INTERNATIONAL FOOD SAFETY ISSUES

Lynne R. Ostfeld, Esq.[1]
Illinois State Bar Association
Hot Topics in Agriculture - February 8, 2008

In 2008, the International Year of the Potato, we find ourselves in a time when much of the U.S. food supply comes not from local farms but from overseas. Worries about the safety of food produced elsewhere are prevalent not only in the U.S. but in other countries as well. The question is how to profit from the benefit of eating somewhat more exotic, or consistently supplied, food than is found close by the consumer without suffering the risks that may arise from eating food coming from far away.

More than ever, the challenges for those concerned about the safety of food include bioterrorism and:

The increasing burden of foodborne illness and new and emerging foodborne hazards;

Rapidly changing technologies in food production, processing and marketing;

Developing science-based food control systems with a focus on consumer protection;

International food trade and need for harmonization of food safety and quality standards;

Changes in lifestyles, including increasing urbanization; and

Growing consumer awareness of food safety and quality issues and increasing demand for better information.

International organizations concerned with food safety

The World Health Organization (WHO), founded in 1948, is the United Nations agency for health whose goal is that all people attain the highest level of health possible, which it believes is the state of complete physical, mental and social well-being possible.

It works closely with the Food and Agriculture Organization of the United Nations (FAO), founded in 1945, to improve food safety. The FAO works to achieve food security through providing technical advice and assistance to create food control systems which are compatible with the recommendations of the FAO/WHO Codex Alimentarius Commission.

The statutes of the Codex Alimentarius Commission were many years in the making and were adopted by the Sixteenth World Health Assembly in 1963. They are a collection of international standards, codes of practice, guidelines and other recommendations to protect the health of consumers and ensure faire practices in food trade.

The Codex Commission meets every two years. Plenary sessions may be attended by as many

1 Lynne R. Ostfeld is a solo practitioner in Chicago with a general practice which includes agri-business. She is adjunct professor at The John Marshall Law School (Chicago) teaching international agri-business to L.L.M level students. She is also legal advisor to the French Consulate in Chicago and is associated with Allain Kaltenbach Plaisant Raimon et Doulet in France. Descendant of some very thrifty farmers, she is part owner, with other family members, of several farms where corn, soybeans, cattle and pigs are raised.

as 600 people. Representation is on a country basis with national delegations led by senior officials appointed by their governments. Observers, which can be international governmental organizations as well as international non-governmental organizations, may present their viewpoints at every stage except for the taking of the final decision. This is the exclusive prerogative of member governments.

The Codex Alimentarius is a science-based activity. It has General Subject Committees for areas such as Food Additives and Contaminants, Food Hygiene, Food Labelling, Methods of Analysis and Sampling and Nutrition and foods for Special Dietary uses. There are Commodity Committees which meet regularly to treat Fats and Oils, Fish and Fishery Products, Fresh Fruits and Vegetables, Milk an Milk Products, and Processed Fruits and Vegetables. Other Commodity Committees meet less often and often act through correspondence: Cereals, Pulses and Legumes; Cocoa Products and Chocolate; Meat Hygiene; Natural Mineral Waters; Sugars; Vegetable Proteins.

The Codex has had success in achieving international harmonization of requirements for food quality and safety. It has formulated international standards for a wide range of food products and specific requirements covering pesticide residues, food additives, veterinary drug residues, hygiene, food contaminants, and labelling and certification systems. The Codex food standards and related text are the global reference point for consumers, food producers and processors, national food control agencies and international food trade and are recognised as international benchmarks in the WTO multilateral trade agreements.

Although not mandatory for international trade, many treaties and trade agreements refer to the Codex Alimentarius as the basis for their requirements or as points of reference.

The Uruguay Round Agreements, of the General Agreements on Tariffs and Trade (GATT) incorporated rules for agriculture and food. Agreements on the Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) were included in the Multilateral Agreements on Trade in Goods, annexed to the 1994 Marrakesh Agreement, which established the World Trade Organization. The SPS Agreement is intended to ensure that internationally traded food is safe but it requires governments to take sanitary and phytosanitary measures only to the extent required to protect human health. Member governments may not discriminate by applying different requirements to different countries unless there is sufficient scientific justification for doing so.

The SPS Agreement requires notification of new or amended SPS measures when:

1) an international standard guideline or recommendation does not exist,

2) the content of the proposed SPS regulation is not the same as the international standard, and

3) the regulation may have a significant effect on trade of other countries.

A companion agreement to the SPS Agreement, the Agreement on Technical Barriers to Trade (TBT), covers technical regulations, standards and conformity assessment procedures which aim to protect human health, prevent deceptive practices or protect the environment. The TBT Agreements

require that technical regulations and standards do not create unnecessary obstacles to trade.

The International Portal on Food Safety, Animal and Plant Health integrates content from FAO's database of national legislation, FAOLEX, and provides access to a variety of databases from a number of countries, including the United States Department of Agriculture and Food and Drug Administration. The Portal is managed by FAO on behalf of the participating agencies and provides information about official national standards and regulations, national scientific evaluations and risk assessments, notifications of new or pending laws and regulations, Codex standards, guidelines and MRLs (maximum residue limit), risk assessments and safety evaluations.

In 1969, the Member States of WHO adopted International Health Regulations (IHR) which are a regulatory framework for global public health. The World Health Organization (WHO), in collaboration with the Food and Agriculture Organization of the United Nations (FAO) developed the International Food Safety Authorities (INFOSAN) to promote the exchange of food safety information and to improve collaboration among food safety authorities at the national and international level. The INFOSAN network provides a mechanism for the exchange of information on both routine and emerging food safety issues. INFOSAN Emergency is designed to provide rapid access to information during food safety emergencies.

As of October 2006, 151 countries are members of the INFOSAN network. Each member country has designated one or several INFOSAN Focal Points. The role of the INFOSAN focal points is to receive and disseminate information relative to food safety issues, food contamination and foodborne disease problems, and act as a liaison during food safety emergencies of internationa significance.

U.S. agencies responsible for food safety issues with imported food

In the U.S., there are a number of federal agencies given authority to investigate and regulate safety issues with imported food:

Department of Health and Human Services' (DHHS)
Food and Drug Administration (FDA)
U.S. Department of Agriculture (USDA)
    Food Safety and Inspection Service (FSIS)
    Animal and Plant Health Inspection Service (APHIS)
Environmental Protection Agency (EPA).

Many agencies and offices have food safety missions within their activities, including DHHS's Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), USDA's Agricultural Research Service (ARS), Cooperative State Research, Education, and Extension Service (CSREES), Agricultural Marketing Service (AMS), Economic Research Service (ERS), Grain Inspection, Packers and Stockyard Administration (GIPSA); and the U.S. Codex office, and the

Department of Commerce's National Marine Fisheries Service (NMFS).

A. The United States Department of Agriculture (USDA)

The USDA is in charge of controlling imported meat, poultry and egg products through two USDA agencies:

1. Food Safety and Inspection Service - FSIS is responsible for assuring that U.S. imported meat, poultry and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS also monitors meat and poultry products in storage, distribution, and retail channels, and takes necessary compliance actions to protect the public, including detention of products, oversight of voluntary recalls, court-ordered seizures of products, administrative withdrawal of inspection, and referral for criminal prosecution.

FSIS inspects all egg products, with the exception of those products exempted under the Egg Products Inspection Act (EPIA). The EPIA specifies that egg products may not be imported into the United States except from countries which have an egg products inspection system equivalent to that in this country, while shell eggs for breaking are eligible from any foreign country. Restrictions may be applied by the APHIS.

2. Animal and Plant Health Inspection Services - APHIS has the primary responsibility to ensure that animal products do not enter the United States if they are contaminated by diseases. When meat products arrive at U.S. ports, APHIS Plant Protection and Quarantine (PPQ) officers review shipment documentation to determine whether the product originated in a country with animal disease restrictions. If the products are determined to be enterable, APHIS releases the products to FSIS for reinspection to determine the effectiveness of foreign countries' inspection systems to ensure that only wholesome, unadulterated, and properly labeled products enter U.S. commerce. FSIS is responsible for performing reinspections of imported meat products.

APHIS is part of the network of federal agencies with food-safety-related responsibilities. APHIS' primary role in this network is to protect U.S. agriculture from plant and animal pests and diseases. The agency implements federal laws pertaining to animal and plant health, international sanitary and phytosanitary regulation, regulation of veterinary biologicals and vaccines, control and eradication of introduced pests and diseases, and humane treatment of animals. APHIS programs are implemented through cooperative activities with other federal agencies, state and foreign governments, and producers.

APHIS' Plant Protection and Quarantine (PPQ) regulates and inspects imports of plants and plant

commodities to prevent the accidental introduction of plant pests and diseases such as citrus canker and exotic fruit flies and noxious weeds. PPQ regulates the planting of genetically engineered crops prevent adverse impacts upon agriculture, and facilitates the export of U.S. plants and plant products by ensuring and certifying that they comply with the requirements of the importing country. PPQ also has programs to eradicate introduced plant pests and diseases.

APHIS' Veterinary Services (VS) regulates the importation of animals and animal products to prevent the accidental introduction of animal diseases, thus ensuring the health, quality, and marketability of U.S. animals and animal products. VS programs are intended to prevent the introduction of foreign animal diseases such as foot-and-mouth disease, classical swine fever, rinderpest, and BSE. VS also has programs to eradicate selected animal diseases such as bovine tuberculosis, brucellosis, and pseudorabies, some of which are food-borne and potentially transmissible to humans. VS participates in and provides guidance to industry sponsored quality assurance programs such as the National Poultry Improvement Plan (NPIP), the swine industry's pork quality assurance program for trichinella certification, and the sheep industry's scrapie certification and eradication program. Veterinary Services also licenses and monitors the production of veterinary biologicals and vaccines to ensure that these products are safe and effective. Similar to PPQ, VS facilitates the export of U.S. animals and animal products by ensuring and certifying that they comply with importing countries, sanitary regulations.

3. The Food and Drug Administration (FDA). The FDA, a federal agency within the Department of Health and Human services, is charged with protecting consumers against impure, unsafe, and fraudulently labeled food other than in areas regulated by FSIS. It is charged to enforce the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 321 et seq.) and other laws which are designed to protect consumers' health, safety, and pocketbook. The FFDCA prohibits distribution in the United States, or importation, of food that is adulterated or misbranded (21 U.S.C. 331). These laws apply equally to domestic and imported products. FDA is responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly, accurately and informatively represented to the public.

A food is "adulterated" (21 U.S.C. 342) if it bears or contains any poisonous or deleterious substance that may render it injurious to health (with stricter rules for added substances than for naturally occurring substances). The word "adulterated" applies to products or materials that are unsafe,

defective, filthy, or produced under insanitary conditions.

The FFDCA forbids distribution of any food or food ingredient required to be approved by FDA and lacking such approval. For example, it deems "adulterated," as a matter of law, any food containing an unapproved food or color additive (21 U.S.C. 342). Similar provisions govern departures from requirements as to use of veterinary drugs. The law covers food for human use and food for animals (both pets and food animals). Food irradiation and indirect additives, including food packaging containing substances that may become part of food, must be approved under the food additive regulations.

4. The Environmental Protection Agency (EPA). The EPA administers the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and section 408 of the FFDCA (21 USC 348a). Under these statutes, EPA regulates the registration and use of pesticides in the United States and issues maximum residue levels, "tolerances," for pesticide residues in food. The objective of these statutes, concisely stated, is to protect public health and the environment.

EPA's mission includes protecting public health and the environment from risks posed by pesticides and promoting safer means of pest management. No food or feed item may be marketed legally in the U.S. if it contains a food additive or drug residue not permitted by FDA or a pesticide residue without an EPA tolerance or if the residue is in excess of an established tolerance.

Under FIFRA, sale of pesticides is prohibited, unless registered by EPA, and EPA also has authority to limit distribution, sale and use of pesticides. The FFDCA (21 U.S.C. 348a (a)(1)) also provides that any pesticide residue in food "...shall be deemed unsafe..." unless a tolerance or a tolerance exemption has been issued. EPA's "default zero" approach to pesticides is based on the determination that pesticides, as a general class of chemicals, are inherently hazardous. The requirement for EPA action before any use is permitted, in order to assure EPA can determine its safety and prescribe conditions of use, could be considered a precautionary approach. Precaution is embedded in EPA decision-making processes to ensure acceptable levels of protection. FSIS enforces EPA's pesticide tolerances as to meat and poultry, while FDA enforces EPA's pesticide tolerances as to other foods.

As part of the pesticide registration process, EPA makes certain risk management decisions. For example, the agency may prescribe conditions of use to limit human exposures and protect the environment. For example: some pesticides may be applied only by those trained and certified to handle the pesticide; protective equipment may be required; methods of application may be limited; and buffer zones around areas of pesticide usage may be required. These risk management steps protect

farm workers and minimize unwanted environmental effects, as well as ensure food safety.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA registers pesticides for use in the United States and prescribes labeling and other regulatory requirements to prevent unreasonable adverse effects on health or the environment. Furthermore, under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 348a), EPA establishes tolerances (maximum legally permissible levels, or MRLs) for pesticide residues in food. Tolerances are enforced by FDA for most foods and by FSIS for meat, poultry, and egg products.

The Environmental Protection Agency (EPA) is the principal Federal agency responsible for the safety of drinking water under the Safe Drinking Water Act (42 USC 300f). This work is carried out in close cooperation with States and municipal governments. FDA regulates bottled water, in close cooperation with EPA. FDA and FSIS carefully monitor the water used in food processing plants under their jurisdictions.

5. The Customs and Border Protection (CBP), within the Department of Homeland Security (DHS) works with these agencies since the adoption and implementation of the BTA (December 12, 2003). The purpose of the BTA is to protect the health and safety of the people of the United States from an intended or actual terrorist attack on the nations food supply. The Act includes a number of provisions designed to improve the food safety efforts of the FDA in cooperation with U.S. CBP, including new authority to protect the food supply against terrorist acts and other threats.

Registration of facilities

Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) all domestic and foreign facilities which manufacture, process, pack, or hold food for human or animal consumption in the United States must register with the FDA. If food undergoes further processing (including packaging) by another facility before it is export to the U.S., both facilities are required to register.

Exempt from registration are farms; retail food establishments; restaurants; non-profit establishments that prepare food for, or serve food directly to, consumers; fishing vessels not engaged in processing [as defined in 21 CFR 123.3 (k)]; and facilities regulated exclusively throughout the entire facility by the U.S. Department of Agriculture.

Registrants must register on Form 3537. Registrations can be submitted electronically *via* the Internet, through surface mail on a paper form or a CD-ROM, or through fax. There is no registration

fee and the agency holds that it should take no more than three hours to read, understand and complete the forms.

The information to be provided is :

- Name, physical address, phone number of the facility
- Same information for the parent company, if the facility is a subsidiary
- All trade names the facility uses
- Food product categories (21 CFR 170.3)
- A statement certifying that the information submitted is true and accurate and submitter is authorized to register the facility
- Name and contact information of the person submitting the certification statement
- Name of foreign facility's U.S. agent and the agent's contact information
- Emergency contact information

If a facility fails to register and exports food or food products to the U.S., the product will be held at the port of entry for further disposition, generally at the exporter's expense.

Procedures for entry

A. Prior Notice

The BTA requires that certain information be provided electronically to the U.S. FDA prior to the arrival of a shipment of food in the United States. U.S. CBP officers, in conjunction with the FDA's authorities, are responsible for enforcing the BTA at all United States ports of entry.

Food is defined in the BTA Interim Final Regulations as :

- Articles used for food or drink for man or animals,
- Chewing gum, and
- Articles used for components or any such article.

Food imported or offered for import into the United States for human or animal consumption is covered by the Act.

Prior Notice consists of (but is not limited to) the following data that must be electronically provided to the FDA prior to the arrival of the article(s) at the first U.S. port:

- The country from which the article originates,
- The country from which the article is shipped,
- Anticipated CBP port of arrival,
- CBP ACS entry type and date,
- In the event of a hold, the information about where it is being held,
- All carriers,
- Firm name and address,
- E-mail address,

- Telephone and fax numbers,
- Registration number,
- Standard carrier abbreviation code

The Prior Notice information is in addition to the normal FDA admissibility information required under section 801(a) of the Food, Drug and Cosmetic Act.

The intent is to provide advance information to target potentially high-risk shipments that could threaten public health and the security of the food chain by an act of bioterrorism.

Prior notice of imported foods must be received and confirmed electronically by FDA no more than ten days before arrival in the United States and no fewer than:

- Two hours before arrival by land via road
- Four hours before arrival by air or by land via rail; or
- Eight hours before arrival by water.

Some commodities are excluded from filing prior notice, including:

- Personal use food accompanying a traveler (although agricultural rules and required declarations still apply)
- Food immediately exported without leaving the port of arrival
- Meat, poultry, and egg products (subject to the exclusive jurisdiction of the U.S. Department of Agriculture)
- Homemade goods shipped as gifts

RESOURCES

International

Codex Alimentarius: www.codexalimentarius.net

Codex Alimentarius Commission: http://www.codexalimentarius.net/web/index_en.jsp.

Codex Contact Points: http://www.codexalimentarius.net/web/members_area.jsp?lang=EN

Codex Trust Fund: www.who.int'foodsafety/codex/trustfund/en/

Food and Agriculture Organization of the United Nations (FAO): www.fao.org
Joint Meeting on Pesticide Residues (JMPR):
http://www.fao.org/ag/agp/agpp/pesticid/jmpr/pm_jmpr.htm
http://www.who.int/pcs/jmpr/jmpr.htm

GM Food Risk Assessment: www.fao.org/es/ESN/food/risk_biotech_en.stm
www.who.int/fsf/GMfood/index.htm

Global Flora of Food Safety Regulators: www.foodsafetyforum.org

GM Food Risk Assessment

International Food Safety Authorities Network (INFOSAN):
www.who.int/foodsafety/ifs_management/infosan/en/

Joint FAO/WHO Codex Secretariat: www.codexalimentarius.net/

Standards and Trade Development Facility: www.standardsfacility.org

World Health Organization (WHO): www.who.int/en/; WHO Food Safety: www.who.int/fsf/en/

World Trade Organization (WTO): www.wto.org

Regional/National

Canadian Food Inspection Agency (CFIA): ww.inspection.gc.ca/

European Food Safety Authority (EFSA): www.efsa.eu.int/

Food Standards Australia New Zealand (FSANZ): www.foodstandards.gov.au

Food Safety Authority of Ireland (FSAI): www.fsai.ie

U.S. Department of Agriculture (USDA): www.fsis.usda.gov

U.S. Food and Drug Administration (FDA): www.fda.gov; FDA Center for Food Safety and Applied Nutrition: www.cfsan.fda.gov/list.html