

November 12, 1999

The Honorable William Jefferson Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Food Safety
Initiative?
International

Dear Mr. President:

We write to urge that the United States take the lead at the upcoming World Trade Organization ("WTO") Ministerial Conference in ensuring that expanding international trade does not jeopardize important public health safeguards in both the United States and other countries. As you said in your 1998 address at the 50th anniversary of the WTO, we must ensure "that spirited economic competition among nations never becomes a race to the bottom in environmental protections, consumer protections, and labor standards. We should level up, not level down."

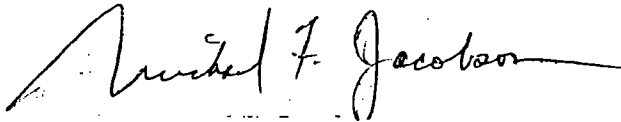
Unfortunately, the experience of the last four years with the WTO's Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") demonstrates that it must be reformed in order to meet your objective. Under the SPS Agreement a subsidiary of the United Nations Food and Agriculture Organization and World Health Organization called the Codex Alimentarius Commission ("Codex") is authorized to set international health standards for food, plants, and animals. At its June 1999 meeting Codex -- without objection from the United States -- agreed to numerous international standards that are weaker than ours:

- an international standard for natural mineral waters that permits higher levels of lead and other contaminants than the Food and Drug Administration ("FDA") now allows;
- an international residue tolerance for methyl parathion (and other pesticides) even though the Environmental Protection Agency (as mandated under United States law) has banned methyl parathion for fruits and vegetables because of its potential adverse effects on children;
- an international standard that does not require pasteurization of dairy products, as is now generally required by the FDA;
- the use of food additives which, while presumably safe, have not been approved by the FDA for use in the United States; and
- an international standard for the labeling of a composite ingredient in prepackaged foods that permits it to be listed by a standardized name without declaring all its component ingredients if it is less than 5 percent of the food, even though the FDA requires these components to always be listed in order to protect consumers who suffer from hypersensitivities.

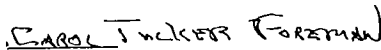
Under the SPS Agreement these Codex decisions may lead to actions by the WTO that could force the United States to choose between lowering its own food safety standards or paying a penalty to a foreign country whose exports to the United States are hindered by our higher health protections.

Our concerns are shared by other groups in this country and Europe. The Transatlantic Consumer Dialogue, which was formed in September 1998, has called on the WTO Ministerial Conference to change specific parts of the SPS Agreement because the current SPS Agreement "undercuts governments' ability to establish and maintain legitimate, non-discriminatory food safety and food-related consumer information labeling policies." We urge you to support the TACD's proposal at the WTO meeting in Seattle on November 30-December 3, thereby demonstrating that, in fact, the United States wants to "level up, not level down."

Sincerely,



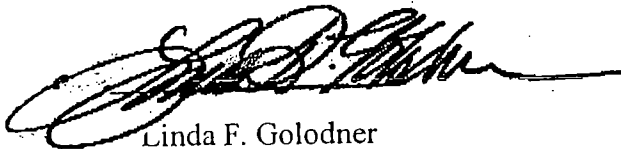
Michael F. Jacobson
Center for Science in the Public Interest



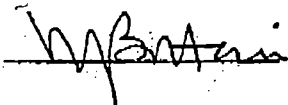
Carol Tucker Foreman
Consumer Federation of America



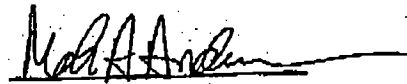
Tom Devine
Government Accountability Project



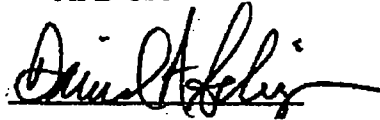
Linda F. Golodner
National Consumers League



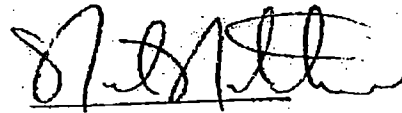
Mary Bottari
Public Citizen



Mark A. Anderson
Food and Allied Service Trades,
AFL-CIO



Daniel A. Seligman
Sierra Club



Niel Ritchie
Institute for Agriculture and Trade
Policy



Richard Caplan
U.S. Public Interest Research Group



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Center for Food Safety and Applied Nutrition Outreach and Information Center

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From: Joseph A. Levitt, Director,
Company: Center for Food Safety and Applied Nutrition
Phone: 1-888-SAFEFOOD
Fax: 1-877-FOODFACS (1-877-366-3322)

*Food Safety
Int'l*

Date: 12/15/1999

Time: 2:02 PM

**Pages including this
cover page:** 24

Subject: Important Information Packette
Message: This Information Packette contains:

1. "Dear Colleague" Letter from Mr. Levitt
2. FR Notice (signed display copy)
3. CFSAN International Affirmative Agenda

FACSIMILE TRANSMISSION RECORD

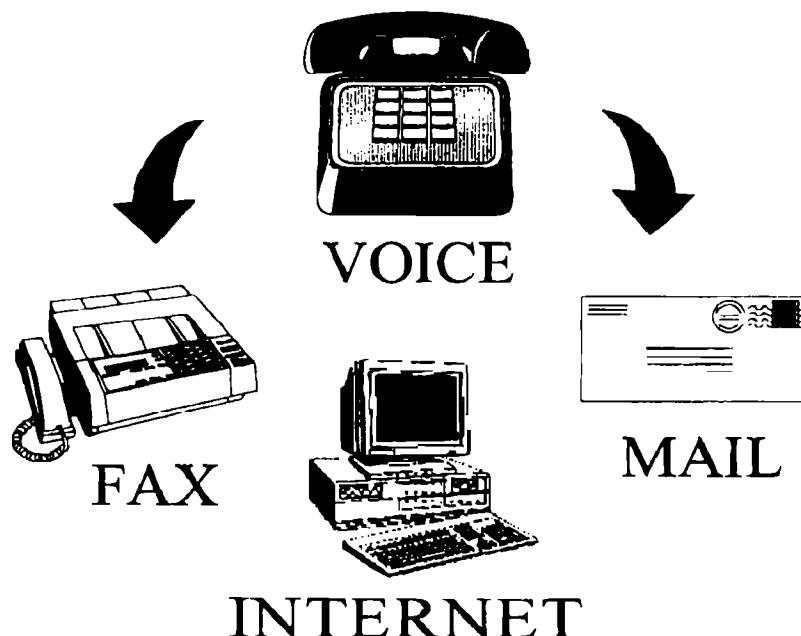
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Visit our HomePage at: [HTTP://WWW.CFSAN.FDA.GOV](http://www.cfsan.fda.gov)



December 15, 1999

Dear Colleague:

I am very pleased to share with you the Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition's (CFSAN's) Affirmative Agenda for International Activities for 2000-2002. This Agenda was developed in response to extensive stakeholder interest in this increasingly important area.

In the International Affirmative Agenda you will find broad priorities in each of the five major categories of CFSAN's international activities: (1) Regulatory (Enforcement, Monitoring, Inspection); (2) Harmonization; (3) Development, Maintenance, and Dissemination of CFSAN's Science Base; (4) Equivalence Evaluations, Food Safety Needs Assessments, and Food Safety Technical Cooperation and Assistance; and (5) Trade-Related Activities. The Center will use the framework of the Affirmative Agenda and the broad priorities identified under each of these categories to develop focussed, specific international programs and activities in each of the next three years.

CFSAN intends to continue to exercise scientific and regulatory leadership in the new international environment in order to protect the health of American consumers and to promote the safety and quality of foods and cosmetics moving in international commerce.

We look forward to working with you to help implement CFSAN's International Affirmative Agenda.

Sincerely yours,

A handwritten signature in cursive script, reading "Joseph A. Levitt".

Joseph A. Levitt
Director
Center for Food Safety
and Applied Nutrition

Enclosure

Affirmative Agenda for International Activities

Center for Food Safety
and Applied Nutrition

Food and Drug Administration

December 1999



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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.

DMB

12/15/99 @ 8:59
12/20/99
gentle

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-3089]

3663

DEC 15 09:25

Affirmative Agenda for International Activities—Center for Food Safety and Applied Nutrition, Availability

AGENCY: Food and Drug Administration, IIIIS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the Center for Food Safety and Applied Nutrition's (CFSAN) Affirmative Agenda for International Activities (International Affirmative Agenda). CFSAN intends to use the general framework of 2000 to 2002 priorities identified in the International Affirmative Agenda during its annual planning process to develop specific international activities for each of the 3 years.

ADDRESSES: The International Affirmative Agenda is available for public examination in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 160 1, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John W. Jones, Office of Constituent Operations, Center for Food Safety and Applied Nutrition (HFS-550), 200 C St. SW., Washington, DC 20204, 202-20543 11.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 1999 (64 FR 505 18), FDA announced the availability of CFSAN's Draft International Affirmative Agenda for 2000 to 2002. FDA also solicited comments on whether to hold a public meeting on the Draft International Affirmative

Agenda. Interested persons were given until October 1, 1999, to request a public meeting and until November 1, 1999, to comment. The current notice summarizes the comments received on the draft document and announces the availability of the final version of CFSAN's International Affirmative Agenda. CFSAN intends to use the general framework of 2000 to 2002 priorities identified in the International Affirmative Agenda during the center's annual planning process to develop specific international activities. CFSAN also intends to solicit public input on these planned international activities on an annual basis. Therefore, there will be continuing opportunity for public comment on CFSAN's planned international activities and on the center's overall international priorities.

II. Summary of Comments

FDA received eight letters, each containing one or more comments, on CFSAN's Draft International Affirmative Agenda from a consumer group, a food and drug professional association, and six industry trade associations. FDA received only one request for a public meeting and, based on this, the agency determined that there was not sufficient interest to conduct such a meeting. All of the substantive comments strongly supported the goals of CFSAN's Draft International Affirmative Agenda for 2000 to 2002. The comments articulated some concerns and made a number of suggestions.

A number of comments were related to FDA's public health mandate, the need for FDA to ensure that this mandate is not compromised by trade concerns, and the suggested need for FDA to promote proactively U.S. public health positions in deliberations of international standard setting bodies.

Most, but not all, of these comments suggested that CFSAN only participate in international activities that are consistent with and directly responsive to FDA's mission to protect the public health that is mandated explicitly by statute. Concern was expressed about possible CFSAN activities that appear to promote a particular technology (e.g., biotechnology) or that pertain to equivalence or mutual recognition agreements where, it was asserted, FDA's ability to protect

public health would be lowered. There was also concern about any CFSAN activity related to the World Trade Organization (WTO) or North American Free Trade Agreement (NAFTA) that is undertaken explicitly to promote international trade at the expense of public health. The suggestion also was made that CFSAN should oppose actively the establishment of any standard by the Codex Alimentarius Commission (Codex) that does not provide a level of consumer protection equivalent to that which is provided by FDA regulation. One comment, however, suggested that FDA should undertake international activities specifically to support U.S. economic, trade, and market development interests overseas.

Some comments recommended that CFSAN strengthen its participation in Codex to ensure that Codex standards are based on sound scientific principles. These comments emphasized that CFSAN should work closely with the appropriate food industry representatives to develop technically accurate U.S. positions on matters before Codex and to ensure that Codex standards are practicable. The comments also suggested that CFSAN's participation in the Codex development process should be an agency priority and its delegates should be appropriately trained to strengthen the agency's participation.

Likewise, comments suggested that CFSAN take a more proactive and leadership role in developing appropriate work plans for the technical working groups (TWG's) convened under the NAFTA Sanitary and Phytosanitary (SPS) committee, particularly in the area of harmonized regulation procedures for food additives, safety assessments for foods derived from biotechnology, product recall and traceback procedures, and harmonized NAFTA positions on issues before Codex. The agency also was encouraged to be more actively involved in articulating the strength of the U.S. food regulatory system within the WTO's SPS committee.

FDA intends that all of CFSAN's international activities have as their basis maintenance and enhancement of U.S. public health. The draft International Affirmative Agenda states that consistency with FDA's primary public health mission is the first guiding principle of CFSAN's participation in any international activity. In this regard, CFSAN intends to participate in

international activities that are intended, directly or indirectly, to enhance the safety, nutritional quality and informative and truthful labeling of foods, and the safety and labeling of cosmetics available to the American consumer, whether the products are produced in or imported into the United States. CFSAN also intends to participate, when practicable, in activities that address other compelling international or domestic public health issues, concerns or priorities identified by the Department of Health and Human Services and other domestic and foreign public health agencies that are important to CFSAN's areas of expertise and authority.

FDA emphasizes that CFSAN's international activities, including participation in committees of the Codex and other standard setting bodies, are aimed primarily at enhancing the agency's ability to protect U.S. public health. In all international areas where standards are developed or decisions are made that bear on the safety and quality of foods and cosmetics that are produced in or imported into the United States, CFSAN intends to exercise leadership, authority, and influence to ensure that American consumers are protected by such standards and decisions. With regard specifically to bilateral agreements, FDA intends to enhance its ability to ensure that foods and cosmetics imported into the United States are safe through development of formal agreements with foreign governments, such as equivalence agreements, mutual recognition agreements, and memoranda of understanding, that are intended to provide FDA with reasonable assurance that products covered by such agreements consistently meet the U.S. level of public health protection.

CFSAN does not intend to undertake trade-related activities that are intended solely to promote U.S. trade interests or that have the effect of diminishing U.S. public health protection. CFSAN believes that it is appropriate, however, for the center to participate, where practicable, in international activities conducted in response to U.S. obligations under international treaties, trade agreements and other recognized, formal or informal arrangements of the United States. These activities include situations where CFSAN's participation is critical to help the United States resolve international trade disputes or preclude trade interruptions associated with foods and cosmetics for which FDA is the recognized competent U.S. authority.

Other comments were more specific in nature and related to the particular interests of the commenting organization. One comment generally supported CFSAN's proposed international priorities and indicated that the proposed activities, if implemented fully, would enhance FDA's ability to protect public health. The comment stated that the particular organization, which represents Federal, State, and local food and drug officials in the United States and Canada, is well positioned to work cooperatively with FDA and CFSAN, specifically, to implement CFSAN's international activities. In particular, the organization stated that a number of States represented by the association are willing to work collaboratively with FDA through Federal-State partnership agreements which, among other activities, might monitor imported foods to determine compliance with U.S. requirements, assist with trace backs of outbreaks of foodborne illnesses to their source, and improve compliance of imported foods with U.S. labeling requirements. The comment encouraged FDA to pursue additional partnerships with the states to help accomplish the regulatory and enforcement components of the CFSAN's international priorities and to work with the association to facilitate development of such partnerships.

FDA recognizes the continuing importance and advantages of working with state and local authorities on critical food and cosmetic issues, both domestic and international. The agency intends to work collaboratively with state and local regulatory officials through formal Federal-State partnerships and other approaches to leverage expertise and resources. The agency appreciates the organization's willingness to facilitate such collaboration with regard to imported foods and will consider means of enhancing cooperative activities in this area.

Additional comments stressed the importance of FDA finalizing its criteria for determining the equivalence of foreign food regulatory systems so that the United States can deal effectively and efficiently with diverse foreign regulatory systems. The agency was encouraged, for example, to conclude an equivalence agreement with Canadian authorities regarding fish and fishery inspection systems.

FDA intends to finalize its equivalence criteria for foods as soon as possible and to use the final criteria in future equivalence evaluations of foreign food safety regulatory systems.

Two comments strongly supported continuation of cosmetic industry trade association involvement in issuance of export certificates. The comments encouraged FDA to continue to permit cosmetic trade associations to issue export certificates on behalf of members, citing the time efficiency of the industry's program relative to that of any corresponding government certificate issuance activity. Conversely, another comment expressed the view that equivalence agreements, memoranda of understanding, and mutual recognition agreements should be developed between FDA and its trading partners as a means of reducing the need for export certificates.

FDA is currently examining the issue of the agency's involvement in issuance of export certificates for U.S.-produced foods and cosmetics. FDA also intends to finalize its equivalence criteria for foods as soon as possible. The agency will consider the associations' comments during its consideration of the agency's role in issuance of export certificates and whether any future equivalence agreements might reduce foreign requirements for such certificates.

One comment strongly encouraged CFSAN to participate in all relevant international discussions concerning development of harmonized international standards for cosmetics, particularly those discussions bearing on cosmetic trade among the United States, Canada, the European Union, and Japan. Other comments supported CFSAN's continuing involvement in development of mutual recognition agreements pertaining to cosmetics and provision of technical assistance to U.S. trade agencies to prevent or resolve trade disputes involving cosmetics. The comments also supported CFSAN's proposed priority to seek alternatives to animal testing for cosmetics.

CFSAN intends to participate, within resource constraints, in relevant international discussions concerning the safety and labeling of cosmetics to work to harmonize scientific and regulatory approaches, where such harmonization is practicable and maintains or enhances U.S. public health protection.

Two of the food trade associations commented that FDA should strengthen its participation in TWG's convened under NAFTA Sanitary and SPS committee in order to take a more proactive role in developing appropriate work plans for these groups. Specifically, one comment suggested that the TWG's could facilitate issues pertaining to harmonized registration procedures for food additives, safety assessments for foods derived from biotechnology, product recall and trace back procedures, and harmonized NAFTA positions on issues before Codex. This comment noted that FDA had not utilized the TWGs fully and encouraged CFSAN to undertake a greater leadership role in the TWGs. Two of the associations also encouraged FDA to become more actively involved in issues before the WTO's SPS committee, particularly with regard to articulating the strengths of the U.S. food regulatory system.

FDA agrees that the NAFTA TWG's provide an appropriate forum to address food safety, quality and labeling issues that are of interest to Canada, Mexico, and the United States. The agency also agrees that these TWG's can have a positive impact on public health protection and facilitation of the trade of safe food products among the three countries. CFSAN intends to strengthen its participation and leadership in these NAFTA TWG's to the extent practicable. CFSAN also intends to continue its participation in the WTO SPS committee in order to promote and enhance public health protection in this forum.

Other comments by the food trade associations related to FDA and CFSAN resources needed to accomplish the proposed international priorities, the need for CFSAN to develop a more detailed list of specific activities within each of the broad priority areas in the draft International Affirmative Agenda, and a suggestion that CFSAN's "first" priority, both in its domestic and international activities, should be development, maintenance, and dissemination of its science base. Finally, several comments stressed that CFSAN should strive to involve the public fully in its international activities through appropriate notice and comment opportunities and other means.

III. Final CFSAN International Affirmative Agenda for 2000 to 2002

FDA appreciates the comments submitted by the eight organizations and recognizes that all of the comments have merit with regard to CFSAN's current and future international activities. The agency agrees, in principle, with most of the comments and believes that the priorities that CFSAN has articulated in its draft International Affirmative Agenda are compatible with all of the comments.

The international priorities as expressed in the International Affirmative Agenda represent a general framework for the center's international activities for 2000 to 2002. Many specific activities within the broader priority areas are to be planned and accomplished by the center on an annual basis over the next 3 years. Therefore, as these specific, annual international activities are identified and developed, CFSAN will solicit and consider additional public comments, in addition to those submitted on the draft International Affirmative Agenda.

Based on CFSAN's intent to consider comments on its specific international activities on an annual basis during development of its annual international program priorities, the center has elected to finalize CFSAN's International Affirmative Agenda without any changes from the original draft text.

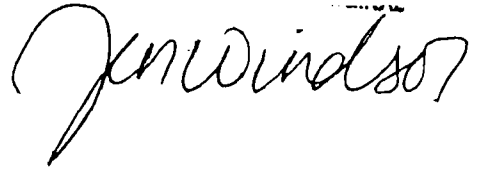
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Margaret M. Dotzel
Acting Associate Commissioner
for Policy

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