriate locations; sampling and inspecting imported foods; working with foreign governments; taking appropriate enforcement actions; and educating consumers.

This involves many Acts, or Laws. A few of those Acts that are relevant to the fresh produce industry are:

Federal Food, Drug and Cosmetic Act

Fair Packaging and Labeling Act

Bioterrorism Act

Nutritional Labeling and Education Act

Food Allergen Labeling and Consumer Protection Act

Dietary Supplement Health and Education Act

Public Health Service Act

Although the U.S. Congress passes legislation to establish the above Laws and Acts, the FDA is responsible for developing and implementing regulations. These FDA Regulations are codified in Part 21 Code of Federal Regulations (21 CFR), which is available online at www.fda.gov and include the following:

Good Manufacturing Practices: 21 CFR 110

Dietary Supplements: 21 CFR 111

Canned Foods: 21 CFR 113

Juice HACCP: 21 CFR 120

Seafood HACCP: 21 CFR 123

Nutrition Labeling: 21 CFR 109

Veterinary Drugs: 21 CFR 500-589

To aid the food industry in interpreting these regulations the FDA develops guidelines and recommendations. One of these documents, the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, is largely the basis for many of the principles discussed throughout this manual. Commodity-specific guidelines also have been developed, with industry collaboration, for leafy greens, tomatoes, melons and sprouted seeds. The development of resources to assist food industries is an ongoing task of the FDA.

Imported Fruits and Vegetables

FDA is the principal food safety regulatory and enforcement agency for most foods imported into the U.S. despite the myriad of agencies listed previously. The key rule to remember is that all imported foods, including fresh produce, must comply with all applicable U.S. laws and FDA regulations. Considerations for imported foods are discussed throughout the remainder of this Module.

The Bioterrorism Act

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, commonly referred to as the Bioterrorism Act, created a number of new requirements for food handlers. The FDA is charged with enforcement of these requirements, which are reviewed here.

Registration of Food Facilities

Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack or hold food (subject to FDA's jurisdiction) for human or animal consumption in the United States must register the facility with FDA. The requirement applies to each covered facility, not to firms or companies as a whole. For example, a large fresh fruit and vegetable company with 10 packing and storage facilities must register each of those facilities separately with FDA.

The list of food products covered by this law is lengthy and can be viewed at the FDA website. Since fresh produce is the focus of this Manual, only the impact on fresh produce will be discussed.

The intent of the facility registration rule is to assist FDA with quickly determining the location and cause of a potential threat to our food supply and to be able to notify other facilities of the threat so that they may respond in a timely manner to protect consumers' health and safety.

There is a special exemption from the registration rule for certain foreign facilities that handle food if a subsequent foreign facility further handles the food. Anyone who believes that their company is affected by this exemption should refer directly to the rule on the FDA site since this Manual is not intended to be a comprehensive resource for information about food law.

The following information is required for food facility registration: name; full address and phone number of the facility; the parent company if there is one, and the owner, operator or agent in charge; all trade names the facility uses; name of U.S. agent and contact information (foreign facilities only); emergency contact phone number (domestic facilities only) and food product categories. Registration can be completed online.

Prior Notice of Imported Food Shipments

The FDA requires advance notice of foods that are to be imported into the U.S. The purpose of this law is to allow FDA time to evaluate information before the product arrives and, if necessary, shift resources to target inspections. This allows the FDA to help intercept contaminated goods and to help ensure movement of safe food into the market.

The following information must be provided in the prior notice: description of the food article, manufacturer and shipper of the article, the grower (if known), country of origin, country from which the article is shipped and anticipated port of entry. Note that most of this information is common invoice data usually provided by importers to U.S. Customs when goods arrive in the U.S.

Unless an exception has been approved, the rule applies to all food for humans and animals that is imported or offered for import into the U.S. for use, storage or distribution. This includes food for gifts and trade, quality assurance/quality control samples, food for future export, transshipment through the U.S. to another country or for use in a U.S. Foreign Trade Zone (FTZ), and food sent by mail or by express couriers.

The required time for prior notice depends upon the method of shipment as follows: by land via road requires no less than 2 hours before arrival, by air or by land via rail requires no less than 4 hours and arrival by water no less than 8 hours. For food carried by or accompanying an individual, the time is based upon the method of transportation. Prior notice cannot be submitted more than 5 days before arrival except for items sent by international mail, for which notice is submitted prior to mailing. Other restrictions may apply due to detention orders, reconditioning options, import alerts or refusals for non-compliance with other rules.

Establishment and Maintenance of Records

The Bioterrorism Act established laws for the maintenance of records to allow food to be traced back to its previous source or traced forward to its recipient. This is discussed in detail in Module 2 of this Section on the Investigation of Outbreaks of Foodborne Illness.

Administrative Detention

The FDA has the authority to detain an article of food if there is credible evidence or information indicating that the food presents a threat of serious adverse health consequences or death to humans or animals. The circumstances leading up to a detention order and the

owner's or consignee's options in responding to such an order are discussed later in this Module.

FDA's Enforcement Organizational Structure

The FDA operates with a set of five Centers as follows:

Center for Drug Evaluation and Research (CDER)

Center for Biologics Evaluation and Research (CBER)

Center for Devices and Radiological Health (CDRH)

Center for Veterinary Medicine (CVM)

Center for Food Safety and Applied Nutrition (CFSAN)

Responsibility for food safety resides in CFSAN and CVM. These agencies have worked with the University of Maryland to establish the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), which now provides much of the FDA-required training in food safety.

Although education is one of the goals of FDA, regulation and enforcement are its primary missions. To this end, the FDA has developed a number of compliance programs for foods with the goal of improving the quality, safety and security of our food supply. Many of those programs are listed below. The reader will note that a few of these have only a marginal connection to the safety of fresh fruits and vegetables. However, the fact that fresh produce is blended or commingled with many other food groups during preparation for consumption, such as in salads, demands that these compliance groups be in communication with each other to identify potential food safety hazards and work together to eliminate those hazards.

FDA Compliance Programs for Foods

Import and Domestic Low Acid and Acidified Canned Foods Programs

Import and Domestic Cheese and Cheese Products Program

National Drug Residue Milk Monitoring Program

Domestic Food Safety Program, General

Imported Food Safety Program, General

Domestic Fish and Fish Products Inspection Program

Imported Seafood Products Program

Juice HACCP Inspection Program

Pesticides and Industrial Chemicals in Domestic Foods Program

Pesticides and Industrial Chemicals in Imported Foods Program

Chemotherapeutics in Seafood Compliance Program

Toxic Elements in Food and Foodware, Import and Domestic Program

Mycotoxins in Domestic Foods Program

Mycotoxins in Imported Foods Program

Food and Color Additives in Imported Foods Program

Retail Food Protection Program

Milk Safety Program

Molluscan Shellfish Evaluation Program

Interstate Travel Program

Medical Foods, Import and Domestic Program

Domestic and Import Food Labeling Programs

Infant Formulas, Domestic and Import Programs

Dietary Supplements, Domestic and Import Programs

Animal Drug Manufacturing Inspection Program

Feed Contaminants Program

Feed Manufacturing Compliance Program

Illegal Drug Residues in Meat and Poultry Program (CVM cooperates with FSIS)

National Drug Residue Milk Monitoring Program

BSE/Ruminant Feed Ban Inspections Program

FDA Organizational Structure for Import Enforcement

There are three offices responsible for enforcement of the above compliance programs for imported foods.

The Office of Regulatory Affairs (ORA) is the lead office for all FDA field activities and provides leadership on imports, inspections and enforcement policy. It supports the 5 FDA Product Centers mentioned previously by inspecting products and manufacturers, conducting sample analyses, reviewing products offered for entry into the U.S., and developing policy on compliance and enforcement. ORA staff are located in sites throughout the U.S.

The Office of Regional Operations (ORO) coordinates and manages field operations. It is intricately involved in development and execution of policy between FDA and

state and local agencies. It serves a vital role in the overall management and execution of field activities.

The Division of Import Operations and Policy (DIOP) is primarily responsible for overseeing import operation policies and procedures and ensuring that the FDA's import operational guidance conforms to statutory and regulatory requirements. The fundamental goal of DIOP is to promote consistent implementation of FDA's importing procedures throughout the agency, regardless of entry point, border type or shipment type. To this end DIOP maintains and manages FDA's Import Alert System, and Operational and Administrative System for Imports Support (OASIS). It is responsible for the dissemination of information nationwide in order to obtain consistent port-by-port implementation of FDA procedures.

FDA Coverage at U.S. Ports of Entry

The FDA is physically present at geographical locations covering only about 100 of Customs' approximately 300 ports of entry. However, the FDA CVM cooperates with FSIS Customs and Border Protection to cover remaining ports of entry. Regardless of their physical presence, the FDA receives notice of entries through Customs at all ports of entry.

FDA's Enforcement Approaches and Practices for Imported Foods

The FDA's authority over importation of FDA-regulated products is derived principally from Section 801 of the Federal Food, Drug and Cosmetic Act (FFDCA). Its import procedures are mainly "administrative" in nature and operate through a set of administrative mechanisms that include the following:

- Review of entries as declared by Importers/Customs House Brokers
- Review of documents and product through field examinations, label examinations, and physical sample analyses
- Detentions, Refusals of Admission, and Re-labeling or Reconditioning of goods that are found to be in violation of regulation(s)
- Verification of final disposition of refused goods

In addition to these administrative instruments, all traditional enforcement mechanisms also are available to the FDA where warranted:

- Product seizures (FFDCA Sec. 304)
- Permanent Injunctions (FFDCA Sec. 302)
- Criminal Prosecution (FFDCA Sec. 301 and 303)
- Debarment (FFDCA Sec. 306)

Section 801(a) of FFDCA gives authority to FDA to "Refuse Admission" of any article that "appears" to be in violation of one of these laws:

*If it **appears** from the examination of such samples **or otherwise** that…It has been manufactured, processed, or packed under unsanitary conditions…It is forbidden or restricted in sale in country in which it was produced or exported…It is adulterated or misbranded…then such article shall be refused admission…"*

The significance of the appearance standard under FDA law is important in that the Government is not required to prove that an actual violation of law or the regulations has occurred. Rather, the FDA must be able to show that there exists an "appearance" of a violation to refuse admission of goods. If that "appearance" exists, the FDA can refuse entry to goods that appear to be adulterated or misbranded or appear to have been manufactured not in accordance with Good Manufacturing Practices (GMP). Further, FDA is allowed to make admissibility decisions using historical data, physical examinations (vs. sample collections), or based upon information from other sources or other evidence. In essence FDA has the authority and the obligation to use any and all resources available to judge the admissibility of food into the U.S.

The FDA Import Process

When a food is being prepared for importation into the U.S., a specific process is followed to assure that it meets FDA standards and is compliant with other rules for admission. First an entry notice is made to Customs. If the food is regulated by FDA, Customs forwards the entry notice to FDA. All food imports must comply with the requirements for prior notice and facility registration information under the Bioterrorism Act as discussed earlier.

If these preliminary requirements are met, the FDA will then review the shipment for admissibility. If all further

requirements are in compliance the FDA may rule that the shipment "may proceed" for admission and distribution.

FDA may decide to detain the goods without examination based on a failure to submit required information if there are import alerts relevant to the shipment (discussed later), or if more information needs to be obtained through additional documentation or through examination of the food and possibly with sample collection.

Notice of Sampling

FDA enforces this policy by employing 21 CFR 1.90—NOTICE OF SAMPLING.

When a shipment arrives, the owner or consignee is provided with a notice, initially through a Customs House Broker, when the FDA intends to examine the shipment.

This regulation requires the importer to hold the imported goods intact until the examination is completed. If an importer fails to hold goods that the FDA has indicated it intends to examine, the FDA will request Customs to demand redelivery of the goods in order for the examination to occur. The importer is then obligated to return the merchandise according to the terms of its Customs entry bond. Customs is able to enforce 21 CFR 1.90. If Customs demands that the importer redeliver the goods and the importer fails to do so, the conditions of the Customs entry bond gives Customs a civil cause of action to claim "Liquidated Damages."

The FDA import process is summarized as follows:

If a release ("may proceed") is issued, the product may be distributed. However, FDA still has jurisdiction and the release decision does not preclude FDA action if a problem is found later.

A detention order may be issued by FDA if there is an "appearance" of a violation. The "appearance" decision can be based on examinations, sampling, historical data or a lack of required processes and/or approvals. Regardless of the nature of the detention the importer has the right to give evidence to refute the appearance of a violation. Based on the evidence, the detention will either stand (refusal) or be overturned (release).

The importer also can also petition to recondition the goods to bring them into compliance. The reconditioning, which must be approved by FDA, may include re-labeling a misbranded product, cleansing an adulterated product or making a product that is not FDA regulated. All of these decisions are costly to the importer, so they should be made carefully.

All FDA field personnel are trained in examination and sampling techniques so there is some confidence that when they uncover the "appearance" of violations, a violation actually does exist. Field personnel will physically examine for evidence of filth, decomposition, packaging defects or misbranding. If there is justification, samples collected by field personnel are analyzed by FDA laboratories.

When a shipment is deemed to be "not in compliance," the FDA can issue either of two rulings regarding the shipment: Detention or Refusal.

Detention is a preliminary action whereby the FDA provides notice to the importer of an appearance of a violation and grants an opportunity for the importer to be heard. The importer and the FDA discuss the apparent violation and the importer is granted a chance to overcome the appearance before a definite refusal, discussed later, is issued.

The importer has several options following a detention notice. The importer may appeal the detention to the FDA, submit a private laboratory report of analyses, provide a certification of the product (where applicable), remove the product from FDA's jurisdiction, submit an application to recondition or re-label the product (under FDA supervision), or request an immediate Refusal of Admission.

If an article that was detained under section 801(a)(3) can, by re-labeling or other action, be brought into compliance with the Act, or rendered other than a food, drug, device or cosmetic, final determination as to admission of such article may be deferred. FDA supervises this process through a reconditioning/re-labeling agreement (FDA Form 766). Reconditioning is either successful, resulting in release of the shipment into U.S. commerce, or reconditioning is unsuccessful, resulting in refusal of admission. The FDA may grant approval to attempt a second reconditioning.

U.S. Refused Admission

Refusal of admission is a FINAL action by FDA preventing a particular shipment from being imported. Once admission is refused the importer has two options: export the product under Customs supervision within 90 days of the date of

refusal, or destroy the product under FDA supervision within 90 days of the date of refusal.

Charges to the Owner/Consignee (Sec 801(c)) state: All expenses (travel, per diem or subsistence, and salaries) in connection with the destruction or re-labeling/ reconditioning provided for in sections 801(a) and (b) shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against future importations.

FDA Import Alerts

Import Alerts are issued by FDA to communicate information to the field offices. Field agents can use the information to detain goods without examining them, e.g., Detention Without Physical Examination (DWPE). When the FDA detains a product without examination, it is providing notice to the importer that there appears to be some violation of law or regulations based upon something other than examination.

Field agents can also use this Import Alert to determine what products to examine or sample. A firm or product may be added to the DWPE order based on evidence from field offices or based on evidence from foreign inspections.

Foreign firms (shippers and manufacturers), products, countries of origin and importers of record may, in varying combinations, appear on an Import Alert. The Alert itself does not constitute evidence that there appears to be a violation, rather, the substance of the Alert describes evidence that the Agency has obtained. Under an Import Alert/DWPE, the importer is granted an opportunity to be heard and to offer testimony (oral, written or documentary) to overcome the "appearance" and obtain release of the entry.

There are a number of reasons for invoking Import Alerts: a shipper or manufacturer may have prior history of products in violation of FDA rules; foreign inspection may indicate processing, packing, or manufacturing problems at a particular foreign facility, or product may be from geographic locations that have experienced environmental events affecting the safety of products. Any of these situations can be the basis for the issuance of an Import Alert.

When a shipment that has arrived to the U.S. is held under DWPE the importer does have some options to have the shipment released. For example, when a firm has had prior violations, additional shipments from that firm can "appear" to violate the Federal Food Drug and Cosmetic Act (FFDEA). This prior history can result in a DWPE even though there are no apparent violations on the current shipment. The importer can offer testimony or evidence that "this current shipment" is not in violation, thereby overcoming the appearance of a violation and effecting release. Usually the evidence/testimony takes the form of private laboratory analyses or some compelling documentation about the company's practices.

Removal of Import Alert/DWPE

Firms may petition the FDA to be removed from DWPE. FDA reviews the petition submitted by the firm and generally requires evidence of non-violative shipments that are analyzed by a laboratory at importer expense.

FDA needs reasonable assurance that the cause of the violation has been corrected. Where a violative inspection caused the issuance of the Alert, a follow-up inspection may be required to overcome the appearance. Where a history of violative shipments resulted in inclusion in an Import Alert, the Agency may require a certain number of consecutive non-violative shipments, e.g., typically a minimum of five consecutive shipments, in order to remove a firm from DWPE.

When all of these requirements are satisfied a recommendation for removal from Import Alerts/ DWPE can originate from an FDA District or from an interested party, e.g., grower, exporter, importer or foreign government. If the appearance of the violation has been removed by adequate demonstration to FDA that the cause of the deficiency no longer exists, FDA can remove the firm from DWPE.

Pesticide Residues on Fresh Fruits and Vegetables

Tolerances for pesticide residues on many raw agricultural commodities, including fruits and vegetables, have been established under Section 408 of the FFDEA. The EPA establishes, revokes, or changes tolerances as the facts warrant such action. It is the responsibility of the grower, shipper or their representative to know the rules governing pesticide residues on their own products. They may contact EPA for this information. This topic was addressed in some detail in Section IV.

APHIS Import Authorization System

Certain fruits and vegetables from certain countries must undergo phytosanitary inspection and in some cases, quarantine treatment before they are allowed entry into the U.S. Entry requirements can be obtained from the APHIS website: www.aphis.usda.gov. These requirements focus on the protection of U.S. crops from insects and diseases that impact crop production.

Summary

Numerous federal, state and local agencies are involved in food safety in the U.S., but the FDA is the principal regulatory and enforcement agency for the safety of fresh fruits and vegetables.

In order to provide the best assurance that all foods (domestic and imported) are safe for consumption, the FDA has a complex enforcement and organizational structure involving numerous Centers and Offices that adhere to specific compliance programs.

The CDC investigates foodborne illnesses, working in collaboration with the FDA when appropriate.

The Bioterrorism Act of 2002 formally placed four general requirements on the produce industry: domestic and foreign food facilities must register with FDA, foreign entities must provide prior notice of imported foods, records must be maintained that allow food to be traced back to its previous source and traced forward to its subsequent recipient, and the FDA has the authority to detain an article of food under specific circumstances.

Imported foods are subject to the same laws, rules, acts, regulations, etc., as food produced within the U.S.

The FDA conducts surveillance and enforcement programs for imported foods that are intended to ensure that imports comply with applicable laws and regulations.

The FDA may detain import consignments that “appear” to violate U.S. law.

Detention Without Physical Examination (DWPE) may be invoked against foreign growers, handlers or manufacturers that violate U.S. laws and regulations.

Foreign entities can work directly with the FDA to overcome problems associated with their products.

Introduction

When an outbreak of foodborne illness or injury occurs, prompt identification of the food and the type of contamination is important both to ensure adequate treatment of sick persons and to protect the public from the risk of reoccurrence or spread of the incident. Biological, chemical or physical hazards all can potentially lead to an outbreak of illness or injuries. In recent years, the most publicized outbreaks have been those resulting from biological causes.

Surveillance of Illness in the U.S.

Possible outbreaks of disease or injury may be identified in a number of ways. Consumers who suspect that a food they ate caused them to be sick may report the incident to the local health department. If they seek medical treatment, the physician may report the illness, which is required for certain diseases. Medical personnel who notice unusual numbers of cases also may report to public health officials.

In the U.S., the reports described above are likely to be forwarded to a central data collection location. Officials who review these surveillance data have the advantage of receiving information from many sources throughout the country. Two surveillance networks, FoodNet and PulseNet, monitor foodborne disease on a national level.

FoodNet is the Foodborne Diseases Active Surveillance Network. It a collaborative project of the Centers for Disease Control (CDC), the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA) and 10 states throughout the U.S. The project involves active surveillance of foodborne diseases caused by at least nine pathogens or parasites. It is designed to assist public health officials with better understanding foodborne illnesses and their causes.

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 though an electronic database at CDC. The system is designed to share fingerprints and other relevant information when an outbreak of disease occurs and determine if the bacteria are related.

FoodNet and PulseNet both have been invaluable resources for the early detection of disease. This assists physicians with diagnosis and treatment of new cases as they appear and it helps epidemiologists to mobilize quickly to identify food(s) that may be linked to the outbreak.

Components of an Outbreak Investigation

Once an outbreak is recognized an investigation is begun immediately to determine the cause. The primary purpose is to prevent additional illnesses from occurring. However, it is still important to conduct an investigation even if no additional illnesses are appearing. Information may be used to evaluate prevention strategies to avoid similar outbreaks in the future, describe new diseases, learn more about existing diseases and address public concerns about the outbreak.

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

Epidemiology is a branch of medical science that deals with the incidence, distribution and control of a disease within a population. Thus, an epidemiological investigation is intended to 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. The linkage of illness to specific food(s) can suggest sources of contamination and eventually lead to strategies for mitigating risk. Sometimes a definitive linkage between a specific food and illness can not be determined and statistical analyses of outbreak data are employed to determine the most probable cause of the outbreak. Epidemiology is not always an exact science.

The laboratory component of the investigation involves analysis of clinical samples, food samples (if implicated portions or lots are still available) and environmental samples. Analysis of clinical specimens is conducted to identify the biological, chemical or physical hazard that

caused the illness or injury and can help to determine if cases are linked. Further, results of clinical analyses are compared to results for food and environmental samples to aid in determining the cause of the illness and source of the hazard.

Environmental investigations usually focus first on the point of food preparation. If the investigators conclude that the contamination most likely did not occur at the point of preparation, a traceback investigation (discussed later) is initiated that focuses on the production and handling environments to which the food has been exposed. Areas investigated may include farms, packinghouses, processing facilities, storerooms, mode of transportation, etc. The potential for temperature abuse, cross-contamination and any other potential risk factor is considered as part of the investigative process.

To summarize, the anatomy of a disease investigation involves: disease surveillance, epidemiological investigation, laboratory analyses, environmental investigation, traceback and traceforward (discussed later) and investigation of the manufacturer/processor and the farms. Collectively these investigations allow authorities to determine where, when and how in the production and handling chain the product became contaminated.

In a perfect world all of the preceding steps would be completed and accurate information would be available prior to the notification of consumers and removal of the product from the market. However, in the interest of protecting consumers, investigators sometimes must take steps to remove product from the market prior to completion of the investigation based on statistical evaluation of available data.

The Importance of Rapid Response

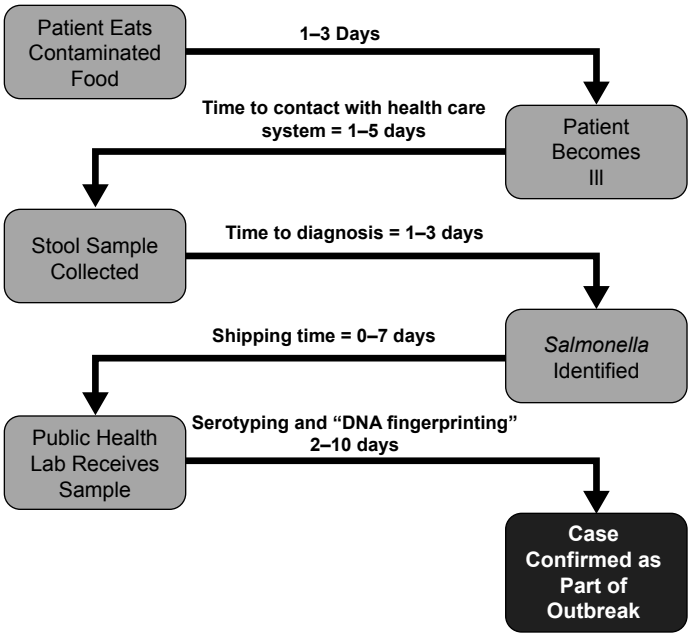
Foodborne disease outbreaks can spread rapidly through large populations. This is due in part to the fact that our food supply today is global, involving trade between states, nations and continents. Distribution networks within a market area, e.g., a country, region, state, etc., may be so well developed that the contaminated food rapidly reaches the hands of consumers. Further, biological and chemical hazards both may cause illness in low doses and can degrade rapidly, making them more difficult to identify with the passage of time. All of these factors emphasize the need for timely action by health authorities.

Rapid response to a foodborne illness outbreak must rely heavily on epidemiological data, which must be shared by county, state, national and international agencies in order obtain control of food distribution and limit exposure to the hazard. Guidelines for improving the coordination and communication on multi-state foodborne illness outbreaks have been developed in the U.S.

International efforts to allow rapid detection of foodborne disease outbreaks require a constant exchange of information and surveillance data. This involves coordination and open communication between various agencies within countries plus a point of contact for sharing the information at the international level. All of this must be supported by an infrastructure of personnel and facilities that allow for accurate sampling and adequate laboratory investigations. Further, the produce industry must maintain accurate information about the source and movement of product to facilitate traceback and traceforward. Many countries do not yet have the resources or networking capability to facilitate the tracking of food in the distribution system, or to monitor foodborne illness outbreaks.

In summary, foodborne illness outbreak investigations are most effective and conducted most rapidly when there is early identification of the outbreak, rapid and coordinated response by all investigative bodies, identification and confirmation of the product(s) and source(s), confirmation of the accuracy of all results obtained in the preceding

Timeline for Reporting of Cases



steps, and a plan to utilize the information to prevent future outbreaks.

Although the above steps and requirements for rapid response are clear, in the real world there are a number of factors that slow the process. The preceding graphic shows approximate delays that can occur with the identification of an outbreak caused by *Salmonella*. As much as three weeks may elapse from the time the patient consumes the food, contracts the illness, reports to a physician, provides a stool sample for identification of the bacterium, and analysis by health authorities who must fingerprint the microorganism and determine if other similar cases have been reported.

In the case of illness caused by a virus, such as Hepatitis A, the process outlined above is much longer. The development of disease may not occur for several weeks and the methods for identification of viruses are somewhat more complicated that those employed for bacteria. Many consumers may be exposed to the virus before the outbreak is identified and the cause confirmed.

Traceback and Traceforward of Fruits and Vegetables

As stated in the previous Module, The Bioterrorism Act requires fresh produce companies to maintain records that allow food to be traced one step back to its source and one step forward to its recipient(s).

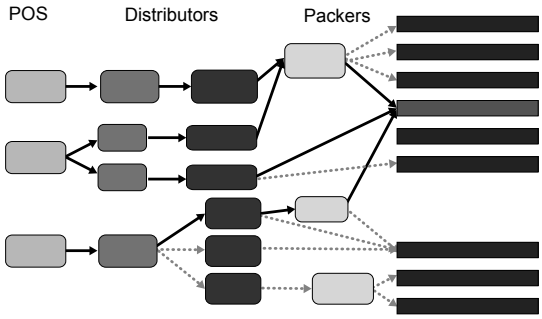
A **traceback** investigation starts with the consumer or point-of-purchase and traces the steps in the handling and distribution of the product back to the specific production area on the farm. This is a key process in response to a foodborne illness outbreak.

A **traceforward** investigation begins with the manufacturer/distributor or the farm, and traces forward to the consumer. This process is used primarily for product recall, but it also can be useful in outbreak investigations.

Traceback investigations are conducted to determine the source of contaminated products, to determine the distribution network for the implicated products, and to help identify potential points in the production and handling system where contamination could have occurred.

An effective traceback provides investigators with clues that may lead to identification of a specific region, field, packinghouse, processing facility, etc., as the contamination source. This allows authorities to narrow the scope of the outbreak rather than implicating an entire commodity group. There are examples of past outbreaks in which specific traceback for the implicated commodity, e.g., tomatoes, melons and others, could not be completed and the industry as a whole suffered because of the consumers' perception that all products were contaminated. Once the traceback has been successfully completed a traceforward can be conducted so that potentially contaminated products can be recalled. An example of a traceback flow diagram is shown here:

Traceback Flow Diagram Example



Although every traceback investigation is unique, there is a general process that investigators employ. Initially, investigators visit the Point of Service (POS) where the product was purchased or prepared for consumption. This might be a food service establishment or the consumers' homes. All records related to the food would be examined. This would include documentation for receiving, inventory, stock rotation, handling and shipping.

From these records, suppliers/distributors would be identified and visits to these establishments would be conducted. Records of shipping and distribution would be examined and charted for the time period covering the shelf life of the product.

These records should identify storage facilities, packinghouses or processors who had possession of the product. Visits to the handlers of the product and examination of their records should identify the farm(s) where the product was produced.

Farm investigations are discussed later. If the product was imported the scope of the investigation would have to be expanded dramatically to include the international producer and distributor.

It is obvious from the above summary that a traceback investigation can be a complex and time-consuming

process. Some unique challenges exist in the fresh produce industry that makes traceback investigations more difficult.

Fruits and vegetables have a relatively short shelf-life and may have been completely consumed or otherwise removed from the market before an outbreak is identified.

Produce items may have been commingled at retail, during distribution or at the POS, which make the identification of a specific product very difficult.

If an implicated location such as a farm or packinghouse can be identified, the contamination may no longer be present by the time investigators arrive.

The above variables and lack of a direct determination of cause have resulted in a high degree of uncertainty in some investigations, leading to 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.

The following two illustrations provide examples of traceback investigations that were either conclusive or inconclusive. In the first example, several clusters of illness were associated with various distributors. Records from those distributors eventually revealed a direct association of the product with Farm A. In the second example, which involves produce from domestic and foreign sources both, many different distributors received product from many different farms. A clear and direct association between the POS and product source could not be established.

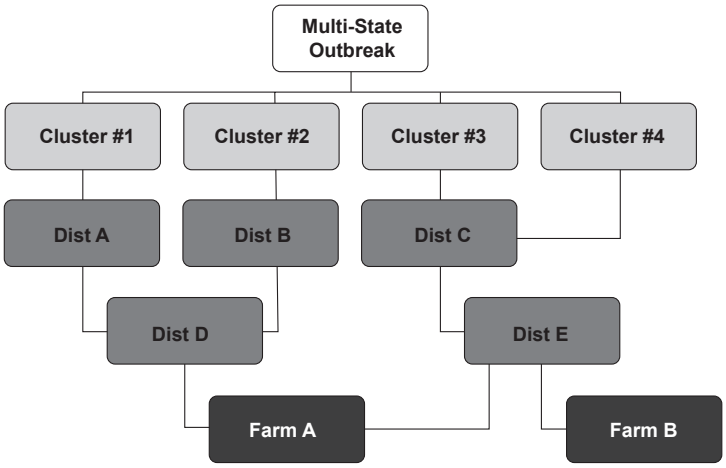
In past investigations, the FDA has faced one highly significant challenge in addition to those mentioned previously. During the investigation an outbreak may be ongoing. This places tremendous pressure on FDA to make an early decision in the interest of protecting consumers. An early decision, which later may be proven to be wrong, results in criticism of the FDA by the industry that may have faced severe economic hardships due to recalls or lost sales.

Further, there may be large numbers of sporadic cases for which there is no clear association with a specific food. Consumers generally have poor recollection of what they have eaten over a period of several days or they might have eaten the same produce item every day during the period in question. Multiple product types or varieties might be identified. For example, the consumer might recall eating tomatoes but may not be able to say if they were round, roma, cherry, or grape tomatoes or if they appeared to be a field-grown type versus a greenhouse-grown type. The tomatoes might have been mixed with other products, as in salsa or guacamole, which would preclude the identification of the specific type. The popularity of salad bars, fruit medleys, and other fresh foods made from a number of produce items are especially challenging for traceback investigators.

Considerations for Record-Keeping

Most of the above challenges for traceback could be overcome with the implementation of thorough record-keeping practices. This is much easier said than done. Large companies that are fully vertically integrated are best positioned to track their products from the farm though the

Example of a Conclusive Traceback



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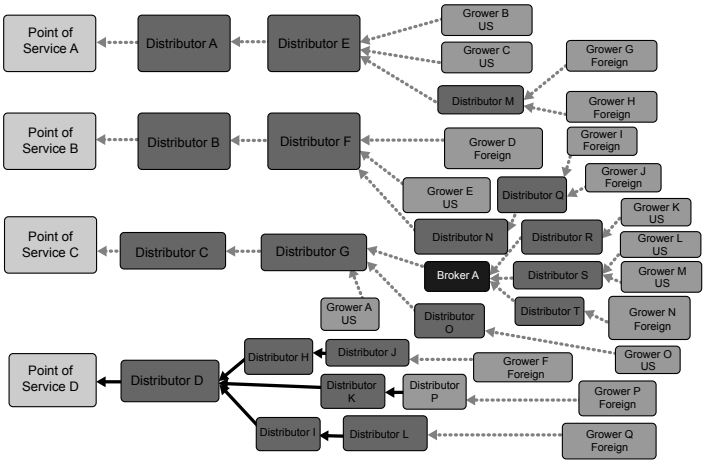
Example of Inconclusive Traceback



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distribution system. There are examples of companies that have control over growing, packing, shipping, re-packing and distribution. In this instance all critical records are held within a single company and can be made more readily available.

In the produce industry it is much more common for the product to pass through the hands of several different companies. Under this system, as stated earlier, FDA requires that each of these companies must have business records that allow tracking of the product only one step backward to the supplier and one step forward to the receiver. This makes traceback extremely cumbersome. It is difficult for a farmer to assign a label with a code to the product and expect that the same label will pass through the handling and marketing system with appropriate addition of new information from every handler to the consumer. Smaller companies are clearly at a disadvantage and must work with their business partners to develop appropriate protocols.

It is important for a company to examine current procedures and develop labeling methods to facilitate traceback. Ideally a label would contain the following information: the commodity type; farm and field location; lot number if one is assigned; date and time of harvest; harvest crew; date of packing; product code if one is assigned; date(s) of storage, ripening or other postharvest treatments; date of shipping; receiver identification; date received; date repacked; date reshipped or distributed; and identification of the final receiver. Under ideal circumstances, FDA would be able to quickly develop a flow chart containing all of this information. Companies identified on the flow chart could be contacted using Facility Registration information.

When tracking product from foreign sources, the FDA can make use of Facility Registration and Prior Notice data to help identify product(s) and source(s). Reliance on the company records and cooperation from the foreign government is still necessary for onsite investigation(s).

Personnel records within individual companies also should be available to traceback investigators. It should be possible to use these records to determine who handled the product at each step. This information is critical to determine if product handlers may have been ill at the time they were working.

Technologies have been developed and are constantly being improved to facilitate rapid traceback. In fact, this has emerged as a new distinct business niche in the food industry as a whole. These include highly specialized labeling systems, such as bar codes, radio frequency devices, stamps, stickers, etc., that allow for rapid identification of the product source and its history in the distribution chain. It is beyond the scope of this Module to review all of the technology that is available today and it is expected that new innovations will be developed on a regular basis.

Farm or Source Investigations

It is important to note that if a traceback investigation successfully tracks to the farm level, it does not necessarily indicate that the farm(s) are the source(s) of the product contamination. Further investigation is required to identify the specific source. The news media often present reports with the inference that the farm is culpable simply because it has been identified, which is not a fair assumption. Contamination might occur at virtually any step identified in the flow chart that is developed in conjunction with a traceback and investigators are expected to have the skills to recognize likely contamination sources.

Farms are investigated in the same thorough manner that is applied to handlers and processors to locate possible sources of contamination. Efforts are focused on factors such as irrigation water quality management, worker health and hygiene, proximity of domestic and wild animals, the effectiveness of animal exclusion methods, field drainage, potential for run-off from surrounding areas during flooding, waste management, manure usage, sanitation and handling of tools and equipment, weather conditions such as prevailing wind direction or other environmental conditions, and any other concern that could potentially result in contamination on the farm. All factors discussed in Section II of this Manual are considered.

The FDA has developed a Farm Investigation Questionnaire that provides an outline of the factors that are studied to identify potential points of contamination. Producers are urged to obtain a copy of this document and to perform a self-evaluation as a part of their GAP program.

Reportable Food Registry

The Reportable Food Registry (RFR) is an electronic portal to which the food industry must submit reports when there is a reasonable probability that an article of food will cause serious health consequences if it is consumed. Fruit and vegetable producers and handlers should review the RFR found at the FDA website and be prepared to comply with

this new requirement if the need should arise. Reports from federal, state and local authorities are not mandatory.

Summary

During an outbreak investigation, prompt identification of the food and the cause of illness or injury are important to limit exposure to the hazard.

Surveillance of possible outbreaks is conducted by physicians, local health authorities and national organizations such as FoodNet and PulseNet.

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

Rapid response by authorities to an outbreak is required in order to limit consumer exposure by informing the public that a hazard exists and by removing contaminated food from the supply chain.

Rapid response also is needed because our food supply in the U.S. is sourced from many different countries, distribution methods are rapid and efficient, and some hazards are rapidly degraded. The timeline for reporting cases of ill persons and the determination of the cause of illness or injury can be long.

Traceback starts with the consumer or point of service and traces the steps in handling and distribution back to the specific farm or product source.

Traceforward starts with the farm, manufacturer or distributor and traces forward to the consumer to facilitate product recall.

Companies in the produce industry are required to maintain records that allow investigators to trace product one step backward to the supplier and one step forward to the receiver.

Thorough and accurate record-keeping by companies that detail all critical information about product production and handling are required in order for effective traceback investigations to be achieved. Foreign entities must adhere to the same practices as domestic entities.

New technologies are emerging to assist growers and handlers with developing effective traceback systems.

The FDA has developed a Farm Investigation Questionnaire that provides an outline of the factors that are studied to identify potential points of contamination. Producers are urged to obtain a copy of this document and to perform a self-evaluation as a part of their GAP program.

The Reportable Food Registry (RFR) is an electronic portal to which the food industry must submit reports when there is a reasonable probability that an article of food will cause serious health consequences if it is consumed.

Introduction

In this Module the term *sanitary* standard refers to those affecting human and animal health. The term *phytosanitary* standard refers to matters of plant health. International standards are necessary to ensure that food is safe for consumers, to prevent the spread of diseases among animals and plants, and to ensure fair practices in trade. World food trade has benefited from discussions and agreements that provide a more precise framework for business and define the rights and obligations of all partners.

Codex Alimentarius

The term *Codex Alimentarius* is taken from Latin and translates literally as "food code" or "food law". It is a series of food standards, codes, and regulations adopted by the Codex Alimentarius Commission (CAC) that countries can use as models in their domestic food regulations. Their use in international trade is a step toward consistency in food laws among countries. Codex is the prevailing international law governing food.

Ideally, the application of Codex standards would assure that any food produced and handled according to its codes of hygienic practices are safe, nutritious and protect human health. In reality, food can never be assured to be completely safe food, but since its inception Codex has dramatically improved the quality and safety of food internationally.

The CAC was created in 1963 by two United Nations (UN) organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Since then, the CAC has been responsible for implementing the Joint FAO/WHO Food Standards Program.

The CAC is an intergovernmental body with a current membership of 183 governing entities. Membership is open to all FAO and WHO member nations and associate members. Additionally, observers from the scientific community, food industry, and food trade and consumer associations may attend sessions of the Commission and of its subsidiary bodies. While observers may participate in the Proceedings of meetings, only Member governments can participate in any decision making process.

The CAC is overseen by a Secretariat and an Executive Committee that is assisted by Regional Coordinating Committees. The work of CAC is divided among three general groups: General Subject Committees address issues that cut across all food classes or groups; Commodity Committees work with specific foods within a class or group, and; Intergovernmental Task Forces work to develop standards, guidelines, and recommendations for foods derived from biotechnology, for animal feeding, and for fruit juices. CAC is a dynamic organization and the number of Committees changes as the needs arise.

There are five documents from CAC, which can be viewed at the Codex Alimentarius website, that have direct relevance to the safety of fresh fruits and vegetables, listed below. The reader will note that specific technical recommendations are largely omitted from the discussion. Rather, they are general in nature and define the minimum requirements for food production, handling, and related areas.

Code of Hygienic Practice for Fresh Fruits and Vegetables CAC/RCP 53 – 2003

Principles for Food Import and Export Inspection and Certification CAC/GL 20 -1995

Principles and Guidelines for the Conduct of Microbiological Risk Assessment CAC/GL 30 – 1999

Principles and Guidelines for the Conduct of Microbiological Risk Management CAC/GL 63 – 2007

Principles for the Establishment and Application of Microbiological Criteria for Foods CAC/GL 21 – 1997

In the first document (*Code of Hygienic Practice*) a discussion of contaminants, including additives and pesticides, is included. Although the CAC has evaluated industrial and environmental contaminants and has published maximum residue levels for many agricultural chemicals, growers and handlers will find more utility in studying the label for any specific chemical and conforming

to US-EPA rules for its use. Agricultural chemicals are treated in detail in Sections III and IV of this Manual.

All Codex standards are developed according to the same procedure. The CAC determines if a standard is needed and assigns the task to an appropriate subsidiary body. A draft standard is prepared and circulated to member countries for comment. The subsidiary body reviews the comments, makes revisions to the draft as needed, and forwards the draft to CAC. If the CAC finds the draft to be acceptable, it is again forwarded to member countries for further review. The CAC and the subsidiary body review the final comments and if the standard is found to be appropriate, it may be adopted as an official Codex Standard.

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 Trades and Tariffs (GATT). The Negotiations dealt first with the liberalization of trade in agricultural products, an area that had not been included in previous negotiations, and secondly, with reducing non-tariff barriers to international trade in agricultural products.

Two binding agreements were reached: The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and The Agreement on Technical Barriers to Trade (TBT). A summary of those agreements follows. It is important to note that the adoption of SPS and TDB Agreements resulted in new emphasis and importance on the work of Codex in establishing international food quality and safety regulations.

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

This agreement confirms the right of WTO member countries to apply measures necessary to protect the life and health of humans, animals, and plants. Rules established by countries must not allow arbitrary or unjustifiable discrimination in trade between countries where the same conditions prevail. It also attempts to establish that the rules developed by Member countries are not disguised restrictions on international trade.

With regard to food safety measures, the SPS requires that WTO members base their requirements on international standards, guidelines, and recommendations adopted by FAO/WHO/CAC. A member country may adopt stricter measures if there is scientific justification or if the Codex standard is inconsistent with the level of food safety practices generally used in the country.

The SPS covers all food hygiene and food safety measures including control of pesticides and other agricultural chemicals. SPS recognizes the International Plant Protection Convention (IPPC) as the organization responsible for establishing international standards and encourages countries to base their phytosanitary measures on IPPC standards as a step towards harmonization.

Finally, SPS states that food policies in general must conform to the Codex Standards, thus acknowledging the importance of Codex. SPS also calls for a harmonization of rules among countries based on international standards.

The Agreement on Technical Barriers to Trade (TBT)

The TBT has the objective of preventing the use of national or regional technical requirements, or standards in general, as unjustified barriers to trade. It does not cover food standards related to sanitary or phytosanitary issues as these are addressed elsewhere. It does include measures designed to protect consumers from deception and economic fraud, for example in its policies related to quality and labeling.

The TBT 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 its purpose. If there are two or more ways of achieving the same purpose, the least trade restrictive should be followed. It places emphasis on international standards and obliges WTO members to use them unless they are judged to be ineffective or inappropriate for the national situation.

Call for Harmonization

Harmonization entails the establishment of national measures that are consistent with international standards, guidelines, and recommendations. The premise is that if all countries are playing by the same rules it will facilitate international trade.

Two examples of harmonization efforts in the fresh produce industry are the Global Food Safety Initiative (GFSI) and, in the U.S., the Produce Traceability Initiative (PTI).

Those involved in harmonization efforts recognize that countries have the right to adopt standards they feel appropriate to protect human, animal, and plant health, and the environment. They also have the right to take steps to ensure that these standards are met. However, preventing these standards from becoming barriers to trade between countries is important for the promotion of trade.

The TBT does not specifically name the international standard setting body, however the SPS specifically recognizes the CAC as having this role. National regulations that are consistent with Codex meet the requirements of SPS and TBT both. When joining the WTO, countries agree to conform to SPS and TBT for the assurance of the safety and quality of food, and to use Codex standards as their point of reference for business policies and for the resolution of trade disputes.

Summary

The term *sanitary* refers to matters of human and animal health and *phytosanitary* refers to plant health.

Codex Alimentarius, which means food code or food law, is a series of standards, codes and regulations adopted by the Codex Alimentarius Commission (CAC).

The CAC is an intergovernmental body composed of 183 governing entities. Membership is open to all FAO and WTO member nations and associate members.

The CAC documents that address the quality and safety of fresh fruits and vegetables may be viewed at the Codex Alimentarius website. These documents are general in nature and define minimum requirements for the production and handling of fresh produce and other foods.

The Uruguay Round of Multilateral Trade Negotiations in 1964 established the World Trade Organization and concluded its work with the adoption two binding agreements for member countries to follow in the international food trade.

The Agreement of the Application of Sanitary and Phytosanitary Measures (SPS) confirms the right of WTO members to apply measures necessary to protect the life and health of humans, animals, and plants.

With regard to food safety, the SPS requires that WTO members base their measures on international standards defined by the CAC.

The Agreement on Technical Barriers to Trade has the objective of preventing the use of national or regional requirements, or standards in general, as unjustified barriers to trade.

Harmonization entails the establishment of national measures that are consistent with international standards, guidelines, and recommendations. The premise is that if all countries are playing by the same rules it will facilitate international trade.