codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COORDINATING COMMITTEE FOR NORTH AMERICA AND THE SOUTH-WEST PACIFIC

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REPORT ON ACTIVITIES RELATED TO ECONOMIC INTEGRATION AND HARMONIZATION OF FOOD LEGISLATION IN THE REGION

ADDITIONAL REPORTS OF MEMBER COUNTRIES

UNITED STATES

Federal Structure

Under the current structure, two Federal agencies have primary statutory responsibility for assuring the safety of our food supply -- FDA of DHHS and FSIS of USDA. FSIS has regulatory and inspection responsibility for meat, poultry, and egg products, and FDA has regulatory responsibility over the remainder of the food supply. FDA has jurisdiction over 78 percent of domestic and imported foods that are marketed in interstate commerce. FDA seeks to ensure that these products are safe, sanitary, nutritious, wholesome, and adequately labeled. FDA has jurisdiction where food is produced, processed, packaged, stored, or sold. FDA's jurisdiction includes much more than food processing plants; it also includes approval and surveillance for new animal drugs, medicated feed, and all food additives (including coloring agents, preservatives, food packaging, sanitizers and boiler water additives) that can become part of food. FDA shares with FSIS responsibilities for egg safety. FDA has authority for shell eggs and FSIS has authority for egg products.

FSIS is charged by statute to prevent the shipment of adulterated meat products to consumers, and to oversee appropriate labeling and provision of other consumer information. FSIS also has authority to oversee poultry and egg products, via the Poultry Products Inspection Act and the Egg Products Inspection Act. The Acts also require any country wishing to ship meat, poultry or egg products to the U.S. to maintain an inspection program that is equivalent to the U.S. inspection program. FSIS inspects each meat and poultry food animal, both before and after slaughter.

The Centers for Disease Control and Prevention (CDC), in DHHS, plays a critical and unique role as a disease monitoring, investigative, and advisory agency that is separate from -- but works closely with -- both food regulatory agencies. CDC leads Federal efforts to gather data on foodborne illness and investigate outbreaks, and monitors the effectiveness of prevention and control efforts. Through its on-going public health efforts, CDC also plays a pivotal role building State and local health department epidemiology and laboratory capacity to support foodborne disease surveillance and outbreak response.

The Environmental Protection Agency (EPA), another important partner, protects our water supply by setting drinking water standards under the Safe Drinking Water Act. It also regulates pesticide products used in this country and establishes tolerances or maximum limits for pesticide residues allowed on imported and domestic food commodities and animal feed. State and local partners also have an important role to play in food safety. The Administration has a long history of reaching out to its State and local partners and has worked effectively with them utilizing a variety of mechanisms: cooperative agreements, contracts, grants, memoranda of understanding and partnerships.

Food safety can only be effective if it has a strong underpinning in scientific research and risk assessment. The Federal government has major capabilities to perform both basic and applied research related to food safety problems. Our Federal research resources include research conducted at CDC, NIH, and FDA, as well as that performed at FDA's National Institute for Food Safety Technology (Moffet Center), and that performed by USDA's Agricultural Research Service (ARS), and USDA's partnerships with the nation's land grant universities via the Cooperative State Research, Education and Extension Service (CSREES).
Together these Federal agencies promote food safety and prevent foodborne illness and food hazards through inspections; surveillance; enforcement; research and risk assessment; premarket approval of food and color additives, pesticides, and new animal drugs; establishing controls for safe processing; working with State, local, and foreign governments; partnering with academia and the private sector, and education.

As part of Executive Order 13100, the President directed the Council on Food Safety to develop annual coordinated food safety budgets. The goal is to develop coordinated budgets that sustain and strengthen existing capacities, eliminate duplication, help identify priority areas for investment, and ensure the most effective use of resources for improving food safety.

Partnerships with State and Local Governments

The NAS report recognized the important role that State and local governments play in food safety. Both FDA, FSIS, and EPA historically have strong partnerships with States. For example, the States are directly involved with FDA in the regulation of milk and shellfish safety through the National Conference of Interstate Milk Shippers, and the Interstate Shellfish Shippers Conference, as well as through the Seafood HACCP Alliance, which provided extensive training to seafood processors after publication of the final seafood HACCP regulation. Twenty-five States operate inspection programs for meat and poultry under cooperative agreements and with shared funding from FSIS.

FDA and FSIS work with the States to encourage uniformity among the State laws affecting food safety in retail and food service establishments. The principal mechanism for this is the Food Code -- a model code published by FDA intended for adoption by State and local authorities for use in regulating retail food and food service establishments. It is essential that the Federal government provide training both to the States and local governments, as well as to the retail and food service industry, to be sure that the critical elements of the Food Code are properly applied. Currently, 14 States have adopted the Food Code and adoption is pending in 22 others.

New Technology Development.

Some of the exciting and new technologies developed by industry as well as our food safety agencies include irradiation, steam pasteurization for meat and poultry carcasses, pulsed light to reduce pathogens on raw or cooked food products, hydrostatic pressure for shellfish, antimicrobial rinses to reduce pathogens on raw products, and competitive exclusion to reduce *Salmonella* levels in poultry on farms. FDA and EPA have also expedited premarket reviews of food additives and safer pesticides as a means to encourage development of these new technologies and tools.

FDA Proposed Regulations on Foods Derived From Modern Biotechnology

The U.S. Food and Drug Administration (FDA) plans to refine its regulatory approach regarding foods derived through the use of modern biotechnology. FDA will soon publish a proposal to revise existing rules to mandate that developers of bioengineered foods and animal feeds notify the agency when they intend to market such products. FDA will also require that specific information be submitted to help determine whether the foods or animal feeds pose any potential safety, labeling or adulteration issues. The proposed rule strengthens the existing process by specifically requiring developers to notify the agency of their intent to market a food or animal feed from a bioengineered plant at least 120 days before marketing. After reviewing the submission, the FDA will issue a letter to the firm describing its conclusion about the regulatory status of the food or animal feed. FDA will propose that submitted information and the agency's conclusion be made available to the public, consistent with the applicable disclosure laws, by posting them on the FDA Web site.

The agency will augment its food and veterinary medicine advisory committees by adding scientists with agricultural biotechnology expertise. FDA will use these committees to address over-arching scientific questions pertaining to bioengineered foods and animal feed.

Additionally, the FDA plans to publish labeling guidance to assist manufacturers who wish to voluntarily label their foods being made with or without the use of bioengineered ingredients. The guidelines will help ensure that labeling is truthful and informative. To receive maximum consumer input, the FDA has been developing the guidelines with the use of focus groups and will seek public comment on the draft guidance.

These documents will be completed soon and will be available on the FDA website at: http://www.fda.gov.

Starlink Corn Investigations

StarLink corn was developed by Aventis Crop Science USA LP and contains a pesticide (*Bacillus thuringiensis* subsp. *tolworthi* Cry9C) that was registered for use by the U.S. Environmental Protection Agency (EPA) with residues established for animal feed. Residue tolerances were not established for human food because of unresolved issues as to whether the pesticidal protein could stimulate an allergic response in humans.

On September 22, Kraft Foods recalled its' taco shell products because DNA-based tests indicated that the shells contained residues of Cry9C. Since that time, FDA has confirmed the presence of StarLink corn in these taco shells and formally classified the action as a Class II recall.

Other manufacturers have issued recalls of products that have the possibility of containing StarLink corn including Mission Foods, manufacturer of tortillas, shells, tostadas and chips, and Wilson Foods, manufacturer of corn tortillas. Other recalls are pending FDA classification.

FDA is collecting other food products containing corn ingredients and testing them to determine whether StarLink corn may be present. The U.S. Department of Agriculture (USDA) is working with the FDA on methods of testing of additional foods.

Aventis has agreed to buy back the current harvest of StarLink corn, and is working with the FDA, USDA, and EPA to segregate possibly commingled corn to ensure it does not end up in human food products. At the urging of EPA, Aventis voluntarily canceled its registration of StarLink corn. This means that StarLink corn can no longer be planted for any agricultural purpose.

EPA published a Federal Register notice on October 31 that Aventis submitted new information in support of its petition for an exemption from the requirement of a tolerance for the genetically engineered plant pesticide material in StarLink corn that is already in commerce. That determination is pending.

FDA is investigating all reports that have been received that attribute adverse health events to eating food products that possibly contain StarLink corn. The FDA, USDA, and EPA are working together in a coordinated effort. As the investigation continues, the FDA will take any action necessary to further protect the public.

Microbiological Risk Assessments

As part of the U.S. Presidential Food Safety Initiative, significant effort has been undertaken to develop and enhance the capability to undertake quantitative microbiological risk assessment (QMRA). QMRA can be a valuable tool in helping risk managers to evaluate and interpret microbiological hazards when the issue is of high regulatory or stakeholder concern, when the exposure system is complex and when data describing a hazard are limited. Over the past four years, a major focus of work on QMRA has been in the development and validation of predictive modeling tools and research to provide data needed for quantitative risk assessment of foodborne pathogens. Over the past year, the focus within FDA has been on two

pathogen/food commodity combinations: *Listeria monocytogenes* in ready-to-eat foods, and *Vibrio parahaemolyticus* raw molluscan shellfish. The *Vibrio parahaemolyticus* risk assessment has been completed and reviewed, is awaiting clearance, and is expected to published by the end of November. The *Listeria monocytogenes* risk assessment is being reviewed and refined and is expected to be released shortly. The release of the LM risk assessment will be accompanied by risk management and risk communication plans to better assist in the control of the pathogen.

Food Safety Initiative Update

Background

FY-2001 will mark the fourth year of a highly successful multi-agency initiative to control and reduce foodborne pathogens in the American food supply. The benefits of this investment are evidenced by the fact that the time it takes to respond to numerous outbreaks has been shortened, resulting in fewer potential deaths and illnesses to American consumers.

Through the initiative the United States has put into place a strong foundation for a science-based, integrated food safety system. The result of these efforts is a system that can continuously deliver food safety technologies, educational messages and programs, and scientific curriculums to stakeholders along the farm-to-table continuum

FSI Accomplishments

Major accomplishments of the FSI program include the following.

Inspection

- Published the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables in English, Spanish, French and Portuguese.
- Produced the "Assuring Safer Produce: A Global Issue" video in English, Spanish, French and Portuguese.

- Sponsored an international conference "Enhancing the Safety of Fresh Produce at the Source: Training Modalities and Methods, Needs and Opportunities.
- Sponsored three international meetings for mid-level government officials and industry representatives with food safety responsibilities. (Santigo, Chile; Mexico City, Mexico; and Auckland, New Zealand).
- Completed a 1000 sample survey of high volume imported fresh produce. The survey focuses on high volume imported fresh produce (celery, lettuce, cantaloupes, strawberries, scallions/green onions, parsley, cilantro and broccoli). These commodities were selected based on their high level of consumption in the US. Around 5% were found to be contaminated by either *salmonella* or *shigella*.
- Initiated a 1000 sample survey of high volume domestically grown fresh produce. Covers the same products as the imported survey (broccoli replaced by tomatoes).
- Conducted an assessment of the food safety systems in Nicaragua, Costa Rica, El Salvador, Guatemala and Honduras.
- Developed, with U.S. Customs Service, an Imported Foods Action Plan to further protect consumers from unsafe imported food.
- Conducted nineteen traceback investigations and visited 10 farms as the result of outbreak tracebacks or positive samples in the Imported Produce Sampling Program.

- Developed and implemented the publication; "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations." In conjunction with the guide, three satellite training courses for FDA and State and Local investigators were conducted and attended by over 10,000 participants.
- Developed an extensive "Farm Investigation Questionnaire" for use on farms implicated in produce related outbreaks. The questionnaire is designed to collect more meaningful information about farm practices to assist in the traceback investigation and refinement of the GAPS.

Research:

- As directed by the President, established the Joint Institute for Food Safety Research (JIFSR) to coordinate planning and priority setting for food safety research among HHS and USDA as well as among other government agencies and the private sector.
- Through CFSAN's Intramural Research program, developed methods for detecting *Cyclospora, Campylobacter*, and *Vibrio parahaemolyticus* as well as a quick test to identify harmful *E. coli* O157:H7 for produce and other products within one working day.
- In collaboration with NCFST, developed a protocol for analyzing sprout irrigation water as a means of monitoring contamination of sprouts by pathogenic bacteria.

Education:

- Initiated an education campaign to provide information to the public about the risk that unpasteurized or untreated fruit and vegetable juices may present to vulnerable populations. Educational materials included a press kit, consumer brochures, video news release and a public service announcement.
- Initiated an education campaign to inform consumers about safe handling and cooking of eggs. A video news release was developed and used by television stations with rated viewship of more than 2 million persons.
- Developed School-based Education Programs: supplemental curriculum for grades 4-6 and a supplementary food science curriculum aimed at middle and high school students.
- Initiated a professional development program in food science to provide science educators with the opportunity to gain an in-depth understanding of new and innovative methods in the field of food science.
- Launched education and outreach efforts to promote prudent use of antimicrobials.

Food Safety Strategic Plan

The President's Council on Food Safety, encompassing food safety agencies (FDA, USDA and EPA) and the Department of Commerce presented in December of 1999 a Draft Preliminary Food Safety Strategic Plan. The Plan was designed to articulate a vision for enhanced food safety and public health protection in the United States and had a number of specific goals.

- Strengthen the scientific basis for food safety policies and regulatory decisions.
- Strengthen farm to table risk management—improved surveillance, improved response to public health emergencies, improved compliance strategies based on risk for domestic and imported food.

- Enhanced food safety communication—through more rapid access to information and improved education and training programs.

Specific objectives and action items were developed for each goal. Additionally, the plan addressed the need to determine whether the existing organizational food safety infrastructure is satisfactory or whether alternative organizational approaches should be considered—including that of a single food safety agency.

Public comment was solicited and obtained on the Plan. Currently, the Plan continues to be under review within the government with the final disposition of the plan still pending.

Antimicrobials

Scientists have shown an association between the use of antimicrobials in food-producing animals and a risk to human health. In the US, the Food and Drug Administration is the lead Agency in addressing the issue of antimicrobial resistance, and it is developing several responses to the problem.

FDA/CVM believes that the safety assessment of antimicrobials must include monitoring for the development of resistance. Monitoring is done through the National Antimicrobial Resistance Monitoring System (NARMS). The program was proposed by CVM as a post-marketing activity to monitor the emergence and spread of resistance in enteric bacteria and to help ensure the continued safety and effectiveness of veterinary antimicrobials. In 1996, the FDA, CDC, and the U.S. Department of Agriculture created NARMS to monitor changes in antimicrobial susceptibilities of zoonotic enteric pathogens from human and animal clinical specimens, from healthy farm animals, and from carcasses of food-producing animals at slaughter. NARMS has been expanded each year since its inception, and is now used to monitor susceptibilities of *Salmonella* and *E. coli* isolates to 17 antimicrobials and *Campylobacter* isolates to eight antimicrobials.

CVM's approach to the issue of antimicrobial resistance is contained in a document, "A proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (the "Framework Document"). A key aspect of the Framework Document is that, rather than institute broad restrictions on all antimicrobial use in animals, FDA would develop a program to classify drugs according to:

- The importance of the drug or the class of drugs to human health; and
- The potential exposure that humans would face to resistant pathogens or resistant elements originating from animals treated with an antimicrobial, and the impact this exposure would have on the availability and effectiveness for human medicine of drugs to which the resistance has developed.

The greater the importance of the drug to human medicine, or the greater the risks of the development of resistance, the greater the burden on sponsors to prove that an antimicrobial can be safely used.

To better estimate the actual risks posed from the use of antimicrobials in food animals, CVM has begun using risk assessments that model the human health effects from the use of certain antimicrobials. The first risk assessment addressed the association of fluoroquinolone resistant *Campylobacter* infections with the consumption of chicken. These are considered direct risks. CVM has also begun for a second risk assessment to examine the indirect risks from transfer of resistance from animals to humans, in which the use of antimicrobials in food-producing animals select for resistance in other bacteria associated with the animal. These bacteria are referred to as commensals and can be passed to humans via the food supply to colonize the human gastrointestinal tract or transfer their resistance genes to bacteria that colonize the human gastrointestinal tract.

Based on the new evidence of risk to human health, the CVM initiated action to withdraw the approval for the use of the fluoroquinolones in poultry.

FDA is also developing regulatory limits on resistance, i.e., thresholds. A threshold would be the regulatory standard defining an intolerable risk from the use of an antimicrobial in food-producing animals.

CVM will hold a public meeting to discuss the Establishment of Resistance and Monitoring Thresholds in Food-Producing Animals January 23-24, 2001. The meeting will discuss the CVM's current thinking on the establishment of thresholds in food-producing animals. CVM will seek scientific input from experts and hear suggestions for alternative approaches.