

DRAFT
**Affirmative Agenda for
International Activities**

Center for Food Safety
and Applied Nutrition

Food and Drug Administration

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Introduction

Over the last twenty years, international issues bearing on the safety, quality and labeling of FDA-regulated foods and cosmetics have become increasingly important to FDA's Center for Food Safety and Applied Nutrition (CFSAN). During this period, the volume and variety of food and cosmetic products imported into the United States has increased dramatically and, as a result, FDA's traditional monitoring and border inspection approaches for imported products are no longer effective as the sole means of ensuring the safety of these commodities. Consequently, the Center has developed and is implementing new strategies for imported foods and cosmetics to complement FDA's traditional enforcement approaches. These new approaches are based on cooperative efforts with governments and industries in producing countries to achieve a higher level of protection for U.S. consumers and to prevent safety problems at their source.

The rules of international trade have also changed significantly. Recent international trade agreements have introduced new requirements that affect how food and cosmetic products are regulated and inspected. For instance, international food safety, quality and labeling standards have been developed through international consensus within the Codex Alimentarius Commission. These standards have become more numerous and their use as benchmark standards for foods moving in international trade is now recognized specifically by the trade agreements. CFSAN has played, and will continue to play, a major role in ensuring that these international standards are based on sound scientific principles and are protective of the health of American consumers.

CFSAN is also challenged by increasing expectations of the Center's role in trade issues. U.S. trade agencies and food and cosmetic industries, as well as foreign governments, now expect FDA, and CFSAN as the principal U.S. regulatory authority for foods and cosmetics, to assume more direct responsibility for attesting to the safety, quality, and label attributes of foods and cosmetics produced in and exported from the United States. These growing stakeholder expectations are above and beyond FDA's traditional domestic public health role and explicit statutory obligations. They present the Center with the dilemma of accomplishing FDA's primary public health mission while assisting other components of the United States government and other stakeholders with issues relating to international trade of foods and cosmetics.

CFSAN believes that activities aimed at improving foreign food and cosmetic regulatory systems and product safety can also improve the agency's ability to fulfill its public health mission and statutory obligations. CFSAN intends to play an active role in appropriate international fora and to strike a balance between its public health mandate and other international issues identified by FDA's stakeholders. CFSAN's participation in the international arena has had and continues to have a very positive impact on the ability of FDA to protect the health of American consumers. The Center's regulatory and scientific expertise has been instrumental in enhancing the strength of international standards for foods and cosmetics and in improving the foreign regulatory systems that oversee the production and safety of products exported to the United States.

Increasingly, scientific and policy decisions made by international organizations and some influential countries impact directly on and contribute to CFSAN's domestic decision making process. Similarly, and just as importantly, CFSAN's policies, regulatory practices, or scientific studies that may be developed to address primarily a domestic issue, often have a direct impact on regulatory positions of other countries and decisions of international organizations. This continuous interplay between domestic and international policy and science is of benefit to consumers worldwide. CFSAN intends to continue, promote, and enhance these interactions.

Yet, resources available for CFSAN to accomplish its international activities are finite and limited. They are not sufficient for CFSAN to undertake all important international activities that may impact on products regulated by the Center. This CFSAN International Affirmative Agenda is intended to present achievable, near-term international priorities for the next three years in critical areas where the Center can and must maintain a strong presence.

CFSAN has developed international principles which recognize that FDA's primary mission is to protect the health and economic interests of American consumers. Most international activities undertaken by CFSAN will be based on their potential to impact positively on U.S. public health protection. However, the principles also acknowledge that CFSAN is the competent regulatory authority in the United States for cosmetics and most foods, and, as such, the Center has the responsibility to offer regulatory and scientific expertise to other components of the U.S. government on issues that fall within its jurisdiction. The principles are based on the factors shown below.

Factors Underlying CFSAN's International Principles

1. Consistency with FDA's Primary Public Health Mission
2. Development of Science-Based International Standards
3. Promotion of FDA's Science Base
4. Development of Bilateral/Multilateral Agreements to Improve the Safety of Imported Food and Cosmetic Products
5. Provision of Technical Cooperation and Assistance to Improve the Safety of Food and Cosmetic Products
6. Promotion of Communication Among Food and Cosmetic Regulatory Authorities
7. Consistency with United States Trade Agreements or Other Obligations
8. Provision of Timely Technical Assistance to U.S. Agencies to Prevent or Resolve Trade Disputes
9. Consistency with Availability of Resources

CFSAN's international principles were used to develop the Center's proposed international priorities for 2000-2002. The proposed CFSAN priorities, shown below in summarized form, encompass five categories: Regulatory (Enforcement, Monitoring, Inspection); Harmonization; Science Base; Foreign Food Safety Assessments and Assistance; and Trade. They are intended to enable the Center to remain an effective force in resolving international issues bearing on the safety, quality, and labeling of foods and cosmetics.

Summarized CFSAN International Priorities, 2000-2002

I. Regulatory (Enforcement, Monitoring, Inspection) Activities

In cooperation with the Office of Regulatory Affairs and assisted, where appropriate, by foreign regulatory authorities

- Monitor Imported Foods
- Inspect Foreign Establishments
- Trace Foodborne Illness Outbreaks Associated With Imported Foods and Prevent Future Outbreaks
- Improve Food Labeling Compliance for Imported Foods

II. International Harmonization

- Strengthen CFSAN Participation and Leadership in Codex
- Participate in the Codex Biotechnology Task Force
- Contribute Scientific Expertise Toward Development of International Standards
- Participate in NAFTA and FTAA Committees/Technical Working Groups
- Participate in Other Standard Setting Bodies

III. Development, Maintenance, and Dissemination of CFSAN's Science Base

- Participate in International Scientific Consultations and Panels
- Strengthen Scientific Collaboration With Foreign Governments
- Strengthen Research and Risk Assessment Approaches
- Investigate Alternatives to Animal Testing

IV. Equivalence Evaluations, Food Safety Needs Assessments, and Food Safety Technical Cooperation and Assistance

- Determine Equivalence of Food Safety Systems of Other Countries
- Assess the Food Production and Food Safety Systems of Other Countries
- Improve the Safety of Foreign-Produced Foods

V. International Trade Agreements and Other Trade-Related Activities

- Participate in the WTO SPS Committee
- Provide Timely Technical Assistance to U.S. Trade Agencies
- Attest to the Safety of Foods Produced in the United States

CFSAN intends to review its international priorities periodically and to seek input from stakeholders to ensure that the priorities remain consistent with (1) the underlying international principles of the Center, (2) FDA policies pertaining to international issues, and (3) available resources.

CFSAN's International Priorities for 2000-2002

The priorities listed below constitute CFSAN's planned international priorities for the next three years. These priorities have been drafted by the Center recognizing that international activities falling outside of these priorities may not be accomplished within resources available in a given year and recognizing that critical, unanticipated international issues may arise that will take precedence over the priorities listed currently. It is anticipated that individual activities will be designated within each priority category for each of the three years. For example, a number of foreign establishment inspections for several different countries and commodities will be scheduled for a particular year under the general priority of "Inspect Foreign Establishments". Similarly, CFSAN participation in activities of various Codex committees will occur each year, but the nature of these activities will change from one year to the next.

I. Regulatory (Enforcement, Monitoring, Inspection) Activities

In cooperation with the Office of Regulatory Affairs and assisted, where appropriate, by foreign regulatory authorities,

Monitor Imported Foods

Enhance the Effectiveness of Monitoring Programs for Imported Foods— Increase surveillance of imported foods, particularly fresh fruits and vegetables, at U.S. borders and otherwise enhance the effectiveness of FDA programs to ensure that imported foods meet U.S. food safety requirements.

Inspect Foreign Establishments

Standardize Procedures for Conducting and Evaluating Foreign Inspections and Increase the Number and Effectiveness of Foreign Compliance Inspections — Develop standard operating procedures for identifying foreign food production establishments for FDA compliance inspection, preparing for and conducting such inspections, and for evaluating the findings of inspections and preparing standardized reports of foreign establishment inspections. Conduct inspections of selected, high-risk foreign food production establishments to determine their compliance with applicable FDA regulations pertaining to low-acid and acidified canned foods, seafood, dairy products, infant formula, and, as warranted, other foods.

Trace Foodborne Illness Outbreaks Associated With Imported Foods and Prevent Future Outbreaks from These Sources

Conduct Tracebacks for Illness Outbreaks — Conduct investigations in countries exporting foods to the United States to determine the cause of food-borne illness outbreaks in the United States attributable directly or indirectly to imported foods from these countries. Take necessary steps to prevent future outbreaks associated with the same or similar foreign sources and/or foods.

Improve Food Labeling Compliance for Imported Foods

Promote Foreign Compliance with U.S. Labeling Requirements — Develop a comprehensive food labeling enforcement policy for imported foods that is based on enhanced FDA outreach and advice to foreign governments and industries to facilitate their compliance with FDA food labeling requirements for foods exported to the United States.

II. International Harmonization

Strengthen CFSAN Participation in Codex

Strengthen Participation in Codex — Participate in and exercise leadership in committees of the Codex Alimentarius Commission, through improved coordination of Codex activities within CFSAN and with other U.S. agencies, in order to elaborate and promote development of science-based, international food safety and

labeling standards that provide a level of consumer protection and label information consistent with that provided by corresponding U.S. regulations and laws. Ensure that processes are in place to develop and articulate clear U.S. delegation positions that enhance and promote consumer protection and reflect input by all stakeholders on matters before relevant Codex committees.

CFSAN intends to give particular priority to participation in the following committees: General Principles; Food Import and Export Inspection and Certification Systems; Food Hygiene; Food Additives and Contaminants; Food Labeling; Nutrition and Foods for Special Dietary Uses; Fish and Fishery Products; Processed Fruits and Vegetables; and Milk and Milk Products. CFSAN also intends to participate in other Codex committees to the extent practicable based on resource availability.

Participate in Codex Task Force on Biotechnology

Participate in Codex Biotechnology Working Group — Participate in the recently convened Ad Hoc Intergovernmental Codex Task Force on Foods Derived from Biotechnology to develop consensus international guidance for assessing the safety of foods obtained from biotechnology.

Contribute Scientific Expertise Toward Development of International Standards

Provide Scientific Leadership — Provide scientific leadership and technical expertise in international technical committees, such as the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA), in order to strengthen the scientific foundation of food safety standards developed by international standard setting organizations.

Participate in the NAFTA and FTAA Technical Committees and Working Groups

Represent FDA Programs, Policies and Science in Relevant Technical Committees of NAFTA and FTAA — Participate in committees and technical working groups relevant to food safety, quality, and labeling that are convened under the North American Free Trade Agreement (NAFTA) and that may be convened under the emerging Free Trade Area of the Americas (FTAA) in order to enhance effectiveness and promote consistency in food regulatory systems among Western Hemisphere countries that are, in combination, the major suppliers of imported foods to the United States.

Participate in Other Standard Setting Bodies

Participate in Other International Standard Setting Bodies — Participate in and exercise leadership in international organizations such as the Organization for Economic Cooperation and Development (OECD), in particular the OECD Task Force on Novel Food and Feeds (biotechnology), International Organization for Standardization (ISO), AOAC International, and the International Dairy Federation (IDF) that are charged with harmonization of approaches for analytical methods validation and with development of other international standards bearing on the safety and quality of FDA-regulated food and cosmetic products.

III. Development, Maintenance, and Dissemination of CFSAN's Science Base

Participate in International Scientific Consultations and Panels

Exercise Leadership on International Scientific Panels — Participate in and exercise leadership in expert consultations and panels convened by the World Health Organization (WHO) and Food and Agriculture Organization (FAO), and other relevant international organizations in order to strengthen the scientific foundations of food safety standards developed by national authorities and international standard setting organizations.

Strengthen Scientific Collaboration With Foreign Governments

Promote Scientific/Technical Exchanges with Appropriate Foreign Countries — Strengthen CFSAN's scientific collaboration with appropriate foreign governments and international organizations, particularly through the Joint Institute of Food Safety and Applied Nutrition (JIFSAN), to enhance the scientific foundation and information base on which FDA's regulatory and enforcement decisions are based and to enhance the ability of foreign governments to base regulatory decisions on sound science.

Strengthen Research and Risk Assessment Approaches

Enhance Research and Risk Assessment Methodologies Relevant to Imported Foods — In collaboration with other FDA units, including JIFSAN and the National Center for Food Safety and Technology (NCFST), refine and enhance FDA's research and risk assessment approaches for microbiological and chemical hazards in order to identify and resolve unique or atypical food safety issues associated with food production and distribution systems in other countries.

Investigate Alternatives to Animal Testing

Investigate Alternatives to Animal Testing for Foods and Cosmetics — In consultation with appropriate foreign governments, investigate alternatives used in

other countries to the use of animal testing for evaluating the safety of food and cosmetic products.

IV. Equivalence Evaluations, Food Safety Needs Assessments, and Food Safety Technical Cooperation and Assistance

Determine Equivalence of Food Safety Systems

Establish Guidance on Equivalence Criteria for Foods — Establish guidance on FDA criteria for evaluating foreign food regulatory systems to determine whether such systems provide a level of consumer protection that is equivalent to that provided by the United States.

Conduct Foreign Equivalence Evaluations — In cooperation with FDA's Office of Regulatory Affairs and appropriate foreign government agencies, conduct evaluations of the food safety regulatory systems of selected exporting countries for seafood, dairy products, and, as warranted, other food products, to determine if these systems provide a level of consumer protection equivalent to that provided by the U.S. system.

Develop Consistent, Resource-Efficient Procedures to Accommodate Evaluations of U.S. Food Safety Systems by Foreign Regulatory Authorities — In cooperation with FDA's Office of Regulatory Affairs, other FDA units, and other U.S. government agencies, develop workable procedures to accommodate evaluations or audits of the U.S. food safety system conducted by foreign food safety regulatory authorities for the purpose of determining whether the U.S. system provides a level of consumer protection equivalent to that provided by the foreign system.

Assess the Food Production and Food Safety Systems of Other Countries

Conduct Foreign Country Food Safety Needs Assessments — In cooperation with other FDA units and U.S. government agencies and in concert with the President's Food Safety Initiative, develop standard protocols for and conduct assessments of the food production infrastructure and food safety systems of selected foreign countries that are major suppliers of fresh fruits and vegetables to the United States in order to identify food safety educational and technical assistance needs and to determine potential areas for future bilateral cooperation aimed at enhancing the safety of foods produced in, consumed in, and exported from these countries to the United States.

Improve the Safety of Foreign-Produced Foods

Enhance the Safety of Imported Foods at Their Source — In cooperation with FDA's Office of Regulatory Affairs, other U.S. government agencies, and appropriate

international organizations such as WHO and FAO, and as warranted to address an actual or potential food safety issue, provide education and training to governments and food industries of foreign countries that represent significant suppliers of foods to the United States in order to improve the safety and quality of such foods that are likely to be exported to the United States.

V. International Trade Agreements and Other Trade-Related Activities

Participate in the WTO and NAFTA SPS Committees

Provide FDA Policy and Technical Guidance to WTO and NAFTA SPS Committees

Participate as member of the multi-agency U.S. Delegation to the World Trade Organization Committee on Sanitary and Phytosanitary Measures (WTO SPS Committee) and NAFTA SPS Committee to ensure FDA's influence and to promote consistency among WTO member countries in the application of food safety measures (standards and controls) pertaining to foods moving in international commerce.

Assist U.S. Trade Agencies

Provide Technical Support to U.S. Trade Agencies — In accordance with Section 410 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), provide technical support within CFSAN's areas of regulatory authority and expertise to U.S. government trade agencies, including the Office of the United States Trade Representative (USTR), Department of Commerce (DoC), and USDA's Foreign Agricultural Service (FAS), to: ensure FDA's public health policies and practices are integrated into the overall U.S. government policy on international trade issues; promote development of harmonized international standards, facilitate development of mutual recognition agreements; provide appropriate technical/policy support in food-related trade negotiations (e.g., FTAA negotiating groups); and prevent or resolve international trade disputes involving FDA-regulated food or cosmetic products.

Attest to the Safety or Other Attributes of Foods and Cosmetics Produced in the United States

Issue Certificates for Export — Issue Certificates for Export (formerly Certificates of Free Sale), or provide for alternative mechanisms for such certificates, to U.S. food and cosmetic producers and exporters as necessary to satisfy the requests of foreign governments for U.S. attestation that the particular products are produced and marketed in the United States in general conformity with U.S. requirements.

Provide Mechanism for U.S. Government Issuance of Foreign-Mandated Export Health Certificates — Develop, in cooperation with other U.S. government

agencies, a resource-efficient procedure based on FDA attestation to the safety of exported products for U.S. government issuance of export health certificates required by some foreign governments for certain animal-derived foods.